

# “RIGHT TO TRY” LAWS: DOES THE LEGISLATURE NEED TO ‘TRY HARDER’?

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## INTRODUCTION

Stemming from the 2006 U.S. Court of Appeals for the District of Columbia’s holding that terminally ill patients have a constitutional right to access experimental drug treatments that may prolong their lives in *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*,<sup>1</sup> legislatures around the country began to introduce and pass “Right to Try” bills introduced nationwide.<sup>2</sup> This legislation seeks to expand terminally ill patients’ access to experimental, but potentially life-saving, treatment, not yet approved by the Federal Drug Administration,<sup>3</sup> where terminal illness is defined as “an incurable and irreversible condition that without the administration of life-sustaining treatment will, in the opinion of the patient’s physician, result in death within a relatively short time.”<sup>4</sup> As of spring of 2015, twenty-one states had enacted “Right to Try” laws, including: Colorado, Florida, Texas, Virginia, and Oklahoma.<sup>5</sup> Over twenty other states have introduced proposed legislation on the issue.<sup>6</sup>

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<sup>1</sup> *Abigail Alliance v. Von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006), *rev’d*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 522 U.S. 1159 (2008).

<sup>2</sup> *Legislation Would Allow ‘Right to Try’ Trial Drugs*, GOLDWATER INST. (Feb. 3, 2015), <http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/legislation-would-allow-right-to-try-trial-drugs/>.

<sup>3</sup> Richard Cauchi, “*Right to Try*” *Experimental Prescription Drugs: State Laws and Legislation for 2014 & 2015*, NAT’L CONFERENCE OF STATE LEGISLATURES (Mar. 31, 2015), <http://www.ncsl.org/documents/health/RighttoTry2015.pdf>.

<sup>4</sup> *See, e.g.*, S.B. 4, 90th Gen. Assemb., Reg. Sess. (Ark. 2015).

<sup>5</sup> Alexander Gaffney, ‘*Right to Try*’ *Legislation Tracker*, REGULATORYAFFAIRS PROF’L SOC’Y (June 25, 2015), <http://www.raps.org/Regulatory-Focus/News/Databases/2015/06/24/21133/Right-to-Try-Legislation-Tracker/>.

<sup>6</sup> *Id.*

Unfortunately, significant issues with the implementation of the legislation have already arisen, and critics of these laws have dubbed them “feel-good” laws, contending that they do not have the punch to make any real impact in the lives of chronically ill patients.<sup>7</sup> Amongst some of the most significant concerns include the role of the U.S. Food and Drug Administration (“FDA”) in the distribution of the drugs and the steep cost of their use before they become available to the public.<sup>8</sup> Opponents of the law fear that the legislation will undermine the authority of the FDA, which has regulated the movement of prescription drugs from the laboratory to the pharmacy since 1906.<sup>9</sup> Challengers also point out that the statutory language allows the manufacturer of the drug to force eligible patients to bear the cost of the drug’s use—without requiring a health care insurer or any state agency to provide coverage—effectively making these expensive treatments unavailable to many Americans even in the face of the legislation.<sup>10</sup>

Part I of this Note will describe the historical impetus behind the push for “Right to Try” legislation.<sup>11</sup> Part II will discuss the practical, logistical, and ethical concerns with “Right to Try” legislation.<sup>12</sup> Finally, Part III will focus on proposed solutions to these issues, and how if successful, “Right to Try” legislation could provide substantial benefits to terminally ill patients.<sup>13</sup>

## I. HISTORICAL BACKGROUND OF ‘RIGHT TO TRY’ LEGISLATION

### A. ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS V. ESCHENBACH

The origins behind “Right to Try” legislation stem from the death of Abigail Burroughs, a twenty-one year old student at the University of Virginia,<sup>14</sup> who was diagnosed with squamous cell

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<sup>7</sup> Kimberly Leonard, *Seeking the Right to Try*, U.S. NEWS & WORLD REPORT (Nov. 18, 2014), <http://www.usnews.com/news/articles/2014/11/18/right-to-try-laws-allowing-patients-to-try-experimental-drugs-bypass-fda>.

<sup>8</sup> See Cauchi, *supra* note 3 (noting some of the concerns of ‘right to try’ legislation critics).

<sup>9</sup> *History*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/> (Nov.. 3, 2016).

<sup>10</sup> Kimberly Leonard, *supra* note 7.

<sup>11</sup> See *infra* text accompanying notes 14-63.

<sup>12</sup> See *infra* text accompanying notes 64-150.

<sup>13</sup> See *infra* text accompanying notes 151-192.

<sup>14</sup> Judy Foreman, *Dying Patient’s Fight to Access Trial Drugs Met With*

carcinoma<sup>15</sup> in her neck and lungs at age nineteen.<sup>16</sup> Burroughs' oncologist recommended that she enroll in clinical trials for two different drugs, Erbitux and Iressa,<sup>17</sup> which targeted the same growth receptors that Abigail's cancer cells expressed.<sup>18</sup> However, despite the fact that the drugs were available and could potentially save her life, Burroughs was denied access to the clinical drugs because they had only been approved for other types of cancers.<sup>19</sup> In May of 2001, Burroughs was admitted to a clinical trial for a different drug, Tarceva,<sup>20</sup> but became too ill to travel to the testing site in Texas and died two weeks later, at the age of twenty-one.<sup>21</sup>

Following her death, Abigail's father and Steven Walker, whose deceased wife had also been denied access to clinical trials,<sup>22</sup> co-founded the Abigail Alliance, a nonprofit patient advocacy organization "committed to helping create wider access to developmental cancer drugs and other drugs for serious life-threatening illnesses."<sup>23</sup> Together with the Washington Legal Foundation, a consumer rights activist organization,<sup>24</sup> the Abigail Alliance initiated an action against FDA Commissioner Andrew von Eschenbach and the U.S. Department of Health and Human Services Secretary Michael Leavitt,<sup>25</sup> seeking to enjoin them from

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*Resistance*, THE BALTIMORE SUN (Sept. 29, 2003), [http://articles.baltimoresun.com/2003-09-29/news/0309290141\\_1\\_experimental-drugs-abigail-burroughs-new-drugs](http://articles.baltimoresun.com/2003-09-29/news/0309290141_1_experimental-drugs-abigail-burroughs-new-drugs).

<sup>15</sup> Squamous cell carcinomas refer to cancer that originates in squamous cells—thin and flat cells found in the tissue that forms the surface of the skin, the lining of the hollow organs of the body, and the lining of the respiratory and digestive tracts. *NCI Dictionary of Cancer Terms*, NAT'L CANCER INST., <https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=46595> (last visited Nov. 9, 2016).

<sup>16</sup> Elizabeth Weeks Leonard, *The Public's Right to Health: When Patient Rights Threaten the Commons*, 86 WASH. U. L. REV. 1335, 1366 (2009); Nicholas J. Plionis, *The Right to Access Experimental Drugs: Why the FDA Should Not Deprive the Terminally Ill of a Chance to Live*, 16 WM. & MARY BILL RTS. J. 901, 901 (2008).

