COMMENTS

FIGHTING FOR THE RIGHT TO TRY: TESTING THE D.C. CIRCUIT'S REASONING IN *ABIGAIL ALLIANCE* IN LIGHT OF *OBERGEFELL*

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INTRODUCTION

Matthew Bellina was flying an EA-6B Prowler out of Naval Air Station Whidbey Island on Washington's Puget Sound when he started twitching and losing coordination.[1] Bellina, now a thirty-four-year-old father and veteran of the United States Navy, suffers from amyotrophic lateral sclerosis (ALS), a debilitating and incurable disease more commonly known as Lou Gehrig's Disease.[2] When he was diagnosed with the fatal disease at age thirty, Bellina's illness was already too advanced for one clinical trial and not advanced enough for the other.[3] As a result, he now lacks the ability to write, uses a walker and a wheelchair to move around, and will eventually lose his ability to speak, eat, and breathe.[4]

He is just one of thousands of terminally ill patients in the United States seeking a miracle through "Right to Try," a legislation that would allow terminally ill patients to access investigational treatments that have passed Phase I safety testing of the clinical trial process but are not yet available to the public.[5] In 2016, Bellina testified before the Senate Homeland Security and Governmental Affairs Committee to advocate for the passage of Right to Try legislation by the federal government.[6] After describing his frustra-

1. *See Matt Bellina: "ALS Is a Worthy Adversary, But Each Day I Am Hopeful,"* CONGRESSIONALLY DIRECTED MED. RES. PROGRAMS, http://cdmrp.army.mil/cwg/stories/2014/bellina_profile (Jan. 27, 2016) (discussing how Bellina's diagnosis with amyotrophic lateral sclerosis (ALS) caused him to be grounded by the Navy due to his worsening symptoms).

2. *Id.*

3. Jo Ciavaglia, *Matt Bellina—The Face of Right to Try*, NAC HAVE A HEART FOUND., http://myrighttotrynow.com/2017/08/matt-bellina-the-face-of-right-to-try (last visited May 8, 2018).

4. *Id.*

5. *See* Matthew Bellina, *FDA Should Allow Treatment of Terminally Ill Patients with Experimental Drugs*, WASH. POST (Sept. 28, 2016), https://www.washingtonpost.com/news/powerpost/wp/2016/09/28/fda-should-allow-treatment-of-terminally-ill-patients-with-experimental-drugs/?utm_term=.51211336c9f6 (arguing that federal Right to Try legislation will give terminally ill patients new treatment options).

6. *See Exploring a Right to Try for Terminally Ill Patients: Hearing Before the S. Comm. on Home-*

tion with the Food and Drug Administration's (FDA's) drug regulation regime and overgeneralized clinical trials for ALS, Bellina questioned why he should not be able to try experimental treatments if the disease is sure to take his life anyway.[7]

Right to Try bills grant terminally ill patients access to and the right to try investigational new drugs that have not yet received the FDA approval but have passed the preliminary safety testing phase (Phase I) of the arduous and costly clinical trial process.[8] Unfortunately, over one million Americans die from a terminal illness each year, either from a disease without a cure or preclusion from a clinical trial.[9] While the federal Food, Drug, and Cosmetic Act (FDCA) sets forth a rigid protocol for the drug approval process, proponents of Right to Try legislation seek to make investigational new drugs easier to access for terminally ill patients without sacrificing the safety and efficacy standards of the FDA.[10]

In 2007, Abigail Alliance for Better Access to Developmental Drugs (Abigail Alliance)[11] brought suit against the FDA for barring access to potentially life-saving unapproved drugs to terminally ill patients.[12] In *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach* (*Abigail Alliance*),[13]

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land Sec. & Governmental Affairs, 114th Cong. 241–42 (2016) (statement of Matthew Bellina, Lieutenant Commander, U.S. Navy) [hereinafter Bellina Senate Testimony] (testifying that federal Right to Try legislation will permit him to receive access to investigative new drugs with approval from drug manufacturers and his doctors); *see also* Right to Try Act of 2017, H.R. 878, 115th Cong. (2017).

7. *See* Bellina Senate Testimony, *supra* note 6, at 284 (describing the ineffectiveness of current ALS clinical trials that seek to create an efficacious drug for the overall patient population rather than working with specific patients' biomarkers and using "known compounds that target a patient's specific disease profile"); *see also* Ciavaglia, *supra* note 3.

8. *See About Right to Try*, RIGHT TO TRY, http://righttotry.org/about-right-to-try (last visited May 8, 2018) (explaining that Right to Try at the state level seeks to give drug manufacturers, doctors, and patients more control over whether patients receive promising investigational new drugs that the Food and Drug Administration (FDA) has not yet approved).

9. *See id.* (considering Right to Try necessary because most terminal patients are too sick to be eligible for clinical trials).

10. *See* Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (2012) (requiring a drug manufacturer to file a new drug application (NDA) with the FDA and to establish that a new drug meets FDA's safety and effectiveness standards); *see also* Bellina Senate Testimony, *supra* note 6, at 241.

11. *See Our Story*, ABIGAIL ALLIANCE, http://www.abigail-alliance.org/story.php (last visited May 8, 2018) (public interest group seeking to cultivate greater access to developmental cancer drugs and other drugs for life-threatening illnesses).

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

13. 495 F.3d 695 (D.C. Cir. 2007).

the D.C. Circuit applied the Supreme Court's substantive due process analysis in *Washington v. Glucksberg*[14] and held that terminally ill patients without alternative treatment options do not have a fundamental right to access experimental drugs that have only passed Phase I testing.[15]

This Comment will analyze *Abigail Alliance* and address whether the Court of Appeals for the D.C. Circuit's reasoning is still applicable as the majority of states have now adopted a Right to Try legislation. Additionally, it will explore whether the due process analysis used in *Abigail Alliance* supports the holding that there is no fundamental right to try investigational drugs after the Supreme Court's decision in *Obergefell v. Hodges*.[16] Part I will discuss the FDA's drug approval process and notable case law in the field of medical freedom rights under substantive due process analysis. Part II will argue that the Court of Appeals for the D.C. Circuit's reasoning in *Abigail Alliance* no longer reflects the nuanced legal framework provided by the Supreme Court in *Obergefell.* It will further analyze the Right to Try movement through an administrative lens and discuss how the FDA can respond to the proliferation of states' Right to Try legislation. Part II will conclude by stating that the legal framework found in *Obergefell* should be applied to cases involving terminally ill patients' rights to access unapproved new drugs. It will also recommend that the FDA address the growing number of states enacting Right to Try legislation through notice-and-comment rulemaking as the agency may be better suited to address this issue through administrative action.

I. BACKGROUND

The FDA regulates a vast array of products including food, human and animal drugs, medical devices, tobacco, cosmetics, animal feed, biologics, and radiation-emitting products.[17] Though the FDA now acts as the gatekeeper for new drugs seeking to enter the commercial market, this has not

14. 521 U.S. 702, 720–21 (1997) (applying substantive due process analysis which inquires whether the asserted fundamental right is (1) deeply rooted in the nation's history and (2) whether the asserted right meets the requirement of "careful description" of liberty interest).

15. *Abigail Alliance*, 495 F.3d at 712–13 (holding that the FDA's interest in protecting the public from unsafe drugs is rationally related to a legitimate state interest); *see also Glucksberg*, 512 U.S. at 728 (holding that the right to receive assistance in "committing suicide is not a fundamental liberty interest protected by the Due Process Clause").

16. 135 S. Ct. 2584 (2015).

17. Priya Brandes, Comment, *Regulation of Drugs: A Death Sentence for the Terminally Ill?*, 46 U.S.F. L. REV. 1149, 1151 (2012).

always been the case.[18] Today, the stringent drug approval regulations set forth by the FDA originate from its response to public outcry stemming from drug-related deaths, adverse side effects from unsafe drugs, and public health scares.[19] Now, in addition to establishing a drug's safety, a drug manufacturer must also establish a drug's efficacy in patients with the listed indication.[20] Today, the FDA's rigorous drug approval process is recognized as the gold standard throughout the world.[21]

A. The FDA's "Gold Standard" for Drug Approval

The FDCA, enacted in 1938 and amended in 1962, grants access to new drugs only if the FDA, following a rigorous and expensive clinical trial process, approves them.[22] Before advancing to clinical trials in human subjects, a drug sponsor must submit to the FDA an Investigational New Drug (IND) application based on the results from its initial testing, which typically involves the testing of the drug on animals.[23] Once the FDA approves the IND application, the drug sponsor must then submit substantial evidence regarding the safety and efficacy of the new drug before the FDA will allow it to be introduced into interstate commerce, a process that involves at least three phases of human clinical testing.[24]

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18. *See generally* Michelle Meadows, *Promoting Safe & Effective Drugs for 100 Years*, FDA CONSUMER MAG., Jan.–Feb. 2006, https://www.fda.gov/aboutfda/whatwedo/history/productregulation/promotingsafeandeffectivedrugsfor100years/default.htm (describing how federal regulation was lacking with respect to protecting the public from dangerous drugs at the turn of the twentieth century).

