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The Cost of Hope at the End of Life: An Analysis of State Right-to-Try Statutes

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NOTES

The Cost of Hope at the End of Life: An Analysis of State Right-to-Try Statutes

Tamara J. Patterson

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1 J.D. Candidate, 2017, University of Kentucky College of Law. I am grateful to Professor Nicole Huberfeld for her guidance and suggestions, as well as the generous use of her personal library.
Abigail Burroughs was a young college student who tragically developed head- and-neck cancer. When standard therapies were ineffective, she sought early access to two investigational drugs the Food and Drug Administration ("FDA") had not yet approved. Because she was ineligible for clinical trials, however, and the drug manufacturers refused to include her in their compassionate-access programs, Abigail died at age twenty-one. The FDA later approved one of the drugs for head- and-neck cancer, and Abigail's father remains convinced that he would not have lost his daughter if she could have had access to the drug. He became an advocate for early access to experimental treatment for the terminally ill and went on to found The Abigail Alliance for Better Access to Developmental Drugs ("Abigail Alliance"). The group eventually brought a federal suit claiming that terminally ill patients have a constitutional right to try non-FDA approved experimental treatments in their efforts to preserve their lives. The D.C. Circuit, sitting en banc, disagreed. The D.C. Circuit noted that its decision need not be the end of the discussion, but that Abigail Alliance’s “arguments about morality, quality of life, and acceptable levels of medical risk are certainly ones that can be aired in the democratic branches, without injecting the courts into unknown questions of science and medicine.”

Supporters of this “right-to-try” movement took the court’s recommendation to heart and began lobbying Congress to pass such legislation. But while several bills were introduced, none were passed. Right-to-try advocates, bolstered by help from the Goldwater Institute, began focusing their lobbying efforts on state legislatures, with great success. Since 2014, more than thirty states have passed right-to-try legislation, with almost all the remaining states’ legislatures having introduced such bills, including Kentucky.

This Note looks at right-to-try statutes and argues that not only do they have hidden costs which are generally not discussed by their supporters, but that these statutes are ultimately ineffective in increasing early access. Part I gives an overview of the FDA new drug approval process and the early access exceptions for the

2 Id.
3 Id.
6 Id. at 710–11.
7 Id. at 713.
9 Right to Try in Your State, RIGHT TO TRY, http://righttotry.org/in-your-state/ [https://perma.cc/S74V-94P3] (last visited Mar. 26, 2017) (maintaining a current list of states where legislation has passed or bills have been introduced).
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I. EARLY ACCESS: FDA REGULATIONS V. STATE RIGHT-TO-TRY STATUTES

The debate surrounding right-to-try legislation centers on the tension between individual patient autonomy and the government's desire to protect its citizens from unsafe drugs through regulation. Manufacturers must first submit a new drug to rigorous testing and gain approval from the FDA before the drug can be placed on the market. The FDA, however, provides a means by which terminally ill patients may obtain treatments that have not yet gained approval through its early access programs. State right-to-try legislation proposes a shortcut around the FDA, attempting to create a right of early access to unapproved therapies for the terminally ill that is outside of the FDA regulatory structure.

A. FDA Drug Regulation and Approved Methods of Early Access

Before any new drug can be marketed, it undergoes extensive testing to determine both its safety and efficacy. First, a manufacturer must obtain an Investigational New Drug exemption from the FDA, allowing the drug to be shipped in interstate commerce for testing purposes. The drug then undergoes three phases of clinical testing. Phase I testing is highly controlled with a limited number of participants, allowing researchers to determine "reasonably safe" maximum dosages. Phase II trials are open to a larger number of participants and have less narrow eligibility requirements. While Phase II trials are primarily devoted to demonstrating an investigational drug's efficacy, researchers must also continue to show that the drug is reasonably safe. If researchers can show that an investigational drug's potential risks are less than its potential benefits, the drug advances to Phase III testing. Only if the drug is shown to be an effective treatment with an acceptable risk of side effects can the manufacturer petition for approval to market the drug. Very few investigational drugs are granted FDA approval. About 30% of new investigational

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10 21 C.F.R. §§ 312.1, 312.20 (2017); Dresser, supra note 1, at 1633.
11 21 C.F.R. § 312.21 (2017); Dresser, supra note 1, at 1634.
12 21 C.F.R. § 312.21; Dresser, supra note 1, at 1634.
13 21 C.F.R. § 312.21; see Dresser, supra note 1, at 1634.
14 21 C.F.R. § 312.21; Dresser, supra note 1, at 1634.
15 21 C.F.R. § 312.21; Dresser, supra note 1, at 1634.
16 21 C.F.R. §§ 314.2, 314.50 (2017); Dresser, supra note 1, at 1634.
drugs are eliminated during Phase I testing for safety reasons. Only about one-third successfully pass both Phase I and II.

Patients with serious illnesses can gain early access to investigational drugs through clinical trials or through the FDA's expanded access program. However, clinical trials are tightly controlled, and many terminally ill patients are therefore not eligible to participate. Through the expanded access program, individual access to an unapproved drug may be granted if the patient has a serious or life-threatening condition for which there are no comparable alternative treatments. A terminally ill patient, however, must first find a physician who is willing to administer the treatment and must gain approval from an Institutional Review Board. Additionally, the patient needs an FDA determination that the benefits of treatment outweigh the associated risks and that the patient's use will not negatively interfere with any clinical trials. During treatment, the manufacturer or the physician must report any adverse effects and also provide a written summary of any treatment results.

