EXPERIMENTAL DRUG ACCESS FOR TERMINALLY-ILL PATIENTS: A REVIEW OF THE RIGHT TO TRY ACT

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ABSTRACT

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Early access to drugs that have not won approval from the United States Food and Drug Administration (FDA) is a heavily debated topic across academics and subject matter experts in the United States, especially regarding use for terminally-ill patients. The debates surrounding whether it should be legal, what restrictions should be put in place, and what freedoms or rights individuals are entitled to continue to raise ethical questions and concerns about policy implementation. The Right to Try Act, signed into law in 2018, is a policy that effectively removes the necessity of FDA approval, granting terminally-ill patients access to non-FDA-approved drugs. This thesis explores the historical examples that underpin the Right to Try Act, the ethical considerations associated with its promulgation, and policy recommendations to improve the current system for accessing experimental drugs. For numerous reasons addressed throughout this paper, granting physicians and pharmaceutical companies sole control of non-FDA approved drugs yields too much risk to the patient and opens these entities to greater liability. The Right to Try Act causes safety concerns and removes supervision over access to under-researched therapeutics. The best system—one that prioritizes patients and their autonomy, manages safety risks of non-FDA approved drugs, and mitigates the potential for unethical practices—requires federal oversight. To build this type of system, the FDA should retain the authority to protect medical ethics and the integrity of the medical establishment.

DISCLOSURE

Given that United States Congress and former United States President Donald Trump recently enacted the Right to Try Act in 2018 and information is therefore limited, this paper relies primarily on data and information that was published up until 2019. Evidence and information that may be necessary to support arguments made throughout this paper may have been unavailable due to processing delays caused by the COVID-19 pandemic or, in certain cases, became available during the process of writing this thesis. For these reasons, since 2019, new information that has been released on the Right to Try Act may not have been incorporated into this thesis.

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INTRODUCTION

Abigail Burroughs was a 19-year-old woman who was ineligible to receive Erbitux—a non-FDA approved drug undergoing clinical trials for colon cancer at the time—and died of terminal head and neck cancer in 2001.[1] The United States Food and Drug Administration (FDA) has a program called 'Expanded Access', also known as Compassionate Use, to offer terminally-ill patients who are ineligible for clinical trials the opportunity to try experimental or investigational treatments.[2] Access—in the context of expanded access programs and early access to non-FDA approved drugs—refers to the ability for a terminally-ill individual to utilize drugs that are not available for the general public's consumption. Occasionally, access is restricted for safety and efficacy standards. The FDA denied the Burroughs family's request for Compassionate Use of Erbitux due to a lack of research, and, in turn, Abigail's father Frank Burroughs formed the Abigail Alliance for Better Access to Developmental Drugs and sued the former FDA Commissioner Mr. Andrew C. von Eschenbach in 2003.[3] In *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail Alliance)*, the Court was called to determine whether a terminally-ill patient's right to purchase a non-FDA approved drug is a fundamental right in accordance with the Fourteenth Amendment, which asserts that the state may not deprive any citizen's right to life. [4] In 2006, the U.S. Court of Appeals for the District of Columbia ruled in support of Abigail Alliance for Better Access to Developmental Drugs in *Abigail Alliance*. The FDA filed an appeal for re-hearing which was granted, and in 2007 the

[1]Peter Hart, 'University Times » Abigail Alliance Case Discussed: Balancing Study Drugs, Safety', accessed 8 March 2021, https://www.utimes.pitt.edu/archives/?p=8605..
[2] 'Expanded Access', FDA (FDA, 23 March 2021), https://www.fda.gov/news-events/public-health-focus/expanded-access.
[3] *Ibid.*
[4]Peter Lurie, 'Exploring a Right to Try for Terminally Ill Patients - 09/22/2016', U.S. Food and Drug Administration, 8 February 2019, https://www.fda.gov/news-events/congressional-testimony/exploring-right-try-terminally-ill-patients-09222016.

Court decided in favour of the FDA. This ultimately determined that the right for terminally-ill patients to access treatments that are not approved by the FDA is not protected as a Constitutional right, therefore maintaining FDA regulations on safety standards for non-FDA approved drugs.[5,6]

For several reasons, accessing under-researched drugs has been controversial throughout history. In November of 1961, thalidomide—a drug used to treat morning sickness—was taken off the market due to safety concerns.[7] Thalidomide— "the biggest man-made medical disaster ever"— caused over 10,000 birth defects, including stillborn births.[8] To prevent similar medical disasters with other under-researched drugs, it is important for the FDA to closely oversee new-to-market drugs. The Kefauver-Harris Amendment to the Federal Food, Drug, and Cosmetic Act, which established higher safety standards and stricter approval processes for pharmaceutical drugs, was signed into law in 1962 in response to the thalidomide tragedy of the late 1950s.[9] This is particularly relevant to the *Abigail Alliance* case, because the main reason her request for Erbitux was denied was lack of research on the drug's efficacy and safety for head and neck cancer. The amendment has since been revised to include expanded access programs, but its core directives focused on efficacy and safety are still in practice today.[10] The expanded access programs were created to address concerns that the new safety standards and drug approval

[5] '*Abigail Alliance v. Eschenbach*, 495 F.3d 695 | Casetext Search + Citator', accessed 8 March 2021, https://casetext.com/case/abigail-alliance-v-eschenbach.
[6] *Ibid.*
[7] James H. Kim and Anthony R. Scialli, 'Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease', *Toxicological Sciences: An Official Journal of the Society of Toxicology* 122, no. 1 (July 2011): 1–6, https://doi.org/10.1093/toxsci/kfr088.
[8] Neil Vargesson, 'Thalidomide-induced Teratogenesis: History and Mechanisms', *Birth Defects Research* 105, no. 2 (June 2015): 140–56, https://doi.org/10.1002/bdrc.21096.
[9] 'Kefauver-Harris Amendments Revolutionized Drug Development'. Accessed 16 September 2021. https://www.gvsu.edu/cms4/asset/F51281F0-00AF-E25A-5BF632E8D4A243C7/kefauver-harris_amendments.fda.thalidomide.pdf.
[10] Jeremy A. Greene and Scott H. Podolsky, 'Reform, Regulation, and Pharmaceuticals — The Kefauver–Harris Amendments at 50', *The New England Journal of Medicine* 367, no. 16 (18 October 2012): 1481–83, https://doi.org/10.1056/NEJMp1210007.

processes would hinder timely access to potentially life-saving treatments for terminally-ill patients.[11]

Sometimes, desperate patients resort to legal loopholes to acquire the treatments they believe they need. In the 1980s, acquired immunodeficiency syndrome (AIDS) buyers' clubs became a means of obtaining drugs to treat human immunodeficiency virus (HIV)/AIDS that were pending FDA approval.[12] Buyers' clubs were organizations wherein individuals paid for membership which provided them with access to non-FDA approved medication. These medications were obtained overseas and sold by foreign pharmaceutical companies but distributed in the United States.[13] The 2013 movie *Dallas Buyers Club* portrays many of the issues and benefits of such buyers' clubs. This film follows the story of Ron Woodroof, an electrician who contracted AIDS and organised an AIDS buyers' club in Dallas, Texas. In the early 1980s, HIV and AIDS were under-researched, and there were very limited medical options for terminally-ill AIDS patients. By 1987, azidothymidine (AZT) became the first government-approved treatment against HIV and AIDS; however, the high dosage initially prescribed in earlier trials had several toxic and harmful effects on the patients to whom it was administered.[14] The toxicity of this drug—similar to the toxicity of most drugs administered for cancer treatments—made AZT an extreme risk for patients in need of treatment. Though it is true that AZT is an antiretroviral which may slow the progression of HIV, AZT alone could not cure an

[11] *Ibid.*
[12]Howard Lune, *Urban Action Network: HIV/AIDS and Community Organizing in New York City* (United States of America: Rowman & Littlefield Publishers, Inc., 2007).
[13] Hannah Dorf, '"Managing Your Own Survival": Buyers Clubs in the AIDS Epidemic – Health & Medicine in American History', accessed 30 November 2021, https://lewiscar.sites.grinnell.edu/HistoryofMedicine/spring2018/managing-your-own-survival-buyers-clubs-in-the-aids-epidemic/.
[14] D. T. Chiu and P. H. Duesberg, 'The Toxicity of Azidothymidine (AZT) on Human and Animal Cells in Culture at Concentrations Used for Antiviral Therapy', *Genetica* 95, no. 1–3 (1995): 103–9, https://doi.org/10.1007/BF01435004.

individual of HIV or AIDS.[15] In *Dallas Buyers Club*, individuals with terminally-ill AIDS stopped taking AZT out of fear that they would die faster taking the drug than they would without pharmaceutical intervention. Though there are many cases in which investigational drugs should be offered to patients, in cases dealing with high-risk viral disease like HIV/AIDS, and when working with extremely toxic drugs like those used in chemotherapy, it is essential to provide in-depth information and realistic expectations to each patient and their families. When patients have limited options—like during the HIV/AIDS crisis or in the case of Abigail Burroughs—they should be granted certain freedoms by the FDA.

Since the establishment of FDA Expanded Access and Compassionate Use programs in 1987, physicians—on behalf of their patients—have been able to apply for rapidly approved access to investigational new drugs (IND) to treat terminally-ill patients.[16] This program allows patients and physicians to complete an application and get approval within one to four days, depending on the emergency of their case. Furthermore, in 2012, 974 of the 977 Compassionate Use requests were granted, leaving only three cases denied.[17] However, despite this program and its commitment to making investigational drugs accessible, not all terminally-ill patients are given the outcome they desire.