<sup>17</sup> Plionis, *supra* note 16, at 901.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> Elizabeth Weeks Leonard, *supra* note 16, at 1366.

<sup>23</sup> Elizabeth Weeks Leonard, *supra* note 16, at 1366; *The Abigail Alliance Mission*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/mission.php> (last visited Nov. 11, 2015).

<sup>24</sup> *WLF Mission*, WASH. LEGAL FOUND., <http://www.wlf.org/org/mission.asp> (last visited Nov. 20, 2016).

<sup>25</sup> *Abigail Alliance v. Von Eschenbach*, 445 F.3d 470, 471-72 (D.C. Cir. 2006).

continuing to ban the sale of new drugs that had passed through Phase I trials and that had been determined safe for “expanded human testing” to terminally ill patients.<sup>26</sup> The complaint was framed as a substantive due process issue,<sup>27</sup> where the plaintiffs alleged that terminally ill patients who exhausted all other government-approved treatment options have a constitutionally guaranteed right to pre-FDA approved experimental drugs.<sup>28</sup> The D.C. Circuit dismissed the complaint for failure to state a claim, noting that never had a court extended the Due Process Clause to include a terminally ill patient’s right to life-prolonging drugs.<sup>29</sup> On appeal, however, the D.C. Circuit reviewed the case using a *de novo* standard, and disagreed - finding that the Alliance’s claims “falls squarely within the realm of rights the Supreme Court has held are ‘implicit in the concept of ordered liberty.’”<sup>30</sup> In finding the right to be fundamental in nature, the Court relied on the U.S. Supreme Court’s determination in *Cruzan v. Director, Mo. Department of Health* that Due Process protects a person’s right to refuse life-sustaining treatment.<sup>31</sup> In announcing the opinion of the court, Justice Rogers stated:

[W]here there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Clause. The prerogative asserted by the FDA - to prevent a terminally ill patient from using potentially life-saving medication to which those in Phase II clinical trials have access - thus impinges upon an individual liberty deeply rooted in our Nation’s history and tradition of self-preservation.<sup>32</sup>

The court’s recognition of the right to experimental drugs as a fundamental right “deeply rooted in our Nation’s history and tradition”<sup>33</sup> was significant; the court even “likened” it to previously recognized constitutional rights to use contraceptives, have abortions, refuse medical treatment, and engage in intimate

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<sup>26</sup> *Id.* at 472..

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 474.

<sup>30</sup> *Id.* at 475, 483–84 (citing *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)).

<sup>31</sup> *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 279 (1990).

<sup>32</sup> *Abigail Alliance*, 445 F.3d at 486.

<sup>33</sup> *Wash. v. Glucksberg*, 521 U.S. 702, 720–21(1997).

association.”<sup>34</sup> However, the court found the right to be narrow, limited to only terminally ill and mentally competent patients who had already exhausted all other options and consulted with their physicians,<sup>35</sup> and applied only to drugs that had passed through Phase I of the FDA’s drug approval process, which only establishes that the drug is not toxic or poisonous to humans.<sup>36</sup>

Unfortunately for proponents of the Abigail Alliance for Better Access to Development Drugs, the D.C. Circuit’s decision only remained precedent for a short sixteen months, at which point the full court en banc overturned it.<sup>37</sup> On August 7, 2008, the D.C. Circuit affirmed the district court determination,<sup>38</sup> “which had declined to recognize a right to experimental drug treatment” as fundamental.<sup>39</sup> The D.C. Circuit framed the issue as a right to access “something currently inaccessible – drugs that the FDA has not yet approved for marketing.”<sup>40</sup> The Supreme Court denied certiorari on January 14, 2008.<sup>41</sup>

Despite the D.C. Circuit’s reversal, the decision generated interest in the access to experimental drugs, along both sides of the Congressional aisle.<sup>42</sup> Free-market proponents advocated for the recognition of increased individual rights, consumer safety supporters urged for increased regulation of drug development, and the FDA responded by proposing amendments to its existing “compassionate use” and “emergency use” policies.<sup>43</sup>

## B. STATE EFFORTS

On May 17, 2014, almost exactly thirteen years after Abigail Burroughs’ death,<sup>44</sup> Governor John Hickenlooper of Colorado signed into law the first “Right to Try” legislation, which passed unanimously in the state legislature.<sup>45</sup> The legislation recognizes

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<sup>34</sup> Elizabeth Weeks Leonard, *supra* note 16, at 1367.

<sup>35</sup> *Id.* at 1367.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 1365.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> Kelly Weeks Leonard, *supra* note 16, at 1373.

<sup>41</sup> *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 552 U.S. 1159 (2008).

<sup>42</sup> Elizabeth Weeks Leonard, *supra* note 16, at 1350.

<sup>43</sup> *Id.*

<sup>44</sup> See Frank Burroughs, *Our Story*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/story.php> (last visited Nov. 28, 2016).

<sup>45</sup> Kristen Wyatt, *Colorado’s ‘Right to Try’ Law Will Give Some Patients*

the urgent need for effective medication some terminal patients face,<sup>46</sup> stating that: “[p]atients who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States Food and Drug Administration.”<sup>47</sup> The eight sections of the defined “Right to Try” Act set forth the purpose of the statute, the qualifications for eligibility, and the required consultation and physician approval process.<sup>48</sup> The law seems to contravene the holding of the D.C. Circuit in *Abigail Alliance*, stating: “Patients who have a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices.”<sup>49</sup> Sponsor Senator Irene Aguilar called the legislation the “Dallas Buyer’s Club” bill,<sup>50</sup> referring to the 2013 award-winning film about the true story of an AIDS patient who smuggled non-FDA approved investigational treatments into the U.S.<sup>51</sup>

Arizona became the fifth state to pass “Right to Try” legislation,<sup>52</sup> and the first state to do so via a ballot initiative, Proposition 303.<sup>53</sup> The ballot passed with more than 78% of the vote,<sup>54</sup> and included provisions that allowed a manufacturer to provide eligible patients with an “investigational drug, biological product or device” without receiving any compensation.<sup>55</sup> The

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*Access to Experimental Drugs*, THE HUFFINGTON POST (May 18, 2014) [http://www.huffingtonpost.com/2014/05/18/colorado-right-to-try-law-experimental-drugs\\_n\\_5347490.html](http://www.huffingtonpost.com/2014/05/18/colorado-right-to-try-law-experimental-drugs_n_5347490.html).

<sup>46</sup> See COL. REV. STAT. § 25-45-102(1)(b) (2016).

<sup>47</sup> COL. REV. STAT. § 25-45-102(1)(b) (2016).

<sup>48</sup> COL. REV. STAT. §§ 25-45-101 to 108 (2016).

<sup>49</sup> COL. REV. STAT. § 25-45-102(1)(c) (2016); See *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 495 F.3d 695, 697 (D.C. Cir. 2007).

<sup>50</sup> Wyatt, *supra* note 45.