Critics claim that FDA regulations are overly burdensome. FDA review times, however, have "decreased considerably and are now similar to or better than those in most industrialized countries." Of the nearly 1,000 requests for early access each year, the FDA approves 99% of them. Additionally, in February 2015, the FDA introduced a "new, simplified" early access application that is estimated to take only forty-five minutes to complete, significantly less than "the 100 hours required to complete a[n]... [Investigational New Drug] application."
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B. Bypassing the FDA: The Goldwater Institute’s Model Legislation and Its Variations in State Right-to-Try Statutes

Despite the continued streamlining of the FDA approval process, many states have concluded that the process for obtaining early access to investigational drugs through the FDA is too long for those battling terminal illnesses.\textsuperscript{29} Claiming that these patients have a fundamental right to seek to preserve their lives,\textsuperscript{30} more than thirty states have enacted right-to-try legislation.\textsuperscript{31} Most states closely base their right-to-try statutes on model legislation developed by the Goldwater Institute,\textsuperscript{32} a conservative and libertarian think tank.\textsuperscript{33} The legislation purports to bypass FDA regulations by creating a right of access for the terminally ill, allowing patients to directly petition manufacturers for investigational drugs.\textsuperscript{34}

i. Theme: The Goldwater Institute’s Model Legislation

Overwhelmingly, states have adopted the Goldwater Institute’s model legislation with slight variations. In some instances, states have adopted the model legislation with very little revision.\textsuperscript{35} Michigan, for example, changed the term “terminal illness” to “advanced illness,” but otherwise adopted the model legislation verbatim—including keeping “food and drug administration” and “medicare” in the lower case.\textsuperscript{36} While the relationship between the Goldwater Institute’s model and the state legislature is not quite so explicit, the Goldwater Institute’s model is clearly the foundational document for many states’ right-to-try legislation.

\textsuperscript{29} See Right to Try in Your State, supra note 9 (showing the number of states that have passed and introduced “Right to Try laws”).
\textsuperscript{30} See, e.g., ARK. CODE ANN. § 20-15-2102(4) (2016) (“[P]atients who have a terminal disease have a fundamental right to attempt to pursue the preservation of their own lives . . . .”).
\textsuperscript{31} Right to Try in Your State, supra note 9.
\textsuperscript{35} See supra note 32 and accompanying text.
\textsuperscript{36} Compare Right to Try Model Legislation, supra note 32, § 1.(2)(a)–(c), with MICH. COMP. LAWS SERV. §§ 333.26451, 333.26455.
The model legislation gives an eligible patient with a terminal illness a right to request access to an "investigational drug, biological product, or device" upon the patient's written informed consent. To be eligible, a patient must: (1) have a "terminal illness, attested to by the patient's treating physician," (2) have considered all other FDA-approved treatments, (3) receive a recommendation from a physician for the investigational drug, (4) give written informed consent to the treatment, and (5) have documentation from the physician certifying the patient's eligibility. The terminal illness must be an irreversible "progressive disease or medical or surgical condition" that causes "significant functional impairment . . . [and] will soon result in death." Only investigational drugs that have passed the FDA's Phase I testing and are currently in an FDA-approved clinical trial are permitted for use under the statute.

The Goldwater Institute model provides minimum standards for the contents of a patient's written informed consent. First, there must be an explanation of currently approved treatments for the patient's terminal illness. The patient and physician must agree that none of these approved treatments will be likely to prolong the patient's life. The specific treatment sought, whether drug, biological product, or device, must be clearly identified, and the best and worst outcomes, as well as a description of the most likely outcome must be described. This includes the possibility that the treatment may produce unexpected results that could worsen the patient's condition or even lead to death. Because of the investigational nature of the treatment, the description of possible outcomes is based upon the physician's knowledge of the treatment and the patient's illness. Finally, the consent must also include statements that the patient's health insurer is not obligated to pay for the treatment or for any effects resulting from the treatment, that a "patient's eligibility for hospice care may be withdrawn" subsequent to treatment, and "that the patient understands that he or she [and his or her estate] is liable for all [treatment-related] expenses."

The model legislation has a series of provisions that allow, but do not require, a manufacturer to make the drug, biological product, or device available either for free or in exchange for a patient's payment of the costs associated with manufacturing the drug. Similarly, health insurers "may, but [are] not required to, provide coverage" for the treatment. However, the model legislation expressly "does not affect any

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37 Right to Try Model Legislation, supra note 32, §§ 1.2(b), 2.1.
38 Id. § 1.2(b).
39 Id. § 1.2(a).
40 Id. § 1.2(c).
41 Id. § 1.2(d)(i).
42 Id. § 1.2(d)(ii).
43 Id. § 1.2(d)(iii)-(iv).
44 Id. § 1.2(d)(v).
45 Id.
46 Id. § 1.2(d)(v)-(vii).
47 Id. § 2.1-(2).
48 Id. § 3.1-(2).
mandatory ... coverage for participation in clinical trials. Government payment of any costs for treatment are not required, nor are hospitals or facilities required "to provide new or additional services" for patients seeking investigational treatments. Under the model legislation, if a patient dies during treatment, that patient's heirs are free from liability for any outstanding debt related to the treatment.

