

Washington University Journal of Law & Policy

Volume 50 *Toward a Healthy First Amendment*

2016

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Recommended Citation

Emily Hogan, *“Right to Try” Legislation and Its Implications for the FDA Drug Approval Process*, 50 WASH. U. J. L. & POLY 171 (2016), https://openscholarship.wustl.edu/law_journal_law_policy/vol50/iss1/8

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“Right to Try” Legislation and Its Implications for the FDA Drug Approval Process

Emily Hogan*

INTRODUCTION

Patrick Henry’s famous words, “Give me liberty, or give me death!”¹ have informed American political attitudes concerning civil liberties since this country’s founding.² However, with substantial advancements in technology since Henry spoke these words in 1775, the contours of “liberty” have become increasingly more difficult to define.³ Particularly in the medical field, questions concerning the freedom of treatment constantly emerge with new discoveries and treatment options.⁴ One of these unanswered questions is whether terminally ill patients have the right to access treatments with potentially devastating risks when those treatments are their only chance of surviving.

Take for example Angelina Fanous, who learned in the summer of 2014 that she had amyotrophic lateral sclerosis (ALS).⁵ She was

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1. WILLIAM WIRT, SKETCHES OF THE LIFE AND CHARACTER OF PATRICK HENRY 123 (1817).

2. J. David Bleich, *Is There a Right to Physician-Assisted Suicide?*, 24 FORDHAM URB. L.J. 795, 797–98 (1997).

3. Charles L. Cohen, *The “Liberty or Death” Speech: A Note on Religion and Revolutionary Rhetoric*, 38 WM. & MARY Q. 702, 702 (1981).

4. For example, physician-assisted suicide is sometimes considered a civil liberty. See Bleich, *supra* note 2. More recently, the Connecticut Supreme Court ordered a seventeen-year-old teen to undergo chemotherapy to treat Hodgkin’s Disease after she rejected the treatment. The teen argued against the ruling, claiming that she has “the right to make [her own] medical decisions.” Samantha Masunaga, *Connecticut Teen Fighting State Justices’ Ruling on Forced Chemotherapy*, L.A. TIMES (Jan. 10, 2015), <http://www.latimes.com/nation/la-na-teen-chemo-20150111-story.html>.

5. Angelina Fanous, *For A.L.S. Patients, a Hopeful Drug That Is Out of Reach*, N.Y. TIMES (Feb. 5, 2015), <http://well.blogs.nytimes.com/2015/02/05/for-a-l-s-patients-a-hopeful-drug-thats-out-of-reach/>.

twenty-nine years old.⁶ Angelina claims that a medication currently being tested to treat ALS, called GM6, has been effective in slowing the advancement of the disease in its test subjects.⁷ She argues that the U.S. Food and Drug Administration (FDA) should act to allow the thousands of people suffering from ALS to access the drug, noting, “I’m dying slowly and painfully and young, and I’m willing to take the risk.”⁸ Other compelling personal anecdotes like Angelina’s suggest that terminally ill individuals desire the ability to try experimental drugs to preserve their own lives in any way possible;⁹ however, the FDA’s intensive drug approval process¹⁰ and its restrictions on accessing experimental drugs¹¹ suggest that the government perceives the potential deadly risks as too great, even for the terminally ill.

Complicating this debate is the fact that the FDA can take up to fifteen years to approve an investigational drug like GM6 and put it on the market.¹² In response to critics of this lengthy approval process, the FDA has enacted initiatives to help individuals who would benefit from experimental drugs access them more quickly.¹³ Several programs, like the “fast track” approach, accelerate the drug approval process, allowing drugs to be out on the market sooner.¹⁴ Another program, called “expanded access,” permits limited exceptions to the restrictions on accessing experimental drugs, as long as the terminally ill patient meets specific criteria.¹⁵

6. *Id.*

7. *Id.*

8. *Id.*

9. For example, two Americans who contracted Ebola in 2014 consented to use of the drug ZMapp, which had not yet been tested on humans. Sanjay Gupta & Danielle Dellorto, *Experimental Drug Likely Saved Ebola Patients*, CNN (Aug. 5, 2014), <http://www.cnn.com/2014/08/04/health/experimental-ebola-serum/>. It is believed that this drug prevented them from dying of the disease. *Id.*

10. *FDA: Drug Approval Process*, FDA, <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (last accessed Mar. 8, 2016).

11. *Expanded Access: Information for Patients*, FDA (Mar. 3, 2016), <http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm>.

12. *PhRMA Profile 2013*, PhRMA (July 2013), <http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf>.

13. *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review*, FDA (Sept. 14, 2015), <http://www.fda.gov/forpatients/approvals/fast/default.htm>.

14. *Id.*

15. *Expanded Access: Information for Patients*, *supra* note 11.

Even though these two measures allow patients quicker access to drugs, some still feel that these measures give the terminally ill insufficient time to save their own lives.¹⁶ In response, several state legislatures have enacted “right to try” laws that allow terminally ill patients to access experimental drugs directly from drug companies and without full FDA approval.¹⁷ The hope is that by eliminating the bureaucratic oversight of the federal entity, patients can access drugs more easily and have a better chance at survival.¹⁸

This Note will provide an in-depth analysis of the realistic implications of these “right to try” laws and provide recommendations on addressing their most problematic consequences. To begin, Part I provides background information on the regulation of drugs in the United States. Specifically, Part I.A discusses the history of federal food and drug regulations from 1848 until the present day. Part I.B outlines in depth the current procedure that manufacturers must follow for the FDA to approve a new drug, including specific programs designed to accelerate the approval process. Part I.C describes the various options a terminally ill patient has to access an experimental drug under the FDA’s regulations. Part I.D then discusses various attempts to circumvent these regulations, including recent “right to try” legislation.

Part II analyzes the limitations that terminally ill patients face in accessing investigational treatments and “right to try” laws themselves, arguing that these laws fail to actually help the terminally ill access experimental drugs more quickly, create problems for medical providers and drug companies producing experimental medications, and are easily preempted by extensive federal regulations that address the topic. Finally, Part III suggests that, although these state laws are problematic in their current form, the FDA should recognize that they reflect a public desire to relax regulatory standards for the terminally ill and streamline the “expanded access” process to allow more individuals to access

16. See, e.g., Starlee Coleman, *Michigan Becomes Fourth State to Adopt ‘Right to Try’ Law*, GOLDWATER INST. (Oct. 17, 2014), <http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/michigan-becomes-fourth-state-to-adopt-right-to-tr>. (noting that the “Compassionate Use” process takes more than one hundred hours of paperwork and months to navigate”).

17. *Id.*

18. *Id.*

experimental drugs in their time of need. Moreover, Part III proposes that the FDA make a concerted effort to educate physicians on its “expanded access” procedures, so that patients will have informed medical care providers who can help them navigate the complex federal regulations.

I. BACKGROUND

A. *The History of U.S. Regulation of Food and Drugs*

The United States first began monitoring food and drugs in 1848, yet it did not enjoy the expansive regulatory authority it now exercises until nearly sixty years later.¹⁹ These increased regulatory functions were enacted in response to the American people voicing growing concerns about the adulteration of various foods when a designated branch of the Department of Agriculture, the Bureau of Chemistry, expanded its focus from regulating agricultural products to include overseeing food and drug research.²⁰

As the American people became more informed about the realities of non-regulation of the food and drug industries throughout the nineteenth century, public demand for heightened monitoring grew.²¹

19. *About FDA: History*, FDA (Mar. 3, 2015), <http://www.fda.gov/aboutfda/whatwedo/history/default.htm>.

