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Patients Battle the FDA

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Patients Battle the FDA

*Robert D. Clark, Jr.**

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I. INTRODUCTION

Patients diagnosed with terminal illnesses often struggle to obtain medication that provides safe and effective treatment of their illnesses. One story illustrates this struggle. In 2011, two brothers, Austin and Max LeClaire, respectively 12 and 9 years old at the time, were diagnosed with a form of muscular dystrophy.¹ Duchenne muscular dystrophy causes muscular degeneration, and, ultimately, death.² After learning of an investigational drug, the boys' mother tried to enroll them in the clinical trial for the drug.³

In the summer of 2011, Max was admitted to the drug's clinical trial.⁴ Austin, however, was not accepted, because his symptoms had progressed too far for the study.⁵ After sixteen weeks on the drug, Max's health improved drastically, and he was able to walk and play like other children his age.⁶ Austin's health continued to

1. Bonnie Rochman, *'Both my Sons Deserve to Live': A Mother's Plea for Quicker Action from the FDA*, TIME (Feb. 7, 2013), <http://healthland.time.com/2013/02/07/both-my-sons-deserve-to-live-a-mothers-plea-for-quicker-action-from-the-fda/>.

2. *Duchenne Muscular Dystrophy (DMD)*, MUSCULAR DYSTROPHY ASS'N, <https://www.mda.org/disease/duchenne-muscular-dystrophy> (last visited Jan. 30, 2016).

3. GoldwaterInstitute, *Goldwater Institute CEO Darcy Olsen Discusses Right to Try with Stossel (3/27/2014)*, YOUTUBE (Apr. 1, 2014), <https://www.youtube.com/watch?v=0pjOJmYA16A> (showing John Stossel's "Government Bullies," which was broadcast on Fox Business television on March 27, 2014).

4. Rochman, *supra* note 1.

5. *Id.*

6. *Id.*

worsen, as he was unable to gain access to the drug.⁷ Max, and the eleven other fortunate patients accepted for the trial, stabilized, with most of them regaining muscular strength they had lost.⁸ The patients in the trial suffered no serious side effects.⁹ Despite the positive results of the testing and the inevitability of death for other patients with this illness, no patients outside the clinical trial could access the drug, because the Food and Drug Administration (FDA) believes that only it can properly assess the safety and efficacy of drugs.¹⁰ The FDA's clinical trial process for the approval of investigational drugs prohibits other patients from gaining access to new drugs, with the stated goal of protecting patients from unsafe or ineffective drugs.¹¹ Due to this lack of access to the experimental drug, other patients may only use the less successful, approved drugs, leaving them likely to die from the illness. As Max improved in health, Austin continued to worsen.¹² Should Austin be denied access to the drug that saved his brother's life just because the FDA's arbitrary rules claim to protect patients from the possible harm of ineffective or unsafe new drugs? This article argues that, even assuming that the FDA rules protect patients from harm, terminally ill patients who have no other treatment options should be able to make their own medical choices concerning use of new drugs, rather than being subject to the hegemony of the FDA.

This article addresses the topic of terminally ill patients accessing investigational new drugs, when those patients have no other remaining treatment options. This article discusses the history of the FDA and the drug approval process, and then examines the current regulations imposed on investigational drugs. Part II explains the history of drug regulation in the United States, as well as the current drug regulation and new drug approval process under the

7. *Id.* While, obviously, admission to a clinical trial or investigational drug does not guarantee a cure, that access at least gives the patient a chance of a cure, when the FDA rules would instead result in access merely to drugs that have provided only marginal treatment for the illness. *See, e.g., id.* It is possible that the new drug would not help Austin at all, but this article argues that, regardless of efficacy, the use of new drugs should be decided by the patient in consultation with the physician, rather than a government bureaucrat.

8. GoldwaterInstitute, *supra* note 3.

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.* Austin LeClaire eventually gained access to the new drug through a different clinical trial, which he believes has helped to slow the progression of the disease. Alex Hogan, Hyacinth Empinado & Jeffery DelViscio, *For Two Brothers with Duchenne, an FDA Drug Approval Brings Joy and Relief*, FOX NEWS (Sept. 20, 2016), <http://www.foxnews.com/health/2016/09/20/for-two-brothers-with-duchenne-fda-drug-approval-brings-joy-and-relief.html>. After the initial writing of this article, the FDA approved the drug in September 2016. *Id.*

FDA. Part III covers the various problems with the current new drug approval process, such as the arbitrariness and delays involved in the approval process, and the lack of new drug access for terminally ill patients.

Part IV analyzes the groups that have formed to advocate for expanded drug access for terminally ill patients, such as the Abigail Alliance for Better Access to Developmental Drugs,¹³ and the efforts they have undertaken to achieve their goals. This section also analyzes Abigail Alliance's federal lawsuit against the FDA, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*,¹⁴ which was the Abigail Alliance's initial effort to expand drug access for terminally ill patients. Part V argues that the Alliance's asserted right of terminally ill patients to access new drugs was fundamental and should have been protected.

Part VI explores the crux of this article: more recent efforts undertaken by advocates for new drug access for terminally ill patients, including states' so-called Right to Try laws.¹⁵ This section also discusses other efforts to expand new drug access that have made less headway but actually provide more realistic opportunities for reform, such as changes in federal law or regulation. The section concludes by noting the possibility that the recent efforts to expand new drug access for terminally ill patients may still provide a political solution to the problem, though the state Right to Try laws will ultimately fail due to the supremacy of federal law. Part VII then concludes by finding that the state Right to Try laws will fail to directly expand access to new drugs, but may succeed in bringing about a political solution to expanding access by pressuring the FDA to modify its regulations.

II. A SHORT HISTORY OF DRUG REGULATION IN THE UNITED STATES TO THE PRESENT DAY

Early federal drug regulation was minor, not widespread, and only began in the United States in the mid-nineteenth century in

13. Abigail Alliance, founded in 2001, advocates for expanded new drug access for terminally ill patients. *Our Story*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/story.php> (last visited Jan. 18, 2016). The group began after Abigail Burroughs was diagnosed with cancer and unable to access experimental drugs, ultimately dying. *Id.*

14. 445 F.3d 470 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

15. See GOLDWATER INST., RIGHT TO TRY MODEL LEGISLATION (Jan. 28, 2015), http://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2016/1/5/GoldwaterInstituteRighttoTryModel.pdf.

response to rampant drug “misbranding” and “adulteration.”¹⁶ Since that time, however, the United States Government created the Food and Drug Administration, which now implements a vast regulatory regime concerning the approval of drugs for sale to patients.¹⁷ The history of the development of drug regulation is important for understanding how the current regime has developed and also in determining whether drug regulation has been part of the nation’s traditions, which is relevant for analyzing any fundamental rights in relation to drug access.¹⁸

A. *The Development of Drug Regulation in the United States*

To resolve the problem of drug adulteration and misbranding, Congress passed the Import Drugs Act of 1848,¹⁹ which was the first federal law regulating drugs, and applied only to drugs imported into the United States.²⁰ Fifty years later, Congress passed the first drug law that directly regulated the entire United States drug market: the Pure Food and Drug Act of 1906.²¹ The 1906 Act applied the prohibitions on adulteration and misbranding to drugs manufactured in the United States and traded in interstate commerce.²² Although the law mandated that any label on the drug be true and that certain ingredients be listed if they were included in the drug,²³ the Pure Food and Drug Act implemented no real safety or effectiveness requirements.²⁴

Congress expanded the drug regulation regime in 1938 with the Federal Food, Drug, and Cosmetic Act,²⁵ which, among other things, required drug manufacturers to provide scientific evidence regard-

16. Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420, 422 (1981).

17. See 21 U.S.C. § 301–399 (2015).

18. See *Abigail Alliance I*, 445 F.3d at 482.

19. Import Drugs Act, ch. 70, 9 Stat. 237 (1848).

20. Janssen, *supra* note 16, at 423.

21. Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (1906); see also *Abigail Alliance II*, 495 F.3d at 705.

22. Pure Food and Drug Act of 1906, 34 Stat. at 768. A drug is adulterated, under the Act, when it differs in “strength, quality, or purity” from the stated professional standard. *Id.* at 769–70. A drug is mislabeled when the label of the drug falsely or misleadingly states the ingredients of the drug, fails to note any narcotics included in the drug, or labels an imitation drug under the name of another drug. *Id.* at 770.

23. *Id.* at 769–70.

24. PHILIP J. HILTS, PROTECTING AMERICA’S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 53–54 (2003).

25. 21 U.S.C. §§ 301–399 (2015).

ing the safety of their drugs before introducing them to the market.²⁶ The addition of the safety-testing element gained support after elixir sulfanilamide—a liquid form of an otherwise safe drug—caused approximately 107 deaths, showing that safety testing was necessary before any new drug could be sold.²⁷ Prior to the Act, drug producers could even sell their drugs over-the-counter without meeting any safety standards.²⁸ The Federal Food, Drug, and Cosmetic Act finally addressed this lack of safety standards.²⁹

By 1945, Congress determined that these regulations and standards should be expanded and created the category of prescription drugs, requiring a physician's prescription for use.³⁰ The Humphrey-Durham Amendment,³¹ enacted in 1951, finally defined the types of drugs that would be considered prescription drugs,³² and effectively codified professional pharmaceutical standards into federal law.³³ Congress then amended the Food, Drug, and Cosmetic Act in 1962, requiring drug manufacturers to provide evidence of effectiveness of the drugs before the FDA would approve the drug for public use.³⁴ This amendment, called the Kefauver-Harris Amendment, created the basic clinical testing framework now in place and required a showing that the new drug was both safe and effective.³⁵

The 1945 and 1962 amendments to the Food, Drug, and Cosmetic Act created the framework for the present-day drug approval process:³⁶ the FDA must review all new drugs to determine their safety and effectiveness and use clinical trials for testing before approval.³⁷ Through these amendments, the FDA was given full law-making power with respect to drug regulations,³⁸ something that

26. Janssen, *supra* note 16, at 429. See 21 U.S.C. § 355 (2015).

27. HILTS, *supra* note 24, at 92–93.

28. See Janssen, *supra* note 16, at 430.

29. See *id.* at 429–30.

30. Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 9 Fed. Reg. 12,255 (Oct. 10, 1944). See also Janssen, *supra* note 16, at 433.