Finally, a provider's license or Medicare certification may not be revoked, nor may a provider be disciplined on account of recommending investigational treatment. In fact, officials, employees, and agents of the state are forbidden to block or attempt to block access to such treatment. However, a licensed health care provider's "[c]ounseling, advice, or ... recommendation consistent with medical standards of care" does not violate this provision. Manufacturers and "any other person or entity involved in the care of an eligible patient using [an] investigational drug" are immune from liability for negative treatment outcomes, provided they "comply[] in good faith with the [provisions] of [the] act and ... exercise[] reasonable care."

ii. The Variations: State Right-to-Try Statutes

While the Goldwater Institute's model served as a first draft for the majority of state right-to-try statutes, many states made significant modifications to certain provisions in the model legislation. These revisions most often occurred in the definitions of eligible patient and written informed consent, as well as in the provisions regarding payment for the experimental drug, standards of liability, and the reporting of adverse treatment reactions.

The definition of an eligible patient is one of the most commonly revised provisions in states' right-to-try statutes. Some states have lowered eligibility requirements, effectively broadening the number of patients granted a right of access to treatment. For example, Utah's only requirement for eligibility is that the patient has a terminal illness. Other states have expanded eligibility by re-defining "terminal illness." Almost ten states define terminal illness to include permanent unconsciousness. Others have more expressly defined terminal illness by creating a time frame within which death is likely to occur. In Illinois, a terminal illness is one...
that can be reasonably expected to cause death within twenty-four months. In Nevada, it’s one year. But other states have omitted any time requirement. In defining a patient’s eligibility, a few states include a balancing test, much like the one used in the FDA’s compassionate use program, mandating that the risk of death be greater than the risk of the experimental treatment. Generally, these balancing test provisions also require that no other comparable or satisfactory FDA-approved treatment options be available.

While some states have expanded eligibility, others have limited it, adding additional requirements. In light of the need for clinical trial participants, some states require that eligible patients be unable to participate in a clinical trial for their terminal illness within 100 miles of their home. In Missouri, a patient only has to consider all relevant clinical trials being held within the state. Other limitations include requiring the patient to consider, in consultation with a physician, all other treatment options (Minnesota), obtaining a second opinion (Florida), and denying eligibility to patients currently receiving inpatient treatment in a hospital (Colorado, Oklahoma, and North Dakota).

Written informed consent is another provision in state right-to-try statutes that often differs from the Goldwater Institute’s model. Some states do not define informed consent within the statute. Others require written informed consent that is at least as comprehensive as that used in clinical trials. A few states do not require a witness. Statutes also differ in the amount and types of treatment outcomes—both positive and negative—that must be disclosed. While the model legislation requires a description of the “potentially best and worst outcomes,” in Utah, a doctor is required to “describe[] the possible positive and negative outcomes,”

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58 410 ILL. COMP. STAT. ANN. 649/10(5) (LexisNexis 2016).
59 NEV. REV. STAT. ANN. § 454.690(5)(c) (LexisNexis 2016).
61 ARIZ. REV. STAT. § 36-1311(1)(b); ARK. CODE ANN. § 20-15-2104(2) (2016); LA. STAT. ANN. § 40:1169.3(1)(b); UTAH CODE ANN. § 58-85-102(6)(a)(1).
62 ARIZ. REV. STAT. § 36-1311(1)(b); ARK. CODE ANN. § 20-15-2104(2); LA. STAT. ANN. § 40:1169.3(1)(b). Interestingly, Utah uses this provision to define terminal illness, not patient eligibility. UTAH CODE ANN. § 58-85-102(6)(b).
64 MO. ANN. STAT. § 191.480(1)(b) (West 2016).
65 MINN. STAT. ANN. § 151.375(3)(2) (West 2017).
67 COLO. REV. STAT. § 25-45-103(1)(b).
68 OKLA. STAT. ANN. tit. 63, § 3091.2(1).
70 See, e.g., ARIZ. REV. STAT. § 36-1311 (LexisNexis 2016); 410 ILL. COMP. STAT. ANN. 649/10 (LexisNexis 2016); WYO. STAT. ANN. § 35-7–1802 (2016).
71 E.g., MO. ANN. STAT. § 191.480(1)(1)(d) (West 2016).
72 See, e.g., FLA. STAT. ANN. § 499.0295(2)(c) (LexisNexis 2016); MINN. STAT. ANN. § 151.375(3) (West 2017). But see Right to Try Model Legislation, supra note 32, § 1(d) (“Written, informed consent’ means a written document signed by the patient . . . and attested to by the patient’s physician and a witness . . .”).
73 Right to Try Model Legislation, supra note 32, § 1(d).
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including any increased risk of death. 74 South Dakota generalizes this provision further, merely requiring a doctor to explain "potential outcomes" of treatment. 75 In Florida, however, a doctor need only provide "[a] realistic description of the most likely outcomes." 76

As in the model legislation, almost all states allow a manufacturer to charge patients for treatment. 77 Texas, alone, prohibits a manufacturer from receiving compensation for providing an experimental drug to an eligible patient. 78 But a few states attempt to limit the costs to patients for treatment. Arkansas does this by allowing a manufacturer to charge patients only for "actual out-of-pocket costs incurred in providing the investigational drug, biological product, or device to the patient in the specific case." 79 Other states include the model legislation's provision that excuses a patient's heirs' from liability for any outstanding treatment-related debt if the patient dies during treatment. 80 But the debt-cancelling provision is one of the most commonly deleted provisions in the model legislation. 81