The desperate need for pharmaceutic drugs during the AIDS crisis in the 1980s and 1990s inspired the "Dallas Buyers Club" bill, also called the "Right to Try Act" (RTT) in several

[15] Dylan Matthews, 'What "Dallas Buyers Club" Got Wrong about the AIDS Crisis - The Washington Post', The Washington Post, 10 December 2013, https://www.washingtonpost.com/news/wonk/wp/2013/12/10/what-dallas-buyers-club-got-wrong-about-the-aids-crisis/.
[16] C. Roberts and F. B. Palumbo, 'The "Treatment IND (Investigational New Drugs)": Public Policy Considerations', *Journal of Pharmaceutical Marketing & Management* 3, no. 1 (1988): 41–59, https://doi.org/10.3109/j058v03n01_04.
[17] Erica Krantz and Joseph L. Fink III, '"Right to Try" Legislation: A Developing Legal Issue Related to Medications', 26 July 2016, https://www.pharmacytimes.com/view/right-to-try-legislation-a-developing-legal-issue-related-to-medications.

states.[18] Although cases like *Abigail Alliance* and the story of Ron Woodroof make compelling arguments for the need of policies like RTT, it is also important to consider the ramifications of allowing patients—most of whom do not have medical training or thorough understanding of novel research—to make their own medical decisions. While in the case of Abigail Burroughs the early access to Erbitux would likely have extended her life, in the case of Ron Woodroof the continued use of an under-researched drug like AZT could have ended his life several years earlier than when he died.[19] The right to try investigational and non-FDA approved drugs like Woodroof did has been a controversial but critical subject in medical, philosophical, scientific, political, and legal fields for several decades.

Drug access is managed by the FDA to protect civilians from harmful side effects and to ensure that all drugs on the market can prove to meet the efficacy claims they make.[20] For this reason, permission to use several drugs undergoing trials and drugs that are under-researched is restricted to patients with very specific diseases or withheld aside from clinical trial enrolment entirely. However, when it comes to terminally-ill patients or patients with gravely debilitating conditions, sometimes exceptions are made.[21] In addition to *Dallas Buyers Club*, the documentary *How to Survive a Plague* is also a part of Ron Woodroof's legacy.[22] Both these films demonstrate how single individuals or small groups of activists can significantly change

[18] Marsha Shuler, '"Dallas Buyers Club" Bill Signed into Law in La.', The Advocate, accessed 4 December 2021, https://www.theadvocate.com/baton_rouge/news/politics/legislature/article_6692bb40-0c56-53e8-a474-8e47492fddb6.html.
[19] Sean Philpott, 'How the Dallas Buyers Club Changed HIV Treatment in the US', The Conversation, accessed 30 November 2021, http://theconversation.com/how-the-dallas-buyers-club-changed-hiv-treatment-in-the-us-22664.
[20] 'The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective', *FDA*, 19 June 2020, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective.
[21] 'Expanded Access', FDA (FDA, 23 March 2021), https://www.fda.gov/news-events/public-health-focus/expanded-access.
[22] Udo Schüklenk, 'AIDS Activism Commuted Death Sentences but Its Spirit Is Lost', The Conversation, accessed 30 November 2021, http://theconversation.com/aids-activism-commuted-death-sentences-but-its-spirit-is-lost-20042.

governmental policies. However, what is best for an individual or a small group—like in the cases of Abigail Burroughs or Ron Woodroof—is not necessarily in the best interest of the general public. While creating policies addressing early access to unproven treatments for terminally-ill patients, several considerations must be made. First, from an ethical standpoint, one must evaluate the potential implications—both positive results and negative consequences—of allowing terminally-ill patients to access non-FDA approved drugs. Second, liability for adverse effects should be evaluated to understand the risk from a financial and legal perspective. Finally, there comes a point in terminal disease progression where pharmaceutical drugs are either no longer effective or patients choose to transition to hospice care instead.[23] In order to ethically deliberate whether a patient with a terminal diagnosis should be allowed access to an unproven treatment, it is important to realistically assess the timeline of their disease progression. This determination is essential in deciding whether one can appropriately expect any drug to improve a patient's condition.[24]

In 2018, the United States Congress under the Trump Administration passed the Right to Try Act (RTT), which allows terminally-ill patients to access experimental drugs with the permission of both their physician and the pharmaceutical company that produces the drug.[25] The Goldwater Institute alongside other similarly conservative groups were strong advocates and financial supporters of RTT. Their goal in defending this policy is to promote patient autonomy, but in many cases, a consequence of patient autonomy is that it enables unsafe and morally questionable behaviour from pharmaceutical companies and other members of the medical

[23] Atul Gawande, 'Letting Go: What Should Medicine Do When It Can't Save You?', The New Yorker, 26 July 2010, https://www.newyorker.com/magazine/2010/08/02/letting-go-2.
[24] Atul Gawande, *Being Mortal: Medicine and What Matters in the End*, September 2017 (New York: Metropolitan Books, 2014).
[25] Robert Pear, 'Congress Approves Bill Giving Patients a "Right to Try" Experimental Drugs - The New York Times', accessed 5 May 2021, https://www.nytimes.com/2018/05/22/us/politics/congress-approves-right-to-try-experimental-drugs.html.

community. RTT effectively undoes the final decision of *Abigail Alliance* and removes the requirement for FDA oversight and approval for access to investigational and unproven treatments. A history of litigation surrounding experimental drugs, combined with valuations on the matter by ethicists, established that terminal cancer patients require a case-by-case basis approval from the FDA to access unproven treatments. Despite the outcome of *Abigail Alliance* and the thorough safety standards outlined by the FDA, RTT enables the following:

> "To authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law, and for other purposes.
>
> `(1) the term `eligible patient' means a patient--
>
> ``(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));
>
> ``(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who--
>
> ``(i) is in good standing with the physician's licensing organization or board; and
>
> ``(ii) will not be compensated directly by the manufacturer for so certifying; and
>
> ``(C) who has provided to the treating physician

> written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent". [26]

It is this authorization that allows terminally-ill patients, their physicians, and pharmaceutical companies to act as sole decision makers on experimental drug administration. This paradigm shift from relatively strict restrictions on non-FDA approved drugs in the 1960s to policies like RTT in 2018 essentially remove regulating power from the government and place that power in the hands of drug manufacturers and individual physicians. The reassignment of power raises several ethical and legal dilemmas that need to be evaluated.

In *Abigail Alliance*, the Court determined that the FDA's regulations to restrict access to Erbitux are valid and that a terminally-ill cancer patient's access to non-FDA approved drugs is not a fundamental right.[27] Although not a fundamental right, many legal critics and ethicists present arguments supporting a terminally-ill patient's ability to access unproven treatments or treatments in the process of clinical trials. While the FDA works to maintain high standards of safety and regulation, entities like the National Cancer Institute are advocating to broaden eligibility criteria for clinical and pre-clinical trials.[28] On the other hand, shortly after the *Abigail Alliance* case ruling, the British Medical Journal published an ethical evaluation on whether terminally-ill patients should be given access to drugs that have passed initial testing or Phase I of FDA approval. The journal also recommends that partially tested therapies ought not be made

[26] Ron Johnson, 'Text - S.204 - 115th Congress (2017-2018): Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017', webpage, 30 May 2018, https://www.congress.gov/bill/115th-congress/senate-bill/204/text.
[27] 'Abigail Alliance v. Eschenbach, 495 F.3d 695 | Casetext Search + Citator'.
[28] P. Ivy et al., 'Making Cancer Clinical Trials Available to More Patients - National Cancer Institute', cgvBlogPost, 3 July 2019, https://www.cancer.gov/news-events/cancer-currents-blog/2019/expanding-clinical-trial-eligibility-criteria.

as a substitute for already approved ones.[29] Furthermore, The Supreme Court case *U.S. v. Rutherford* (1979) decision predating the *Abigail Alliance* suits concluded likewise that terminal cancer patients do not have the right to access unproven therapies.[30] These conflicting opinions demonstrate how controversial it is to suggest that terminally-ill patients be granted early access to unproven drugs. Today, Erbitux is prescribed by oncologists to treat head and neck cancer—the type of cancer Abigail died of—which suggests that had the Court ruled in favour of Abigail Alliance instead of supporting the FDA, perhaps Abigail's life could have been extended. However, it was impossible to have known the life-saving potential of Erbitux when it was applicable to Abigail Burroughs. At a larger scale, and with regards to generally applicable policy, it is unwise to assume safety or efficacy without having first done thorough research.

