Bioethical Considerations of Right to Try and What It Means for the Patient-Physician Relationship

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INTRODUCTION

Patients are able to get experimental drugs that have not been fully approved by the Food and Drug Administration (FDA) in one of three primary ways: (1) randomized clinical trials, (2) FDA's Expanded Access Program, and (3) Right to Try.[1] Randomized clinical trials have been the "gold standard" method of getting access to experimental treatment options, but this was expanded in the 1970s by the FDA after the agency received increased pressures from patients who did not qualify for clinical trials but still wanted treatment options via experimental drugs.[2] While the Expanded Access Program made experimental drugs a lot more accessible to qualifying patients, more recently, organizations and the United States government (state and federal) have sought to further expand access to experimental drugs by enacting Right to Try laws, which "remov[es] the oversight and approval of the FDA."[3] Right to Try is likely a "politically motivated" bend[4] that has proven to be ineffective for a number of reasons. For instance, since its passing, only two patients have actually participated in federal Right to Try procedures.[5] In contrast, the FDA's Expanded Access Program, a very similar program that has been in place for many years prior to Right to Try, has helped thousands of patients get access to investigational drugs with the help of FDA oversight and approval.[6] To contribute to the debate regarding the effects of the Right to Try, this Note will argue that, while Right to Try is a well-intentioned

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1. *See* NAT'L CANCER INST., *Access to Experimental Cancer Drugs*, https://www.cancer.gov/about-cancer/treatment/drugs/access-experimental [https://perma.cc/Y58K-VY7F] (last updated July 22, 2019).

2. *See* D. Carrieri, F.A. Peccatori & G. Boniolo, *The Ethical Plausibility of the 'Right To Try' Laws*, 122 CRITICAL REV. IN ONCOLOGY/HEMATOLOGY 64, 65 (2017).

3. *Id.* at 64.

4. *See* Jennifer Bryne, *Right to Try: A 'Well-Intentioned' but 'Misguided' Law*, HEALIO NEWS (Mar. 10, 2020), https://www.healio.com/news/hematology-oncology/20200303/right-to-try-a-wellintentioned-but-misguided-law [https://perma.cc/9ETF-SKSF].

5. *See* Arthur L. Caplan, *Why the Right-to-Try Law is a Complete Failure*, MEDSCAPE (Apr. 16, 2019), https://www.medscape.com/viewarticle/911220 [https://perma.cc/QA5X-T3QJ].

6. *See id.*; U.S. GOV'T ACCOUNTABILITY OFFICE, INVESTIGATIONAL NEW DRUGS - FDA HAS TAKEN STEPS TO IMPROVE THE EXPANDED ACCESS PROGRAM BUT SHOULD FURTHER CLARIFY HOW ADVERSE EVENTS DATA ARE USED (2017), https://www.gao.gov/products/GAO-17-564#summary [https://perma.cc/KL49-VKKD] (stating "of the nearly 5,800 expanded access requests that were submitted to FDA from fiscal year 2012 through 2015, FDA allowed 99 percent to proceed").

law for terminally ill patients, the law creates an excessive risk to the patient-physician relationship. Part I of this paper provides a background regarding the legal landscape of experimental drugs. Parts II and III argue that Right to Try laws overvalue autonomy at the detriment of beneficence and create a burden on the patient-physician relationship. Part IV provides a potential solution to help protect the patient-physician relationship in the context of the Right to Try legislation by inserting attorneys (who would be governed by Rule 2.4 of the ABA Model Rules of Professional Conduct) into the informed consent process of Right to Try.

I. THE CREATION OF RIGHT TO TRY

On multiple occasions, the Supreme Court has asserted that patients do not have a constitutional right to use experimental drugs. In *United States v. Rutherford*, terminally ill cancer patients sought to gain access to a clinically unapproved drug, Laetrile, which actually never ended up making it through clinical testing.[7] In its decision, the Supreme Court stated that terminally ill patients do not have a right to drugs that have not been approved by the FDA because the Food, Drug, and Cosmetic Act (FDCA) provides no indication that terminally ill patients are able to receive medical drugs that have not been proven to be safe and effective.[8] In a more recent landmark case, *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, the United States Court of Appeals for the District of Columbia dealt with a similar issue and held again, in an 8-2 decision, that patients do not have a right to use experimental drugs even if they have exhausted all other treatment options.[9] Thus, in combination with *Rutherford*, the decision in *Abigail Alliance* did not create a federal right to use experimental drugs.