Defining the limits of liability for experimental treatment is another area where states often diverge from the model legislation. Most states provide some protection for manufacturers and health care providers, so long as the treatment complies with good faith and reasonable care. 82 But the standard of care varies, with some states not explicitly requiring reasonable care, 83 and others changing the standard to "gross negligence." 84 Indiana’s statute only protects manufacturers and not health care providers, 85 while Louisiana’s statute only provides immunity for physicians. 86 Texas is silent on any standard of care, excluding a private right of action for "any harm done to the eligible patient resulting from the investigational drug, biological product, or device." 87 Arizona’s statute has no provision excluding a private right of

77 See supra note 47 and accompanying text.
78 TEX. HEALTH & SAFETY CODE ANN. § 489.053(c) (West 2015).
81 See, e.g., ARIZ. REV. STAT. §§ 36-1311 to -1314 (LexisNexis 2016); LA. STAT. ANN. §§ 40:1169.1-1169.3 (2016); MINN. STAT. ANN. § 151.375 (West 2017); MO. ANN. STAT. §191.480 (West 2016); UTAH CODE ANN. §§ 58-85-101 to -105 (LexisNexis 2016); WYO. STAT. ANN. §§ 35-7-1801 to -1806 (2016).
82 See, e.g., COLO. REV. STAT. § 25-45-107; FLA. STAT. ANN. § 499.0295(8); N.D. CENT. CODE § 23-48-05 (2016); OKLA. STAT. ANN. tit 63, § 3091.6 (West 2016).
83 See, e.g., WYO. STAT. ANN. § 35-7-1806 (requiring only "good faith" medical treatment).
84 See, e.g., Ark. Code Ann. § 20-15-2110(a) (granting immunity from civil liability for experimental treatment provided in good faith except in cases of "gross negligence or willful misconduct").
86 La. Stat. Ann. § 40:1169.5(A) (granting broad immunity to physicians for "any adverse action, condition, or other outcome resulting from the patient's use of the investigational drug, biological product, or device").
action for experimental treatment. Utah takes a completely different approach; instead of limiting liability for harm resulting from experimental treatment, Utah’s statute protects physicians and hospitals from liability for refusing to administer experimental treatment. Similarly, it protects manufacturers from liability for refusing to provide patients with experimental drugs or devices.

Variations on the model legislation’s provision prohibiting official attempts to block access to experimental treatments generally follow one of three forms. Most commonly, states either follow the wording of the model legislation or remain entirely silent on the issue. A few states not only prohibit any attempt to block patient access to experimental treatment, but also have defined such attempts as misdemeanors. Almost all states temper any potential liability from these provisions by expressly stating that counseling, advice, or medical recommendations do not violate the statute. Interestingly, however, in states where attempts to block access are considered misdemeanors, there is no statutory carve out for this type of medical advice. But several states, following language in the model legislation, do not require hospitals or medical facilities to provide new or additional services to comply with the statute. Some extend this protection to physicians.

Only a few states require collaborative reporting between the manufacturer and the patient. Arizona explicitly allows a manufacturer to require a patient to participate in data collection in order to gain access to its investigational drugs. Tennessee requires a patient’s physician to notify the manufacturer the patient’s adverse responses to the treatment. Missouri requires a manufacturer to notify a patient if the treatment is found to be unsafe in any trial.

Thus, while there are several variations among the states, particularly in defining an eligible patient and informed consent, the Goldwater Institute’s model underlies

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88 ARIZ. REV. STAT. §§ 36-1311 to -1314 (LexisNexis 2016).
89 Id. § 58-85-104(3)(c)(ii) (LexisNexis 2016).
90 Id. § 58-85-104(3)(c)(ii).
93 ARIZ. REV. STAT. § 36-1314; 410 ILL. COMP. STAT. ANN. 649/25 (LexisNexis 2016); NEV. REV. STAT. ANN. § 454.690(3)-(4) (LexisNexis 2016).
95 ARIZ. REV. STAT. § 36-1314; 410 ILL. COMP. STAT. ANN. 649/25; NEV. REV. STAT. ANN. § 454.690.
96 Compare, e.g., Right to Try Model Legislation, supra note 32, § 3(4), with ARK. CODE ANN. § 20-15-2110(b)-(c), FLA. STAT. ANN. § 499.0295(5), MICH. COMP. LAWS SERV. § 333.26453(4), and MONT. CODE ANN. § 50-12-106(1)(d) (West 2017).
97 ARK. CODE ANN. § 20-15-2110(b).
98 ARIZ. REV. STAT. § 36-1312(B)(3).
99 TENN. CODE ANN. § 63-6-309.
100 MO. ANN. STAT. § 191.480(7) (West 2016).
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most state right-to-try legislation. These states hope that this legislation will bypass the FDA’s regulatory structure, granting terminally ill patients the right to directly petition manufacturers and ultimately increasing access to experimental treatment.

II. AN ANALYSIS OF STATE RIGHT-TO-TRY STATUTES

Because state right-to-try legislation ostensibly only defines a right of early access, it is often seen as a no-cost solution to aid the terminally ill in their quest for potentially life-saving treatment options. A more nuanced analysis, however, shows that there are many costs inherent in these laws: costs to public health, drug manufacturers, doctors, and even to the patients themselves. Furthermore, looking deeper to the underlying assumptions of right-to-try legislation shows that many of these assumptions are false, making the laws themselves ineffective in actually providing early access for the terminally ill.

