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The Right to Try Act: a bibliographic review of the legislation since its implementation

El *Right to Try Act* (derecho a tratar): una revisión bibliográfica sobre la legislación desde su puesta en marcha

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Abstract

The *Right to Try Act* in the United States has authorized access for terminally ill patients to experimental drugs without approval or intervention by the Food and Drug Administration (FDA) and without review by bioethics committees since 2018, which has generated controversy regarding respect for patient autonomy and the risks associated with its implementation. The main objective of this article is to describe the evolution of legislation regarding the Right to Try in the United States based on a review of documentary sources. A literature review of academic articles on the legal framework of the Right to Try was conducted. Ultimately, the Right to Try Act represents a compassionate response to terminally ill patients with no treatment options, reinforcing freedom of choice; however, it entails regulatory risks regarding access, so it is recommended to move toward models that allow for both flexibility and protection.

Keywords: bioethics, right to try, *Right to Try Act*, experimental treatments, expanded access to drugs, food, and drug administration, FDA.

1. Introduction

In May 2018, the U.S. Congress passed the *Right to Try Act*, a federal law that allows terminally ill patients to access experimental drugs without the intervention or approval of the Food and Drug Administration (FDA) and without requiring an evaluation by a bioethics committee for their use (1).

The Right to Try Act, championed by patient advocacy groups and lawmakers who viewed the FDA's process as excessively bureaucratic, was presented as an act of compassion and hope, aimed at those who have exhausted all available treatment options. However, since its enactment, it has sparked debates and controversies in the medical, ethical, and legal spheres by challenging the balance between patient autonomy and regulatory protection (2).

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The main argument in favor of the Right to Try legislation is patient autonomy, understood as the right of every individual to make informed decisions about their own health. Its proponents argue that, when death is imminent, access to potentially beneficial treatments should not be restricted. In contrast, some point out that the law weakens regulatory protections designed to ensure the safety and efficacy of medications, exposing patients to unknown risks and expectations with little scientific basis (3–5).

The drug approval system in the United States, regulated by the FDA, is recognized for its rigor, as it aims to protect the public by ensuring that medications are safe and effective. New drugs must undergo three phases of clinical trials before being approved for general use, a process that can take a long time, which for many patients with terminal illnesses represents an obstacle in the search for therapeutic alternatives (1,2).

Prior to the *Right to Try Act*, the Expanded Access Program (EAP) or Compassionate Use already existed, a mechanism that allows patients to request the use of experimental therapies under controlled conditions. Through this program, thousands of people have gained access to experimental treatments, with medical supervision and prior ethical review (6).

The *Right to Try Act* created a parallel pathway. Under this law, a patient with a terminal illness can directly request access from the pharmaceutical company to an experimental drug that has completed Phase I clinical trials, without requiring formal FDA approval or review by an institutional ethics committee (7).

2. Materials and Methods

This study was conducted using a qualitative, documentary, and analytical approach, based on a review of scientific, regulatory, and bioethical literature related to the *Right to Try Act* and policies regarding access to experimental drugs in the United States.

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A literature search was conducted in academic and legal databases as well as the official repository of the U.S. Food and Drug Administration (FDA). Articles in English and Spanish were included from databases such as PubMed, Oxford Academic, and ResearchGate. Thematic chapters previously developed on historical background, legal factors, and bioethical considerations of the right to try, as well as information obtained from the doctoral thesis of the author of this article, were also incorporated.

The selection of sources followed criteria of thematic relevance, recency (2018–2025), and academic relevance. Subsequently, a review was conducted based on the bioethical principles of autonomy, beneficence, non-maleficence, and justice.

Thus, the article does not seek to offer empirical evidence, but rather a well-founded review that articulates the ethical and legal debate surrounding the right to access experimental treatments outside traditional regulatory frameworks.

3. Development

3.1. Origin and Evolution of the Right to Try

The Right to Try movement emerged in the United States as a social response to the perceived overregulation of medical treatment authorization by the FDA. Beginning in 2014, some states proposed laws to allow terminally ill patients to request experimental drugs without going through FDA procedures or entering the expanded access program. Finally, in May 2018, President Donald Trump approved and signed the federal law known as the *Right to Try Act* (8,9).

The central proposal of the Right to Try is that patients with serious illnesses, without viable therapeutic options and without access to clinical trials, may request a Phase 1 treatment directly from the manufacturer, without requiring FDA approval or oversight (8,9).

