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## FIGHTING FOR YOUR LIFE IN AMERICA: A STUDY OF “RIGHT TO TRY” LAWS THROUGHOUT THE COUNTRY

DANIELLE DELGROSSO<sup>†</sup>

### INTRODUCTION

On June 9, 2011, cancer took the life of twenty-one-year-old Abigail Burroughs.<sup>1</sup> Abigail spent the final seven months of her life fighting for access to an experimental drug, Erbutrix, not yet approved by the Food and Drug Administration (“FDA”) that her treating physician and family believed could save her life.<sup>2</sup> Her efforts were unsuccessful.<sup>3</sup>

Abigail’s death spawned the Abigail Alliance, a non-profit advocacy organization working for FDA regulatory changes that would allow terminally ill patients access to experimental drugs.<sup>4</sup> Spear-headed by Abigail’s father, Frank Burroughs,<sup>5</sup> the Alliance has made noise in the media,<sup>6</sup> in the courtroom,<sup>7</sup> and on Capitol Hill.<sup>8</sup> The commotion prompted “Right to Try” legislation to be

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<sup>1</sup> Frank Burroughs, *Our Story*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/story.php> (last visited Dec. 27, 2017).

<sup>2</sup> Sue Kovach, *The Abigail Alliance: Motivated by Tragic Circumstances, Families Battle an Uncaring Bureaucracy*, LIFE EXTENSION 26 (2007), <http://www.abigail-alliance.org/LEMSEP07pAbigailLR.pdf>.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.* For purposes of this Note, the term “experimental drug[s]” refers to experimental drugs, biological products, or devices.

<sup>5</sup> Burroughs, *supra* note 1.

<sup>6</sup> See Kovach, *supra* note 2, at 30.

<sup>7</sup> See *Abigail All. for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

<sup>8</sup> Kovach, *supra* note 2, at 29.

passed in thirty-two states,<sup>9</sup> and proposed in sixteen others.<sup>10</sup> In May of 2016, a federal “Right to Try” bill was proposed in Congress.<sup>11</sup> Problematically, not all of these laws look the same.

Congress’s bill, the Trickett Wendler Right to Try Act of 2016 (“the Trickett Wendler Act”),<sup>12</sup> is named after a young mother of three who lost her battle against Amyotrophic Lateral Sclerosis (“ALS”) in March of 2015.<sup>13</sup> Trickett and Abigail have similar stories. Both suffered from conditions that would ultimately take their lives,<sup>14</sup> were treated with drugs that could not and did not save them,<sup>15</sup> and were denied access to unapproved drugs.<sup>16</sup> Had the Trickett Wendler Act been law while Trickett or Abigail were alive, their stories may have had different endings.

This Note argues that there should be a federal statute granting terminally ill patients access to experimental drugs, but that the Trickett Wendler Act, as written is not the proper vehicle for change. An ideal congressional “Right to Try” statute

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<sup>9</sup> Lenore Skenazy, Opinion, *The Dying Deserve a Last Chance at Life*, TIMESLEDGER NEWSPAPERS, Dec. 22, 2016.

<sup>10</sup> Editorial, *Right-to-Try*, COURIER (Northwestern Ohio) (Dec. 14, 2016), <http://thecourier.com/opinion/couriers-view/2016/12/14/right-to-try/>.

<sup>11</sup> See S. 2912, 114th Cong. (2016); see also *Trickett Wendler Right to Try Act of 2016*, CONGRESS.GOV, <https://www.congress.gov/bill/114th-congress/senate-bill/2912?q=%7B%22search%22%3A%5B%22s+2912%22%5D%7D&r=1> (last visited Dec. 27, 2017).

<sup>12</sup> S. 2912 114th Cong. (2016). In January 2017, a revised version of S.2912 was introduced in and subsequently passed by the Senate. See S. 204, 115th Cong. (2017) (The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017). In February, 2017, yet another version was introduced in the House. See H.R. 878, 115th Cong. (2017) (Right to Try Act of 2017). While this Note focuses exclusively on S. 2912, its analysis applies to all versions.

<sup>13</sup> Jenna Sachs, *Fighting for the “Right to Try:” 14 Months After Her Death from ALS, Trickett Wendler’s Legacy Taking Shape*, FOX6 NEWS (MILWAUKEE) (May 17, 2016, 9:56 PM), <http://fox6now.com/2016/05/17/fighting-for-the-right-to-try-14-months-after-her-death-from-als-trickett-wendlers-legacy-taking-shape/>.

<sup>14</sup> *Id.* (“ALS has no treatment, no cure, no survivors . . .”); Sean Alfano, *Fighting for a Miracle*, CBS NEWS (Nov. 13, 2005, 3:26 AM), <http://www.cbsnews.com/news/fighting-for-a-miracle/> (reporting that Abigail knew early that her situation was hopeless).

<sup>15</sup> Joseph Gulfo, *A Hearing Brought to Tears over Right to Try Legislation*, THE HILL (May 17, 2016, 7:00 AM), <http://thehill.com/blogs/pundits-blog/healthcare/280127-a-hearing-brought-to-tears-over-right-to-try-legislation> (explaining that Trickett’s current treatment would slow the process of her disease, but would not cure it); Burroughs, *supra* note 1 (stating that Abigail had run out of conventional options).

<sup>16</sup> Ann-Elise Henzl, *Terminally Ill Patients and Their Loved Ones Push for Greater Access to Experimental Drugs*, UW-MILWAUKEE: MILWAUKEE PUBLIC MEDIA (May 11, 2016), <http://wuum.com/post/terminally-ill-patients-and-their-loved-ones-push-greater-access-experimental-drugs#stream/0>; see also Burroughs, *supra* note 1.

should be crafted to make experimental drugs realistically obtainable for terminally ill patients while protecting those patients and their quality of life. The Trickett Wendler Act's weaknesses prevent it from reaching this objective because it is too deferential to already unclear state Right to Try laws. Part I explores the right to try movement generally, explaining what a "right to try" is and the obstacles currently standing in its way. Part II examines and critiques different "Right to Try" laws that have been adopted in the states. Part III proposes a model congressional "Right to Try" bill.

### I. THE RIGHT TO TRY

Essentially, "Right to Try" laws provide terminally ill patients with access to experimental treatments that have successfully passed the first of the FDA's three phases of clinical trials.<sup>17</sup> According to FDA guidelines, a drug normally cannot go to market until it has successfully passed a phase-three trial.<sup>18</sup> It is only at this point that the drug is considered safe and effective for human consumption.<sup>19</sup> Right to Try laws effectively bypass the FDA's system, allowing access to a drug before it receives the FDA's stamp of approval.<sup>20</sup> Right to Try proponents say this will reduce terminal patients' waiting time for drugs not yet approved<sup>21</sup>—time that they simply do not have.

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<sup>17</sup> CHRISTINA CORIERI, GOLDWATER INST., EVERYONE DESERVES THE RIGHT TO TRY: EMPOWERING THE TERMINALLY ILL TO TAKE CONTROL OF THEIR TREATMENT 1 (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); Kimberly Leonard, *Seeking the Right to Try*, U.S. NEWS (Nov. 18, 2014, 12:01 AM), <http://www.usnews.com/news/articles/2014/11/18/right-to-try-laws-allowing-patients-to-try-experimental-drugs-bypass-fda>.