<sup>51</sup> See *Id.*

<sup>52</sup> See Starlee Coleman, *Arizona Voters Pass “Right to Try” For Terminally Ill Patients* (Nov. 5, 2014), <http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/arizona-voters-pass-right-to-try-for-terminally-il/>.

<sup>53</sup> Coleman, *supra* note 52; Jason Millman, *Voters in Arizona Just Overwhelmingly Backed a ‘Dallas Buyers Club’ Law. Will it Help Patients?*, THE WASH. POST (Nov. 5, 2014), <https://www.washingtonpost.com/news/wonk/wp/2014/11/05/voters-in-arizona-just-overwhelmingly-backed-a-dallas-buyers-club-law-will-it-help-patients/>.

<sup>54</sup> Chuck Warren & Tim Mooney, *Your ‘Right to Try’ Belongs on Arizona Ballot*, ARIZ. CAP. TIMES, (Mar. 27, 2014), <http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/arizona-voters-pass-right-to-try-for-terminally-il/>.

<sup>55</sup> ARIZ. REV. STAT. ANN. § 36-1312(B)(1)(2016).

statutory provisions are structured similarly to Colorado's groundbreaking legislation.<sup>56</sup>

As of June 25, 2015, twenty-one states had passed "Right to Try" legislation,<sup>57</sup> and more than twenty others, including New York, Massachusetts, and California, had submitted pending legislation.<sup>58</sup> Texas became the twenty-first state to pass this legislation,<sup>59</sup> signing Texas House Bill 21 into law on June 16, 2015 by an 87-44 vote.<sup>60</sup> The Goldwater Institute is the major lobbying firm behind these legislative efforts,<sup>61</sup> calling the FDA the "arbiter of life and death" and classifying the FDA-imposed burdens faced by terminally ill patients as a "violation of [their] personal liberty."<sup>62</sup> The Institute applauds the states that have passed such legislation thus far, and expect the trend to continue.<sup>63</sup>

## II. PRACTICAL PROBLEMS WITH IMPLEMENTING 'RIGHT TO TRY' LEGISLATION

Although the legislation is relatively new, there are already some significant issues with its implementation.<sup>64</sup> The promise behind the legislation lies in its attempt to cut through "bureaucratic red tape" that threatens the ability of the terminally ill to access potentially life-saving drugs.<sup>65</sup> However

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<sup>56</sup> Compare ARIZ. REV. STAT. ANN. §§ 36-1311 to 1312 (2016) with COL. REV. STAT. § 25-45-102 (2016).

<sup>57</sup> Gaffney, *supra* note 5.

<sup>58</sup> Gaffney, *supra* note 5.

<sup>59</sup> Starlee Coleman, *Texas Becomes 21st State to Allow Terminally Ill to Access Investigational Medications*, GOLDWATER INST. (June 12, 2015), <http://www.goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/texas-becomes-21st-state-to-allow-terminally-ill-t/>.

<sup>60</sup> *Texas House Bill 21*, LEGISCAN (June 16, 2015), <https://legiscan.com/TX/bill/HB21/2015>.

<sup>61</sup> Julie Turkewitz, *Patients Seek 'Right to Try' New Drugs*, N.Y. TIMES (Jan. 10, 2015), [http://www.nytimes.com/2015/01/11/us/patients-seek-right-to-try-new-drugs.html?\\_r=0](http://www.nytimes.com/2015/01/11/us/patients-seek-right-to-try-new-drugs.html?_r=0).

<sup>62</sup> Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill To Take Control of Their Treatment*, GOLDWATER INST. (Feb. 11, 2014), [https://goldwater-media.s3.amazonaws.com/cms\\_page\\_media/2015/1/28/Right%20To%20Try.pdf](https://goldwater-media.s3.amazonaws.com/cms_page_media/2015/1/28/Right%20To%20Try.pdf).

<sup>63</sup> Wall Street Journal Staff, *'Right to Try' Rolls On*, GOLDWATER INST. (Aug. 20, 2015), <http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/opinion-journal-right-to-try-rolls-on/>.

<sup>64</sup> See Cauchi, *supra* note 3.

<sup>65</sup> Steven Ross Johnson, *Despite Political Support, State Right-to-Try Bills Show No Takeup*, MODERN HEALTHCARE (Oct. 17, 2015), <http://www.modernhealthcare.com/news/despite-political-support-state-right-to-try-bills-show-no-takeup>.

the statutes provide little guidance to patients, physicians and pharmaceutical companies on how to effectively implement the statutory directives.<sup>66</sup> For example, although Louisiana was one of the first five states to pass the legislation,<sup>67</sup> a spokeswoman for the Louisiana State Medical Society said the organization has only received two requests thus far from terminally ill patients seeking access to investigational drugs.<sup>68</sup> Alison Bateman-House, a postdoctoral fellow at New York University's Langone Medical Center's Division of Medical Ethics,<sup>69</sup> summarized the issues facing implementation, saying: "I think that politically, (right to try) has been seen as a very positive and proactive thing to support. . . . There seems to be some sort of willful blindness to seeing whether it works or not."<sup>70</sup> The various practical and ethical issues facing efficient implementation of "Right to Try" legislation will be discussed in Part II of this note.<sup>71</sup>

A. POTENTIAL TO UNDERMINE THE FOOD AND DRUG  
ADMINISTRATION'S AUTHORITY.

First, critics of the "Right to Try" laws caution that the legislation undermines the FDA's expertise and authority to aid in pharmaceutical development and regulation.<sup>72</sup> Under FDA protocol, pharmaceutical drugs must pass through several phases.<sup>73</sup> In the first phase, sponsors of the proposed drug must test the drugs on animals before starting to test the drug on about 20-80 healthy humans in order to determine what the drug's most frequent side effects are and how the drug is

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thcare.com/article/20151017/MAGAZINE/310179969.

<sup>66</sup> *Id.*

<sup>67</sup> Gaffney, *supra* note 5; Alison Bateman-House, "Right to Try" Laws, *Compassionate Use, and Adverse Events: A Second Cautionary Tale*, BIOETHICS.NET (Mar. 11, 2015), <http://www.bioethics.net/2015/03/right-to-try-law-s-compassionate-use-and-adverse-events-a-second-cautionary-tale/>.

<sup>68</sup> Johnson, *supra* note 65.

<sup>69</sup> Alison Bateman-House NYU School of Medicine Faculty and Staff Profile, NYU SCHOOL OF MEDICINE <http://www.med.nyu.edu/pophealth/staff/batema02> (last visited Nov. 27., 2016).

<sup>70</sup> Johnson, *supra* note 65.

<sup>71</sup> See *infra* text accompanying notes 64-150.

<sup>72</sup> Cauchi, *supra* note 3 ("There is also concern that such bills attempt to undermine FDA's authority and medical expertise in the regulations of pharmaceutical products.").