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The goal is to accelerate access to treatment and uphold patient autonomy; however, this initiative also bypasses several ethical and scientific safeguards established over decades to protect patient safety.

To utilize the Right to Try, the law stipulates the following conditions:

1. The patient must have been diagnosed with a terminal illness.
2. The patient must have exhausted all commercially available treatment options.
3. The patient is ineligible to participate in clinical trials.
4. The patient must have been evaluated by a physician who considers the potential benefit of the requested experimental treatment.
5. The patient must have signed an informed consent form.
6. The drug has completed Phase I of clinical trials.
7. The drug has not been approved for any other use (1).

Table 1 outlines the requirements of the Right to Try Act.

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Table 1. Requirements of the Right to Try Act

Patient	Medicine	Manufacturer	Doctor	Coverage
A serious or life-threatening condition. Standard treatments have been exhausted without success. Ineligible to participate in existing clinical trials. Must provide informed consent. Do not have an inherent right to medication.	Phase I clinical trial completed. Ongoing Phase II or III clinical trials focused on efficacy and safety. Active development plan to seek FDA approval. Not approved for any other indication	Follow standard labeling and research procedures. Submit an annual report to the FDA regarding the drug and its effects. -You may refuse to provide the requested treatment.	Determine that the patient is ineligible to participate in a clinical trial. Obtain written informed consent. Receive no compensation from the manufacturer. May refuse to prescribe the medication.	There is no requirement that the cost be covered by an insurance company or other government entities.

Source: Compiled by the author based on Agarwal R. (2) and Paradise J. (7).

3.2. Bioethical Issues

The *Right to Try Act* lies at the intersection of several fundamental principles of bioethics: autonomy, beneficence, nonmaleficence, and justice (10,11).

1. *Autonomy*

The principle of autonomy holds that every person has the right to make decisions about their own health (5,12–14). In the context of

https://doi.org/10.36105/mye.2026v37n3.06

the *Right to Try Act*, this idea translates into the possibility of opting for experimental therapies when alternatives have been exhausted, without requiring prior evaluation by a regulatory body. However, autonomy is only genuine when exercised with sufficient information.

In many cases, terminally ill patients find themselves in situations of emotional and physical vulnerability, which can compromise their ability to assess risks objectively. Early-phase trials rarely provide solid evidence regarding efficacy or safety, so informed autonomy may be distorted by desperation and hope.

2. *Beneficence*

The principle of beneficence requires acting in the patient's best interest, while non-maleficence requires avoiding harm. In theory, the *Right to Try Act* seeks to benefit the patient by offering a final therapeutic opportunity. However, Phase I treatments are primarily designed to assess toxicity, not efficacy (13).

3. *Non-maleficence*

The principle of non-maleficence is based on the premise of not intentionally causing harm and avoiding, as much as possible, subjecting the patient to unnecessary risks (15).

Premature access to experimental therapies can cause serious adverse effects without evidence of clinical benefit. Furthermore, since FDA oversight and ethical review are not required, the risk of misuse or commercial exploitation increases. At the same time, the omission of a potentially useful treatment could be considered harm by omission. Therefore, the balance between potential benefit and likely harm is, in this context, highly uncertain (16).

4. *Justice*

Health equity requires an equitable distribution of resources and opportunities (17). The *Right to Try Act* may highlight inequalities since

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the program does not guarantee universal access or funding. Patients with greater resources or connections in the pharmaceutical industry may be more likely to access experimental treatments; furthermore, the law does not require pharmaceutical companies to provide the requested medications or cover the costs, which may exclude those who cannot afford them (1).

3.3. Expanded Access to Medications and the Right to Treat

Expanded access programs offer a broader balance between access and protection. Under this mechanism, the FDA approves more than 99% of requests, generally within five days. Additionally, requests go through institutional ethics committees that evaluate the risks and potential benefits of the requested treatment for each individual case (7,18).

Although both programs share the goal of offering therapeutic options to patients who have exhausted available treatments, there are significant differences:

In expanded access to medications, the treating physician is required to request permission for a specific patient from the FDA by presenting the patient's case. The case is also reviewed by a bioethics committee before deciding whether the experimental drug should be administered to that patient, and subsequently, the pharmaceutical company will decide whether to grant access to the treatment or not (19).

