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I. INTRODUCTION

This Note will examine the federal Right to Try Act, which was enacted on May 30, 2018. The federal statute followed the passage of Right to Try legislation in thirty-eight states, including California.[1] Much controversy has surrounded "Right to Try" as an alternative to preexisting pathways to investigational drug treatments, such as traditional clinical trials and the FDA[2]-regulated Expanded Access program, also commonly known as "Compassionate Use."[3]

Previously, the Expanded Access program was the only pathway outside of clinical trials to provide terminally ill patients with a last chance at survival with non-FDA approved experimental drug treatments.[4] Proponents contend that the "Right to Try" pathway is a more streamlined method of providing access to experimental drugs, free from burdensome paperwork and FDA regulation. However, prior to the bill being enacted by Congress, over one hundred patient's rights groups opposed it.[5]

This Note will examine those criticisms, evaluate the federal Right to

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1. Jacqueline Howard, *What you need to know about right to try legislation*, CNN (Mar. 22, 2018, 1:50 PM), https://www.cnn.com/2018/03/22/health/federal-right-to-try-explainer/index.html.

2. Food and Drug Administration.

3. Jacqueline Howard, *What you need to know about right to try legislation*, CNN (Mar. 22, 2018, 1:50 PM), https://www.cnn.com/2018/03/22/health/federal-right-to-try-explainer/index.html; Michael Nedelman & Jacqueline Howard, *'Right-to-Try' bill passes Congress*, CNN, (May 29, 2018, 1:48 PM), https://www.cnn.com/2018/05/22/health/right-to-try-legislation-congress/index.html.

4. Michael Nedelman & Jacqueline Howard, *'Right-to-Try' bill passes Congress*, CNN, (May 29, 2018, 1:48 PM), https://www.cnn.com/2018/05/22/health/right-to-try-legislation-congress/index.html.

5. Letter from A Twist of Fae-ATS et al., Patient and Provider Orgs., to Paul Ryan, Speaker, U.S. House of Reps. & Nancy Pelosi, Minority Leader, U.S. House of Reps (May 21, 2018), https://www.acscan.org/sites/default/files/National%20Documents/Senate%20Right%20to%20Try%20%28S.204%29%20Coalition%20Opposition%20Letter%205.21.2018.pdf.

Try Act, and propose amendments through the lenses of health care quality, patient autonomy, and long-term scientific innovation. Some controversy stems from the federal Right to Try Act, which affirmatively absolves drug companies of legal liability in order to incentivize them to participate in Right to Try programs. This feature is yet to be proven effective and raises red flags in patients' rights. This Note proposes to amend the federal Right to Try Act to include a comprehensive informed consent section mimicking both the California's Right to Try Act and the safeguards used in the Oregon Death with Dignity Act. Additionally, the business structure that the federal Right to Try Act creates brings about exploitation concerns and exposes vulnerable patients to serious financial risks. Lastly, this Note proposes to amend the federal Right to Try Act to include anti-price gouging language and to re-incorporate FDA oversight of charging as safeguards against exploitation.

II. FDA APPROVAL OF INVESTIGATIONAL DRUGS

In the 1950s, a German company, Chemie Grünenthal, developed thalidomide and marketed the drug in Europe as the first safe sleeping pill.[6] Thalidomide was also seen as a highly effective treatment for pregnant women with morning sickness, and it gained widespread popularity in Europe.[7] The first known victim of thalidomide was a girl born with no ears in 1956, though the cause was not discovered until years later.[8] Progressively, thousands of mothers who had taken thalidomide while pregnant gave birth to thousands of children born with extreme disfigurations.[9] Thalidomide-affected children were born with flipper-like arms and legs, which some parents had amputated in order to accommodate for prosthetic limbs.[10] Other parents rejected thalidomide-affected children and had them institutionalized, and in one case, a young mother and her doctor were charged with the mercy killing of her deformed child.[11] The Food and Drug Administration ("FDA") reviewed thalidomide for drug approval in 1960, but delayed approval due to lack of rigorous research supporting the drug's safety.[12] The FDA never approved thalidomide.[13] By

6. Michael Winerip, *The Death and Afterlife of Thalidomide*, N.Y. TIMES, Sept. 23, 2013, https://www.nytimes.com/2013/09/23/booming/the-death-and-afterlife-of-thalidomide.html.

7. *Id*.

8. The girl was born in 1956, but evidence linking thalidomide to birth defects did not become public until 1961. *Id*.

9. *Id*.

10. *Id*.

11. *Id*.

12. *Id*.

13. *Id*.

1962, the drug was banned worldwide, and the thalidomide crisis is one principal reason for the FDA's strict drug regulation.[14]

The FDA must approve all drugs introduced into interstate commerce.[15] Although lengthy, the approval process is designed to thoroughly investigate the safety and efficacy of investigational new drugs in four clinical trial phases.[16] First, drug sponsors submit an Investigational New Drug ("IND") application to the FDA to demonstrate that a drug has been tested on animals and is reasonably safe for initial use on humans.[17] Phase I involves a months-long study of the drug's safety and dosage on 20-100 participants.[18] Approximately seventy percent of drugs pass Phase I.[19] Phase II trials test the drug's efficacy and side effects on up to several hundred participants for a duration of anywhere between months to two years.[20] Approximately thirty-three percent of drugs pass Phase II.[21] Phase III trials further test drug efficacy in addition to adverse reactions on 300 to 3,000 participants; the duration of the trials last between one to four years, and only approximately twenty-five to thirty percent of drugs pass this phase.[22] The investigational new drugs then move on to Phase IV, where the FDA reviews all results from previous phases along with any additional reports, proposed labeling and directions for use, and safety updates.[23] Under this process, it can take up to ten years for the FDA to approve a drug for prescription.[24]

III. ALTERNATIVE ACCESS TO INVESTIGATIONAL DRUGS

The FDA approval process for new drugs takes time, a luxury that some terminally ill patients cannot afford.[25] In response, the FDA created the

14. *Id*.

15. 21 U.S.C. § 355(a) (2018) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.").

16. *Investigational New Drug (IND) Application*, FDA (Oct. 5, 2017), https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm.

17. *Id*.

18. *Step 3: Clinical Research*, FDA (Jan. 4, 2018), https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm#Clinical_Research_Phase_Studies.

19. *Id*.

20. *Id.*

21. *Id*.

22. *Id*.

23. *See Step 4: FDA Drug Review*, FDA (Jan. 4, 2018), https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405570.htm.

24. *How Long Does the FDA Take to Approve a Drug?*, U.S. DEPT. OF VET. AFFS., https://www.hiv.va.gov/patient/clinical-trials/drug-approval-process.asp (last visited Fed. 23, 2020).