Since the implementation of the 2018 Right to Try Act, the burden of determining the safety experimental drugs for use on terminally-ill patients has fallen on pharmaceutical companies and physicians rather than an overarching government agency, like the FDA.[31] Prior to RTT, the FDA had mechanisms in place—like the expanded access program—to allow certain terminally-ill patients to access non-FDA approved drugs or unproven treatments, including Compassionate Use and privileges for terminally-ill patients who do not qualify for existing clinical trials.[32] These programs, which have government oversight, are safer for patients than deferring the entire decision-making responsibility to members of the private sector. This

[29] Dean Gesme, "Should Terminally-ill Patients Have the Right to Take Drugs That Pass Phase I Testing? No," *BMJ* 335, no. 7618 (September 6, 2007): 479–479, accessed March 9, 2021, https://www.bmj.com/content/335/7618/479.
[30] Valarie Blake, "The Terminally-ill, Access to Investigational Drugs, and FDA Rules," *AMA Journal of Ethics* 15, no. 8 (August 1, 2013): 687–691, accessed March 9, 2021, https://journalofethics.ama-assn.org/article/terminally-ill-access-investigational-drugs-and-fda-rules/2013-08.
[31] Vijay Mahant, '"Right-to-Try" Experimental Drugs: An Overview', *Journal of Translational Medicine* 18, no. 1 (23 June 2020): 253, https://doi.org/10.1186/s12967-020-02427-4.
[32] 'Expanded Access', FDA.

dissemination of power to the private sector requires policies surrounding access to non-FDA approved drugs to be re-evaluated.

This thesis works to explain the necessity for FDA oversight with regards to accessing investigational and non-FDA approved drugs for terminally-ill cancer patients. First, this paper will examine the court cases and decisions on *Abigail Alliance*, policy inspired by the HIV/AIDS crisis, and other similar historic examples, in order to understand why RTT is not only unnecessary but also potentially dangerous. Then, it will explore the ethical implications of the decisions that were reached, and liability related concerns associated with them. Finally, this paper will provide policy analysis and recommendation on the conditions under which terminally-ill cancer patients may access non-FDA approved or investigational drugs.

DEBATING THE CASES of *ABIGAIL ALLIANCE* and RON WOODROOF

The great philosopher Voltaire once said, "Doctors pour drugs of which they know little, to cure diseases of which they know less, into human beings of whom they know nothing."[33] Although scientific and medical research has come a long way since Voltaire's era, there is still much that is under-researched and unknown about medicine. This was made evident in several examples throughout history, specifically during the HIV/AIDS crisis in the 1980s and 1990s, when the FDA granted approval for the first drugs used in treatment for HIV/AIDS.[34] Similar to the drugs used during the HIV/AIDS crisis, medical professionals cannot accurately determine the potential risks or benefits associated with releasing cancer therapeutics without conclusive research. In fact, according to recent studies, approximately 45% of new cancer drugs show no association or unknown association with extending overall survival by at least three months.[35] Furthermore, 42% of novel cancer treatments were associated with improved quality of life, but 45% were associated with reduced patient safety.[36] When evaluating some of the landmark cases that shaped the current FDA and federal law pertaining to early access of investigational drugs, it is important to approach the decision wholistically. The general lack of knowledge as well as the toxic nature of many drugs used in cancer treatment are major factors that must be considered when evaluating the ethics of access to experimental drugs for terminally-ill cancer patients. Thus, one must analyse the implications and the precedent set when early access to an investigational drug is or is not permitted. Lastly, there needs to be a way to account for outlier

[33] 'The Big Apple: "Doctors Pour Drugs of Which They Know Little, to Cure Diseases of Which They Know Less"', accessed 30 November 2021, https://www.barrypopik.com/index.php/new_york_city/entry/doctors_pour_drugs_of_which_they_know_little.
[34] Lisa Cisneros, '40 Years of AIDS: A Timeline of the Epidemic | UC San Francisco', accessed 30 November 2021, https://www.ucsf.edu/news/2021/06/420686/40-years-aids-timeline-epidemic.
[35] Sebastian Salas-Vega, Othon Iliopoulos, and Elias Mossialos, 'Assessment of Overall Survival, Quality of Life, and Safety Benefits Associated With New Cancer Medicines', *JAMA Oncology* 3, no. 3 (1 March 2017): 382–90, https://doi.org/10.1001/jamaoncol.2016.4166.
[36] *Ibid.*

cases and the exceptions to the law that are made on a case-by-case basis. All these factors combined help to evaluate and understand the ethical dilemmas that challenge decision makers when determining the conditions under which unproven and non-FDA approved drugs may be accessed.

In order to evaluate the circumstances under which a terminally-ill cancer patient may access a non-FDA approved and therefore risky drug, it is important to consider several ethical implications. Both the *Abigail Alliance* case and Ron Woodroof's experiences with investigational drugs should be examined to understand the ethics of early access to experimental drugs. Since RTT effectively removes FDA oversight, it conflicts with FDA safety standards and restrictions, naturally causing heavy debate. While medical and technological advancements yield remarkable opportunities for patients to extend their lives before reaching their inevitable death, the use of under-researched and new-to-market treatments has been the cause of many controversies across medical, philosophical, political, and legal communities. This paper will address the 'right to life' outlined in the United States Declaration of Independence, honouring patient autonomy over their own medical decisions, and the dilemma created when the patients choose not to pursue their 'right to life'.

I. The Right to Life

The 'right to life', which in the case of experimental drugs can be viewed as the right to pursue life-saving or potentially life-saving treatments, is an important factor to consider when determining if a patient should be granted access to unproven or investigational treatments.[37] The right to access investigational drugs, as established by *Abigail Alliance for Better Access to*

[37] Jukka Varelius, 'The Value of Autonomy in Medical Ethics', *Medicine, Health Care, and Philosophy* 9, no. 3 (December 2006): 377–88, https://doi.org/10.1007/s11019-006-9000-z.

Developmental Drugs v. von Eschenbach 495 F.3d 695 (D.C. Cir. 2007), is not a constitutionally protected right.[38] This is particularly relevant to the Congressional 'Right to Try' Act that advocates for a patient's right to try non-FDA approved treatments in hope that it will improve their condition. However, the hope that it may improve a terminally-ill cancer patient's condition must be balanced against the potential that a highly toxic, cell-killing cancer therapeutic may have ramifications that are more harmful than they are beneficial.[39] One major argument that experts in medicine and philosophy debate is whether it is more ethical to 'do nothing'—meaning to transition patients to palliative or hospice care once the terminal disease progresses to a 'point of no return'—or to pursue extreme measures including use of investigational and non-FDA approved drugs.

The difficult determination that must be made is whether 'doing nothing' or pursuing extreme measures will shorten the patient's life the most. Physicians swear the Hippocratic Oath, pledging to 'first, do no harm'.[40] This oath prompts a few concerns: can a physician take an action on a patient with the knowledge that it may cause harm? Is it ethical to subject a patient to a certain amount of risk if the potential benefits outweigh the harms? Despite their potential to extend a patient's lifespan, FDA approved and non-FDA approved cancer therapeutics alike are generally highly toxic and tend to have harmful adverse side effects. Patients undergoing chemotherapy experience numerous adverse side effects including nausea, weakness, hair loss, and worse, but it is deemed ethical to administer these treatments because they could reduce the size of a tumour that may otherwise kill the patient. So, in the case of FDA approved cancer

[38] 'Abigail Alliance v. Eschenbach, 495 F.3d 695 | Casetext Search + Citator'.
[39] Rebecca Kirk, 'The Toxic Reality of New Drugs', *Nature Reviews Clinical Oncology* 9, no. 9 (September 2012): 488–488, https://doi.org/10.1038/nrclinonc.2012.134.
[40] Kathy Oxtoby, 'Is the Hippocratic Oath Still Relevant to Practising Doctors Today?', *BMJ* 355 (14 December 2016): i6629, https://doi.org/10.1136/bmj.i6629.

treatments, the criterion for ethical use is simply whether that treatment may extend a person's lifespan, even if it induces harmful side effects. The issue this poses with unapproved therapeutics is that even medical practitioners do not fully understand the potential ramifications of the drug.

When it comes to non-FDA approved drugs, there is reason to believe that a specific treatment undergoing trials *might* help a patient, but neither doctors nor researchers truly know whether the drug is effective or even safe to use.[41] In this absence of scientific certainty, one should weigh all available information, as well as intention, to determine if it is ethical to give patients access to unproven drugs. The toxic nature of most cancer therapeutics, combined with the fact that only approximately 14% of experimental drugs win FDA approval, suggests that there is a high risk involved in using non-FDA approved drugs.[42] That being said, many experimental drugs— despite their harsh potential side effects—are worth the risk for terminally-ill patients. If there is both sufficient information to suggest that using a non-FDA approved drug will help extend a terminally-ill patient's lifespan and informed consent from the patient or proxy, the administration of that treatment should be considered ethical since the intent is to extend a patient's life. In the case of Abigail Burroughs, the request for Erbitux was made after she was diagnosed as 'terminal' and had no other options for medical intervention to postpone her impending death.[43] Similarly, with Ron Woodroof and other HIV/AIDS patients in the 1980s and 1990s, there were no other FDA approved alternatives to treat their terminal illnesses.[44] What is the ethical objection to allowing a terminally-ill patient the autonomy to try a potential

[41]Bruce K. Rubin and Kenneth P. Steinberg, 'When Caring for Critically Ill Patients, Do Clinicians Have a Responsibility to Be Innovative and Try Unproven Approaches When Accepted Approaches Are Failing?', *RESPIRATORY CARE* 52, no. 4 (2007): 8.
[42]Conor Hale, 'New MIT Study Puts Clinical Research Success Rate at 14 Percent', accessed 27 April 2021, https://www.centerwatch.com/articles/12702-new-mit-study-puts-clinical-research-success-rate-at-14-percent.
[43] 'Abigail Alliance v. Eschenbach, 495 F.3d 695 | Casetext Search + Citator'.
[44] Cisneros.

remedy? In cases like this, the arguments against permitting use of unproven or non-FDA approved drugs for terminally-ill patients have less to do with ethics and more to do with liability.