19. *See* Robert M. Harper, *A Matter of Life and Death: Affording Terminally-Ill Patients Access to Post-Phase I Investigational New Drugs*, 12 MICH. ST. U. J. MED. & L. 265, 268–69 (2008).

20. *See id.* at 269–70.

21. Meadows, *supra* note 18.

22. *See* 21 U.S.C. § 355(a) (2012); John Patrick Dillman, Note, *Prescription Drug Approval and Terminal Diseases: Desperate Times Require Desperate Measures*, 44 VAND. L. REV. 925, 935 (1991) (estimating the cost of drug approval processes at one million dollars); Clayton R. Portell, Note, *Live or Let Die: Will the Courts Recognize in Terminally Ill Patients a Fundamental Right to Choose Non-FDA Approved Drugs or Does the FDA's Stringent Approval Process Carry Sufficient Merit?*, 5 IND. HEALTH L. REV. 123, 128–29 (2008) (discussing how the drug approval process can take ten to fifteen years).

23. 21 U.S.C. § 355(i)(1)(A); *see The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (last updated Nov. 24, 2017) (explaining that the drug sponsor must show results of preclinical testing in laboratory animals in its proposal before the FDA decides whether the drug is reasonably safe for the drug manufacturer to continue to human trials).

24. *See* 21 U.S.C. § 321(p)(1) (defining a "new drug" as one that is not generally recog-

In Phase I, a drug manufacturer introduces an IND to a small group of healthy human subjects for a short period of time to evaluate its safety.[25] Phase II evaluates the efficacy of the IND by introducing the drug into a larger group of individuals who are affected by the indicated disease or condition.[26] The duration of a Phase II trial can range from several months to two years.[27] In Phase III testing, the drug sponsor conducts another study within a large population group affected by the disease to assess "optimum dosage ranges, safety, and efficacy."[28] Phase III testing can last from one to four years.[29] Upon completion of the IND process, the drug sponsor files a New Drug Application (NDA) with the FDA, which contains test results, manufacturing methods, chemical makeup of the drug, proposed labeling, and data regarding safety and effectiveness.[30] The FDA then reviews the NDA and determines whether the drug is safe and effective for human consumption.[31] In its decision to approve or deny a new drug, the

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nized among qualified experts as safe and effective). *See generally* United States v. Rutherford, 442 U.S. 544, 553–55 (1979) (affirming the federal Food, Drug, and Cosmetic Act's (FDCA's) safety and effectiveness standards and finding no exception for terminally ill patients to access unapproved drugs).

25. *See* Dillman, *supra* note 22, at 928–29 (describing how Phase I can last several months).

26. *Id.* at 929 (explaining that Phase II results indicate whether the drug is effective in treating the disease); *see also* Abigail All. for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 698 (D.C. Cir. 2007) (Phase II trials usually composed of no more than several hundred subjects).

27. *See Step 2: Preclinical Research*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForPatients/Approvals/Drugs/default.htm (last updated Jan. 4, 2018).

28. *See* Dillman, *supra* note 22, at 929.

29. *See Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm (last updated Jan. 4, 2018) (describing that Phase III trials involve a population group ranging from 300 to 3,000 volunteers with the disease or condition to determine the drug's efficacy and whether any adverse reactions exist).

30. *See* Dillman, *supra* note 22, at 930 (emphasizing that an NDA can span tens of thousands of pages with results from thousands of human subjects for which the FDA has sixty days to file the application and then one hundred eighty days to approve or disapprove the NDA); *see also* Jennifer Kulynych, *Will FDA Relinquish the "Gold Standard" for New Drug Approval? Redefining "Substantial Evidence" in the FDA Modernization Act of 1997*, 54 Food & Drug L.J. 127, 129 (1999) (noting that the FDA requires a demonstration of "substantial effectiveness," which is usually satisfied by two independent clinical trials).

31. *See Step 4: FDA Drug Review*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405570.htm (last updated Jan. 4, 2018).

FDA not only evaluates the scientific findings but also makes a calculated determination based upon whether the product's benefits significantly outweigh its risks.[32]

However, the FDA did not always regulate the public's access to medical products.[33] After the widespread use of elixir sulfanilamide[34] led to a public health crisis and prompted mass public outcry throughout the United States,[35] Congress enacted the FDCA in 1938.[36] In 1962, another public health crisis received significant attention after thousands of women, who had ingested thalidomide, gave birth to infants with severe birth defects.[37] In response, Congress amended the FDCA by requiring drug sponsors to establish the efficacy of their drug products.[38] By requiring a drug manufacturer to demonstrate substantial evidence of a drug's safety and efficacy, the United States has established one of the most complicated and conservative drug regulation systems in the world.[39] The FDA continues to maintain a highly protective, costly, and lengthy approval process to ensure that only the safest and most effective drugs reach the market.[40] As a result of the earlier public health crises, the risk of drug-related injuries continues to influence the FDA's stringent standards of approval.[41]

While many proponents uphold the FDA's approval system as the gold standard for ensuring consumer safety,[42] critics maintain that the FDA's

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32. *See* Lewis A. Grossman, *AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution*, 42 AM. J.L. & MED. 687, 697 (2016) (contending that the FDA's decisions on the basis of "risk assessment" to consumers can be challenged as policy decisions subject to attack).

33. *See* Meadows, *supra* note 18.

34. Brandes, *supra* note 17, at 1152 (explaining that elixir sulfanilamide, an untested antibiotic intended to treat streptococcal infections, turned out to be a highly toxic chemical analogue of antifreeze).

35. *Id.*

36. *Id.* (explaining that the FDCA required demonstration of a drug's safety before its entrance on the market).

37. *Id.*

38. *See id.* (describing public health crises as a cause for the FDA strengthening its drug approval process); *see also* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962). *See generally Kefauver-Harris Amendments Revolutionized Drug Development*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm322856.htm (last updated Dec. 5, 2017).

39. Julie C. Relihan, Note, *Expediting FDA Approval of AIDS Drugs: An International Approach*, 13 B.U. INT'L L.J. 229, 230 (1995).

40. *Id.*

41. *Kefauver-Harris Amendments Revolutionized Drug Development*, *supra* note 38.

42. *See* Maggie Fox, *Speed Up Drug Approvals? FDA Already Did,* NBC NEWS (Feb. 1, 2017, 4:19 PM), https://www.nbcnews.com/health/health-news/speed-drug-approvals-fda-

"deadly over-caution" results in the denial of "potentially life-saving or life-prolonging treatments already approved abroad."[43] The potential for adverse outcomes resulting from untested or partially tested drugs is significant; however, terminally ill patients lacking alternative treatment options are less likely to be concerned with side effects if there is even a slim chance of prolonging their lives.[44] Ultimately, although the federal government may have a legitimate interest in protecting the health of its citizens, the FDA consistently fails to acknowledge that the veracity of that interest diminishes as death becomes imminent or recovery is practically impossible for terminally ill patients.[45]

1. FDA's Expanded Access Exception

Lengthy drug approval processes and pressure from patients suffering from life-threatening diseases prompted Congress to enact the Expanded Access program,[46] putting drugs on the market quicker and permitting access to investigational new drugs outside of the strict bounds of a clinical trial.[47] The program also permits drug manufacturers to distribute dosages of unapproved drugs to qualifying patients with serious diseases, or where

already-did-n715481 (reporting that proponents of the FDA's process condemn President Trump's promise to pharmaceutical companies to speed up the FDA's drug approval process as it will inhibit the ability of the FDA to protect patients and consumers from unsafe or ineffective medications or medical devices).

43. Relihan, *supra* note 39, at 231.

44. *See* Portell, *supra* note 22, at 138 (discussing how Dr. Scott Gottlieb, the current Commissioner of the FDA, recognized the complexities inherent in delaying terminally ill patients' access to investigational new drugs and acknowledged that many more patients will die waiting for the "good" drugs than from using the "bad ones"). *Contra* Amy Harmon, *Fighting for a Last Chance at Life*, N.Y. TIMES (May 16, 2009), http://www.nytimes.com/2009/05/17/health/policy/17untested.html (arguing that Right to Try legislation will endanger terminally ill patients through unnecessary harm and false hope).

45. *See* Leah Voigt Romano & Peter D. Jacobson, *Patient Access to Unapproved Therapies: The Leading Edge of Medicine and Law*, J. HEALTH & LIFE SCI. L., Jan. 2009, at 45, 62 (arguing that the risk-benefit ratio for terminally ill patients in taking an unapproved drug is typically different from that of the general public).

46. 21 U.S.C. § 360bbb (2012).