<sup>73</sup> See *The FDA's Drug Approval Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD AND DRUG ADMIN. (Nov. 6, 2014), <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm>

metabolized.<sup>74</sup> If Phase I does not reveal “unacceptable toxicity” to humans, the effectiveness of the drug is tested in Phase II by comparing patients receiving the treatment to patients receiving a comparable drug or placebo.<sup>75</sup> The safety of the drug continues to be evaluated in Phase II,<sup>76</sup> and if the results are positive at the end of this phase, the FDA determines how comprehensive trials in Phase III will be.<sup>77</sup> Phase III involves a more comprehensive evaluation of the drug’s safety level and effectiveness, using differentiated sample populations, various dosage levels, and combining the drug with other prescriptions.<sup>78</sup> This final phase of testing generally involves testing of several hundred to thousands of subjects, and generally takes several years to complete.<sup>79</sup>

Under “Right to Try” legislation, eligible patients may obtain access to clinical trials of drugs after they have passed through Phase I, determined not “unacceptabl[y] toxic[.]”<sup>80</sup> Critics of the legislation note that patients seeking these treatments may be “exposed to the dangers of drugs” with more limited clinical testing, possibly worsening the patient’s condition rather than offering any effective solution.<sup>81</sup>

Furthermore, opponents of “Right to Try” legislation worry that the allowing early access to these drugs will “disrupt” the current FDA process for approving “compassionate use” of unapproved drugs.<sup>82</sup> Under current federal policy, a physician review board and FDA representatives evaluate requests by terminally ill patients to access experimental medications, weighing whether the patient has already exhausted other

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<sup>74</sup> *Id.*

<sup>75</sup> *Id.*; *Guidance for Industry: E10 Choice of Control Groups and Related Issues in Clinical Trials*, U.S. DEP’T OF HEALTH AND HUMAN SERVICES ET AL., (May 2001), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073139.pdf> (“In a placebo controlled trial, subjects are randomly assigned to a test treatment or to an identical-appearing treatment that does not contain the test drug.”).

<sup>76</sup> See *The FDA’s Drug Approval Process*, *supra* note 73.

<sup>77</sup> See *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*; Plionis, *supra* note 16, at 903.

<sup>81</sup> See Cauchi, *supra* note 3 (“They also say that patients may be exposed to the dangers of drugs with limited testing . . .”).

<sup>82</sup> Lisa Rapaport, *U.S. ‘Right to Try’ Laws May Not Help Dying Get Unapproved Drugs*, REUTERS (Sept. 28, 2015), <http://www.reuters.com/article/2015/09/28/us-health-dying-experimental-drugs-idUSKCN0RS2LN20150928>. See 21 C.F.R. §312.

options and any potential risks of the medication.<sup>83</sup> Although the FDA approved over 99% of “compassionate use” applications received between 2010 and 2014,<sup>84</sup> “Right to Try” advocates point out that the arduous application process can take a physician up to 100 hours to complete,<sup>85</sup> and the 99% approval rate reflects only a fraction of the patients who may have benefited from receiving experimental treatment.<sup>86</sup> Goldwater Institute President Kurt Altman explains that “Right to Try” legislation is necessary because the current “compassionate care” system does not move quickly enough for terminally ill patients seeking access to potentially life saving clinical treatment.<sup>87</sup> On February 4, 2015, the FDA announced plans to significantly cut down the application preparation time,<sup>88</sup> streamlining the process so that the application only takes about 45 minutes to complete, but have not implemented this new process thus far.<sup>89</sup> “Right to Try” advocates point out that despite an updated “compassionate care” drug use process, the amount of terminally ill patients needing use of experimental drugs is too overwhelming for the FDA to process, and a separate approval system is necessary to be effective.<sup>90</sup>

Moreover, “Right to Try” opponents suggest that without FDA oversight of experimental use, clinical data from patients who try the drugs will be “lost knowledge”<sup>91</sup> - with no way for the FDA to collect, analyze or use this data for their own clinical testing.<sup>92</sup>

Another concern of “Right to Try” opponents is that the legislation will instill a false sense of hope that the experimental treatments will prove successful even with limited clinical testing,<sup>93</sup> although the reality is that the treatments may fail to cure or even treat the patient’s illness.<sup>94</sup> Supporters of “Right to

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<sup>83</sup> See Rapaport, *supra* note 82.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> Cauchi, *supra* note 3.

<sup>89</sup> See Rapaport, *supra* note 82.

<sup>90</sup> *Id.*

<sup>91</sup> *Expansion of ‘Right to Try’ Legislation Raises Ethical, Safety Concerns*, HEALIO HEMONC TODAY (April 25, 2015), <http://www.healio.com/hematology-oncology/practice-management/news/print/hemonc-today/%7Bc801b6ee-318e-4fce-9dfa-a29c597028b9%7D/expansion-of-right-to-try-legislation-raises-ethical-safety-concerns>.

<sup>92</sup> *Id.*

<sup>93</sup> Cauchi, *supra* note 3.

<sup>94</sup> See *id.*

Try” legislation contend that any sense of hope is better than having none,<sup>95</sup> that providing the drugs to patients willing to experiment with them may actually accelerate the FDA approval process,<sup>96</sup> and that terminally ill patients have little to lose even if the drugs end up being ineffective.<sup>97</sup>

#### B. COST.

Most importantly, “Right to Try” legislation does not address what critics say presents the largest barrier to implementation: cost.<sup>98</sup> Although providing theoretical access to the experimental prescription treatments, current “Right to Try” legislation does not require health insurers to pay for any portion of the experimental treatment or subsequent care that may be required as a result of the treatment.<sup>99</sup> For example, Arizona’s legislation specifically provides that a manufacturer may “[r]equire an eligible patient to pay the costs of or associated with the manufacture of the investigational drug, biological product or device.”<sup>100</sup> The statutory language makes the cost-shifting issue very clear, indicating that: “This article does not require a health care insurer or any state agency to provide coverage for the cost of any investigational drug, biological product or device. A health care insurer may provide coverage for an investigational drug, biological product or device.”<sup>101</sup> Similarly, the Texas Insurance Code stipulates that although the law requires insurance companies to provide coverage for medically necessary services or treatment for chronically ill patients, “[the law] does not require a health benefit plan to cover experimental drugs that are not otherwise approved for an indication by the United States Food and Drug Administration.”<sup>102</sup>

Of course, paying for a patient to use a not-yet approved clinical trial drug that is still in the clinical trial phase subjects the pharmaceutical company to enormous liability,<sup>103</sup> and does

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<sup>95</sup> *Id.*

<sup>96</sup> See Rapaport, *supra* note 82.

<sup>97</sup> See Cauchi, *supra* note 3.

<sup>98</sup> See FAQ, RIGHTTO TRY.ORG, <http://righttotry.org/faq/> (last visited Nov. 27, 2016).

<sup>99</sup> Johnson, *supra* note 65.

<sup>100</sup> ARIZ. REV. STAT. ANN. § 36-1312(B)(2) (2014).

<sup>101</sup> ARIZ. REV. STAT. ANN. § 36-1312(C) (2014).