<sup>18</sup> *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last updated Nov. 24, 2017) [hereinafter *FDA Drug Review Process*]; *Conducting Clinical Trials*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/conductingclinicaltrials/default.htm> (last updated June 15, 2016) ("Clinical trials are an integral part of new product discovery and development and are required by the Food and Drug Administration before a new product can be brought to the market.").

<sup>19</sup> *FDA Drug Review Process*, *supra* note 18.

<sup>20</sup> Leonard, *supra* note 17.

<sup>21</sup> Matthew Bellina, *FDA Should Allow Treatment of Terminally Ill Patients with Experimental Drugs*, WASH. POST: POWER POST (Sep. 28, 2016, 10:17 AM), [https://www.washingtonpost.com/news/powerpost/wp/2016/09/28/fda-should-allow-treatment-of-terminally-ill-patients-with-experimental-drugs/?utm\\_term=.1d7591d80ec4](https://www.washingtonpost.com/news/powerpost/wp/2016/09/28/fda-should-allow-treatment-of-terminally-ill-patients-with-experimental-drugs/?utm_term=.1d7591d80ec4).

State Right to Try laws embrace the belief that it is a terminally ill patient's fundamental right to access unapproved drugs.<sup>22</sup> At the heart of that belief is the idea that a person has the fundamental right to try to save his or her own life.<sup>23</sup> Advocates' bottom line is that individuals should not have to ask the government for permission to survive.<sup>24</sup>

However, there are three chief obstacles to Right to Try laws' success: (1) there is no recognized constitutional right to try; (2) state Right to Try laws are federally preempted by FDA guidelines; and (3) there is no consensus as to whether a right to try should exist.

First, despite proponents' assertions that the terminally ill have a fundamental right to access investigational drugs, courts have not agreed.<sup>25</sup> In *Abigail Alliance v. Eschenbach*, the United States Court of Appeals for the District of Columbia Circuit stated that, "such rights are not set forth in the language of the Constitution," and "there is no fundamental right 'deeply rooted in this Nation's history and tradition' of access to experimental drugs for the terminally ill."<sup>26</sup>

Second, the United States Constitution's Supremacy Clause disallows any state law that contravenes a federal statute or statutorily authorized federal regulation.<sup>27</sup> Such a state law is

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<sup>22</sup> Rebecca Dresser, *The "Right to Try" Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. L. REV. 1631, 1640 (2015) (It is "the fundamental right of people to save their own lives") (quoting CORIERI, *supra* note 17, at 1).

<sup>23</sup> *Id.*

<sup>24</sup> *See id.*

<sup>25</sup> Alexandra Tsakopoulos, et al., Note, *The Right to Try: An Overview of Efforts To Obtain Expedited Access to Unapproved Treatment for the Terminally Ill*, 70 FOOD & DRUG L.J. 617, 620 (2015).

<sup>26</sup> *Abigail All. for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695, 697, 702 (D.C. Cir. 2007) (quoting *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997)), *cert. denied*, 552 U.S. 1159 (2008). The Supreme Court, denying certiorari, has not directly answered this question. Thus, it remains possible that eventually the Supreme Court will opine that such a fundamental right exists. As of today, access to experimental drugs is not considered a fundamental right.

<sup>27</sup> U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."). *See also* Caitlyn Martin, Note, *Questioning the "Right" in State Right to Try Laws: Assessing the Legality and Effectiveness of These Laws*, 77 OHIO ST. L.J. 159, 178 (2016) (citing to *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *McCulloch v. Maryland*, 17 U.S. 316, 427 (1819); *City of New York v. FCC*, 486 U.S. 57, 63–64 (1988)).

preempted, or trumped, by the federal statute or regulation, making the state law ineffective.<sup>28</sup> Although the question of whether or not state Right to Try laws are federally preempted has not been answered definitively, they are most likely trumped by FDA guidelines.

The FDA derives its authority to regulate the premarket drug approval process from the Food, Drug, and Cosmetic Act (“FDCA”).<sup>29</sup> In accordance with this authority, the FDA created its three-phase drug approval process,<sup>30</sup> which state Right to Try laws attempt to circumvent.<sup>31</sup> It is not possible to comply with both state Right to Try laws and federal regulatory requirements simultaneously.<sup>32</sup> Thus, although the FDCA does not contain any express preemption provision,<sup>33</sup> such state laws, which upset the congressional purpose set forth in the FDCA,<sup>34</sup> would likely be preempted.<sup>35</sup>

For state Right to Try laws to escape federal preemption, federal action is necessary. Although the FDA has its own Expanded Access program to address the needs of terminally ill patients,<sup>36</sup> the FDA does not support Right to Try laws.<sup>37</sup> In a

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<sup>28</sup> U.S. CONST. art. VI, cl. 2.

<sup>29</sup> Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2012).

<sup>30</sup> *Id.* § 355(D)(i)(II); *see also* Martin, *supra* note 27, at 168.

<sup>31</sup> Emily Hogan, Note, “Right to Try” Legislation and Its Implications for the FDA Drug Approval Process, 50 WASH. U. J.L. & POL’Y 171, 186–87 (2016).

<sup>32</sup> 21 U.S.C. § 355(a) (2012); *see also* Martin, *supra* note 27, at 163 (“A ‘direct conflict’ exists between the FDCA and state Right to Try laws because it is impossible for organizations to comply with both laws, and the purpose of the FDA to regulate new drugs is undoubtedly frustrated.”).

<sup>33</sup> 21 U.S.C. § 301 (2012).

<sup>34</sup> *United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (“[T]he Act’s overriding purpose [is] to protect the public health, and specifically, § 507’s purpose [is] to ensure that [drugs] marketed serve the public with ‘efficacy’ and ‘safety.’”) (first citing *United States v. Sullivan*, 332 U.S. 689, 693–95 (1948); and then citing *United States v. Dotterweich*, 320 U.S. 277, 283–84 (1943)).

<sup>35</sup> Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 NEW ENG. J. MED. 279, 283 (2015). “[R]ight-to-try laws are unlikely to withstand a constitutionality challenge that is based on conflict with the FDA’s enabling legislation and existing expanded-access regulations.” *Id.*

<sup>36</sup> 21 C.F.R. § 312 (2016); *see also Expanded Access (Compassionate Use)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm> (last updated Oct. 3, 2017). Unfortunately, Right to Try law advocates do not believe that the FDA’s expanded access program is speedy enough nor that it helps enough people. *See, e.g.*, Bellina, *supra* note 21 (describing the FDA’s compassionate use program as “severely flawed”).

September 2016 statement, Peter Lurie, the FDA's Associate Commissioner for Public Health and Analysis, stated that "[c]linical trials remain the best option for patients wishing to gain access to investigational products and . . . the approval process remains the best way to assure the development of and access to safe and effective new medical products for all patients."<sup>38</sup>

Although there is no fundamental right to try, and state Right to Try laws are likely federally preempted, a congressional statute would transcend both obstacles.<sup>39</sup> However, right to try opponents, and their valid concerns, complicate the passage of such a statute.<sup>40</sup> Two opposing arguments are particularly powerful.

First, if experimental drugs become more readily available outside of clinical trials, it becomes increasingly difficult to maintain the numbers necessary to perform these trials, which harms the public health at large.<sup>41</sup> Phase-three trials require anywhere from three-hundred to three-thousand participants suffering from the disease or condition.<sup>42</sup> Relatively few patients enroll in trials as is.<sup>43</sup> The three-phase clinical-trial system is

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<sup>37</sup> *Exploring a Right to Try for Terminally Ill Patients: Hearing on S. 2912 Before the S. Comm. On Homeland Sec. and Gov't Aff.*, 114th Cong. 5 (2016) [hereinafter *Senate Hearing*] (statement of Peter Lurie, Associate Commissioner for Public Health Strategy and Analysis, U.S. FDA).