A. Costs and Benefits of State Right-to-Try Legislation

In analyzing right-to-try legislation, examining the costs and benefits of the laws can create a framework for determining whether early access legislation is an appropriate means of supporting the terminally ill. There are no explicit costs associated with right-to-try legislation, and thus a state would not need to generate additional tax revenues. But there are implicit costs—financial or otherwise—to society, drug manufacturers, physicians, and patients. By balancing these costs with the potential benefits derived from the statutes, states can more accurately assess right-to-try legislation.

The primary beneficiaries of right-to-try legislation, of course, are terminally ill patients and their loved ones. It must be emphasized, though, that the benefit of right-to-try legislation is not an actual cure or life sustaining treatment. It is merely the chance of one. Put more simply, the primary benefit is hope. But a correlated benefit to patients is the dignity of acting as an autonomous individual. According to this view, society should not deny a competent individual the ability to take the risks inherent in experimental treatment when death is otherwise a certainty. Patients should have the freedom to balance the known risks of their condition with the potential risks and benefits of experimental treatments. Some have even argued

101 See Why We Need Right to Try: About Right to Try, supra note 34 ("Right to Try gives life-saving hope back to those who’ve lost it.").
102 See Udo Schüllken & Christopher Lowry, Terminal Illness and Access to Phase 1 Experimental Agents, Surgeries and Devices: Reviewing the Ethical Arguments, 89 BRIT. MED. BULL., Mar. 2009, at 7, 10–12, https://academic.oup.com/bmb/article/89/1/7/359991/Terminal-illness-and-access-to-Phase-1 (follow “PDF” hyperlink) [https://perma.cc/7X8S-FU8J].
103 See id. at 11.
104 See id.
that access to experimental treatment is a form of medical self-defense that should be recognized as a constitutional right.105

This hope for a cure is offset by costs to public health, drug manufacturers, physicians, medical facilities, and even the patients themselves. Patient access to experimental treatment has the potential to reduce participation in the research necessary for these treatments to gain FDA approval and become available to the general public.106 Because Phase II and Phase III testing require large numbers of people to demonstrate a treatment’s efficacy, allowing individuals early access could potentially slow down—or for rare conditions, even block—the completion of FDA testing.107 Likewise, because many states’ right-to-try statutes have no reporting requirements, the adverse side effects of experimental treatments will take longer to be recognized.108 Some states have addressed this issue by defining eligible patients as those who have been unable to participate in a clinical trial within 100 miles of their home.109 Others require reporting of adverse side effects (or general reporting) to the manufacturer.110 Even with these reporting requirements, because there is often no control group when patients receive early access, it would be difficult to determine a treatment’s efficacy.111 Without understanding a treatment’s efficacy, it is impossible to balance the risks inherent in the treatment.112

While the ability to bypass FDA regulations and sell directly to customers may appear to provide only financial gain to manufacturers, it also brings several potential costs. The most obvious of these costs—liability for adverse reactions to treatment—is mitigated by an express grant of immunity in almost all state statutes.113 But legal liability is not the only cost manufacturers face. Because of the ubiquitous reach of social media, an adverse reaction to an experimental treatment—or even a denial of a patient’s request for access to treatment—can have serious financial effects on a manufacturer.114 For example, after initially denying a 7-year-old cancer patient’s

105 See Eugene Volokh, Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs, 120 Harv. L. Rev. 1813, 1816–17, 1824, 1826–27 (2007); see also FAQ, supra note 34 (stating that “FDA regulations cannot preempt state laws that preserve constitutionally protected rights, such as the fundamental right to life and medical self-preservation”).
106 See Darrow et al., supra note 26, at 284.
107 Schikleen & Lowry, supra note 102, at 16–17.
108 See supra notes 98–100 and accompanying text.
109 See, e.g., supra note 63 and accompanying text.
112 See Schikleen & Lowry, supra note 102, at 17. For example, breast cancer treatment with high-dose chemotherapy and bone marrow transplant was widely available before definitive trials were conducted. Id. The treatment ultimately proved ineffective but not before “tens of thousands of women” were subjected to the burdens and risks of the treatment, resulting in “an avoidable surplus of life-years lost.” Id.
114 Vicki G. Norton, How Drug Cos. Can Minimize Risks of ‘Right to Try’ Laws, Law360 (June 30, 2015), 12:02 PM,
request for early access, Chimerix, Inc. was subjected to a negative social media campaign, eventually leading to the CEO's resignation. Chimerix eventually reconsidered and after the boy was successfully treated, the ensuing positive social media coverage led to a fifty percent increase in Chimerix stock. When a different patient died while undergoing the same treatment, however, Chimerix stock fell by fifteen percent. For small companies in particular, these potential financial swings could be disastrous, creating a chilling effect on manufacturers' willingness to provide experimental drugs to terminally ill patients.