<sup>102</sup> TEX. INS. CODE ANN. §1369.004(d)(1) (2003) (effective April 1, 2005).

<sup>103</sup> See Alison Bateman-House, “Right to Try” Laws, Compassionate Use, and

not provide much benefit financially.<sup>104</sup> By the nature of their business, pharmaceutical companies derive their profit margins from population-not individual-use.<sup>105</sup> Companies like Pfizer and Merck & Co. pour millions of dollars into the development of a single drug, and rely on a population of subjects to test it.<sup>106</sup> During testing, the companies draw distinctions based on the age, sex, genetic markers, and hormone receptors of the test subjects as a gauge as to the side effects of each group.<sup>107</sup> If the pharmaceutical companies were to provide a clinically ill patient with access to a drug that had not yet been fully approved, and that patient had a negative or even fatal reaction, this could heavily damage the drug's marketability to the population.<sup>108</sup> It is not surprising that pharmaceutical companies choose to prioritize the needs of the "population" over the life of a dying individual, as they market their products off the very population results they test for.<sup>109</sup> Big Pharma's refusal to pay for the experimental drug treatments isn't due to a lack of compassion for the patients requesting them, it's strategic and business-oriented.<sup>110</sup>

The IMS Institute for Healthcare Informatics reported that total spending on FDA approved prescription drugs alone hit a record high in 2014, increasing to 10.3% of real capital and totaling \$373.9 billion.<sup>111</sup> Over 4.3 billion prescriptions were filled by pharmacies across the United States, and just the introduction of new—FDA approved—drugs to the market alone cost a steep \$20.3 billion.<sup>112</sup> The IMS attributes this jump in prescription drug spending to increased spending on "innovative new treatment options" and price tag increases for brand-name medicines.<sup>113</sup>

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*Adverse Events: A Second Cautionary Tale*, BIOETHICS.NET (March 11, 2015), <http://www.bioethics.net/2015/03/right-to-try-laws-compassionate-use-and-adverse-events-a-second-cautionary-tale/>.

<sup>104</sup> *See Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *See Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *See Id.*

<sup>109</sup> *See* Alison Bateman-House, *supra* note 103.

<sup>110</sup> *See id.*

<sup>111</sup> Tor Constantino, *IMS Health Study: 2014 a Record-Setting Year for U.S. Medicines*, IMS HEALTH (Apr. 13, 2015), <http://www.imshealth.com/en/about-us/news/ims-health-study-2014-a-record-setting-year-for-u.s.-medicines>.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

And that price tag is hefty. The average cost of developing a single experimental prescription drug that obtains FDA approval totals at a cool \$350 million.<sup>114</sup> For companies that develop several drugs per year—somewhere between eight and thirteen—the total spikes to about \$5.5 billion per year.<sup>115</sup>

Number of drugs approved	R&D cost per drug (\$MIL) <sup>116</sup>	
	<i>Median</i>	<i>Mean</i>
8 to 13	5459	5998
4 to 6	5151	5052
2 to 3	1803	2303
1	351	953

**Sources: Innothink Center For Research In Biomedical Innovation; FactSet Systems.**

These high production costs ultimately shift to consumers of the drug, producing brand name prescriptions ranging up to \$750 a tablet.<sup>117</sup> Without FDA approval, the price tag on the Phase I drugs would be determined exclusively by the manufacturer of the drug and it is unlikely they would be anywhere as affordable as over the counter medications in an unregulated and novel area of pricing.<sup>118</sup> In addition, the patient would likely need to travel in order to obtain access to the drug while it is in clinical trials, in

<sup>114</sup> Matthew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013, 11:10 AM), <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#6650b8ec6bfc>.

<sup>115</sup> *Id.*

<sup>116</sup> Matthew Herper, *supra* note 114 (citing Innothink Center For Research in Biomedical Innovation; Factset Systems).

<sup>117</sup> See, Elizabeth O'Brien, *Why Drug Prices Remain Insanely High and 6 Things You can do to Save*, MARKET WATCH, (Sept. 21, 2015 12:40 PM), <http://www.marketwatch.com/story/six-tips-for-fighting-rising-prescription-drug-costs-2015-09-15> (explaining that Daraprim, a drug that treats serious parasitic infections, rose in price from \$13.50 to \$750 a tablet overnight).

<sup>118</sup> Kimberly Leonard, *supra* note 7.

some cases<sup>119</sup> requiring travel of long distances.<sup>120</sup> Dr. Ezekiel Emmanuel, Chair of the Department of Medical Ethics & Health Policy at the University of Pennsylvania,<sup>121</sup> worries that “Right to Try” legislation will widen the gap between the rich and poor’s access to healthcare, explaining that those who are able to travel and can afford the cost of this experimental medicine without healthcare insurance are likely to be well-connected and well-resourced.<sup>122</sup> Calling the drugs “implicitly discriminatory,”<sup>123</sup> Emmanuel states that “they are widening disparities rather than helping people get access to medication that works.”<sup>124</sup>

Proponents of “Right to Try” legislation argue that some companies may elect to provide access to the clinical trials without cost,<sup>125</sup> that travelling within the United States to access the experimental drug is preferential to travelling abroad,<sup>126</sup> and that a substantial push for the passage of “Right to Try” legislation has come from patients – indicating their willingness, in part, to accept these unintended consequences of access to potentially life-saving treatment.<sup>127</sup> However, determining how these terminally ill patients, already facing steep medical bills, will be able to afford these experimental drugs in the face of rising prescription costs has yet to be addressed by any of the enacted “Right to Try” statutes.<sup>128</sup>

### C. ACTUAL IMPLEMENTATION LOGISTICS.

The third major area of concern for “Right to Try” opponents and advocates alike is in the area of implementation.<sup>129</sup> Although allowing patients access to the experimental drugs, most of the relevant legislation does not address how this program will be implemented.<sup>130</sup> For example, Arizona’s three part statute

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<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> Kimberly Leonard, *supra* note 7.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *See infra* Part II(b).

<sup>129</sup> *See* Cauchi, *supra* note 3.

<sup>130</sup> *See Expansion of ‘Right to Try’ Legislation Raises Ethical, Safety Concerns*, *supra* note 91.

consists of only seven sentences,<sup>131</sup> none of which address how the patients can apply for access, who will actually review the requests, what board, agency or other entity will distribute the experimental drugs, and how manufacturers will supply the patients with the drugs, among other unanswered concerns.<sup>132</sup> Even Florida's more comprehensive nine-part statute does not address actual implementation of the program,<sup>133</sup> completely failing to speak to how the state health department will seek to enforce the law.<sup>134</sup>

In a statement to HemOnc Today, W. Thomas Purcell, M.D., Associate Director for Clinical Services at the University of Colorado Cancer Center and Executive Medical Director of Oncology Services at University of Colorado Hospital,<sup>135</sup> emphasized that not addressing implementation issues makes the execution of the bill more "challenging" and effectiveness less certain.<sup>136</sup> Speaking to Colorado's pioneering statute, he asks:

If the drug is made available, who is going to administer it? Who is going to pay for any side effects related to the treatment? Are insurance companies going to cover any treatment-related complications? There are a lot of practical things that come into play with the introduction of the law, although the law doesn't address any of those things.<sup>137</sup>

Arthur Caplan, Director of the Division of Medical Ethics in NYU Langone Medical Center's Department of Population Health,<sup>138</sup> goes a bit further, stating: "[Right to try laws] promise more than they can deliver. These laws are easy to vote for but accomplish almost nothing. They're feel-good laws."<sup>139</sup> In states with "Right to Try" legislation in place, terminally ill patients have to request access to the not-yet approved drugs directly from the manufacturer pharmaceutical company.<sup>140</sup> How the patient

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<sup>131</sup> ARIZ. REV. STAT. ANN. § 36-1312 (2014).