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

<sup>39</sup> James M. Beck, *Developments in Compassionate Use and Right to Try Laws*, DRUG & DEVICE LAW (June 9, 2016), <https://www.druganddevicelawblog.com/2016/06/developments-in-compassionate-use-and-right-to-try-laws.html> (explaining that state Right to Try laws would no longer be preempted if a federal Right to Try law was adopted.).

<sup>40</sup> For example, Senator Ron Johnson, the Trickett Wendler Act's sponsor, recently went to the Senate floor to seek unanimous consent for the bill, but was blocked by Senate Minority Leader Harry Reid, an opponent of Right to Try laws. *Johnson Fails in Bid To Hotline 'Right to Try' Bill Through Senate*, INSIDE HEALTH POLICY (Sept. 28, 2016), <https://insidehealthpolicy.com/daily-news/johnson-fails-bid-hotline-right-try-bill-through-senate>. See also *supra* note 12.

<sup>41</sup> VICTORIA WEISFELD ET AL., PUBLIC ENGAGEMENT AND CLINICAL TRIALS: NEW MODELS AND DISRUPTIVE TECHNOLOGIES 2 (2012) (identifying "the increasing difficulty of recruiting and retaining an appropriate human subject population for specific clinical trials" as a "significant problem"); see also Manik Chahal, *Off-Trial Access to Experimental Cancer Agents for the Terminally Ill: Balancing the Needs of Individuals and Society*, 36 J. MED. ETHICS 367, 368 (2010).

<sup>42</sup> *The Drug Development Process, Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., [http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm#Clinical\\_Research\\_Phase\\_Studies](http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm#Clinical_Research_Phase_Studies) (last updated May 25, 2017).

<sup>43</sup> WEISFELD ET AL., *supra* note 41, at 2.

essential to determining whether experimental drugs are sufficiently safe and effective for consumption by the general patient population.<sup>44</sup> Thus, if trials cannot recruit patient volunteers, then an already lengthy process loses all efficacy and speed, and in turn cannot serve the public as intended.<sup>45</sup>

Second, early access to a drug may cause a person more harm than good.<sup>46</sup> Right to Try laws grant access to investigational drugs that have passed the first of three phases of FDA clinical trials.<sup>47</sup> Unfortunately, Phase One trials are small, usually conducted on about twenty to a hundred human subjects, and are not designed to evaluate effectiveness; the purpose is simply to supply initial information about the drug's adverse effects on humans.<sup>48</sup> About seventy percent of drugs move on to the second phase, which provides researchers with additional safety data.<sup>49</sup> Although Phase Two studies are conducted on several hundred people, they are still not considered large enough to demonstrate whether the drug will be beneficial, as evidenced by the fact that two more phases are conducted on up to several thousand subjects.<sup>50</sup> The determination of how beneficial a drug is, is made during phase-three studies, which demonstrate whether or not a product offers a treatment benefit to a specific population.<sup>51</sup>

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<sup>44</sup> See 21 U.S.C.A. § 355(d) (West 2014) (requiring clinical investigations of the safety and efficiency of a drug prior to FDA approval).

<sup>45</sup> *Senate Hearing, supra* note 37 (statement of Peter Lurie, Associate Commissioner for Public Health Strategy and Analysis, U.S. FDA) (“Enrollment in clinical trials helps to ensure adequate protection for patients and leads to the collection of vital data that could eventually result in FDA approval of the investigational product.”).

<sup>46</sup> David Gorski, *The False Hope of “Right-to-Try” Metastasizes to Michigan*, SCI.-BASED MED. (July 21, 2014), <https://www.sciencebasedmedicine.org/the-false-hope-of-right-to-try-metastasizes-to-michigan/> (explaining that disaster can result when compassion gets in the way of medical decision making).

<sup>47</sup> See COLO. REV. STAT. § 25-45-103(2) (2014) (an experimental drug is one “that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the [FDA]”).

<sup>48</sup> *The Drug Development Process, Step 3: Clinical Research, supra* note 42.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* (“Phase 3 studies provide most of the safety data. In previous studies, it is possible that less common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects[.]”).



Yet, terminal patients and their advocates remain eager to access unapproved “miracle drugs,” believing they will save lives if only patients could get their hands on them.<sup>52</sup> Patients and their advocates are thus ignoring the suffering that can come from trying novel drugs. But, if a patient is terminal, what is the harm in trying? One expert responds, “If there’s anything worse than dying of a terminal illness, it’s dying of a terminal illness and suffering unnecessary complications or pain for no benefit[.]”<sup>53</sup> Even patients with life-threatening diseases require protections from unnecessary risks.<sup>54</sup> For a federal Right to Try law to be successful, it must address these concerns.

## II. COMPARING RIGHT TO TRY LAWS

State “Right to Try” laws are new, controversial, and, most problematically, different from one another. Inviting states with varying views on the right to try to fill in Congress’s blanks muddles the already shaky definition of a “right to try.” This Part highlights several critical differences between Right to Try laws that, without well-defined congressional intervention, will remain problematic.

### A. Eligibility Requirements

All “Right to Try” laws include a list of criteria that a patient must meet to become an “eligible patient” for right to try purposes.<sup>55</sup> Generally, a state’s eligibility list is comprised of some combination of five conditions: (1) The patient has a terminal illness, attested to by his or her physician; (2) The patient has considered all other treatment options currently

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<sup>52</sup> 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/> (alluding to the “misperception that there are ‘miracle drugs’ out there that we will have to wait years for because the FDA is too slow to approve them”); see also Julie Brintnall-Karabelas et al., *Improving Recruitment in Clinical Trials: Why Eligible Participants Decline*, 6 J. EMPIRICAL RES. ON HUM. RES. ETHICS 69, 70 (2011).

<sup>53</sup> Gorski, *supra* note 52.

<sup>54</sup> *Senate Hearing*, *supra* note 37 (statement of Peter Lurie, Associate Commissioner for Public Health Strategy and Analysis, U.S. FDA).

<sup>55</sup> *Right to Try Model Legislation*, GOLDWATER INST., § 1(2)(b), [https://goldwater-media.s3.amazonaws.com/cms\\_page\\_media/2015/1/28/RIGHT%20TO%20TRY%20MODEL%20LEGISLATION%20%282%29\\_1.pdf](https://goldwater-media.s3.amazonaws.com/cms_page_media/2015/1/28/RIGHT%20TO%20TRY%20MODEL%20LEGISLATION%20%282%29_1.pdf) (last visited Dec. 27, 2017); see also POLICY SURVEILLANCE PROGRAM STAFF, RIGHT TO TRY LAWS 1 (Oct. 2016).

approved by the FDA; (3) The patient has received a recommendation from his or her physician for the investigational treatment sought; (4) The patient has given written, informed consent for the use of the investigational treatment; and (5) The patient has documentation from his or her physician that he or she meets all of the eligibility requirements.<sup>56</sup>

Two of these requirements have been adopted by all states with Right to Try laws. The first is requirement number two, that the patient has considered all other currently approved treatment options.<sup>57</sup> This is also a necessary requirement to be eligible for the FDA's Expanded Access program.<sup>58</sup> This requirement aligns with the very important policy interest that the unapproved drug be a last resort option. If a patient can receive the treatment he or she needs without having to shoulder the potential risks of an unapproved drug, Right to Try laws need not and should not be utilized.

