STATE "RIGHT TO TRY" ACTS: A GOOD START, BUT A FEDERAL ACT IS NECESSARY

Ellen A. Black*

INTRODUCTION

Dr. Kent Brantley and Nancy Writebol, two American medical missionaries, traveled to Liberia on behalf of charitable organizations to help Liberians who were suffering from a massive outbreak of the Ebola virus.[1] In spite of their careful efforts to not catch the virus, both Brantley and Writebol became infected with Ebola, a virus with a fatality rate of up to ninety percent.[2] These Americans undoubtedly feared for their lives, especially considering all the Liberians' deaths they had witnessed due to this dreadful disease.[3] However, prior to transportation from Liberia to Emory University Hospital in Atlanta, Georgia, the American missionaries received a dose of ZMapp, a drug composed of antibodies from Ebola-infected mice, in an effort to treat the missionaries.[4] Three weeks after

* Ellen A. Black is an Assistant Professor of Law at Belmont University College of Law. She wishes to thank her research assistants, Jamie Sawyer and Zachary Barker, for their valuable assistance with this article.

1. *See* Brady Dennis & Lenny Bernstein, *Two Americans Who Contracted Ebola in Africa Received an Experimental Serum*, WASH. POST (Aug. 4, 2014), http://www.washingtonpost.com/national/health-science/2014/08/04/dbc44a48-1c07-11e4-ae54-0cfe1f974f8a_story.html.

2. *See Ebola Virus Disease Fact Sheet*, WORLD HEALTH ORG. (Jan. 2016), http://www.who.int/mediacentre/factsheets/fs103/en/.

3. *See* Dr. Sanjay Gupta & Danielle Dellorto, *Experimental Drug Likely Saved Ebola Patients*, CNN (Aug. 5, 2014, 8:22 PM), http://www.cnn.com/2014/08/04/health/experimental-ebola-serum/ (describing how "Dr. Kent Brantly thought he was going to die. It was the ninth day since the American missionary worker came down sick with Ebola in Liberia. His condition worsening by the minute, Brantly called his wife to say goodbye.").

4. *See id.*

being admitted to Emory, both missionaries were released and sent home, both totally cured of the Ebola virus.[5] The precise role that ZMapp played in curing the missionaries is unknown, but some medical experts agree that it played a pivotal role in the missionaries' quick recovery.[6]

The drug ZMapp, which was administered to both missionaries, had not been approved by the Federal Food and Drug Administration ("FDA") when it was administered.[7] Indeed, it had not been tested on humans prior to being given to Brantley and Writebol; rather, only monkeys had participated as test subjects.[8] But in an effort to save the lives of these Americans who had risked their own to help Liberians in desperate need, ZMapp, an untested and unapproved drug, was given with the hope that it would work and save the lives of these two courageous missionaries.[9]

The account of Brantley and Writebol and their unique experience with ZMapp epitomizes the debate surrounding access for terminally ill patients to unapproved drugs. In the above scenario, the American missionaries were given a chance that terminally ill patients are not given, but arguably should be given – access to an unapproved drug outside the FDA's expanded access protocols that has the chance, even if very small, to improve the patients' condition. For most terminally ill patients, they must agonizingly wait for a drug to become available on the general market before they are allowed access. But before a drug manufacturer may bring a new drug to the marketplace, the manufacturer must receive approval from the FDA.[10] But to gain approval, the drug manufacturer must conduct expansive testing that may take several years, not to mention the millions of dollars these companies must invest with the hope that the drug is ultimately approved by the FDA.[11] The FDA has an emergency access

5. *See* Liz Szabo, *Kent Brantley, U.S. Missionary Doctor, Discharged After Recovering From Ebola*, HUFFINGTON POST (Aug. 24, 2014, 8:14 PM), http://www.huffingtonpost.com /2014/08/24/kent-brantly-recovered_n_5697991.html.

6. *See* Gupta & Dellorto, *supra* note 3 (describing how within an hour of receiving the medication, Brantley's condition dramatically improved, causing one of his doctors to describe the events as "miraculous").

7. *See* Lindsay M. Boyd, *Ebola, The "Right to Try," and Why We Should Care*, FORBES (Aug. 12, 2014, 10:53 AM), http://www.forbes.com/sites/realspin/2014/08/12/ebola-the-right-to-try-and-why-we-should-care/ (advocating the same access to unapproved drugs for terminally ill patients as the American missionaries received).

8. *See* Gupta & Dellorto, *supra* note 3 (reporting that according to company documents, four monkeys infected with Ebola survived after being given the therapy within 24 hours after infection; two of four other monkeys that started therapy within 48 hours after infection also survived; one monkey that was not treated died within five days of exposure to the virus).

9. *See id.*

10. *See infra* Part I.

11. *See infra* note 25 and accompanying text.

program, referred to as "compassionate use," that allows a patient to petition the FDA for quicker access to an unapproved drug, but the program has received increased criticism from its inception because it is too complicated and often takes far too much time for approval.[12]

In an effort to help terminally ill patients bypass the FDA's arduous, time-consuming approval process and have quicker access to potentially life-saving drugs, states across the country have passed "right to try" acts.[13] These state acts allow a terminally ill patient the right to access an investigational drug that has completed initial safety testing, known as Phase I, but that has not been approved by the FDA.[14] The reasoning behind these acts is that terminally ill patients, like missionaries Brantley and Writebol, with the guidance and counsel of their physicians, should have the choice whether to pursue an unapproved drug, rather than placing their fate and survival in the hands of the FDA, a complex governmental bureaucracy operating on its own timeframe.[15] This reasoning appears to align with the mindset of most Americans; however, the right to try acts have also been subject to intense criticism regarding whether the acts will be effective in granting terminally ill patients greater access to investigational drugs.[16]

This article analyzes whether the right to try acts will be effective in achieving their purpose of greater access for terminally ill patients. To provide context for the right to try acts, Part I of this article outlines the current FDA drug approval process and discusses the FDA's compassionate use program along with its inherent problems. Part II of the article reviews the right to try acts found in many states, with an analysis of the specific provisions of those acts. Part III of the article considers the criticisms voiced by legal and medical scholars, and analyzes whether those criticisms have validity, concluding that a federal right to try statute would likely be more effective. Part IV contemplates the enactment of a federal right to try statute and reviews federal right to try legislation that has previously been introduced to Congress.

I. FDA DRUG APPROVAL PROCESS

Before a drug enters the marketplace, drug makers, in addition to conducting their own preliminary research and development, must take

12. *See infra* Part I.A.
13. *See infra* Part II.
14. *See infra* note 94 and accompanying text.
15. *See infra* note 99 and accompanying text.
16. *See infra* Part III.

several steps to gain FDA premarket approval. In brief, the first step involves the drug manufacturer filing an Investigational New Drug Application ("IND"), where the manufacturer presents evidence of animal testing and proposals for how to test the drug on humans.[17] If the FDA decides the drug is safe to test on humans through clinical trials, a local Institutional Review Board ("IRB"), comprised of both scientists and non-scientists in hospitals or research institutions,[18] reviews the proposed clinical trial on humans. The IRB then reviews and monitors all aspects of the clinical trial protocols, from dosages to the length of the clinical trial.[19] The IRB also ensures that participants give informed consent.[20] The next three steps involve different phases of testing of the proposed drug. In Phase I Testing, the drug is given to healthy patients or volunteers, ranging from twenty to eighty participants, to study the safety of the drug and its side effects.[21] If the Phase I Testing illustrates that the drug is safe, the drug manufacturer may proceed to Phase II Testing. Phase II Testing, in contrast to Phase I Testing, involves a test group usually ranging from 30 to 300 participants and focuses primarily on the effectiveness of the drug, where the drug is given to participants with a particular condition and their responses are measured against a control group.[22] If the drug's effectiveness is shown in Phase II, then Phase III Testing may begin, where the test group is much larger, usually ranging from 300 to 3,000 participants.[23] This final phase of testing is "intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling."[24] After the different phases of testing are completed, the drug maker submits to the FDA a New Drug Application, which includes all data from the testing phases, and formally requests approval.[25]

17. *See* 21 C.F.R. §§ 312.20-.22 (2015).

18. *See* 21 C.F.R. § 56.107(c).

19. *See* 21 C.F.R. § 56.103; *see also* IRB Review of Research, 21 C.F.R. § 56.109(a) (2015) ("An IRB shall review and have authority to approve, require modifications in [to secure approval], or disapprove all research activities covered by these regulations.").

20. *See* 21 C.F.R. § 56.109(b).

21. *See* 21 C.F.R. § 312.21(a).

22. *See* 21 C.F.R. § 312.21(b).

23. *See* 21 C.F.R. § 312.21(c).

24. *Id.* However, the FDA may halt clinical trials at any point if it deems necessary based upon pretesting clinical data or if proposed testing protocols provide inadequate safety measures to proceed. *See* 21 C.F.R. § 312.42.

25. *See* 21 C.F.R. § 314.50.

The amount of time it takes a drug manufacturer to follow the above process to get a drug on the marketplace is extraordinarily long, ranging anywhere from 10 to 15 years, and the amount of money the drug manufacturer spends can easily exceed $1 billion.[26] Thus, drug manufacturers invest inordinate time and money in developing drugs that will ultimately safely and effectively treat patients. Yet in many instances, terminally ill patients, who may be unable to participate in clinical trials, need access to particular drugs that have not yet received approval from the FDA, in spite of the drugs demonstrating the possibility of curing the terminally ill patients' condition, prolonging their life, or improving their quality of life during their remaining days. For these patients, the FDA has an exception to the typical drug approval process that allows expanded access to investigational drugs.

A. Compassionate Use

To give terminally ill patients the possibility of accessing investigational drugs, the FDA has a "compassionate use" program, formerly known as "expanded access program," that allows drug companies who agree to participate an exemption from complying with the FDA's typical drug approval regulations for clinical trials.[27] However, to be eligible for the compassionate use program the following conditions must be met: (1) patient must "have a serious or immediately life-threatening disease or condition" for which "there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition"; (2) the benefit of the investigational drug must outweigh the risks of the treatment, and "the risks are not unreasonable in the context of the disease or condition to be treated"; and (3) use of the investigational drug must "not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access

26. *See* PHARMACEUTICAL RES. & MANUFACTURERS AM., 2013 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE (July 2013), http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf (estimating it takes between 10 and 15 years to bring a drug to market); *see also* Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5B*, SCI. AM. (Nov. 24, 2014), http://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/ (discussing "[a] new report published by the Tufts Center for the Study of Drug Development pegs the cost of developing a prescription drug that gains market approval at $2.6 billion" based upon an average out-of-pocket cost of $1.4 billion and an estimate of $1.2 billion in returns the investors forego on that money during the 10-plus years a drug candidate spends in development).

27. 21 C.F.R. § 312.300.

use or otherwise compromise the potential development of the expanded access use."[28]

If a patient meets the above three criteria, then the drug company must decide the appropriate category of access for the patient.[29] Then an "expanded access submission" must be submitted that either includes a new IND or a protocol amendment to an existing IND.[30] The submission must also include a specific cover sheet – referred to as Form FDA 1571 – along with seven other pieces of information about the drug and its intended use.[31] There are three different categories of compassionate use for which a patient may be eligible: single patient; intermediate size; or treatment.[32]

1. Single Patient Access

For the single patient access category, patients may be eligible to receive an investigational drug for treatment by a physician under "regular" access or "emergency" access.[33] For regular or emergency access, the patient's physician must conclude that the risk of taking the investigational drug is not greater than the risk from the patient's disease or condition.[34] In addition, the FDA must conclude that the patient cannot access "the drug under another IND or protocol."[35] If these requirements are met, either a

28. 21 C.F.R. § 312.305(a).

29. *See infra* Part I.A.1-3.

30. *See* 21 C.F.R. § 312.305(b).