II. Patient Autonomy

A patient's freedom to make their own medical decisions is extremely important, not only for their individual sense of autonomy, but also to honour their cultural and familial values.[45] After receiving their diagnosis, terminally-ill patients must decide who should ultimately dictate the next steps that will be taken in their medical care.[46] This issue, in conjunction with the previously outlined ethical dilemmas, contributes to the underlying question: to what extent can a state or the federal government regulate an individual's choices about their life and death with regards to their medical care and health? Cultural and religious practices influence individuals' healthcare-related decisions, and therefore healthcare can be a deeply personal topic for many patients and their families.[47] Preserving patient autonomy is crucial. Doing so respects a patient's individuality, their ability to die with dignity and in line with their spiritual priorities, and the mental wellbeing of their family members and friends.[48] In the case of Abigail Burroughs, the FDA and Courts did not honour her desire and her family's desire for her to pursue experimental drugs. The government's denial of Abigail's autonomy may have led to a lack of peace or closure for her family. The death of a child is one of the most traumatic losses a parent can

[45] Paul Kalanithi and Abraham Verghese, *When Breath Becomes Air* (London, England: Random House (US), 2017).
[46] David H. Lee, 'Approach to End of Life Care', *The Ochsner Journal* 4, no. 2 (2002): 98–103.
[47] Gawande, *Being Mortal: Medicine and What Matters in the End*.
[48] Varelius, 2006.

experience.[49] Her family's trauma manifests in her father's efforts to pursue a lawsuit and enduring the burden of multiple court cases after her death. Giving her family the peace of knowing that they did everything possible, even if the use of Erbitux had unintended consequences, may have provided them with a sense of closure and reduced their stress after Abigail's death. However, patient autonomy should only be prioritised until the point where safety and drug efficacy become a concern.

Ron Woodroof, similar to Abigail Burroughs and her family, wanted to try every option possible to extend his life.[50] Through the buyers' clubs he founded and his own volition, he sought non-FDA approved treatments for HIV/AIDS from other countries.[51] He self-medicated even without the recommendation or approval of a board-certified physician within the United States.[52] Although there are risks involved with allowing patients to use non-FDA approved drugs, as a person is nearing guaranteed end-of-life there are many difficult decisions that must be made to honour their autonomy and to respect their cultural and religious practices. Furthermore, when a patient dies of a chronic and terminal sickness—like Abigail's head and neck cancer—their death takes a toll on the people who watched the patient suffer and are now left without their loved one. The decision between 'fighting to the end' or choosing to transition to hospice care, palliative care, or other end-of-life services is a choice that individuals and families should make without restrictions from the FDA or other federal government influence. In certain cultures, the choice to withdraw drug treatment when a patient is diagnosed as

[49] Roberta Lynn Woodgate, 'Living in a World without Closure: Reality for Parents Who Have Experienced the Death of a Child', *Journal of Palliative Care* 22, no. 2 (1 June 2006): 75–82, https://doi.org/10.1177/082585970602200203.
[50] Chris McNary, 'Buying Time: World Traveler Ron Woodroof Smuggles Drugs — and Hope — for People with AIDS', accessed 30 November 2021, https://www.dallasnews.com/news/1992/08/09/buying-time-world-traveler-ron-woodroof-smuggles-drugs-and-hope-for-people-with-aids/.
[51] *Ibid.*
[52] *Ibid.*

'terminal' or even before that point is accepted and perhaps encouraged, whereas in other cultures the choice to seek further treatment and explore experimental drugs may be more appropriate.[53] Patient autonomy is an important factor in preserving the individual's dignity at the end of their life especially as it relates to cultural practices and death rites. When the FDA restricts access to non-approved but potentially life-saving drugs, such restriction may hinder a person's ability to choose the advanced directives and end-of-life care methods most suitable for themselves. The opportunity to understand every possible option and to make decisions about one's own health is essential to patient autonomy.[54]

An accurate medical determination of the patient's timeline and disease progression is crucial in determining whether they should be granted access to unproven or non-FDA approved treatments. The distinction between a patient having a few months or having a few years left to live has serious ethical weight when it comes to the decision to try unproven or non-FDA approved drugs. However, such a precise timeline is difficult to achieve when research indicates that doctors only reach an accurate prognosis in 20% of their patients. [55] For this reason, protocols and procedures must be implemented to protect patients from choosing a harmful drug when they are not *about to* die. Clear communication between physicians and their terminal patients, then, is crucial for respecting patient autonomy–if the patient is not clearly informed of their medical condition and the expected outcomes, they will be unable to prepare advanced directives, think about cultural rights and rituals, or any other end-of-life customs they may want to practice.

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[53] Christopher P. O'Brien, 'Withdrawing Medication', *Canadian Family Physician* 57, no. 3 (March 2011): 304–7.
[54] 'Your Guide to Living Wills and Other Advance Directives', Mayo Clinic, accessed 5 December 2021, https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/living-wills/art-20046303.
[55] Manoj Jain, 'When Terminally Ill Patients Ask How Long They Have, Doctors Find It Hard to Say', *Washington Post*, 19 December 2011, sec. Health & Science, https://www.washingtonpost.com/national/health-science/when-terminally-ill-patients-ask-how-long-they-have-doctors-find-it-hard-to-say/2011/09/23/gIQALTzm4O_story.html.

III. The United States Congress and Supreme Court

The United States Congress is the legislative branch of the federal government that writes and passes bills that, if signed by the President, will dictate the 'law of the land,' but there are several concerns regarding Congressional Acts that deal with pharmaceutical regulation. When it comes to ethical debates surrounding end-of-life care, there are numerous divisions of the federal government (as well as state governments) that legislate this topic. For example, Supreme Court case *Washington v. Glucksberg 1997* was a landmark decision that determined that the "right" to assisted suicide is not protected by the Due Process clause of the Fourteenth Amendment to the Constitution.[56] While this decision determines that physician assisted suicide and euthanasia are not constitutional rights, it also does not render physician assisted suicide illegal. This Supreme Court ruling, combined with a lack of legislation by Congress, leaves decision making to individual state governments. Similarly, if the Supreme Court were to hear a case—like the *Abigail Alliance* case—their ruling would determine whether an individual's 'right to try' is constitutionally protected. However, the ruling would not necessarily allow or prevent early access to non-FDA approved drugs.

The benefit of Congress acting as the primary decision-making body regarding early access to experimental drugs is that by federally legalising it, individuals with terminal diagnoses can legally access experimental treatments in any state. However, when laws are signed into effect, the consequences and implications do not always reflect the intention of the law. RTT passed by Congress allows an individual patient diagnosed with a terminal illness, with the consent of their board-certified physician, to request access to investigation drugs from a drug manufacture, with certain restrictions. However, we see through examples like the federal

[56] 'Washington v. Glucksberg | Case Brief for Law School | LexisNexis', Community, accessed 5 May 2021, https://www.lexisnexis.com/community/casebrief/p/casebrief-washington-v-glucksberg.

legalization of abortion that permission from the federal government does not always work. Supreme Court case *Roe v. Wade* made abortion legal in all U.S. states, but since states may set their own regulations and restrictions, abortion is not equally accessible to all individuals who may want or require that medical service.[57, 58] Although Congress determines the 'law of the land', they are not always effective in evenly implementing their laws. Furthermore, for regulations to be enforced, FDA and state involvement are required in addition to Congressional legislation.[59, 60]

Through the 1980s, buyers' clubs like Ron Woodroof's Dallas Buyers Club sold illegal pharmaceutical drugs to terminally-ill HIV/AIDS patients. However, these clubs in themselves were not exactly illegal. RTT—also known as the 'Dallas Buyers Club Act' in some states—enables these risky practices and can result in gross liability for civilians and patients like Ron Woodroof who orchestrate the sale of non-FDA approved drugs.[61] Through the AIDS crisis in the 1980s, many of the experimental drugs that people tried were more toxic than helpful, due to both inaccurate dosages and a lack of research. When Congress leaves decision making power in the hands of individuals like patients or their physicians, more people are put at risk of unwanted complications from taking under-researched drugs. Congress's role regarding permission for access to unproven treatment should be limited to enacting the federal laws that establish the FDA as the overarching body responsible for making these decisions.

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[57] 'Jane ROE, et al., Appellants, v. Henry WADE.' n.d. LII / Legal Information Institute. Accessed 5 May 2021. https://www.law.cornell.edu/supremecourt/text/410/113.
[58] 'Federal and State Bans and Restrictions on Abortion'. n.d. Accessed 5 May 2021. https://www.plannedparenthoodaction.org/issues/abortion/federal-and-state-bans-and-restrictions-abortion.
[59] The Office of the Commissioner 2021. 'Laws Enforced by FDA'. FDA. FDA. 19 April 2021. https://www.fda.gov/regulatory-information/laws-enforced-fda.
[60] Howard S. Gans, 'Some Consequences of Unenforceable Legislation', *Proceedings of the Academy of Political Science in the City of New York* 1, no. 4 (1911): 563–89, https://doi.org/10.2307/1172067.
[61] 'Colorado First State to Pass "Right to Try," or the 'Dallas Buyers' Club' Law', PBS NewsHour, 19 May 2014, https://www.pbs.org/newshour/health/colorado-first-state-pass-right-try-dallas-buyers-club-law.