31. Humphrey-Durham Amendment, ch. 578, 65 Stat. 648 (1951) (amending the Federal Food, Drug, and Cosmetic Act).

32. See *id.* at 649.

33. Janssen, *supra* note 16, at 435. See also 21 U.S.C. § 353 (2015).

34. See Kefauver-Harris Amendment, Pub. L. No. 87–781, 76 Stat. 780 (1962). Congress enacted these amendments, known as the Kefauver-Harris Amendments, after Thalidomide, a drug for morning sickness, resulted in severe birth defects in some children whose mothers took the drug. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 725 (D.C. Cir. 2007) [*Abigail Alliance II*].

35. See § 102, 76 Stat. at 781.

36. See *id.* at 782–84.

37. *Id.* at 781–82.

38. See *id.* at 782–83.

has allowed the FDA to implement arbitrary regulations that ultimately prohibit terminally ill patients from accessing investigational new drugs to attempt to save their lives.³⁹

B. *The Current Scheme for New Drug Approval*

Congress requires FDA approval before any new drugs may enter interstate commerce, giving the FDA massive control over the marketing and sale of prescription drugs.⁴⁰ Congress has defined “drug” under the Food, Drug, and Cosmetic Act, as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,” among other things.⁴¹ A “new drug,” which requires approval for use, is a drug that “is not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested,” or which medical experts recognize as safe and effective “but which has not . . . been used to a material extent or for a material time under such conditions.”⁴² However, critics of the Food, Drug, and Cosmetic Act have decried the law for its complexity and length, which is symbolic of much of the FDA’s regulation in the area of new drugs.⁴³

The FDA’s rules, which control the Investigational New Drug application (“IND”)⁴⁴ and the testing and approval of new drugs, lay out the approval process for new drugs.⁴⁵ The manufacturer often must undertake animal testing of the new drug before submission of the IND to test the toxicological effects of the drug.⁴⁶ After sufficient animal testing concerning the drug’s toxicity, the drug’s manufacturer may submit an IND to the FDA to formally begin the approval process.⁴⁷ Within the IND, the manufacturer must include information regarding its plan for clinical testing, as well as the results of animal testing to show that the drug is safe enough to begin human testing.⁴⁸ The FDA then reviews the application, along with

39. See Janssen, *supra* note 16, at 439.

40. See 21 U.S.C.A. § 355(a) (West 2015).

41. *Id.* § 321(g)(1).

42. *Id.* § 321(p)(1)–(2).

43. See, e.g., Kimiya Sarayloo, *A Poor Man’s Tale of Patented Medicine: The 1962 Amendments, Hatch-Waxman, and the Lost Admonition to Promote Progress*, 18 QUINNIPIAC HEALTH L.J. 1, 25 (2015) (quoting Judge Roger W. Titus as stating that, “[t]here’s a special place in Hell where they torture people who write things like this”).

44. The IND is the application form that declares a drug manufacturer’s desire to start human clinical trials in an attempt to bring the new drug to market. HILTS, *supra* note 24, at 168.

45. See Investigational New Drug Application, 21 C.F.R. § 312.1 (West 2015).

46. See *id.* § 312.23(a)(8). The animal testing varies widely in extent and type based on other FDA requirements not discussed in this article. See *id.*

47. *Id.* § 312.20.

48. *Id.* § 312.23(a)(3)(iv).

an Institutional Review Board (“IRB”) made up of faculty from hospitals and drug research groups.⁴⁹ Once the FDA and IRB review the animal testing results, the FDA and IRB must approve the drug for clinical testing on humans in order for the new drug to continue on the approval process.⁵⁰

C. *The FDA’s Three Phase Approval Process*

The FDA’s new drug approval process consists of three phases of human clinical testing,⁵¹ involving studies in which physicians give human subjects the new drug or, often in the second and third phase, a placebo or a previously-approved drug created for the same purpose as the new drug being tested.⁵² The physicians and other health care experts then monitor the subjects to examine the new drug’s effects on the subjects.⁵³ The first phase of clinical trials “[is] designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.”⁵⁴ This phase usually involves between twenty and eighty healthy volunteers, not patients, with a focus on understanding the basic reaction of the drug in the body and determining basic levels of safety.⁵⁵ After the drug passes the first stage of testing, meeting basic safety standards and showing a lack of toxicity, the manufacturer may begin phase two testing.⁵⁶

The drug manufacturer’s phase two testing consists of a controlled, highly monitored study, with an increased number of patients and a different focus.⁵⁷ The second phase’s purpose is to determine the effectiveness of the drug, as well as discovering any side

49. *Id.* § 312.23(a)(1)(iv); see also *The FDA’s Drug Review Process: Ensuring Drugs are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2014), <http://www.fda.gov/drugs/re-sourcesforyou/consumers/ucm143534.htm> [hereinafter *FDA’s Drug Review Process*].

50. 21 C.F.R. § 312.23(a)(1)(iv); see also *FDA’s Drug Review Process*, *supra* note 49.

51. See 21 C.F.R. § 312.21.

52. *FDA’s Drug Review Process*, *supra* note 49.

53. *Id.*

54. 21 C.F.R. § 312.21(a)(1).

55. *Id.* See *FDA’s Drug Review Process*, *supra* note 49. The FDA’s requirement of basic safety levels means that the testing does not show “unacceptable toxicity,” as determined by the FDA. *Id.*

56. *FDA’s Drug Review Process*, *supra* note 49.

57. 21 C.F.R. § 312.21(b). Whereas the phase one testing focuses on toxicity and is not a highly controlled study, phase two studies focus on effectiveness and consist of controlled testing, with some patients receiving the new drug and others receiving a placebo or other drug designed to treat the illness. *FDA’s Drug Review Process*, *supra* note 49.

effects or risks of using the drug.⁵⁸ The second stage of testing usually involves “no more than several hundred subjects.”⁵⁹

Once the clinical testing in phase two has shown the drug is effective,⁶⁰ phase three begins with both controlled and uncontrolled testing.⁶¹ The third phase provides the final testing of the drug’s safety and effectiveness in order to provide a fuller understanding of the risks and benefits of the drug to aid physicians in properly labeling the drug before prescribing it to a patient.⁶² As many as several thousand patients may take part in phase three testing.⁶³ Once the FDA determines the drug has shown sufficient levels of safety and effectiveness,⁶⁴ the drug passes the third and final phase of clinical testing, moving the new drug to the next step of the total approval process.⁶⁵

The data collected from the clinical trials must be included in the drug manufacturer’s New Drug Application (“NDA”) to the FDA.⁶⁶ The NDA is the final, formal request that the FDA approve the new drug for marketing and sale,⁶⁷ and must include all the data collected from the drug’s human and animal testing.⁶⁸ The FDA has sixty days to decide whether to even consider the application, as the FDA may decide that the manufacturer must carry out further testing or include more information and thus refuse to consider the

58. 21 C.F.R. § 312.21(b).

59. *Id.*

60. The FDA’s effectiveness standards require that the new drug “have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in its labeling.” Applications for FDA Approval to Market a New Drug, 21 C.F.R. § 314.125(b)(5) (West 2016). For the FDA to consider the drug to be effective, the drug must result in a “statistically significant effect on a clinically meaningful endpoint.” EILEEN NAVARRO, EVIDENCE OF CLINICAL EFFECTIVENESS AND DATA REQUIREMENTS 11 (2015), <https://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm466488.pdf>. In other words, the FDA requires that the drug show a positive impact in accordance with its labelling in at least two independent, controlled studies, when compared to the placebo or the other drugs used as a control in the study. *Id.* at 11.

61. 21 C.F.R. § 312.21(b)–(c). The third phase normally consists of both controlled and uncontrolled tests. The controlled tests involve giving one group of patients the new drug and another group being given a placebo or other drug that treats the illness, in order to eliminate bias in examining the test’s results. The uncontrolled tests merely give all the patients the new drug. *See id.*; *FDA’s Drug Review Process*, *supra* note 49.

62. *See* 21 C.F.R. § 312.21(c).

63. *Id.*

64. *See supra* note 60 and accompanying text. Concerning its safety standards, the FDA requires that the new drug undergo “adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.” 21 C.F.R. § 314.125(b)(2).

65. *See FDA’s Drug Review Process*, *supra* note 49.

66. *See* 21 C.F.R. § 314.50(f).

67. *See* HILTS, *supra* note 24, at 168.

68. *See* 21 C.F.R. § 314.50(d), (f).

NDA.⁶⁹ The FDA's consideration of the NDA takes several months, with the FDA making a determination on 90% of applications within ten months.⁷⁰ The FDA's decision concerning the NDA concludes the required application process. Accepted drugs proceed to market, with continued post-market monitoring of the drug's safety and effectiveness.⁷¹ After drug development, animal testing, the IND application, at least three phases of human clinical testing, and submission, review, and approval of the NDA application, the drug manufacturer may finally label and market the drug for sale, though the drug manufacturer must receive approval from the FDA throughout the entire approval process.⁷²

III. PROBLEMS WITH THE CURRENT FDA APPROVAL PROCESS

While the FDA claims that its entire drug approval process is necessary for all drugs, the approval process includes many inefficiencies and delays that make the process more harmful than helpful, particularly in relation to terminally ill patients. The IND process is complicated, time-consuming, and expensive. In the 1970s, the approval process took an average of eight years, from a drug manufacturer's initial research to the FDA's approval of the NDA, costing an average of \$50 million.⁷³ Since then, the process has only increased in length and cost.⁷⁴

While proponents of the FDA's approval process may argue that the length and cost of the process are essential, even if the process restricts patients from accessing new drugs,⁷⁵ this article contends that the many requirements create an unnecessarily long approval process for new drugs. Due to the time-consuming nature of new-drug approval, there is a drug lag in the United States compared to Europe, where many drugs attain approval more quickly.⁷⁶ The drug lag between Europe and the United States means that many

69. *FDA's Drug Review Process*, *supra* note 49.

70. *Id.*

71. *Id.*

72. *See FDA Drug Approval Process Infographic*, U.S. FOOD & DRUG ADMIN. (Apr. 25, 2014), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm295473.htm>.

73. Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POLY, 295, 306 (2000).

74. *Id.*

75. *See, e.g.*, Ed Silverman, *'Right to Try' Laws Wrong to Skirt FDA*, BOSTON GLOBE (Oct. 12, 2015), <https://www.bostonglobe.com/business/2015/10/12/right-try-laws-are-wrong-usurp-fda/54t1CnBEQ4DHM1kYd1ZIdJ/story.html>.

76. *See* Greenberg, *supra* note 73, at 306. The existence of the drug lag is significant because it calls into question the necessity of the American new drug approval process's complexity and length in comparison to that of other developed nations, such as those in Europe that approve new drugs under a faster process. *See id.*

drugs that have been approved for use in Europe are unavailable to American patients, despite the determination under European nations' standards that the drugs are safe and effective.⁷⁷ The drug lag resulted because the United States has historically maintained the highest standards of any nation with respect to drug effectiveness requirements.⁷⁸

The FDA's high standard may be desirable in many cases, but with respect to terminally ill patients, the FDA's standard is unnecessarily high. Terminally ill patients possess a right to life, and that right should include a right to try to preserve their lives by taking non-FDA-approved medication in an effort to live.⁷⁹ Terminally ill patients have nothing or little to lose if the new drug proves ineffective; death is inevitable for terminally ill patients, who often have no other treatment options.⁸⁰ The fact that many other European nations have a lower standard for efficacy shows that it may not be particularly dangerous to loosen the FDA's requirements, at least with respect to terminally ill patients.

A. *The Excessive Delays of the New Drug Approval Process*

While the FDA has shortened the time required for most drugs to obtain FDA approval, the length of time it takes a new drug to get from development to market is still several years, which raises serious problems for terminally ill patients awaiting approval of new drugs.⁸¹ The FDA approval process takes approximately seven and a half years, on average, from phase one testing to marketing of the drug.⁸² That time period includes an average of eighteen months of wait time after completion of testing in order for the FDA to consider approving the NDA,⁸³ though it can take the FDA up to two

77. Daniel Henninger, *Drug Lag*, LIBR. OF ECON. & LIBERTY (2002), <http://www.econlib.org/library/Enc1/DrugLag.html> (last visited Jan. 21, 2016).

78. STEPHEN J. CECCOLI, *PILL POLITICS: DRUGS AND THE FDA* 81 (2004). While high standards may seem desirable, the standards may be unnecessarily high. One may understand the possibility of unnecessarily high standards by considering a hypothetical drug standard requiring 100% effectiveness and no side effects for the FDA to approve any drug. At some point, the detriments of heightened safety and effectiveness standards outweigh the benefits. *See id.*

79. *See generally* Kurt Altman & Christina Sandefur, *Right-To-Try Laws Fulfill the Constitution's Promise of Individual Liberty*, HEALTH AFF. BLOG (July 14, 2015), <http://healthaffairs.org/blog/2015/07/14/right-to-try-laws-fulfill-the-constitutions-promise-of-individual-liberty/>.

80. *See id.*

81. *See* Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 164 (2003).

82. *Id.*

83. *Id.* at 165.

and a half years to approve the NDA.⁸⁴ For a terminally ill patient who has no treatment option besides a new drug that has just passed the first phase of clinical trials, this wait time ensures a death sentence.

While the length of the FDA's approval process may be necessary in many cases, the process's wait time makes new drugs that are currently in phase two testing practically inaccessible within the lives of terminally ill patients. Due to the lengthy delays in the new drug approval process, the FDA created a certain process by which a terminally ill patient may apply for access to non-approved new drugs.⁸⁵ This expanded access provision allows terminally ill patients with no other treatment options to apply for access to an investigational drug that has passed phase one of clinical trials, based on a physician's recommendation.⁸⁶ These provisions require a lengthy application process and case-by-case determination by the FDA, however, before a patient may access the new drug.⁸⁷

B. The Lack of Investigational New Drug Access for Terminally Ill Patients

Despite the expanded access process created by the FDA, that process provides little aid to terminally ill patients, because few patients use the expanded access program due to the complexity and length of the applications.⁸⁸ The patient's doctor must file an IND application, patient history, treatment plan, and an assurance that the doctor will receive informed consent from the patient.⁸⁹ The doctor must also receive approval from the Institutional Review Board.⁹⁰ The expanded access application process requires complex filings that take an average of 100 hours to complete, which must be done by the physician at the patient's expense.⁹¹ Few patients are able to have a physician complete such a task, or at best can

84. *New Drug Approval Process*, DRUGS.COM, <http://www.drugs.com/fda-approval-process.html> (last visited Jan. 21, 2016).

85. *See* Investigational New Drug Application, 21 C.F.R. §§ 312.300–312.320 (West 2015).

86. *See* Thomas A. Hemphill, *Is State 'Right to Try' Legislation Misguided Policy?*, REGULATION, Fall 2014, at 2.

87. *See id.*

88. Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment*, 266 GOLDWATER INST. POL'Y REP. 1, 10–11 (Feb. 11, 2014) (noting that despite the millions of terminally ill patients, fewer than 1,000 were able to gain expanded access in 2012).

89. *Id.* at 9.

90. *Id.*

91. *Id.* at 9–10.

only do so at great expense.⁹² Doctors often ignore expanded access as a possibility because of the time required to file an application with the FDA, with smaller hospitals often unable to gain expanded access at all due to their lack of resources for applying and obtaining that access.⁹³ While the FDA regularly accepts the applications that it does receive, after a 30-day review, the administration reserves the right to reject the application.⁹⁴ The expanded access process has resulted in minimal new drug access for terminally ill patients though, due to the complexity of the application, as only 940 patients gained expanded access in 2012.⁹⁵ The complexity and difficulty of obtaining investigational drug access for terminally ill patients led to the formation of groups advocating for further expanded access and changes to the law,⁹⁶ including by a federal lawsuit⁹⁷ and passage of state laws.⁹⁸

IV. ATTEMPTS TO EXPAND NEW DRUG ACCESS FOR THE TERMINALLY ILL

Historically, many terminally ill patients sought to gain access to non-FDA-approved drugs in an attempt to save their lives, such as AIDS patients in the 1980s.⁹⁹ Similarly-situated individuals have more recently coalesced into groups advocating for drug access for terminally ill patients, with the Abigail Alliance for Better Access to Developmental Drugs (“the Alliance”) being one of the most well-known examples.¹⁰⁰ The Abigail Alliance formed after Abigail Burroughs, a cancer patient, was unable to gain access to a promising cancer drug that her doctor had suggested.¹⁰¹ Abigail lobbied the drug companies and engaged in television and newspaper interviews to gain popular support for her cause, but ultimately never

92. *Id.* at 10.

93. *Id.* at 11.

94. *Id.*

95. *Id.* Even in 2015, the FDA only received 1,262 IND applications for expanded access to investigational drugs. FOOD & DRUG ADMIN. EXPANDED ACCESS SUBMISSIONS, FY 2010–2015 GRAPH, at 6 (Jan. 27, 2017), <http://www.fda.gov/downloads/NewsEvents/PublicHealth-Focus/ExpandedAccessCompassionateUse/UCM471305.pdf>.

96. See, e.g., *The Abigail Alliance Mission*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/mission.php> (last visited Jan. 22, 2016).

97. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance III*].

98. See GOLDWATER INST., *supra* note 15.

99. See Editorial Staff, *The Right-to-Try Revolt*, WALL ST. J. (Feb. 9, 2015, 7:16 PM), <https://www.wsj.com/articles/the-right-to-try-revolt-1423527365>.

100. See ABIGAIL ALLIANCE, *supra* note 96.

101. ABIGAIL ALLIANCE, *supra* note 13.

gained access to the drug and died in 2001.¹⁰² Her father, Frank Burroughs, continued the mission of the Alliance, attempting to broaden new drug access for terminally ill patients.¹⁰³

The Alliance and similar groups fought to change the FDA rules in the past and continue to do so in the present.¹⁰⁴ The possible paths for change include challenging the FDA rules in court, enacting state or federal statutes, and affecting regulatory change by the FDA itself. Advocates for change may also effect a change in the rules by using state and federal statutes as a source of persuasion to obtain a political solution.¹⁰⁵ State “Right to Try” laws are the most recent form of attempted change to the FDA rules.¹⁰⁶

A. *The First Attempt for Change: A Federal Lawsuit*

The Alliance brought a federal lawsuit against the FDA in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*.¹⁰⁷ The Alliance sought to gain access for terminally ill patients to investigational drugs that had passed the first phase of clinical trials.¹⁰⁸ The Alliance argued that the FDA rules violated the substantive due process rights of terminally ill patients by infringing patients’ fundamental rights to life, privacy, and liberty.¹⁰⁹ The district court dismissed the Alliance’s claim after finding that the Alliance failed to assert a fundamental right and the FDA rules satisfied a rational basis test.¹¹⁰ A panel of the court of appeals reversed the district court decision, determining that terminally ill patients have a fundamental right to access investigational drugs that passed the first phase of clinical trials.¹¹¹ Ultimately, on re-hearing before the court of appeals, the court held that terminally

102. *Id.*

103. *See id.*

104. *See, e.g., Compassionate Use Programs*, ALS ASS’N, <http://www.alsa.org/als-care/resources/publications-videos/factsheets/compassionate-use.html> (last visited Dec. 16, 2015); *Mission Statement*, TREATMENT ACTION GRP., <http://www.treatmentactiongroup.org/mission> (last visited Feb. 5, 2016).

105. AIDS patients obtained expanded access in this manner. *See Corieri, supra* note 88.

106. *See GOLDWATER INST., supra* note 15.

107. 495 F.3d 695 (D.C. Cir. 2007).

108. *See Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 471–72 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

109. *Id.* at 472.

110. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, 2004 WL 3777340, at *11–12 (D.D.C. Aug. 30, 2004).