31. *See id.* Specifically, along with the cover sheet, the submission must include:

(1) The rationale for the intended use of the drug, including a list of available therapeutic options that would ordinarily be tried before resorting to the investigational drug or an explanation of why the use of the investigational drug is preferable to the use of available therapeutic options; (2) The criteria for patient selection or, for an individual patient, a description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition; (3) The method of administration of the drug, dose, and duration of therapy; (4) A description of the facility where the drug will be manufactured; (5) Chemistry, manufacturing, and controls information adequate to ensure the proper identification, quality, purity, and strength of the investigational drug; (6) Pharmacology and toxicology information adequate to conclude that the drug is reasonably safe at the dose and duration proposed for expanded access use (ordinarily, information that would be adequate to permit clinical testing of the drug in a population of the size expected to be treated); and (7) A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks. 21 C.F.R. § 312.305(b)(ii)-(viii).

32. For individual patient access, see 21 C.F.R. § 312.310; for intermediate-size access, see 21 C.F.R. § 312.315; for treatment access, see 21 C.F.R. §312.320.

33. *See* 21 C.F.R. § 312.305.

34. *See* 21 C.F.R. § 312.310(a).

35. *Id.*

physician or sponsor[36] may submit the expanded access submission as previously discussed.[37]

Should a patient qualify for single patient access, the expanded access program contains specific safeguards in an effort to protect the patient from unknown dangers.[38] Specifically, the patient may only receive a single course of treatment of the investigational drug for an explicit duration unless the FDA approves otherwise.[39] If a patient uses an investigational drug for an extended duration, the FDA may require the sponsor to monitor the patient.[40] In addition, at the end of the treatment, the sponsor or physician must provide the FDA with the results of the treatment, including whether there were any adverse reactions to the investigational drug.[41]

In some instances, a patient's condition may be considered emergent and require immediate access to an investigational drug, in which case the compassionate use program allows these patients to obtain access without having to submit the written submission to the FDA.[42] Instead, the emergency access may be requested by electronic means, including telephone or facsimile, and the FDA may authorize the emergency access via telephone.[43] The physician or sponsor must describe how the expanded access meets the requirements of the compassionate use program and must then within fifteen working days of the FDA's authorization of emergency access submit a written submission as required by the program.[44]

2. Intermediate-Size Populations

The intermediate-size population category allows access to an investigational drug for patient groups that are "smaller than that typical of a treatment IND or treatment protocol."[45] If a "significant number" of patients requests individual expanded access, the FDA may require the sponsor to consolidate the individual access requests to become an

36. A sponsor "takes responsibility for and initiates a clinical investigation . . . [and] may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization." 21 C.F.R. § 312.3.

37. *See* 21 C.F.R. § 312.310(b).

38. *See* 21 C.F.R. § 312.310(c).

39. *See id.*

40. *See id.*

41. *See id.*

42. *See* 21 C.F.R. § 312.310(d).

43. *See id.*

44. *See id.*

45. 21 C.F.R. § 312.315.

intermediate-size population.[46] The compassionate use program statute outlines three scenarios for which this type of access might be needed.[47] First, the drug may no longer be in the process of development because the disease or condition for which it was created is so rare and there were not enough patients to recruit for a clinical trial.[48] In other cases, the drug may be in the development stage, but the patients desiring access are not able to participate in the clinical trial for various reasons.[49] Lastly, the drug may have already been approved, but is no longer being marketed due to safety reasons or it no longer "meet[s] the conditions of the approved application."[50]

In addition to satisfying the criteria generally applicable to the compassionate use program,[51] the FDA must also conclude that "[t]here is enough evidence that the drug is safe at the dose and duration proposed for expanded access use to justify a clinical trial of the drug in the approximate number of patients expected to receive the drug" under the program and that "[t]here is at least preliminary clinical evidence of effectiveness of the drug, or of a plausible pharmacologic effect of the drug to make expanded access use a reasonable therapeutic option in the anticipated population."[52] Similar to the individual access category, the program provides various safeguards to patients in this category to ensure they are protected. For example, the FDA reviews the IND annual report to determine whether expanded access should continue under this category.[53] Also, the drug's sponsor must monitor the expanded access protocol to ensure that physicians are appropriately complying with the protocol and applicable regulations.[54]

3. Treatment IND or Protocol Access

The final category of expanded access allows an investigational drug to be given "for widespread treatment use."[55] Three criteria must be met for

46. *Id.*

47. *See id.*

48. *See* 21 C.F.R. § 312.315(a).

49. *See id.* The statute provides examples for why a patient might not be able to participate in the clinical trial, such as "they have a different disease or stage of disease than the one being studied or otherwise do not meet the enrollment criteria, because enrollment in the trial is closed, or because the trial site is not geographically accessible." *Id.*

50. 21 C.F.R. § 312.315(a)(3).

51. *See supra* note 28.

52. 21 C.F.R. § 312.315(b).

53. *See* 21 C.F.R. § 312.315(d).

54. *See id.*

55. 21 C.F.R. § 312.320.

access pursuant to this category: trial status, marketing status, and evidence. For trial status, it must be shown that either "[t]he drug is being investigated in a controlled clinical trial under an IND designed to support a marketing application for the expanded access use" or "[a]ll clinical trials of the drug have been completed."[56] Regarding marketing, the sponsor must be "actively pursuing marketing approval" of the investigational drug for expanded access and with "due diligence."[57] For the evidentiary criteria, the level of clinical evidence depends upon the seriousness of the patient's condition. If "the expanded access use is for a serious disease or condition," there must be "sufficient clinical evidence of safety and effectiveness."[58] If the condition is "for an immediately life-threatening disease or condition," the evidence must show "that the investigational drug may be effective" and "would not expose patients to an unreasonable and significant risk of illness or injury."[59]

B. Compassionate Use – Not So Compassionate

The FDA's compassionate use program seeks to abate the onerous FDA drug approval process by allowing those patients who are eligible and fit into one of the three expanded access categories to receive earlier and quicker access to a non-approved drug that could greatly assist the patient.[60] The number of patients participating in the compassionate use program appears to be increasing, and the FDA estimates it approves more than 99 percent of all requests.[61] At first glance, it appears that the FDA's compassionate use program may solve terminally ill patients' need for immediate access. However, these figures may be somewhat misleading because in some cases, a patient contacts the drug manufacturer directly for expanded access, but the drug manufacturer directly denies the patient access to the drug.[62] These figures do not include those denials, which are

56. 21 C.F.R. § 312.320(a).

57. 21 C.F.R. § 312.320(a)(2).

58. 21 C.F.R. § 312.320(a)(3)(i). This type of evidence could consist of "data from phase 3 trials" or "compelling data from completed phase 2 trials." *Id.*

59. 21 C.F.R. § 312.320(a)(3)(ii). This type of evidence "would ordinarily consist of clinical data from phase 3 or phase 2 trials, but could be based on more preliminary clinical evidence." *Id.*

60. *See* Alexander Gaffney, *Regulatory Explainer: FDA's Expanded Access (Compassionate Use) Program*, REG. AFF. PROF. SOC'Y (Feb. 4, 2014), http://www.raps.org/Regulatory-Focus/News/2015/02/04/18343/Regulatory-Explainer-FDAs-Expanded-Access-Compassionate-Use-Program/.

61. *Id.*; Ed Silverman, *The FDA Says It's More Compassionate Than You Think*, WALL ST. J. (May 5, 2014), http://blogs.wsj.com/corporate-intelligence/2014/05/05/the-fda-says-its-more-compassionate-than-you-think.

62. *See infra* note 193 and accompanying text.

not tracked or reported to the FDA. Additionally, "in April 2014, only 86 of the 32,304 studies listed at ClinicalTrials.gov as enrolling new participants were available for expanded access."[63] Many terminally ill patients desire access to investigational drugs, but with so few clinical trials open for expanded access, they are left with very few, if any, options under the FDA's compassionate use program. The FDA's compassionate use program has been subject to increasing criticism through the years.

A common criticism of the FDA's compassionate use program mirrors the criticism of its drug approval process – too complicated and time consuming.[64] As mentioned previously, when a physician requests expanded access for an individual patient, the physician must submit an application, which must include painstaking volumes of information, including Form FDA 1571.[65] Form FDA 1571, the IND application that drug manufacturers – not physicians – typically complete, is overly burdensome for a physician. In fact, the form itself inadvertently acknowledges this burden by stating: "The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information."[66] Physicians are notoriously busy professionals with very little spare time, and they especially do not have 100 hours to complete one form for one patient for permission for expanded access.[67]

In an effort to ease the burden for physicians when applying for expanded access for a terminally ill patient, the FDA recently announced a new proposal to eliminate the use of Form FDA 1571, which required 26 separate types of information and 7 attachments, and replace it with Form

63. Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 NEW ENG. J. MED. 279, 280 (2015).

64. *Id.* at 280-81 (discussing the FDA's estimate "that 120 hours of human effort are required for a company to prepare a protocol for an intermediate-size patient population, with the task divided among a director of clinical research [60 hours], a regulatory affairs director [24 hours], and a clinical research associate [36 hours]").

65. *Physician Request for an Individual Patient IND Under Expanded Access for Non-emergency or Emergency Use*, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm (last updated May 26, 2015).

66. *Investigational New Drug Application*, FDA, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdf (last visited Aug. 2, 2015).

67. *See* Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment*, GOLDWATER INST., no. 266, Feb. 11, 2014, at 9-10 (quoting physician Dr. Judy Stone who stated, "Except perhaps for academic settings with an extensive infrastructure, INDs are incredibly burdensome, time-consuming and expensive for an independent practitioner to obtain").

3926, which requires only 8 types of information and 1 attachment.[68] According to the FDA, a physician can complete the new form in 45 minutes, compared to the 100 hours listed on the old form.[69] The FDA's revised application process for compassionate use appears to be a much-needed change for making the process less onerous for physicians and for getting patients quicker access. Even if the implementation of this procedure may somewhat improve the FDA's compassionate use program, it is very doubtful this sole change will completely resolve the problem of limited investigational drug access for terminally ill patients.

Another problematic aspect of the FDA's compassionate use program is the limited number of drug manufacturers who choose to participate in the program.[70] The FDA does not mandate that drug manufacturers provide expanded access to their investigational drugs, which from a free market standpoint correctly balances the need for voluntary innovation and quality research and development, but the result is significantly reduced participation.[71] And with so few drug manufacturers participating, the chance for terminally ill patients to access potentially lifesaving drugs is greatly diminished. So the issue becomes determining what inhibits drug manufacturer participation and whether it can be resolved.

There are several reasons why more drug manufacturers do not participate in the FDA's compassionate use program. First, if a terminally ill patient is granted access to an investigational drug through the program and that patient experiences an adverse condition, it must be reported to the FDA.[72] The FDA can then consider that adverse condition when deciding whether to approve the drug for entry into the market.[73] Thus, drug

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68. *See Individual Patient Expanded Access Applications: Form FDA 3926, Draft Guidance for Industry*, FDA (Feb. 2015), http://www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/UCM432717.pdf.

69. *Id.* App. at 8-9 (attaching new Form 3926 which states that the burden time for completing the form is 45 minutes).

70. Darrow, *supra* note 63, at 280-81.

71. *See generally id.* (discussing reluctance of manufacturers to participate in the FDA's compassionate use program due to practical difficulties).

72. 21 C.F.R. § 312.310(c)(2); *see also* Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. 40,900, 40,919 (Aug. 13, 2009) (explaining that "the physician, in his or her capacity as a sponsor, is required to report adverse events to FDA and other investigators"); Darrow, *supra* note 63, at 281 ("All adverse events that occur in any patient receiving a drug during its pre-approval period must be reported to the FDA, and patients receiving treatment under expanded access protocols are often sicker than trial participants. Companies may worry that this obligation could reduce the chance of approval, lead to additional label warnings, or create negative publicity.").