However, since *Rutherford*, and before *Abigail Alliance*, the FDA had worked to accommodate the increased pressures of patients requesting access to drugs that have not been fully approved for marketability, beyond those available through randomized clinical trials.[10] As a prime example, the FDA created the Expanded Access Program, which provides an additional avenue to use medical treatments that have not made it through all three phases of the FDA's drug and treatment approval process.[11] While this increases access to drugs that are not yet readily available to many patients, critics of the Expanded Access Program, such as the Goldwater Institute and Abigail Alliance, have pushed for Right to Try and

7. *See* United States v. Rutherford, 442 U.S. 544, 544 (1979).

8. *See id.* at 545.

9. *See generally* Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 697 (D.C. Cir. 2008); cert denied, 552 U.S. 1159 (2008).

10. Jennifer Piel, *Informed Consent in Right-To-Try Cases*, 44 J. Am. Acad. Psychiatry & L. 290, 291 (2016).

11. *See id.*

urged that the FDA's regulatory walls be further removed when it comes to accessing experimental drugs outside of randomized clinical trials.[12]

A. RIGHT TO TRY

As a general matter, both the Expanded Access Program and Right to Try are extremely similar. The Expanded Access Program, also known as Compassionate Use, was created by the FDA in 1987 to allow patients to have access to last-resort treatment options that have not yet been fully approved to be sold on the market.[13] In other words, under Expanded Access (like Right to Try), a terminally ill patient is able to access investigational medical products when there is no alternative care option available.[14]

Right to Try was first introduced by the Goldwater Institute as a response to the FDA's Expanded Access Program, thereby creating an additional avenue for patients to gain access to unapproved medical drugs for treatment purposes—at least, that has been the goal.[15] Right to Try started at the state level in 2014, when the Goldwater Institute assisted the Colorado legislature in drafting and passing the United States' first Right to Try law.[16] Since then, forty-one states have passed Right to Try laws, eight states are in the process of reviewing it, and only one state (Hawaii) has vetoed it.[17] Moreover, Right to Try has also gained bipartisan support at the federal level.[18] On May 30, 2018, President Donald Trump signed into law the Right to Try Act, also known as the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act.[19] While states have adopted their own twist on the federal mandate,[20] all follow the basic guidance that terminally ill patients who cannot participate in clinical trials are able to access investigational drugs that have not yet been fully approved by the FDA, as long as they qualify.[21] Moreover, the federal Right to Try law also interacts with each state's Right to Try law by normalizing the qualification requirements across state lines.[22]

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12. *See id.* at 292.

13. *See* Jonathan J. Darrow, Ameet Sarpatwari, Jerry Avorn & Aaron S. Kesselheim, *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 New Eng. J. Med. 279, 279 (2015).

14. *See* U.S. Food & Drug Admin., Expanded Access (2020), *https://www.fda.gov/news-events/public-health-focus/expanded-access* [https://perma.cc/9YJG-UD25] (articulating the requirements of Expanded Access).

15. *See* Piel, *supra* note 10, at 292.

16. *See id.*

17. *See* Goldwater Inst., *What is Right to Try?* (2017), https://righttotry.org/about-right-to-try/ [https://perma.cc/KH88-QCA3].

18. *See id.*

19. *See* U.S. Food & Drug Admin., Right to Try (2020), *https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try* [https://perma.cc/BS2A-VYJR].

20. *See* Darrow et al., *supra* note 13, at 282-83.

21. *See* U.S. Food & Drug Admin., *supra* note 19 (stating that "clinical trials provide information about whether a product is safe to use and can effectively treat or prevent a disease").

22. *See* Goldwater Inst., *supra* note 17.

B. QUALIFICATION AND APPROVAL PROCESS UNDER RIGHT TO TRY

Eligibility requirements under Right to Try and Expanded Access are quite similar. A patient is eligible to participate in Right to Try experimental treatments if she has been "diagnosed with a life-threatening disease or condition, exhausted approved treatment options, is unable to participate in a clinical trial, and has provided . . . written informed consent regarding the eligible investigational drug to the treating physician."[23] Similarly, a patient may request an unapproved drug under Expanded Access when the patient has a life-threatening disease where there are no alternative treatment options, she is unable to participate in randomized clinical trials, and the administration of the treatment will not interfere with current trials.[24] An investigational drug may be used under Right to Try if it has completed Phase 1 (out of a total of three phases[25]) of clinical trials, "has *not* been approved or licensed by the FDA for *any* use," and has not been "discontinued by the manufacturer or placed on clinical hold by the FDA."[26]