20. James Robert Dean, Jr., *FDA at War: Securing the Food That Secured Victory*, 53 FOOD DRUG L.J. 453, 455 (1998). See also Sharon B. Jacobs, *Crises, Congress, and Cognitive Biases: A Critical Examination of Food and Drug Legislation in the United States*, 64 FOOD & DRUG L.J. 599 (2009). The growing concerns led to Congress passing the Biologics Control Act in 1902, which ordered all biologic products sold in the country to receive federal licenses in order to regulate the growing field of medicinal bacteria. *Id.* at 601. The passage of the Biologics Control Act followed a 1901 incident where thirteen children, after receiving diphtheria antitoxin shots produced from the blood of horses, died after the shots proved to be contaminated with tetanus spores. *A Short History of the National Institute of Health: Biologics*, NAT'L INST. HEALTH, http://history.nih.gov/exhibits/history/docs/page_03.html (last accessed Mar. 11, 2016).

21. Arlene Finger Kantor, *Upton Sinclair and the Pure Food and Drugs Act of 1906*, 66 AMER. J. OF PUB. HEALTH 1202, 1202–05 (1976). Before the nineteenth century, many states had laws regulating the production and distribution of food, but they were “markedly inconsistent from state to state.” John P. Swann, *About FDA: FDA's Origin*, FDA (June 23, 2014), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm>.

Moreover, the way that many states' laws were structured, companies could manufacture adulterated products, but as long as they were sold in other states, the companies could not be

First, certain interest groups in the United States expressed their opinions on federal legislation aimed at purifying these industries.²² Additionally, the popularity of Upton Sinclair’s provocative novel *The Jungle*, an exposé of the realities of the Chicago meat packing industry,²³ accompanied by the Department of Agriculture’s chief chemist Harvey W. Wiley’s activism²⁴ and the work of other journalists,²⁵ provided the public with reliable information about the detrimental effects of drug and food contamination. This information outraged the public and fueled the increase of demands for heightened oversight.²⁶

prosecuted. C. C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 LAW & CONTEMP. PROBS. 3, 10 (1933).

22. For example, meat packers, like other food industrialists, exploited immigrant labor and unsanitary manufacturing techniques to mass produce meat and keep costs down; so to them, regulation meant higher costs. *Illinois History: Packingtown*, ILL. STATE UNIV., http://history.illinoisstate.edu/downloads/Vignette_Packingtown_.pdf (last accessed Mar. 11, 2016).

23. Kantor, *supra* note 21, at 1203. Sinclair, a socialist writer concerned with the “wage slavery” prevalent in food production industries, published *The Jungle* in 1906. *Id.* The book details the life of a Lithuanian immigrant who works in the meat-packing industry in early 1900s Chicago. UPTON SINCLAIR, *THE JUNGLE* (1906). The book exposes some of the truly terrible working conditions that poor immigrants working in the industry experienced and the unregulated, unsanitary factories where much of the country’s food was manufactured. *Id.* Interestingly, Sinclair wrote the book as socialist propaganda and to comment on the treatment of poor immigrants, but the public was outraged only by the reports on unclean meat. Regier, *supra* note 21, at 9.

Sinclair responded by noting, “I aimed at the public’s heart, and by accident I hit it in the stomach.” Upton Sinclair, *What Life Means to Me*, COSMOPOLITAN MAG., Oct. 31, 1906, at 591, 594.

24. Kantor, *supra* note 21, at 1202; *see also* Jacobs, *supra* note 20, at 601; Dean, *supra* note 20, at 455. Wiley spent years publicly advocating for increased federal regulation of the food and drug industries and sparked public outcry after publicizing an experiment showing the negative effects of consuming contaminated food. Kantor, *supra* note 21, at 1202.

25. In addition to Wiley and Sinclair, writers Edward Bok and Mark Sullivan of *The Ladies Home Journal* and Samuel Hopkins Adams of *Collier’s Weekly* embraced muckraking journalism techniques to expose the need for drug regulation. Regier, *supra* note 21, at 7. In his description of the pre-1906 conditions of the drug industry, Adams noted: “Floods of potions, avalanches of pills and powders, had been pouring out from the various nostrum shops, without let or hindrance, to overflow the land. Seventy-five million dollars a year is a moderate estimate of the volume of business done by pseudo-medical preparations which ‘eradicated’ asthma with sugar and water, ‘soothed’ babies with concealed and deadly opiates, ‘relieved’ headaches through the agency of dangerous, heart-impairing, coal-tar drugs, ‘dispelled’ catarrh by cocaine mixture, enticing to a habit worse than death’s very self, and ‘cured’ tuberculosis, cancer, and Bright’s disease with disguised and flavored whiskies and gins.” *Id.*

26. Kantor, *supra* note 21, at 1205.

Such demands ultimately spurred federal action. Congress responded to the public outrage by passing the Food and Drugs Act of 1906, criminalizing the manufacture or sale of “food or drug which is adulterated or misbranded” and authorizing the Department of Agriculture, among other departments, to create regulations to enforce the Act’s mission and inspect potentially adulterated or misbranded items.²⁷ Though the Act was the first to give regulatory authority to the federal government, Congress passed the legislation only after serious compromise;²⁸ thus, the “poorly constructed” Act contained substantial flaws.²⁹ In fact, during the subsequent three decades, both Congress and the courts wrestled with details of the 1906 Food and Drug Act; however, these problems did not hinder the Bureau of Chemistry from greatly expanding their influence in food and drug regulation.³⁰

27. Pure Food (Wiley) Act, Pub. L. No. 59-384, 34 Stat. 768 (1906). Interestingly, the Act had an exception for the definition of “adulterated” which noted that “no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container. . . .” Wiley Act § 7. As can be seen, the Act’s definition of adulterated aimed more at misbranding than at actual adulteration of food and drugs. Juan Joel Tovanche, *Dying to Wait: How the Abigail Court Got It Wrong*, 22 J.L. & HEALTH 53, 81–82 (2009).

28. Ilyse Barkan writes that before the passage of the 1906 Act, even “[e]loquent exposés of industrial horrors and paternalistic tendencies of the federal government could not force a Congress dominated by special interests to enact laws that those interests did not want.” Ilyse D. Barkan, *Industry Invites Regulation: The Passage of the Pure Food and Drug Act of 1906*, 75:1 AM. J. PUB. HEALTH 18 (1985). She notes that between 1879 and 1906, over two hundred legislative proposals were introduced in Congress and promptly rejected, showing that serious conflicts of interests prevented the Houses from reaching an agreement for a long time. *Id.*

29. James T. O’Reilly, *The Food and Drug Administration: A Brief History*, 1 U.S. FOOD & DRUG ADMIN. § 3:3 (2014). Specifically, the fact that regulations under the Act had to be approved by the Treasury, Agriculture, and Commerce Departments meant that new regulations were infrequently passed and diluted when they were approved. *Id.* Moreover, the Act specifically defined the standards for drug regulation but was less specific about the standards for food, leading to confusion and many legal disputes. *Id.* See also *FDA History—Part I: The 1906 Food and Drugs Act and Its Enforcement*, FDA, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last updated June 18, 2009). As the 1906 law did not define “adulterated” and “misbranded” well, courts determined violations on a case-by-case basis, making the act a “legal, as opposed to administrative, regime.” Dean, *supra* note 20, at 456. For example, in 1909, the government seized forty barrels and twenty kegs of Coca-Cola under the Act, claiming that the caffeine added to the beverage was a harmful additive. Ludy T. Benjamin, *Pop Psychology: The Man Who Saved Coca-Cola*, 40 AMER. PSYCHOL. ASS’N 18 (2009).