73. *But see* 74 Fed. Reg. 40,900, 40,905 (FDA stating "although adverse events first identified during expanded access use of certain drugs have been included in the drugs' approved

manufacturers are hesitant to participate in a voluntary program, when it might ultimately hinder the drug's ultimate approval – the theory being that it is better for the individual terminally ill patient to sacrifice for the greater population.[74]

Another reason for drug manufacturers' limited participation involves the time and resources that must be expended coupled with diminished financial rewards. First, as mentioned previously, to participate in the program, the drug sponsor (or the physician) must submit extensive paperwork.[75] A drug manufacturer may have very few employees, most of whom are solely dedicated to getting the drug to the marketplace, and may not have the manpower to complete the necessary application for expanded access. In addition, a drug manufacturer may not have a sufficient supply of the investigational drug to cover the hundreds or thousands of requests it may receive for early access.[76] Not to mention the significant costs that would be involved in supplying the investigational drug, when some patients would be unable to pay and insurance companies would likely not cover.[77] All of these factors heavily weigh on a manufacturer's decision to participate in the FDA's compassionate use program. But when external pressure, often times in the form of social media, enters the picture and a drug manufacturer receives immense pressure to supply the drug, the drug manufacturer may acquiesce and provide the drug even if it threatens the future success of the investigational drug.[78]

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product labeling, we are unaware of any cases in which adverse event information obtained from expanded access use has resulted in denial of approval for a product.").

74. *See* Seema Shah & Patricia Zettler, *From a Constitutional Right to a Policy of Exceptions: Abigail Alliance and the Future of Access to Experimental Therapy*, 10 YALE J. HEALTH POL'Y L. & ETHICS 135, 184 (2010).

75. *See supra* note 66 and accompanying text.

76. *See* Rebecca Dresser, *The "Right to Try" Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. L. REV. 1631, 1646-47 (2015) (mentioning the high costs of "producing investigational drugs for patients outside trials"); Katie Thomas, *Company Creates Bioethics Panel on Trial Drugs*, N.Y. TIMES, May 7, 2015, at A1 ("Manufacturers often have a limited supply of such treatments, leading to anguished decisions over who should be given the products.").

77. *See* Dresser, *supra* note 76, at 1646-47 (emphasizing that although "the FDA permits [drug companies] to recover their costs, companies may be unable to manage the logistics involved in operating a treatment-access program."); Thomas, *supra* note 76 (discussing how drug companies typically waive payment for investigational drugs in expanded access programs because the law only permits them to charge the manufacturing and direct costs of the drug and how insurance companies do not typically pay for costs of investigational drugs).

78. *See* Thomas, *supra* note 76 (discussing how patient Josh Hardy, discussed in Part III below, shamed the drug company through social media to provide access to its drug, which ultimately tremendously helped Josh's condition).

From the objective standpoint of the drug manufacturer, participation in the FDA's compassionate use program involves a huge risk without an obvious benefit. Commentators have suggested numerous ways to improve the FDA's program. For example, one suggestion is to make it easier for patients to participate in clinical trials by making the trials larger and more accessible to those located outside the testing region.[79] Another suggestion is to create a national institutional review board, which would not only make participation easier but also make it less costly.[80] These suggestions are intended to make access to investigational drugs quicker and more efficient. However, the broader suggestion has been to revamp the FDA's drug approval process to get drugs to the marketplace quicker, which would assist in obviating the need for the compassionate use program.[81] Yet the likelihood of these changes to the compassionate use program or to the drug approval process in the near future is dubious, so in the meantime, states across the county have enacted "right to try" acts in an effort to overcome the hurdle of inefficient access to investigational drugs for the terminally ill.

II. RIGHT TO TRY MOVEMENT

When discussing the right to try acts, the story of Abigail Burroughs, a young woman diagnosed with cancer at the age of nineteen, provides the necessary backdrop for the right to try movement. Abigail's oncologist believed that a cancer-fighting drug that had not yet been approved by the FDA might save Abigail.[82] Although her family and her doctors fought hard for access to this drug, she was not able to timely access it before her death, which occurred just two years after her diagnosis.[83] The FDA ultimately approved the investigational drug that Abigail sought to treat her cancer.[84]

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79. *See* Shah & Zettler, *supra* note 74, at 189.

80. Darrow, *supra* note 63, at 284 ("For example, since the FDA has acknowledged that gaining approval from an institutional review board can pose a barrier, states could partner with the FDA to fund multicenter institutional review boards that focus specifically on expanded-access requests. Such multicenter panels would conduct full reviews, but their subject-matter expertise and limited dockets would translate into faster review times. Through subsidies, states and the FDA could eliminate the need for patients or clinicians to incur fees for proposal review, which would facilitate expanded-access requests outside of academic medical centers.").

81. *See id.*

82. *See Our Story*, ABIGAIL ALLIANCE, http://www.abigail-alliance.org/story.php (last visited July 23, 2015); Juan Joel Tovanche, *Dying to Wait: How the* Abigail *Court Got It Wrong*, 22 J.L. & HEALTH 53, 53-55 (2009) (describing the background of Abigail Alliance).

83. Tovanche, *supra* note 82, at 53-54.

84. *Id.* at 55.

Abigail's father formed the Abigail Alliance for Better Access to Developmental Drugs ("Abigail Alliance") with the mission of "helping create wider access to developmental cancer drugs and other drugs for serious life-threatening illnesses."[85] One of the first actions of Abigail Alliance was to file suit against the FDA, seeking to enjoin enforcement of the ban on Phase I experimental drugs that had been deemed safe for human testing.[86] The Abigail Alliance alleged that the FDA regulations restricted a terminally ill patients' fundamental right pursuant to the Due Process Clause of the Fifth Amendment to access unapproved drugs.[87] The district court dismissed the case, finding that there was no constitutional right to access unapproved drugs, so the Abigail Alliance appealed to the D.C. Circuit.[88] A three-judge panel of the D.C. Circuit Court of Appeals disagreed with the district court and reversed, instead finding that terminally ill patients did have a constitutional right to access unapproved drugs.[89] However, on an en banc rehearing, the D.C. Circuit Court of Appeals vacated the panel's decision, finding that no constitutional right existed.[90] The U.S. Supreme Court denied the Abigail Alliance's petition for certiorari.[91] Therefore, the most recent legal authority on this issue holds that terminally ill patients do not have a constitutional right to access unapproved drugs; thus, governmental intrusion must only have a rational basis to withstand constitutional challenges.[92]

Although the D.C. Circuit Court of Appeals did not find a constitutional right for the terminally ill, the Abigail Alliance case raised public awareness of the necessity for improved access to investigational drugs for the terminally ill.[93] This increased awareness created the pathway for "right to try" statutes. Right to try statutes seek to provide greater access to prescription drugs for terminally ill patients by allowing these patients the right to try drugs that have not yet received FDA approval

85. ABIGAIL ALLIANCE, *supra* note 82.

86. *See* Abigail Alliance for Better Access to Dev. Drugs v. McClellan, No.03-1601, 2004 WL 3777340, at *2 (D.D.C. Aug. 30, 2004).

87. *See McClellan*, 2004 WL 3777340, at *2.

88. *See McClellan*, 2004 WL 3777340, at *12; Abigail Alliance for Better Access to Dev. Drugs v. Von Eschenbach, 445 F.3d 470, 474 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

89. *Von Eschenbach*, 445 F.3d at 472.

90. *Von Eschenbach*, 495 F.3d at 701.

91. *Id.* at 695.

92. *Id.* at 710.

93. *See Highlights of Abigail Alliance Accomplishments*, ABIGAIL ALLIANCE, http://abigail-alliance.org/docs/Accomplishments-09.pdf (last visited Aug. 2, 2015).

through the lengthy process previously discussed.[94] So far, twenty-one states have enacted right to try statutes, with most of them receiving unanimous bipartisan congressional support.[95] These statutes are unsurprisingly popular because they attempt to help those individuals who are at the end stages of their life and desperately need help.[96] And most people either personally know someone who has been at the end stage of life and needed an investigational drug or have heard about such an individual through the media or friends.[97]

The perceived success of the right to try movement can be traced in part to the Goldwater Institute ("GI"), a libertarian think tank that created the framework for the right to try statutory language enacted in most of those states with right to try statutes.[98] According to GI, their "initiative would allow terminal patients access to investigational drugs that have completed basic safety testing, thereby dramatically reducing paperwork, wait times and bureaucracy, and most importantly, potentially saving lives."[99] Most states that have enacted right to try statutes followed the GI's proposed "Right to Try Act" framework; thus, the right to try statutes across the country are very similar and all seek to achieve the same purpose – providing terminally ill patients with much greater access to potentially life-saving drugs.[100]

The right to try statutes not only provide that access to investigational drugs should be allowed, but also access to biological products[101] and devices.[102] The statutes define "investigational drug, biological product, or

94. Corieri, *supra* note 67, at 20.

95. *See* 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/.

96. *See* Dresser, *supra* note 76, at 1648 (describing how right to try advocates use compelling patient stories to support their argument).

97. *See id.*

98. Corieri, *supra* note 67, at 1.

99. *Id.*

100. *See* Elizabeth Richardson, *Health Policy Brief; Right-to-Try Law*, HEALTH AFF. (Apr. 9, 2015), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=136.

101. Biological products are "medical products" such as vaccines, blood, and gene therapies. *See What is a Biological Product?*, FDA, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm (last visited Aug. 2, 2015).

102. *See* ALA. CODE § 22-5D-3 (West, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1312(A) (West, Westlaw through 2015 Reg. Sess.); ARK. CODE ANN. § 20-15-2004 (West, Westlaw through 2015 Reg. Sess.); COLO. REV. STAT. ANN. § 25-45-104(1) (West, Westlaw through 2015 Reg. Sess.); FLA. STAT. ANN. § 499.0295(3)(a) (West, Westlaw through 2015 Leg. Sess.); IND. CODE ANN. § 16-42-26-2 (West, Westlaw through 2015 Reg. Sess.); LA. STAT. ANN. § 1300.424 (West, Westlaw through 2014 Reg. Sess.); MICH. COMP. LAWS ANN. § 333.26452(1) (West, Westlaw through 2015 Reg. Sess.); MINN. STAT. ANN. § 151.375(4)(a)

device" as "[a] drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the U.S. Food and Drug Administration and remains under investigation in a U.S. Food and Drug Administration approved clinical trial."[103] But to qualify for use of an investigational drug,[104] a physician must document that a patient meets four specific criteria for eligibility.[105] First, the patient must have a terminal disease, which is defined as "an advanced stage of a disease with an unfavorable prognosis and no known cure."[106] Also, the patient, "in consultation with a physician," must have

(West, Westlaw through 2015 Reg. Sess.); S.B. 2485, 2015 Leg., Reg. Sess. (Miss. 2015); H.B. 1685, 97th Gen. Assemb., 2d Reg. Sess. (Mo. 2015); MONT. CODE ANN. § 50-12-103 (West, Westlaw through 2015 Reg. Sess.); Assemb. B. 164, 2015 Leg., 78th Sess. (Nev. 2015); S.B. 2259, 64th Leg. Assemb., Reg. Sess. (N.D. 2015); H.B. 1074, 2015 Leg., Reg. Sess. (Okla. 2015); S.D. CODIFIED LAWS § 34-51-4 (West, Westlaw through 2015 Reg. Sess.); TENN. CODE ANN. § 63-6-303 (West, Westlaw through 2015. Reg. Sess.); TEX. CODE ANN. § 489.053 (West, Westlaw through 2015 Reg. Sess.); UTAH CODE ANN. § 58-85-103 (West, Westlaw through 2015 Leg. Sess.); VA. CODE ANN. § 54.1-3442.3 (West, Westlaw through 2015 Reg. Sess.); WYO. STAT. ANN. § 35-7-1803 (West, Westlaw through 2015 Leg. Sess.).

103. *See* ALA. CODE § 22-5D-2 (West, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1311(e)(2) (West, Westlaw through 2015 Reg. Sess.); ARK CODE ANN. § 20-15-2003 (West, Westlaw through 2015 Reg. Sess.); COLO. REV. STAT. ANN. § 25-45-103 (West, Westlaw through 2015 Leg. Sess.); FLA. STAT. ANN. § 499.0295(2)(b) (Westlaw); IND. CODE ANN. § 16-42-26-2 (Westlaw); LA. STAT. ANN. § 1300.423 (West, Westlaw through 2014 Reg. Sess.); MICH. COMP. LAWS ANN. § 333.26451 (West, Westlaw through 2015 Reg. Sess.); MINN. STAT. ANN. § 151.375 (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-102 (West, Westlaw through 2015 Reg. Sess.); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-2 (West, Westlaw through 2015 Reg. Sess.); TENN. CODE ANN. § 63-6-302 (West, Westlaw through 2015. Reg. Sess.); UTAH CODE ANN. § 58-85-102 (West, Westlaw through 2015 Leg. Sess.); VA. CODE ANN. § 54.1-3442.1 (West, Westlaw through 2015 Reg. Sess.); WYO. STAT. ANN. § 35-7-1802(a)(ii) (West, Westlaw through 2015 Leg. Sess.). Mississippi and Missouri add an additional sentence: "The term shall not include Schedule I substances." Miss. S.B. 2485, Mo. H.B. 1685.