<sup>132</sup> ARIZ. REV. STAT. ANN. § 36-1312 (2014).

<sup>133</sup> FLA. STAT. § 499.0295 (2016).

<sup>134</sup> FLA. STAT. § 499.0295 (2016).

<sup>135</sup> *Expansion of 'Right to Try' Legislation Raises Ethical, Safety Concerns*, *supra* note 91.

<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

<sup>138</sup> *Faculty & Staff*, N.Y.U., LAGONE MED. CTR., DEPT OF POPULATION HEALTH, <http://www.med.nyu.edu/pophealth/faculty/caplaa01>.

<sup>139</sup> Kimberly Leonard, *supra* note 7.

<sup>140</sup> See Shawn Radcliffe, *'Right to Try' Legislation Movement Wants Terminally Ill to Get Experimental Drugs*, HEALTHLINE NEWS (June 8, 2015), <http://www.healthline.com/health-news/right-to-try-movement-wants-terminally>

or patient's physician goes about doing this, whether the pharmaceutical company has a formal process in place, how long it will take for the company to respond to the applicant, and whether the company has a surplus supply of the drug, outside what is being used in clinical trials, is left up to the individual manufacturing companies.<sup>141</sup>

Pfizer Inc. has actually launched its own separate website devoted to dealing with the concerns of terminally ill patients looking for experimental access, named PfizerCAREs.<sup>142</sup> Through this webpage, a patient's physician can submit a "compassionate access" request and communicate directly with Pfizer representatives while using the experimental drug so Pfizer can track the patient's progress, answer any questions the physician has, and address patient health concerns.<sup>143</sup> In a press release by Pfizer's Chief Medical Officer, Freda Lewis-Hall,<sup>144</sup> the company outlined the experimental use request process, clarifying that the company strives to respond to compassionate access inquiries within five days of submittal and promises to work with the patient's care team to determine whether the potential benefits and risks of using the experimental drug are suitable for the terminally ill patient.<sup>145</sup> However, the document specifies that even if Pfizer approves the experimental drug request, it will be sent to the U.S. Food and Drug Administration for final approval.<sup>146</sup> How long this total process will ultimately take and what criteria the FDA will use to review these requests is not specified.<sup>147</sup> Other pharmaceutical manufacturers, like Abbott Laboratories, Merck & Co., and Proctor & Gamble do not provide any information about how terminally ill patients can request compassionate access to their not-yet approved prescription

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-ill-to-get-experimental-drugs-060815#5.

<sup>141</sup> *See id.*

<sup>142</sup> *Pfizer Compassionate Access Request System*, PFIZERCAREs, [http://www.cybergrants.com/pls/cybergrants/quiz.display\\_question?x\\_gm\\_id=5686&x\\_quiz\\_id=6884&x\\_order\\_by=1](http://www.cybergrants.com/pls/cybergrants/quiz.display_question?x_gm_id=5686&x_quiz_id=6884&x_order_by=1) (last visited Dec. 6, 2016).

<sup>143</sup> *Id.*

<sup>144</sup> *Meet Our Executives: Freda C. Lewis-Hall, M.D., DFAPA*, PFIZER, [http://www.pfizer.com/about/leadership\\_and\\_structure/leadership\\_executives/freda-c-lewis-hall-md-dfapa](http://www.pfizer.com/about/leadership_and_structure/leadership_executives/freda-c-lewis-hall-md-dfapa) (last visited Dec. 6, 2016).

<sup>145</sup> *Transcript of video: A Message from Pfizer's Chief Medical Officer, Fred Lewis-Hall, M.D. about Compassionate Access*, [http://www.pfizer.com/files/research/Compassionate\\_Access\\_video\\_transcript.pdf](http://www.pfizer.com/files/research/Compassionate_Access_video_transcript.pdf).

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

drugs.<sup>148</sup>

### III. PROPOSALS TO FIX

Although there has yet to be a push by lawmakers towards enacting a federal “Right to Try” law,<sup>149</sup> the major vehicle for patching up the holes in “Right to Try” legislation lies in the passage of federal legislation.<sup>150</sup> The proposed ‘21<sup>st</sup> Century Cures Act,’ sponsored by Republican representative Fred Upton of Michigan<sup>151</sup> has already been proposed and was introduced to the House on May 19<sup>th</sup>, 2015.<sup>152</sup> The stated purpose of the legislation was “[t]o accelerate the discovery, development, and delivery of 21<sup>st</sup> century cures.”<sup>153</sup> The legislation has three parts:<sup>154</sup> focusing on how the pharmaceutical industry can improve its overall collection and analysis of patient data, how the FDA can improve its current compassionate care program, and improving prescription drug manufacturing efficiency.<sup>155</sup>

Although this bill is comprehensive in its’ regulation of the pharmaceutical drug industry,<sup>156</sup> it attempts to front-load patient concerns without addressing or bolstering “Right to Try” legislation specifically.<sup>157</sup> The legislation is preventative,<sup>158</sup> targeting the provision of healthcare and drug approval process directly by trying to beef up the federal government’s regulation of the drug industry, inter-company relations among drug manufacturing companies, and FDA protocols in an effort to produce a more efficient FDA drug approval process, making eradication of the need for “Right to Try” legislation the likely goal.<sup>159</sup>

First, the legislation focuses heavily on the coordination of

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<sup>148</sup> See ABBOTT LABORATORIES, <http://www.abbott.com> (last visited Dec. 2016); MERCK & CO., <http://www.merck.com/index.html> (last visited Dec. 2016); PROCTOR & GAMBLE, <http://us.pg.com> (last visited Dec. 2016).

<sup>149</sup> Johnson, *supra* note 65.

<sup>150</sup> H.R. 6, 114th Cong. (1st Sess. 2015–2016).

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> See H.R. 6, 114th Cong. (1st Sess. 2015–2016).