While the two avenues of last resort treatment options have similar eligibility requirements, the approval process under each is different in two primary ways (see Table 1). First, under Right to Try, the FDA is not involved in authorizing the use of the experimental medicine.[27] In contrast, under the Expanded Access Program, the FDA plays an active role in thoroughly reviewing the treatment plan and making adjustments based on the (limited) information that the Administration has collected through its trials.[28] Second, there is also no Institutional Review Board (IRB) review requirement prior to treating a patient with the drug under Right to Try.[29] At least in the context of treating a patient with an investigational product under Expanded Access, the IRB is responsible for ensuring that there is proper informed consent, and that the physician is trained to administer an experimental drug.[30]

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23. *Id.*
24. *See* U.S. Food & Drug Admin., *supra* note 14.
25. *See* Phases of an Investigation, 21 C.F.R § 312.21 (2020).
26. *See* U.S. Food & Drug Admin., *supra* note 19.
27. *See* Darrow et al., *supra* note 13, at 283.
28. *See* NYU Langone Health Div. of Med. Ethics, *Working Group on Compassionate Use & Preapproval Access Frequently Asked Questions*, https://med.nyu.edu/departments-institutes/population-health/divisions-sections-centers/medical-ethics/research/working-group-compassionate-use-preapproval-access/frequently-asked-questions#what-is-right-to-try [https://perma.cc/CN9W-DV85] (last visited Feb. 17, 2020).
29. *Id.*
30. *See* U.S. Dep't of Health and Human Servs., Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers Guidance for Industry (2017), https://www.fda.gov/media/85675/download [https://perma.cc/H2PJ-P9DT].

TABLE 1

Expanded Access Approval Process	Right to Try Approval Process
1. Physician and manufacturer must be willing to provide drug for treatment purposes 2. Physician sends the request to the FDA for review; four FDA criteria must be satisfied a. FDA may alter the treatment plan, dosage, schedule, etc. 3. IRB reviews request a. Review and approval take a few hours or a few days	1. Physician and manufacturer must be willing to provide drug for treatment purposes 2. Manufacturer makes decision whether the patient qualifies for the drug under RTT 3. No FDA or IRB approval required a. Back-end FDA involvement: manufacturer has to annually report all uses under RTT and adverse events to FDA

II. RIGHT TO TRY UNDERMINES PRINCIPLISM

Under the widely accepted principlism theory devised by Beauchamp and Childress, biomedical ethics is governed by four principles:

> (1) respect for autonomy (a principle of respect for the decision-making capacities of autonomous persons); (2) nonmaleficence (a principle of avoiding the causation of harm to others; (3) beneficence (a group of principles for providing benefits and balancing benefits against risks and costs), and (4) justice (a group of principles for fairly distributing benefits, risks, and costs).[31]

While all four of these principles are play a crucial role in medicine, different theories have governed throughout the social history of medicine. In particular, nonmaleficence is the theory that used to "triumph even over the patient's autonomy rights in a circumstance of potential harm to patients" because it used to be the norm created through social conventions and traditional practice in health care. [32] To put this into context, physicians used to take the view that if there was detrimental information that she knew about her patient, the physician was to keep that information confidential, even from the patient because it was more important to avoid causing more harm.[33] While nonmaleficence still plays an interactive role in medical practice, modern-day medicine has shifted to an

31. Tom L. Beauchamp, *Principals and Other Emerging Paradigms in Bioethics*, 69 Ind. L.J. 955, 956, 969 (1994).

32. *See id.* at 957, 958.

33. *See id.* at 958.

emphasis on the concept of patient autonomy, meaning that not only are patients able to voice their preferred method of treatment options, but the physician is also bound by a duty to respect that preference.[34]

Right to Try relies heavily on the principle of autonomy because proponents of the law reason that "patients should have a right to life *and a right to choose an agent that might prolong their lives*."[35] While this notion may be true as a general matter within medicine, federal Right to Try both weighs autonomy too heavily at the detriment of beneficence, and it is not written in a way that actually respects patient autonomy.