104. Although the right to try statutes also includes access to biological products and devices as well as investigational drugs, for purposes of this article, investigational drugs will be the focus.

105. *See* ALA. CODE § 22-5D-2 (Westlaw 1975); ARIZ. REV. STAT. ANN. § 36-1311 (Westlaw); ARK. CODE ANN. § 20-15-2004 (Westlaw); COLO. REV. STAT. ANN. § 25-45-103 (Westlaw); FLA. STAT. ANN. § 499.0295 (Westlaw); IND. CODE. ANN. § 25-22.5-1-2.1 (West, Westlaw through 2015 Reg. Sess.); LA. STAT. ANN. § 1300.423 (Westlaw); MICH. COMP. LAWS ANN. § 333.26451 (Westlaw); MINN. STAT. ANN. § 151.375 (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-104 (West, Westlaw through 2015 Reg. Sess.); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-2 (Westlaw); TENN. CODE ANN. § 63-6-302 (Westlaw); TEX. CODE ANN. § 489.051 (West, Westlaw through 2015 Reg. Sess.); UTAH CODE ANN. § 58-85-103 (Westlaw); VA. CODE ANN. § 54.1-3442.2 (West, Westlaw through 2015 Reg. Sess.); WYO. STAT. ANN. § 35-7-1802 (Westlaw).

106. *See* ALA. CODE § 22-5D-2 (Westlaw, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1311(1)(a) (Westlaw); ARK CODE ANN. § 20-15-2003 (Westlaw); COLO. REV. STAT. ANN. § 25-45-103 (Westlaw); FLA. STAT. ANN. § 499.0295 (Westlaw); IND. CODE. ANN. § 25-22.5-1-2.1 (Westlaw); LA. STAT. ANN. § 1300.423 (Westlaw); MICH. COMP. LAWS ANN. § 333.26451 (Westlaw); MINN. STAT. ANN. § 151.375 (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685;

considered any and all other treatment options currently FDA approved.[107] After considering all other treatment options, the patient's physician must provide a recommendation or prescription for the investigational drug.[108] Lastly, the patient must give "informed consent in writing for the use of the investigational drug."[109]

The eligibility requirements previously discussed seek to protect the patient by ensuring all other medical options have been considered and that the patient is aware of the risks of pursuing the right to try path. However, the statutes also safeguard third parties, which include physicians, manufacturers and insurers that are involved in a patient's access to investigational drugs. First, the act protects a physician from liability for any harm caused to a patient due to an investigational drug.[110] It also

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MONT. CODE ANN. § 50-12-102 (Westlaw); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-2 (Westlaw); TENN. CODE ANN. § 63-6-302 (Westlaw); UTAH CODE ANN. § 58-85-102 (Westlaw); VA. CODE ANN. § 54.1-3442.1 (Westlaw); WYO. STAT. ANN. § 35-7-1802 (Westlaw).

107. *See* ALA. CODE § 22-5D-2 (Westlaw, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1311(1)(b) (Westlaw); ARK CODE ANN. § 20-15-2004 (Westlaw); COLO. REV. STAT. ANN. § 25-45-103(I)(a)(II) (Westlaw); FLA. STAT. ANN. § 499.0295(2)(a)(2) (Westlaw); LA. STAT. ANN. § 1300.423 (Westlaw); MICH. COMP. LAWS ANN. § 333.26451(2)(b)(ii) (Westlaw); MINN. STAT. ANN. § 151.375(3)(2) (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-104 (West, Westlaw through 2015 Reg. Sess.); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-2(2) (Westlaw); TENN. CODE ANN. § 63-6-302 (Westlaw); TEX. CODE ANN. § 489.051 (Westlaw); UTAH CODE ANN. § 58-85-102 (Westlaw); VA. CODE ANN. § 54.1-3442. 2(A)(2) (Westlaw); WYO. STAT. ANN. § 35-7-1802(a)(i)(B) (Westlaw).

108. *See* ALA. CODE § 22-5D-2 (Westlaw, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1311(1)(c) (Westlaw); ARK CODE ANN. § 20-15-2004 (Westlaw); COLO. REV. STAT. ANN. § 25-45-103(1)(a)(IV) (Westlaw); FLA. STAT. ANN. § 499.0295 (Westlaw); LA. STAT. ANN. § 1300.423 (Westlaw); MICH. COMP. LAWS ANN. § 333.26451(2)(b)(iii) (Westlaw); MINN. STAT. ANN. § 151.375(3)(3) (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-104 (Westlaw); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-2(3) (Westlaw); TENN. CODE ANN. § 63-6-302 (Westlaw); TEX. CODE ANN. § 489.051 (Westlaw); UTAH CODE ANN. § 58-85-102 (Westlaw); VA. CODE ANN. § 54.1-3442. 2(A)(4) (Westlaw); WYO. STAT. ANN. § 35-7-1802(A)(i)(C) (Westlaw).

109. *See* ALA. CODE § 22-5D-2 (Westlaw, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1311(1)(d) (Westlaw); ARK CODE ANN. § 20-15-2004 (Westlaw); COLO. REV. STAT. ANN. § 25-45-103(1)(A)(V) (Westlaw); FLA. STAT. ANN. § 499.0295(2)(a)(3) (Westlaw); IND. CODE. ANN. § 25-22.5-1-2.1 (Westlaw); LA. STAT. ANN. § 1300.423 (Westlaw); MICH. COMP. LAWS ANN. § 333.26451(2)(b)(iv) (Westlaw); MINN. STAT. ANN. § 151.375(3)(4) (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-104 (Westlaw); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-2(4) (Westlaw); TENN. CODE ANN. § 63-6-302 (Westlaw); TEX. CODE ANN. § 489.052 (West, Westlaw through 2015 Reg. Sess.); UTAH CODE ANN. § 58-85-103(3) (Westlaw); VA. CODE ANN. § 54.1-3442. 2(B) (Westlaw); WYO. STAT. ANN. § 35-7-1802(a)(i)(D) (Westlaw).

110. However, the act does not protect a physician if he fails to exercise reasonable care. *See* ALA. CODE § 22-5D-10 (West, Westlaw through 2015 Reg. Sess.); ARK CODE ANN. § 20-15-2010 (West, Westlaw through 2015 Reg. Sess.); COLO. REV. STAT. ANN. § 25-45-107 (West, Westlaw

prevents a licensing board or disciplinary committee from taking any action against a physician's license based on the physician's recommendation to a patient.[111] As to manufacturers, the act does not force a manufacturer to make its investigational drugs available to a patient, even if the patient is eligible.[112] Just like a physician, the act protects a manufacturer from liability for any harm done to the patient due to the investigational drug.[113] Regarding insurers, they are not required to cover the cost of an

through 2015 Leg. Sess.); FLA. STAT. ANN. § 499.0295(8) (Westlaw); IND. CODE. ANN. § 25-22.5-1-2.1(f) (Westlaw); LA. STAT. ANN. § 1300.425 (West, Westlaw through 2014 Reg. Sess.); MINN. STAT. ANN. § 151.375(8) (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-110 (West, Westlaw through 2015 Reg. Sess.); N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-8 (West, Westlaw through 2015 Reg. Sess.); TENN. CODE ANN. § 63-6-308 (West, Westlaw through 2015 Reg. Sess.); TEX. CODE ANN. § 489.054 (West, Westlaw through 2015 Reg. Sess.); UTAH CODE ANN. § 58-85-104(2) (West, Westlaw through 2015 Leg. Sess.); VA. CODE ANN. § 54.1-3442.4(C) (West, Westlaw through 2015 Reg. Sess.).

111. *See* ALA. CODE § 22-5D-6 (West, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1313(A) (West, Westlaw through 2015 Reg. Sess.); ARK CODE ANN. § 20-15-2008 (West, Westlaw through 2015 Reg. Sess.); COLO. REV. STAT. ANN. § 25-45-105 (Westlaw); FLA. STAT. ANN. § 499.0295(7) (Westlaw); LA. STAT. ANN. § 1300.426 (West, Westlaw through 2014 Reg. Sess.); MICH. COMP. LAWS ANN. § 333.26455 (West, Westlaw through 2015 Reg. Sess.); MINN. STAT. ANN. § 151.375(6) (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-108 (West, Westlaw through 2015 Reg. Sess.); N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-7 (West, Westlaw through 2015 Reg. Sess.); TENN. CODE ANN. § 63-6-306 (West, Westlaw through 2015 Reg. Sess.); UTAH CODE ANN. § 58-85-104(2)(c) (Westlaw); VA. CODE ANN. § 54.1-3442.4(D) (Westlaw); WYO. STAT. ANN. § 35-7-1804 (West, Westlaw through 2015 Leg. Sess.).

112. *See* ALA. CODE § 22-5D-3 (West, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1312(A) (Westlaw); ARK CODE ANN. § 20-15-2005 (West, Westlaw through 2015 Reg. Sess.); COLO. REV. STAT. ANN. § 25-45-104(1) (Westlaw); FLA. STAT. ANN. § 499.0295 (Westlaw); IND. CODE ANN. § 16-42-26-1(b) (West, Westlaw through 2015 Reg. Sess.); LA. STAT. ANN. § 1300.424 (Westlaw); MICH. COMP. LAWS ANN. § 333.26452(1) (Westlaw); MINN. STAT. ANN. § 151.375(4)(b) (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-103 (West, Westlaw through 2015 Reg. Sess.); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-4 (Westlaw); TENN. CODE ANN. § 63-6-303 (West, Westlaw through 2015 Reg. Sess.); TEX. CODE ANN. § 489.053 (Westlaw); UTAH CODE ANN. § 58-85-104(3)(a) (Westlaw); VA. CODE ANN. § 54.1-3442.3(A) (Westlaw); WYO. STAT. ANN. § 35-7-1803(a) (Westlaw).

113. But the act does not protect a manufacturer if he fails to exercise reasonable care. *See* ALA. CODE § 22-5D-10 (Westlaw, Westlaw through 2015 Reg. Sess.); ARK CODE ANN. § 20-15-2010 (West, Westlaw through 2015 Reg. Sess.); COLO. REV. STAT. ANN. § 25-45-107 (Westlaw); FLA. STAT. ANN. § 499.0295(8) (Westlaw); IND. CODE ANN. § 16-42-26-5 (West, Westlaw through 2015 Reg. Sess.); MICH. COMP. LAWS ANN. § 333.26457(1) (West, Westlaw through 2015 Reg. Sess.); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-102 (Westlaw); N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-10 (West, Westlaw through 2015 Reg. Sess.); TENN. CODE ANN. § 63-6-308 (Westlaw); TEX. CODE ANN. § 489.054 (Westlaw); UTAH CODE ANN. § 58-85-104 (Westlaw); VA. CODE ANN. § 54.1-3442.4(B) (Westlaw); WYO. STAT. ANN. § 35-7-1806 (West, Westlaw through 2015 Leg. Sess.).

investigational drug.[114] These provisions of the act ensure that no party is forced, whether it is the patient, physician, manufacturer or insurer, to participate in accessing the investigational drug. Instead, the act allows each party the freedom to decide whether that party should participate, without awaiting the FDA's prolonged approval process.

In addition, some states have other provisions included within their right to try act. For example, several states include the following provision: "If the patient dies while being treated, her heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment."[115] This provision protects the patient's family from responsibility for any debt after the patient's death, thereby also encouraging a patient to move forward with an investigational drug without the fear of the patient's family being responsible for the costs of the treatment should the patient not survive. A terminally ill patient who seeks access under the act has considered all FDA approved options and decided that an investigational drug may be the only life sustaining treatment. Thus, a patient in this scenario need not be apprehensive about potential debt from the treatment after death.