47. *See generally* Caitlyn Martin, Note, *Questioning the "Right" in State Right to Try Laws: Assessing the Legality and Effectiveness of These Laws*, 77 OHIO ST. L.J. 159, 168–69 (2016) (describing FDA's Fast Track, Accelerated Approval, and Expanded Access programs for treatment of serious medical conditions); *see* Grossman, *supra* note 32, at 701–04 (discussing how the AIDS epidemic played a role in the rulemaking of the Treatment IND protocols for the FDCA).

there is no satisfactory alternative treatment for the patient's condition.[48] While the FDA prohibits commercialization of new drugs prior to FDA approval, it has a long history of allowing the use of investigational drugs for treatment outside of clinical trials.[49] In response to its near-loss in *Abigail Alliance*, the FDA proposed two new regulations regarding Expanded Access that provided patients with life-threatening diseases increased access to new drug therapies prior to their approval.[50] Instead of ceding its drug-regulating authority to oftentimes delayed and politically gridlocked Congress,[51] the FDA promulgated the regulations through notice-and-comment rulemaking that would later be codified as the Expanded Access program.[52]

To qualify for Expanded Access, four criteria must be met: (1) a patient must have a life-threatening or severely debilitating disease for which the physician decides there is "no comparable or satisfactory alternative therapy," and the potential benefits to the patient justify the potential risks of treatment, and those risks are not unreasonable given the disease; (2) the drug is considered safe and effective enough to support the use of it in a patient; (3) the use of the drug will not interfere with the "initiation, conduct, or completion of a clinical trial"; and (4) the patient's sponsor must submit a clinical protocol describing the use of the IND in a single patient.[53] The patient must also sign an informed consent form to affirm that they understand and accept the risks associated with taking an unapproved drug.[54] Additionally, the patient's physician must submit an IND application or protocol amendment to an existing IND application on the patient's behalf

48. Martin, *supra* note 47, at 169; *see also* 21 U.S.C. § 360bbb.

49. *See* Benjamin R. Rossen, *FDA's Proposed Regulations to Expand Access to Investigational Drugs for Treatment Use: The Status Quo in the Guise of Reform*, 64 FOOD & DRUG L.J. 183, 193, 201 (2009) (noting that medical professionals used orphan drugs for treatment under INDs since 1962 even though pharmaceutical companies had little incentive in developing drugs for rare diseases affecting small patient populations).

50. Expanded Access to Investigational Drugs for Treatment Use, 21 C.F.R. §§ 312.300–.320 (2017); Charging for Investigational Drugs, 21 C.F.R. § 312.8 (2017); *see also* Rossen, *supra* note 49, at 203 (discussing how patient advocacy groups issued citizen petitions to the FDA in an attempt to ease access to INDs and for the FDA to clarify the requirements for access to Expanded Access protocols).

51. *See* Jerome Groopman, *The Right to a Trial*, NEW YORKER (Dec. 18, 2006), https://www.newyorker.com/magazine/2006/12/18/the-right-to-a-trial.

52. *See generally* 21 U.S.C. § 360bbb.

53. *Id.*; *see also* Alexandra Tsakopoulos et al., Note, *The Right to Try: An Overview of Efforts to Obtain Expedited Access to Unapproved Treatment for the Terminally Ill*, 70 FOOD & DRUG L.J. 617, 629 (2015).

54. Victoria Howard, *Accessing Indiana's Right-to-Try Law: Is It Enough to Expand Access for Terminally Ill Patients?*, 14 IND. HEALTH L. REV. 267, 276–77 (2017).

and receive consent from the drug manufacturer willing to provide the experimental drug.[55]

2. Expanded Access & Barriers to Entry for the Terminally Ill

As drug approval can take ten years or more, a terminally ill patient is left with few options: the individual either applies to enter a clinical trial or one of the FDA's Expanded Access programs.[56] Still, terminally ill patients face yet another hurdle when applying for Expanded Access—receiving consent from the drug manufacturer.[57] Because drug manufacturers are not obligated to participate in Expanded Access under the FDCA, the costs of doing so may outweigh the benefits.[58] The manufacturer's hesitation to participate in an Expanded Access protocol may be three-fold: (1) it may deter patients from entering a placebo-based clinical trial and encourage "gaming" of the system;[59] (2) any adverse side effects may risk the drug's chances for approval and lead to negative publicity;[60] and (3) it may not be financially logical for the manufacturer.[61]

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55. *See* Martin, *supra* note 47, at 171 (emphasizing that an IND application takes a significant amount of time for a physician to complete).

56. *See id.* (acknowledging that many terminal individuals will be rejected from clinical trials and that Expanded Access depends upon FDA approval and the consent of the drug sponsor); *see also* Howard, *supra* note 54, at 275–76 (noting that while FDA approves most applicants for Expanded Access, the FDA still prefers patients to participate in clinical trials in order to generate data, facilitate the drug approval process, and increase availability of drugs).

57. *See* Tsakopoulos et al., *supra* note 53, at 630 (explaining that drug manufacturers may deny a patient's request if it is possible that the use could negatively impact the drug's development program).

58. *Id.*; *accord* Katie Thomas, *Why Can't Dying Patients Get the Drugs They Want?*, N.Y. TIMES (Mar. 23, 2018), https://www.nytimes.com/2018/03/23/health/right-to-try-drugs-fda.html (discussing how the main barrier that terminally ill patients face is getting permission from the drug companies and how the companies' policies on granting early access to new drugs tend to favor "affluent and well-connected patients at leading medical centers").

59. Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, NEW ENG. J. MED. (Jan. 15, 2015), http://www.nejm.org/doi/full/10.1056/NEJMhle1409465 (referring to how patients may be against entering clinical trials given the 50% chance of receiving the placebo and how that encourages patients to drop out of control group studies and instead seek Expanded Access).

60. *See id.* (discussing how all adverse events prior to approval, even in an Expanded Access protocol, must be reported to the FDA and how those patients are typically sicker than those in the actual clinical trial).

61. *Id.* (referring to the significant manufacturing costs of drugs and the possible backlash resulting from charging patients directly for the cost of the drug).

The additional time required for the FDA to approve an Expanded Access application acts as another roadblock for terminally ill patients who may not have the luxury of waiting for FDA approval.[62] In most situations, the patient and physician requesting the single patient IND must work in tandem with the FDA, the drug manufacturer, and the Institutional Review Board throughout the application process.[63] Once the patient and physician decide to proceed with the Expanded Access program, the drug manufacturer must then agree to provide the drug to the patient.[64] After the drug manufacturer agrees to participate in the treatment, the FDA must then approve the request, which can sometimes take up to two to four months for approval.[65]

Given the FDA's bureaucratic and time-consuming processes, the Right to Try movement continues to gain momentum at the state level.[66] Proponents of the legislation argue that it gives individuals the right to make their own medical treatment decisions—a right that courts continue to affirm.[67] While various Supreme Court cases protect the rights of the individual to reject medical treatment under the Due Process Clause,[68] Right to Try legislation creates an affirmative right for terminally ill patients to receive a particular treatment.[69] In both situations, an individual's due process rights

62. Tsakopoulos et al., *supra* note 53, at 617–18 (asserting that many patients do not have the time to wait for FDA approval given the severity of their illnesses).

63. *Expanded Access Categories for Drugs (Including Biologics)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm431774.htm (last updated Jan. 4, 2018).

64. *Id.*; *see also* Darrow et al., *supra* note 59 (discussing how the FDA allows drug manufacturers to charge patients or their insurers "for the direct costs of the expanded-access program, including manufacturing and shipping costs").

65. *Expanded Access Categories for Drugs (Including Biologics)*, supra note 63; *see also* Howard, *supra* note 54, at 277; *Expanded Access Navigator*, REAGAN-UDALL FOUND., http://navigator.reaganudall.org (last visited May 9, 2018).

66. *See Right to Try in Your State*, RIGHT TO TRY, http://righttotry.org/in-your-state (last visited May 9, 2018).

67. *See, e.g.*, Cruzan v. Director, 497 U.S. 261, 286–87 (1990) (upholding a patient's right to withdraw life-sustaining medical care); Roe v. Wade, 410 U.S. 113, 153 (1973) (holding that the constitutional right of privacy is broad enough to encompass a woman's right to terminate her pregnancy); England v. La. State Bd. of Med. Exam'rs, 259 F.2d 626, 627 (5th Cir. 1958) (holding that a state cannot deny an individual the right to make his own choice in treating his medical ailments). *But see, e.g.*, Raich v. Gonzales, 500 F.3d 850, 866 (9th Cir. 2007) (rejecting the argument that clinically ill patients have a fundamental right to use physician prescribed medical marijuana to alleviate pain and suffering).

68. *E.g.*, *Cruzan*, 497 U.S. at 285 (right to refuse medical treatment when the prognosis is fatal).