<sup>156</sup> See *id.*

<sup>157</sup> *Id.*

<sup>158</sup> See *Id.*

<sup>159</sup> See *supra* notes 135-150 and accompanying text.

research and analysis efforts by both the FDA and other independent data collection centers and laboratories.<sup>160</sup> Section A details how “patient experience data” will be collected in order to enhance risk-benefit assessments of prescription drugs and treatments.<sup>161</sup> This Section is intended to tighten up how the FDA analyzes prescription drug use – possibly intended to supplement what opponents fear “Right to Try” legislation is lacking.<sup>162</sup> Patient experience data is defined as,

data collected by patients, parents, caregivers, patient advocacy organizations, disease research foundations, medical researchers, research sponsors, or other parties determined appropriate by the [Department of Health and Human Services] Secretary that is intended to facilitate or enhance the Secretary’s risk-benefit assessments, including information about the impact of a disease or therapy on patients’ lives.<sup>163</sup>

Likewise, Subtitle B qualifies how drug development data will be collected among data collection entities,<sup>164</sup> prescribing a “transparent” and multi-entity coordination process meant to “encourage the development of accessible databases for collecting relevant drug development tool data” which can be used to determine the effectiveness of the drugs.<sup>165</sup>

Subtitle C shifts the focus to the FDA specifically, calling for the FDA’s advancement of precision medicine, or “the provision of care for diseases that can be precisely diagnosed, whose causes are understood, and which consequently can be treated with rules-based therapies that are predictably effective.”<sup>166</sup> This Subtitle is preventative – pushing the medical profession to target health issues before they develop into more threatening conditions, with the goal of eventually eradicating the need for “Right to Try” legislation.<sup>167</sup> Also preventative, Subtitle D focuses

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<sup>160</sup> H.R. 6, 114th Cong. (1st Sess. 2015-2016) at § II(A)–(B).

<sup>161</sup> *Id.* at § II(A).

<sup>162</sup> *Id.*; See Johnson, *supra* note 65.

<sup>163</sup> H.R. 6 at § II(A)(2001)(y)(2).

<sup>164</sup> *Id.* at § II(B).

<sup>165</sup> *Id.* at § II(B)(2021)(b)(1)(A)–(C).

<sup>166</sup> See *Id.* at §II(C); Adrienne Saltz, *Maine: Setting the Example for the Role of Nurse Practitioners*, 23 ANNALS OF HEALTH L. 198, 199 n.7 (2013).

<sup>167</sup> H.R. 6 at § II(C).

on FDA implementation of modern trial design and evidence development, and includes an outline of proposals for the FDA to use in creating more advanced clinical trials and more comprehensive evidence analysis, in the hopes of creating a more streamlined system in which a drug moves from ‘experimental’ to tested.<sup>168</sup> Subtitle E targets the FDA’s slow-moving drug approval process of so-called “breakthrough therapies,” with the legislation urging the FDA to expedite the approval of these life-prolonging drugs, hopefully reaching future terminally ill patients before “Right to Try” drugs become their last resort.<sup>169</sup> For manufactures of investigational drugs used to treat more serious diseases or conditions, the law requires the manufacturer to make publicly available the company’s policy on “evaluating and responding to requests . . . for the provision of such a drug,”<sup>170</sup> where the policy must include certain practical consumer information.<sup>171</sup> These provisions are meant to make it easier for consumers to obtain information about experimental drugs, for manufacturers to advertise their research, and for terminally ill patients to request access directly from the FDA.<sup>172</sup> Again, this Subtitle is forward-looking, meant to downplay the need for “Right to Try” legislation over time.

On the same note, Subtitles F through P of the law turn to drug manufacturer concerns, aimed at the prevention and improvement of existing procedures and protocols for drug manufacturing companies.<sup>173</sup> Subtitle F strives to make it easier for drug manufacturing companies to communicate with each other about the “health care economic information” on clinical drugs.<sup>174</sup> Subtitle G provides for drug resistance monitoring.<sup>175</sup> Furthermore, Subtitle L provides for priority review of “breakthrough devices” in an effort to establish “long-term clinical efficiencies” in the “best interests of patients.”<sup>176</sup> Lastly, Subtitle P, entitled “Improving Scientific Expertise and Outreach

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<sup>168</sup> *See Id.* at § II(D).

<sup>169</sup> *Id.* at § II(E)(2081).

<sup>170</sup> *Id.* at § II(E)(561A)(a)

<sup>171</sup> *Id.* at § II(E)(2082)(561A)(a)–(b).

<sup>172</sup> *See* H.R. 6 at § II(E)(2081).

<sup>173</sup> *See id.* at § II(F)–(P).

<sup>174</sup> *Id.* at § II(F)(2101)(2)(A) (“ . . . the term ‘health care economic information’ means any analysis . . . that identifies, measures or describes the economic consequences . . . of the use of a drug”).

<sup>175</sup> § II(G)(317U).

<sup>176</sup> § II(L)(515B)(a)(1)–(4).

at the FDA,” contains provisions encouraging FDA involvement in scientific conferences and meetings, granting the agency additional employee hiring power, and expanding membership to the Silvio O. Conte Senior Biomedical Research Service.<sup>177</sup> Again, these provisions are targeted at the shortcomings of “Right to Try” legislation, specifically at opponents’ fear the process will undermine FDA authority.<sup>178</sup> This section responds by legitimizing the FDA’s efforts and command over the drug industry.<sup>179</sup>

The legislation was introduced by the House Committee on Energy and Commerce and Republican Michigan representative Fred Upton on May 19, 2015, and passed in the House on July 10, 2015 by a 344 - 77 vote.<sup>180</sup> The bill was received and read twice by the Senate on July 13, 2015<sup>181</sup> before being referred to the Senate Committee on Health, Education, Labor and Pensions and Committee on Ways and Means.<sup>182</sup> Overall, the bill has received substantial bipartisan support, with 174 Democrats and 170 Republicans showing their support for the bill in the House.<sup>183</sup>

Although the legislation creates important regulatory protocols likely to streamline the functioning of the prescription drug industry, the effects of this legislation will be long-term, unlikely to be realized by terminally ill patients seeking access to experimental and potentially life-saving prescription drugs now.<sup>184</sup>

Without a federal “Right to Try” counterpart that more adequately addresses the weaknesses of the state initiatives, it will be difficult for “Right to Try” legislation to work effectively for the patients who most need it. Although as of June 25, 2015,

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<sup>177</sup> *Id.* at §§ II(P)(2282), (714A), (2281). The Silvio O. Conte Senior Biomedical Research Service (SBRS) is a governmental research board spearheaded by Republican Congressman Silvio O. Conte and included appropriations bill 42 U.S.C. § 237 in 1991. Robin Eisner, *Top Researchers in PHS Positions to Get Pay Hikes*, (Apr. 15, 1991), <http://www.the-scientist.com/?articles.view/articleNo/11772/title/Top-Researchers-In-PHS-Positions-To-Get-Pay-Hikes/>. The creation of SBRS was meant to help retain and recruit skilled senior scientists to work for governmental agencies, and meant to consist of individuals “outstanding in the field of biomedical research or clinical research evaluation.” 42 U.S.C. § 237(b) (2016).

<sup>178</sup> *See supra*, Part IIA.

<sup>179</sup> *See supra*, Part IIA.

<sup>180</sup> H.R. 6, 114th Cong. (1st Sess. 2015-2016).