Prior to RTT, the FDA was already granting most terminal patients Compassionate Use of non-FDA approved drugs. When early access to unproven treatments was restricted, like in the case of Abigail Burroughs, it was due to a lack of scientific findings that supported use of the experimental treatment. The FDA established a program in 2009 that created three categories of access to experimental treatments: individual patients, intermediate-size patient populations, and larger populations under a treatment protocol or treatment investigational new drug application (IND).[62] This program, along with other FDA policies, allows the autonomy mandated by RTT while also mitigating the risks and liability associated with allowing unregulated access to experimental drugs.[63] The FDA receives over one thousand requests for drug access under its expanded access program every year and grants access to approximately 99% of these requests.[64] Furthermore, the median processing time for non-emergency requests is approximately four days and the median processing time for emergency requests is less than a day. Clearly, the FDA's Compassionate Use program did not pose a barrier to accessing investigational drugs.[65] Since the FDA already had similar programs in place, RTT can be rendered effectively useless. Furthermore, it can be described as destructive to individual health and safety due to its unregulated nature. Congress should not have passed an act that cuts out oversight from a federal agency that was ensuring the safety and efficacy of unproven drugs. For these reasons, United States Congress should not utilise their decision-making power on this topic and should not have passed RTT.

[62] 'Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers Guidance for Industry', *Questions and Answers*, 2016, 25.
[63] *Ibid.*
[64] Jonathan P. Jarow et al., 'Overview of FDA's Expanded Access Program for Investigational Drugs', *Therapeutic Innovation & Regulatory Science* 51, no. 2 (1 March 2017): 177–79, https://doi.org/10.1177/2168479017694850.
[65] *Ibid.*

IV. The Food and Drug Administration

The FDA protects public health by ensuring the safety and efficacy of drugs, which is why the FDA should be the entity with most power to determine whether a terminal individual should be granted early access to an unproved treatment.[66] Although letting the FDA serve as the primary decision-making entity in cases of Compassionate Use of unproven drugs may lead to potential wrongful deaths like in the case of Abigail Burroughs, it maintains a high standard of safety and appropriate regulations. The requirement for FDA approval to use experimental and unproven drugs is important for maintaining certain ethical standards, for promoting health equity, and for ensuring 'checks and balances' are in place to limit the power of pharmaceutical companies and physicians.

RTT passed by Congress makes it especially difficult for the FDA to serve its purpose in ensuring the safety and efficacy of drugs. The FDA has two equally important areas of safety assurance: premarket review and post market monitoring. Under RTT, the FDA is left out of the loop, and in extreme cases could be cut out of late-stage clinical trial processes entirely. This is especially dangerous when paired with potential conflicts of interest or unethical behaviour on the part of the drug manufacturer and the researchers involved in the development of a new therapy. The FDA has existing programs and procedures in place to help terminal patients safely access experimental drugs, which is why they should be the primary decision-making entity in determining which terminal patients can access non-FDA approved drugs. As long as the FDA continues to support programs such as the three-part allowance program for investigational drugs established in 2009 and the Compassionate Use policies, they should have the power to allow or restrict access to experimental drugs. This allows terminally-ill patients to try potentially life-

[66] 'What We Do', FDA (FDA, 11 March 2018), https://www.fda.gov/about-fda/what-we-do.

saving drugs in a safe manner and under appropriate oversight while still honouring patient autonomy.

The Right to Try Act relies on the bold assumption that physicians and pharmaceutical companies will always act in the best interest of patients and will not engage in unethical behaviour in the absence of government oversight. Furthermore, while the ultra-conservative billionaire Koch brothers who influence US politics,[67] former Vice President of the United States Michael Pence, and the conservative Goldwater Institute all insist that RTT works to promote patients' rights and autonomy, the truth of RTT is much less noble.[68] RTT is a policy created to deregulate drug access and has the potential to dismantle the system that ensures patient safety and public health.[69] The Goldwater Institute seeks to advance a conservative agenda to remove federal oversight on most matters pertaining to individual autonomy. However, a concern with that agenda is the failure to acknowledge and preserve a high standard of ethics and safety within the medical establishment. The FDA must monitor physician and pharmaceutical companies to ensure they abide by certain ethical standards, to prevent the potential for bias or discrimination, and to oversee the way financial inequities affect health access. In 1964, the Helsinki Declaration established a set of guidelines for ethical behaviour regarding the use of experimental drugs.[70] In a somewhat joint effort, the Helsinki Declaration and the World Medical Association created standards in response to the inhumane treatment of individuals in the name of science during the Nazi reign in Germany. Some of the protections outlined in this Declaration are the necessity for

[67] Alexander Hertel-Fernandez, Caroline Tervo, and Theda Skocpol, 'How the Koch Brothers Built the Most Powerful Rightwing Group You've Never Heard Of', *The Guardian*, 26 September 2018, sec. US news, https://www.theguardian.com/us-news/2018/sep/26/koch-brothers-americans-for-prosperity-rightwing-political-group.
[68] Michael Hiltzik, 'Right-to-Try Laws Are Hazardous to Your Health--and Now They're Backed by the Koch Brothers', Los Angeles Times, 22 January 2018, https://www.latimes.com/business/hiltzik/la-fi-hiltzik-right-to-try-20180122-story.html.
[69] Michael D. Becker, 'I'm the Ideal Person to Support Right to Try. But It's a Disaster in the Making', *STAT* (blog), 1 February 2018, https://www.statnews.com/2018/02/01/right-to-try-cancer-fda/.
[70] 'AMA Code of Medical Ethics' Opinions on Clinical Research', *AMA Journal of Ethics* 17, no. 12 (1 December 2015): 1136–41, https://doi.org/10.1001/journalofethics.2015.17.12.coet1-1512.

informed consent, recognition of individuals unable to give informed consent for themselves, benevolent intent, and respect for individuals.[71] Although the cases examined in this paper are not nearly as extreme as the human rights violations in Nazi Germany, it is still important to analyse how the current law in the United States may create the potential for deviation from these ethical standards.

I. Physician and Pharmaceutical Company Morality

First, RTT neglects to consider that physicians and drug manufacturers—who are now essentially left with total decision-making capacity—may face conflicts of interest with the patients they treat.[72] Oftentimes, physicians have a stake in whether new drugs are approved and thus may have ulterior or subconscious motives when it comes to recommending an experimental drug to their patient.[73] Sometimes, clinical research and treatment of patients overlap, which may lead to obvious conflicts of interest.[74] This is especially plausible in highly specialised fields of medical research where there are few individuals who understand the latest research. Furthermore, since many physicians have their own medical theories that may contradict or support new research, doctors may not be objective in their decision to recommend experimental drug use.[75] Although the FDA has its own downfalls, it strives for the type of objectivity that cannot be attained by an individual or group of physicians.

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[71] 'WMA - The World Medical Association-WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects', accessed 1 December 2021, https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.
[72] Brandon Brown, Cameron Ortiz, and Karine Dubé, 'Assessment of the Right-to-Try Law: The Pros and the Cons | Journal of Nuclear Medicine', October 2018, https://jnm.snmjournals.org/content/59/10/1492.
[73] Larry D. Scott, 'Conflicts of Interest in Clinical Practice and Research', *The American Journal of Gastroenterology* 103, no. 5 (May 2008): 1075–78, https://doi.org/10.1111/j.1572-0241.2008.01843.x.
[74] Carl Elliott, 'Relationships between Physicians and Pharma', *Neurology: Clinical Practice* 4, no. 2 (April 2014): 164–67, https://doi.org/10.1212/CPJ.0000000000000012.
[75] David J. Casarett, 'When Doctors Disagree', *AMA Journal of Ethics* 8, no. 9 (1 September 2006): 571–76, https://doi.org/10.1001/virtualmentor.2006.8.9.ccas3-0609.

Bribery and other forms of corrupt financial incentives constitute another major ethical concern regarding physician and drug company morality. This is unethical because it challenges the integrity of practicing medicine. Although bribery and most financial incentivising are technically illegal, there are several feasible loopholes to this policy. In the past, pharmaceutical companies have given money and other benefits to physicians in exchange for the promotion of their drugs. ProPublica analysis shows that "more than 2,500 physicians have received at least half a million dollars apiece from drugmakers and medical device companies in the past five years alone". [76] This is a clear example of why the FDA needs to monitor physician and pharmaceutical behaviour, especially as it relates to experimental drug access.[77] On a similar note, patients can directly incentivise drug manufacturers to grant them access to coveted drugs. A very recent example of this is the distribution of COVID-19 vaccines produced by Pfizer and Moderna drug manufacturers in the United States. The US government made COVID-19 vaccines produced by Pfizer, Moderna, and Johnson & Johnson available free-of-charge to all individuals in the US. Although the COVID-19 vaccine was initially restricted to frontline medical workers and individuals with severe medical conditions, numerous wealthy, non-qualifying individuals tried to 'purchase' the vaccine before they could justifiably access it.[78] The failure to prevent financial incentives from influencing patients' access to medication further requires the need for the FDA to act as an overarching regulator in these matter.[79] The lack of

[76] Charles Ornstein, Tracy Weber, Ryann Grochowski Jones, 'We Found Over 700 Doctors Who Were Paid More Than a Million Dollars by Drug and Medical Device Companies', ProPublica, accessed 7 December 2021, https://www.propublica.org/article/we-found-over-700-doctors-who-were-paid-more-than-a-million-dollars-by-drug-and-medical-device-companies?token=U6YPJH2o8tEdYqJTDehddU4i3TwLH1Jb.
[77] *Ibid.*
[78] Matt Donnelly, 'Hollywood Elite in COVID-19 Vaccine Scramble: "It's the Hunger Games Out There"', *Variety* (blog), 25 January 2021, https://variety.com/2021/film/news/covid-vaccine-hollywood-skipping-line-1234891647/.
[79] Olivia Goldhill and Nicholas St. Fleur, 'How the Rich and Privileged Can Skip the Line for Covid-19 Vaccines - STAT', accessed 1 December 2021, https://www.statnews.com/2020/12/03/how-rich-and-privileged-can-skip-the-line-for-covid19-vaccines/.