69. *See* Romano & Jacobson, *supra* note 45, at 63.

are implicated, creating a tension between individual choice and bodily integrity, and the state's interests in protecting and prolonging human life.[70]

B. Glucksberg*: The Right to Die and Substantive Due Process*

In *Washington v. Glucksberg*, three terminally ill patients, four physicians, and a nonprofit organization brought suit against the state of Washington alleging that a statute banning assisted suicide violated the Due Process Clause of the Fourteenth Amendment.[71] The Court, in analyzing whether a terminally ill patient has a fundamental right to receive assistance in dying, used a two-pronged substantive due process analysis: (1) whether the fundamental right in question is deeply rooted in this nation's history and tradition; and (2) whether the case provides a careful description of the asserted fundamental liberty interest.[72] In holding that the Fourteenth Amendment did not provide a fundamental right to receive assistance in suicide, the Court relied upon the long-standing condemnation of assisted suicide in our nation's history—even for the terminally ill.[73]

Through ballot initiatives, citizens in their respective states were able to draft their own proposed physician-assisted suicide laws, circulate petitions to receive the required number of signatures, and place the proposed law on the ballot for election day.[74] This form of direct democracy enables citizens to vote directly on issues that may be too controversial for the state legislature, or where legislators are unresponsive to divisive issues.[75] It is through this legislative process that voters were able to carry out Death with Dignity initiatives in Oregon, Washington, and California.[76]

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70. *Id.*

71. Washington v. Glucksberg, 521 U.S. 702, 707–08 (1997) (analyzing whether a terminally ill patient has a fundamental right to receive assistance in dying). *See generally* U.S. CONST. amend. XIV ("No state shall . . . deprive any person of life, liberty, or property, without due process of law . . . ."); *Cruzan*, 497 U.S. at 261 (deciding whether, under the Fourteenth Amendment, an individual's constitutional rights were violated where the individual has an undisputed liberty interest in refusing medical treatment). *But cf.* Griswold v. Connecticut, 381 U.S. 479, 485–86 (1965) (finding various "zones of privacy" within the penumbra of the Bill of Rights).

72. *Glucksberg*, 521 U.S. at 720–21 (asserting a right to choose how to die).

73. *See id.* at 725 (reasoning that while the decision to commit physician-assisted suicide "may be just as personal and profound as the decision to refuse unwanted medical treatment," assisted suicide has never had the same legal protections).

74. Judith F. Daar, *Direct Democracy and Bioethical Choices: Voting Life and Death at the Ballot Box*, 28 U. MICH. J.L. REFORM 799, 800 (1995).

75. *Id.* at 801–02.

76. *Id.* at 802–03; *see also Resources*, DEATH WITH DIGNITY, https://www.deathwithdignity.org/learn (last visited May 9, 2018).

Such end-of-life treatment decisions are private, personal, and undeniably intimate to patients and their families. Many proponents of both Right to Die and Right to Try legislations challenge whether the government should be able to curtail the personal autonomy intrinsic to such decisions.[77]

C. Abigail Alliance*: The Right to Try under* Glucksberg

Abigail Burroughs was eighteen years old when she was diagnosed with head and neck cancer.[78] While undergoing treatment at Johns Hopkins, her doctors fought for access to two promising experimental cancer drugs even though Burroughs did not qualify for the clinical trials.[79] Burroughs also attempted to obtain access to treatment through the FDA's Expanded Access program but ultimately failed as she was unable to obtain consent from the drug manufacturer to provide the drug.[80] At age twenty-one, Burroughs succumbed to her cancer, but her father, Frank Burroughs, continued to strive for terminally ill patients' rights to access experimental drugs by first founding the Abigail Alliance, and later challenging the FDA in court.[81]

Abigail Alliance filed suit against the FDA, asserting that the FDA's policy barring the use of drugs that had passed Phase I testing violated the Fourteenth Amendment Due Process rights of terminally ill patients who were ineligible for clinical trials.[82] In arguing that the FDA's current proto-

77. *See, e.g.*, Brandes, *supra* note 17, at 1173–74.

78. *See generally* Sean Alfano, *Fighting for a Miracle*, CBS NEWS (Nov. 13, 2005, 3:26 AM), http://www.cbsnews.com/news/fighting-for-a-miracle.

79. *See* Amy Dudash, *All I Need Is a Miracle (And a Constitutional Right to Access It): The Constitutional Rights of the Terminally Ill Reconsidered*, 14 MICH. ST. U. J. MED. & L. 249, 251 n.7 (2010) (explaining how many terminally ill patients are unable to qualify for clinical trials given their narrow requirements, "such as age, gender, type and stage of disease, previous treatment history, and other medical conditions").

80. Martin, *supra* note 47, at 172; *see also* Complaint at 15, Abigail All. for Better Access to Developmental Drugs v. McClellan, No. 03-0611, 2004 WL 3777340 (D.D.C. Aug. 30, 2004) (stating that Expanded Access programs are usually small because drug sponsors are prohibited from charging more than a cost recovery fee to participants).

81. *See* Abigail All. for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 697–98 (D.C. Cir. 2007) (arguing that the FDA's current protocol for early access to experimental drugs was inadequate as terminally ill patients do not have months or years to wait for FDA approval).

82. *Id.* at 700–01; *see* Dudash, *supra* note 79, at 269–70 (arguing that the D.C. Circuit correctly applied the *Glucksberg* substantive due process test but failed to consider recent scientific discovery and changing societal views that could have impacted the *Glucksberg* analysis).

col for Expanded Access functioned as a practical death sentence for terminally ill patients, Abigail Alliance emphasized that terminally ill patients are typically willing to assume the risks of taking an unapproved drug.[83] Abigail Alliance based its claim for constitutional protection on two arguments: (1) that American history and practices have given almost full autonomy to doctors and their patients to decide the efficacy of certain treatments; and (2) FDA policy conflicts with the way the legal system typically treats persons in other life-threatening situations.[84]

In evaluating whether terminally ill patients have a fundamental right to access an unapproved treatment, the Court of Appeals for the D.C. Circuit utilized the two-pronged Due Process test found in *Glucksberg*.[85] The court assumed *arguendo* that the asserted right fulfilled the second prong of careful description, which requires the right's description to be narrowly tailored to the most specific level at which a relevant tradition protecting the asserted right can be identified.[86] As for the other prong, the court considered whether the right was "deeply rooted in the Nation's history and implicit in the concept of ordered liberty."[87]

The court rejected Abigail Alliance's arguments, as it failed to demonstrate a tradition of access to drugs that have not yet been proven safe and effective—instead, it found a tradition of *preventing* access to unsafe drugs.[88] The court concluded that Abigail Alliance's claimed right was not fundamental, subjecting it to rational basis review.[89] Holding that the government interest in protecting individuals from unsafe or ineffective drugs bore a rational relation to a legitimate state interest, the court ruled in favor of the FDA.[90] Nevertheless, the court did recognize that the democratic branches are better suited to decide the necessary balance between the un-

83. *Abigail Alliance*, 495 F.3d at 700–01 (noting that the court also declined to address the broader question of whether "access to medicine might ever implicate fundamental rights").

84. *Id.* at 703.

85. *Id.* at 702.

86. *Id.* at 702–03; *see also* Portell, *supra* note 22, at 132.

87. *Abigail Alliance,* 495 F.3d at 703 (citing Washington v. Glucksberg, 521 U.S. 702, 720 (1997) (asserting a fundamental "right for 'persons in mortal peril' to 'try to save their own lives, even if the chosen means would otherwise be illegal or involve enormous risks.'")).

88. *See id.* at 703, 706 ("The fact that a drug has emerged from Phase I with a determination that it is safe for limited clinical testing in a controlled and closely-monitored environment after detailed scrutiny of each trial participant does not mean that a drug is safe for use beyond supervised trials.").

89. *Id.* at 712.

90. *Id.* at 713 (reasoning that the use of potentially unsafe drugs can hasten a terminally ill patient's death).

certain risks and benefits of medical technology.[91]

D. Obergefell *and Fundamental Rights*

In *Obergefell v. Hodges*, the Court addressed whether the Constitution protects the right of same-sex couples to marry.[92] Same-sex couples from Michigan, Kentucky, Ohio, and Tennessee—states defining marriage only as a union between a man and woman—brought suit against state officials alleging that the denial of their right to marry in their state, or to have their marriages recognized after being lawfully performed in another state, violated their Fourteenth Amendment rights.[93] The Court acknowledged the traditional legal framework for substantive due process analysis, but emphasized that historical and legal tradition are just the beginning of the legal analysis in modern substantive due process cases.[94]

The Court's analysis first focused on the history of marriage, homosexuality, and legal battles fought in courts.[95] It outlined four separate principles supporting the majority's designation of marriage as a fundamental right: (1) the right of individual autonomy in personal choice; (2) the right to private intimacy; (3) the right of procreation; and (4) the function of marriage as a keystone in our society.[96] As *Obergefell* enumerates, the Due Process Clause implicates the right to personal dignity, or one's ability to choose how to live his or her life.[97] In light of the Supreme Court's support of the rights to personal dignity and autonomy with respect to marriage, the Court should reevaluate this right in the context of a terminally ill patient's right to access experimental drugs.[98]

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91. *Id.*

92. Obergefell v. Hodges, 135 S. Ct. 2584, 2606 (2015).

93. *Id.* at 2593.

94. *Id.* at 2594–95.

95. *Id.* at 2596 (detailing that for most of the twentieth century, society treated homosexuality as an illness, forcing homosexuals to lead hidden lives); *see also* Bowers v. Hardwick, 478 U.S. 186, 190 (1986) (upholding a Georgia statute banning sodomy as it did not violate the due process rights of homosexuals). *But see* Lawrence v. Texas, 539 U.S. 558, 578–79 (2003) (holding a Texas statute criminalizing sodomy was a violation of the Due Process Clause).