25. *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of Their*

Expanded Access program ("EA"), also known as "Compassionate Use," to allow terminally ill patients access to investigational drugs that have not yet passed the final FDA approval phase.[26] States have also responded with Right to Try legislation, permitting drug companies to provide very sick patients with Phase I investigational drugs even without EA approval.[27] These efforts toward alternative access to investigational drugs came to a head when Congress enacted The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, the federal counterpart to state Right to Try legislation.[28] Through the federal Right to Try Act, Congress sought to permit drug companies to provide Phase I investigational drugs to patients with life threatening diseases.[29]

A. FDA EXPANDED ACCESS POLICY

Under EA, a patient with a serious or life threatening disease left with no other comparable treatment may have access to an investigational drug.[30] The requirements for this access are that a licensed physician or drug company must submit an EA application form to the FDA on the patient's behalf and find a willing drug company to provide the investigational drug.[31] The physician is responsible for filling out the paperwork, obtaining the patient's informed consent pursuant to the codified informed consent elements for investigational drug use, which must also be reviewed by an Institutional Review Board ("IRB"), and monitor the course of treatment.[32] In approving the application, the FDA must determine that the potential benefit of the EA drug use justifies the risks of the treatment, and that providing the drug will not interfere with the clinical investigations of the drug for marketing approval.[33] In 2017, the FDA approved 1,632 out of 1,637 received EA applications for investigational drugs.[34]

Treatment, GOLDWATER INST. (Oct. 7, 2014), https://goldwaterinstitute.org/article/everyone-deserves-right-try-empowering-terminally/.

26. 21 C.F.R. § 312.305 (2009).

27. Daniel A. Kracov et al., *National Right to Try Legislation Passes Congress*, ARNOLD & PORTER (May 23, 2018), https://www.arnoldporter.com/en/perspectives/publications/2018/05/national-right-to-try-legislation-passes-congress.

28. 21 U.S.C. § 360bbb-0a (2018).

29. *Id*.

30. 21 C.F.R. § 312.300 (2009); 21 C.F.R. § 312.305 (2009).

31. 21 C.F.R. § 312.305(c) (2009); 21 C.F.R. § 312.305(a) (2009).

32. General responsibilities of investigators, 84 Fed. Reg. 5968-02, 312, 812 (Feb. 25, 2019) (to be codified at 21 C.F.R. § 312.60); 21 C.F.R. § 312.305(c)(1) (2009); 21 C.F.R. § 312.305(c)(4) (2009).

33. 21 C.F.R. § 312.305(a) (2009).

34. *CDER, CBER and CDRH Expanded Access INDs and Protocols (2014-2018)*, FDA, https://www.fda.gov/newsevents/publichealthfocus/expandedaccesscompassionateuse/ucm443572.htm#Expanded_Access_IND1 (last visited Feb. 23, 2020).

By 2015, in response to repeated criticism to alleviate the administrative burden of EA requirements, the FDA made efforts to streamline EA approval.[35] The agency introduced simplified application forms that were purported to take only forty-five minutes for a physician to complete, and included expedited IRB full-board approval processes for treatment by only requiring one IRB member to approve treatment.[36]

Despite these efforts to streamline the EA process, drug companies have been reluctant to participate in EA in fear that adverse reactions to investigational drugs will become an obstacle to drug approval.[37] To dispel discouragement, the FDA published guidance for the industry, clarifying that adverse reactions are reviewed through the FDA approval process under a causation requirement.[38] In the guidance, the FDA reassures that it reviews adverse events within the context of the treatment, acknowledging how various uncontrolled factors inherent in EA often create difficulty in linking treatment to a particular adverse event.[39]

EA was created to treat very sick patients, but with close FDA oversight.[40] The FDA purportedly approves ninety-nine percent of EA applications and approves applications within days or even hours over the phone for emergencies.[41] Despite the FDA's continued efforts to streamline the EA application process, drug companies remain reluctant to participate.

B. STATE RIGHT TO TRY LEGISLATION

In May 2014, Colorado enacted their Right to Try Act, allowing terminally ill patients who are unable to participate in clinical trials, and have exhausted all other methods of treatment, to receive investigational drugs provided by willing drug manufacturers without FDA approval of the treatment.[42] Since then, forty states have enacted Right to Try legislation,

35. *FDA Voices: Perspectives From FDA Experts*, FDA, https://blogs.fda.gov/fdavoice/index.php/2017/10/expanded-access-fda-describes-efforts-to-ease-application-process/ (last visited Mar. 10, 2020); Alexander Gaffney, *From 100 Hours to 1: FDA Dramatically Simplifies Its Compassionate Use Process*, REGULATORY AFF. PROF'LS SOC'Y: REGULATORY FOCUS (Feb. 4, 2015), https://www.raps.org/regulatory-focus™/news-articles/2015/2/from-100-hours-to-1-fda-dramatically-simplifies-its-compass ionate-use-process.

36. *FDA Voices: Perspectives From FDA Experts*, FDA, *supra* note 31.

37. *Id*.

38. *Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers: Guidance for Industry*, FDA (June 2016), *available at* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf.

39. *Id*. at 18.

40. *Id*. at 2.

41. *FDA Voices: Perspectives From FDA Experts*, FDA, *supra* note 31.

42. H.B. 14-1281, Gen. Assemb., Reg. Sess. (Co. 2014); CAL. HEALTH & SAFETY CODE §

including California.[43] As of April 2018, those states are Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.[44] The state versions of the legislation vary, such as Colorado's and California's, which include robust informed consent requirements, whereas other versions, like Arkansas's, do not.[45] California's Right to Try Act also includes a section absolving manufacturers against liability for any injury that results from the non-negligent investigational drug treatment.[46]

State efforts to introduce Right to Try investigational drug access were still not enough as critics considered state Right to Try laws mere "placebo legislation."[47] Treatment under the Right to Try pathways have gone unused.[48] Drug companies still seemed reluctant to provide investigational drugs due to concerns that the Food Drug & Cosmetic Act preempted any state legislation on the subject and for fear of scaring away investors.[49] Even under State Right to Try legislation similar to California's, drug companies also feared that any adverse results from the treatment would be used to by the FDA to pull the drug from the clinical trial process.[50]

111548.1(h) (West 2017).

43. Jacqueline Howard, *What you need to know about right to try legislation*, CNN (Mar. 22, 2018, 1:50 PM), https://www.cnn.com/2018/03/22/health/federal-right-to-try-explainer/index.html.

44. Michael Nedelman & Jacqueline Howard, *'Right-to-Try' bill passes Congress*, CNN, (May 29, 2018, 1:48 PM), https://www.cnn.com/2018/05/22/health/right-to-try-legislation-congress/index.html.

45. 2015 Ark. S.B. 4, 90th Gen. Assemb., Reg. Sess. (Ark. 2015) (enacted).