FDA oversight creates a greater schism between who can and cannot access healthcare, but also opens the floodgate to several cases of unethical practice.

Without government regulation, there is too much room for uncouth and immoral behaviour from patients, physicians, and drug manufacturers. When there are no structured checks or balances in place to limit any individual party from having too much decision-making power there is potential for corruption. For this reason, RTT should be re-evaluated taking into consideration the necessity for government regulation to ensure ethical behaviour on the part of physicians and drug manufacturers. Since conflicts of interest are possible and certain parties may benefit from financial incentives, the role of the government or another overarching entity is necessary in mitigating the risk of unethical activity.

II. Comparing Patients, Bias, and Discrimination

A vital variable to consider is that permission to access unproven and non-FDA approved drugs is granted on a case-by-case basis, which yields room for discrimination, prejudice, or bias in individual patient decisions.[80]Although the FDA is not guilt-free when it comes to preventing discrimination, the FDA has thorough processes in place to ameliorate discrimination. There is no guarantee that hospitals or private physicians will have policies as thorough and well-researched as those of the FDA to prevent discrimination. In order to determine whether a specific patient should be granted early access to a specific non-FDA approved drug, certain structured guidelines should be implemented to ensure both safety and fairness. Furthermore, government oversight is important to protect patients from risk exposure based on racial discrimination. As previously explained in this paper, RTT allocates more decision-making

[80] Mary May, 'Racism and Exploitation in Phase I Clinical Trials', *Science in the News* (blog), 24 October 2020, https://sitn.hms.harvard.edu/flash/2020/racism-and-exploitation-in-phase-i-clinical-trials/.

power to the hands of physicians and drug manufacturers instead of the FDA. A serious ethical concern that rises from this act is that physicians and drug manufacturers may be able to bypass some of the FDA's safety and efficacy regulations for drug trials. This not only puts patients at risk, but also makes data collection especially difficult because it is unclear whether the FDA can mandate recording this data. This may hinder the progress of drug trials and FDA approval processes. The consequences and solutions for this issue will be outlined in the Policy Analysis and Recommendations sections of this thesis.

An important question to consider is: can marginalised patients truly provide informed consent if the existing medical system was built against them? The medical establishment has a long history of racism and other forms of discrimination that result in current fallacious beliefs, including the belief that pain tolerance thresholds are partial to race[81] or that women overdramatise their suffering. The medical establishment today continues to discriminate against and dismiss the health concerns of minority individuals, especially when it is linked to cancer and other chronic illnesses.[82] Furthermore, a recent study explains:

> "in the USA, members of minority racial and ethnic groups suffer disproportionately from cancer. This is well documented for many affected communities, including Black Americans, who experience higher cancer mortality rates than those of the white population. For colorectal, prostate, and female breast cancer in particular, both incidence and mortality are higher for Black people. Black patients also have lower participation in clinical trials, even when these are testing treatments for cancer types that are highly prevalent in their population. As a result, they are denied access to potentially life-extending therapies, and clinical findings become skewed toward a non-representative, white majority."[83]

[81] Janice A. Sabin, 'How We Fail Black Patients in Pain', AAMC, accessed 5 May 2021, https://www.aamc.org/news-insights/how-we-fail-black-patients-pain.
[82] Bryn Nelson, 'How Structural Racism Can Kill Cancer Patients', *Cancer Cytopathology* 128, no. 2 (2020): 83–84, https://doi.org/10.1002/cncy.22247.
[83] 'Speaking up against Inequity and Racism', *Nature Cancer* 1, no. 6 (June 2020): 563–64, https://doi.org/10.1038/s43018-020-0091-x.

Due to the inherent prejudices built into the medical establishment, it is even more important for standardized government regulations to limit the risk of discrimination. Allowing individual physicians to work directly with drug manufacturers blocks out the government entirely. In a worst-case scenario, this may undo years of activism and work towards health equity because potentially-biased physicians and drug manufacturers have complete discretion to decide which terminally-ill patients to treat and how to treat them.

In order for patients to give informed consent to accept the use of investigational and unproven treatments, they must first have a baseline understanding of the benefits, consequences, and risks of the drugs they are trying.[84] Physicians have an obligation to provide patients with access to educational resources including updated research about the experimental drugs they're considering because patients cannot always be expected to advocate for themselves.[85] When the burden of research is placed on patients, it creates inherent discrimination based on socioeconomic background because less educated patients are unable to access the same level of research and information as higher educated patients are.[86] There are several controversies associated with under-researched drugs and informed consent. First, it is important to consider is that individual doctors may have biased opinions of individual patients—including gender-based, racial, cultural, socioeconomic, linguistic, and other similar biases—which could therefore result in them wrongfully attaining an unproven drug or could restrict patients from accessing non-FDA approved but potentially life-saving treatments. Patients with the financial means to afford drugs that insurance companies likely will not cover may have an easier time accessing these

[84] Parth Shah et al., 'Informed Consent', in *StatPearls* (Treasure Island (FL): StatPearls Publishing, 2021), http://www.ncbi.nlm.nih.gov/books/NBK430827/.
[85] David Epstein, 'An Epidemic of Unnecessary Treatment', The Atlantic, 22 February 2017, https://www.theatlantic.com/health/archive/2017/02/when-evidence-says-no-but-doctors-say-yes/517368/.
[86] Marion Kalabuanga et al., 'The Challenges of Research Informed Consent in Socio-Economically Vulnerable Populations: A Viewpoint From the Democratic Republic of Congo', *Developing World Bioethics* 16, no. 2 (August 2016): 64–69, https://doi.org/10.1111/dewb.12090.

treatments than patients on government-sponsored healthcare plans or those without coverage entirely. An additional risk factor to consider is that government officials, pharmaceutical company representatives, and physicians may work together to promote the prescription and sale of certain drugs. Without the FDA's restrictions and regulations, it becomes increasingly difficult to identify when drug companies are creating financial or other incentives for physicians to prescribe unproven drugs and non-FDA approved treatments. This issue is of financial incentives and barriers is not entirely resolved by returning the decision-making power to the FDA; however, it is better managed by a consistent overarching system, like the FDA, rather than by individuals who cannot maintain a universal standard of ethics.

III. Financial Inequities and Accessibility

An important consideration when evaluating if a policy is ethical is whether the policy can be applied equitably to everyone affected. As aforementioned, there are several barriers to healthcare in the United States, most of which stem from financial inequities and accessibility based on socioeconomic status. Since health insurance is tied so closely to employment status in the United States, accessing care from physicians or visiting doctors may be an undue burden on several civilians.[87] Certain barriers for individuals seeking healthcare are the cost of monthly premiums on insurance, the cost of co-pays for visits and prescriptions, and even the cost of transportation for people who live in rural parts of the country. Furthermore, insurance companies are not required to cover the purchase of non-FDA approved drugs and often do not pay for or reimburse the cost of off-label drug use. If a policy cannot be applied equitably, it is inherently discriminatory. The inequitable access of healthcare means that policies like RTT are

[87] Robert H. Shmerling, MD, 'Is Our Healthcare System Broken?', Harvard Health, 13 July 2021, https://www.health.harvard.edu/blog/is-our-healthcare-system-broken-202107132542.

less ethical than what is ideal. Since use of these underdeveloped drugs that are oftentimes not available on the market has to a certain extent become legal, there need to be thoroughly outlined guidelines for insurance companies to support terminal patients in paying for their potentially life-saving treatment. However, while RTT establishes permission to access investigational drugs, it does not offer a solution to compensate drug manufacturers for the cost associated with developing the drugs. RTT The research and development costs associated with bringing a new drug to market are extremely high, costing approximately $648.0 million for a single cancer drug.[88] If pharmaceutical companies are required to give investigational drugs to eligible patients under RTT without charging them, it may disincentivise them from providing these drugs to patients. Furthermore, if patients are expected to pay for their drugs themselves, given the extremely high cost of development, it is unlikely that the average American will be able to afford access to investigational drugs without financial support from an insurance company or the government. This raises ethical concerns, because without a clear policy regarding payment and compensation that does not place the burden on patients or manufacturers, RTT cannot be applied to all patients equitably.

Since this thesis argues that the financial burden should not be placed on either the patients seeking drugs or the manufacturers providing drugs, the determination of on whom the financial burden will fall must be addressed. The Policy Analysis and Recommendations section of this thesis works to address how the financial aspect of accessing investigational drugs should be managed.

[88] Vinay Prasad and Sham Mailankody, 'Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval', *JAMA Internal Medicine* 177, no. 11 (1 November 2017): 1569–75, https://doi.org/10.1001/jamainternmed.2017.3601.