A. DETRIMENT TO BENEFICENCE

When thinking of patient autonomy in the context of medical access to treatments and the right to life, the ideology is primarily underscored by the notion that the only person harmed by a potential adverse effect of that decision is going to be the patient seeking to exercise her autonomous choice.[36] For instance, consider the following illustration by Thomas McCormick at the University of Washington Medicine Department of Bioethics and Humanities:

> Jehovah's Witnesses have a belief that it is wrong to accept a blood transfusion. Therefore, in a life-threatening situation where a blood transfusion is required to save the life of the patient, the patient must be so informed. The consequences of refusing a blood transfusion must be made clear to the patient at risk of dying from blood loss. Desiring to "benefit" the patient, the physician may strongly want to provide a blood transfusion, believing it to be a clear "medical benefit." When properly and compassionately informed, the particular patient is then free to choose whether to accept the blood transfusion in keeping with a strong desire to live, or whether to refuse the blood transfusion in giving a greater priority to his or her religious convictions about the wrongness of blood transfusions, even to the point of accepting death as a predictable outcome.[37]

In the above example, exercising autonomous choice to receive a blood transfusion does not impact the greater good of medicine because, while it is a life-or-death situation, the administration of the blood transfusion will not impact another person's ability to receive a blood transfusion in the future. In contrast, the same cannot be said with respect to experimental drugs administered under Right to Try because there is very little known about the drug being administered. One of the reason for

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34. *See id*. at 958-59; *see also* Jacquineau Azétsop and Stuart Rennie, *Principlism, Medical Individualism, and Health Promotion in Resource-Poor Countries - Can Autonomy-Based Bioethics Promote Social Justice and Population Health?*, 5 Phil., Ethics, & Human. Med. 1, 2 (2010).

35. Piel, *supra* note 10, at 293 (emphasis added).

36. Thomas R. McCormick, *Principles of Bioethics*, UW Medicine Department of Bioethics and Humanities, https://depts.washington.edu/bhdept/ethics-medicine/bioethics-topics/articles/principles-bioethics#:~:text=In%20health%20care%20decisions%2C%20our,a%20free%20and%20voluntary%20act [https://perma.cc/BSP9-LTNW] (last visited Feb. 18, 2020).

37. *Id*.

this is because there is no FDA involvement in approving and recommending dosages for administration, "the adverse outcomes [patients] may develop could delay or even derail the eventual approval of the product."[38] In other words, if an adverse effect of the drug is found by administering the drug in an already vulnerable population (i.e., terminally ill patients), then this "may discourage companies from proceeding with the [randomized clinical trials] or it may lead the FDA to deny approval,"[39] thereby prolonging the drug approval process (which can already take between ten and fifteen years outside of the Right to Try context).[40] In turn, with a prolonged approval process, the time it would take to make the drug available to the general population is also extended.[41] While it is true that the adverse impacts of Right to Try drugs cannot be used by the FDA during the approval process, it is hard to imagine why or how manufacturers would ignore the detrimental effects that their drugs cause to terminally ill patients because this information can still be harmful to the publicity of the company and the particular drug, even if it makes it through the FDA's strict three-phase drug approval procedure.[42] As a general matter, while patient autonomy should be upheld in medicine, laws like Right to Try that greatly devalue the greater good of future medical access to drugs should weigh the patient-welfare model more than autonomy. Thus, unlike blood transfusions and other approved clinical treatments, experimental drugs administered under Right to Try should be viewed from a utilitarian lens, where there is a greater weight on social interests and needs as a whole.

B. NO ACTUAL RESPECT FOR PATIENT AUTONOMY

Even if beneficence is not considered in light of a patient's autonomous choice to use an experimental drug for treatment purposes under Right to Try, the law, as written, creates a fabricated illusion of sovereignty over one's autonomy because it does not create a "substantive" right to try.[43] While the federal law creates no liability against a manufacturer or prescriber for administering the drug (assuming that all of the requirements are satisfied and there is no gross negligence or willful misconduct),[44] there is nothing in the law that incentivizes or requires manufacturers or insurers to provide the experimental drug, even if a proper request is filed.[45] As a matter of fact, many big-name pharmaceutical companies such as BrainStorm and Janssen have openly stated that they are hesitant

38. *See* Carrieri et al., *supra* note 2, at 67.
39. *Id*.
40. *See id*. at 65.
41. *See* Darrow et al., *supra* note 13, at 283.
42. *See* Carrieri et al., *supra* note 2, at 66.
43. *See id*.
44. *See* Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, Pub. L. No 115-176, 132 Stat. 1372.
45. *See id*.; *see also* Brandon Browbm, Camerin, Ortiz & Karine Dubé, *Assessment of the Right-to-Try Law: The Pros and the Cons*, 59 J. Nuclear Med. 1492, 1492 (2018).

to provide patients with drugs under Right to Try.[46] In particular, these companies are concerned that providing drugs under Right to Try is not financially feasible and fear going around FDA oversight and regulations.[47] While proponents of Right to Try argue that the FDA's approval process under Expanded Access Program is too cumbersome, it is likely that patients have a higher chance of getting a drug under Expanded Access than under Right to Try because drug companies want to protect the FDA oversight and safety.[48] Thus, while the law is based largely on the emphasis of "patient autonomy," patients do not really have an *autonomous* "right to try" if they are not able to get the drug for treatment purposes from the pharmaceutical companies. Consequently, for the aforementioned reasons, Right to Try is written in a misleading way because it (a) overvalues autonomy at the detriment of other principles of biomedical ethics and (b) does not actually create an additional avenue for patients to exercise their autonomous right.