30. *FDA History—Part I*, *supra* note 29; see also Benjamin, *supra* note 29.

The Bureau of Chemistry, which eventually became the present day FDA,³¹ changed drastically with the passage of the Federal Food, Drug, and Cosmetic Act in 1938.³² The Act, among other things,³³ mandated that all new drugs be approved for safety by the administration before they could be marketed.³⁴ The Act also allowed the FDA to promulgate its own regulations, laws, and definitions without seeking approval from other departments.³⁵ A 1962 amendment, the Drug Efficacy Amendment, created a general

31. See Swann, *supra* note 21. The Bureau of Chemistry was renamed the Food, Drug, and Insecticide Administration after its “non-regulatory research functions” were moved to another part of the Department of Agriculture in 1927 and was eventually shortened to the present day Food and Drug Administration in 1930. *Id.*

32. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 (2012)).

This law superseded the 1906 Food and Drugs Act. *Id.* § 902(a). Congress enacted this law following review of the significant flaws of the previous legislation and after a particular “wonder drug” poisoned and killed over one hundred people with antifreeze. *FDA History—Part II: The 1938 Food, Drugs, and Cosmetic Act*, FDA, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm> (last updated Sept. 24, 2012). Specifically, the drug company S.E. Massengill Co. developed a new, liquid version of their wonder drug, Sulfanilamide, that “successfully passed all tests for flavor, appearance, and fragrance.” BENJAMIN ROSSEN, FDA’S PROPOSED REGULATIONS TO EXPAND ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE: THE STATUS QUO IN THE GUISE OF REFORM 6 (2008), available at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965551>. Under the 1906 Act regulations, the company had no responsibility to check for toxicity in their products; thus, only after their new medication, the “equivalent of modern day antifreeze,” killed people across the nation did it become clear that the medication was poisonous. *Id.* As is common in food and drug regulations, Congress finally enacted stricter guidelines following this public health crisis. *Id.* at 6–7.

33. The law expanded the FDA’s administrative scope to include medical devices and cosmetics, added much-needed definitions of food items, and allowed for factory inspections. See Federal Food, Drug, and Cosmetic Act § 301.

34. *Id.*; see also Jacobs, *supra* note 20, at 602, 607. This Act defines “drug” as “(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).” § 321(g)(1). Interestingly, there is no exception clause, showing that this new law focused more heavily on the safety of drugs than on the Act that it replaced. See Tovanche, *supra* note 27, at 83; ROSSEN, *supra* note 32, at 7. Later, the Federal Food, Drug, and Cosmetic Act’s approval process led to an amendment in 1951 introducing the idea of “prescriptions drugs” that could only be administered under supervision. Durham-Humphrey Act, 65 Stat. 648 (1951). Before 1951, non-narcotic drugs were commonly accessible in a pharmacy without doctor approval. Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & ECON. 91 (1979).

35. Dean, *supra* note 20, at 457.

standard for the drug approval process, requiring that each new drug be proved safe and effective.³⁶ Today, “safe and effective” remains the standard that new drugs must meet for FDA approval.³⁷

Currently the FDA, now housed in the Department of Health and Human Services, oversees goods accounting for twenty cents of every dollar³⁸ spent by consumers in the United States and employs over fifteen thousand “chemists, pharmacologists, physicians, microbiologists, veterinarians, pharmacists, lawyers, and many others.”³⁹ As evidence of its great expansion of regulation, the FDA’s drug approval process has become extremely complex, with four different levels of testing, multiple applications, and strict labeling, manufacturing, and marketing guidelines.⁴⁰ As described in Section II, the drug approval process, created to ensure that only the highest quality drugs are marketed to the public, also comes at a cost.

B. FDA Drug Approval Process

Before the FDA can begin to review and test an application for a new drug, a pharmaceutical company or other drug sponsor must create a compound that it hopes to market.⁴¹ The drug company must first test the drug on animals for at least two and a half years to record the toxicity of the drug and potential side effects.⁴² Following

36. Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781–82 (1962). “Section 201(p)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(p)(1)), defining the term ‘new drug,’ is amended by (A) inserting therein, immediately after the words ‘to evaluate the safety,’ the words ‘and effectiveness,’ and (B) inserting therein, immediately after the words ‘as safe,’ the words ‘and effective.’” *Id.*

37. 21 U.S.C. § 355(b)(1)(A) (2012).

38. The FDA is responsible for “most food products (other than meat and poultry), human and animal drugs, therapeutic agents of biological origin, medical devices, radiation-emitting products for consumer, medical, and occupational use, cosmetics, and animal feed.” Swann, *supra* note 21.

39. *Id.* The FDA’s 2014 budget was \$4.4 billion, when it monitored over \$1 trillion in products. *Id.*

40. *FDA: Drug Approval Process*, *supra* note 10.

41. *Id.*

42. *Id.* See also Melissa Marie Bean, *Fatal Flaws in the Food and Drug Administration’s Drug-Approval Formula*, 2003 UTAH L. REV. 881, 884 (2003). However, sometimes, in order to properly identify the chemicals being used and gather enough evidence of sufficient safety to move on to human trials, the animal testing process can take around three and a half years, which occurs prior to even submitting the Investigational New Drug application. See ROSSEN, *supra* note 32, at 10.

animal testing, a company must file an initial Investigational New Drug Application with the FDA, requesting approval for human testing.⁴³ After this initial application, three phases of human trials must be successfully completed before the FDA will approve a new drug.⁴⁴ The three phases range from using a sample of less than one hundred humans in Phase I to testing on thousands in Phase III.⁴⁵ Following the human trials, the drug company must file a New Drug Application, giving detailed information regarding the composition of the drug, potential labeling, the step-by-step manufacturing process, research on the drug’s safety and efficacy gathered from the animal testing, and the drug’s patent information.⁴⁶ Subsequently, the FDA has 180 days⁴⁷ to either make a decision on the drug or defer the adjudication on its application to a later date.⁴⁸

This stringent approval process,⁴⁹ though historically known for its efficiency in weeding out harmful drugs,⁵⁰ is accompanied by

43. Bean, *supra* note 42, at 884.

44. FDA: *Drug Approval Process*, *supra* note 10. Phase I experiments are usually conducted on healthy individuals and test for unacceptable toxicity. Phase II and III experiments are then conducted on individuals with the addressed ailment. Thus, Phase I tests mainly address a drug’s safety, while subsequent tests address a drug’s effectiveness. *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> last accessed Mar. 14, 2016) [hereinafter *The FDA’s Drug Review Process*]. A drug will only proceed to Phase III testing if the results of Phases I and II “offer a reasonable assurance that the drug is effective and safe, and that the potential benefits of the drug outweigh the risks of a large-scale clinical trial.” See ROSSEN, *supra* note 32, at 11. Because Phase III attempts to find the best “dose-response relationship” and records the most common side effects, it is usually the longest and most intense, often lasting up to three years. *Id.* at 11–12.

45. See ROSSEN, *supra* note 32, at 11–12.

46. Bean, *supra* note 42, at 884–85; 21 U.S.C. § 355(b) (1938).

47. The FDA circumvents this required timeframe by using questionable logic; the administration will sometimes say that a New Drug Application has not been “filed” until it is approvable. See ROSSEN, *supra* note 32, at 12.

48. 21 U.S.C. § 355(c).