46. H.B. 14-1281, 68th Gen. Assemb., Reg. Sess. (Colo. 2014); CAL. HEALTH & SAFETY CODE § 111548 (2019).

47. David Gorski, *The Very Worst Version of the Sham Known as "Right to Try" is Poised to Become Law*, SCI. BASED MEDICINE (May 21, 2018), https://sciencebasedmedicine.org/the-very-worst-version-of-the-sham-known-as-right-to-try-is-poised-to-become-law/.

48. Kate Gallin Heffernan et al., *Expanded Access and Right to Try: The Impact of Recent Legislative Changes*, ADVARRA (May 30, 2018), https://www.advarra.com/resource-library/expanded-access-and-right-to-try-the-impact-of-recent-legislative-changes/.

49. Nicole Van Groningen, *The Right-To-Try Bill Puts Patients At Risk In The Name Of Helping Them*, HUFFINGTON POST (May 30, 2018), https://www.huffingtonpost.com/entry/opinion-vangroningen-righttotry-bill_us_5b0ebcc4e4b0fdb2aa58c732; Marianne Spencer, *Prescribing a Cure for Right-to-Try Legislation*, 86 GEO. WASH. L. REV. ARGUENDO 30 (2018).

50. Sammy Caiola, *Federal Right To Try Proposal Could make Califoria Law More Effective*, CAP. PUB. RADIO (Jan. 31, 2018), http://www.capradio.org/articles/2018/01/31/federal-right-to-try-proposal-could-make-california-law-more-effective.

C. FEDERAL RIGHT TO TRY ACT

On May 30, 2018, Congress enacted a federal Right to Try Act, expanding this alternative pathway to investigational drugs nationwide.[51] Similar to the state versions, the federal statute allows anyone with a "life threatening disease" who has exhausted all other treatment options to receive investigational drugs past Phase I clinical trial approval from a willing drug company.[52] A "life threatening disease" is defined as a disease or condition with a high likelihood of death unless the course of the disease is interrupted.[53] The eligible patient must be left with no other option for treatment, including treatment through clinical trial participation, and must submit written informed consent to their physician.[54]

In an attempt to encourage drug companies to provide investigational drugs to eligible patients, the federal Right to Try Act absolves drug companies from liability for negligent investigational drug treatment.[55] Further, the statute prohibits the FDA from using any clinical outcome associated with the use of the investigational drug to delay or adversely affect the ongoing FDA approval of the investigational drug.[56] Drug companies are required to report annual summaries of each investigational drug used, which includes information regarding any known serious adverse events.[57] Serious adverse events include those involving death, life-threatening adverse events, inpatient hospitalization, prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to function normally, and congenital anomalies or birth defects.[58] These serious adverse events cannot affect the investigational drug's FDA approval unless the Secretary of the Health and Human Services Department ("HHS") decides that the serious adverse event is critical to determining the investigational drug's safety.[59] In any case, the Secretary of the HHS must post an annual summary report of the amount of investigational drugs for which serious adverse events were or were not reviewed in the FDA approval process on the FDA website.[60] These provisions set out to promote Right to Try treatment by reducing a drug company's risk when providing an eligible patient with an investigational drug.

51. 21 U.S.C. § 360bbb-0a (2018).
52. *Id*.
53. 21 C.F.R. § 312.81(a)(1); 21 U.C.S. § 360 bbb-0a(a)(1)(A) (2018).
54. 21 U.S.C. § 360bbb-0a(a)(1)(B) (2018).
55. 21 U.S.C. § 360bbb-0a (2018).
56. 21 U.S.C. § 360bbb-0a(c) (2018).
57. 21 U.S.C. § 360bbb-0a(d) (2018).
58. 21 C.F.R. § 312.32 (2011).
59. 21 U.S.C. § 360bbb-0a(c)(1)(A) (2018).
60. 21 U.S.C. § 360bbb-0a(d) (2018).

IV. CRITICISMS OF THE RIGHT TO TRY

Since its introduction, critics have accused the Right to Try campaign of furthering a hidden agenda to eliminate FDA oversight of drugs.[61] When the FDA monitors investigational drug treatment through EA, it often changes treatment protocol based on its exclusive expert consultant information.[62] Patient advocates have grown concerned that without FDA consultation, investigational drug treatment increases risk to patients.[63] Safety concerns also stem from the fact that Phase I investigational drugs are typically only tested on twenty to eighty healthy volunteers, which does not thoroughly establish the drugs' safety.[64] Finally, unlike EA, which requires IRB review of treatment protocol and references a list of informed consent standards for investigational drug treatment, Right to Try laws bypass IRB review of treatment protocol and do not establish informed consent standards.[65] Taken together, the absence of these safeguards have elicited over one hundred patient advocacy groups to oppose the federal Right to Try Act.[66]

These one hundred patient and provider groups expressed their strong opposition to the Senate version of the Right to Try Act—which is now the enacted federal Right to Try Act—in a letter to House leadership.[67] The patient and provider groups preferred the House version of the Right to Try bill, which was safer for patients because it established informed consent standards equivalent to those of EA and its FDA reporting requirements were more transparent and stringent.[68]

61. Michael Hiltzik, *Right-To-Try Laws Are Hazardous To Your Health—And Now They're Backed By The Koch Brothers*, L.A. TIMES (Jan. 22, 2018, 2:35 PM), http://www.latimes.com/business/hiltzik/la-fi-hiltzik-right-to-try-20180122-story.html.

62. *Id*.

63. *Id*.

64. *Id*.

65. Heffernan et al., *supra* note 44.

66. Letter from A Twist of Fae-ATS et al., Patient and Provider Orgs., to Paul Ryan, Speaker, U.S. House of Reps. & Nancy Pelosi, Minority Leader, U.S. House of Reps (May 21, 2018), https://www.acscan.org/sites/default/files/National%20Documents/Senate%20Right%20to%20Try%20%28S.204%29%20Coalition%20Opposition%20Letter%205.21.2018.pdf.

67. *Id*.

68. *Id*.

A. CONCERNS REGARDING LIMITED LIABILITY AND INFORMED CONSENT

Perhaps the most concerning feature of the federal Right to Try Act is the section that completely exculpates drug sponsors and manufacturers and exculpates physicians against ordinary negligence. A prescriber, dispenser, or other individual entity providing such treatment may only be found liable as a result of reckless or willful misconduct, gross negligence, or an intentional tort.[69] This feature of the statute was meant to incentivize drug companies to make investigational drugs available to terminally ill patients.[70] However, tort law is the primary method of dealing with providers' medical errors, and without the option of filing negligence claims, injured patients are left with no legal recourse.[71]

Another concerning feature of the federal Right to Try Act is that it leaves patients unprotected without robust informed consent standards. Medical ethicists have warned against the dangers of investigational drug treatment.[72] Many investigational drugs can hasten death or produce negative side effects that reduce a patient's remaining quality of life instead of heal the patient.[73] While the federal Right to Try Act does explicitly require that the eligible patients provide written informed consent to the investigational drug treatment, it is silent as to the criteria the informed consent must meet.[74]

In the past, courts have used informed consent and adequate warning as tools to offset limited liability for drug companies. For example, drug manufacturers in California can avoid strict liability for drug injuries if the drug is properly prepared and accompanied by warnings of any risks known at the time of distribution.[75] Also, under the learned intermediary doctrine, drug manufacturers can avoid prescription drug liability for injuries as long as the manufacturers provide appropriate warning to a patient's physician.[76] Once the physician has been adequately warned, he or she

69. 21 U.S.C. § 360bbb-0a (2018).