111. *Abigail Alliance I*, 445 F.3d at 486.

ill patients do not have a fundamental right to access investigational drugs, denying the Alliance's claim and ending their lawsuit.¹¹²

1. *Background of the Case*

The Alliance's federal lawsuit against the FDA, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*,¹¹³ constituted the first organized attempt to change the current FDA regulations and approval process. The Alliance sought to enjoin the FDA from banning the sale of phase two investigational drugs to terminally ill patients who were not enrolled in the clinical trials.¹¹⁴ Beginning in 2003, the Alliance made a proposal to the FDA requesting access to post-phase one investigational drugs for terminally ill patients.¹¹⁵ The FDA denied the request three months later.¹¹⁶ The Alliance filed a Citizen's Petition¹¹⁷ in June 2003, making the same request as in the initial proposal.¹¹⁸ When the FDA did not respond to the Petition within the allotted time, the Alliance brought suit, challenging the constitutionality of the FDA's rules regarding the approval process for investigational drugs when applied to terminally ill patients.¹¹⁹ The Alliance asserted that the FDA's rules violated terminally ill patients' "substantive due process rights to privacy, liberty, and life."¹²⁰

2. *Overview of Substantive Due Process Analysis*

The characterization of the substantive due process right asserted by the Alliance represented the crucial decision for the court, as the existence of that right determines the applicable standard of review for the court's analysis of the law at issue.¹²¹ Standard of review is crucial in constitutional law cases.¹²² In this case, the Alliance's claim turned on whether the alleged right—"the right to

112. *Abigail Alliance II*, 495 F.3d at 712.

113. *Id.*

114. *Abigail Alliance I*, 445 F.3d at 471–72.

115. *Id.* at 473.

116. *Id.*

117. A Citizen's Petition consists of a formal petition to the FDA to remove or alter a regulation or cease an administrative action. Initiation of Administrative Proceedings, 21 C.F.R. § 10.25 (West 2015).

118. *See Abigail Alliance I*, 445 F.3d at 473.

119. *Id.* at 473–74.

120. *Id.* at 472.

121. *See Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997).

122. The standard of review means the level of scrutiny the court applies in considering whether the government's law infringes on the claimant's rights. Strict scrutiny is the highest standard of review, requiring the court to overturn the law unless the law's "infringement

access potentially life-sustaining medication where there are no alternative government-approved treatment options”¹²³—was fundamental.¹²⁴ The court of appeals initially determined that the Alliance’s claim implicated a fundamental right and analyzed the FDA rules under the heightened level of strict scrutiny, requiring that the law be narrowly tailored to a compelling state interest to survive review.¹²⁵ Based on the characterization of the right and application of the heightened standard of review, the court recognized the Alliance’s claim and held that the FDA rules violated the Alliance’s due process rights.¹²⁶ When the court of appeals later reheard the case, however, the court determined that the Alliance failed to assert a fundamental right and applied a mere rational basis test to the FDA rules, analyzing whether the rule was rationally related to a legitimate government interest.¹²⁷ The court held that the FDA rules did not violate the Alliance’s due process rights.¹²⁸ The court’s characterization of the asserted right ultimately played a crucial role in deciding whether the FDA rules violated the Alliance’s due process rights to life and liberty.

3. *District Court Rules Against Expanding New Drug Access*

When the Alliance’s case initially came before the District Court, the Alliance argued that the FDA’s new drug approval scheme vio-

is narrowly tailored to serve a compelling state interest.” *Id.* at 721 (citing *Reno v. Flores*, 507 U.S. 292, 302 (1993)). The lowest level of scrutiny that the court applies in substantive due process cases is rational basis review, requiring that the law “be rationally related to legitimate government interests” to survive review. *Id.* at 728.

123. *Abigail Alliance I*, 445 F.3d at 472.

124. Fundamental rights “are, 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 they were sacrificed.’” *Glucksberg*, 521 U.S. at 720–21 (citing *Moore v. City of E. Cleveland, Ohio*, 431 U.S. 494, 503 and *Palko v. Connecticut*, 302 U.S. 319, 325–26 (1937)). The claimants of the right must also provide a “‘careful description’ of the asserted fundamental liberty interest.” *Id.* at 721. If a law implicates a claimant’s fundamental rights, then the court applies the strict scrutiny standard of review in determining whether the law violates the substantive due process rights of the claimant. *See id.* at 720; *supra* note 122 and accompanying text. If a law does not implicate a fundamental right, then the court merely applies the rational basis standard of review in determining whether the law violates the claimant’s rights. *See id.* at 728; *supra* note 122 and accompanying text.

125. *Abigail Alliance I*, 445 F.3d at 486.

126. *Id.* *See also* U.S. CONST. AMEND. V. (“No person shall . . . be deprived of life, liberty, or property, without due process of law.”); *supra* note 122 and accompanying text; *supra* note 124 and accompanying text.

127. *Abigail Alliance II*, 495 F.3d at 712.

128. *Id.* *See supra* note 122 and accompanying text; *supra* note 124 and accompanying text.

lated the Fifth Amendment's Due Process Clause by denying fundamental rights to terminally ill patients.¹²⁹ Specifically, the Alliance alleged that the FDA rules infringed upon the privacy and liberty rights of the terminally ill by improperly interfering with the patients' medical treatment decisions and their fundamental "right to life" by prohibiting the sale of new drugs, effectively giving these patients "a death sentence."¹³⁰

The trial court found that the Alliance's alleged fundamental right was more analogous to the right to physician-assisted suicide—which the U.S. Supreme Court has not yet recognized—than the right to refuse life-saving medical treatment, as the Alliance had argued.¹³¹ The court characterized the alleged "right to life" as an affirmative right to drug access, rather than a right to be free from government interference in medical treatment decisions.¹³² The court held that this affirmative right was not fundamental, because no protection of it existed in American history and traditions.¹³³ Therefore, the FDA rule was not subject to strict scrutiny and the court instead applied rational basis review, which the court found that the FDA rules satisfied based on the importance of protecting patient and public health.¹³⁴ The court dismissed the Alliance's complaint for failure to state a claim.¹³⁵

4. *Court of Appeals Panel Recognizes a Fundamental Right*

On appeal to the D.C. Circuit Court of Appeals, a panel of three judges reversed the district court, finding in favor of the Alliance.¹³⁶ The court considered the Alliance's claim 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."¹³⁷ The

129. See Complaint at 10–11, *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, 2004 WL 3777340 (D.D.C. Aug. 30, 2004) (No. 1:03CV1601).

130. *Id.* at 10–11.

131. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, 2004 WL 3777340 at *10 (D.D.C. Aug. 30, 2004) (noting the Supreme Court's decisions recognizing a fundamental right to refuse life-saving medical treatment and denying a fundamental right to physician-assisted suicide).

132. *Id.* at 11.

133. *Id.* at 10.

134. *Id.* at 12.

135. *Id.*

136. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

137. *Abigail Alliance I* at 472.

court of appeals panel found that this was a fundamental right because it was both “carefully described” and the United States government had not historically interfered with the right.¹³⁸ In fact, the panel noted that the common law held individuals liable for interfering with a third party’s efforts to save the life of another.¹³⁹ Likewise, the court decided that the practice of regulating drugs based on their efficacy was a relatively recent development in American drug regulation and the traditions of the United States, meaning that the FDA’s rules were not rooted in the nation’s traditions.¹⁴⁰ The court determined that “the right to access potentially life-sustaining medication where there are no alternative government-approved treatment options” more closely resembled the right to refuse life-saving treatment, rather than that of physician-assisted suicide.¹⁴¹ The court ultimately held that “a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Clause.”¹⁴²

5. *Court of Appeals Reverses on Rehearing En Banc*

On rehearing en banc,¹⁴³ the D.C. Circuit Court of Appeals reversed itself in *Abigail Alliance II*, finding that the Alliance’s claimed right was not a fundamental right.¹⁴⁴ In making this determination, the court focused on the history of safety-based drug regulation, rather than simply efficacy-based regulations, beginning in the colonial era.¹⁴⁵ Therefore, the majority found that “our Nation has long expressed interest in drug regulation, calibrating its response in terms of the capabilities to determine the risks associated with both drug safety and efficacy.”¹⁴⁶ The court approached the claimed right as one of assuming “enormous risks’ in pursuit of *potentially* life-saving drugs,” which was not based in the nation’s traditions.¹⁴⁷ Applying rational basis review, the majority

138. *Id.*

139. *See id.* at 480–81.

140. *See id.* at 482.

141. *Abigail Alliance I*, 445 F.3d. at 472.

142. *Id.* at 486. *See* U.S. CONST. amend. V.

143. A rehearing en banc means that all the judges for that court, the entire bench, rehear the case, rather than merely the panel that initially heard the case. FED. R. APP. P. 35.

144. *See Abigail Alliance II*, 495 F.3d at 712. *See also supra* note 122 and accompanying text; *supra* note 124 and accompanying text.

145. *See Abigail Alliance II*, 495 F.3d at 703–04.

146. *Id.* at 703.

147. *Id.* at 710.

held that “the Government has a rational basis for ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits of such a drug.”¹⁴⁸ The court recognized that “the FDA’s policy of limiting access to investigational drugs is rationally related to the legitimate state interest of protecting patients, including the terminally ill.”¹⁴⁹ Therefore, the FDA rules passed a rational basis test and the Alliance’s claim failed.¹⁵⁰

However, the court did note that the Alliance could challenge the FDA’s new drug approval process through the “democratic process,” which is “better suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so.”¹⁵¹ While the Alliance’s fundamental right arguments ultimately failed, they possessed strong persuasive power and may result in a different holding if the federal courts take up the issue again.

V. THE RIGHT TO ACCESS INVESTIGATIONAL DRUGS: A FUNDAMENTAL RIGHT

In light of *Abigail Alliance II*, this article sets forth the relevant arguments to combat the en banc panel’s decision. While the en banc court rejected the Alliance’s claim that the right of terminally ill patients to access investigational new drugs was fundamental, this section argues that the en banc court was incorrect because the fundamental rights to autonomy, privacy, and life suggest that terminally ill patients should have access to new drugs in limited circumstances. The autonomy and privacy rights are interconnected and have both been recognized by the Supreme Court in a medical context,¹⁵² though not in the particular context of accessing unapproved, experimental drugs. The autonomy and privacy rights suggest that the government should not interfere with the private and autonomous medical decision-making of patients, unless the interference passes strict scrutiny review.¹⁵³ Terminally ill patients

148. *Id.* at 713.

149. *Id.*

150. *See Abigail Alliance II*, 495 F.3d at 712.

151. *Id.* at 713.