The second widely adopted requirement is number four, that the patient provide "written, informed consent for the use of the" experimental treatment.<sup>59</sup> A majority of states additionally define "written, informed consent," specifying information that must be included in the informed consent document.<sup>60</sup> The FDA's Expanded Access program also requires written, informed

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<sup>56</sup> *Right to Try Model Legislation*, *supra* note 55. The Goldwater Institute is a public policy think tank that has outlined proposed Right to Try legislation. Michelle J. Rubin & Kristin R.W. Matthews, *The Impact of Right to Try Laws on Medical Access in the United States*, 66 BAKER INST. POL'Y REP. 1, 6 (2016). State Right to Try laws are generally similar to the Goldwater Institute's template. *Id.*

<sup>57</sup> *Right to Try Model Legislation*, *supra* note 55, § 1(2)(b)(ii).

<sup>58</sup> 21 C.F.R. § 312.305(a)(1) (2016).

<sup>59</sup> *Right to Try Model Legislation*, *supra* note 55, § 1(2)(b)(iv).

<sup>60</sup> *E.g.*, COLO. REV. STAT. § 25-45-103(4) (2014) (stating that "written, informed consent" documents must, at the very least, (a) "explain[] the currently approved products and treatments for the disease or condition from which the patient suffers;" (b) "attest[] to the fact that the patient concurs with his or her physician" that all currently approved treatments are inadequate; (c) define[] the specific experimental drug; (d) "describe[] the potentially best and worst outcomes of using the [experimental] drug . . . including the possibility that new, unanticipated, different, or worse symptoms might result" and could precipitate death; (e) "[m]ake[] clear that the patient's health insurer and provider are not obligated to pay for any care or treatments consequent to the use of the [experimental] drug"; (f) clearly state that the patient may no longer be eligible for hospice care; (g) clearly state that the patient may be denied in-home healthcare because of the treatment; and (h) "state[] that the patient understands that he or she is liable for all expenses consequent to the use of the [experimental] drug . . . unless a contract between the patient and the manufacturer of the drug . . . states otherwise.").

consent and provides for what information must be included in that document.<sup>61</sup> This requirement reflects the state's interest in protecting the patient. Opponents' concern that a desperate patient may be lured by the idea of a miracle drug is softened when that patient is provided with enough information to make an informed, autonomous decision. While a patient may still hope for a miracle, a comprehensive informed consent document emphasizes that the drug remains unapproved, and, thus, its outcome cannot be predicted and worse symptoms might result.

While these two requirements evoke widespread acceptance, the first and arguably most basic requirement, that the patient be terminally ill, lacks any single accepted definition.<sup>62</sup> State Right to Try laws tend to define a "terminally ill" patient in one of three ways: (1) He or she has a disease or condition not considered to be reversible, even with the administration of currently approved and available treatment options; (2) He or she has a disease or condition that, in running its normal course, will end his or her life within a certain period of time; or (3) He or she has a disease or condition likely to result in death or is in a permanent state of unconsciousness from which recovery is unlikely.<sup>63</sup>

At least seven states have taken the first approach.<sup>64</sup> This approach generally defines a terminal illness as "[a] progressive disease or medical or surgical condition that (i) entails significant functional impairment, (ii) is not considered by a treating physician to be reversible even with administration of available

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<sup>61</sup> 21 C.F.R. § 50.25(a) (2016).

<sup>62</sup> See *United States v. Rutherford*, 442 U.S. 544, 556 (1979) (noting the difficulties of defining terminally ill and applying that definition to patients); see also Joanne Lynne et al., *Defining the "Terminally Ill."* *Insights from Support*, 35 *Duq. L. Rev.* 311, 311–12 (1996).

<sup>63</sup> Victoria Howard, Note, *Assessing Indiana's Right-to-Try Law: Is It Enough To Expand Access for Terminally Ill Patients?*, 14 *IND. HEALTH L. REV.* 267, 292–99 (2017). Only one state, Indiana, does not require that the patient's disease or condition be life-threatening. *IND. CODE ANN.* § 25-22.5-1-2.1 (West 2015) (stating that an individual may access an experimental drug if he or she has been diagnosed with a terminal condition or if the patient's treating physician determines that "there is no reasonable basis to conclude" that the experimental drug, when administered appropriately, "poses an unreasonable and significant risk" to the patient).

<sup>64</sup> Alabama, Michigan, Minnesota, Montana, North Carolina, South Dakota, and Tennessee.

treatments approved by the [FDA], and (iii) will soon result in death without life-sustaining procedures.”<sup>65</sup> This definition is comprised of several important components.

First, it requires that the patient’s condition causes or involves “significant functional impairment.” No state explicitly defines “significant functional impairment.”<sup>66</sup> The sixth edition of the American Medical Association’s *Guides to the Evaluation of Permanent Impairment*, defines impairment as “a significant deviation, loss, or loss of use of any body structure or function in an individual with a health condition, disorder, or disease.”<sup>67</sup> The Social Security Administration defined a medically determinable impairment as “an impairment that results from anatomical, physiological, or psychological abnormalities that can be shown by medically acceptable clinical and laboratory diagnostic techniques.”<sup>68</sup> Thus, there is no explicit determinable factor of a “significant functional impairment.” Minnesota, one of the nine states adopting this approach, deleted this distinction from its definition, asserting simply that a terminal disease or condition is one “not considered reversible” and that “will soon result in death.”<sup>69</sup>

Despite the lack of clarity as to what exactly constitutes a “significant functional impairment,” or if such characteristic is necessary, it is clear that the legislators intended for the patient’s condition to be significant enough to warrant the extraordinary permission being granted. This cautions against unjustified determination of an eligible “terminally ill” patient and reinforces the idea of the right to try as a last resort.

Second, this approach requires that the disease or condition not be reversible by current FDA approved treatments.<sup>70</sup> Once again, this is consistent with the intent that the law be used only as a last resort. If a patient’s condition can be treated through an approved option, experimenting with an unapproved drug outside of a clinical trial is unwarrantedly risky.

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<sup>65</sup> *E.g.*, N.C. GEN. STAT. § 90-325.1(3) (2015).

<sup>66</sup> *See id.*

<sup>67</sup> ROBERT D. RONDINELLI ET AL., *GUIDES TO THE EVALUATION OF PERMANENT IMPAIRMENT*, 876 (6th ed. 2008).

<sup>68</sup> *Disability Evaluation Under Social Security: Part I—General Information*, SOC. SEC. ADMIN., <https://www.ssa.gov/disability/professionals/bluebook/general-info.htm> (last visited Dec. 27, 2017).

<sup>69</sup> MINN. STAT. § 151.375(2)(d) (2015).

<sup>70</sup> *See supra* note 64.

Third, this approach requires that the patient's disease or condition "will soon result in death."<sup>71</sup> This requirement goes to the heart of what a terminal illness realistically is—an illness that will take a patient's life—and illustrates why Right to Try laws are necessary; without them, the patient will die. The keyword in this first approach is "soon."