96. *Obergefell*, 135 S. Ct. at 2599–602. *See generally* Jack B. Harrison, *At Long Last Marriage*, 24 AM. U. J. GENDER, SOC. POL'Y & L. 1, 52–53 (2015).

97. *See Obergefell*, 135 S. Ct. at 2599–602.

98. Abigail All. for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 701 (D.C. Cir. 2007) (arguing that the Due Process Clause protects a terminally ill patient's right to receive unapproved new drugs based on the high risk of injury or death in the absence of the drug); *see infra* Part II, A (discussing why a court should utilize the *Obergefell* standard for substantive due process in reviewing a Right to Try case).

II. HOW TO FIND A RIGHT TO TRY

As Right to Try legislation becomes law in more states across the country and lawmakers continue to draw public attention to this complex issue, Congress and the FDA are faced with an interesting dilemma: thirty-eight states,[99] interest groups,[100] members of Congress,[101] and now even the President[102] have signaled overwhelming support for Right to Try. The next logical step in the democratic process is examining what, if anything, can be done to ameliorate the existing tensions between the patients, the FDA, the courts, and Congress.[103]

A. A Judicial Solution

In *Obergefell*, Justice Kennedy elaborated that the generations that "ratified the Bill of Rights and the Fourteenth Amendment did not presume to know the extent of freedom in all of its dimensions," thereby leaving later generations to determine and enjoy new liberty interests as society evolved.[104] Given the advent of new technological, scientific, and medical advances; the dawn of the Internet; and more medically informed patients combined with the overall increase in life expectancy, the courts must settle upon a legal framework for medical freedom rights cases that reflects societal innovation.[105] A nuanced legal standard and response from the FDA is necessary to reconcile terminally ill patients' access to experimental drugs with the contravening public interests of public health and safety.[106]

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99. *Right to Try in Your State*, *supra* note 64.

100. *See Abigail Alliance For Better Access to Developmental Drugs*, ABIGAIL ALLIANCE, http://abigail-alliance.org (last visited May 9, 2018); *The Right to Try*, GOLDWATER INST. (Oct. 5, 2014), https://goldwaterinstitute.org/article/right-try.

101. *See* Right to Try Act of 2017, H.R. 878, 115th Cong. § 2(a) (2017).

102. *See* President Donald J. Trump, State of the Union Address (Jan. 30, 2018) (proclaiming that terminal patients in the United States should have access to experimental treatments that could potentially save their lives, and endorsing Right to Try legislation).

103. *See, e.g.*, Roger D. Klein, *"Right to Try" Preserves Patient Freedom, Puts Regulators on Right Path*, HILL (Apr. 2, 2018, 3:00 PM), http://thehill.com/opinion/healthcare/381232-right-to-try-laws-preserve-patient-freedom-put-regulators-on-right-path (opining that a federal Right to Try law will pressure the FDA to continuously review and update its Expanded Access program and ensure that it responds to contemporary needs).

104. *See* Obergefell v. Hodges, 135 S. Ct. 2584, 2598–602 (2015).

105. *See* Dudash, *supra* note 79, at 270 (arguing that the *Glucksberg* analysis in *Abigail Alliance* fails to account for evolutionary advances in science and changes in societal mores).

106. *Id.*

1. Obergefell *& The Right to Try*

Considering the analysis in *Obergefell* and recent scientific and technological advancements in the United States over the last fifty years, courts presiding over medical treatment decisions must adapt to the evolutionary field of medicine and technology.[107] Accordingly, the court in *Abigail Alliance* should have utilized reasoning that accounted for the scientific and medical leaps, as well as the proliferation of incurable and chronic diseases, that took place over the past fifty years.[108]

a. Obergefell*'s History and Tradition*

As previously mentioned, the Court in *Glucksberg* utilized a two-prong substantive due process test. In evaluating a potential Right to Try challenge, courts must consider the history and tradition of individual patient autonomy in medical decisionmaking under *Obergefell.*[109] Rather than depending solely upon the history of drug regulation, a court should focus more keenly on the history of medical freedom rights in the United States.[110] The Supreme Court has reaffirmed the right of mentally competent, adult individuals to make their own medical decisions after receiving informed consent from their doctors.[111] However, in *Abigail Alliance*, the court focused solely upon the FDA's history and tradition of drug regulation without fully reflecting on the history of medical freedom rights that the Supreme Court has protected under the Fourteenth Amendment.[112]

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107. *See Obergefell*, 135 S. Ct. at 2598 (acknowledging the history of homosexuality in the United States but emphasizing that fundamental rights must not be based on history and tradition alone).

108. *See* Abigail All. for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 721–22 (2007) (Rogers, J., dissenting) (disagreeing with the FDA's suggestion that there is no "deeply rooted privilege to attempt to save one's own life" with medical advances).

109. *See Obergefell*, 135 S. Ct. at 2600.

110. *See Abigail Alliance*, 495 F.3d at 716–17 (Rogers, J., dissenting) (demonstrating that our nation's history clearly implicates a right for competent individuals to make fundamentally personal medical treatment decisions that "lie at the core of personal autonomy, self-determination, and self-defense").

111. *See* Cruzan v. Director, 497 U.S. 261, 289 (1990) (finding that a mentally competent adult has the right to refuse life-sustaining treatment, as it implicates the person's liberty interest under the principles of self-determination and informed consent); Roe v. Wade, 410 U.S. 113, 153 (1973) (holding that the fundamental right of privacy is broad enough to encompass a woman's decision to choose whether or not to terminate her pregnancy, even after recognizing the long history of condemnation of the practice of abortion).

112. *See Abigail Alliance*, 495 F.3d at 703–04 (claiming that the United States has a long

The court in *Abigail Alliance* missed an opportunity to consider the long-standing tradition of choice in one's medical decisions, instead choosing to focus on FDA's relatively short regulatory history. At its inception, the FDCA was primarily concerned with evaluating a drug's safety.[113] In 1962, when Congress amended the FDCA, it granted the FDA greater authority over the regulation of drugs.[114] The amended FDCA required pharmaceutical companies to provide "substantial evidence" of a drug's safety and efficacy through adequate and well-controlled investigations prior to FDA approval.[115] Had the court in *Abigail Alliance* undertaken a more liberal application of the substantive due process analysis, akin to the approach used by the Supreme Court in *Obergefell*, the court of appeals may have reached a different outcome.[116] The court could have acknowledged the FDA's tradition of drug regulation and its relatively short history in requiring efficacy standards, but still underscored the importance of the nation's history of protecting individual rights to make informed medical decisions protected by the Fourteenth Amendment.[117]

b. The Right to Personal Autonomy

In reframing its due process analysis, *Obergefell* describes how personal choice in one's decision to marry is inherent in the concept of individual autonomy and self-determination—two pivotal principles in the United States.[118] Analogously, autonomy in choosing one's own medical treatment

history of drug regulation and that Abigail Alliance would have to prove, under *Glucksberg*, that there is a tradition of access to unapproved new drugs that have not yet been proven safe or effective). *But see Cruzan*, 497 U.S. at 280 (acknowledging that the choice between life and death is a deeply personal one that implicates one's right to self-determination).

113. Jamie L. Aldes, Note, *The FDA Clinical Trial Process: Effectuating Change in the Regulatory Framework Governing Clinical Trials to Account for the Historical Shift from "Traditional" to "New" Phase I Trials*, 18 HEALTH MATRIX: J.L. MED. 463, 466–67 (2008); *see also Abigail Alliance*, 495 F.3d at 703.

114. *See* Aldes, *supra* note 113, at 467.

115. *See id.*

116. Obergefell v. Hodges, 135 S. Ct. 2584, 2598 (2015).

117. *See id.* at 2595–96 (recognizing both the history and tradition of marriage being a unity between one man and one woman, but emphasizing that evolving societal understandings of marriage are a characteristic of a nation where new ideals of freedom become apparent to new generations); *Abigail Alliance*, 495 F.3d at 714 (Rogers, J., dissenting) (arguing that the court fails to consider the nation's deeply respected and protected right to preserve life, "a corollary to the right to life enshrined in the Constitution").

118. *See Obergefell*, 135 S. Ct. at 2599 (describing the connection between marriage and liberty as similar to the choices of contraception, family relationships, procreation, and child-drearing, which the Constitution protects); *see also* Loving v. Virginia, 388 U.S. 1, 12 (1967)

depends upon those very same concepts.[119] The Court first considered a case involving medical decisionmaking within the context of the marital home in *Griswold v. Connecticut.*[120] In finding a fundamental right to privacy within the penumbra of the Bill of Rights, the Court in *Griswold* utilized privacy interests and self-autonomy to uphold a right for married couples to access and use contraceptives.[121] Similarly, in *Cruzan v. Director,*[122] the Supreme Court relied upon the same fundamental concept of privacy in finding a protected liberty interest in refusing life-sustaining medical treatment. Years later, the Court again identified and reaffirmed the value of privacy in a woman's right to choose whether to terminate her pregnancy.[123] However, *Abigail Alliance* dismissed the importance of bodily integrity, privacy, and the freedom of choice in medical treatment, and instead focused on public health concerns and governmental interests.[124]

As courts lack a single bright-line test for analyzing medical decisionmaking, they must balance the rights of individuals with the interests of the government and those of public health and safety.[125] Furthermore, the gap be-

(invalidating the prohibition of interracial marriages under the Due Process Clause as it violated an essential personal right and one of the most intimate choices a person can make).