49. During the drug approval process, the FDA scrutinizes everything “from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured” in order to guarantee that the drug is truly safe and effective. *The FDA’s Drug Review Process*, *supra* note 44.

50. In the 1950s and 1960s, Gruenthal, a German drug company, began marketing Thalidomide worldwide as a “wonder drug” that, among other things, effectively treated pregnant women’s morning sickness. However, the drug eventually led to thousand of physical and mental birth defects. See *Thalidomide: The Canadian Tragedy*, THALOMIDE VICTIM’S ASS’N OF CANADA, <http://www.thalidomide.ca/the-canadian-tragedy> (last visited Oct. 28, 2015); Jacobs, *supra* note 20, at 611. The drug was unavailable in the United States, as the

serious issues in the development of new treatments and the standard of care in the United States. First, it takes a drug manufacturer anywhere between ten and fifteen years to get a new drug approved by the FDA.⁵¹ The FDA claims that these years of testing are necessary to properly dispel concerns of a drug's safety and efficacy and fears of approving a drug that could have serious adverse consequences in the future.⁵² Moreover, the estimated cost of research and development for a new drug is estimated to cost between \$4 and \$11 billion.⁵³ This price tag, combined with the extraordinary time needed for approval, means that relatively few drugs get approved every year.⁵⁴ Even for drugs that do get approved, drug companies must recoup these high costs, and consequently, patients who need these treatments bear the burden of covering them.⁵⁵ Finally, many drugs developed overseas are not marketed in the United States because the cost of obtaining FDA approval exceeds projected revenues.⁵⁶ As a result, many potentially beneficial foreign treatment options are unavailable in America.⁵⁷

In response to growing criticism of the FDA's approval process for new drugs,⁵⁸ Congress implemented a "fast track" program

FDA refused to approve it. Bean, *supra* note 42, at 883. This decision earned the FDA a "sterling reputation" as an effective consumer protection organization. *Id.* This "near miss" was the impetus for the 1962 Drug Amendments that added an efficacy requirement before FDA approval. See ROSSEN, *supra* note 32, at 8; see also *FDA History—Part I*, *supra* note 29; and Benjamin, *supra* note 29 for more information on the amendments.

51. *PhRMA Profile 2013*, *supra* note 12.

52. Dale H. Gieringer, *The Safety and Efficacy of New Drug Approval*, 5:1 *CATO J.* 177 (1985). Gieringer argues that the "safety" and "efficacy" standards should not be applied with society-wide standards, as these ideas are subjective and depend on an individual's characteristics. *Id.* at 180.

53. Mathew Herper, *The Truly Staggering Cost of Inventing New Drugs*, *FORBES* (Feb. 10, 2012), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/print/>. Less than one in ten drugs succeed in the trial phase, so the cost of failure can be steep. *Id.*

54. *The FDA's Drug Review Process*, *supra* note 44. The FDA approved thirty-nine new drugs in 2012, the most in fifteen years. Barry Werth, *A Tale of Two Drugs*, *MIT TECH. REV.* (Oct. 22, 2013), <http://www.technologyreview.com/featuredstory/520441/a-tale-of-two-drugs/>.

55. Werth, *supra* note 54.

56. Gieringer, *supra* note 52 at 179. Drugs that are available in other countries but not the United States are sometimes referred to as "orphan drugs." *Id.*

57. Amelia A. Esber, Note, *Curing the Drug Lag: A Proposal for International Harmonization of Pharmaceutical Approval*, 31 *ARIZ. J. INT'L COMP. L.* 125, 132 (2014).

58. For example, the rise of the AIDS epidemic in the United States and the inevitability of death due to a lack of treatment options prompted many people suffering from the illness to

whereby drugs for “serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments” can be approved more quickly.⁵⁹ Congress codified this process and several others by passing the Food and Drug Administration Modernization Act of 1997, still in effect today.⁶⁰ The Act allows for faster approval if the drug is truly needed to advance medical treatment for certain illnesses.⁶¹ Currently, the FDA has four different expedited processes for reviewing potentially life-saving drugs:⁶² (1) the fast track approach, which covers drugs that “fill an unmet medical need;” (2) the breakthrough therapy approach, which addresses therapies that could be significantly more effective than existing ones; (3) the accelerated approval approach, which allows for certain drugs to be approved if some evidence of a future clinical benefit is met; and (4) the priority review approach, which covers FDA plans to make a decision on a specific drug within six months.⁶³ Section III discusses circumstances where individuals who require these drugs to battle a terminal illness may access drugs even before their approval for sale to the public.

protest the “paternalistic and risk-averse procedures for FDA drug approval.” Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL’Y 295, 296 (2000). An organized political movement eventually convinced the FDA to relax its standards for treatment and allow the patients themselves to determine the acceptable risks of taking certain medications. *Id.* at 296–97.

59. Bean, *supra* note 42, at 886; David Willman, *How a New Policy Led to Seven Deadly Drugs*, L.A. TIMES (Dec. 20, 2000), <http://www.latimes.com/nation/la-122001fda-story.html#page=1>; 21 C.F.R. § 314.500 (2001).

60. Bean, *supra* note 42, at 887; Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 112, 111 Stat. 2296 (1997).

61. 21 U.S.C. § 356 (2012).

62. *For Patients: Fast Track*, *supra* note 13.

63. *Id.* Generally, drug companies push for their drugs to be reviewed in an accelerated process because they want to quickly recoup the large amounts of money invested in developing the drug. Bean, *supra* note 42, at 887. However, though these processes are useful in putting drugs on the market faster, the increase in drug companies seeking a faster approval time has led to speculation that some drugs may not be fully vetted before their approval. Colleen Curry, *Fast-Track FDA Approval for Big Drug Companies Might Be a Bad Thing*, VICE NEWS (Sept. 25, 2015), <https://news.vice.com/article/fast-track-fda-approval-for-big-drug-companies-might-be-a-bad-thing>.

C. Experimental Drug Access Through the FDA

Despite these fast track approval methods, for many patients suffering from terminal illness, the process is still too long for the potentially life-saving therapies to benefit them. Currently, terminally ill patients have two ways in which they can access new drugs before they are approved and marketed nationwide.⁶⁴

Their first option is to be selected to participate in one of the clinical trials required for FDA approval.⁶⁵ However, participation in a clinical trial carries several risks. First, a potential participant must meet certain criteria regarding the condition of their ailment and other requirements that the researchers identify.⁶⁶ Moreover, Phase II and Phase III trials often employ control groups who are given placebos, so participants using a clinical trial to receive potentially life-saving medications may not actually be receiving the medicines.⁶⁷ In all, less than 3 percent of terminally ill patients have access to experimental drugs through a clinical trial, making it a difficult path to pursue for most of these patients.⁶⁸

The second way to access experimental drugs is through an FDA program called “Expanded Access” or “Compassionate Use.”⁶⁹ This program allows individuals with life-threatening diseases to access drugs and medical devices that have passed the early stages of clinical trials.⁷⁰ The requirements for access through this program are rather stringent: a potential participant must prove that they are suffering from a life-threatening disease and that no reasonable

64. *Learn About Expanded Access and Other Treatment Options*, FDA, <http://www.fda.gov/ForPatients/Other/default.htm> (last updated Feb. 2, 2016).

65. U.S. NAT'L INST. OF HEALTH, *Learn About Clinical Studies*, CLINICALTRIALS (Dec. 2014), <https://clinicaltrials.gov/ct2/about-studies/learn>.