III. HARM TO THE PATIENT-PHYSICIAN RELATIONSHIP

The medical profession is based largely on trust between the patient and physician.[49] Studies have shown that one of the biggest reasons that the patient-physician relationship gets destroyed is poor communication.[50] For instance, a study of litigation cases demonstrated that there are primarily four types of communication problems in roughly 70% of malpractice lawsuits: (1) deserting the patient, (2) devaluing the patients' views, (3) delivering information poorly, and (4) failing to understand the parties' perspectives.[51] Kristin Schleiter's analysis of such studies further shows that there was "little or no objective evidence of malpractice in these cases yet the physicians were still sued," thereby indicating that the malpractice suits are not a result of a physician's lack of clinical knowledge or ineptitude as a physician, but rather due to how information is communicated between the two parties.[52]

The Goldwater Institute criticizes the Expanded Access Program as being too cumbersome due to the time it takes to get approval because of the FDA's involvement.[53] Practically speaking, it is likely true that a patient would be able to get a drug faster under Right to Try than under FDA's Expanded Access because there are fewer barriers to approval given the FDA and IRB are taken out

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46. *See* Piel, *supra* note 10 (stating that Janssen has instead "sought independent assistance for a fair method to review compassionate-use requests under the FDA's expanded access and emergency provision").

47. *See* Carrieri et al., *supra* note 2, at 66.

48. *See id*. at 66, 67.

49. *See* Steven D. Pearson & Lisa H. Raeke, *Patients' Trust in Physicians: Many Theories, Few Measures, and Little Data*, 15 J. Gen. Internal Med. 509, 509 (2000).

50. *See* Kristin E. Schleiter, *Difficult Patient-Physician Relationships and the Risk of Medical Malpractice Litigation*, 11 Am. Med. Ass'n J. Ethics 242, 242, 244 (2009).

51. *See id*. at 243.

52. *Id*.

53. *See* Mark Flatten, *Dead on Arrival*, Goldwater Inst. (Feb. 24, 2016), https://goldwaterinstitute.org/article/dead-on-arrival/ [https://perma.cc/33H9-MPZB].

of the picture.[54] However, while Right to Try seeks to accelerate access to experimental medical drugs for treatment purposes, removal of the FDA from the review process puts unique pressures on the patient-physician relationship. Under Right to Try, the physician can recommend the drug to the patient but does not have to get official approval from the FDA to use the drug; the only approval required for a patient is from the drug manufacturer and physician, both of whom incur no liability for any mishaps that may occur, notwithstanding gross negligence.[55] As a result, at least as written, the risks on balance are not acceptable under Right to Try.

While the administration of experimental drugs under Expanded Access presents physicians with similar challenges in communicating information about the risks and benefits of the drug given that little is known about it, these challenges are likely heightened under Right to Try. Under Right to Try, the FDA is taken out of the drug approval process, which effectively limits the amount of information immediately available to a treating physician.[56] For instance, according to Dr. Steven Joffe, a bioethics professor at the University of Pennsylvania Perelman School of Medicine, there are only two to three parties that truly know the little data that is available on the investigational product: the manufacturers, the FDA, and the doctors, if any, who were involved in developing the drug.[57] To illustrate this point, in *Canterbury v. Spence*, even the United States Court of Appeals for the District of Columbia stated 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.'"[58] However, under Right to Try, many of the physicians who would in reality be prescribing and administering the drug would be "flying blind with respect to things like how much of the drug to give, how to give it, what kind of side effects to look for."[59] Thus, under Right to Try, physicians are inherently at a greater disadvantage with the limited information that they have regarding the drug, and they must ultimately make a judgment call that they may not be truly confident about without support and guidance from outside experts.

This absolutely does not mean that physicians are likely to be reckless under Right to Try. However, it is hard to see how taking away guidance and review standards from a federal agency that is largely trusted by the public[60] could not

54. *See* NYU Langone Health Div. of Med. Ethics, *supra* note 28.