119. *See, e.g.*, Planned Parenthood v. Casey, 505 U.S. 833, 870–71 (1992) (reaffirming a woman's right to an abortion until the point of viability of the fetus); Roe v. Wade, 410 U.S. 113, 153 (1973) (holding that denying a woman the right to terminate her pregnancy could cause medical, psychological, and physical harm to everyone involved); Baxter v. State, 224 P.3d 1211, 1217 (Mont. 2009) (holding that receiving physician aid in dying is not against public policy). *But see* United States v. Rutherford, 442 U.S. 544, 551 (1979) (refusing to recognize an exception under FDA's safety and effectiveness standards for terminally ill patients to access an unapproved cancer treatment).

120. 381 U.S. 479, 485–86 (1965) (invalidating a Connecticut law prohibiting the use of contraception as it violated the constitutional right to marital privacy).

121. *Id.* (holding that prohibiting the use of contraception in marital relationships would achieve its purpose by imposing a detrimental impact on married couples).

122. 497 U.S. 261, 281 (1990).

123. *See Planned Parenthood*, 505 U.S. at 846–47 (explaining that a woman's right to an abortion stems from the Due Process Clause of the Fourteenth Amendment); *Roe*, 410 U.S. at 153 (finding a right to privacy in the penumbra of the Bill of Rights that covers a woman's right to abortion).

124. *See* Abigail All. for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 721–22 (D.C. Cir. 2007) (deciding that the arguments of medical necessity and self-defense did not create a fundamental right for terminally ill patients to access unapproved drugs, even if patients accepted the higher risks of taking new drugs that passed only Phase I testing).

125. *See generally* Romano & Jacobson, *supra* note 45, at 62 (explaining that without a single constitutional test, judicial attempts to balance the interests of the government, the autonomy of the individual, and the interests of public health do not consistently or ade-

tween end-of-life treatment decisions, such as those in *Glucksberg* and *Cruzan*, and right-to-life cases, such as *Abigail Alliance,* presents conflicting approaches on how to determine the extent of an individual's right to personal choice in his or her medical care, especially where the prognosis is terminal.[126] In light of *Obergefell*, courts must consider, along with the history of drug regulation in the United States, the deep-rooted history of the individual's role in making his or her own healthcare choices, as such decisions shape an individual's future and may involve the choice between life and death.[127] By taking this history into account, a court, utilizing the more expansive due process analysis found in *Obergefell*, could find a fundamental right for terminally ill patients to receive experimental treatment.[128]

2. Using the Due Process Clause to Find a Fundamental Right to Choose One's Medical Treatment

The Due Process Clause of the Fourteenth Amendment provides that no "State shall deprive any person of life, liberty, or property without due process of law."[129] In *Abigail Alliance,* the court decided that the FDA's policy barring terminally ill patients from accessing investigational new drugs to potentially save their own lives did not violate the Due Process Clause of the Fourteenth Amendment.[130] Today, thirty-nine states have already passed Right to Try legislation.[131] Societal changes, advances in medical technology, and the increase in the human lifespan as well as in rates of incurable diseases may reflect an impetus for change in the legal analysis for deciding whether terminally ill patients have a right to access investigational new drugs.[132]

The dissent in *Abigail Alliance* argued that the majority misunderstood the

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quately balance all necessary factors when deciding cases involving medical decisionmaking).

126. *See id.*

127. *See* Obergefell v. Hodges, 135 S. Ct. 2584, 2599 (2015) (stating that a right to choose one's partner in marriage shapes an individual's destiny).

128. *See id.* at 2596 (acknowledging the history of prohibition of homosexuality in the United States and that substantial cultural and political developments created the impetus for change).

129. U.S. CONST. amend. XIV, § 1.

130. Abigail All. for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 712 (D.C. Cir. 2007) (holding that the FDA's policy barring access to unapproved new drugs was rationally related to protecting public health).

131. *Right to Try in Your State*, *supra* note 64.

132. *See* Romano & Jacobson, *supra* note 45, at 62 (concluding that more people will be seeking treatment for incurable diseases given the high incidence rate of cancer in our society, our aging population, and the longer average lifespan of Americans).

right claimed by Abigail Alliance in failing to consider the nation's "deep respect and protection for the right to preserve life."[133] Addressing the various fundamental rights found under the purview of the Due Process Clause, the dissent questioned how the right to try to save one's life with experimental drugs falls outside of those protections.[134] In focusing on the historical prong of the substantive due process analysis, the dissent revealed that an individual's right to make fundamentally personal medical decisions exists at the very core of personal autonomy, self-determination, and self-defense.[135] This begs the question of whether terminally ill patients have the right to save their own lives through potentially life-saving drugs, therein asserting their own form of medical self-defense.[136]

Ultimately, the Court has been reluctant to recognize new rights through the Due Process Clause.[137] The *Glucksberg* Court expressed concern over expanding the concept of substantive due process when deciding the landmark physician-assisted suicide case, given that the "guideposts for responsible decisionmaking" in novel legal areas are limited.[138] Thus, the Court elaborated that it must be sure to act with utmost care in exercising judgment in such areas, "lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of [the] Court."[139] Fortunately, the Court's decision in *Obergefell v. Hodges* provides some hope for a positive legal outcome for proponents of Right to Try, as *Obergefell* adopts a less stringent substantive due process analysis than the Court previously applied in *Glucksberg* and even in *Lawrence v. Texas*.[140]

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133. *Abigail Alliance*, 495 F.3d at 714 (Rogers, J., dissenting).

134. *Id.* at 715 (discussing the right to marry, to fornicate, to have children, to control the education and upbringing of children, to perform varied sexual acts in private, and to control one's own body even if it results in one's own death or the death of a fetus).

135. *Id.* at 717 (explaining that under the common law theory of self-defense, a person facing imminent death may take reasonable steps to protect her own life).

136. *Id.* at 710. *But see* Seema Shah & Patricia Zettler, *From a Constitutional Right to a Policy of Exceptions:* Abigail Alliance *and the Future of Access to Experimental Therapy*, 10 YALE J. HEALTH POL'Y L. & ETHICS 135, 146–47 (2010) (rejecting the idea of medical self-defense and distinguishing *Abigail Alliance* from *Roe v. Wade* based on termination of a pregnancy having a known therapeutic effect, while an experimental drug may not).

137. *See* Washington v. Glucksberg, 521 U.S. 702, 720 (1997) (refusing to recognize a fundamental right to physician-assisted suicide); United States v. Rutherford, 442 U.S. 544, 551 (1979) (finding no exception for terminally ill patients to access ineffective cancer drugs).

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

139. *Id.*

140. *See, e.g.*, 539 U.S. 558, 578–79 (2003) (declaring that the Founders could not know the breadth of liberty at the time of ratification of the Fifth and Fourteenth Amendments, but persons in every generation may rely upon the Constitution for greater freedoms).

3. Obergefell *as a Framework for Medical Decisionmaking*

In light of the decisions in *Abigail Alliance* and *Obergefell*, one thing is clear: the rigid substantive due process framework of *Glucksberg* no longer supports the continuous evolution of the medical and pharmaceutical fields and their advancing technologies, nor does it suit the needs of an aging population with higher rates of incurable diseases.[141] Even prior to *Obergefell*, *Lawrence v. Texas* effectively set aside the history and tradition of prohibitions against same-sex sodomy, and instead privileged equality of treatment and the privacy interest in consenting adults engaging in intimate conduct within their homes.[142] However, until the *Obergefell* decision in 2015, the Court largely ignored the *Lawrence* decision and its more encompassing due process analysis.[143] While the *Glucksberg* analysis accomplishes its goal of refusing to recognize new constitutional rights,[144] *Obergefell* tested the applicability of the *Glucksberg* analysis by recognizing the growing trends of acceptance and tolerance toward homosexuals.[145]

While *Obergefell* and *Abigail Alliance* do not seem to have much in common on the surface, the substantive due process analysis applied in *Obergefell* could make all the difference if a court were to hear a case involving Right to Try and a challenge to FDA regulation in the future.[146] Based upon the Court's heavy reliance on personal autonomy in *Obergefell*, as well as the consideration of growing societal trends,[147] a court would be obliged to consider the growing Right to Try movement among the states, as well as the evolution of science and medicine in today's society.