70. Caiola, *supra* note 46.

71. Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J.L. & MED. 7, 10 (2011).

72. *See* Interview with Arthur Caplan, NYU Langone Medical Center, *'Right to try' law gives terminal patients access to drugs not approved by FDA*, PBS: PBS NEWS HOUR WEEKEND (June 21, 2014, 11:59 AM) https://www.pbs.org/newshour/show/right-try-law-gives-terminal-patients-access-non-fda-approved-drugs.

73. *Id*.

74. 21 U.S.C. § 360bbb-0a(a)(1)(C) (2018).

75. Brown v. Superior Court, 44 Cal.3d 3d 1049, 1069 (Cal. 1988).

76. *Id*.

inherits the duty to provide adequate warning to the patient.[77] Then, as the learned intermediary, the physician must provide adequate warning by obtaining the patient's informed consent.[78]

In theory, a patient with informed consent has all the material information necessary to exercise patient autonomy, but critics have questioned whether the requirement effectively facilitates truly informed decisions.[79] Genuine informed consent is particularly difficult to attain in the experimental treatment context because even the physician may not know how safe or effective the treatment is.[80] As mentioned above, some experimental treatments have only passed Phase I of clinical trials, which only monitors basic patient safety information.[81] Under these circumstances, because drug sponsors have not tested for efficacy at all, or completed more thorough tests for safety, physicians administering the experimental treatments may not be able to provide patients with a precise idea of the risks the patient should be considering.[82]

Nonetheless, even if informed consent is not sufficient to allow patients to make the best medical decisions for themselves, history has shown that informed consent is at least necessary for patient safety.

In *Mink v. University of Chicago*, in the early 1950s, the University of Chicago's teaching hospital provided over 1,000 women diethylstilbestrol ("DES") for "prenatal care."[83] The women did not know until almost two decades later that the hospital administered the DES to them or that they were part of a clinical trial sponsored by the manufacturer to determine whether DES prevented miscarriages.[84] Fearing that their children faced an increased risk of cancer from the in utero exposure to DES, the women filed a class action lawsuit against the manufacturer and the University.[85] The defense argued that the women consented to any course of treatment by simply entering the hospital for prenatal care.[86] The court, however, disagreed and ruled that the women had genuine claims for battery.[87] This

77. Hill v. Novartis Pharms. Corp., 944 F. Supp. 2d 943, 954 (E.D. Cal. 2013).

78. Jerica L. Peters, *Developments in Science and Technology Law—Part I, State v. Karl: An Unreasonable Rejection of the Learned Intermediary Doctrine*, 48 JURIMETRICS J. 285 (2008).

79. Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 364 (2002).

80. Michael Imbroscio & Gabriel Bell, *Adequate Drug Warnings in the Face of Uncertain Causality: The Learned Intermediary Doctrine and the Need for Clarity*, 107 W. VA. L. REV. 847, 859 (2005).

81. *Investigational New Drug (IND) Application*, FDA, *supra* note 12.

82. Imbroscio & Bell, *supra* note 76.

83. Mink v. University of Chicago, 460 F. Supp. 713, 715 (Ill. Cir. Ct. 1978) [hereinafter *Mink*].

84. *Id*.

85. *Id*. at 718.

86. *Id*.

87. *Id*.

case illustrates why informed consent is necessary as a safeguard against drug companies exploiting people seeking safe treatment. Without such safeguards in place, drug companies and physicians embody medical paternalism and act without regard to public safety by providing experimental treatment to patients without their knowledge or consent that potentially exposed more than 1,000 children to cancer as a direct result.[88]

The idea of informed consent between a physician and a patient is central to the drug manufacturer's defense of the learned intermediary doctrine.[89] This doctrine operates as a manufacturer's defense against liability by distributing some of the responsibility to warn about the risks of a prescription drug to the prescribing physician.[90] The doctrine provides that as long as the drug manufacturer fulfills its duty to warn the physician about the risks, it does not need to give any warning to the patient.[91] Most states have accepted the learned intermediary doctrine as a common law defense.[92] Typically, exceptions to it are only found in circumstances when a physician's ability to provide the patient with informed consent is diminished, like when the manufacturer directly advertises the drug to the consumer.[93]

In *Perez v. Wyeth*, the Supreme Court of New Jersey found that when mass marketing influences a patient's choice of prescription drug, the manufacturer that makes direct claims to consumers regarding the drug's efficacy should not be relieved of its duty to provide the consumer with adequate warnings under the learned intermediary doctrine.[94] The Supreme Court of New Jersey is one of the only courts to apply this exception to the learned intermediary doctrine, which has not been accepted in federal court.[95] Nonetheless, this narrow exception to the learned intermediary doctrine clarifies how absolving drug companies from liability is fair when physician informed consent safeguards are in place, but if the physician-patient relationship is altered so that adequate informed consent is not likely to occur, drug companies may still be liable.[96] The key feature of the standard learned intermediary doctrine in absolving drug company liability is the reliance on the physician as the learned intermediary to provide the patient with proper information about the dangers or side effects of the

88. *See id*.

89. Frank C. Woodside & Margaret M. Maggio, *The Learned Intermediary Doctrine: Is it Eroding?*, 52 FED. LAW. 28, 30–32 (2005).

90. *Id*. at 30.

91. *Id*. at 29.

92. *Id*. at 30.

93. *Id*. at 32–35.

94. Perez v. Wyeth, 161 N.J. 1, 4 (N.J. 1999) [hereinafter *Perez*].

95. *Id*.