66. *Id.* Researchers typically want a wide range of people represented in their study's group, so as to guarantee that the results are the least biased possible. See *Drugs: Inside Clinical Trials: Testing Medical Products in People*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm> (last updated Nov. 6, 2014).

67. *Drugs: Inside Clinical Trials*, *supra* note 66.

68. Mary Lou Byrd, *Third State Passes 'Right to Try' Legislation*, WASH. FREE BEACON, (July 17, 2014), <http://freebeacon.com/issues/third-state-passes-right-to-try-legislation/>.

69. *For Patients: Understanding Expanded Access*, *supra* note 11.

70. *Id.* See also 21 C.F.R. § 312.305 (2009).

alternative treatment exists, including clinical trials.⁷¹ Moreover, the FDA suggests that applicants take several proactive measures, such as searching for expanded access programs online, contacting drug companies themselves to inquire about their policies, contacting patient advocacy groups about group programs they may have, and finding a physician willing to oversee the treatment before they can access the drugs.⁷² Also, physicians must follow stringent requirements during the application process and afterward, including reviewing all potential risks and benefits of a drug, completing hours of paperwork, working with an Institutional Review Board at their place of work, and monitoring the patient for the entire treatment period.⁷³ All in all, roughly one thousand people participate in this program per year,⁷⁴ and a drug company must agree to give their drugs to the individuals,⁷⁵ even after the FDA grants the exception.⁷⁶

71. 21 C.F.R. § 312.305; *For Patients: Understanding Expanded Access*, *supra* note 11. The FDA considers factors such as: the likelihood that death will occur, or will occur prematurely, without the experimental medication; if there is a “comparable or satisfactory alternative therapy” to treat the patient; the risks of using and not using the treatment; and the effects of allowing access on clinical studies of the drug. *For Patients: Understanding Expanded Access*, *supra* note 11.

72. *For Patients: Understanding Expanded Access*, *supra* note 11. As many patients will not have the knowledge or resources to learn what experimental drugs are being tested, applicants will have to complete extensive research in order to find a potentially helpful drug in development.

73. *Expanding Access: Information for Physicians*, FDA (Dec. 15, 2013), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm429624.htm>; see also Kimberly Leonard, *Seeking the Right to Try*, U.S. NEWS & WORLD REPORT (Nov. 18, 2014), <http://www.usnews.com/news/articles/2014/11/18/right-to-try-laws-allowing-patients-to-try-experimental-drugs-bypass-fda> (noting that it can take doctors up to one hundred hours to complete the requisite paperwork).

74. Not much evidence exists of the experiences of those who have participated in the program, and the number of people rejected from the “compassionate use” program is not published. However, the FDA has said that it approves nearly 99 percent of applications. Elizabeth Cohen, *Dying Patients Denied Drugs*, CNN (Apr. 6, 2014), <http://www.cnn.com/2014/04/05/health/cohen-compassionate-use/>. Also, the FDA usually defers to a drug company’s decision to grant access to one of its experimental drugs. Stephanie Baum, *NYU Prof: Right to Try Laws Will Not Get Experimental Drugs to the Sick People Who Need Them*, MEDCITY NEWS (Dec. 22, 2014), <http://medcitynews.com/2014/12/fdas-compassionate-use-process-needs-efficient-beats-right-beg-laws-pased-states/>.

75. Even if the FDA allows the compassionate use and the drug company is willing to provide the treatments, many of the drugs, if not provided gratuitously by the drug manufacturers, will not be covered by insurance and therefore may still be unaffordable. Baum, *supra* note 74.

76. See John Tozzi, *Do Dying Patients Have a Right to Try Experimental Drugs?*

Thus, accessing these drugs can still be an extraordinary burden of time and effort for a terminally ill individual.⁷⁷

D. Responses to Experimental Drug Access Procedure

In response to the overwhelming time and effort that drug companies spend developing drugs along with the difficulty in accessing experimental drugs through clinical trials and FDA accelerated programs, several entities have taken action to fight for more liberal access to these drugs.⁷⁸ For example, in November 2001, Frank Burroughs, whose daughter Abigail died from squamous cell carcinoma earlier that year,⁷⁹ founded an organization on her behalf called the Abigail Alliance for Better Access to Developmental Drugs (Abigail Alliance).⁸⁰ Before she died, Abigail, her family, and her oncologist unsuccessfully petitioned the FDA and certain Congressmen⁸¹ for access to Erbitux or Iressa, two investigational drugs recommended by her oncologist to address her terminal,

Libertarians Say Yes, BLOOMBERG BUS. (Aug. 21, 2014), <http://www.bloomberg.com/bw/articles/2014-08-21/do-dying-patients-have-a-right-to-try-experimental-drugs-libertarians-say-yes>; *Factsheet: Access to Investigational Drugs*, NAT'L CANCER INST. (Aug. 4, 2009), <http://www.cancer.gov/about-cancer/treatment/drugs/investigational-drug-access-fact-sheet>.

77. On average, the FDA receives around one thousand applications a year and approved almost all of them. Kardish, *infra* note 116.

78. See Lewis A. Grossman, *The Origins of American Health Libertarianism*, 13 YALE J. HEALTH POL'Y L. & ETHICS 76, 81 (2013).

79. Kate Gilchrist & Sara Love Swaney, *A Right to Access Unapproved Experimental Drugs? Abigail Alliance Battles the FDA for a New Constitutional Right*, MISS. MED. NEWS, May 2007, at 17, available at <http://arwebservice.arlaw.com/pdf/MississippiMedicalNews0507.pdf>.

80. See Frank Burroughs, *Our Story*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/story.php> (last accessed Mar. 16, 2016); Sue Kovach, *The Abigail Alliance*, LIFE EXTENSION MAG., Sept. 2007, at 67, available at http://www.lifeextension.com/magazine/2007/9/report_abigail/page-01.

The mission of the Abigail Alliance includes "helping [to] create wider access to developmental cancer drugs and other drugs for serious life-threatening illnesses," "promoting creative ways of increasing expanded access and compassionate use programs," and "helping better inform cancer patients, other patients, and their doctors about the website, clinicaltrials.gov." *The Abigail Alliance Mission*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/mission.php> (last visited Jan. 3, 2016).

81. Abigail and her family launched a media campaign to bring awareness to her fight for these investigational drugs and to influence the FDA and Congress to consider her cause; Abigail participated in several newspaper and television interviews throughout her battle with cancer. Burroughs, *supra* note 80.

otherwise untreatable illness.⁸² In 2003, the Abigail Alliance finally took legal action and submitted a petition to the FDA proposing new guidelines for terminally ill patients trying to access experimental drugs.⁸³ The FDA responded to the Abigail Alliance by letter, explaining why their proposals could not be implemented and noting that allowing earlier access could frustrate their goal of guaranteeing that drugs be safe and effective for public use.⁸⁴ Nevertheless, the Abigail Alliance subsequently submitted a citizen’s petition, but the FDA failed to respond, prompting the Abigail Alliance to file a claim against the FDA in federal court.⁸⁵

82. Erbitux is the brand name for cetuximab, a drug now approved by the FDA to treat colo-rectal cancer that has spread to other parts of the body. ERBITUX, <http://www.erbitux.com> (last updated Sept. 2015).