In the expanded access program, the recording of clinical data is mandatory, and evaluation and monitoring of patients undergoing experimental therapy are required. (20)

In contrast, the Right to Try does not require FDA oversight or approval by a bioethics committee; individual cases are not analyzed; risks and benefits are not evaluated prior to administration; and there is no systematic evaluation or monitoring of the drug's effects on the patient, as the only information the pharmaceutical company is required to report under this law is the number of doses

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administered, the number of patients to whom it was administered, the indications for which it was used, and any serious adverse effects, once a year (21).

Considering that only 13.8% of drugs that complete Phase I trials are ultimately approved by the FDA, there are doubts as to whether offering treatments based solely on preliminary safety data truly constitutes a responsible alternative (3).

Various studies show that medical professionals hold conflicting views regarding the Right to Try. Some recognize the positive emotional potential of offering a "last chance," while others warn of clinical risks, the lack of evidence, and the emotional impact on the treating physician, the patient, and their family (19, 22, 23).

A survey of pediatric oncologists revealed that most of the physicians interviewed are unaware of the legal procedures for the Right to Try and feel more comfortable with Expanded Access, as it involves greater oversight. In contrast, the study reveals that many physicians believe the Right to Try may be used as a political strategy rather than as an effective therapeutic tool (18, 19, 22).

In Manley's article "Prescribing unproven cancer drugs," it is noted that many physicians fear they may be legally unprotected or face ethical dilemmas if experimental treatments fail (18).

Table 2 compares the Right to Try Act and the Expanded Access Program for Medications in the United States.

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Table 2. Key Provisions of the Right to Treatment Act and the Expanded Access Drug Program

Appearance	Right to Try Act	Expanded Access Program
Objective	Allow patients with terminal or serious illnesses to access investigational drugs without direct FDA intervention.	Facilitate access to investigational drugs for patients with serious or terminal illnesses through the FDA, with a more structured review and approval process.
FDA Review	It does not require active oversight by the FDA; it only requires compliance with certain requirements for drugs and patients.	The FDA reviews and approves each application individually to ensure patient safety and the integrity of the treatment.
Patient requirements	The patient must have a terminal illness, have exhausted all approved treatment options, and not have access to the drug through a clinical trial.	
Drug requirements	The drug must have completed Phase 1 clinical trials and must not have been approved by the FDA. The manufacturer must be willing to supply it for the patient's use.	The drug must be in development, have completed Phase 1, or be part of an ongoing clinical trial. The manufacturer must be willing to supply it for patient use.
Informed consent	The patient must provide informed consent, but oversight by an Institutional Review Board is not required.	Informed consent from the patient and ethical approval from an Institutional Review Board are required.
The physician's involvement	The doctor should recommend the treatment, but there is no formal FDA intervention or oversight.	The doctor must submit the application to the FDA, provide details about the patient, and obtain authorization to access the medication.

https://doi.org/10.36105/mye.2026v37n3.06

Insurance coverage	There are no guarantees regarding insurance coverage for the treatment.	
Reports and documentation	No formal documentation or regular reports are required, although manufacturers may be required to provide certain reports.	Drug manufacturers are required to submit regular reports to the FDA regarding the use of the drug in patients, including adverse reactions.
Applicability	Applicable only to patients with serious or terminal illnesses and medications that are neither approved nor part of clinical trials.	Available to patients with serious or terminal illnesses, including cases where clinical trials are currently underway.
Ease of access	Simpler and more straightforward, with less red tape, but also less oversight.	More structured and bureaucratic, with direct involvement by the FDA, but offering greater safety assurances.

Source: Compiled by the author based on Paradise J. (7), Michaeli DT. (6), and Walker S. (24).

Legal Implications of the Right to Try

The Right to Try establishes a direct process between the physician, the pharmaceutical company, and the patient; however, there is no binding agreement or actual legal liability among the participants.

One of the main legal issues raised by the Right to Try is the implicit waiver of federal regulatory oversight, as it significantly reduces the FDA's authority and undermines its role in analyzing risks and benefits, since it does not monitor cases, approve applications, or systematically collect safety data.

If a patient suffers serious adverse effects, there is no legally liable party, as the law grants immunity to physicians and pharmaceutical companies, which hinders accountability. In this regard, it has been questioned whether the *Right to Try Act* undermines the foundations of the regulatory system that protects public safety (4).