IV. Drug Manufacturers and Pharmaceutical Companies

Drug manufacturers and pharmaceutical companies should not be primary decision makers in the determination of whether a terminally-ill patient can access an experimental treatment, even if the drug is potentially lifesaving. In the time of *Abigail Alliance*, drug manufacturers could choose to approve or deny access to an experimental drug after the FDA approves it under the Compassionate Use program. However, under RTT, the FDA can be kept out of the loop and drug manufacturers can work directly with physicians to give terminally-ill patients an experimental drug.[89] If drug manufacturers had greater decision-making power than they already do, the FDA would be excluded from the safety assurance process, which could also open pharmaceutical companies to greater risk of lawsuits and tort liability. Patients and physicians together should discuss the benefits and consequences of experimental drug use and seek approval from the FDA to access non-FDA approved drugs. There are several ethical evaluations that must be made with regards to the role of drug manufacturers and pharmaceutical companies in access to non-FDA approved drugs for terminally-ill cancer patients. First, there is the matter of incentives—financial or otherwise—for drug manufacturers, especially if there are ongoing clinical trials for the drug in question. Since drug manufacturers have an obvious stake in their product, the conflict of interest and potential for bias is too high to give them decision-making power without additional government oversight. Second, there is the potential for a lack of record-keeping and accountability of experimental drug use under RTT. Furthermore, in relation to the above ethical concerns, there is a lack of protection for patients since drug manufacturers may be able to avoid liability for adverse effects of the experimental drugs.

[89] Right to Try Act 2017.

A great potential for abuse of power lies in the fact that drugs eligible under RTT only need to have passed Phase I of a clinical trial and cannot have been discontinued by the manufacturer.[90] Phase I of a clinical trial generally focuses on small sample populations and may not even have been tested on human beings.[91] This low standard for drug eligibility under RTT means that Phase II clinical trials overseen by the FDA may not have begun. In a grossly immoral hypothetical situation, manufacturers could—with physician aid—distribute drugs to eligible patients under RTT without regulation or FDA oversight prior to the appropriate Phase II clinical trials. Pharmaceutical companies may be able to get clinical value out of offering their under-researched drugs to terminally-ill cancer patients. In an extreme scenario, the dispersion of drugs pending Phase II clinical trials to eligible patients under RTT could technically reduce the need for formal Phase II clinical trials. While off-the-record use of drugs under RTT is not a substitution for Phase II clinical trials, it may permit pharmaceutical companies to use RTT eligible patients as a stepping stone between Phase I and Phase II experiments without Internal Review Board (IRB) or FDA approval. This possibility is not only objectively unethical, but it also puts patients in situations in which they are receiving therapeutics outside of rigorous safety and oversight protocols, thereby creating a regulatory lapse. Although it is unlikely for such grave malpractice to occur, RTT does not protect patients from these potential scenarios.

Drug companies offering unproven treatments to terminally-ill patients have much to gain from letting people try their products 'off-record'. In an extreme situation, if the patient dies—they were destined to die anyway, so the drug company may be able to avoid liability for wrongful death; and if their life expectancy is significantly improved—drug companies can

[90] *Ibid.*
[91] 'Types and Phases of Clinical Trials | What Are Clinical Trial Phases?', accessed 9 December 2021, https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/phases-of-clinical-trials.html.

profit off the new drug they unethically tested on dying patients. Despite the high potential for liability when administering unproven drugs 'off-record' to terminal patients, the drug companies' potential to gain is high enough to illicit ethical deviance. As such, it is necessary that pharmaceutical companies are regulated by a government agency such as the FDA.

Allowing physicians and drug companies to determine whether a patient can access a non-FDA approved drug not only poses greater risks to patients, but also increases liability for physicians and pharmaceutical companies. Since the FDA no longer needs to evaluate requests for "Compassionate Use" or other similar cases, liability falls on individual prescribers and drug companies. This shift in liability results in not only in looser restrictions to accessing non-approved drugs, but also greater risk for the individual medical providers who do choose to grant their patients access to these drugs. Physician discretion and judgement in the absence of oversight, the use of waivers that absolve patients from the right to sue, and how the new decision-makers under RTT can protect themselves from liability must be considered when evaluating how the RTT, in tangent with the *Abigail Alliance* case, shapes the way terminally-ill patients may access unproven but potentially life-saving treatments.

In terms of liability mitigation, liability waivers or other similar contractual agreements are essential for physicians and drug manufacturers who administer unproven drugs or non-FDA approved treatments to their patients. With so little research done on so many novel therapies, there is a cascade of potential unknown adverse side effects that patients may harm patients. This is dangerous from an innovation standpoint as well as a policy standpoint, because harm to patients could halt research on promising drugs undergoing clinical trials or still in research phases, or even interfere with FDA approval in the future. However, when the risk of liability is placed on patients—most of whom do not have enough medical or scientific background to truly

know if the drug is safe to use—the system places heavy burdens on already-sick individuals without offering them protections or compensation for their role in scientific advancement. If pharmaceutical companies were to act as a primary decision-maker, it would reduce protections of patients.

When dealing with under-researched pharmaceutical drugs the potential for unknown negative effects on the patients raises questions regarding tort liability. The recent development of COVID-19 vaccinations demonstrates some of the liability-related implications of under-researched drug. Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Immunity from Liability, individuals who received COVID-19 vaccinations in the United States may not sue the drug developer regardless of the side effects they experience as a result of the drug.[92] Although cancer is a very different disease than COVID-19, policies to allow access to under-researched drugs for both diseases are not that different. As more information and research has become available about the Moderna and Pfizer vaccines, studies suggest that the long-term side effects of the Moderna vaccine are more extreme than the Pfizer vaccine, even though the immunity against COVID-19 is comparable between the two.[93] Moderna vaccine recipients who have experienced debilitating long-lasting side effects are ineligible for any form of compensation including financial support to pay for the additional healthcare they need to manage symptoms.[94] Similarly, when it comes to investigational cancer therapies, the first version of the drug made available to the public through clinical trials or compassionate-use

[92] MacKenzie Sigalos, 'You Can't Sue Pfizer or Moderna If You Have Severe Covid Vaccine Side Effects. The Government Likely Won't Compensate You for Damages Either', CNBC, 17 December 2020, https://www.cnbc.com/2020/12/16/covid-vaccine-side-effects-compensation-lawsuit.html.
[93] Alexandra Kelley, 'New Study Says Moderna Vaccine Leads to More Side Effects than Pfizer Vaccine', Text, The Hill, 9 April 2021, https://thehill.com/changing-america/well-being/prevention-cures/547305-new-study-says-moderna-vaccine-leads-to-more.
[94] Sigalos, 'You Can't Sue Pfizer or Moderna If You Have Severe Covid Vaccine Side Effects. The Government Likely Won't Compensate You for Damages Either'.

programs are not always the correct dose, like during the 1980s HIV/AIDS crisis, or correct composition of ingredients. When under-researched drugs are made accessible to the public, especially those with pre-existing conditions, it also forces patients to incur risks that they cannot fully comprehend. Patients should not bear the entire liability of their medical decisions due to medical illiteracy issues. According to Dr. David Gorski, "right-to-try laws limit what patients can do in the event of malpractice negligence".[95] The Policy Analysis and Recommendations section of this thesis works to address structures that could be implemented to provide eligible patients with better protections.

Although RTT limits the option for patients to hold drug companies liable, there are circumstances under which international and domestic pharmaceutical companies can be made responsible for misconduct and improper promotion of non-FDA approved drugs. During the 1980s HIV/AIDS crisis, the disease as well as the drugs to treat it were severely under-researched. To evade the need for FDA approval and to address the urgent need for treatment, individual citizens like Ron Woodroof obtained drugs overseas and brought them back to the United States. This brings up the topic of liability for the use of non-FDA approved drugs provided by pharmaceutical companies in the United States or overseas. International and domestic manufacturers can be held accountable for selling unapproved or mislabelled drugs within the United States. In 2019, the FDA sent a warning notice to several domestic and international drug manufacturers regarding their sale and advertisement of dietary supplements and other unapproved drugs for the treatment of Alzheimer's disease.[96] The FDA stated that

[95] David Gorski, 'The Koch Brothers and Vice President Mike Pence Back a Final Push to Pass the Cruel Sham Known as "Right-to-Try"', *RESPECTFUL INSOLENCE* (blog), 22 January 2018, https://respectfulinsolence.com/2018/01/22/the-koch-brothers-and-vice-president-mike-pence-back-a-final-push-to-pass-the-cruel-sham-known-as-right-to-try/.

[96] 'FDA Takes Action against 17 Companies for Illegally Selling Products Claiming to Treat Alzheimer's Disease', FDA (FDA, 24 March 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-action-against-17-companies-illegally-selling-products-claiming-treat-alzheimers-disease.