For physicians and medical facilities, right-to-try legislation comes with two potential financial costs: liability from adverse reactions to experimental treatment and from allegations of blocking access to experimental treatments. First, because of the lack of information available regarding the effects of experimental treatments, physicians face a difficult challenge in weighing the risks and benefits of treatment. Manufacturer's clinical information is proprietary, and thus, physicians can only gain access to it at the discretion of the manufacturer. To say the least, this creates difficulties for physicians to determine possible outcomes or even realistic outcomes of experimental treatment. While many right-to-try statutes limit a physician or medical facility's liability for a patient's adverse reactions to experimental treatments, if adverse reactions occur, it is likely that physicians and facilities will face the same risk of financial loss from negative media attention as manufacturers. Second, physicians may also face liability from accusations of blocking patient access to experimental treatment. Generally, state provisions prohibiting actions that block access to investigational drugs exclude normal physician-patient counseling. If a patient is adamant in desiring experimental treatment, how certain must the negative effects of that treatment be for a physician to escape a charge of blocking a patient from access? While several states did not enact this provision of the model legislation, others not only included it, but made any attempt at blocking access to experimental treatment a misdemeanor.

These blocking provisions can lead to an ethical dilemma for physicians, who are called to "do no harm." If a physician believes that the risk of side effects is greater than any potential benefit, is it ethical for the physician to prescribe the experimental treatment? Considering that "the probability of clinically meaningful benefit from
early-stage experimental trials may be less than 10%,” this scenario, where the risk of harm outweighs the potential benefits, is much more likely to be the norm than the exception. Generally, the goal of physicians is to keep patients alive and healthy. But at the end of life, calculus of this decision may change. Right-to-try legislation seems to tip the scale in favor of maintaining life at all costs and by any means. If physicians fear being viewed as blocking access to experimental treatment, physicians could be effectively discouraged from having necessary end-of-life discussions with their terminally ill patients.

Right-to-try legislation also comes with costs for the terminally ill patients themselves. Under right-to-try statutes, health insurance is not required to cover the costs associated with treatment—which includes the treatment of any side effects. And while manufacturers may provide the drug free of charge, they are not required to do. If a manufacturer refuses to provide the experimental drug, it is unlikely to be covered by a patient’s insurance. Medicare and most private insurance only cover costs for “reasonable and necessary” treatments and payment for an experimental treatment will generally be denied. Many states have tried to mitigate cost to patients by eliminating the patient’s (and the patient’s estate’s) liability for any outstanding debt related to treatment if death occurs. Furthermore, under many statutes, once treatment begins, hospice benefits are often terminated. This essentially means that right-to-try legislation only expands access for those with the means to pay, “generally favor[ing] the rich or well-connected over the poor.”

Weighing these costs and benefits leads to no simple result. On the one hand, the costs of right-to-try legislation primarily stem from potential liability for manufacturers, physicians, and medical facilities; reduced participation in clinical trials, leading to potentially worse public health outcomes; the cost burden patients bear for treatment; and, the inherent inequity in access between rich and poor. These are balanced against the terminally ill patient’s autonomy in making medical decisions and the hope for a cure or other life-sustaining treatment. Often, however, this hope for a cure may be futile. But, “futility is in the eye of the beholder,” and patients may wish to try every available treatment—even if the chance of any meaningful clinical benefit is less than ten percent. This decision may be based

124 Darrow et al., supra note 26, at 284.
125 See, e.g., COLO. REV. STAT. § 25-45-104(3); FLA. STAT. ANN. § 499.0295(4) (LexisNexis 2016); MICH. COMP. LAWS SERV. § 333.26453.
126 See, e.g., COLO. REV. STAT. § 25-45-104(1)-(2); FLA. STAT. ANN. § 499.0295(3); MICH. COMP. LAWS SERV. § 333.26452(2).
127 Darrow et al., supra note 26, at 284.
128 See id.
130 See, e.g., COLO. REV. STAT. § 25-45-103(4)(f); FLA. STAT. ANN. § 499.0295(2)(e)(6); MICH. COMP. LAWS SERV. § 333.26451(2)(d)(vi).
131 Darrow et al., supra note 26, at 284.
more on “assuag[ing] feelings of helplessness” and less on a rational analysis of treatment options.133

This has led some observers to question terminally ill patients’ ability to give informed consent. In the context of clinical research trials, medical ethics researchers have explored the process of informed consent for the terminally ill.134 The findings show that terminally ill patients tend to “overestimate[] their chances of experiencing [clinical] benefit and underestimate[] their chances of experiencing harm.”135 A patient who experiences this “unrealistic optimism” in clinical trials can accurately describe the clinical trial process—in which some participants are placed in the control group and excluded from the treatment under investigation—and yet still expect to receive therapeutic benefit for themselves.136 In one survey, 69% of respondents said a person should participate in a clinical trial to benefit society.137 But when asked why they personally would participate in a clinical trial, 52% of respondents acknowledged they would do it to receive the best medical care.138

Like a gambler who understands the negligible odds of winning and yet believes the next roll is his lucky roll, unrealistic optimism “interfer[e]s with an individual’s ability to apply information, or to use the information she is given with understanding.”139 In essence, unrealistic optimism compromises a patient’s ability to make autonomous treatment choices because the patient is reasoning from false beliefs.140 This has led many to conclude it would be unethical to allow patients who exhibit unrealistic optimism to participate in clinical trials.141 The same might be said of patients asking for experimental treatments. If patients are overestimating the probability of benefit and underestimating the probability of harm, their ability to give informed consent is called into question. While this poses less of an ethical dilemma than in clinical trials (because the patient is being treated, not being experimented upon), it still creates a much murkier picture of a terminally ill patient’s ability to give informed consent for experimental treatment.

Thus, the two primary benefits to terminally ill patients of right-to-try legislation—hope and autonomy—seem to be inflated by proponents of these laws. When weighed against the various costs of the legislation, right-to-try laws are found wanting.