152. *See, e.g., Cruzan v. Dir., Mo. Dept. of Health*, 497 U.S. 261, 269 (1990) (noting the individual’s right of possession and control over one’s own person and the importance of bodily integrity); *Griswold v. Connecticut*, 381 U.S. 479, 485–86 (1965) (recognizing the right of privacy’s protection against government interference in the context of accessing contraceptives).

153. *See B. Jessie Hill, The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 306–07 (2007).

have a fundamental right to life that protects them against any government interference that puts their lives at risk, or prevents them from preserving their lives.¹⁵⁴ Government interference with terminally ill patients' lives occurs, however, when the FDA's rules prevent terminally ill patients from obtaining potentially life-saving drugs when those drugs are the only remaining option. The right to life also arguably relates to the right of an individual to self-defense, applied in the medical context, as a right to defend one's self from death by taking experimental medication.¹⁵⁵

A. *The Rights to Autonomy and Privacy*

The Supreme Court recognized the right to autonomy in making medical decisions, based on an individual form of autonomy and dignity.¹⁵⁶ The idea of autonomy in medical decision-making particularly played a role in the Court's decisions regarding contraceptives in *Griswold v. Connecticut* and *Eisenstadt v. Baird*.¹⁵⁷ The Court recognized the right "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."¹⁵⁸ Along with the fundamental importance of the decision to bear a child, "[t]he choice between life and death is a deeply personal decision of obvious and overwhelming finality."¹⁵⁹ The decision to attempt to preserve one's life may be equivalently fundamental to that of bearing a child, and the state should recognize that an individual's autonomy extends to this area as well. Personal medical decisions are essential "to personal dignity and autonomy, [and] are central to the liberty protected by the Fourteenth Amendment" under the Due Process Clause's substantive protection.¹⁶⁰ The substantive due process protection of autonomy should extend to an individual's decision to try new drugs that are currently in the midst of the FDA approval

154. See THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776); *Abigail Alliance II*, 495 F.3d at 722 (Rogers, J., dissenting).

155. See Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1818 (2007). While the Supreme Court has never recognized the right to life in this context, the Alliance argued, and some courts of appeal judges agreed, that the right to life is applicable in the context of terminally ill patients' access to new drugs. See *Abigail Alliance II*, 495 F.3d at 722 (Rogers, J., dissenting).

156. See Hill, *supra* note 153, at 305–06.

157. See *id.* at 306–07 (describing the theme of individual autonomy, developed by these cases, in the context of making individual medical treatment decisions without interference from the government); see also *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Griswold*, 381 U.S. 479.

158. *Eisenstadt*, 405 U.S. at 453.

159. *Cruzan*, 497 U.S. at 281.

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

process, particularly when the individual is terminally ill and has no other treatment options.

The right to individual privacy is related to that of autonomy and similarly presents a strong argument for protecting a terminally ill patient's ability to use experimental drugs.¹⁶¹ The autonomy arguments discussed in *Griswold* and *Eisenstadt* eventually evolved into right to privacy arguments in which two landmark decisions were grounded, *Roe v. Wade*¹⁶² and *Doe v. Bolton*,¹⁶³ the initial abortion cases.¹⁶⁴ The privacy arguments generally involve an element of privacy in the patient-doctor relationship and in making certain medical decisions.¹⁶⁵ The *Roe* Court noted that the absolute denial of the choice to have an abortion would impose a great harm on the woman.¹⁶⁶ In contrast to the government absolutely making the decision for the woman, as the state abortion ban had intended, the Court stated that only the woman, with her physician's consultation, could properly consider all the factors and make the appropriate decision.¹⁶⁷

The Court's analysis in *Roe* focused on the fact that only the woman could properly weigh the many factors inherent in the abortion decision,¹⁶⁸ which applies similarly to the decisions of terminally ill patients who have exhausted all other medical treatment options and seek to obtain experimental drugs to treat the illness. Only the patient, in consultation with the physician, can properly consider the risk of harm if the drug is unsafe, the results if it is not effective, the price of the drug, and the results of not taking the

161. See Hill, *supra* note 153, at 310.

162. 410 U.S. 113 (1973).

163. 410 U.S. 179 (1973). The abortion ban at issue in *Doe* differed from that in *Roe* because it included exceptions for the health of the mother, particular mental or physical defects in the child, and when the pregnancy resulted from rape. *Id.* at 183. The Court held that the abortion law must defer to the medical decision-making of the patient and physician, rather than giving only limited circumstances when abortion was lawful. *Id.* at 192. The abortion law also required that any abortions be performed at hospitals that held particular accreditation, which the Court overturned. *Id.* at 193–94. The Court similarly found that a requirement that a hospital abortion committee review all abortions before allowing the procedure was unconstitutional. *Id.* at 198. The abortion law required that two physicians give their confirmation before the performance of any abortions, which the Court held was an unconstitutional interference with the decision of the patient and the physician's own best medical judgment. *Id.* at 199. Finally, the Court determined that the law's requirement that the patient be a Georgia resident to receive an abortion in Georgia was unconstitutional. *Id.* at 200.

164. Hill, *supra* note 153, at 309.

165. See *id.* at 309–10.

166. See *Roe*, 410 U.S. at 153.

167. See *id.* (discussing the ability of the woman alone to consider the relevant factors, including the harms of pregnancy, the stress of being a mother, the difficulties of raising a child, and the current family environment the child would live in if born).

168. *Id.*

experimental drug. The privacy right of *Roe* is not absolute though, as the government may limit the right to protect other government interests, such as public health.¹⁶⁹ Similarly, any privacy argument in the context of the FDA's new drug approval process could be limited based on the government's interest in protecting public health. However, the *Roe* decision made clear that the government could not interfere with the privacy right when the woman's life was at stake.¹⁷⁰ The limitation on government interference with the privacy right when the individual's life is at stake analogizes to the case of terminally ill patients because the interest of the woman and the patient in their own lives should overcome the government's interests in interfering with their privacy. While the FDA rules may serve compelling state interests, the privacy right of the individual to make medical decisions "to preserve the life or health of the [patient]" may override the state's interest in implementing the FDA rules on new drugs.¹⁷¹

B. *The Right to Life*

Terminally ill patients have a fundamental right to life that similarly supports recognition of the right asserted in *Abigail Alliance*.¹⁷² The right to life includes, as a corollary, a right "to attempt to preserve life," which must exist for the right to life to provide the fullest protection to the individual against the state.¹⁷³ Historically, many legal commentators believed that the right to life includes a right to self-preservation, meaning that one has a right not to be murdered as well as a right to live.¹⁷⁴ The Supreme Court's jurisprudence on the right to life has largely focused on the right only in the contexts of abortion¹⁷⁵ and the death penalty.¹⁷⁶

The right to life found in the Fifth Amendment cannot possibly exist fully, however, if terminally ill patients are prohibited from a

169. *See id.* at 154. The privacy right eventually falls when the government's interests, such as protecting health or medical standards, become dominant. When a fundamental right is implicated, then the privacy right only yields to a compelling government interest and a law narrowly tailored to that interest. *Id.* at 155.

170. *See id.* at 163–64.

171. Hill, *supra* note 153, at 310 (quoting *Roe*, 410 U.S. at 164).

172. *See* *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695, 715 (D.C. Cir. 2007) [*Abigail Alliance II*] (Rogers, J., dissenting).

173. *Id.* at 722.

174. *See* Valerie L. Myers, *Vacco v. Quill and the Inalienable Right to Life*, 11 REGENT U. L. REV. 373, 387 (1999) (citing John Locke, William Blackstone, and other legal commentators and discussing their beliefs that individuals have a "right of self-preservation").

175. *See Roe*, 410 U.S. at 156–57.

176. *See* *Furman v. Georgia*, 408 U.S. 238, n.141 (1972) (Marshall, J., concurring).

final attempt to save their lives by taking non-FDA-approved new drugs. The right does not involve special treatment by the government, but merely requires that the government not interfere with a dying patient's attempts to obtain potentially life-saving medication.¹⁷⁷ The FDA rules violate the right to life of terminally ill patients by removing the only possible means of preserving life those patients have remaining, even if that possibility of life may be highly speculative. While the FDA rules may protect the lives of some patients, the rules also sacrifice the lives of terminally ill patients who are awaiting potentially life-saving drugs that are stuck in the new drug approval process. The government exists to secure the right to life of its citizens;¹⁷⁸ it should seek to protect the ability of terminally ill patients to fight for their lives, as they attempt to obtain the last possible chance for life by way of investigational drugs.

C. *The Right to Medical Self-Defense*

Related to the patients' right to life, the right to access potentially life-saving medication may be analogized to the right to self-defense.¹⁷⁹ The doctrine of self-defense allows a person to use force when the life or health of that person or another is placed at risk.¹⁸⁰ The doctrine of self-defense has been long-recognized as a defense against a criminal conviction or tort claim, allowing a person to "use force against another to protect himself from bodily harm or offensive contact."¹⁸¹ The doctrine of self-defense even allows the use of lethal force in some cases: lethal force against an attacker is justified when the attacker places another individual at risk of death or serious injury, even if the attacker does not have the moral culpability necessary for a crime.¹⁸²

Applying the doctrine of self-defense in a medical context, if an individual may even kill an attacker to preserve one's life, then it follows that an individual may use experimental drugs in order to preserve one's life.¹⁸³ The state may limit the right to self-defense as well as the medical self-defense right. The individual may only use lethal self-defense against the source of harm if the source

177. See *Abigail Alliance II*, 495 F.3d at 727–28 [*Abigail Alliance II*] (Rogers, J., dissenting).

178. See THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776).

179. See Volokh, *supra* note 155, at 1816.

180. *Id.* at 1817.

181. 33 AM. JUR. 2D *Proof of Facts* § 211 (1983).