Iressa is the brand name for gefitinib, a drug that targets epidermal growth factor receptors, common in “non-small cell lung cancer.” IRESSA, <http://www.iressa.com> (last updated July 2015). Abigail’s oncologist thought that these drugs would treat her tumor, as it “was rich in epidermal growth factor receptors” and the two new drugs worked to inhibit these receptors. See Gilchrist, *supra* note 79. Abigail, however, was denied these treatments. The FDA denied Iressa because Abigail did not qualify for the drug’s clinical trials, and it denied Erbitux because that drug’s intended target was colon cancer, not Abigail’s diagnosis of squamous cell carcinoma. *Id.*

83. This petition creates the right for a citizen to ask the FDA to “issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action,” argued that there exists a “different risk-benefit tradeoff facing patients who are terminally ill and who have no other treatment options,” and that delays in the current regulatory scheme prevent many of those who could benefit from experimental drugs from accessing them. 21 C.F.R. § 10.25 (2015); *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695, 699 (D.C. Cir. 2007) (quoting *In re Tier 1 Initial Approval Program to Expedite the Availability of Lifesaving Drugs* 9 (June 11, 2003)). The petition asked the FDA to create new regulations that would allow access to certain drugs after they passed Phase I clinical trials. *Id.*

84. *Abigail Alliance*, 495 F.3d at 699–700. Specifically, the FDA noted that the proposed regulatory changes “would upset the appropriate balance that [it is] seeking to maintain, by giving almost total weight to the goal of early availability and giving little recognition to the importance of marketing drugs with reasonable knowledge for patients and physicians of their likely clinical benefit and their toxicity.” *Id.* at 700 (quoting Letter from Peter J. Pitts, Associate Commissioner for External Relations, Dep’t of Health and Human Servs., to Frank Burroughs, President, Abigail Alliance for Better Access to Developmental Drugs 3 (Apr. 25, 2003)).

85. The citizen’s petition was filed under 21 C.F.R. § 10.30, which advises applicants on the appropriate formatting, content, and mailing location of their petitions, as well as the procedure under which the petition will be reviewed. In this case, as the FDA did not respond to the petition in the required 180 days, the Abigail Alliance was entitled to judicial review of their petition. See C.F.R. § 10.30(e)(2) (2015). Byron R. Chin, *One Last Chance: Abigail Alliance v. Von Eschenbach and the Right to Access Experimental Drugs*, 41 U.C. DAVIS L. REV. 1969, 1973 (2008).

In their claim, the Abigail Alliance sued to enjoin the FDA from preventing terminally ill patients from accessing drugs that passed Phase I testing and claimed that a patient's "right to life" included the right to access potentially life-saving drugs.⁸⁶ The District Court in Washington D.C. granted the FDA's motion to dismiss, claiming that no right to access unapproved drugs existed.⁸⁷ On appeal, a three-judge panel in the D.C. Circuit reviewed the case and reversed the lower court's decision, finding that a fundamental right to access post-Phase I drugs existed.⁸⁸ Nevertheless, after the FDA appealed for an en banc review, the D.C. Circuit reversed and confirmed that no fundamental right to experimental drugs exists.⁸⁹ Though the Abigail Alliance appealed the decision, the Supreme Court denied a writ of certiorari; thus, as the matter stands, there is currently no recognized fundamental right to access drugs before FDA approval.⁹⁰

Nonetheless, the recent passage in several states of "right to try" legislation is evidence that the public's opinion on access to

86. Chin, *supra* note 85, at 1985. The Abigail Alliance found this "right to life" in the Due Process Clause of the U.S. Constitution, which holds that the government cannot deprive anyone "of life, liberty, or property, without due process of law." U.S. CONST. amend. V; U.S. CONST. amend. XIV. Specifically, the Abigail Alliance relied on *Washington v. Glucksberg*, where the Supreme Court held that "the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, 'deeply rooted in this Nation's history and tradition,'" to argue that this was, indeed, a fundamental right. 521 U.S. 702, 720-21 (1997); *see also* Tovanche, *supra* note 27, at 56. This interest has been compared to the right of self-defense, the right to privacy, the doctrine of necessity, interfering with rescue, and the right to "refuse life sustaining care." *See* Allen J. Jacobs, *Is State Power to Protect Health Compatible with Substantive Due Process Rights?*, 20 ANNALS HEALTH L. 113, 122-23 (2011) (emphasis added).

87. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, 2004 WL 3777340, at *9 (D.D.C. 2004) (noting that "[t]he court is not persuaded that the plaintiffs seek a recognized right").

88. *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006); Chin, *supra* note 85, at 1985.

89. *Abigail Alliance*, 495 F.3d at 711. The court wrote: "[W]e conclude that the Alliance has not provided evidence of a right to procure and use experimental drugs that is deeply rooted in our Nation's history and traditions. To the contrary, our Nation's history evidences increasing regulation of drugs as both the ability of government to address these risks has increased and the risks associated with drugs have become apparent. Similarly, our legal traditions of allowing a necessity defense, prohibiting intentional interference with rescue, and recognizing a right of self-defense cannot justify creating a constitutional right to assume any level of risk without regard to the scientific and medical judgment expressed through the clinical testing process." *Id.*

90. *Abigail Alliance For Better Access to Dev. Drug v. Von Eschenbach*, 552 U.S. 1159 (2008).

experimental drugs may be more sympathetic to the terminally ill than the D.C. Circuit.⁹¹ Such laws, currently in place in at least twenty-four states and introduced in most others,⁹² allow terminally ill patients to petition drug companies for access to experimental drugs that have passed Phase I trials without receiving prior approval from the FDA.⁹³ Generally, a terminally ill patient would need only the approval of his or her doctor and a drug company’s agreement to sell its product in order to access a potential experimental treatment option.⁹⁴ The libertarian think tank behind this legislation, the Goldwater Institute, believes that these laws will help dying patients obtain potentially life-saving treatments without having to navigate the bureaucracy of the FDA and without wasting valuable time in accessing drugs.⁹⁵ However, many in the medical community oppose these laws; they note that drugs that move past Phase I trials have passed a basic safety test to determine a non-lethal dosage but their long-term safety, side effects, and effectiveness are, at this stage, unknown.⁹⁶ Those in opposition also highlight that many states have included clauses shielding medical providers from tort liability for

91. See Coleman, *supra* note 16. Not only have these laws received the support of the public, but also, they generally pass with heavy bipartisan support in state legislatures. *Id.* See also *Arizona Voters Pass ‘Right to Try’ for Terminally Ill*, GOLDWATER INSTITUTE (Nov. 5, 2014), <http://goldwaterinstitute.org/article/arizona-voters-pass-right-try-terminally-ill-patients>.

92. *Right to Try*, TENTH AMENDMENT CENTER, <http://tracking.tenthamendmentcenter.com/issues/right-to-try/> (last visited Jan. 3, 2016). Some examples of state “right to try” laws are as follows: COLO. REV. STAT. ANN. § 25-45-101 (West 2014); LA. REV. STAT. ANN. §§ 40:1300.381-1300.386 (2014); MO. ANN. STAT. § 191.480 (West 2014); MICH. ADMIN. CODE r. 333.1101 (2015); Arizona Terminal Patients’ Right to Try Referendum, Prop. 303 (2014); and N.C. GEN. STAT. ANN. § 90-325 (West 2015). See generally Alexander Gaffney, “Right to Try” Legislation Tracker, REG. AFF. PROF. SOC’Y (June 24, 2015), <http://www.raps.org/Regulatory-Focus/News/Databases/2015/06/24/21133/Right-to-Try-Legislation-Tracker/>.