96. *See id*.

drug.[97]

In the landmark case, *Canterbury v. Spence*, the nineteen-year-old patient, Canterbury, sought treatment for back pain.[98] After consulting different practitioners, he eventually met Doctor Spence, who recommended that he undergo a laminectomy, which is the excision of the posterior arch of the vertebra, to correct a suspected ruptured disc.[99] Doctor Spence did not disclose to Canterbury that the recommended surgery posed a risk of paralysis, and Canterbury did not raise any objections or inquire further regarding the procedure.[100] After the surgery and a series of complications, Canterbury ended up paralyzed from the waist down and brought suit against Doctor Spence for his failure to reveal the risk of paralysis from the procedure.[101] The U.S. Court of Appeals for the District of Columbia expounded that "the average patient has little to no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision."[102] The court held that the physician-patient dynamic creates the need, and therefore, the requirement, for the physician to provide the patient with the necessary information to make such a decision.[103]

Adequate warning and informed consent continue to be an issue for drug manufacturers and physicians.[104] In *Thom v. Bristol Myers-Squibb Co*., Thom developed permanent penile injury from taking the prescription drug Serzone to treat his sleep problems and depression.[105] Thom sued the drug manufacturer, Bristol Myers-Squibb, for failure to provide adequate warning of the risks of permanent penile injury in Serzone's package inserts, which caused his physician, Doctor Schueler, to not discuss the possibility of such risks with Thom prior to prescribing it.[106] The United States Court of Appeals for the Tenth Circuit reversed the grant of the manufacturer's motion for summary judgment due to genuine issues regarding proximate cause.[107]

In *Parker v. Harper*, the Parkers sued Doctor Harper for the failure to inform them of the potential side effects of Dilantin, which Doctor Harper

97. *Id*. at 30–32.
98. Canterbury v. Spence, 464 F. 2d 772, 776 (D.C. Cir. 1972) [hereinafter *Canterbury*].
99. *Id*.
100. *Id*.
101. *Id*. at 777.
102. *Id*. at 780.
103. *Id*.
104. Thom v. Bristol-Myers Squibb Co., 353 F. 3d 848 (10th Cir. 2003).
105. *Id*. at 850 [hereinafter *Thom*].
106. *Id*.
107. *Id*. at 858.

prescribed to treat their minor daughter's seizures.[108] The treatment left her with disfiguring scars and vision impairment that were more likely than not symptoms of Steven-Johnson syndrome.[109] The Parkers argued that had they been informed that ingesting Dilantin poses a risk of Stevens-Johnson syndrome, they would not have consented to the treatment.[110] The Louisiana Third Circuit Court of Appeal reversed the trial court's grant of summary judgment in favor of Doctor Harper because there was a genuine issue of material fact as to whether he provided the Parkers with informed consent.[111] Each of these cases—*Mink*, *Perez*, *Canterbury*, *Thom*, and *Parker*—illustrate the crucial role informed consent plays in a patient's decision to accept the risks in treatment.

Courts have consistently supported the idea that as long as patients are fully informed of the material risks of their medical treatment, then they are capable of making decisions to accept the treatment, and that decision absolves the physician and drug manufacturers from liability. As such, it is a red flag that the new federal Right to Try Act gives drug companies and physicians so much protection against liability yet does not give patients equal protection with strong informed consent requirements, as discussed *infra*.

1. The Imbalanced Federal Right to Try Act Raises Quality and Individual Autonomy Issues

Upon taking a closer look at the implications of the imbalanced federal Right to Try Act, it seems that this federal statute is inconsistent with two health care principles: quality of care and the preservation of individual autonomy.

Quality of care is a chief concern of the health-care system, and informed consent is meant to safeguard against poor quality health care, amongst other dangers.[112] The act of informing patients encourages physicians to carefully consider their decisions while practicing medicine.[113] Further, informed consent requirements formally facilitate trust in the physician-patient relationship, which is a critical component of providing quality medical care.[114]

108. Parker v. Harper, 803 So. 2d 76, 79 (La. Ct. App. 2001) [hereinafter *Parker*].
109. *Id*. at 85. Stevens-Johnson syndrome is a skin rash. *Id*. at 84.
110. *Id*. at 80.
111. *Id*. at 86.
112. BARRY R. FURROW ET AL., HEALTH LAW CASES, MATERIALS AND PROBLEMS 1, 132 (8th ed. 2018)
113. *Id*.
114. Mark Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 489 (2002).

Trust is the defining characteristic of the physician-patient relationship, and preserving it is a prominent objective in health care law and medical ethics.[115] Even the most ordinary illness can create a profound sense of vulnerability in a patient, which can attack the fundamental unity of mind and body.[116] This deep vulnerability causes many people to revert to a childlike state with a strong desire to be cared for.[117] Psychologically, under these circumstances, a patient has little choice but to place his or her trust in a physician, and there is strong evidence that the effectiveness of treatment depends on that trust.[118] This placebo-like effect is one example of how trust in treatment can enhance healing.[119] The phenomenal effects of trust in health care is largely supported by anecdotal evidence because it is not empirically studied but most people resonate with the therapeutic benefits of trust in clinical encounters.[120]

Along with quality, individual autonomy is another chief concern within the health-care system.[121] The information physicians provide to patients fosters rational decision-making by the patient and promotes individual autonomy.[122] The doctrine of informed consent is based on the principle of bodily self-determination—the notion that "every human being of adult years and sound mind has a right to determine what shall be done with his own body."[123] As such, patients exercise their right to autonomy with informed consent.[124] Without informed consent, patients may lose autonomy by making decisions without fully understanding the proposed treatment or its full benefits and risks.[125] Moreover, the principles of quality health care and patient autonomy are intertwined, as research also suggests that patients exercising autonomy by being fully involved in the management of their treatment leads to better quality healthcare.[126]

Given the risks associated with a terminally ill patient's circumstances, having trust and reliance on a conscientious physician is especially important.[127] As such, a health care statute that does not have robust informed consent requirements may give way to poor quality health care and neglect

115. *Id*. at 471.
116. *Id*. at 477–78.
117. *Id*.
118. *Id*.
119. *Id*. at 479.
120. *Id*. at 482.
121. Furrow, *supra* note 108.
122. *Id*.
123. Peters, *supra* note 74, at 299.
124. *See id*.
125. *Id*.
126. Furrow, *supra* note 108, at 133.
127. Caplan, *supra* note 68.

of the principles of patient autonomy.

2. Solution: Heightened Informed Consent Will Offset Liability Issues

Generally, adequate informed consent is obtained when a patient understands their diagnosis or nature of the problem, the nature and purposes of the proposed treatment, reasonably foreseeable risks associated with the treatment and the likelihood of the occurrence of risk, potential severity of the risks, reasonable alternatives and the benefits and risks of those alternatives, and the probable risks and benefits of foregoing the proposed treatment.[128] The FDA deems that adequate informed consent is obtained in clinical trials for investigational drugs when the patient has signed a written statement that describes and explains the research.[129] EA also incorporates the same informed consent requirements.[130] The description must include reasonably foreseeable risks, discomfort, or benefits from the drug, what appropriate alternative treatments exist, that the treatment may involve unforeseeable risks, and any consequences that would follow a decision to withdraw from the clinical trial.[131]

Although previous federal Right to Try bills referenced an informed consent section, the enacted federal Right to Try Act is silent as to the standards of informed consent for investigational drug treatment.[132] Silence on the informed consent issue could be detrimental to the quality of health care these already terminally ill patients receive, as well as strip them of what little autonomy they have left. It may be possible that courts could interpret the Federal Right to Try Act to incorporate the FDA's clinical trial informed consent requirements as parts of the same legislative scheme. However, those informed consent criteria may not be appropriate because the research purpose of providing drugs under clinical trials is inherently different from the purpose of providing treatment under the Right to Try Act.[133] Thus, section 360bbb-oa(a)(1)(C), which requires eligible investigational drug patients to provide written informed consent, must be amended to incorporate informed consent requirements suitable for a Right to Try patient's circumstances.