182. See Volokh, *supra* note 155, at 1817.

183. See *id.* at 1818.

threatens the life of the defender, or at least serious harm to the defender.¹⁸⁴ Thus, again, if the self-defense doctrine was applied in a medical context, only terminally ill patients could use the doctrine as a theory for accessing investigational drugs.¹⁸⁵

The doctrine of medical self-defense has already been used in the context of abortion.¹⁸⁶ A pregnant woman always has the right to obtain an abortion when her life or health is at risk.¹⁸⁷ In other words, medical self-defense applies in the abortion context because the mother always has the right to self-defense against the fetus when her life is at stake. The mother's interest in her own life prevails against that of the unborn child because the child threatens her life and the mother has a right to defend herself against that threat, based on her own right to life.¹⁸⁸

As another limitation on the right to self-defense, the individual engaging in self-defense may not use force against a person who is not creating the threat, meaning that the ill patient may not steal medication or harm others to obtain it.¹⁸⁹ The limitation does not affect the ability of the patient to obtain voluntarily exchanged medication, though.¹⁹⁰ Similarly, as the defender may not interfere with others' rights, the patient has no affirmative right to receive access to drugs, but does have a right to not be interfered with in attempts to obtain access.¹⁹¹ Just as the right of self-defense is limited to situations involving imminent harm, the medical self-defense right similarly requires that the medical harm be sufficiently imminent, meaning that this right only applies for terminally ill patients who have no other medical treatment options.¹⁹² The right to self-defense may be applied to terminally ill patients, as this right has already been applied in the medical context in other situations.¹⁹³

184. *See id.* at 1821.

185. *See id.*

186. *Id.* at 1824.

187. *See* Petition for a Writ of Certiorari at 2, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 2007 WL 2846053 (U.S. Sep. 28, 2007) (No. 07-444). "If the State is interested in protecting fetal life after viability, it may go so far as to proscribe abortion during that period, except when it is necessary to preserve the life or health of the mother." *Roe v. Wade*, 410 U.S. 113, 163-64 (1973). Therefore, the states must always allow for an abortion to protect the mother's life and health, placing the interest in the mother's life above that of the unborn child. *See* Volokh, *supra* note 155, at 1824.

188. *See* Volokh, *supra* note 155, at 1824.

189. *See id.* at 1821-22.

190. *See id.* at 1822.

191. *See id.* at 1827.

192. *Id.* at 1823-24.

193. *Id.* at 1824.

While the right to an abortion is highly controversial, the medical self-defense portion of the abortion right is widely accepted, likely due to the grounding in self-defense itself.¹⁹⁴ While the Supreme Court has only implicitly recognized the right to medical self-defense in the abortion context,¹⁹⁵ the right logically applies to the context of investigational drugs. If a woman has the right to abort a potential life to protect her own life without government interference,¹⁹⁶ then it follows that the woman has a right to attempt to obtain investigational drugs to save her life without government interference.¹⁹⁷ Post-viability, the woman's right to an abortion derives from her right to medical self-defense, not her reproductive right to choose an abortion, and this cannot be distinguished from the context of investigational drugs.¹⁹⁸ The right to medical self-defense, as used in abortion cases, applies equally as a justification for expanding investigational drug access for the terminally ill and supports the argument that the terminally ill have a fundamental right to access these drugs in limited situations.

D. Substantive Due Process Analysis if Recognized as a Fundamental Right

If the right to privacy, autonomy, life, and medical self-defense arguments were to prevail, resulting in recognition of the fundamental right to access investigational drugs, then the strict scrutiny standard would apply when reviewing the FDA's rules. While the state's interests in the FDA rules may overcome the rights of most patients, terminally ill patients are in a life-threatening situation and the FDA rules are not narrowly tailored to protect the state's interests when applied in these situations.¹⁹⁹ The state has an interest in protecting patients from drugs that are either unsafe or

194. *Id.* at 1825 (noting the acceptance of the medical self-defense abortion by the dissenting justices in *Roe*, the many restrictive state abortion laws prior to *Roe*, and the subsequent public recognition of the right to an abortion when the mother's life is at stake); *see also* *Roe v. Wade*, 410 U.S. 113, 173 (1973) (Rehnquist, J., dissenting).

195. *See Roe*, 410 U.S. at 164–65.

196. *See id.*

197. Volokh, *supra* note 155, at 1826.

198. *Id.*

199. For example, the state's interest in protecting the health of patients from unsafe drugs does not fully apply for terminally ill patients because their lives are at risk already from their illness and they are likely willing to take the risk of harm from the drugs in order to attempt to find a cure for their deadly illnesses. Similarly, the state's interest in protecting patients from ineffective medication that would waste their time and resources does not fully apply for terminally ill patients who have no effective treatment options and are likely willing to try a potentially ineffective medication as a last resort when no other options are available. *See generally* Corieri, *supra* note 88.

ineffective, but neither of those interests fully apply in the case of terminally ill patients.

The state's interest in protecting patients from harm from unsafe drugs is drastically mitigated for terminally ill patients because the greatest risk for those patients is to die from the illness. The drug may hasten the inevitable, but may also prevent the patient's death. Furthermore, the fact that the drug has already passed animal testing and phase one basic safety testing means that the drug has been shown to be reasonably safe for patients in clinical testing, meaning most harm would be irrelevant due to the patient's inevitable death regardless.²⁰⁰ When the terminally ill patient is certain to die without access to an unproven, but potentially life-saving medication, the FDA rules are not narrowly tailored to protecting the health and safety of those patients, because the rules actually rob the patients of the only possible option to protect them. This analysis holds true even if the medication ultimately fails to save the patient or if it hastens death.²⁰¹ Therefore, the FDA fails to narrowly tailor its rules on investigational drugs to its compelling interest in protecting the health and safety of patients, in the context of terminally ill patients.

The FDA fails to narrowly tailor its rules to protect terminally ill patients from ineffective drugs as well.²⁰² The state's protection against ineffective drugs provides little aid to terminally ill patients, as they have no other options but to die without any medication.²⁰³ Because of the situation in which terminally ill patients are placed, the state has a much less compelling interest in protecting them from ineffective drugs, considering they have no other options and the drugs have at least passed basic testing that analyzes effectiveness.²⁰⁴ The state interests that justify the FDA's rules on investigational new drugs fail under strict scrutiny review when applied in the context of terminally ill patients. While these arguments have failed in the federal courts, the ever-changing medical world and momentum of public support for expanded access may require the law to change and recognize these arguments as compelling.

200. See Brief of Appellants at 43–44, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006) (No. 04–5350).

201. See *id.* at 44–45.

202. See *id.* at 46.

203. See *id.*

204. See *id.* at 46–47.

VI. OTHER OPTIONS FOR EXPANDING NEW DRUG ACCESS: RIGHT TO TRY LAWS AND BEYOND

After the court rejected the Alliance's claim on rehearing, advocates for expanded new drug access sought other avenues for reform. The primary method for reform consisted of state "Right to Try" laws.²⁰⁵ The state laws allegedly give terminally ill patients access to new drugs in a manner similar to that sought by the Alliance in its lawsuit.²⁰⁶ A similar federal statute provides an alternative and more legally solid method for reform, with the Senate having passed such a bill, though the House bill is currently sitting in committee with minimal support.²⁰⁷ Advocates for reform may achieve success by directly appealing to the FDA to change its regulations and expand access to terminally ill patients, which has succeeded in the past.²⁰⁸ Even if these methods for reform fail to directly achieve expanded access, the pressure on the FDA from state governments, some members of Congress, and the popular support of the people may force the FDA to alter its rules and expand access to terminally ill patients.

A. *State Right to Try Laws*

Despite the failure of the D.C. Circuit Court of Appeals to recognize the Alliance's right asserted as fundamental, advocates for post-phase one investigational drug access for terminally ill patients began to push for a change in the law using Right to Try laws passed by individual states, while also lobbying the United States Congress and the FDA directly.²⁰⁹ Right to Try laws attempt to resolve the issue of terminally ill patients' access to new drugs by allowing a terminally ill patient, who has exhausted all FDA-approved options for treating the disease, to gain expanded access to investigational drugs.²¹⁰ The Right to Try laws are tailored to assert that individuals have a right to try to save their lives by taking not fully approved drugs, based on the recommendation of a

205. See, e.g., GOLDWATER INST., *supra* note 15.

206. See *id.*

207. See Right to Try Act of 2017, S. 204, 115th Cong. (2017); H.R. 878, 115th Cong. (2017).

208. See Corieri, *supra* note 88, at 7–8.

209. See Shari Rudavsky, *Legislation Would Allow 'Right to Try' Trial Drugs*, USA TODAY (Feb. 3, 2015), <http://www.usatoday.com/story/news/nation/2015/02/03/legislation-would-allow-right-to-try-experimental-drugs/22821457/>.

210. See, e.g., GOLDWATER INST., *supra* note 15 (providing the model legislation on which many states based their own Right to Try laws).

physician.²¹¹ This was essentially the same relief sought in *Abigail Alliance*.²¹²

Similar to the Alliance's arguments in its Circuit case, advocates for the Right to Try argue that the right is based on the fundamental right to life.²¹³ The advocates insist that the FDA's investigational process improperly interferes with the fundamental right to life with respect to terminally ill patients.²¹⁴ Right to Try advocates argue that a terminally ill patient who meets the requirements of the Right to Try laws, including having no other treatment options, receiving a physician's recommendation, and giving informed consent, should have the right to at least *negotiate with* drug manufacturers to gain access to the investigational drug.²¹⁵

1. *State Right to Try Laws Gain Wide Support*

Many state legislatures have agreed with the arguments of Right to Try advocates, as thirty-three states have passed Right to Try laws and another sixteen have recently considered Right to Try bills.²¹⁶ The laws have reportedly not been used by any terminally ill patients yet, as there are concerns about how the FDA and federal government will react and how the laws would actually work in reality.²¹⁷

The Right to Try laws are generally based on model legislation published by the Goldwater Institute.²¹⁸ The Right to Try law's investigational drug access for terminally ill patients applies only to

211. *See id.* at 1.

212. *Compare id. with* *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 471–72 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

213. *See* Corieri, *supra* note 88, at 20.

214. *See id.*

215. *See id.* at 20–21.