This differs from the second approach, embraced by four states,<sup>72</sup> which demarcates a particular period of time in which death must be likely to occur. For example, Florida defines a terminal illness as a condition that, in running its normal course, will result in death "within 1 year after diagnosis."<sup>73</sup> Oregon defines it as a disease or condition that, in the "physician's reasonable medical judgment," will result in death within six months.<sup>74</sup>

Conversely, at least nine states do not draw a definitive line for the time period within which death must occur, simply requiring that death be projected to occur soon,<sup>75</sup> in the near future,<sup>76</sup> or imminently.<sup>77</sup>

Regardless of which method a state adopts, this provision reinforces the objective that Right to Try laws be utilized only as a last resort. While states like Florida and Oregon are stricter in their definition of "terminally ill," the other thirteen states that do not demarcate a "death-by-date" allow more room for interpretation. Still, the point remains clear—the right to try only becomes a "right" when accompanied by a patient's foreseeable demise.

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<sup>71</sup> *Right to Try Model Legislation*, *supra* note 55, § 1(2)(a).

<sup>72</sup> Florida, Nevada, Illinois, and Oregon.

<sup>73</sup> FLA. STAT. ANN. § 499.025(2)(c) (West 2015).

<sup>74</sup> H.R. 2300 § 1(9), 78th Leg. Assemb., Reg. Sess. (Or. 2015).

<sup>75</sup> Alabama, Colorado, Maine, Michigan, Minnesota, Montana, North Carolina, Wyoming, and Oklahoma. *See e.g.*, COLO. REV. STAT. § 25-45-103(3) (2014) ("Terminal Illness" means a disease that, without life-sustaining procedures, will soon result in death . . .").

<sup>76</sup> Mississippi, Missouri, and Vermont. *E.g.*, MISS. CODE ANN. § 41-131-1(2)(c) (West 2016) ("Terminal illness" means a disease that without life-sustaining procedures will result in death in the near future . . .").

<sup>77</sup> VA. CODE ANN. § 54.1-3442.1 (West 2015) ("Terminal condition" means a condition caused by an injury, disease, or illness, from which . . . the patient's death is imminent . . .").

The third approach, adopted by at least seven states,<sup>78</sup> includes as “terminal illness” not only parties with death-triggering diseases, but also patients in “a state of permanent unconsciousness from which recovery is unlikely.”<sup>79</sup> By expanding their definition, these states include patients who may ordinarily not be categorized as “terminally ill,”<sup>80</sup> but have similarly hopeless prognoses.<sup>81</sup>

Unfortunately, having three different definitions of “terminally ill” will ultimately result in numerous bioethical issues for patients and physicians.<sup>82</sup> For example, different definitions cause similar patients across the country to receive different levels of access to experimental drugs.<sup>83</sup> Additionally, physicians and patients, or physicians and patients’ family members, might disagree over whether or not a patient is eligible for the right to try, which might result in litigation.<sup>84</sup>

To supplement the five typical eligibility requirements, some states have adopted their own additional eligibility requirements. Two noteworthy requirements are (1) The patient is “unable to participate in a clinical trial,”<sup>85</sup> and (2) The potential risks of using the experimental drug do not outweigh the potential benefits.

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<sup>78</sup> Colorado, Maine, Mississippi, Missouri, North Dakota, Oklahoma, and Wyoming.

<sup>79</sup> COLO. REV. STAT. § 25-45-103(3) (2014).

<sup>80</sup> See Sally J.T. Necheles, *Particular Medical Conditions for Which Withdrawal of Treatment May Be Available*, 77 C.J.S. RIGHT TO DIE § 18 (2017); see also *Health Maintenance Guidelines Terminology*, PALO ALTO MED. FOUND., <http://www.pamf.org/preventive/AHCD-terminology.html> (last visited Dec. 27, 2017) (stating that a “[p]ersistent vegetative state” is “[n]ot normally regarded as a terminal condition and the patient can survive for many years with medical care, artificial fluids and nutrition”).

<sup>81</sup> The Multi-Society Task Force on PVS, *Medical Aspects of the Persistent Vegetative State*, 330 NEW ENG. J. MED. 1572, 1575–76 (1994) (explaining that survival rates for patients in a persistent vegetative state is extremely low).

<sup>82</sup> See Diane E. Hoffman & Anita J. Tarzian, *The Role and Legal Status of Health Care Ethics Committees in the United States*, in *LEGAL PERSPECTIVES IN BIOETHICS* 52 (Ana S. Iltis et al. eds., Taylor & Francis e-Library ed. 2007) (explaining how states’ differing definitions of terminal illness present bioethical problems).

<sup>83</sup> Richard M. Doerflinger, *Conclusion: Shaky Foundations and Slippery Slopes*, 35 DUQ. L. REV. 523, 525 (1996) (stating that an arbitrary definition of “terminal illness” raises prompt “‘equal protection’ claims by patients who fall just outside the definition’s borders”).

<sup>84</sup> See Hoffman & Tarzian, *supra* note 82, at 54 (explaining that physicians and family members might have differing views on a patient’s medical prognosis).

<sup>85</sup> OKLA. STAT. ANN. tit. 63, § 3091.2(1)(c) (West 2015).

According to the first, a patient is only an “eligible patient” for purposes of the law if he or she is unable to participate in a clinical trial for the requested experimental treatment. Oklahoma, for example, requires that the patient either be “unable to participate in a clinical trial for the terminal illness within one hundred . . . miles of the patient’s home address, or not been accepted to the clinical trial within one . . . week of the completion of the clinical trial application process[.]”<sup>86</sup> By requiring that patients first attempt to access the drug through the clinical trial process, these additional requirements mitigate the concern that trials will suffer if Right to Try laws are legalized.<sup>87</sup> Oklahoma’s distance limitation remains compassionate to terminally ill patients that are unable to travel far distances from their homes or hospitals.<sup>88</sup> Oklahoma’s timing limitation recognizes that many terminally ill patients do not have the time to wait for an acceptance to a clinical trial.<sup>89</sup>

The second additional requirement, adopted by three states,<sup>90</sup> requires a physician to ascertain that the experimental drug’s potential risks to the patient do not outweigh its potential benefits to the patient.<sup>91</sup> The FDA’s expanded access program similarly requires a determination by the FDA that the “patient benefit justifies the potential risks of the treatment use and [the] potential risks are not unreasonable in the context of the disease . . . .”<sup>92</sup>

Such risk-benefit analyses compel physicians to look at their patients’ situations analytically and objectively, allowing the physician to make a more informed, and ideally less emotional, decision for his or her patient. Although the risks and benefits of

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<sup>86</sup> *Id.* Maine includes a similar provision, stating that an “eligible patient” is one who has “[n]ot been accepted into a clinical trial within one week of completion of the clinical trial application process[.]” ME. STAT. tit. 602-A, § 2671(1)(c) (2016).

<sup>87</sup> See WEISFELD, *supra* note 41 and accompanying text for an explanation of the argument that clinical trials might suffer as a result of Right to Try legislation.

<sup>88</sup> CORIERI, *supra* note 17, at 11 (stating that many patients “do not live near or have the ability to travel to a medical facility where [a clinical] trial is being conducted”).

<sup>89</sup> *See id.*

<sup>90</sup> Indiana, Virginia, and Utah.

<sup>91</sup> *See* VA. CODE ANN. § 54.1-3442.2(A)(3) (West 2015) (“The potential benefits of use of the investigational drug . . . are greater than the potential risks of the use of the investigational drug . . .”).

<sup>92</sup> FDA Expanded Access to Investigational Drugs, 21 C.F.R. § 312.305(a)(2) (2016).

a potential drug to a particular patient are largely undeterminable at this state, “the physician should make this determination based on the information about the drug available to the physician and the physician’s knowledge of the patient’s clinical situation.”<sup>93</sup> This analysis thus ensures that the current foreseeable risks are no greater than the current foreseeable benefits, in the patient’s particular circumstance. The patient should be made aware that they may suffer unanticipated risks, and that foreseeable benefits are not guaranteed, in his or her informed consent document.