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

<sup>184</sup> H.R. Res. 6, 114th Cong., 1<sup>st</sup> Sess. (2015).

most of the fifty states have passed or introduced “Right to Try” legislation,<sup>185</sup> discrepancies among the state laws, a grave lack of implementation directives, and non-universal implementation will further hinder terminally ill patients from realizing the benefits that access to experimental non-approved clinical drugs may have.<sup>186</sup> Analysis of the trials and tribulations of “Right to Try” legislation indicate that a comprehensive and detailed piece of federal legislation would provide the glue needed for this to be an effective solution that could potentially save the lives of those with no other options.

Some proponents of “Right to Try” welcome the possibility of an in-court challenge to the legislation, arguing that judicial review of the legislation may pressure the federal government to issue a directive that could be heard country-wide.<sup>187</sup> Frank Burroughs of the Abigail Alliance for Better Access to Development Drugs explains, “[A lawsuit] wouldn’t be all bad news because it would further elevate this issue in the public arena and put pressure on Congress and the FDA to make this change and literally save thousands of lives every year.”<sup>188</sup>

#### IV. CONCLUSION

With the two-year anniversary of the passage of the first “Right to Try” law in the State of Colorado<sup>189</sup> approaching, it may be time to reevaluate how the mission behind “Right to Try” legislation can be better realized. Although concerns about what role the FDA will play in the aftermath, vague implementation logistics and lack of oversight over the drug use are major concerns, by far the biggest obstacle to the operation of the “Right to Try” legislation is cost.<sup>190</sup> Without the necessary funds to purchase the experimental drugs and/or travel to the treatment site, none of the other issues with the implementation of the

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<sup>185</sup> See Alexander Gaffney, ‘Right to Try’ Legislation Tracker, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Jun. 24, 2015) <http://www.raps.org/Regulatory-Focus/News/Databases/2015/06/24/21133/Right-to-Try-Legislation-Tracker/>.

<sup>186</sup> See *supra*, Parts I(b), II.

<sup>187</sup> See Michael Ollove, *Right to Try for the Terminally Ill*, USA TODAY (June 19, 2014), <http://www.usatoday.com/story/news/nation/2014/06/19/stateline-fda-terminal-illness-drugs/10836705/>.

<sup>188</sup> *Id.*

<sup>189</sup> Wyatt, *supra* note 45.

<sup>190</sup> See *supra* Part II.

program result.<sup>191</sup>

Although the current legislation is not perfect, the accessibility of experimental drugs under “Right to Try” laws has had an impact on the lives of some terminally ill patients who have taken advantage of them, and have the potential to save many others.<sup>192</sup> Take Ted Harada, who was diagnosed with ALS, commonly known as “Lou Gehrig’s Disease”<sup>193</sup> in 2010 at the age of thirty-eight years old.<sup>194</sup> Upon diagnosis, Ted was told: “There is no known cause, and no known cure.”<sup>195</sup> Ted was able to enroll in a safety trial for a new ALS treatment at Emory University in Atlanta, Georgia.<sup>196</sup> Within weeks of receiving the experimental treatment, Ted’s symptoms began to subside, and he was able to walk in a 2.5 mile ALS Awareness Walk that same year.<sup>197</sup> Although the experimental drugs did not cure Ted’s illness, it slowed the progression of his deadly disease, and provided his family and friends with some comfort.<sup>198</sup>

Other examples include those of Diego Morris and Jordan McLinn. Diego Morris was diagnosed with Osteosarcoma, a very rare form of bone cancer, at the age of ten.<sup>199</sup> Mifamurtide (MTP-PE or MEPACT), an experimental drug that Diego’s physicians believed might help him, became available in the United Kingdom, but was not available in the United States.<sup>200</sup> Diego and his family immediately made the move from Phoenix, AZ to London, where Diego spent over a year undergoing treatment.<sup>201</sup> After completing the treatment in England and undergoing chemotherapy back in Phoenix, Diego’s cancer regressed and he is now cancer free.<sup>202</sup> Diego was named the ‘Honorary Chair’ of “Right to Try” in his home state of Arizona.<sup>203</sup>

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<sup>191</sup> See *supra* Part II.

<sup>192</sup> See *supra* notes 189–212 and accompanying text.

<sup>193</sup> Goldwater Institute, *Right to Try Patient Stories: Ted Harada*, (Mar. 3, 2014), <http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/right-to-try-life-stories-ted-harada/>.

<sup>194</sup> *Id.*

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

<sup>198</sup> *Id.*

<sup>199</sup> Goldwater Institute, *Right to Try Patient Stories: Diego Morris*, (Mar. 3, 2014), <http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/right-to-try-life-stories-diego-morris/>.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*

Effective “Right to Try” legislation could make the difference for Jordan McLinn, a five-year old boy diagnosed with Duchenne muscular dystrophy (DMD), a deadly degenerative condition that causes muscle weakness.<sup>204</sup> Typical DMD patients have a life expectancy of only twenty-five years, and are usually confined to a wheelchair by age twelve.<sup>205</sup> Last March, Jordan was invited by Indiana Governor, Mike Pence, to the signing of the state’s “Right to Try” legislation.<sup>206</sup> Although there are currently no available treatments for Jordan’s condition, Jordan’s parents are big supporters of “Right to Try” legislation, and are eager to try an experimental drug that had “promising preliminary results” for a child with symptoms similar to Jordan’s.<sup>207</sup> When signing the bill, Republican Governor Pence remarked: “I’ve signed this today with a prayer that the “Right to Try” will be a pathway towards healing for Hoosiers for generations to come.”<sup>208</sup>

In order for “Right to Try” legislation to aid clinically ill patients like Jordan in the most effective manner, comprehensive federal legislation is essential to address implementation logistics, provide some sort of cost coverage for manufacturers and patients alike, and arrange for FDA data oversight so that the results of experimental drug use can be utilized fully by future patients.<sup>209</sup> Without a federal counterpart to current widespread state legislation, clinically ill patients will be forced to shop the states for access to experimental drugs, possibly still road blocked by costly drug prices and red tape.<sup>210</sup> In order for Abigail Burroughs’ legacy to be fully realized, the federal government needs to act –recognizing the “Right to Try” experimental drugs as a fundamental right “fall[ing] squarely within the realm of rights the Supreme Court has held ‘implicit in the concept of ordered liberty.’”<sup>211</sup>

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<sup>204</sup> Jessica Firger, *Indiana Governor Signs ‘Right to Try’ Drug Law*, CBS NEWS, (Mar. 24, 2015), <http://www.cbsnews.com/news/indiana-governor-signs-right-to-try-drug-law/>.

<sup>205</sup> *Id.*

<sup>206</sup> *Id.*

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> Firger, *supra* note 204.

<sup>210</sup> *See supra* Part II.

<sup>211</sup> *Abigail All. v. Eschenbach*, 445 F.3d 470, 483–84 (D.C. Cir. 2006) (citing *Palko v. Connecticut.*, 302 U.S. 319, 325 (1937)).