Another provision found in many states' acts prohibits agents of the state from blocking an eligible patient's access to treatment.[116] State agents

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114. *See* ALA. CODE ANN. §22-5D-4 (West, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1312(C) (Westlaw); ARK CODE ANN. § 20-15-2007 (West, Westlaw through 2015 Reg. Sess.); COLO. REV. STAT. ANN. § 25-45-104(3)(c) (Westlaw); FLA. STAT. ANN. § 499.0295(9) (Westlaw); IND. CODE. ANN. § 25-22.5-1-2.1(e)(1) (Westlaw); LA. STAT. ANN. § 1300.424(C)(2) (Westlaw); MICH. COMP. LAWS ANN. § 333.26453(1) (West, Westlaw through 2015 Reg. Sess.); MINN. STAT. ANN. § 151.375(7) (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-106 (West, Westlaw through 2015 Reg. Sess.); N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-3(5) (West, Westlaw through 2015 Reg. Sess.); TENN. CODE ANN. § 63-6-304 (West, Westlaw through 2015 Reg. Sess.); UTAH CODE ANN. § 58-85-105(1)(a) (West, Westlaw through 2015 Leg. Sess.); VA. CODE ANN. § 54.1-3442.3(C) (Westlaw); WYO. STAT. ANN. § 35-7-1803(b) (Westlaw).

115. *See* ALA. CODE § 22-5D-5 (Westlaw 1975); Act of Mar. 10, 2015, Ark. Laws. Act 374 § 20-15-2006(b) (2015); COLO. REV. STAT. ANN. § 25-45-104(4) (Westlaw 2015); FLA. STAT. ANN. § 499.0295(6) (Westlaw 2015); MICH. COMP. LAWS ANN. § 333.26454 (West, Westlaw through 2015 Reg. Sess); MONT. CODE ANN. § 50-12-107 (Westlaw 2015); N.D. CENT. CODE Ann. § 23-48-02 (Westlaw 2015); OKLA. STAT. ANN. § 3091.3(E) (Westlaw 2015); S.D. CODIFIED LAWS § 34-51-6 (Westlaw through 2015 Reg. Sess.); TENN. CODE ANN. § 63-6-305 (Westlaw 2015).

116. *See* ALA. CODE § 22-5D-9 (West, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1314 (Westlaw); COLO. REV. STAT. ANN. § 25-45-106 (West, Westlaw through 2015 Reg. Sess.); MICH. COMP. LAWS ANN. § 333.26456 (West, Westlaw through 2015 Reg. Sess); MONT. CODE ANN. § 50-12-109 (West, Westlaw through 2015 Reg. Sess.); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. CODIFIED LAWS § 34-51-9 (West, Westlaw through 2015 Reg. Sess.); TENN. CODE ANN. § 63-6-307 (West, Westlaw through 2015 Reg. Sess.); TEX. CODE ANN. § 489.055 (West, Westlaw through 2015 Reg. Sess.); WYO. STAT. ANN. § 35-7-1805 (West, Westlaw through 2015 Leg. Sess.).

cannot use FDA regulations or any other reason to prevent an eligible patient from access under the right to try act.[117] This provision would apply to any state agent, which would include a large, broad group of people. This provision not only protects a patient's right to access an investigational drug, but it also signals to those agents of the state that they cannot impede this access.

Other states have a provision that seeks to protect hospitals and other healthcare facilities by providing that these facilities "are not required to provide new services."[118] If a patient's access under the state's right to try act would require a hospital to provide services that it does not already provide, the hospital would have no obligation under the act to provide such services.[119] For example, suppose a patient is seeking access to an investigational drug for cystic fibrosis, but the particular drug requires a specific breathing machine for administration of the drug to the patient. If the hospital does not already have this machine or provide this type of service, it is not required to do so under the right to try act.

Even though the provisions in states' right to try acts may differ slightly, the amalgamation of the statutes reveals that all the states seek to achieve the same purpose of providing terminally ill patients with greater access to investigational drugs in a quicker manner than the FDA's compassionate use program allows.[120] And the bipartisan, unanimous congressional support in almost all states that have enacted the right to try act clearly signifies that these statutes resonate loudly with a significant majority of their constituents.[121] Yet, there are copious critics of the right to

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117. *Id.*

118. *See* ALA. CODE § 22-5D-7 (Westlaw 2015); FLA. STAT. ANN. § 499.0295(5) (Westlaw 2015); MICH. COMP. LAWS ANN. § 333.26453(4) (Westlaw 2015); MISS. CODE ANN. § 41-131-1(6) (Westlaw 2015); TENN. CODE ANN. § 63-6-304(d) (Westlaw 2015).

119. *Id.*

120. *See* ALA. CODE § 22-5D-3 (Westlaw, Westlaw through 2015 Reg. Sess.); ARIZ. REV. STAT. ANN. § 36-1312 (Westlaw); ARK CODE ANN. § 20-15-2002 (West, Westlaw through 2015 Reg. Sess.); COLO. REV. STAT. ANN. § 25-45-102 (Westlaw); FLA. STAT. ANN. § 499.0295 (Westlaw); IND. CODE ANN. § 16-42-26-4 (West, Westlaw through 2015 Reg. Sess.); LA. STAT. ANN. § 1300.422 (West, Westlaw through 2014 Reg. Sess.); MICH. COMP. LAWS ANN. § 333.26452 (Westlaw); MINN. STAT. ANN. § 151.375 (Westlaw); Miss. S.B. 2485; Mo. H.B. 1685; MONT. CODE ANN. § 50-12-103 (Westlaw); Nev. Assemb. B. 164; N.D. S.B. 2259; Okla. H.B. 1074; S.D. Codified Laws § 34-51-4 (Westlaw); TENN. CODE ANN. § 63-6-303 (Westlaw); TEX. CODE ANN. § 489.051 (Westlaw); UTAH CODE ANN. § 58-85-103 (Westlaw); VA. CODE ANN. § 54.1-3442.3 (Westlaw); WYO. STAT. ANN. § 35-7-1803 (Westlaw).

121. *See Right to Try Law Signed into Law in Arkansas*, OZARKS FIRST (March 11, 2015), http://www.ozarksfirst.com/news/health-and-medical/right-to-try-bill-signed-into-law-in-arkansas ("The state House and Senate passed the bill on unanimous bipartisan votes."); *"Right to Try": States Move to Expand Access to Experimental Drugs*, NBC NEWS (May 18, 2014), http://www.nbcnews.com/health/health-news/right-try-states-move-expand-access-experimental-

try act who justifiably question the efficacy of the act and whether it will indeed achieve its purpose of aiding terminally ill patients.[122]

III. CRITICISMS OF THE RIGHT TO TRY ACTS

Legal scholars, pharmaceutical representatives, and medical professionals continue to question whether the right to try acts will indeed provide greater access to life saving drugs for terminally ill patients. These critics point out several perceived deficiencies in the right to try acts that they argue essentially nullify the acts. Instead, these critics call the right to try acts "feel-good placebo" legislation that all legislators can support due

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drugs-n108316 (stating that the bill passed unanimously in the Colorado state Legislature); *Signed as Law in Florida: Right to Try Act Helps Protect Terminal Patients from FDA Restrictions,* TENTH AMEND. CTR. (June 10, 2015), http://blog.tenthamendmentcenter.com/2015/06/signed-as-law-in-florida-right-to-try-act-helps-protect-terminal-patients-from-fda-restrictions/ (stating that the bill passed in the Florida state House unanimously with a 113-0 vote, and passed in state Senate with a 39-1 vote); *Indiana Governor Mike Pence Signs Right to Try Legislation Into Law,* GOLDWATER INST. (March 24, 2015), http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/indiana-governor-mike-pence-signs-right-to-try-leg/ (stating that the bill passed both the Indiana state House and Senate with unanimous, bipartisan votes); *12 States and Counting: Mississippi Right to Try Act Signed Into Law,* TENTH AMEND. CTR. (March 30, 2015), http://blog.tenthamendmentcenter.com/2015/03/12-states-and-counting-mississippi-right-to-try-act-signed-into-law/ ("It passed the Senate 48-3 and the House concurred with a vote of 118-0."); *13 States and Counting: Montana "Right to Try" Act Signed into Law, Effectively Nullifies Some FDA Restrictions on Terminally-ill,"* TENTH AMEND. CTR. (March 13, 2015), http://blog.tenthamendmentcenter.com/2015/03/13-states-and-counting-montana-right-to-try-act-signed-into-law-effectively-nullifies-some-fda-restrictions-on-terminally-ill/ ("It passed the Senate unanimously and the House concurred with a vote of 93-7."); *Nevada Lawmakers Send Right to Try Act to Governor Sandoval,* GOLDWATER INST. (May 20, 2015), http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/nevada-lawmakers-send-right-to-try-act-to-governor/ (stating that the Right to Try Act passed the Nevada House and Senate with bipartisan, unanimous support); *Oklahoma Governor Signs "Right to Try Act" into Law: Will Nullify in Practice Some FDA-Restrictions on Terminally-Ill,* TENTH AMEND. CTR. (April 21, 2015), http://blog.tenthamendmentcenter.com/2015/04/oklahoma-gov-signs-right-to-try-act-into-law-will-nullify-in-practice-some-fda-restrictions-on-terminally-ill/ (stating that the Right to Try Act passed through the Oklahoma House and Senate with a unanimous vote); Alex Harris, *"Right to Try" Becomes Law in TN,* TN REP. (May 10, 2015), http://tnreport.com/2015/05/10/right-try-becomes-law-tn/ (stating that the measure unanimously passed both chambers of the Tennessee General Assembly in April.).

122. *See, e.g.*, Katelyn Mineo, *False Promises of Hope: A Look at How the State "Right to Try" Laws Will Prove Detrimental to the Drug Approval Process and Public Health*, 8 HEALTH L. OUTLOOK 1, 4-5 (2015) (arguing that right to try laws will be ineffective in making expanded access more readily available and that they could have a detrimental effect on the public health at large in undercutting the integrity of the approval process). *See generally* David Gorski, *"Right to Try" Laws and Dallas Buyers' Club: Great Movie, Terrible for Patients and Terrible Policy*, SCI.-BASED MED. (Mar. 8, 2014), https://www.sciencebasedmedicine.org/right-to-try-laws-and-dallas-buyers-club-great-movie-terrible-public-policy/ ("In reality, the likelihood of saving the lives of even a handful of cancer patients by giving them access to early-stage investigational agents is quite low and hard to justify on a moral and practical basis.").

to the bump in approval ratings the acts will generate for those legislators.[123] They claim the acts will not result in terminally ill patients receiving better access. Rather, they claim the acts will do absolutely nothing and patients will gain no access; or, if terminally patients do gain access, the unapproved, untested drugs could cause more harm than good in the patients' last days of life.

A. Critics Argue Right to Try Acts Are Preempted by Federal Law

At the outset, critics argue that the right to try acts, although well-intentioned, will ultimately have no effect because they are preempted by federal law.[124] Specifically, the right to try acts allow terminally ill patients the right to access investigational drugs that have not received approval from the FDA to be sold to the public; rather, the investigational drugs have only completed Phase I Testing – initial testing that shows the drug is safe.[125] Thus, the right to try acts are contrary to the FDA's approval process, which requires a minimum of three phases of testing, and are also contrary to the FDA's compassionate use program, which requires permission from the FDA for a terminally ill patient to receive access to investigational drugs.[126] The right to try acts operate outside the constraints of the FDA. Instead, the acts place the decision-making among the patient, physician and drug manufacturer.[127] When conducting preemption analysis, it appears the critics have a valid argument that the right to try acts are preempted.

The Supremacy Clause of the United States Constitution provides the basis for preemption and states "[t]his Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, anything in the Constitution or Laws of any State to the contrary notwithstanding."[128] When a state law conflicts

123. *See* Gorski, *supra* note 122.

124. Sam Adriance, Note, *Fighting for the "Right to Try" Unapproved Drugs: Law as Persuasion*, 124 YALE L.J. F. 148, 153 (Dec. 4, 2014), http://www.yalelawjournal.org/forum/right-to-try-unapproved-drugs (explaining that "FDA regulations still prevent drug companies from providing experimental drugs to terminal patients . . . [and a right to try law] does not meaningfully change the legal regime to which drug companies are subject and so is unlikely to bring unapproved drugs to more patients").