### B. *Manufacturer Protections*

All Right to Try laws share one important aspect: it is entirely the drug manufacturer’s decision whether to make its investigational drug available to an eligible patient.<sup>94</sup> If the manufacturer, having ultimate control over the drug, chooses not to participate in the “right to try” process, then the law cannot achieve its purpose.

Manufacturers are “rational economic actor[s],” whose purpose is to get their drugs on the market.<sup>95</sup> Thus, factors such as the threat of liability and the FDA’s approval process will likely deter any voluntary action by a manufacturer.<sup>96</sup> Because Right to Try laws cannot succeed without manufacturer participation, some states have included provisions to protect manufacturers from liability and the FDA’s approval process. The FDA’s Expanded Access program offers no such protections for manufacturers.

Nineteen states have adopted provisions protecting manufacturers from liability.<sup>97</sup> Generally, such provisions provide that there is no private cause of action created against a

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<sup>93</sup> FOOD & DRUG ADMIN., EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT AND USE—QUESTIONS AND ANSWERS 11 (Oct. 2017), <https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf>.

<sup>94</sup> James M. Beck, *On “Right to Try” Legislation*, DRUG & DEVICE LAW (Oct. 23, 2014), <https://www.druganddevicelawblog.com/2014/10/on-right-to-try-legislation.html>.

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

<sup>96</sup> *Id.* (“You won’t induce a manufacturer to participate in a voluntary program by painting a target on its back.”).

<sup>97</sup> Alabama, Arizona, Colorado, Florida, Indiana, Maine, Michigan, Minnesota, Mississippi, Montana, Nevada, North Carolina, North Dakota, Oklahoma, South Dakota, Texas, Virginia, and Wyoming.



manufacturer, or any other person or entity involved in the care of an eligible patient using an investigational drug, if the manufacturer or other person or entity is complying with the statute in good faith and with reasonable care.<sup>98</sup>

Two states, Indiana and Texas, have adopted slightly edited versions of this provision, which may ultimately have destructive effects.<sup>99</sup> Both states' laws provide that there is no cause of action against a manufacturer, but neither requires that the manufacturer act in good faith or with reasonable care to invoke the protection. Critics have expressed concern, echoed by the FDA, that unregulated manufacturers might take advantage of desperate patients.<sup>100</sup>

Umbrella protection generates concern that less scrupulous manufacturers may negligently, or even willfully, provide a desperate patient with an unsafe drug. A manufacturer who knows, or reasonably should know, that its drug is unsafe for human consumption, may be less prudent when distributing the drug if it cannot be held liable.

Additionally, a majority of Right to Try laws allow manufacturers to decide whether and what to charge a patient for its drug.<sup>101</sup> Under all Right to Try laws, a patient's health insurance provider is not required to cover costs associated with an experimental drug.<sup>102</sup> Thus, patients may be left with costly medical bills. Concern follows that "without proper oversight" a manufacturer could "inflate the cost associated with the production of the drug and take advantage of" a distressed and

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<sup>98</sup> See, e.g., COLO. REV. STAT. § 25-45-107 (2014).

<sup>99</sup> IND. CODE ANN. § 16-42-26-5 (West 2015); TEX. HEALTH AND SAFETY CODE ANN. § 489.054 (West 2015).

<sup>100</sup> *Senate Hearing, supra* note 37 (statement of Peter Lurie, Associate Commissioner for Public Health Strategy and Analysis, U.S. FDA) ("FDA is concerned about the ability of unscrupulous individuals to exploit such desperate patients."); see also Jonathan Friedlaender, *The Proposed Federal "Right-To-Try" Law is Not the Answer for Critically Ill Patients*, HEALTH AFFAIRS (Sept. 27, 2016), <http://www.healthaffairs.org/doi/10.1377/hblog20160927.056819/full> ("Without safeguards, less scrupulous providers will take advantage.").

<sup>101</sup> See, e.g., MINN. STAT. § 151.375(5) (2015).

<sup>102</sup> See, e.g., *id.* § 151.375(7).

desperate class of people.<sup>103</sup> Umbrella protection for manufacturers, with no requirement that they act with good faith or reasonable care, makes this concern more realistic.

Some states have taken steps to mitigate this concern. Arizona, for example, allows a manufacturer to charge only the out-of-pocket costs expended in providing that particular drug to that particular patient.<sup>104</sup> This is also the approach taken by the FDA's Expanded Access program.<sup>105</sup> Other states, such as Texas, prohibit the manufacturer from charging at all.<sup>106</sup>

In states that do not specify what the manufacturer may charge, an equality discussion has transpired. If a patient bears the total cost of an experimental drug, and there is no cap on the cost, this law in effect is a law for the wealthy.<sup>107</sup> The "right" in right to try is the right to fight to save your life, but that right would only be available for those who can afford it.<sup>108</sup> South Dakota allows a manufacturer to use its discretion to provide a drug to an eligible patient without compensation.<sup>109</sup> Requiring a manufacturer to provide a drug removes any financial incentive for the manufacturer to participate in "right to try"; laws such as South Dakota's at least encourage a manufacturer to act when an eligible patient is unable to afford the drug.

The second factor important in encouraging manufacturers' voluntary participation is to prohibit the use of adverse events suffered by right to try patients in the drug's FDA approval process.<sup>110</sup> Typically, a drug manufacturer's end goal is to market its drug to the public. If negative side effects suffered by a single patient, outside the scope of mandatory clinical trials, deter achievement of that goal, a manufacturer is less likely to

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<sup>103</sup> Jessica M. Maxwell, *Patients' Right to Choose; The Right-To-Try Law Movement*, 9 HEALTH L. OUTLOOK 1, 4 (2016), <http://scholarship.shu.edu/health-law-outlook/vol9/iss1/5>.

<sup>104</sup> ARIZ. REV. STAT. ANN. § 36-1312(B)(1)–(2) (2014).

<sup>105</sup> FOOD & DRUG ADMIN., CHARGING FOR INVESTIGATIONAL DRUGS UNDER AN IND—QUESTIONS AND ANSWERS 7–8 (June 2016), <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351264.pdf>.

<sup>106</sup> TEX. HEALTH AND SAFETY CODE. ANN. § 489.053(c) (2015).

<sup>107</sup> Y. Tony Yang et al., "Right-To-Try" Legislation: Progress or Peril?, 33 J. CLINICAL ONCOLOGY 2597, 2598 (2015) (explaining the issue of "access disparities because only the wealthy would be able to access" experimental treatments).

<sup>108</sup> *Id.*; see also Joel B. Finkelstein, *FDA Clarifies Rules for Getting Experimental Drugs*, 99 J. NAT'L CANCER INST. 584, 585 (2007).

<sup>109</sup> H.B. 1080, 90th Leg. Assemb. Sess. (S.D. 2015).