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The law does not require pharmaceutical companies to provide the experimental drug they are developing, nor does it limit the cost they may set. Furthermore, since there is no oversight and they are exempt from legal liability in the event of adverse effects, monitoring of treatment administration may be reduced (25).

In the Mexican context, although there is not yet legislation equivalent to the Right to Try, the discussion surrounding compassionate use has begun to emerge within the framework of human rights and the right to health, allowing access to experimental drugs through regulatory mechanisms under protocols authorized by the Federal Commission for Protection against Health Risks (COFEPRIS), the regulatory body equivalent to the FDA in Mexico (26,27).

4. Conclusions

The Right to Try represents a societal response to the frustration of patients and their families in the face of terminal illnesses and regulations perceived as excessively restrictive or cumbersome. However, this legal alternative lacks many of the ethical safeguards that have historically protected patients.

The Right to Try can be approached from different perspectives: on the one hand, the law is used as an extension of patient autonomy; on the other hand, it may weaken patient protection by excluding ethical review processes and sound scientific criteria. The exclusion of ethics committees, the absence of standardized protocols, and scientific uncertainty regarding treatments create a scenario in which patients may find themselves even more vulnerable.

Mexico does not have a law equivalent to the *Right to Try Act*, although the Federal Commission for Protection against Health Risks (COFEPRIS) may authorize the compassionate use of medications in exceptional cases under regulations that include protocols and medical supervision (26,27).

A review of the literature reveals that the Right to Try has reignited the debate on the role of the state in the right to health, the

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economics of medicine, the protection of patient rights, and applied bioethics.

Declaration of Conflicts of Interest

The author of this article declares that there are no conflicts of interest regarding the research and publication of this article.

Referencias

1. Dighe A. Experimental Drug Access for Terminally-Ill Patients: A Review of the Right to Try Act. 2021. http://dx.doi.org/10.26153/tsw/43219
2. Agarwal R, Saltz LB. Understanding the right to try act. Clinical Cancer Research. 2020; 26(2):340-3. https://pubmed.ncbi.nlm.nih.gov/31666248/
3. Trageser J. The "Right to Try" Law: What Does It Mean for Patients?; 2019. Available at: https://www.igliving.com/magazine/articles/IGL_2019-04_AR_The-Right-to-Try-Law-What-Does-It-Mean-for-Patients.pdf
4. Gabay M. RxLegal: a rapid review of right-to-try. Hospital Pharmacy. 2018; 53(4):234-5. https://doi.org/10.1177/0018578718783992
5. Mellado J. Autonomía, consentimiento y responsabilidad. Parte 1: limitaciones del principio de autonomía como fundamento del consentimiento informado. Radiología. 2016; 58(5):343-51. https://doi.org/10.1016/j.rx.2016.06.009
6. Michaeli DT, Michaeli T, Albers S, Boch T, Michaeli JC. Special FDA designations for drug development: orphan, fast track, accelerated approval, priority review, and breakthrough therapy. The European journal of health economics: HEPAC: health economics in prevention and care. https://doi.org/10.1007/s10198-023-01639-x
7. Paradise J. Three Framing of" Faster" at the FDA and the Federal Right to Try. Wake Forest JL & Pol'y. 2020; 11:53. https://ssrn.com/abstract=3599624
8. Lin B. Federal right to try act: Heightened informed consent and price regulation measures will improve quality, autonomy, and exploitation issues. Hastings Bus LJ. 2020; 16:207. Available at: https://repository.uclawsf.edu/hastings_business_law_journal/vol16/iss2/6
9. Lynch HF, Zettler PJ, Sarpatwari A. Promoting patient interests in implementing the Federal Right to Try Act. JAMA. 2018; 320(9):869-70. https://doi.org/10.1001/jama.2018.9880
10. Carrieri D, Peccatori FA, Boniolo G. The ethical plausibility of the 'Right To Try'laws. Critical Reviews in Oncology/Hematology. 2018; 122:64-71. https://doi.org/10.1016/j.critrevonc.2017.12.014