216. *See Right to Try*, TENTH AMENDMENT CTR., <http://tracking.tenthamentendmentcenter.com/issues/right-to-try/> (last visited Jan. 5, 2017). The following states have passed Right to Try legislation: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Louisiana, Maine, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, Wyoming. *Right to Try in Your State*, RIGHT TO TRY, <http://righttotry.org/in-your-state/> (last visited Feb. 2, 2017). The following states have recently considered Right to Try bills: Alaska, Delaware, Hawaii (vetoed), Iowa, Kansas, Kentucky, Massachusetts, Maryland, Nebraska, New Jersey, New York, Pennsylvania, Rhode Island, Washington, Wisconsin, Vermont. *Id.*

217. *See* Trevor Brown, "Right to Try" Laws in 24 States Not Working, *Medical Experts Say*, WYO. TRIBUNE EAGLE (Aug. 28, 2015), http://www.wyomingnews.com/articles/2015/08/28/news/19local_08-28-15.txt#_ViD_TfVikp.

218. *See* GOLDWATER INST., *supra* note 15.

drugs that have passed the first phase of FDA clinical testing.²¹⁹ The model legislation notes that a drug manufacturer is not required to provide the drug, and if the manufacturer does then it may do so either without compensation, or by charging the patient at cost.²²⁰ Further, the patient's health insurance company does not have to pay for the drug, but it may do so.²²¹ The law provides that there is no cause of action against a manufacturer who has complied with the law in good faith and exercised reasonable care.²²² The law places no obligation on any party involved; it merely prohibits state officials from blocking the patient's access to the investigational drug. The model legislation prohibits the state's medical licensing or disciplinary board from punishing the patient's physician merely for recommending the drug to the patient.²²³

2. *The Failure of Nullification and States' Rights to Support State Right to Try Laws*

Advocates of the Right to Try laws argue that these state laws provide access to investigational drugs for terminally ill patients, despite the FDA rules.²²⁴ These arguments rely on theories of states' rights related to the Tenth Amendment and nullification of federal law by states.²²⁵ Advocates of the Right to Try laws insist that the FDA rules unconstitutionally interfere with the privacy and right to life of terminally ill patients, meaning that the state laws could nullify the unconstitutional federal rules.²²⁶ For these arguments to prevail, however, the advocates must show that the FDA rules are unconstitutional in one of two possible ways, either:

219. *See id.* at 1.

220. *See id.* at 2–3.

221. *See id.* at 3.

222. *See id.* at 4.

223. *See id.* at 3.

224. *See* T.J. Martinell, *Right to Try: States Take on the FDA*, TENTH AMENDMENT CENTER (Nov. 30, 2014), <http://tenthamendmentcenter.com/2014/11/30/right-to-try-states-take-on-the-fda/>.

225. *See id.* *See also* U.S. CONST. amend. X (“The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”).

226. *See* Martinell, *supra* note 224. According to advocates for the use of nullification to obtain expanded new drug access for terminally ill patients, nullification has two possible meanings. In its legal form, opponents of the FDA rules may nullify the rules legally by passing other laws that would make the FDA rules null and void. In its practical form, opponents of the FDA rules may nullify the rules by rendering the rules ineffective, in any manner possible. *See* TENTH AMENDMENT CTR., 2015 STATE OF THE NULLIFICATION MOVEMENT: REPORT ON THE GROWTH OF STATE-LEVEL RESISTANCE TO FEDERAL POWER 1, 4 (2015), <https://s3.amazonaws.com/TACHandbooks/2015-state-of-the-nullification-movement-report.pdf>.

(1) the FDA rules improperly interfere with the rights of the terminally ill; or (2) the United States Constitution did not delegate the power to the federal government to create the FDA rules regulating new drugs.²²⁷ The first argument failed in the *Abigail Alliance* cases,²²⁸ meaning that the state laws cannot nullify the FDA rules on that ground unless the Supreme Court were to hear a case on the issue and overrule the *Abigail Alliance II* ruling. The second argument will also fail because the United States Constitution gave the federal government broad powers to regulate interstate commerce, which would include prescription drugs sold in interstate commerce.²²⁹

If advocates for the Right to Try laws argued that the United States Constitution never delegated the power to the federal government to make rules regarding new drugs, this argument would fail as well. Congress gave the FDA the power to make regulations regarding the sale, marketing, and testing of new drugs sold in interstate commerce.²³⁰ Congress' power to make a law regulating new drugs sold in interstate commerce clearly derives from the Commerce Power, granted to Congress by the United States Constitution, because it regulates prescription drugs in interstate commerce.²³¹ Therefore, Congress acted in a constitutional manner, in passing the Food, Drugs, and Cosmetic Act that allowed the FDA rules,²³² under the Commerce Clause.²³³ Thus, the FDA rules are

227. See U.S. CONST. art. VI, cl. 2. The Supremacy Clause of the United States Constitution states that any constitutional federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." *Id.* Therefore, the FDA rules, as long as they are constitutional, are supreme and defeat any contrary state laws. See *id.*

228. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 712 (D.C. Cir. 2007) [*Abigail Alliance II*].

229. See U.S. CONST. art. I, § 8, cl. 3.

230. See 21 U.S.C. § 355 (2015).

231. See U.S. CONST. art. I, § 8, cl. 3. The Commerce Power gives Congress the constitutional authority to regulate commerce between the states. See *id.* Because the FDA's rules on new drugs are limited to regulating drugs "introduc[ed] . . . into interstate commerce," the rules remain within the powers granted to Congress by the Constitution. 21 U.S.C. § 355(a). When Congress determines that an activity affects interstate commerce, then it may regulate that activity under the Commerce Power, as long as Congress' determination is rational. See *Hodel v. Va. Surface Mining and Reclamation Ass'n, Inc.*, 452 U.S. 264, 277 (1981). Under the Commerce Power, Congress may regulate the production of "goods shipped in interstate commerce," even when produced intrastate, as long as the goods have an effect on interstate commerce. *Id.* at 281. The regulation of the production of prescription drugs (which are goods) that are shipped in interstate commerce clearly falls within this power of Congress, making the FDA's new drug rules constitutional under the Commerce Power.

232. 21 U.S.C. §§ 301–399 (2015).

233. See U.S. CONST. art. I, § 8, cl. 3 (giving Congress the power "[t]o regulate Commerce . . . among the several States").

constitutional and any Tenth Amendment or nullification arguments challenging the rules would fail.

Because the FDA rules are constitutional exercises of federal power, the rules prevail against any state laws that contradict them, preempting the state laws under the Supremacy Clause.²³⁴ Therefore, the state laws provide no direct access for terminally ill patients, nor do they protect physicians or drug manufacturers from liability for violating the FDA rules. State Right to Try laws are powerless as far as providing a direct solution to the issue of expanding new drug access for terminally ill patients, though they may provide an indirect solution. Other avenues for change still exist as well, such as a change in the federal law or regulations, or use of the state and federal law initiatives as pressure to effect a political solution, as discussed in the following sections.

B. Federal Right to Try Law

While the Right to Try laws fail to directly provide access to terminally ill patients, the state laws may instigate a change in the law on the federal level. A change in the federal law would directly alter the FDA rules by congressional legislation. For example, recently introduced before the House of Representatives, H.R. 3012²³⁵ attempted to alter federal law to give Right to Try laws effective power in expanding new drug access to terminally ill patients.²³⁶ The bill prohibited the federal government from restricting the sale and manufacture of investigational new drugs for terminally ill patients when authorized by a state law, such as the Right to Try laws.²³⁷ In another federal attempt to expand new drug access, H.R. 790²³⁸ sought to directly enact the Right to Try laws in federal form, which would apply to the entire nation, rather than merely recognizing Right to Try laws in the states that passed the law.²³⁹ The law involved essentially the same elements that are present in the

234. See U.S. CONST. art. VI, cl. 2 (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).

235. H.R. 3012, 114th Cong. (2015).

236. See *id.*

237. See *id.* The bill died in the most recent Congress. See *H.R. 3012 (114th): Right to Try Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/hr3012> (last visited Feb. 2, 2017).

238. H.R. 790, 114th Cong. (2015).

239. See *id.*

state laws and model legislation.²⁴⁰ Despite the success of state legislatures in passing Right to Try laws, H.R. 3012 gathered sixty-one cosponsors and failed to even come up for a vote.²⁴¹ Similarly, only four congressmen cosponsored H.R. 790, which also failed to come up for a vote.²⁴² In the Senate, Senator Ron Johnson had introduced S. 2912, which sought to enable terminally-ill patients to access unapproved drugs when authorized by state law.²⁴³ Despite gaining forty-three cosponsors, S. 2912 did not come up for a vote.²⁴⁴ However, Senator Johnson reintroduced the bill as S. 204, on January 24, 2017, which has since been passed by unanimous consent of the Senate, on August 3, 2017.²⁴⁵ A change to the federal law or regulations presents the most definitive method for change, which seems to have become significantly more possible under the presidency of Donald Trump.²⁴⁶

In January 2017, President Donald Trump met with several pharmaceutical CEOs and told them that he planned to “[cut] regulations at a level no one has ever seen before.”²⁴⁷ President Trump specifically focused on cutting regulations regarding the new drug approval process, in order to shorten the time required to obtain FDA approval.²⁴⁸ He also explicitly noted the problem that Right to Try laws attempt to address, stating that “one thing that’s always

240. See *id.* The bill died in the most recent Congress. *H.R. 790 (114th): Compassionate Freedom of Choice Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/hr790> (last visited Feb. 2, 2017).

241. See *H.R. 3012: Right to Try Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/hr3012> (last visited Feb. 2, 2017).

242. See *H.R. 790: Compassionate Freedom of Choice Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/hr3012> (last visited Feb. 2, 2017).

243. S. 2912, 114th Cong. (2016). See *S. 2912 (114th): Trickett Wendler Right to Try Act of 2016*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/s2912> (last visited Feb. 2, 2017).

244. See GOVTRACK, *supra* note 243.

245. S. 204, 115th Cong. (2017). See *S. 204: A Bill to Authorize the Use of Unapproved Medical Products by Patients Diagnosed with a Terminal Illness in Accordance with State Law, and for Other Purposes*, GOVTRACK, <https://www.govtrack.us/congress/bills/115/s204> (last visited Nov. 12, 2017). A parallel bill currently exists in the House of Representatives, but it is still in committee and has 45 co-sponsors. See *H.R. 878: Right to Try Act of 2017*, GOVTRACK, <https://www.govtrack.us/congress/bills/115/hr878> (last visited Nov. 12, 2017).