55. *See* Bryne, *supra* note 4.

56. *See* Jacqueline Howard, *What You Need to Know About Right to Try Legislation*, CNN Health (May 29, 2018), https://www.cnn.com/2018/03/22/health/federal-right-to-try-explainer/index.html [https://perma.cc/BYX2-E5WV].

57. *See id.*

58. Brenda Lin, *Federal Right to Try Act: Heightened Informed Consent and Price Regulation Measures Will Improve Quality, Autonomy, and Exploitation Issues*, 16 Hastings Bus. L. J. 207, 218 (2020) (quoting *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972)).

59. Howard, *supra* note 56.

60. *See* Sarah D. Kowitt, Allison M. Schmidt, Anika Hannan & Adam O. Goldstein, *Awareness and Trust of the FDA and CDC: Results from a Mational Sample of US Adults and Adolescents*, 12 PLOS One 1, 4 (2017)

negatively impact the level of communication, and thus the trust, between a patient and physician before the investigational treatment is administered. Moreover, according to a leading bioethicist, Alison Bateman-House, "the FDA is responsible for weighing the risks and benefits of an investigational agent and, in some cases, advising on dosage or administration."[61] Thus, unlike the Expanded Access Program, which provides a level of protection to physicians and patients through expert FDA guidance, Right to Try has the potential to take away the already little information that is available on the Phase I approved drug that will be given to the patient, thereby increasing the risk that the information is going to be miscommunicated from the physician to the patient, if the patient participates in the state-derived, federal mandate.

Right to Try also creates a unique pressure on the patient-physician relationship because a physician may not have an ethical duty to fulfill a Right to Try request made directly by a patient. It is generally understood that "desperate patients have desperate hopes."[62] In practice this can lead to a greater number of terminally ill patients requesting investigational products under Right to Try, especially given that economic market analysis indicates that pharmaceuticals and patients' rights organizations such as Abigail Alliance market directly to consumers.[63] However, in reality, a physician who is not comfortable administering a drug under Right to Try faces a difficult situation on whether or not she can say "no," because "a healthcare provider has a duty to try to help his or her patient."[64] This creates somewhat of a dilemma because if this duty is not addressed, and providing treatment options under Right to Try becomes a standard practice, then "a physician who refuses may be liable for medical malpractice" because "physicians are held to the standard of care of the profession."[65]

While a similar issue can arise under Expanded Access requests as well, a physician may have an easier "ethical out" if the FDA does not find the request to be appropriate. In other words, if a patient insists that he wants to use the drug as a last resort treatment assuming he meets the requirements, but the physician does not feel comfortable administering the drug even after having educated herself on the risks and benefits, and subsequently communicated the (limitedly available) information to the patient, the physician still has to get guidance and support from experts at the FDA, who are also able to provide dosage and treatment plan

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(finding that not only do over 62% of adults and over 78% of adolescents trust the FDA, but many also trust the FDA more than the federal government as a whole).

61. Leah Lawrence, *The Realities of "Right to Try,"* ASH Clinic News (Oct. 1, 2018), https://www.ashclinicalnews.org/spotlight/realities-right-try/ [https://perma.cc/RRA5-VLFT].

62. Gail A. Van Norman, *Expanded Patient Access to Investigational Drugs*, 3 J. Am. Coll. Cardiology 280, 288 (2018).

63. *See* Elizabeth Weeks Leonard, *Right to Experimental Treatment: FDA New Drug Approval, Constitutional Rights, and the Public's Health*, 37 J. L. Med. & Ethics 269, 272 (2009).

64. Arthur L Caplan & Allison Bateman-House, *Should Patients in Need be Given Access to Experimental Drugs?*, 16 Expert Opinion on Pharmacotherapy 1275, 1275 (2015).

65. Leonard, *supra* note 63, at 274.

recommendations.[66] Given the fact that "the FDA receives updates after each phase of the clinical trial and has information most [healthcare providers] do not,"[67] this can directly lead to not only more confidence on the part of the administering-physician, but also more clear and robust communication between the patient and physician. In contrast, these "outs" are not available to physicians under Right to Try because there are no requirements regarding such review or recommendations.[68] In fact, the FDA only plays a limited, back-end role under Right to Try because they are "limited to receipt and posting of certain information submitted regarding Right to Try use."[69] Thus, Right to Try, as written, likely creates a unique burden on physicians, and in turn, risks the stability of the patient-physician relationship.