A proposed solution to this issue is to amend the federal Right to Try

128. Peters, *supra* note 74.

129. 21 C.F.R. § 50.25 (2011).

130. General responsibilities of investigators, 84 Fed. Reg. 5968-02, 312, 812 (proposed Feb. 25, 2019) (to be codified at 21 C.F.R. § 312.60); 21 C.F.R. § 312.305(c)(1) (2009); 21 C.F.R. § 312.305(c)(4) (2009).

131. 21 C.F.R. § 50.25 (2011).

132. 21 U.S.C. § 360bbb-oa(a)(1)(C) (2018).

133. Noah, *supra* note 75, at 388.

Act to reflect California's state Right to Try Act's ("California Act")[134] robust informed consent standards specifically aimed toward informing terminally ill patients of the implications of using investigational drugs for treatment. The California Right to Try Act contains a comprehensive list of elements of informed consent for investigational drug treatment.[135] Under the California Right to Try Act, written informed consent must include an explanation of existing approved products and treatments for the disease or condition and the potentially best and worst outcomes of the new treatment, including new, unanticipated, different, or worse symptoms that may result.[136] The description must also disclose that death could be hastened by the treatment.[137] These California informed consent criteria take into account that terminally ill patients may be so desperate for marginal results that they may not fully comprehend the risks of their condition worsening as a result of going through investigational treatment.

Another solution to the problem of the federal Right to Try Act's lacking informed consent requirements is to incorporate the measures required by Oregon's Death with Dignity Act ("Oregon Act"). Laws such as the Oregon Act dealing with a different type of end-of-life decision making, known as Right to Die statutes, have heightened requirements in evaluating whether a patient's end-of-life decision is one that is fully informed.[138] While some terminally ill patients seek experimental treatment to save their lives, other terminally ill patients seek medical aid in dying.[139] State Right to Die laws, such as Oregon's Death with Dignity Act, require that a physician provide information on the patient's diagnosis, prognosis, potential risks associated with, and probable result of, taking the medication, and available feasible alternatives.[140] Additionally, Oregon requires that the patient submit a signed and dated written request, with two witnesses as well as an oral request, that has been reiterated to the physician within fifteen days of the original request.[141] Further, the physician must verify that the patient is making an informed decision, and if he or she feels that a patient's judgment is impaired due to psychiatric or psychological order or depression, then the physician must refer the patient for counseling.[142] Here, we have two analogous situations where terminally ill patients are making end-of-life

134. Cal. Health & Safety Code § 111548.1(h) (2019).
135. Cal. Health & Safety Code § 111548.1(h) (2019).
136. *Id*.
137. *Id*.
138. Furrow, *supra* note 108, at 1450.
139. Medically assisted death is "medical care designed to help a patient die how and when the patient wants to die." *Id*. at 1425.
140. *Id*. at 1450.
141. *Id*. at 1453.
142. *Id*. at 1452.

decisions that will, or likely will, result in death. As such, the set of laws governing rational decision making in each circumstance should be equally robust.

Patients who are facing end-of-life medical decisions are subject to external pressure, whether it is familial, financial, or other.[143] As such, other laws besides the federal Right to Try Act regulating terminally ill patients making end-of-life decisions require some form of heightened informed consent to ensure that the patient is making a rational decision; under EA, for example, the FDA requires IRB approval of informed consent.[144] As another example, the California Act informed consent requirement includes language tailored to ensure that a patient understands he or she is facing death.[145] Finally, the extensive protective requirements in the Oregon Act were put in place as mechanisms to protect vulnerable patients against ill-advised rejection of life-sustaining treatment.[146] Moreover, courts have also emphasized that where an experiment is risky and of uncertain benefit to the patient, the adequacy of the patient's informed consent should be closely scrutinized.[147]

Going against this trend, the federal Right to Try Act removes those important heightened protections for patients by bypassing FDA requirements and IRB approval.[148] In conjunction with absolving drug companies and physicians of liability, this leaves already vulnerable patients extremely unprotected, which is unacceptable. However, if the federal Right to Try Act adopts California's and Oregon's heightened informed consent requirements, this may compensate for its limited liability feature. Such an amendment would keep limited liability intact, which would appease drug companies and physicians, and still allow a proactive protection of quality care and patient autonomy.

B. CONCERNS REGARDING EXPLOITATION OF TERMINALLY ILL PATIENTS

Since its enactment, there has been widespread fear that the federal Right to Try Act will bring about ethical consequences with drug companies and sponsors commoditizing desperation, finding ways to profiteer from the

143. Alan Meisel, *Managed Care, Autonomy, and Decisionmaking at the End of Life*, 35 HOUS. L. REV. 1393, 1435 (1999).

144. 21 C.F.R. § 312.305(c)(4) (2009).

145. *See* Cal. Health & Safety Code § 111548.1(h) (2019).

146. Meisel, *supra* note 138, at 1434.

147. Jennifer Piel, *Informed Consent in Right-To-Try Cases*, 44 J. OF THE AM. ACAD. OF PSYCHIATRY AND THE LAW 290 (2016).

148. *Id*.

new avenue of putting non-FDA approved drugs on the market.[149] Critics claim that the federal Right to Try Act will legitimize what is known as the "Burzynski practice model,"[150] a business model whereby the highly controversial Doctor Stanislaw Burzynski ("Burzynski") provided treatment to cancer patients as an alternative to chemotherapy for the price of $20,000 to start, and $7,500 per month to continue.[151] In the late 1990s, Burzynski was prosecuted for violations of the Food, Drug, and Cosmetics Act, and he was ordered to administer his drugs exclusively through FDA clinical trials.[152] Since then, Burzynski has still been able to treat his patients through Phase II clinical trials, but virtually none of his treatments pass on to Phase III.[153] After decades of implementing treatments that have not yet proven effective, Burzynski has gained a bad reputation for profiting by taking advantage of his sick and vulnerable patients.[154] According to the U.S. National Institute of Health, Burzynski started over sixty medical studies over the years, but has only completed one, with the status of "unknown" or "withdrawn" for virtually all of his remaining studies.[155] Now that the federal Right to Try Act allows investigational drug treatment without the requirement that patients be enrolled in Phase II clinical trials at all, there is concern that it will be even easier for Burzynski to continue and other companies to follow his business model.[156]

New companies are already appearing, ready to do business under the federal Right to Try Act, such as Brainstorm Cell Therapeutics Inc. ("Brainstorm").[157] Brainstorm is a small biotechnology company that plans on offering investigational cell therapy treatment to patients with Lou Gehrig's disease, which its CEO estimates will cost patients over $300,000.[158] Additionally, Brainstorm has plans to offer an investigational treatment called NurOwn to help patients who have amyotrophic lateral

149. Max Nisen, *'Right-to-Try' Drug Law Offers No Miracle Cure*, BLOOMBERG (May 24, 2018), https://www.bloomberg.com/opinion/articles/2018-05-24/right-to-try-drug-law-risks-exploiting-desperate-patients.