Although the Supreme Court denied certiorari to *Abigail Alliance*, legal

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141. *Abigail Alliance*, 495 F.3d at 716 (Rogers, J., dissenting) (opining that the *Glucksberg* analysis fails to account for the tradition of self-preservation and the careful description requirement fails to account for the multitude of Supreme Court cases deriving a narrower right (such as abortion) from a broader right (such as the penumbral right to privacy)); *see also* Dudash, *supra* note 79, at 266–67 (discussing the inapplicability of *Glucksberg* to due process cases as the rigid requirements fail to recognize the evolving nature of society and technology).

142. *Lawrence*, 539 U.S. at 575.

143. *See generally* Brian Hawkins, Note, *The* Glucksberg *Renaissance: Substantive Due Process Since* Lawrence v. Texas, 105 MICH. L. REV. 409, 421, 424–25 (2006) (noting that the substantive due process analysis in *Lawrence* diverged from *Glucksberg*'s restrictive reasoning and took into account "emerging awareness" of liberty giving protection to adults deciding how to engage in matters pertaining to sex).

144. *Id.* at 426.

145. Obergefell v. Hodges, 135 S. Ct. 2584, 2596 (2015).

146. *Id.* at 2597–98; *Abigail Alliance*, 495 F.3d at 712.

147. *Obergefell*, 135 S. Ct. at 2596.

action stemming from the widespread proliferation of Right to Try legislation may eventually reach the courts again.[148] In that event, the reviewing court will be obligated to address the passage of Right to Try bills in over a majority of the fifty states, as well as the public pressure to address the rights of the terminally ill. However, in the meantime, an administrative law approach undertaken by the FDA may be more adept to address this issue, especially given the current political climate and the FDA Commissioner's views on Expanded Access.[149] The FDA, supported by Congress, may be able to tackle this legal challenge to current FDA laws and regulations.[150]

B. An Administrative Solution

Abigail Alliance highlighted a controversial issue—the historical authority of the FDA to regulate pharmaceutical drugs and the autonomy of an individual to choose medical treatment that he or she believes may improve his or her chances of survival.[151] At first glance, the drug approval process currently in place under the FDCA exemplifies a labyrinth of bureaucracy, risk aversion, and long-windedness.[152] For example, although the FDA prohibits access to experimental drugs for terminally ill patients with no alternative treatment options, it permits "off-label" usage[153]—referring to the practice of physicians prescribing drugs for conditions other than what the FDA originally approved the drug to treat—under the FDCA.[154] Rather than requiring drug manufacturers to submit a Supplemental New Drug Application for approval of an additional indication, the FDA permits off-label use despite the lack of evidence demonstrating efficacy or knowledge of

148. *Abigail Alliance*, 495 F.3d at 712, *cert. denied*, 128 S. Ct. 1069 (2008).

149. *See Examining Patient Access to Investigational Drugs: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115th Cong. 2–3 (2017) (testimony of Dr. Scott Gottlieb, Comm'r, U.S. Food & Drug Admin.) [hereinafter Testimony of Gottlieb] (affirming the FDA's commitment to working with Congress and helping terminally ill patients glean access to more treatment options, including through Right to Try legislation); President Donald J. Trump, *supra* note 102 (arguing that terminally ill patients should not have to travel abroad to seek treatments).

150. *See* Testimony of Gottlieb, *supra* note 149, at 8–9.

151. Portell, *supra* note 22, at 136.

152. *E.g.*, Ellen A. Black, *State "Right to Try" Acts: A Good Start, but a Federal Act Is Necessary*, 45 SW. L. REV. 719, 728 (2016) (criticizing the FDA's Expanded Access program as too complicated and time consuming).

153. 21 U.S.C. § 396 (2012).

154. *See* Christina Sandefur, *Safeguarding the Right to Try*, 49 ARIZ. ST. L.J. 513, 516 (2017).

proper dosage through a new clinical trial.[155] Yet another example, while not directly pertaining to the FDA, is state legislation legalizing both medical and recreational marijuana in a direct affront to the federal Controlled Substances Act.[156] The trend toward legalizing marijuana, even in direct contradiction to a federal statute, demonstrates that lawmakers can achieve a solution for Right to Try that coexists with the FDCA.[157]

Until recently, the relationship between state and federal drug regulation was somewhat distinct. States upheld authority over the practice of medicine pursuant to their police powers, while the federal government regulated medical products, including drugs.[158] Amid concerns about FDA oversight being too restrictive, states have continued to challenge the scope and implicitly blur the lines of FDA jurisdiction.[159] Given the preemption challenges inherent in states' attempts to assert jurisdiction over drug regulation, this underscores the significance of why states would enact laws that challenge the scope of the FDA's authority.[160] After the second federal Right to Try Act failed in Congress, and in responding to the signal of support from the FDA Commissioner,[161] states are likely enacting Right to Try laws as a vehicle for change in federal policy.[162]

1. The Ups-and-Downs of Right to Try in Practice

Deregulation of the FDA's drug approval process would certainly come with a price.[163] The FDA is primarily concerned with potentially unsafe and ineffective drugs entering the marketplace—regardless of who is receiving such drugs.[164] Granting access to unapproved drugs, even to terminally

155. *Id.*

156. *See generally* Michael A. Cole Jr., Note, *Functional Preemption: An Explanation of How State Medicinal Marijuana Laws Can Coexist with the Controlled Substances Act*, 16 MICH. ST. U. J. MED. & L. 557, 558 (2012).

157. *See* Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 848–49 (2017).

158. *Id.* at 849.

159. *See id.* (suggesting that Maine's law permitting the importation of unapproved drugs from certain countries (although held preempted under federal law), the passage of Right to Try laws throughout the country, and medical marijuana laws present challenges to federal drug regulation).

160. *Id.* at 850.

161. *See* Right to Try Act of 2017, H.R. 878, 115th Cong. (2017); Testimony of Gottlieb, *supra* note 149, at 8–9.

162. *See* Zettler, *supra* note 157, at 850–51 (synthesizing that states may be regulating in this area to motivate the federal government to adopt particular policies and to make Congress and the FDA more honest and democratically accountable to their constituents).

163. *See* Portell, *supra* note 22, at 140–42.

164. Brandes, *supra* note 17, at 1168.

ill patients without any alternative treatment options, does not resolve the uncertainty of the actual effectiveness of the drug itself, or the potential adverse side effects.[165] While proponents of deregulation pose that terminally ill patients faced with impending death are less likely to be concerned about side effects, critics assert that the ingestion of such a drug may actually hasten the deaths of terminally ill patients, acting contrarily to the governmental interest in preserving life.[166]

More importantly, widespread consumption of investigational drugs compromises the integrity and efficacy of the clinical trial process.[167] A patient's ability to obtain an experimental drug outside of a clinical trial or Expanded Access program would eviscerate the current drug approval regime,[168] as well as jeopardize the collection of quality data necessary for determining a drug's safety and efficacy.[169]

Right to Try supporters argue that doctors, on behalf of their patients, should be able to negotiate directly with drug companies, thereby eliminating the government's role in the experimental drug process.[170] However, allowing physicians to negotiate the use of experimental drugs on behalf of their patients, without more than a preliminary showing of safety, could expose the profession to an influx of litigation where the side effects of a given drug are largely unknown.[171]

Currently, pharmaceutical companies have virtually no incentive to pro-

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165. *Id.*

166. Romano & Jacobson, *supra* note 45, at 62; *see also* United States v. Rutherford, 442 U.S. 544, 555–56 (1979) (finding that the concept of drug safety for terminally ill patients is the same as for anyone else).

167. Brandes, *supra* note 17, at 1168.

168. Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147 (Dec. 14, 2006) (codified at 21 C.F.R. pt. 312) ("[A] system of blindly permitting uncontrolled access to investigational drugs could make it difficult or impossible to enroll adequate numbers of patients in clinical trials . . . .").

169. Brief for the Respondents in Opposition at 5, Abigail All. for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007) (No. 07-444).

170. Martin, *supra* note 47, at 168–69. *See generally* Robert Pear, *House Rejects Bill to Give Patients a "Right to Try" Experimental Drugs*, N.Y. TIMES (Mar. 13, 2018), https://www.nytimes.com/2018/03/13/us/politics/house-rejects-right-to-try-bill.html (noting that under the House bill, Right to Try would mostly immunize pharmaceutical companies, doctors, and hospitals for the risks associated with providing unapproved drugs, and restrict the FDA from using any data to "delay or adversely affect" federal approval of the drug).