93. Leonard, *supra* note 73.

94. *Id.*

95. Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of Their Treatment*, GOLDWATER INST. (Feb. 11, 2014) https://goldwater-media.s3.amazonaws.com/cms_page_media/2015/1/28/Right%20To%20Try.pdf. The Goldwater Institute’s model “right to try” legislation describes the right to try an investigational therapy as a “fundamental right” and notes that the government should not be involved in making this decision for anyone. *Id.*

96. David Gorsky, *‘Right to Try’ Laws and Dallas Buyer’s Club: Great Movie, Terrible for Patients and Terrible Policy*, SCI. BASED MED. (Mar. 8, 2014), <http://www.sciencebasedmedicine.org/right-to-try-laws-and-dallas-buyers-club-great-movie-terrible-public-policy/>; John Tozzi, *supra* note 76. See also Rebecca Dresser, *The ‘Right to Try’ Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. L. REV. 1631, 1632 (2015).

aiding patients in accessing drugs and note that this immunity could encourage providers to be more liberal in their pursuit of experimental drugs than is safe.⁹⁷ Other legal critics claim that if the laws were to be challenged in court under constitutional grounds, they may be found to be preempted by the federal government's exclusive control over food and drug regulation.⁹⁸

II. ANALYSIS

The FDA's "expanded access" program is currently the only real opportunity a terminally ill patient has to access an experimental drug if not approved for a clinical trial.⁹⁹ However, the process of getting approval is frustrating, time-consuming, and complicated, and even when applications are approved, it is often too late for the treatment to be effective.¹⁰⁰ For example, the process as a whole can take months to complete, severely limiting the precious time a terminally ill patient has to obtain a potentially life-extending or life-saving drug.¹⁰¹ Moreover, for a patient to benefit from "expanded access," his or her physician must have knowledge of both a current experimental drug and the program itself and be willing to guide their

97. For example, Colorado's "right to try" law states:

This article does not create a private cause of action . . . against any other person or entity involved in the care of an eligible patient . . . for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, so long as the manufacturer or other person or entity is complying in good faith with the terms of this article, unless there was a failure to exercise reasonable care.

COLO. REV. STAT. ANN. § 25-45-107. *See also* MO. ANN. STAT. § 191.480.2(2)(8).

98. *Maryland v. Louisiana*, notes that in regard to U.S. CONST. art. VI, § 2, "[i]t is basic to this constitutional command that all conflicting state provisions be without effect." 451 U.S. 725, 746 (1981); U.S. CONST. art. VI, § 2. Moreover, *Pennsylvania R.R. Co. v. Pub. Serv. Comm'n*, stands for the proposition that if the United States has exercised enough power over interstate commerce "as to take possession of the field," states may not add to or take away from the United States' power to regulate. 250 U.S. 566, 569 (1919).

99. *FAQ: ClinicalTrials.gov—What is "Expanded Access"?*, NAT'L INST. HEALTH, <https://www.nlm.nih.gov/services/ctexpaccess.html> (last visited Jan. 3, 2016).

100. Cohen, *supra* note 74; *Compassionate Drug Use*, CANCER, <http://www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/compassionate-drug-use>, (last visited Jan. 3, 2016).

101. Corieri, *supra* note 95.

patient through the various steps.¹⁰² The burdens for both patients and physicians to comply with the requirements of “expanded access” programs suggest that the process is inefficient in its current form.

At first glance, “right to try” laws, providing a quicker and easier method for terminally ill patients to access investigational drugs without bureaucratic oversight from the FDA, appear to solve the issues discussed above, and all of these laws have passed in state legislatures with relatively little or no resistance.¹⁰³ The Goldwater Institute and the politicians who put forth these bills argue that patients will basically be able to access these drugs anyway through expanded access and compassionate use programs but are unduly burdened by “bureaucratic red tape” that complicates the process, wastes precious time, and violates a patient’s liberty to try to save their own life.¹⁰⁴ In essence, they argue that “right to try” legislation is necessary in order to save more lives.¹⁰⁵

Nonetheless, these laws create a myriad of problems in the medical and legal fields and ultimately do not serve to improve terminally ill patients’ odds of benefiting from an experimental drug. To begin, these laws are mainly “feel good” laws with no real ability to improve access to experimental drugs.¹⁰⁶ Because drug companies are under no obligation to give a patient an experimental drug even if the patient receives FDA approval, “right to try” legislation does no more to guarantee a patient access to investigational drugs than the current laws in place.¹⁰⁷ In fact, removing the FDA from the process

102. Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 N. ENGL. J. MED. 279, 282 (2015). This article explains the heavy administrative burden on physicians overseeing a patient’s use of an experimental drug. *Id.* A physician must abide by strict procedures to get informed consent, comply with an institutional review board, and record case history, drug disposition, and side effects. *Id.*

103. Not many politicians appear willing to disagree with the concept that everyone has the “basic freedom . . . to preserve one’s own life,” as the “right to try” is framed by the Goldwater Institute. *See* Corieri, *supra* note 95. *See also* Tozzi, *supra* note 76.

104. Corieri, *supra* note 95. *See also* Tozzi, *supra* note 76; Eleanor Clift, “The Dallas Buyer’s Club” Bill, DAILY BEAST (Mar. 4, 2014), <http://www.thedailybeast.com/articles/2014/03/04/the-dallas-buyers-club-bill.html>.

105. Tozzi, *supra* note 76; Corieri, *supra* note 95.

106. Michelle Andrews, *More States Adopt Laws to Ease Access to Experimental Treatments*, NPR (Nov. 18, 2014), <http://www.npr.org/blogs/health/2014/11/18/364935413/more-states-adopt-laws-to-ease-access-to-experimental-treatments>.

107. David Kroll, *The False Hope of Colorado’s ‘Right to Try’ Investigational Drug Law*, FORBES (May 19, 2014, 5:26 PM), <http://www.forbes.com/sites/davidkroll/2014/05/19/the->

could make drug companies less likely to provide drug samples to patients due to the adverse effect the arrangement could have on the experimental drug's approval process, such as patients choosing to forego participation in a clinical trial and instead obtain experimental drugs on their own.¹⁰⁸ Because of these limitations, the laws are more likely to give terminally ill patients false hope than a cure.¹⁰⁹

Furthermore, the Abigail Alliance's legal pursuit for courts to confirm a right to access experimental drugs, as described above, raises several concerns with an unfettered system for accessing experimental drugs.¹¹⁰ First, if a terminally ill patient could access experimental drugs simply by requesting them, drug companies would have difficulty finding participants for their clinical trials, making final approval more costly and time-consuming.¹¹¹ "Right to try" laws arose from these perceived faults with the strenuous drug approval process, so the fact that they would actually exacerbate the process's problems showcases their fundamental contradiction. Second, as the court touched upon in *Abigail Alliance*, it is a far stretch to argue that the right to self-defense includes the right to assume risks from drugs.¹¹² Experimental drugs have yet to meet national public health standards, and administering them this liberally could just as easily cause serious harm instead of a cure.¹¹³ In fact, because no particular drug can be said to be safe or effective before FDA approval, none can truly offer protection to an individual; therefore, the self-defense argument necessarily fails.

false-hope-of-colorados-right-to-try-act/; see also Andrews, *supra* note 106; Tozzi, *supra* note 76. Moreover, pharmaceutical companies are reluctant to sell drugs to individuals without FDA approval because any adverse side effects of the drug must be reported in the drug trials, and people with terminal illnesses are more likely to have other problems that exacerbate the side effects. *Id.*; Leonard, *supra* note 73. Even if drug companies do decide to sell an investigational drug to a terminally ill patient, insurance companies will probably not cover the expense, causing many treatments to only be available to the wealthy. *Id.*

108. Leonard, *supra* note 73; Peter Hart, *Abigail Alliance Case Discussed: Balancing Study Drugs, Safety*, U. PITT. U. TIMES (Feb. 19, 2009), <http://www.utimes.pitt.edu/?p=8605>.