150. David Gorski, *Right-to-Try is Now Law. Let Patients Beware!*, SCIENCE BASED MED. (June 4, 2018), https://sciencebasedmedicine.org/right-to-try-is-now-law-let-patients-beware/.

151. *Cancer Doctor Under Fire for Providing False Hope to Patients*, FOX NEWS, (Nov. 18, 2013), https://www.foxnews.com/health/cancer-doctor-under-fire-for-providing-false-hope-to-patients.

152. Gorski, *supra* note 145.

153. *Id*.

154. FOX NEWS, *supra* note 146.

155. *Id*.

156. Gorski, *supra* note 145.

157. Michelle Cortez, *The 'Right to Try' Could Cost Dying Patients a Fortune*, BLOOMBERG (June 20, 2018), https://www.bloomberg.com/news/articles/2018-06-20/the-price-to-try-a-drug-could-be-300-000-for-dying-patients.

158. *Id*.

sclerosis, or ALS, for an estimated $375,000.[159] As insurers typically do not offer coverage for unproven treatment methods, terminally ill patients will be adding serious financial risk to their grave medical conditions.[160]

1. Protecting Patients versus Scientific Innovation

The U.S. health care industry has long been subject to health care price gouging[161] and profiteering. Total U.S. health care spending reached $3.3 trillion in 2016, which was 17.9% of the GDP.[162] Among the eleven developed nations, Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States, the U.S. spends the most money on health care and is ranked as the worst performing.[163] In 2014, these nations spent 9%, 10%, 11.1%, 11%, 10.9%, 9.4%, 9.3%, 11.2%, 11.4%, 9.9%, and 16.6% of their GDP on health care, respectively.[164] As the money is apparently not going toward quality health care, it is worth pointing out that the U.S. health care industry's total annual profit in 2009 was $200 billion, with a median annual compensation of more than $12.4 million for CEO's at big health care companies, surpassing finance CEO's by two-thirds.[165] For-profit and non-profit health insurance companies, hospital operators, laboratory testing companies, and health care real estate investment trusts, are all among the parties that stand to profit from the industry, but "Big Pharma" is "the 800-pound gorilla in the room," with more than $300 billion in annual revenue.[166] Since 1980, the pharmaceutical industry's share of the GDP has more than tripled.[167]

Despite this critique, the industry's innovations have undeniably increased life expectancy and quality for countless lives.[168] Since 2000, the

159. *Id*.

160. *Id*.

161. Black's Law Dictionary (10th ed. 2014) defines 'gouging' as "the unlawful or unfair raising of prices."

162. Micah Hartman et al., *National Health Care Spending in 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions*, HEALTH AFFAIRS (Dec. 6, 2017), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.1299.

163. Ryan Bort, *How Bad is U.S. Health Care? Among High Income Nations, It's the Worst, Study Says*, NEWSWEEK (July 14, 2017), https://www.newsweek.com/united-states-health-care-rated-worst-637114.

158. Eric C. Schneider et al., *Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care*, THE COMMON WEALTH FUND (July, 2017), https://interactives.commonwealthfund.org/2017/july/mirror-mirror/.

165. Matt Kapp, *The Sick Business of Health-Care Profiteering*, VANITY FAIR (Sept. 24, 2009), https://www.vanityfair.com/news/2009/09/health-care200909.

166. *Id*.

167. *Id*.

168. *Id*.

top pharmaceutical Research and Development ("R&D") spenders, including Roche, Johnson & Johnson, Novartis, Pfizer, Merck, Bristol-Myers Squibb, AstraZeneca, Sanofi, Eli Lilly, and GlaxoSmithKline,[169] have increased their R&D spending annually by a growth rate of 1.76%.[170] R&D spending is what yields success in scientific innovation.[171] For example, in 2004, Janssen, a Johnson & Johnson company, made a breakthrough discovery of a new anti-tuberculosis treatment, which received FDA Accelerated Approval in 2012 and was proven to be highly effective in curing tuberculosis.[172] Novartis also pushed through big medical breakthrough in 2017, when it received FDA approval for a CAR-T cell therapy called Kymriah, used to treat cancer in children.[173] Such medical breakthroughs are critical in the advancement of society and are made possible because drug companies have the profits to spend on R&D.[174]

The controversy surrounding pharmaceutical price regulation is generations old. Drug companies have made a profound impact on millions of lives, fighting illnesses that account for a substantial portion of the nation's health problems, such as arthritis, asthma, Alzheimer's disease, heart disease, Crohn's disease, cancer, multiple sclerosis, Lou Gehrig's disease, and AIDS.[175] Unfortunately, as medicine advances, the price tag on pharmaceuticals increase at an alarming rate, as well, sometimes to the point of price gouging.[176] In the past, this has led to government regulation of pharmaceuticals, such as the enactment of the Hatch-Waxman Act, which created abbreviated regulatory pathways for generic versions of chemical drugs to reach the market.[177] Today, the government is attempting to regulate generic versions of biologics in a similar way.[178] Other attempts to regulate

169. John Carroll, *The 15 Top R&D Spenders in the Global Biopharma Business: 2016*, ENDPOINTS NEWS (July 13, 2016), https://endpts.com/top-pharma-biotech-research-development-budgets/.

170. Frank David, *Pharma's Not So Stingy With R&D After All*, FORBES (May 14, 2017), https://www.forbes.com/sites/frankdavid/2017/05/14/pharma-rd-2005-2015/#3894622931c1.

171. *Id*.

172. Hallie Levine, *The Quest to End Tuberculosis: 13 Memorable Moments in Innovation*, JOHNSON & JOHNSON (Sept. 25, 2018), https://www.jnj.com/innovation/key-moments-tuberculosis-treatment-history.