133 Id. at 15.
135 Id. at 1, 3.
136 Id. at 3.
137 Id. at 4.
138 Id.
139 Id. at 1, 5.
141 See id. at 403–05; see also Swekoski & Barnbaum, supra note 134, at 1, 5.
B. Assumptions Underlying State Right-to-Try Statutes

Beyond the costs associated with right-to-try legislation, right-to-try statutes are also incapable of substantively increasing a patient’s likelihood of gaining early access. The legislation is ultimately ineffective because it is based on several false assumptions. The first is that the FDA is the source of obstruction to early access. The Right To Try website notes that the FDA only grants early access to about 1,000 patients a year.\(^{142}\) It fails to mention that this represents an approval rate of 99% of such requests.\(^{143}\) And while the website claims that right-to-try legislation helps patients gain “immediate access” to treatment options, it fails to note that access is contingent upon the manufacturer’s consent to provide the treatment.\(^{144}\) Of the four patients whose cases were described in the Abigail Alliance complaint, none offered facts showing that FDA regulations kept them from obtaining treatment.\(^{145}\) There are many reasons why manufacturers deny these early access requests.\(^{146}\) Manufacturers often have limited supplies of investigational drugs, or they may be concerned that offering the medications for early access will undermine their chance of having the drug approved, whether through a reduced number of clinical trial participants or because of adverse side effects in the terminally ill patient.\(^{147}\) And, as discussed above, manufacturers may be adversely affected by negative media attention they receive if early access experimental treatment produces adverse effects.\(^{148}\) In fact, because terminally ill patients are often sicker than those admitted in clinical trials, they are more likely to experience negative outcomes than the participants in Phase I trials.\(^{149}\)

The second false assumption of right-to-try legislation is that unapproved drugs that have passed the FDA’s Phase I testing are unquestionably safe. While Phase I testing is primarily designed to determine maximum safe dosage levels, those trials are extremely limited in scope and the participants are tightly screened.\(^{150}\) Safety continues to be tested in Phases II and III in larger clinical trials.\(^{151}\) Yet, most right-to-try laws seem to presume that safety is definitively determined by completion of Phase I testing.\(^{152}\) As the court noted in Abigail Alliance, simply because Phase I

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\(^{142}\) FAQ, supra note 34.

\(^{143}\) Jacob, supra note 27, at 758.

\(^{144}\) FAQ, supra note 34; Okie, supra note 111, at 439.


\(^{146}\) See Darrow et al., supra note 26, at 280–82.

\(^{147}\) Jacob, supra note 27, at 759.

\(^{148}\) Norton, supra note 114.


\(^{150}\) See Dresser, supra note 1, at 1634.

\(^{151}\) Id.

\(^{152}\) See, e.g., FAQ, supra note 34 (affirmatively answering that treatments available under Right to Try laws are safe because they “have already passed the FDA’s basic safety testing”).
testing determines that a drug is "safe for limited clinical testing in a controlled and closely-monitored environment after detailed scrutiny of each trial participant does not mean that a drug is safe for use beyond supervised trials."153

Finally, right-to-try legislation assumes that federal law will not preempt these state laws. The Right to Try website claims that:

FDA regulations cannot preempt state laws that preserve constitutionally protected rights, such as the fundamental right to life and medical self-preservation. The United States Supreme Court has never addressed Right To Try specifically, but it has held that states have great latitude in regulating health and safety, including medical standards, which are primarily and historically a matter of local concern.154

While acknowledging that the Supreme Court has not addressed the right-to-try issue, the website fails to mention that this issue has come up in federal court.155 In Abigail Alliance, the D.C. Circuit held that a right of access to experimental drugs is not a fundamental constitutional right.156 And while the court noted that there were no Supreme Court decisions directly on point, it supported its decision with several related Supreme Court rulings.157

Additionally, even if preemption were an open question, it is unlikely that manufacturers would ignore federal regulations in favor of state right-to-try laws. Shipping investigational drugs by means of interstate commerce without obtaining FDA approval is illegal.158 With so much time and money invested in an investigational drug, manufacturers are unlikely to ignore this regulation if trying to gain FDA approval.159 Because bypassing the FDA's regulatory structure is "against [manufacturers'] self-interest," experts doubt that right-to-try legislation will effectively increase public access to experimental treatment.160

Thus, because the assumptions underlying state right-to-try legislation are false, the laws are ultimately ineffective. Combined with the many costs inherent in the legislation, right-to-try laws are an inadequate means to support the terminally ill.

154 FAQ, supra note 34.
155 See generally Abigail All. for Better Access to Developmental Drugs, 495 F.3d 695.
156 Id. at 711.
157 Id. at 710–11 ("Although it has not addressed the precise constitutional argument urged by the Alliance, we find it highly significant that the Supreme Court has rejected several similar challenges to the FDCA and related laws brought on statutory grounds.").
158 Richardson, supra note 19, at 4.
159 See Dresser, supra note 1, at 1647.
160 Id. at 1646–47.
III. KENTUCKY SHOULD REJECT RIGHT-TO-TRY LEGISLATION AND INSTEAD PROVIDE EFFECTIVE MEANS FOR ACHIEVING TERMINALLY ILL PATIENTS' TREATMENT GOALS

Ultimately, right-to-try legislation seems to be a form of political theater. It seems to be more of a statement in support of limited government oversight and less of a tool to help terminally ill patients fulfill their treatment goals. The purported benefits of these statutes are questionable, and the laws do nothing to substantially increase early access to experimental treatment for terminally ill patients. But because these statutes are financially neutral, they allow state legislators to say they have "done something" while sidestepping difficult ethical and moral questions surrounding end-of-life issues, particularly regarding the terminally ill. While right-to-try statutes may not impose a direct cost to the state, there are inherent costs in the legislation—to public health, manufacturers, physicians, and patients—but with no real benefits. For these reasons, Kentucky should reject the legislation.