125. Corieri, *supra* note 67, at 20 (explaining how right to try acts "address the legitimate government interest of protecting the lives of citizens [and] only allows access to medications that have passed basic safety testing (Phase I)").

126. *See infra* Part I.

127. Corieri, *supra* note 67, at 22 (arguing that states should pass right to try laws and return "medical decision making back to the rightful hands of patients and doctors").

128. U.S. CONST. art. VI, cl. 2.

with a federal law, the federal law prevails and the state law is invalid to the extent it conflicts with the federal law.[129] The cornerstone of preemption jurisprudence is the purpose of Congress, coupled with the assumption that the historic police powers of the States were not to be superseded by federal laws unless that was the clear and manifest purpose of Congress.[130] While states have traditionally held the power to regulate matters of health and safety of the citizenry, the FDA has regulated the drug market for the last century as Congress has continued to expand the role of the FDA.[131]

There are two types of preemption: express or implied. With express preemption, Congress has clearly stated that the federal law supersedes the state law dealing with the same subject.[132] Yet with implied preemption, even though Congress has not explicitly addressed the issue of preemption, the state law is still preempted to the extent it conflicts with the federal law.[133] Implied preemption can occur in three different ways, referred to as obstacle, field, and conflict. Conflict preemption occurs if it would be impossible to comply with both the federal law and state law.[134] Field preemption applies if "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state law on the same subject."[135] Obstacle preemption applies if the federal legislation "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[136]

When considering whether the right to try statutes are preempted by federal law, the analysis begins with determining whether there is express or implied preemption.[137] There is no express preemption for the regulation of unapproved drugs in the Federal Food, Drug, and Cosmetic Act, so the next step involves considering whether there is implied preemption.[138] At

129. *See* Fed. Sav. & Loan Ass'n v. De La Cuesta, 458 U.S. 141, 153 (1982).

130. Wyeth v. Levine, 555 U.S. 555, 565 (2009).

131. *See* Howard L. Dorfman et al., *Presumption of Innocence: FDA's Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate*, 61 FOOD & DRUG L.J. 585, 607 (2006) ("[S]tate authority to regulate certain aspects of the pharmaceutical industry and state deference to the FDA strongly refute the states' rights argument against preemption. States should and do have authority to protect the health of their citizens as long as such regulation does not serve as a basis for 'second-guessing' the sound medical judgment of the FDA.").

132. *See* Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977).

133. *See* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

134. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963); Mut. Pharm. Co. v. Bartlett, 133 S.Ct. 2466, 2473 (2013).

135. *Rice*, 331 U.S. at 230.

136. Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

137. *See* Cipollone v. Liggett Grp., 505 U.S. 504, 516 (1992).

138. *See* 21 U.S.C.A. § 355 (implicitly imposing that neither the New Drugs statute nor the codes regarding the Investigational New Drug Application for life-threatening illnesses expressly

first glance, the right to try statutes are most likely impliedly preempted because it would be physically impossible to comply with both the state right to try statutes and the federal regulations, which would be considered conflict preemption.[139] Specifically, it would be impossible for a drug manufacturer to provide a terminally ill patient with a new drug that had only passed Phase I of FDA trials and comply with federal regulations that require more testing.[140]

In addition, the right to try statutes could also be preempted pursuant to obstacle preemption because the statutes pose an obstacle to the purposes and objectives of Congress.[141] In United States. v. Rutherford, the Court analyzed the legislative history of the 1938 Food, Drug, and Cosmetic Act and noted that Congress desired to shield patients with terminal diseases from fraudulent cures.[142] However, in contravention of this Congressional intent, right to try statutes would allow terminally ill patients to access medication that had not been subjected to the trials required by current FDA regulations.

As many legal scholars have argued, it appears likely that the right to try acts are impliedly preempted by the FDA regulations.[143] However,

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preempts state law); 21 C.F.R. §§ 312.80-.88. In addition, in the field of health and safety, the Court is reluctant to infer intent to preempt solely from comprehensiveness of federal regulation. Hillsborough Cnty., Fla. v. Automated Med. Lab., Inc., 471 U.S. 707, 717 (1985).

139. *See Mut. Pharm. Co.*, 133 S.Ct. at 2473 (finding it was impossible for the manufacturer of a generic drug to comply with both state and federal law when state law would require the manufacturer to change its label to avoid liability and federal law forbids a generic manufacturer from changing the label on medicine independent from the brand name manufacturer).

140. *See supra* Part I.

141. One could also argue that field preemption applies, considering Congress has regulated the field of drugs for over one hundred years. *See generally Rice*, 331 U.S. at 230. The right to try acts directly impede into the area of drug regulation that the FDA has dominated, so implied field preemption would also likely apply, which would preclude enforcement of the right to try statutes.

142. United States v. Rutherford, 442 U.S. 544, 552 (1979).

143. Although beyond the scope of this article, some scholars argue that terminally ill patients do have a constitutional right to access unapproved drugs. *See e.g.*, Patricia Marisa do Coito Cruz, Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*: Is There a Right to Live?*, 25 T.M. COOLEY L. REV. 347 (2008) (arguing that substantive due process precedent supports a finding that terminally ill patients with no remaining approved treatment options have the right to attempt to save their own life by deciding in consultation with their doctor to seek access to post-Phase I experimental drugs); 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 (2008) (arguing that the D.C. Circuit's decision in Abigail Alliance was incorrect because it should have found a limited fundamental right to access experimental drugs under *Planned Parenthood of Southeastern Pennsylvania v. Casey*); Tovanche, *supra* note 82 (arguing that the D.C. Circuit's decision in Abigail rested on faulty conclusions about American history and an accurate account of our nation's history under Glucksberg would have resulted in a finding that a particular group of persons has a fundamental right of access to experimental drugs); Robert M. Harper, *A Matter of Life and Death: Affording Terminally Ill Patients Access to Post-Phase I*

whether the U.S. Supreme Court would definitively find the state statute preempted is unknown, but should a drug manufacturer provide access to an investigational drug pursuant to a right to try act and outside the approval of the FDA, and if the FDA seeks to enjoin the access, the issue could ultimately make its way to the Supreme Court.

B. Critics Argue Participation Is Not Mandated

A recurring negative comment about the right to try acts is that drug manufacturers, physicians and insurance companies are not required to participate in providing access to the investigational drugs.[144] Instead, the acts allow voluntary participation from all parties and do not force anyone down the path of investigational drugs. Although freedom from mandated participation sounds preferable, especially for free market advocates, critics point out that a drug manufacturer is the least likely participant because it is extremely unlikely to offer its investigational drug to a terminally ill patient in contravention of the FDA's compassionate use program.[145] This point is particularly salient considering the FDA is the agency responsible for granting final drug approval, and a drug manufacturer will not want to jeopardize final drug approval that will allow the drug to be sold on the marketplace, just to aid a smaller group of terminally ill patients.[146] As Dr. David Gorski, a surgical oncologist explains, "[t]he FDA regulates drug development, and [a right to try act] doesn't do anything to change that [,and a drug company] wouldn't do anything to endanger a drug they're potentially spending hundreds of millions of dollars to bring to market."[147] Yet, the reasoning behind voluntary drug manufacturer participation seems clear – if participation was mandatory, drug manufacturer entry innovation

Investigational New Drugs, 12 MICH. ST. U. J. MED. & L. 265 (2008) (arguing that terminally-ill patients should be permitted to use post-Phase I investigational new drugs to save and extend their lives when they have no other medical alternatives).

144. Mineo, *supra* note 122, at 5 (emphasizing right to try laws "do not require a manufacturer to provide an investigational product to a terminally ill patient, but instead the manufacturer retains discretion").

145. *See id.* ("As such, it is hard to imagine the manufacturer who would provide a patient an investigational drug under these state laws while the FDA still prohibits such use and possesses the authority to approve or reject the manufacturer's application prior to marketing to the public at large.").

146. Adriance, *supra* note 124, at 154-55 (emphasizing that "it takes, on average, ten years and roughly $1 billion to complete the FDA approval process, the money a company might make from such experimental sales would likely be nominal compared to the costs of development").

147. *'Right to Try': States Move to Expand Access to Experimental Drugs*, ASSOCIATED PRESS (May 18, 2014), http://www.nbcnews.com/health/health-news/right-try-states-move-expand-access-experimental-drugs-n108316.

would be stifled and everyone would suffer from fewer drugs coming onto the market.

Although critics of the right to try acts consistently claim that drug manufacturer participation is not mandatory, which will result in diminished participation, the critics fail to highlight that the FDA's compassionate use program suffers from the same dilemma, i.e., drug manufacturers are not required to grant expanded access to patients, even if the FDA would approve the access.[148] Thus, both the right to try acts and the FDA's compassionate use program equally share this problem. However, there are drug manufacturers who appear to genuinely desire to grant expanded access to patients under right to try acts, without the constraints of the FDA. For example, drug manufacturer Neuralstem has developed a highly promising drug to treat amyotropic lateral sclerosis ("ALS"), better known as Lou Gehrig's Disease, and its CEO, I. Richard Garr, plans to make the treatment available now to the thousands of people who suffer from ALS.[149] He constantly hears from terminally ill patients who would like to receive treatment.[150] But the average life expectancy for an ALS sufferer is between two to five years after diagnosis, so Garr knows most of them will die before final FDA approval.[151]

Although drug manufacturers are not required to participate in either the FDA's compassionate use program or a state's right to try act, there is at least one drug company that is taking a novel approach to providing expanded access to patients. Johnson & Johnson, a large and influential drug maker, has created a bioethics panel that will review requests for access to a limited number of experimental drugs and decide how Johnson & Johnson should respond.[152] Overseeing this panel of doctors, ethicists, and patient advocates will be Dr. Arthur L. Caplan of New York University.[153] Johnson and Johnson's institution of this new panel signifies that drug manufacturers may be increasingly more open to participating in expanded access programs.

148. *See supra* Part I.A.

149. Clint Bolick, *The End of FDA Paternalism?*, HOOVER INST. (Aug. 14, 2014), http://www.hoover.org/research/end-fda-paternalism.

150. *Id.*

151. *Id.*

152. Thomas, *supra* note 76.

153. *Id.* Dr. Caplan will not be paid for his work in the program, and the board will be independent of the drug company with Johnson & Johnson paying the university to fund the program. *Id.*

Insurance companies are also not required to pay for the costs of the investigational drug under the right to try acts.[154] So, if a drug manufacturer agrees to supply the investigational drug to a patient, the patient's insurer is not required to pay for the drug.[155] Perhaps the insurance company will pay for the drug, but if not, either the patient must pay for the drug or the drug manufacturer must supply the drug free of charge.[156] For those patients unable to pay, critics argue it will further the disparate financial impact on lower income Americans.[157] Yet requiring insurance companies to pay for investigational drugs that may or may not improve the terminally ill patient's condition would strain the already stressed insurance market and unnecessarily raise premiums for all, not to mention the likelihood of creating a marketplace where drug manufacturers might prey on terminally ill patients by creating drugs unlikely to improve the patient's condition but with a guaranteed payment from insurers.

A physician is also not required to participate, but the ramifications for a physician not participating are not as detrimental for a patient – if one physician refuses to assist a patient in accessing an investigational drug, the patient has the option to find another physician to assist him in the process.[158] Patients in rural areas with fewer physicians would not have as many options should the patient's initial request for assistance with accessing investigational drugs be denied. Also as to physicians, critics question the comprehensiveness of the right to try acts, which only require a physician's recommendation or prescription to gain access.[159] These critics opine that more physician involvement is necessary, such as requiring physicians to follow the patient's condition and report such findings to the FDA.[160]

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154. *See* Patricia J. Zettler & Henry T. Greely, *The Strange Allure of State 'Right-to-Try' Laws*, 174 JAMA INTERN MED. 1885 (2014); Kristen Wyatt, *Colorado's 'Right To Try' Law Will Give Some Patients Access To Experimental Drugs*, HUFFINGTON POST, May 18, 2014, http://www.huffingtonpost.com/2014/05/18/colorado-right-to-try-law-experimental-drugs_n_5347490.html.