173. *Novartis Receives First Ever FDA Approval for a CAR-T Cell Therapy, Kymriah(TM) (CTL019), for Children and Young Adults with B-cell ALL That is Refractory or Has Relapsed at Least Twice*, NOVARTIS (Aug. 30, 2017), https://www.novartis.com/news/media-releases/novartis-receives-first-ever-fda-approval-car-t-cell-therapy-kymriahtm-ctl019-children-and-young-adults-b-cell-all-refractory-or-has-relapsed-least-twice.

174. David, *supra* note 164.

175. Brian R. Bouggy, *Follow-On Biologics Legislation: Striking A Balance Between Innovation and Affordability*, 7 IND. HEALTH L. REV. 367, 368 (2010).

176. *Id*. at 369.

177. *Id*. at 374.

178. *Id*. at 347.

the pharmaceutical industry include price control and price transparency.[179] These regulatory efforts open the debate of whether competition is harmful or helpful in the long run and if price regulation is necessary.[180] Opponents of regulation argue that studies show that price control is harmful to long-term research and development because it reduces research investment, which stifles the discovery of promising therapies, leading to a shortage of life-enhancing and life-saving treatments.[181] They argue instead that competition is the best way to lower prices while maintaining incentives for innovation, and that price transparency laws may be able to assist.[182] The federal Right to Try Act pathway to experimental drugs creates an analogous dilemma between providing affordable life-saving treatment and allowing the pharmaceutical industry to act freely and stimulate competition.

2. Solution: Anti-Price Gouging and FDA Inclusion Will Provide Middle Ground

Drug companies are for-profit corporations that need incentives in order to produce products; it is unrealistic to expect them not to charge patients for investigational drugs.[183] One proposed solution is to amend the federal Right to Try Act to include an anti-price gouging section. In 2017, Maryland passed HB 631, "[a]n Act concerning Public Health- Essential Off-Patent or Generic Drugs-Price Gouging-Prohibition" ("Maryland Act"), a state price gouging law enacted to prevent the sharp increase in price of generic drugs and safeguard Maryland residents' access to prescription drugs.[184] The Maryland Act defined "price gouging" as "an unconscionable increase in the price of a prescription drug."[185] The Maryland Act further defined "unconscionable increase" as one that is "excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health" and "results in consumers having no meaningful choice about whether to purchase the drug at an excessive price" due to the consumer's conditions.[186] Unfortunately, one year later, the United

179. Matthew Glans, *Research & Commentary: Drug Price Controls and Price Transparency*, THE HEARTLAND INST. (Nov. 14, 2016), https://www.heartland.org/publications-resources/publications/research--commentary-drug-price-controls-and-price-transparency?source=policybot.

180. *Id*.

181. *Id*.

182. *Id*.

183. *See* Cortez, *supra* note 152.

184. Ian Duncan, *Maryland Law Against Price-Gouging by Drug Companies is Unconstitutional, Appeals Court Rules*, BALTIMORE SUN (Apr. 13, 2018), https://www.baltimoresun.com/news/maryland/bs-md-drug-price-gouging-unconstitutional-20180413-story.html.

185. Ass'n for Accessible Medicines v. Frosh, 887 F. 3d 664, 666 (4th Cir. 2018).

186. *Id*.

States Court of Appeals for the Fourth Circuit ruled that the law unconstitutionally violated the Dormant Commerce Clause as a direct state-imposed limitation on interstate commerce.[187] However, a price-gouging amendment to the federal Right to Try Act would not run into the same Dormant Commerce Clause issues because the federal government holds a constitutional right to regulate interstate commerce, and should therefore be constitutional.[188]

Although pharmaceutical anti-price-gouging laws that prohibit unconscionable price increases do protect consumers in disaster markets, price-gouging regulations in general raise potentially serious long-term economic effects.[189] Opponents claim that artificially low prices from anti-price-gouging laws quickly create shortages and end up creating higher transactional costs for buyers."[190] Also, sellers may face a higher cost of operation for a lower or similarly priced good, which may cause the seller to stop selling.[191] However, as legitimate as these concerns are, the market for experimental drugs is distinguished from the typical disaster market in which general price gouging occurs, in that the gouging is due to having an untreatable terminal illness rather than sharing in a state of disaster such as a hurricane.[192] Also, the expensive price of experimental drugs is not per se due to a high consumer demand, but rather due to drug companies financial interests in covering costs and profiting.[193] Therefore, the long-term economic concerns that critics raise over general price-gouging laws may not apply in the context of the federal Right to Try Act.

Another proposed solution is to re-incorporate FDA oversight over the price setting of experimental drugs. The FDA already monitors charging for investigational drugs under EA.[194] If a sponsor is providing a patient with a drug under EA, it must obtain FDA authorization to charge for that drug.[195] The FDA will authorize charging if the sponsor submits documentation that shows calculations reviewed and approved by an independent certified public accountant that comply with the recoverable costs.[196] The recoverable

187. *Id*. at 693.

188. *See id*. at 666.

189. Duncan, *supra* note 179; Emily Bae, *Are Anti-Price Gouging Legislations Effective Against Sellers During Disasters?*, 4 ENTREPRENEURIAL BUS. L. J. 79, 80–83 (2009).

190. Bae, supra note 184, at 82.

191. *Id*.

192. *See id*.

193. *See id.*; Cortez, *supra* note 152.

194. 21 C.F.R. § 312.8 (2009).

195. *Id*. A sponsor "means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization." 21 C.F.R. § 312.3(b).

196. 21 C.F.R. § 312.8 (2009).

costs may only include the direct costs of manufacturing and making the investigational drug available, such as the cost of "raw materials, labor, and nonreusable supplies and equipment used to manufacture the quantity of drug needed for which charging is authorized."[197] Incorporating FDA oversight into the charging of experimental drugs under the federal Right to Try Act might defeat the purpose behind the Act of eliminating the FDA's role in giving patients access to experimental drugs.[198] However, requiring the federal Right to Try Act to limit charges on direct costs, as the FDA already requires under EA, is the middle ground that protects patients from being financially exploited by drug companies and also ensures that drug companies will at least recover direct manufacturing costs for providing the experimental drugs.

V. CONCLUSION

In conclusion, the federal Right to Try Act as currently enacted is imbalanced to favor drug companies because it raises issues of quality, individual autonomy, and financial exploitation of vulnerable patients. The issues of quality and individual autonomy must be addressed by amending the Act to include robust informed consent requirements as seen in California's version of the Right to Try Act and in Oregon's similar Death with Dignity Act. Such amendments would protect terminally ill patients in the same way that the federal Right to Try Act currently protects drug companies and physicians from liability for experimental treatment. As for the financial exploitation issues, adding amendments to the federal Right to Try Act that incorporates anti-price-gouging law or incorporates FDA oversight of charging for only direct costs of investigational drugs should protect vulnerable patients without chilling scientific innovation incentives.

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197. 21 C.F.R. § 312.8(d) (2009).
198. *See* Hiltzik, *supra* note 57.