246. See, e.g., Carolyn Y. Johnson, *Trump Calls for Lower Drug Prices, Fewer Regulations in Meeting with Pharmaceutical Executives*, WASH. POST (Jan. 31, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/01/31/trump-calls-for-lower-drug-prices-fewer-regulations-in-meeting-with-pharmaceutical-executives/?utm_term=.6b83c12bd7bd; Patrick Cox, *Trump's FDA Chief May Implement Progressive Approval For Drugs*, FORBES (Dec. 14, 2016, 5:36 PM), <http://www.forbes.com/sites/patrickcox/2016/12/14/trumps-fda-chief-may-implement-progressive-approval-for-drugs/#449846b71c34>.

247. Zachary Brennan, *Trump to Pharma CEOs: 75% to 80% of FDA Regulations Will be Eliminated*, REGULATORY AFFAIRS PROF'LS SOC'Y (Jan. 31, 2017), <http://raps.org/regulatoryDetail.aspx?id=26745>.

248. *Id.*

disturbed me, they come up with a new drug for a patient who is terminal and the FDA says ‘we can’t have this drug used on the patient’ . . . but the patient is not going to live for more than 4 weeks.”²⁴⁹ On the campaign trail, Vice President Mike Pence specifically addressed the Right to Try laws, one of which he signed into law as Indiana Governor,²⁵⁰ and “promise[d]” to “open the doors to treatment” at the federal level.²⁵¹ The Trump White House seems to support patients’ right to try, though it is unclear whether President Trump will push for change through a federal law or regulatory change.²⁵²

C. Regulatory Change: Lobbying and Pressuring the FDA for Change

Advocates for expanded new drug access could also lobby the FDA to change its own regulations in order to effect change. Similar efforts to alter the FDA rules and obtain expanded access have succeeded in the past. In the 1980s, the FDA made major changes to its rules in order to give terminally ill patients greater access to new drugs after AIDS patients demanded access.²⁵³ Though the FDA proved reluctant to alter its rules, the dire situation of AIDS patients—who had no approved treatment options and would likely die before any became available—eventually brought about a change to the rules.²⁵⁴

In 1987, the FDA altered its rules to create Expanded Access Programs (EAPs), also known as “compassionate use’ programs.”²⁵⁵ The primary EAP, called the treatment investigational new drug (IND) program, allows a company to apply to allow a new drug in phase three clinical testing to be accessible to certain groups of terminally ill patients.²⁵⁶ Approval of the EAP makes the drug available “to a pre-defined patient group.”²⁵⁷ The clinical testing of the drug must be nearly complete, however, for the FDA to approve the

249. NBC Nightly News with Lester Holt, FACEBOOK (Jan. 31, 2017), <https://www.facebook.com/nbcnightlynews/videos/10155090457778689/>. See also Brennan, *supra* note 247.

250. See Starlee Coleman, *Indiana Governor Mike Pence Signs Right to Try Legislation into Law*, GOLDWATER INST. (Mar. 24, 2015), <http://www.goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/indiana-governor-mike-pence-signs-right-to-try-leg/>.

251. Goldwater, *Boy Pleads for “Right to Try” at Mike Pence Rally*, RIGHT TO TRY (Aug. 9, 2016), <http://righttotry.org/boy-pleads-for-right-to-try-at-mike-pence-rally/>.

252. See Cox, *supra* note 246; Johnson, *supra* note 246; NBC Nightly News with Lester Holt, *supra* note 249.

253. See Corieri, *supra* note 88, at 7–8.

254. See *id.* at 7–8.

255. *Id.* at 8.

256. See *id.*

257. *Id.*

treatment IND.²⁵⁸ The treatment INDs provided significantly less aid to terminally ill patients than had initially been anticipated, with fewer than three being approved each year for any type of illness.²⁵⁹

Because of the failure of the treatment IND program to provide the necessary aid to terminally ill patients, the FDA created an individual IND program in 1997.²⁶⁰ Individual INDs allowed a drug sponsor or a patient's physician to apply for access to a new drug for an individual patient who failed to gain access to the clinical trials.²⁶¹ The FDA approves individual INDs only if the application includes sufficient information to show that no other treatment options exist, the drug is sufficiently safe and effective, and giving access to the drug will not interfere with ongoing clinical trials or drug marketing.²⁶² Due to the time and effort required from physicians in completing applications, the individual INDs have failed in providing much greater access for terminally ill patients.²⁶³ The advocates for expanded access may successfully lobby the FDA to change its rules and allow the access sought by the Right to Try laws, as that strategy has achieved expanded access in a limited manner in the past.

D. Right to Try Laws as a Political Solution

Despite the failure of direct appeals to the FDA and Right to Try laws to bring a significant improvement in expanded access, the Right to Try laws may provide a political solution by instigating the FDA to alter its rules. With many states enacting Right to Try laws and pressure growing from advocates of expanded access, the FDA attempted to simplify and expand the EAPs in order to give better access to terminally ill patients and weaken the opposition against its rules.²⁶⁴ While the requirements for gaining access through an EAP remain similar to its initial requirements, the primary

258. *See id.*

259. *Id.* at 9.

260. *See id.*

261. *See id.*

262. *See id.*

263. *See id.* at 10.

264. *See* Alexander Gaffney, *From 100 Hours to 1: FDA Dramatically Simplifies its Compassionate Use Process*, REGULATORY AFFAIRS PROF'L SOC'Y (Feb. 4, 2015), <http://www.raps.org/Regulatory-Focus/News/2015/02/04/21243/From-100-Hours-to-1-FDA-Dramatically-Simplifies-its-Compassionate-Use-Process/>. *See also* Investigational New Drug Application, 21 C.F.R. § 312.310 (2015).

changes since 1997 have consisted of simplification of the application and the creation of two new EAP processes.²⁶⁵

Released on February 4, 2015, the new application provides a much shorter and more streamlined version of the old EAP, while also requiring less complex information that a physician could more easily provide.²⁶⁶ In limited circumstances, patients' physicians may even apply online or by telephone.²⁶⁷ The two new EAPs consist of a single patient emergency program and an intermediate size program.²⁶⁸ The intermediate size program presents an option similar to the treatment IND, but for smaller patient groups.²⁶⁹ The single patient emergency program allows an individual patient to apply for access, similar to the individual IND, but does so with faster access due to an emergency that limits the time that patient has to obtain access.²⁷⁰ While these changes have made it much easier for terminally ill patients to access experimental drugs, the access is severely limited compared to that sought by Right to Try laws and their advocates.

By creating the new EAPs, the FDA granted greater access to drugs for terminally ill patients, attempting to relieve the pressure placed on the FDA by the Right to Try laws.²⁷¹ For the desires of Right to Try advocates to be satisfied, the FDA must undertake significant further change. The EAPs provide no access to new drugs that have passed phase one, with access only allowed during or after phase three testing or, under seriously limited circumstances, after phase two.²⁷² Further, the FDA still maintains full power to deny any EAP application at its discretion.²⁷³

Ultimately, because the FDA's EAPs only aid patients after a tedious application process and allow access merely to drugs that are nearly approved already, the EAPs provide little help to patients, particularly compared to the potential access that would exist under the Right to Try laws. The EAPs fail to provide the fuller access to terminally ill patients that Right to Try laws seek. These patients may need a new drug currently in earlier phases of testing,

265. See Gaffney, *supra* note 264.

266. *Id.*

267. *Id.* The physician may file an EAP application by phone or online when the drug is required for an emergency situation, which means that the patient needs the drug before the required written application can be filed. See 21 C.F.R. § 312.310(d).

268. See Gaffney, *supra* note 264.

269. See *id.*

270. See *id.*

271. See *id.*

272. See Corieri, *supra* note 88, at 8.

273. See *Expanded Access: Information for Patients*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2015), <http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm>.

which would have several years still before its approval. If Right to Try laws continue to grow in popularity among the states, or even in Congress, then they may pressure the FDA into loosening its rules with respect to investigational new drug access for terminally ill patients. By this process, the Right to Try laws may ultimately provide a political solution to the issue of investigational new drug access for terminally ill patients.

VII. CONCLUSION

While the FDA's rules regulating investigational new drugs may provide protection for many patients against unsafe or ineffective drugs, the rules also prevent many terminally ill patients from obtaining their last potentially life-saving treatment option. The FDA clinical testing rules result in inefficient delays in the approval of new drugs, as well as restrict access for patients who have no other treatment options. Advocate groups challenged the FDA rules by bringing a federal lawsuit against the FDA, arguing that the FDA approval process infringed terminally ill patients' rights to privacy, autonomy, and life. This attempt failed, however, as the D.C. Circuit Court of Appeals rejected the argument that access to investigational new drugs constituted a fundamental right, and finding the FDA rules did not infringe the patients' due process rights.²⁷⁴ Strong arguments support the belief that investigational new drug access for terminally ill patients does, in fact, constitute a fundamental right, considering the circumstances of these patients who have no other treatment options and will inevitably die without the new drug, even if the probability of the new drug's success is low.

Since their federal lawsuit failed, advocates for expanded new drug access for terminally ill patients have supported state Right to Try laws as the most recent source for change in the law.²⁷⁵ These state laws provide no direct aid to patients, however, due to the supremacy of the federal law and regulations enacted by the FDA. An advocate for expanded access could successfully use the state laws to pressure the FDA into changing its regulations to expand access, as has been done in the past by advocates for expanded access to AIDS patients.

The state Right to Try laws have already succeeded in instigating a simplification and expansion of access programs for terminally ill

274. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 712 (D.C. Cir. 2007) [*Abigail Alliance II*].

275. See, e.g., GOLDWATER INST., *supra* note 15. See also TENTH AMENDMENT CTR., *supra* note 216 (displaying a map that shows each state's current position on the Right to Try laws and providing information on each state's proposed or enacted Right to Try law).

patients and may continue to push the FDA to expand access. Therefore, the advocates for expanded access have gained limited success with Right to Try laws and could reach further success as the laws continue to gain political support, particularly under the Trump presidency. The Right to Try laws may ultimately provide a political solution to the issue of investigational new drug access for terminally ill patients who have no other treatment options. The state Right to Try laws may eventually bring about the long-sought-after expanded access for terminally ill patients and will surely aid in continuing the decades-long struggle of the Abigail Alliance and similar advocates for expanded access.