109. Andrews, *supra* note 106.

110. Andrew Pollack, *Court Rejects the Right to Use Drugs Being Tested*, N.Y. TIMES (Aug. 8, 2007), http://www.nytimes.com/2007/08/08/health/08cancer.html?_r=0.

111. RAYMOND J. DEVETTERE, PRACTICAL DECISION MAKING IN HEALTH CARE ETHICS: CASES AND CONCEPTS 473 (3d ed. 2010); Hart, *supra* note 108.

112. Pollack, *supra* note 110; see also *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 495 F.3d 695, 710 (D.C. Cir. 2007).

113. Hart, *supra* note 111.

Further complicating the benefits of “right to try” laws is the limited liability for physicians who help their patients receive an experimental drug, which could serve to undermine the standards of the medical profession. Some physicians may use the “right to try” laws as a money-making scheme, setting up a practice that specializes in acquiring investigational drugs for patients who may not truly qualify.¹¹⁴ These schemes could influence terminally ill patients to forego approved treatments in favor of risky, unproven drugs without appropriate advice from their physicians.¹¹⁵ Also, the relative ease with which patients could acquire investigational drugs could lead them to use “right to try” laws for treatment instead of enrolling in clinical trials. As noted above, this risk could undermine the entire drug approval process, skew results, and increase the time and money needed to put a new drug on the market.¹¹⁶

Finally, “right to try” laws are unconstitutional. The federal government has been evaluating the safety of drugs since at least 1902,¹¹⁷ and the expansive regulations that it has developed since, evidenced by the historical background regarding the expansion of the FDA discussed in Section I, demonstrates that it has taken “possession of the field” entirely.¹¹⁸ Therefore, federal regulations created by the FDA preempt any state laws that attempt to modify its requirements, rendering such state laws invalid.¹¹⁹ Here, “right to try”

114. Jann Bellamy, *The Illusions of “Right to Try” Laws*, SCL-BASED MED. (Mar. 6, 2014), <http://www.sciencebasedmedicine.org/the-illusions-of-right-to-try-laws/>; see also Arthur Caplan, *Bioethicist: ‘Right to Try’ Law More Cruel Than Compassionate*, NBC NEWS (May 19, 2014, 4:20 PM), <http://www.nbcnews.com/health/health-news/bioethicist-right-try-law-more-cruel-compassionate-n108686>.

115. Bellamy, *supra* note 114. Bellamy worries that patients with no other cure will be lured into dangerous treatment options during their last few months instead of accepting “palliative care and a meaningful opportunity to spend time with loved ones.” *Id.*

116. Leonard, *supra* note 73; Chris Kardish, *State ‘Right to Try’ Laws Would Get Drugs to the Dying Faster*, GOVERNING (June 3, 2014), <http://www.governing.com/topics/health-human-services/gov-states-push-experimental-drug-access.html>. Although over 60 percent of drugs move past the first clinical stage, only 7 percent of drugs tested make it past all three clinical trial stages. Corieri, *supra* note 95; Kardish, *supra* note 116.

117. See NAT’L INST. HEALTH, *supra* note 20.

118. *Pa. R.R. Co. v. Pub. Serv. Comm’n of Commw. of Pa.*, 250 U.S. 566, 569 (1919) (interpreting the Supremacy Clause, U.S. CONST. art. VI, § 2). The federal government gets its power to regulate the production and sale of drugs from the Commerce Clause. U.S. CONST. art. I, § 8.

119. *Pa. R.R. Co.*, 250 U.S. at 569; see also Bellamy, *supra* note 114.

laws remove the expanded access procedures developed by the FDA from the application process for investigational drugs. In other words, these state laws attempt to take control of a process over which the federal government has complete control.¹²⁰ Therefore, regardless of the policy reasons that weigh against these laws, if one of these laws were challenged in court, they very well may be stuck down on constitutional grounds.

III. PROPOSAL

Although the current “expanded access” program does not necessarily serve the needs of all terminally ill patients who seek to utilize the program, the “right to try” laws are ultimately ineffective in providing more efficient access to experimental drugs and are preempted by the FDA’s control over the drug approval process. Nevertheless, the fact that so many states have passed similar legislation and many more are considering it demonstrates that the public finds a speedier, less cumbersome process for experimental drug access to be a necessary responsibility of the government.¹²¹ Because states themselves cannot constitutionally address this issue through regulation, the burden must fall to the FDA. This Note recommends that the FDA recognize that the states’ reasoning behind passing these laws stems from a genuine fault with the “expanded access” program and implement two improvements to its “expanded access” program to better serve terminally ill patients’ needs.

First, the FDA should compile an easily accessible list of experimental drugs and their expected treatment uses for potential participants in the program. Currently, many of the requirements for qualifying for the program, like researching potential clinical trials and contacting drug companies about drugs in development, unnecessarily burden terminally ill patients.¹²² Moreover, the FDA has already accumulated data on all of the drugs that are currently under investigation due to the Investigational New Drug

120. Bellamy, *supra* note 114.

121. Gaffney, *supra* note 92.

122. FDA, *supra* note 11.

Application¹²³ requirement and its oversight of clinical trials, so this would be a logical next step.¹²⁴ This would streamline the application process immensely—applicants could find all relevant information in one place and the FDA would have the added benefit of knowing where the applicants obtained that information. This system would ease the burden on patients from taking numerous proactive measures and reduce the frustration, complication, and time needed to meet the requirements of the “expanded access” program.

Second, the FDA should make a concerted effort to educate physicians about their role in the “expanded access” process and encourage them to have their qualifying patients participate.¹²⁵ Patients generally rely on their physicians to inform them of all potential treatment options, but most physicians have little knowledge of specific exceptions to FDA regulations, evidenced by the relatively low numbers of participants each year in the “expanded access” program.¹²⁶ Educating physicians on the requirements to apply to participate in the program and the responsibilities involved in monitoring enrolled patients is mutually beneficial because the patients would receive more sound advice about this option earlier in the treatment process, and physicians would be better equipped to provide support in the enrollment process and in the disposition of an experimental drug. Moreover, instruction on the “expanded access” program could easily be incorporated into medical school curricula and continuing medical education programs for practicing physicians. With these two improvements, the FDA would be better able to address the needs of the terminally ill while avoiding the complications associated with “right to try” legislation.

CONCLUSION

The recently popular “right to try” laws reflect states’ modern interpretation of Patrick Henry’s most famous words. Proponents of these laws believe that, for terminally ill patients, having the freedom

123. See Bean, *supra* note 42, at 884.

124. *Id.*

125. See Darrow, *supra* note 102.

126. See NAT’L CANCER INST., *supra* note 76.

to take experimental medications without government interference is their only chance for survival. Nevertheless, as this Note demonstrates, these laws not only fail to provide the expanded access for terminally ill patients to experimental drugs that proponents desire, but also suffer from several medical and legal defects that complicate their practical application.

In recognizing that current drug approval procedures, including accelerated approval programs, do not adequately serve the expediency needs of terminally ill patients, this Note suggests two improvements to the current “expanded access” program. The FDA should provide patients with the relevant information on current experimental drugs, and it should educate physicians on the specific requirements of the “expanded access” program, so more terminally ill patients will benefit from experimental drugs while preserving the federal government’s role in regulating the drug industry. In this way, the FDA could incorporate the efficiency of “right to try” laws while avoiding the aforementioned defects of this legislation.