<sup>110</sup> Beck, *supra* note 39.

voluntarily provide its drug to that patient. While no state Right to Try law has addressed whether or not a manufacturer must report adverse events suffered by a patient to the FDA, the Trickett Wendler Act prevents the FDA from using such side effects to adversely impact review or approval of the drug.<sup>111</sup> Conversely, the FDA's Expanded Access program requires that any side effects be reported as part of the drug's approval process.<sup>112</sup>

The FDA has an interest in protecting the public health at large. If not properly addressed, a negative side effect suffered by one person could become a negative side effect suffered by another.<sup>113</sup> Thus, while a manufacturer's voluntary participation is necessary for a successful Right to Try statute, it remains critical that the FDA account for all possible side effects of a drug in that drug's approval process.<sup>114</sup> Further, there may be other ways to incentivize manufacturer participation without disrupting our system, such as by offering tax breaks or federal subsidies for manufacturers that comply;<sup>115</sup> or, better yet, requiring manufacturers to report adverse side effects while barring the FDA from rejecting a drug on the basis of reports from terminally ill patients.

### C. *Similarities Between Right To Try Laws*

While Right to Try laws are permeated with differences, they also share two notable similarities: (1) the definition of "experimental drug," and (2) physical protection.

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<sup>111</sup> S. 2912, 114th Cong. § 2(b)(2) (2016) ("[T]he outcome of any production, manufacture, distribution, prescribing, dispensing, possession, or use of" such a treatment "shall not be used by a Federal agency . . . [to] adversely impact review or approval of [the treatment].").

<sup>112</sup> 21 C.F.R. § 312.305(4)–(5) (2016). The FDA has a responsibility to protect the public health. Therefore, the FDA has a substantial interest in gathering all information about the effects of a drug in order to safely make that drug available for the public. *Senate Hearing, supra* note 37 (statement of Peter Lurie, Associate Commissioner for Public Health Strategy and Analysis, U.S. FDA).

<sup>113</sup> *How FDA Evaluates Regulated Products: Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm269834.htm> (last updated Nov. 16, 2017).

<sup>114</sup> *Id.*

<sup>115</sup> Rubin & Matthews, *supra* note 56, at 11 ("Congress and the FDA can incentivize manufacturers' participation in expanded access by offering tax breaks if the company participates.").

First, all Right to Try laws have the same definition for “experimental drug.” An experimental drug is “a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States food and drug administration and remains under investigation in a United States food and drug administration-approved clinical trial.”<sup>116</sup>

Despite the definition’s wide adoption by state Right to Try laws, the Trickett Wendler Act, and even the FDA Expanded Access program, substantial debate remains over whether Phase One drugs are safe enough for Right to Try purposes.<sup>117</sup> By their definition, Phase One drugs are not considered safe and effective.<sup>118</sup> Phase One trials are conducted on only about twenty to eighty participants with the purpose of gathering preliminary information about the drug’s dosage and acute side effects.<sup>119</sup> Most of the drug’s safety data is not gathered until Phase Three studies, which are conducted on hundreds, sometimes thousands, of patients.<sup>120</sup> Additionally, about eighty-six percent of drugs that move beyond Phase One “prove to be less effective than” drugs already on the market.<sup>121</sup> Nonetheless, legislators have accepted Phase One as the threshold for Right to Try laws nationwide.

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<sup>116</sup> See, e.g., COLO. REV. STAT. § 25-45-103(2) (2014).

<sup>117</sup> See ‘Right to Try’ Laws Make Safety, Efficacy Secondary to Speedy Access, SCIEDAILY (May 19, 2016), <https://www.sciencedaily.com/releases/2016/05/160519121110.htm> (arguing that Right to Try laws make safety secondary to speedy access); see also Finkelstein, *supra* note 108 (arguing that asking for access to experimental drugs is like “asking the government to sanction the sale of toxic placebos . . . to say those should be sold to [terminal patients] is just irresponsible”). But see *Frequently Asked Questions*, RIGHT TO TRY, <http://righttotry.org/faq/> (last visited Dec. 27, 2017) (arguing that experimental drugs that have passed Phase One testing are no different than the treatments currently available to patients who are lucky enough to be accepted into clinical trials).

<sup>118</sup> See *The Drug Development Process, Step 3: Clinical Research*, *supra* note 42 (FDA explains its three-phase approval process).

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

<sup>120</sup> *Id.* (pre-phase three studies might not have detected less common side effects).

<sup>121</sup> Jeff Schriber et al., *Doctors: Prop. 303 Isn’t in Patients’ Best Interests*, ARIZ. REPUBLIC (Oct. 14, 2014, 3:20 PM), <https://www.azcentral.com/story/opinion/op-ed/2014/10/14/no-prop-303-right-to-try/17270791/>.

At their core, Right to Try laws are intended to serve the terminally ill. It is estimated that the entire drug approval process, on average, takes between eight to twelve years.<sup>122</sup> Terminally ill patients, therefore, may die while waiting for a drug to come to market or to pass on to a higher phase.<sup>123</sup> Terminal patients are often ineligible from participating in a clinical trial for a variety of reasons, such as age, gender, medical history, or current medical status.<sup>124</sup> With death imminent, patient advocates argue that risky but potentially beneficial treatment is better than inaction.<sup>125</sup>

Second, all Right to Try laws offer some form of protection for physicians who prescribe, advise, dispense, administer, or are otherwise involved in the care of an eligible patient using an experimental drug.<sup>126</sup> No law requires that a physician partake in the process; that decision is solely within the discretion of the physician.<sup>127</sup> However, if a physician chooses to participate and acts with reasonable care, he or she is protected from liability and his or her medical license is protected from any form of reprimand.<sup>128</sup> This is an important feature of Right to Try laws because it allows physicians to act in the best interest of their patients without fear of being penalized. It also encourages voluntary participation from physicians.

### III. A MODEL CONGRESSIONAL RIGHT TO TRY STATUTE

Despite the inconsistencies among state Right to Try laws, the Trickett Wendler Act is a meager six sentences.<sup>129</sup> While there is power behind those six sentences, there is not enough clarity. The Trickett Wendler Act is extremely deferential to state Right to Try laws in areas where there is no consensus.<sup>130</sup>

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<sup>122</sup> Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. MED. 362, 364 (2001).

<sup>123</sup> Rubin & Matthews, *supra* note 56, at 4.

<sup>124</sup> Roswell Park Cancer Institute, *What Are Eligibility Criteria, and Why Are They Important?*, <https://www.roswellpark.org/clinical-trials/eligibility-criteria> (last visited Dec. 27, 2017).

<sup>125</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>.

<sup>126</sup> *E.g.*, ALA. CODE §§ 22-5D-6, 22-5D-10 (2015).

<sup>127</sup> *Id.* § 22-5D-7(b) (2015).

<sup>128</sup> *Id.* §§ 22-5D-6, 22-5D-10 (2015).

<sup>129</sup> *See* Trickett Wendler Right to Try Act of 2016, S. 2912, 114th Cong. (2016).

<sup>130</sup> *Id.*

If America truly wants terminal patients to have the right to try, Congress must provide clearer guidelines. The model legislation outlined in the following four Sections is not meant to be exclusive, but delineates the minimum that should be included in a congressional Right to Try statute.

*A. Eligibility Requirements*

First, a list of eligibility requirements is necessary. At minimum, that list should include the following seven requirements: (1) The patient has a terminal illness, attested to by his or her physician and a consulting physician; (2) The patient has considered all other currently approved treatment options; (3) The patient has received a recommendation from his or her physician for the experimental treatment sought; (4) The patient has given written, informed consent for the treatment; (5) The patient is unable to participate in a clinical trial within one-hundred miles of the patient's home, or has not been accepted into a clinical trial within one week of applying; (6) The patient's physician has determined that the potential risks of using the experimental drug do not outweigh the potential benefits of using the experimental drug, and that the risks are not unreasonable in the context of the patient's condition; and (7) The patient has documentation from his or her physician that he or she meets all of the eligibility requirements.