Lastly, while a physician has no liability for any adverse effects that may result from the drug under Right to Try, there is nothing about the law that will prevent the actual trust between the physician and patient from being negatively affected. In other words, Right to Try mistakenly takes away a regulatory body that was created for the primary purpose of safeguarding patient safety without providing any kind of protection to the patient-physician relationship. This is because the non-legal, unenforceable emotional liability ultimately falls on the physician since she is the one with the most direct connection to the patient, given that she likely met with the patient on numerous occasions prior to filling out the Right to Try request form.[70] Thus, while it may take longer for a patient to get a drug under Expanded Access compared to Right to Try, these hurdles are not only in place to help protect the patient's health, but they may also be necessary to help preserve the patient-physician relationship.

IV. A SOLUTION – CREATING A ROLE FOR LAWYERS IN RIGHT TO TRY

As described above in Part I, one of the requirements for experimental drug approval under the Expanded Access Program is that the IRB must review the informed consent documents to ensure that the experimental drug request discloses the investigational nature of the treatment and the inherent unknowns in terms of benefits and risks.[71] In doing so, the IRB also conducts other safety checks, such as making sure that the physician administering the drug has "relevant training and experience that the facility where the product will be used is able to properly treat and care for the patient in the event that problems arise related to the use of the product."[72] In contrast, under the Right to Try Act, there is no IRB

66. *See* Lawrence, supra note 61.

67. *See* Carrieri et al., *supra* note 2, at 68.

68. U.S. Food & Drug Admin., Right to Try (2020), *https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try* [https://perma.cc/BS2A-VYJR].

69. *Id.*

70. *See* Lin, *supra* note 58, at 210.

71. *See* NYU Langone Health Div. of Med. Ethics, *supra* note 28.

72. *Id.*

review or approval requirement, thereby bypassing a major safety framework set up by the FDA to ensure that terminally ill patients are fully aware of the risks associated with experimental drugs.[73] Because Right to Try takes away the IRB review and approval process, and because Right to Try creates no liability on the physician or the drug manufacturer providing the drug, there needs to be an amendment that creates a substituted safety measure under the federal statute.

Just like the fiduciary relationship between an attorney and a client, there exists a fiduciary relationship between a patient and a physician. To protect the patient-physician relationship under Right to Try, there needs to be a provision within the statute that allows a lawyer to intervene *during* the informed consent process to ensure that the standard has been properly met. The intervening lawyer will not only prevent the physician from missing any underlying steps to providing informed consent, and in turn, protect her from legal liability, but the lawyer's presence will also, and more importantly, serve as a way to directly protect the patient's health. While this will allow lawyers to intervene in Right to Try cases other than when there is gross negligence, this is not to say that physicians should be held liable for adverse effects a patient may experience. Rather, because the IRB is not able to double-check informed consent documents, a lawyer should be present when the informed consent documents are signed to ensure that the physician has met the appropriate standards at both the federal and state levels, if they are different.

The point of inserting a lawyer is not to "police" the informed consent process, but rather to serve as a substitute for the IRB's role in only Right to Try cases. This is particularly important because a study of general informed consent encounters between a patient and physician shows that "physicians rarely meet even the minimal standards of disclosure."[74] For instance, "out of 1057 physician–patient encounters involving 59 primary care physicians and 65 general or orthopedic surgeons . . . only 9% of the 2553 clinical decisions made during these encounters met the criteria for completely informed decision-making."[75] In the context of experimental drugs where there is already very little known about the benefits and risks, it is all-the-more important to ensure that informed consent is properly met. Thus, because the IRB is not involved to ensure that a patient, who is likely desperate for the medication, has truly provided informed consent, a lawyer can serve as an effective substitute.

Creating a role for attorneys as a substitute under Right to Try makes sense and is an effective choice for a couple of reasons. First, while IRBs usually have at least five members on the board, at least one of the members has to be a person whose "primary concerns are nonscientific" and one who is "not otherwise

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73. *See id.*

74. Daniel E. Hall, Allan V. Prochazka & Aaron S. Fink, *Informed Consent for Clinical Treatment*, 184 Canadian Med. Ass'n J. 533, 536 (2012).