155. *See supra* Part II (discussing the requirements of the state to right acts, which do not include an insurance company's obligation to cover the costs of the investigational drug).

156. *See* Darrow, *supra* note 63, at 281.

157. Mineo, *supra* note 122, at 9 (discussing the potential inequity where the patient would bear the cost of the experimental drug and many lower-income individuals would be unable to pay the cost).

158. *See supra* notes 105, 107-08 and accompanying text (discussing the right to try act requirements for a physician).

159. *See* Jann Bellamy, *The Illusions of "Right to Try Laws,"* SCI.-BASED MED. (Mar. 6, 2014), https://www.sciencebasedmedicine.org/the-illusions-of-right-to-try-laws/.

160. *See id.*

Critics accurately argue that the right to try acts do not mandate participation by any party. And although this voluntary participation requirement might limit the involvement of some patients, alternatively, required participation would likely result in harsher consequences, such as stifled drug innovation and increased insurance premiums.

C. Critics Argue Investigational Drugs Not Sufficiently Tested

Another critique of the right to try acts is that they only require Phase I Testing before a patient may access the investigational drug.[161] A typical drug that is approved under the FDA's process undergoes three phases of testing before it may be offered on the marketplace.[162] As previously discussed, Phase I Testing is meant to test the safety of the drug, with the subsequent phases testing the safety and efficacy of the drug.[163] Critics argue that terminally ill patients who desperately seek an investigational drug will be given false hope that the investigational drug will cure them or improve their health condition; however, with the investigational drug having undergone such little testing, the likelihood of the drug meeting the patients' expectations is slight.[164] Instead, in the final days of the patients' lives, they may experience increased pain and suffering due to the side effects of the investigational drug – side effects that were not shown during Phase I Testing.[165] These critics further argue that very few drugs that pass Phase I Testing ultimately receive FDA approval.[166] However, according to the Abigail Alliance, the nonprofit organization previously discussed that advocates for quicker access to drugs for terminally ill patients, "Every drug for cancer and other serious life-threatening illness that the Abigail Alliance for Better Access to Developmental Drugs pushed for earlier approval of in [their] fourteen year history is now approved by the FDA. Not one of the 30 drugs [they] pushed for earlier approval of failed to make it through the

161. Zettler & Greely, *supra* note 154 (highlighting that "[a] drug that 'successfully completed' phase I trials has limited evidence of safety and no evidence of efficacy").

162. *See supra* Part I.

163. *See supra* Part I.

164. Zettler & Greely, *supra* note 154 ("Indeed, these [right to try] laws may be harmful if they draw attention and resources away from efforts to develop effective treatments, engender confusion about the FDA pathway for compassionate use of medications, or create false hopes for terminally ill patients.").

165. *See* Gorski, *supra* note 122 (empathizing that the only thing worse than dying of a terminal illness is dying of a terminal illness and suffering unnecessary complications as a result of an investigational or experimental drug).

166. *Id.*

clinical trial process."[167] Thus, the Abigail Alliance claims that thousands of lives could have been saved if quicker access had been granted.[168]

Although investigational drugs accessed through right to try acts will not have undergone the necessary testing for FDA approval, they will have been tested for safety.[169] Additionally, the right to try acts require that a patient give informed consent before accessing an investigational drug, so the patients should be aware of the possible risks of taking a drug that has only been through Phase I Testing.[170] The right to try acts do not guarantee a terminally ill patient that the accessed investigational drug will cure the patient or improve his condition, but what the act does do is give a terminally ill patient the chance to access an investigational drug that would likely be unavailable to a patient otherwise. The patient, in consultation with his physician, has the opportunity to weigh the risks and benefits and decide whether to try the investigational drug. Assuming the manufacturer agrees to supply the investigational drug, the act gives the patient the choice, not the FDA.

D. Critics Argue that Inhibiting Drug Availability Will Serve the Greater Good

Another recurring criticism of the right to try acts is that they will ultimately harm the greater population for the sake of a few.[171] Specifically, critics claim that if terminally ill patients are allowed to access investigational drugs outside of the FDA's compassionate use program and outside of clinical trials, the value of clinical trials will decline as fewer patients will participate in them.[172] With this decreased participation in clinical trials, comes decreased evidence about the efficacy of the investigational drug and diminished potential for the drug's ultimate approval by the FDA.[173]

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167. ABIGAIL ALLIANCE, http://www.abigail-alliance.org/ (last visited Aug. 2, 2015). Frank Burroughs formed Abigail Alliance because his twenty-one year old daughter died of cancer without having the chance to try potentially life-saving drugs before her death – drugs that were ultimately approved by the FDA – and he did not want other parents to endure the heartache that he suffered. *Id.*

168. *See id*.

169. *See supra* Part I.

170. *See supra* note 109.

171. Mineo, *supra* note 122, at 6 (discussing how patients will have little incentive to enroll in clinical trials if they can access drugs through the right to try statutes instead).

172. *Id.* (hypothesizing how human clinical trials could eventually end altogether, resulting in a negative impact on public health).

173. *See id.* at 5-6.

A subset of this argument that critics have raised is how a patient's access pursuant to a right to try act could ultimately jeopardize whether the FDA approves the drug.[174] For example, if a terminally ill patient accesses an investigational drug pursuant to the right to try act and experiences an adverse reaction, this adverse reaction could thwart the FDA's decision to approve the drug.[175] Once again, the drug manufacturer would be risking the investigational drug's final FDA approval, which allows the drug to be offered to a broader population, to assist a smaller group of patients. Additionally, if drug companies participate in the right to try acts, they will expend time and resources away from clinical trials, which will also inhibit the drug's final FDA approval.[176]

These concerns of jeopardizing or delaying FDA approval of a drug to assist patients pursuant to right to try acts have some validity; however, they fail to consider that alternatively, earlier access for terminally ill patients could assist in determining whether a drug is effective and should be granted FDA approval. With the clinical trials required for FDA approval, drug manufacturers are constrained to find patients that fit very specific eligibility criteria.[177] In many instances, a patient who could greatly benefit from participating in the clinical trial is not eligible for a very narrow reason. For example, patient Ted Harada suffered from ALS, and during a Phase I clinical trial he received one treatment of drug manufacturer Neuralstem's treatment for ALS.[178] After just one treatment, he recovered to the point that he no longer needed a cane, but he did not fit the criteria for Phase II FDA Testing due to the timing of when he contracted the disease; thus, he could not receive any more treatments.[179] Under the right to try acts, Mr. Harada would only have to establish that he was terminally ill to receive access to the treatment.[180] His reaction to the

174. *Id.* at 5 ("Adverse reactions to the investigational drug may eventually provide the FDA with reasons to withhold approval of the drug."); *see also* Craig Klugman, *Cost of Compassionate Use Is Simply Too High*, BIOETHICS.NET (May 8, 2015), http://www.bioethics.net/2015/05/cost-of-compassionate-use-is-simply-too-high/ (pontificating how one negative outcome from expanded access could unfairly affect the drug's ultimate approval).

175. *See* Klugman, *supra* note 174.

176. David Farber et al., *How State Right-to-Try Laws Create False Expectations*, HEALTH AFF. BLOG (May 22, 2015), http://healthaffairs.org/blog/2015/05/22/how-state-right-to-try-laws-create-false-expectations/.

177. *See* Bolick, *supra* note 149.

178. *Id.*

179. *Id.*

180. *See id.*

treatment, whether positive or negative, could assist Neuralstem in determining the safety and effectiveness of its drug.[181]

E. Critics Question Using Patient Stories

Critics also argue that the right to try acts are bipartisan and unanimously passed, because politicians, the media, and access advocate organizations unfairly use poignant patient stories as the catalyst to enact change.[182] For example, in Virginia, the Congressman who introduced the bill used the story of Josh Hardy to move its members of Congress to vote for the right to try act.[183] At only nine months old, Josh was diagnosed with a rare form of kidney cancer and over the next few years, he battled with cancer in his thymus, lung, and bone marrow.[184] Time and time again, Josh Hardy beat cancer, but after his bone marrow transplant, his immune system was very weak, which lead to an adenovirus that spread through his body.[185] Josh's doctors wanted to try the oral form of a drug, but it had not been approved by the FDA.[186] The Hardy family begged the drug company for access, but the drug company said that allowing "compassionate use" of the drug would slow down their progress toward FDA approval.[187] After pressure from the Hardy family and their supporters, the company finally caved to the pressure and supplied Josh with the medicine that he needed.[188] After just three doses of the drug, Hardy was no longer deathly ill; instead,

181. In response to critics who worry that terminally ill patients will unfairly be used as test subjects, informed consent, which is required under the right to try acts, should curtail unjust testing practices, as long as the informed consent is obtained appropriately. *See supra* note 109. Mr. Harada, the patient in the example above, testified at an FDA hearing: "I'd suggest your paternalistic approach puts patients in more harm's way than it does to protect them. . . . Patients diagnosed with fatal diseases should be given the opportunity to take elevated risks with informed and educated consent in regards to their treatment options." Bolick, *supra* note 149.

182. Dresser, *supra* note 76, at 1648-49 (emphasizing how patient stories "are a staple of [right to try acts]").

183. *See Del. Margaret Ransone's Right to Try Legislation Passes House Committee*, AUGUSTA FREE PRESS (Jan. 29, 2015, 12:58 PM), http://augustafreepress.com/del-margaret-ransones-right-try-legislation-passes-house-committee/.

184. Elizabeth Cohen, *Company Denies Drug to Dying Child*, CNN (Mar. 11, 2014, 2:57 PM), http://www.cnn.com/2014/03/10/health/cohen-josh/.

185. *See id.*

186. *See id.*

187. *See id.*

188 Catherine E. Shoichet & Elizabeth Cohen, *Drug Company Will Give Ailing 7-year-old Medicine That Could Save Him*, CNN (Mar. 12, 2014, 8:13 AM), http://www.cnn.com/2014/03/11/health/josh-hardy-drug-study/.

he could sit up, do his homework, and play board games with his family.[189] Although Josh sustained damage to his kidneys, just two weeks after receiving the oral form of brincidofovir, the adenovirus was gone.[190]

Patient Nick Auden was the catalyst for the passage of the right to try act in Colorado, although his ending is heartbreakingly different than Josh Hardy's.[191] In September 2011, Nick, the father of three children, was diagnosed with melanoma and told that he would probably die within a year.[192] Merck and Bristol-Myers Squibb had developed an immune-boosting anti-PD-1 drug during Nick's time with cancer that would likely have helped his immune system shrink his cancerous tumors.[193] Initially, Nick did not qualify for a clinical trial because of his growing brain tumors, but eventually his brain tumors stabilized, thereby making him eligible for the clinical trial.[194] Unfortunately, Nick's intestine perforated, which once again rendered him unable to participate in the clinical trial.[195] Nick's doctors informed him that this was the end of the road and gave him six to nine months to live.[196] Nick's only chance at receiving the drug was through an individual compassionate use trial; however, neither Merck nor Bristol-Myers Squibb allowed outside clinical trials citing safety considerations as the reason for denying access.[197] Nick's family started a massive media campaign and began gathering signatures for a petition to the drug companies to allow him to receive the drugs, but unfortunately, Nick never received the treatment and passed away on November 22,

189. Elizabeth Cohen, *Drug Brings Remarkable Improvement for Boy*, CNN (Mar. 24, 2014, 11:36 AM), http://www.cnn.com/2014/03/21/health/cohen-josh-hardy/.

190. Elizabeth Cohen, *Once Near Death, Boy Is 'Getting Stronger Every Day,'* CNN (May 7, 2014 2:34 PM), http://www.cnn.com/2014/05/07/health/josh-hardy-update/.

191. *See* Kristen Watt, *Colorado's 'Right to Try' Law Will Give Some Patients Access to Experimental Drugs*, HUFFINGTON POST (May 18, 2014), http://www.huffingtonpost.com/2014/05/18/colorado-right-to-try-law-experimental-drugs_n_5347490.html.