Requirements number three and seven are standard, straightforward requirements. The patient's physician must recommend, or prescribe, the experimental treatment being sought by the patient, and the patient must have documentation certified by his or her physician that he or she meets all of the eligibility requirements. These two requirements ensure that a patient is acting under the recommendation of a doctor, and not on his or her own whim to access new medication.

Requirement number one should instruct that the patient be "terminally ill" as attested to by the patient's physician and a secondary physician. Often, treating physicians have long-term relationships with patients that may, even unintentionally, cloud their decision making.<sup>131</sup> The second physician's opinion will

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<sup>131</sup> Although physicians should act objectively and in the best interests of their patients, there is the possibility that a physician's personal feelings towards her patient will unconsciously direct her medical decisions.

(1) ensure that the patient is “terminally ill” for purposes of the law and (2) safeguard against overly compassionate treating physicians who may be unable to evaluate the situation objectively.<sup>132</sup>

Eligibility requirement number two, that the patient has considered all other currently approved options, is another safeguard for the safety of the patient. Emphasis remains on access being the patient’s last viable option.

Requirement number four, that the patient has provided written, informed consent, ensures that a patient understands the risks of experimenting with an investigational treatment outside the scope of a controlled clinical trial. Bringing a new life to the notion of patient autonomy, the right to try movement argues that it should be the patient’s, not the government’s, decision whether to try an investigational drug.<sup>133</sup> A patient cannot competently make such a decision without being fully informed about the treatment. That argument is heightened in a right to try situation where the risks are greater and the outlook drearier.

A federal statute should additionally include a specific definition of “written, informed consent,” highlighting what must be included in the informed consent document.<sup>134</sup> This ensures that all eligible patients receive enough information to make an informed decision.

Requirement number five mandates that the patient be unable to participate in a clinical trial within one-hundred miles of his or her home, or has not been accepted into the clinical trial within one week of applying. This requirement counteracts the fear that Right to Try laws will undermine the clinical trial process by requiring that patients first volunteer to participate in a clinical trial before turning to investigational treatment. Additionally, this reinforces the law’s intent to be a last resort option. By setting distance and time limitations, this requirement also takes into account that patients are often ineligible or unable to participate in a clinical trial.

Requirement number six requires the patient’s physician to undertake a risk-benefit analysis. The physician must

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<sup>132</sup> This is a common requirement of death by dignity laws throughout the country. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 443.6 (2015).

<sup>133</sup> Maxwell, *supra* note 103, at 3.

<sup>134</sup> *See supra* notes 60–61 and accompanying text.

confidently affirm that the experimental drugs' potential risks do not outweigh its potential benefits to the patient, and that the risks are not unnecessary in the context of the patient's condition. The physician should perform such an analysis using information about the drug available to him and his knowledge of the patient's clinical condition. This protects the patient from taking unreasonable risks.

*B. Definitions of Unsettled Terms*

Second, clear definitions should be provided for unsettled terms. "Terminally ill" should be defined as a progressive disease or medical condition that is not considered by a treating physician to be reversible even with administration of current FDA approved and available treatments, and that, without life-sustaining treatment, will likely result in death within one year, or a state of permanent unconsciousness from which recovery is unlikely.

This definition does four important things. First, it removes the requirement that the disease or condition entail "significant functional impairment." There is no agreed upon definition for this term, and the same disease or condition often manifests itself differently in one person from the next.<sup>135</sup> By removing the phrase altogether, the statute avoids identifying which terminal patients are suffering from significant functional impairment and which are not.

Second, it requires that the condition not be reversible even with the administration of currently approved treatments. This statute must be a last resort option. If a patient has a chance at survival through another approved, and arguably safer, line of treatment, the patient should take that option.

Third, the definition requires that death will likely occur within one year. Once again, this statute is a last resort option. There is very minimal knowledge about the safety of Phase One drugs. If a patient can reasonably wait for further safety testing of a drug, they should. This definition does not state that death is certain to occur within one year, only that it is likely to occur

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<sup>135</sup> EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT AND USE—QUESTIONS AND ANSWERS, *supra* note 93, at 12 (explaining that one individual may be denied for expanded access while another individual is approved expanded access for the same drug because there may be significant differences in the clinical presentation of the disease or condition among the two patients).



within one year. If there is medical reason to believe that the patient has a year or less to live, that should be sufficient to trigger this statute.

*C. Additional Provisions*

Third, a congressional statute should also address the protection and incentives available to induce a manufacturer's voluntary participation. Manufacturer participation should remain voluntary because a federal statute forcing participation in distributing a drug that has not yet been legally approved undermines the FDA's approval process.

To encourage voluntary participation, a provision should be included protecting manufacturers who act in good faith with reasonable care from liability. Manufacturers are more likely to comply with a statute that does not threaten liability. The requirement that the manufacturer act with good faith and reasonable care to invoke the protection *at the same time* protects patients from unscrupulous manufacturers.

Although a federal statute should encourage manufacturer participation, the statute should not prevent the reporting of adverse side effects suffered by a right to try patient to the FDA. While this may deter voluntary participation from manufacturers who have an interest in getting their drugs to the market, the FDA's interest in providing the public with safe drugs, and the public's interest in consuming the safest drugs possible, is stronger. If a drug induces a certain side effect, even a rare side effect, the FDA should account for that side effect in the drug's approval process.

A federal statute should also include a provision specifying what a manufacturer may charge for its drug. Such a provision should leave the decision of whether to charge with the manufacturer, but limit any charges to the out-of-pocket costs related to the drug's distribution to a specific patient. Allowing a manufacturer to charge may serve as an additional incentive for participation. But, by capping the amount chargeable, unscrupulous manufacturers will be unable to over-charge a patient. Additionally, limiting the amount chargeable makes it more realistic that economically disadvantaged patients will be able to benefit from the law. This should not be a law for only wealthy patients.

*D. Reconciling State Laws*

Lastly, the noted similarities among state Right to Try laws should be adopted into a federal Right to Try statute. First, the definition of an “experimental drug,” which has been adopted in state statutes across the country, should also be adopted in the federal statute. An “experimental drug” is defined as “a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States food and drug administration and remains under investigation in a United States food and drug administration-approved clinical trial.”<sup>136</sup> Currently, this is the strongest definition available, allowing the earliest access for terminal patients possible while still providing some safety-check.

Second, physicians’ participation should remain voluntary. To encourage participation, a federal statute should ensure that physicians, if complying with the statute in good faith and with reasonable care, be granted protection from liability and from reprimands to their medical licenses. Physician participation is critical for the success of a federal statute and for the safety of patients. Under the watch of a physician, a patient can more safely be prescribed and administered experimental drugs.

## CONCLUSION

Right to Try laws are highly controversial, and for good reason. Notwithstanding the debate between proponents and opponents, the right to try movement has only gained momentum since its inception, and will likely continue on that path. If such a law is to be adopted federally, the law must be drafted to protect the safety of terminal patients and the safety of the public health as a whole. Achieving this balance is possible.

A federal statute must not rely on new, untested state laws, as the Trickett Wendler Act does. By combining the strongest state policies, the FDA’s view, and the arguments of proponents and opponents, a federal statute can reach its potential, creating a successful and unquestionable “right to try” for terminal patients.

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<sup>136</sup> See, e.g., COLO. REV. STAT. § 25-45-103(2) (2014).