11. Borysowski J, Górski A. Compassionate use of unauthorized drugs: legal regulations and ethical challenges. European Journal of Internal Medicine. 2019; 65:12-6. https://doi.org/10.1016/j.ejim.2019.04.008
12. Lima AFdA, Machado FIdS. Physicians as choice architects: paternalism and respect for autonomy. Revista Bioética. 2021; 29:44-54. http://dx.doi.org/10.1590/1983-80422021291445
13. Araujo LV, Gutiérrez LM. Toma de decisiones en el contexto de muerte digna desde los principios bioéticos de autonomía y beneficencia a la práctica clínica, 2022. Available at: https://apidspace.javeriana.edu.co/server/api/core/bitstreams/09fdda73-d334-4679-b621-4abdbdfb79d7/content
14. Papakonstantinou T, Kolettis T. Investigational Therapies and Patients' Autonomy. Canadian Journal of Bioethics / Revue canadienne de bioéthique. 2020;3(3):115-7. https://doi.org/10.7202/1073786ar
15. Shayma CB, Karina CR, Roberto CR, editors. Los principios de la bioética médica como solución a los dilemas bioéticos que se producen en el actuar médico. aniversariocimeq2021; 2021. Available at: https://aniversariocimeq2021.sld.cu/index.php/ac2021/Cimeq2021/paper/viewFile/267/215
16. Magadán CE. Evolución Histórica de la Bioética Médica; 2023. Available at: https://cibamanz.sld.cu/index.php/cibamanz/2023/paper/download/142/402
17. Mora FC, Tobler CA. Una aproximación arqueológica al concepto de justicia en los discursos de Beauchamp y Childress. Revista Colombiana de Bioética. 2024; 19(1). https://doi.org/10.18270/rcb.v19i1.4400
18. Manley H, Sisk BA, Master Z, Scott CT. Prescribing unproven cancer drugs: physician perspectives on expanded access and right to try. Journal of Law and the Biosciences. 2022; 9(2). https://doi.org/10.1093/jlb/lsac031
19. Zettler ME, Jeune-Smith Y, Feinberg BA, Phillips Jr EG, Gajra A. Expanded access and right to try requests: The community Oncologist's experience. JCO Oncology Practice. 2021; 17(11):e1719-e27. https://doi.org/10.1200/OP.20.00569
20. Smith C, Stout J, Adjei AA, Buckner J, Wentworth M, Tilburt J, et al. "I Think It's Been Met With a Shrug:" Oncologists' Views Toward and Experiences With Right-to-Try. JNCI: Journal of the National Cancer Institute. 2020; 113(6):735-41. https://doi.org/10.1093/jnci/djaa137
21. Zoffer WM. Recent Legislation That Secured a" Right to Try" Unapproved Drugs: Why the" Fuss" over a" Fix" of What" Ain't Broke"? Wake Forest JL & Pol'y. 2020; 11:119. http://dx.doi.org/10.2139/ssrn.3511840
22. Chapman CR, Belli HM, Leach D, Shah LD, Bateman-House A. A survey of pediatric hematologists/oncologists' perspectives on single patient Expanded Access and Right to Try. Medicine Access @ Point of Care; 2021. https://doi.org/10.1177/23992026211005991
23. Folkers K, Chapman C, Redman B. Federal Right to Try: where is it going? Hastings Center Report. 2019; 49(2):26-36. https://doi.org/10.1002/hast.990
24. Walker S. Expanded access versus right-to-try. SAGE Publications Sage CA: Los Angeles, CA; 2020. https://doi.org/10.1177/0018578719883801

25. Brown B, Ortiz C, Dubé K. Assessment of the right-to-try law: the pros and the cons. Journal of Nuclear Medicine. 2018; 59(10):1492-3. https://doi.org/10.2967/jnumed.118.216945
26. Svarch-Pérez AE, Molina-Gasman AM, Enríquez-Ríos N, Olivares-Trejo MP, Molina-Leza JF, Alcocer-Varela JC. Eficiencia en las autorizaciones sanitarias de medicamentos por la Cofepris, 2019-2022. salud pública de méxico. 2024; 66(3):296-303. https://doi.org/10.21149/15286
27. Simplificación D. Revisión y análisis de la guía para el sometimiento para protocolo de investigación en seres humanos, homoclave COFEPRIS 04-010 ay propuesta: Universidad Nacional Autónoma de México; 2020. Available at: https://ru.dgb.unam.mx/server/api/core/bitstreams/7a8b33a4-ce6e-445c-9a7c-a096d26903b9/content