There are, however, specific measures that Kentucky could take to support the terminally ill in making autonomous treatment decisions. First, legislators should be prepared to educate the public about the effects of early access and the costs of right-to-try legislation. Early access programs for terminally ill patients is inevitably an emotionally charged discussion. Therefore, legislators should be prepared to discuss not only facts, but also stories from both sides of the debate. To date, right-to-try proponents have controlled the creation of the narrative in the public imagination, in which the FDA's "red tape and government regulations" deprive the terminally ill of access to "potentially life-saving treatment." There are also stories on the other side of the debate, however, in which early access to investigational treatments leads not to "a longer and better life" but rather to "a painful and distressing death." These cautionary stories must also be told so that the terminally ill and the public in general understand the magnitude of the decision to obtain investigational treatments.

Second, Kentucky should work collaboratively with the FDA to help patients who wish to obtain early access to experimental treatments. One concrete way to do this is to create multi-center review boards that focus exclusively on expanded-access requests. Because gaining approval from an independent review board is required before a patient can begin treatment with an investigational drug, this can be a significant barrier to early access, especially in smaller facilities that do not have their own in-house review board. By limiting the multi-center review board to early access requests, Kentucky can make it easier and faster for patients to obtain experimental treatments.

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161 See id. at 1648 (noting that advocates often neglect to tell stories of patients who had negative experiences with investigational drugs).
162 See id. at 1656-57.
163 FAQ, supra note 34.
164 Dresser, supra note 1, at 1650.
165 Darrow et al., supra note 26, at 284.
166 See id. at 282.
access requests, the review time of patient requests can be reduced. Maintaining a multi-center review board would require funding, but it would be a substantive and effective means to increase access to experimental treatments for the terminally ill.

Finally, Kentucky should encourage physicians to have frank discussions with their terminally ill patients about the patient's goals for medical treatment. As Dr. Atul Gawande observes, "The seemingly easiest and most sensible rule for a doctor to follow is: [a]lways [f]ight." And yet, he notes that to "always fight" does not always mean doing more. Weighing the potential benefits and risks of continued treatments is an extremely personal determination, so physicians should take the time to understand what it is their patients truly desire from their medical care. Is their goal to live as long as possible even if their quality of life is reduced? Or is quality of life more important than duration? Perhaps there is an important event in the near future (a child's wedding, an anniversary) that they hope to attend. Physicians often do not receive the training necessary to develop the communication skills required for these end-of-life discussions. Yet, it is only with this level of information that a physician can help a patient understand the trade-offs inherent in different treatment options and determine which one will be most effective in helping reach the patient's goals. For example, after Colorado passed its right-to-try legislation, several ALS patients asked for experimental stem cell therapy. But after discussions with their doctors, all the patients decided to forego the treatment for less expensive or more easily available options.

To help spark these discussions, a standardized end-of-life questionnaire could be created that could be filled out as part of a patient's normal intake forms. This questionnaire could be left in a patient's medical record and thus be accessible to any treating physician. Not only would this allow physicians to more clearly understand their patient's treatment goals, it could also serve as a non-threatening way to begin end-of-life care discussions with patients and their families. The American Bar Association's Commission on Law and Aging has developed a Consumer's Tool Kit for Health Care Advance Planning that could easily be adapted for this purpose. While a simple intake form is by no means the best way for patients to evaluate their treatment goals for end-of-life care, it can be an effective way to introduce the topic in patient-physician discussions. Similarly, the National POLST (Physician Orders for Life-Sustaining Treatment) Paradigm approaches end-of-life planning by encouraging "thoughtful, facilitated advance care planning conversations" between...
patients, their families, and health care professionals, which a health care professional then documents in a POLST form. Kentucky’s POLST program is still developing, but once completed, it could provide another avenue for promoting end-of-life conversations between the terminally ill and their physicians.

By educating the public, working collaboratively with the FDA, and encouraging physician-patient dialogue regarding end-of-life issues, Kentucky can ensure that the terminally ill are given the chance to choose the most appropriate medical care to meet their personal treatment goals.

CONCLUSION

Right-to-try legislation delivers only a false hope for the terminally ill. Because it is based on faulty assumptions, right-to-try legislation cannot deliver expanded access to the terminally ill. It also comes with implicit costs for public health, manufacturers, physicians, medical facilities, and the patients themselves. Kentucky would do well to reject right-to-try legislation. However, this need not be a denial of the plight of her terminally ill citizens. Encouraging physicians to have those difficult end-of-life discussions with their patients can help patients more precisely define their own treatment goals. For those patients that wish to try experimental treatments, physicians can more effectively help them gain early access by working within the existing federal regulatory structure. Instead of pushing a one-size-fits-all approach to end-of-life care for the terminally ill, Kentucky has the chance to create meaningful avenues for terminally ill patients to make truly autonomous treatment choices.