192. *See* Sydney Lupkin, *Dad Pleading for Unapproved Cancer Drug Dies*, ABC NEWS (Nov. 25, 2013), http://abcnews.go.com/Health/dad-pleading-unapproved-cancer-drug-dies/story?id=21004482.

193. *See id.* ("In studies of Merck's version of the drug, 38 percent of participants with melanoma in a clinical trial saw tumors shrink. That percentage jumped to 52 where patients took the highest doses of the drug.").

194. *Terminally Ill Father-of-Three, 40, Begs Drug Companies to Give Him Unapproved Cancer 'Wonder Medicine' to Save His Life*, DAILY MAIL (Sept. 13, 2013, 12:39 EST), http://www.dailymail.co.uk/news/article-2420245/Terminally-ill-Nick-Auden-begs-drug-companies-unapproved-wonder-medicine.html.

195. *Id.*

196. *Id.*

197. *Id.* (In response to the drug manufacturers' denial of access due to concerns of safety, Auden stated, "When you've been given a terminal diagnosis, you're prepared to accept a drug that's 50 percent effective[.] Safety concerns don't really figure in the same way.").

2013.[198] In March 2014, Merck announced that it would allow expanded access to the medication through compassionate use in the United States to people "who have serious or immediately life-threatening illnesses for which no comparable or satisfactory alternate therapies are available."[199]

Admittedly these patient stories are tragic and moving, but critics stringently disagree about using such stories to advance right to try acts that greatly diminish the FDA's role in ensuring that drugs are both safe and effective and that could ultimately cause these patients more harm than good.[200] These critics claim that using such heart wrenching stories clouds the true issue, which is not quicker access for terminally ill patients but, rather, how to improve the FDA's approval process to make safe and effective drugs more quickly available to the general population, not just a small subset.[201] Instead, the passage of right to try acts does nothing to solve the real issue and instead deceitfully gives false hope to terminally ill patients.[202]

IV. IMPROVEMENT TO RIGHT TO TRY

Legal scholars have voiced considerable concerns about the likely effectiveness of right to try acts. Some of these concerns, such as federal preemption and manufacturer nonparticipation, appear to have some cogency. Yet, the popularity of the right to try acts, as evidenced by their unanimity and bipartisanship, should signal to the FDA (and accordingly Congress) that its compassionate use program needs significant modification and should be more aligned with state right to try acts. To ameliorate the state right to try acts and solve their perceived deficiencies, a

198. Amy Auden, *Merck & Brisol-Myers Squibb: Save Locky's Dad. Provide Nick Auden Access to the PD1 Drug on a Compassionate Basis*, CHANGE.ORG, https://www.change.org/p/merck-bristol-myers-squibb-save-locky-s-dad-provide-nick-auden-access-to-the-pd1-drug-on-a-compassionate-basis?utm_medium=website (last visited July, 29 2015) (noting that when the change.org petition closed after Nick's death, it had 525,738 signatures); Lupkin, *supra* note 192 (providing the information on Auden's death).

199. Julia Medew, *Bittersweet Victory for 'Save Locky's Dad' Campaign Come Too Late for Nick Auden*, SYDNEY MORNING HERALD (Mar. 13, 2014), http://www.smh.com.au/national/bittersweet-victory-for-save-lockys-dad-campaign-comes-too-late-for-nick-auden-20140313-34o4o.html.

200. Dresser, *supra* note 76, at 1657 ("The selective storytelling that has dominated right-to-try campaigns presents a distorted picture of patient experiences, contributing to policies that could actually disserve patients.").

201. *See id.*

202. *See id.*; David Faber et al., *How State Right-To-Try Laws Create False Expectations*, HEALTH AFF. BLOG (May 22, 2015), http://healthaffairs.org/blog/2015/05/22/how-state-right-to-try-laws-create-false-expectations/.

federal right to try act should be enacted.[203] To be sure, certain members of Congress have taken notice of the nationwide desire to allow terminally ill patients to have access to investigational drugs and have introduced legislation to that effect. An analysis of this proposed legislation reveals whether it will be more effective than the states' attempt at right to try acts in assisting terminally ill patients to access investigational drugs. To date, several federal bills have been introduced to Congress in response to the state right to try acts.

A. Compassionate Freedom of Choice Act of 2014

One of the first bills, known as the Compassionate Freedom of Choice Act of 2014 ("CFCA"), was introduced April 10, 2014.[204] The CFCA mirrors the state right to try acts in seeking to assist terminally ill patients' access investigational drugs.[205] Importantly, the CFCA prohibits the implementation or enforcement of any law that prevents or restricts the importation, distribution, or sale of investigational drugs or devices for terminally ill patients.[206] Thus, the CFCA would allow states to enact right to try acts that would bypass FDA regulations. The CFCA only applies to terminally ill patients and requires the patients to execute an informed consent document.[207] The CFCA also prohibits the FDA from requiring the disclosure, collecting or reporting of any information related to the use of an investigational drug or device or any information related to the outcomes experienced by a terminally ill patient given an investigational drug or device.[208] Lastly, the CFCA protects from liability any person who manufactures, imports, distributes, prescribes, dispenses, or administers an investigational drug or device in any action under state or federal law for any injury arising out of use of the investigational drug, except in cases of gross negligence or willful misconduct.[209]

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203. Adriance, *supra* note 124, at 155 ("So long as the Right to Try remains a creature solely of state law, it will be unlikely to get many more drugs to patients.").

204. Compassionate Freedom of Choice of Act of 2014, H.R. 4475, 113th Cong. (2014) (hereinafter "H.R. 4475"); *see also* Right to Try Act of 2015, H.R. 3012, 114th Cong. (2015) (hereinafter "H.R. 3012"). The CFCA was referred to the Subcommittee on Health on April 11, 2014, but it never made it out of the Subcommittee. *See* All Actions Except Amendments H.R. 4475, 113th Congress, CONGRESS.GOV (April 11, 2014), https://www.congress.gov/bill/113th-congress/house-bill/4475/all-actions-without-amendments.

205. *See generally* H.R. 4475.

206. H.R. § 561A(a).

207. H.R. § 561A(b).

208. H.R. § 561A(c). Instead, reporting requirements are voluntary. H.R. § 561A(c)(2).

209. H.R. § 561B.

The CFCA appears to resolve many of the problems critics voiced about state right to try acts. At the outset, the CFCA eliminates the problem of federal preemption, since this federal law expressly allows the implementation of state right to try acts and prohibits the FDA or any other agency from prohibiting access to investigational drugs for the terminally ill.[210] The CFCA also addresses the problematic issue of drug manufacturer nonparticipation. A predominant reason for drug manufacturer nonparticipation is the perceived drug manufacturer's concern that should a terminally ill patient experience an adverse reaction to an unapproved drug it would have to be reported to the FDA, which could jeopardize the drug's final FDA approval.[211] The CFCA's exemption from reporting requirements explicitly obviates this concern and increases the likelihood for drug manufacturer participation. In addition, the waiver of liability for physicians and drug manufacturers, except in cases of gross negligence or willful misconduct, provides further incentive for participation juxtaposed with a necessary shield of protection for terminally ill patients.[212]

Representative Morgan Griffith (R-VA) who introduced the CFCA explained its importance of providing terminally ill patients with the ultimate healthcare decision-making:

> The Compassionate Freedom of Choice Act would empower patients battling deadly diseases with more control over their health care decisions. For patients whose doctors have exhausted current medical options and the patient has been told that the end of life is nearing, why should the government in Washington care what treatment the patient may choose? If I'm dying anyway, shouldn't I have the freedom to decide if the risk is worth it?[213]

The CFCA does not require the participation of the drug manufacturer, the physician or the insurance company, but it removes significant barriers to their participation, which would likely result in increased access to investigational drugs for terminally ill patients.[214]

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210. H.R. 4475 § 561A(a). *But see* David Gorski, *The Compassionate Freedom of Choice Act: Ill-advised "Right to Try" Goes Federal,* SCI.-BASED MED. (Apr. 27, 2014), https://www.sciencebasedmedicine.org/the-compassionate-freedom-of-choice-act-ill-advised-right-to-try-goes-federal/#more-31234 (acknowledging that CFCA eliminates the preemption problem, but criticizing how the expanded access will allow patients to access drugs having only undergone Phase I Testing).

211. Mineo, *supra* note 122, at 5.

212. *See* H.R. 4475 § 561B.

213. *Compassionate Freedom of Choice Act Could Save Many Lives*, ANH-USA (Apr. 15, 2014), http://www.anh-usa.org/compassionate-freedom-of-choice-act/.

214. *See id.* (describing how CFCA likely increases the willingness of drug company participation by removing FDA opposition).

B. The Right to Try Act of 2015

The federal Right to Try Act of 2015 ("the Act") was recently introduced, and as its name implies, it seeks to advance the purposes of state right to try acts.[215] Specifically, it provides the following:

> Notwithstanding the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Controlled Substances Act (21 U.S.C. 801 et seq.), and any other provision of Federal law, the Federal Government shall not take any action to prohibit or restrict the production, manufacture, distribution, prescribing, dispensing, possession, or use of an experimental drug, biological product, or device that . . . (1) is intended to treat a patient who has been diagnosed with a terminal illness; and (2) is authorized by, and in accordance with, State law.[216]

Thus, the Act facilitates state right to try acts by prohibiting the federal government from restricting terminally ill patients from access to investigational drugs pursuant to a state right to try act.[217]

The Right to Try Act of 2015 attempts to alleviate the supposed problems of state right to try acts. At the outset, federal preemption is no longer an issue, since the Act explicitly eliminates any conflict between state and federal laws by granting states the right to implement right to try laws without fear of prosecution.[218] In addition, the Act allows states the autonomy to implement the most beneficial laws for their respective states, without specifying what provision must be included. Thus, if one state desires to include a waiver of liability, except in cases of gross negligence, but another state desires to limit all liability, the Act provides for this individual state decision-making. Generally, the Act should encourage drug manufacturer participation, because the primary reason for nonparticipation by drug manufacturers is the concern of violating federal regulations and risking the wrath of the FDA should a drug manufacturer proceed with allowing terminally ill patients to access its drugs.[219] The Act easily dispels of this concern.

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215. H.R. 3012; *see also* All Actions H.R. 3012, 114th Congress, CONGRESS.GOV (July 9, 2015) (acknowledging that this Act was introduced July 9, 2015, and referred to the Committee on Energy and Commerce and the Committee on the Judiciary on the same day).

216. H.R. 3012 §2(a).

217. *Id.*

218. *Id.*

219. *See generally* James C. Shehan, *The Right to Try Act of 2015—A Serious Challenge to FDA Control of Expanded Access?*, FDA LAW BLOG (July 13, 2015), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2015/07/the-right-to-try-act-of-2015-a-serious-challenge-to-fda-control-of-expanded-access-.html (positing whether the state right to try laws will alleviate the concerns of companies to violate regulations that require prior FDA approval of expanded access).

Although the Act is not as comprehensive as the CFCA, and some commentators may suggest it does not go far enough to ease the concerns of drug manufacturers, the Act presents the necessary balance for states to enact preeminent legislation that best serves each state in creating investigational drug access for terminally ill patients, but it fundamentally safeguards from federal action those who proceed under a right to try act. A less intrusive federal act, such as the Right to Try Act of 2015, would be more likely to pass in Congress than the CFCA, which contains more far-reaching provisions. For example, the voluntary reporting requirement to the FDA could create more chance for controversy and less chance of passage.

CONCLUSION

Terminally ill patients should be afforded the same privilege as the American medical missionaries, Dr. Kent Brantley and Nancy Writebol, to access unapproved drugs that have the potential to significantly improve the patients' condition. These patients, who are nearing the end of their lives, deserve the opportunity to weigh the risks and benefits of taking an investigational drug, even if the drug could ultimately cause more harm. State right to try acts properly attempt to provide this opportunity to the terminally ill, and although these right to try acts have succeeded in bringing public awareness to this issue, the acts clearly fall short on successful implementation. To remedy the inadequacies of state right to try acts, a federal right to try act, such as the Right to Try Act of 2015, is necessary to enable the implementation of state right to try acts. If a federal right to try act is not enacted, terminally ill patients' sole option will be the FDA's broken drug approval process, a process that requires time these patients do not have.