75. *Id.*

affiliated with the institution."[76] Instead of stripping this entire process of non-scientific and ethical review under Right to Try, a medical malpractice attorney, for instance, would be able to serve an independent third party and serve in place of the IRB to help ensure that consent is truly informed and voluntary. Second, the Goldwater Institute, a major advocate for Right to Try, has a sample form on their affiliated website that patients and physicians can use when sending a Right to Try request to manufacturers.[77] On the form, the second to last paragraph states "although not a *lawyer*, it is *my understanding* that [State Name's] law protects your company from any liability for providing the drug and provides your company the appropriate *constitutional protection* allowing you to provide direct access to Drug Name."[78] This indirectly indicates that including a lawyer the process would be beneficial because they are equipped with the knowledge and ability to interpret and understand the law, both at a federal and state level. Similarly, because many states have their own take on Right to Try laws,[79] health and medical lawyers are likely to be the ones who have specific knowledge regarding the interpretation of the laws in their respective states. Additionally, it is unclear whether signing the form provided by the Goldwater Institute essentially waives the fact that the patient and physician are not lawyers, and thus they are effectively giving up a potential defense that the patient or physician may have during litigation. Consequently, there are many reasons why lawyers should be involved under Right to Try–a major one being to ensure that patients are trust informed before taking the investigational drug.

In practice, the lawyer's role and conduct in this process should be guided by Rule 2.4 of the ABA Model Rules of Professional Conduct. Rule 2.4 of the ABA Model Rules of Professional Conduct states that when serving as a third-party neutral, the lawyer should serve as an "arbitrator, a mediator or in such other capacity as will enable the lawyer to assist the parties to resolve the matter."[80] In Right to Try cases, resolving the matter could include ensuring that the informed consent standard has been effectively and thoroughly met. Moreover, the lawyer should also make clear that the patient and physician know that she is a neutral party and not representing either party.[81] The lawyer should also make clear that she has no decision-making authority with respect to the medical advice of whether the drug should be administered because the law heavily disfavors lawyers making decisions on behalf of clients. In addition to creating objectivity to ensure that the entire process of informed consent is upheld, involving a lawyer

76. Am. Psych. Ass'n, *Frequently Asked Questions About Institutional Review Boards*, (2017), https://www.apa.org/advocacy/research/defending-research/review-boards#:~:text=Who%20Serves%20on%20an%20IRB,whose%20primary%20concerns%20are%20nonscientific [https://perma.cc/3YB8-EEBJ].

77. *See* Goldwater Inst., *supra* note 17.

78. *Id*. (emphasis added).

79. *See* Darrow et al., *supra* note 13, at 282-83.

80. Model Rules of Prof'l Conduct R. 2.4(a) [hereinafter Model Rules].

81. Model Rules R. 2.4(b).

will necessarily protect the physician-patient relationship because meeting such standards and requirements "formally facilitate[s] trust in the physician-patient relationship."[82] Because approval from the FDA or IRB is not required under Right to Try, and because the federal statute does not clearly articulate a standard for informed consent that must be met under the statute,[83] the patient's reliance on whether to take the drug will be based on what her physician recommends (assuming the manufacturer is willing to provide the drug). This trust is ultimately at risk in the context of Right to Try because physicians do not have all of the information to truly inform the patient of the risks and benefits of taking the experimental drug given the fact that the relationship between the patient and physician is based largely on a high level of trust.[84] Therefore, using a third-party attorney to at least ensure that informed consent standards have been met as much as possible is an option to effectively maintain the level of trust between a patient and physician – at least in the context of Right to Try – because it can provide the patient with peace-of-mind, knowing that all of the information is disclosed and communicated properly.[85]

CONCLUSION

While Right to Try attempts to expediate the process of gaining access to experimental drugs by removing FDA oversight, the law goes against the principles of bioethics and poses a threat to the patient-physician relationship. First, the law overly values patient autonomy at the expense of the beneficence of medical progression. Moreover, even if upheld under the principle of autonomy, the law creates a false hope of patient autonomy because there is no clear substantive right to try. Second, Right to Try also threatens the patient-physician relationship because the lack of proper information, coupled with the absence of expert FDA support and guidance, can weaken the trust between patients and their physician in the event of an adverse effect. However, one way to protect and preserve this relationship is to allow an attorney to be present and approve the consent process, which is usually done by the IRB.

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82. Lin, *supra* note 58, at 219; *see generally* discussion *supra* Part III.

83. *See id*. at 214, 215.

84. *See* Hall et al., *supra* note 74, at 536 (finding that "patients and physicians view the consent process primarily as a tool for building trust rather than as a technique for decision-making").

85. *See* Piel, *supra* note 10, at 294 ("There are potential conflicts of interests for the treating doctor when he or she also participates in the administration of an investigational treatment because the physician may have personal motives to try the investigational agent.").