171. Brandes, *supra* note 17, at 1150. *But see* Pear, *supra* note 170 (discussing how the federal bill would protect physicians and hospitals unless they "engaged in gross negligence or willful, reckless or criminal misconduct, or they intentionally harmed a patient").

vide experimental new drugs to patients outside of the clinical trial process.[172] Since the FDA prohibits incurring any profit from the clinical trial or Expanded Access programs, pharmaceutical companies would have to produce extra quantities for patients outside of their clinical trials, which could be costly and yield negative data.[173] Another consideration for pharmaceutical companies is their capacity to supply investigational drugs to willing participants outside of a clinical trial.[174] Additionally, as the FDA does not require drug manufacturers to participate in the Expanded Access program, terminally ill patients have an even smaller pool from which they are able to access investigational drugs.[175] In addition to the lack of financial incentive, there are a variety of reasons as to why drug manufacturers choose not to participate in the Expanded Access program.[176]

2. More Access, More Lives Saved

The pivotal question becomes how the FDA can legally implement the principles behind the Right to Try movement without circumventing its regulatory authority under the FDCA and without ceding its regulatory power to Congress. Although bills have been introduced in Congress to enact a federal Right to Try law, federal legislation thus far has been stymied,[177] and it will primarily fall upon the FDA to take regulatory action through notice-and-comment rulemaking, similar to its response during the height of the AIDS epidemic and after its near-loss in *Abigail Alliance*.[178]

With this in mind, how can terminally ill patients influence the administrative process of the FDA? Under the Administrative Procedure Act, citizens have a right to submit comments on an agency's proposed rule, as well

172. Portell, *supra* note 22, at 142–43; *accord* Thomas, *supra* note 58 (criticizing both federal Right to Try bills for failing to address the main barrier of pharmaceutical consent to providing experimental drugs to patients).

173. Tsakopoulos et al., *supra* note 53, at 629–30. *But see* Howard, *supra* note 54, at 287–88 (extrapolating that the Expanded Access program permits manufacturers to charge for investigational drugs within the parameters set by the program).

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

175. Black, *supra* note 152, at 729.

176. Tsakopoulos et al., *supra* note 53, at 638.

177. *See* Pear, *supra* note 170 (declaring that the House of Representatives rejected the federal bill).

178. *See, e.g.*, Grossman, *supra* note 32, at 692 (contending that the AIDS activist movement to reform FDA drug regulation "demonstrates how extralegal popular mobilization can play an important constitutive function in the administrative law sphere," deeming it a form of "administrative constitutionalism").

as petition an agency for new rules.[179] However, the typical notice-and-comment process is time and resource intensive and can take several years before an agency issues a final rule.[180] Terminally ill patients do not have this kind of time. Unlike other reforms to rulemaking procedures that aim to decrease the time between the proposed and final rules,[181] negotiated rulemaking can shorten the overall process by bringing stakeholders together in one large negotiation to work toward issuing a draft rule.[182] This strategy would provide an avenue for the FDA, members of Congress, terminally ill patients and their representatives, and pharmaceutical companies to meet to consider the broad implications of the Right to Try movement, and how to address growing the public pressure to reform drug regulation.

Nevertheless, any FDA action would still be subject to review under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*.[183] Under *Chevron*, a court reviewing an agency's action under the agency's own enabling statute must first address whether Congress has spoken directly on the issue.[184] If Congress has not spoken directly on the issue, it is in within the court's discretion to determine "whether the agency's answer is based on a permissible construction of the statute."[185] A proposed rule suggesting further expansion of the Expanded Access program to grant terminally ill patients access to unapproved therapies could be interpreted as an extension of the Expanded Access program. Applying *Chevron*, as Congress has not spoken directly on this specific issue, a court would have to determine whether the FDA was acting within a permissible construction of the FDCA in its proposal for Right to Try.[186] As there have been no challenges to the Expanded Access program operated by the FDA, a court could reasonably find that, in the event the FDA does propose a less stringent and more encom-

179. 5 U.S.C. § 553(c) (2012). *But see* Grossman, *supra* note 32, at 709 (elaborating that despite the various court decisions directing administrative agencies to consider and address the comments submitted to them, "agencies maintain extremely broad discretion to reject commenters' objections and suggestions").

180. *See* Julia Kobick, Note, *Negotiated Rulemaking: The Next Step in Regulatory Innovation at the Food and Drug Administration?*, 65 FOOD & DRUG L.J. 425, 431 (2010).

181. *Id.* at 432 (referring to Direct Final Rulemaking and Interim Final Rulemaking).

182. *Id.* at 432, 434–35 (noting how FDA has never voluntarily initiated a rulemaking negotiation, even though it is encouraged by Congress and FDA has experienced ossification in its rulemaking).

183. 467 U.S. 837 (1984).

184. *Id.* at 842–43 (stating that where Congress's intent is clear, both the court and the agency "must give effect to the unambiguously expressed intent of Congress").

185. *Id.*

186. *See id.*

passing Expanded Access protocol for terminal patients, the FDA acted within its authority in its interpretation of the statute.[187]

Though the FDCA preempts current Right to Try legislation in the states,[188] the FDA still must address its growing popularity. One of the many arguments in favor of Right to Try is the arduous process that doctors must endure in order to even apply under the FDA's Expanded Access program—one that involves one hundred hours of the FDA-required paperwork.[189] The FDA responded to such complaints, in light of the publicity garnered by the Right to Try movement, by proposing Form 3926 which can be completed in forty-five minutes.[190] This change certainly reflects the FDA's initiative to assuage concerns of the public, as well as terminally ill patients.[191]

While this step addresses one of the concerns with drug regulation, the FDA can still do more. Spearheaded by activists during the peak of the AIDS crisis, the FDA proposed, and executed, a "parallel track"[192] option for HIV/AIDS patients who were ineligible for participation in other clinical trials or who could not tolerate the harsh side effects of azidothymidine, the only FDA-approved therapy at the time.[193] In its proposed policy statement for the "parallel track" program for AIDS, the FDA mentioned its willingness to expand the program to other life-threatening diseases at a later time.[194] Analogously, in response to Right to Try, the FDA could revisit its "parallel track" approach to life-threatening diseases, and designate "parallel track" status to certain diseases, such as ALS, that severely affect

187. *Id.*

188. Black, *supra* note 152, at 740.

189. *Id.* at 728.

190. *Id.* at 728–29 (stating that the new form only requires eight types of information and one attachment, compared to Form 1571, which required twenty-six separate types of information and seven attachments).

191. *Individual Patient Expanded Access Applications: Form FDA 3926, Guidance for Industry*, U.S. FOOD & DRUG ADMIN. (Oct. 2017), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM432717.pdf.

192. *See* Grossman, *supra* note 32, at 720 (describing "parallel track" as a post-Phase I protocol "permitting the treatment use of experimental drugs while controlled efficacy trials are ongoing").

193. *See id.* at 688, 725 (explaining how the parallel track program was a success for the AIDS activists as it allowed eligible patients to receive experimental treatment very early in the development process).

194. Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and HIV-Related Disease, 55 Fed. Reg. 20,856 (May 21, 1990); *see also* Grossman, *supra* note 32, at 725 (providing that the parallel track required physicians to collect and report safety and even efficacy data).

the morbidity and mortality of the American people.

Another potential solution could be to drastically reform the clinical trial process by making "trials larger and more accessible to those located outside the testing region."[195] Larger trials would also allow drug manufacturers to expand the inclusion criteria for applicants.[196] Scientists suggest that increasing the size of clinical trials, as well as including a broader array of patients subject to less restrictive criteria, may make Phase II testing more useful by providing significant scientific evidence and limiting the effects of Expanded Access programs on clinical investigations.[197] The FDA, and Congress, could also create a national institutional review board.[198] States could partner with the FDA to fund national institutional review boards that focus specifically on Expanded Access requests by patients.[199] As the FDA has previously acknowledged that institutional review boards create a barrier for patients seeking approval for Expanded Access,[200] a national board could yield faster review times given that its sole focus is on Expanded Access requests.

CONCLUSION

Based upon the growing number of states enacting their own Right to Try legislation, as well as the proposed federal legislation, the FDA must respond to the growing Right to Try movement. While a judicial ruling in favor of a fundamental right to access investigational new drugs for terminally ill patients would be ideal, it is unlikely under the current *Glucksberg* legal analysis for substantive due process. If a court adopted a more expansive approach toward fundamental rights by incorporating *Obergefell* into its due process decision, the court would be able to take into account the evolving state of science and medicine, as well as decisions in favor of personal autonomy and dignity, and a case similar to *Abigail Alliance* would prevail. Under the *Obergefell* standard, it is more likely that a court would find

195. Black, *supra* note 152, at 731; *see also* Shah & Zettler, *supra* note136, at 189.

196. Shah & Zettler, *supra* note 136, at 189.

197. *Id.* (suggesting that such a change in clinical trials would also ensure patient safety by providing individuals exposed to unapproved drugs with monitoring akin to clinical trials).

198. Black, *supra* note 152, at 731 (noting that the creation of a national institutional review board would make patient participation easier and less costly).

199. *See* Darrow et al., *supra* note 59, at 280.

200. *See generally Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers, Guidance for Industry*, U.S. FOOD & DRUG ADMIN. 8 (Oct. 2017), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351261.pdf.

a fundamental right to access experimental therapies for terminally ill patients.

However, a more pragmatic solution may be through administrative action by the FDA in the form of notice-and-comment rulemaking or by reforming the clinical trial system to be more inclusive for terminally ill patients. As the FDA possesses the relevant expertise in the area of drug regulation, the agency may be better suited than the courts in crafting and defining the Right to Try in practice, without compromising the safety and effectiveness standards of the FDCA.