"science and evidence are the cornerstone of the FDA's review process and are imperative to demonstrating medical benefit, especially when a product is marketed to treat serious and complex diseases".[97] Although the issue of manufacturers misbranding dietary supplements as treatments for Alzheimer's disease is quite different from the processes of drug access under RTT, this example demonstrates how manufacturers may behave unethically and can be held accountable for their actions. Even if a drug is permitted for use under RTT, there are some cases in which patients retain the right to hold manufacturers responsible. Unlike the COVID-19 example where manufacturers were protected by the PREP Act, for non-emergent drug use the drug manufacturers may still be held liable for unforeseen side effects of the drugs. Although patients might be allowed to request access to these drugs under RTT, they would still be able to hold manufacturers liable if it were uncovered that the drugs either do not work or were inappropriately advertised. Finally, citizens of the United States are able to sue overseas drug companies even if they decide to act against medical advice and seek non-FDA approved remedies for their illness. For example, in the case of Ron Woodroof's buyers' clubs, either Woodroof or any of the people to whom he sold his drugs may have been able to sue an international drug manufacturer for supplying them with toxic substances under the pretence that it would treat HIV/AIDS. RTT allows—and arguably encourages—individuals to resort to extreme measures without considering the ways different entities could be held liable. The risk of liability and fear of lawsuit may be a deterrent for drug manufacturers. If manufacturers are concerned about lawsuits, it becomes less likely that they will release doses of investigational drugs to patients. RTT aimed to expand access to investigational drugs, but by removing FDA oversight and leaving physicians and manufactures open to liability, it created a new issue

[97] *Ibid.*

regarding access. To reduce the liability risk for physicians, hospitals, and pharmaceutical manufacturers, oversight and decision-making capacity about investigational drug access should be held by the FDA.

There is already a relatively high liability risk associated with giving access to a severely under-researched drug in non-emergency situations, but RTT creates an even greater liability risk because the investigational drugs might become accessible earlier in their approval process when there is less information available. On the contrary, this lack of information makes it difficult to regulate the substance and difficult to hold parties such as drug manufacturers accountable. When drug manufacturers know that they face low risk of liability, there is greater room for misconduct. Without the FDA or other federal entity providing protections for patients, the entire medical establishment is at risk of becoming more corrupt and terminal patients who have exhausted all approved drugs have further limitations on their alternatives. If the federal government is creating a policy that puts people at risk of harm—like RTT—they should also provide certain protections for the public without opening well-meaning physicians, hospitals, and drug manufacturers to liability. The Policy Analysis and Recommendations section of this thesis will further explore solutions to the liability related issues associated with RTT.

V. Physicians and Hospital Administrations

Physicians, hospitals, and similar medical establishments should not be able to create their own policies regarding early access to experimental drugs for terminal patients without government oversight because it poses too great a threat to medical ethics. However, under the current federal and state guidelines, most major hospitals do have their own policies in place. Physicians have their patients' best interest in mind and give medical advice based on concrete

scientific research. When experimental and investigational drugs come into question, it becomes difficult to advise patients based on scientific knowledge since so much is unknown. This creates a problem within the medical community and increases the level of tort liability to which a physician or hospital may be held. Furthermore, since the use of non-FDA approved or investigational drugs in itself can be controversial, it is important to evaluate the role of the physician in determining the conditions under which unproven treatments should be recommended to terminally-ill cancer patients. With regards to ethics, one must also investigate the potential for uncouth practices. Although uncommon, in some cases physicians and hospitals may be motivated by financial incentives instead of the interests of their patients. In order to protect patient rights and promote patient autonomy, regulation over early access to experimental drugs should be maintained by the FDA.

The role of the physician in helping their terminally-ill patients gain early access to experimental drugs should be that of a recommender and not a decision maker. Under RTT, physicians can work directly with drug manufacturers to access experimental drugs for their patients, which gives individual physicians a great deal of power.[98] A significant risk of this allocation of power is that it creates room for unmonitored biases discrimination against patients. This risk would be mitigated if there were universal guidelines that determine which patients can access experimental drugs instead of leaving that decision-making power to individual physicians, each of whom have their own preconceived notions and perceptions.

An example of this is with regards to the off-label use of ivermectin to prevent or treat COVID-19.[99] Ivermectin is a drug commonly used in developing countries to treat intestinal

[98] *Ibid.*
[99] Andrew Bryant et al., 'Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-Analysis, and Trial Sequential Analysis to Inform Clinical Guidelines', *American Journal of Therapeutics* 28, no. 4 (August 2021): e434, https://doi.org/10.1097/MJT.0000000000001402.

strongyloidiasis and onchocerciasis or other gastrointestinal parasitic infections and has not been approved by the FDA or other similar entity for the treatment of COVID-19. International research suggested that toxic effects of ivermectin may be associated with the prevention and treatment of COVID-19, so some doctors in the United States chose to prescribe ivermectin to their COVID-19 patients for off-label use. This practice is controversial and is also entirely dependent on what each patient's individual physician believes in.[100] When physician discretion is the primary determinant of whether a patient can access experimental drugs it is difficult for all patients to be treated equitably.

One component to evaluate is how physician discretion and judgment—without any guidance or governance from the FDA—impacts the quality of patient care. Theoretically, there could always be a physician who will agree to a controversial treatment for their terminal patient. And, physicians may have differing opinions of the efficacy of a drug. For example, whether this stems from genuine medical findings or from a sizeable direct deposit, convincing a physician to give permission or write a prescription for unproven drugs may not be a barrier for all patients. This creates room for systemic discrimination based on wealth and has the potential to make investigational drug access less attainable for lower-income individuals. The lack of a structured, overarching governance that allows the whims of physician discretion to determine access to or denial of unproven and non-FDA approved drugs results in the potential for numerous ethical catastrophes.

Allowing physicians such a high level of freedom to prescribe also puts physicians and hospitals at higher risk of liability if the drug proves to be more harmful than beneficial. Furthermore, without structured 'best practices' set by an overarching entity like the federal

[100] James Heathers, 'The Real Scandal About Ivermectin', The Atlantic, 23 October 2021, https://www.theatlantic.com/science/archive/2021/10/ivermectin-research-problems/620473/.

government or FDA, it becomes difficult to make sure that all patients are treated with equal priority and given equal opportunity for survival. For these reasons, physicians' and hospitals' power should be limited to medical advice and recommendations instead of decision-making omnipotence.

VI. Patients and Proxies

When evaluating the extent to which each relevant party should be allowed to exercise decision-making power, an important yet controversial group is the patient themselves. Patients or their proxies should not have sole or primary decision-making power regarding the terminally-ill patient's access to experimental drugs without righteous and unbribed support from medical professionals. Although patient autonomy is vitally important and patients should have the right to choose what path they pursue, physicians with approval from the FDA should reserve the right to regulate and deny access to certain drugs based on their safety and efficacy standards. The primary reason for FDA oversight is to prevent patients from incentivising physicians to support their medical treatment when the physician in question may not wholly agree. While individuals in the United States do reserve the right to make their own medical decisions, systems and procedures need to exist in order to promote public health and individual life. It is legal for patients to refuse medical treatment including life-saving treatment. However, the 'status quo' remains for physicians to administer every medical avenue of treatment especially in life-saving circumstances. This is especially pertinent in cases where patients may have low medical literacy which oftentimes results in harmful medical consequences. As medical information becomes increasingly available to the general public with widespread internet access and drug advertisements, patients and their families may choose to research investigational drugs

themselves without fully understanding the pharmacological and medicinal implications of using that drug.[101,102] The accessible information and misinformation challenges medical safety standards because patients may begin consulting unreliable sources instead of their trained medical physicians. An example of this is in the case of COVID-19 anti-vaxxers who exercise their right to not receive the COVID-19 vaccine but consequently experience more severe cases of an extremely potent virus. Had many of these individuals trusted guidelines recommended by the Centres for Disease Control (CDC), they may not have suffered the same adverse consequences of contracting the COVID-19 virus.[103] In the world of social media and omnipresent internet access in the US, patients today are able to access medical information more easily than they could in the era of *Abigail Alliance* or the 1980s HIV/AIDS crisis. This makes it significantly easier for patients to find information that suggests certain unproven or off-label treatments could improve their condition. However, patients themselves cannot always understand the unintended negative consequences of using certain investigational drugs.[104] Furthermore, through social media connections patients may provide feedback or share their experiences with certain investigational drugs that could influence other patients. While this is not necessary a bad thing, there are situations in which media influence for use of investigational drugs may have unintended harmful ramifications. Although RTT is not the same as off-label use of a drug, when it comes to media influence and patients requesting experimental drugs, these two conditions can be quite similar. It is important for patients to thoroughly understand

[101] Julia Belluz, 'The Truth about WebMD, a Hypochondriac's Nightmare and Big Pharma's Dream - Vox', 5 April 2016, https://www.vox.com/2016/4/5/11358268/webmd-accuracy-trustworthy.
[102] Alex Guarino, 'Study Finds 89% of US Citizens Turn to Google before Their Doctor', https://www.wect.com, accessed 5 December 2021, https://www.wect.com/2019/06/24/study-finds-us-citizens-turn-google-before-their-doctor/.
[103] CDC, 'Benefits of Getting a COVID-19 Vaccine', Centers for Disease Control and Prevention, 29 November 2021, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html.
[104] Carissa Stephens, R.N., CCRN, CPN, 'Anonymous Nurse: Stop Using Dr. Google to Diagnose Symptoms', Healthline, 21 March 2019, https://www.healthline.com/health/please-stop-using-doctor-google-dangerous.

their medical decisions with guidance from their physician instead of relying on influence from individuals who may not have formal medical training.

The patient's choice to pursue options against medical advice was clearly demonstrated when Ron Woodroof sought his own treatment for HIV/AIDS. Throughout Woodroof's journey with various non-FDA approved drugs, government agencies were often in disagreement with Woodroof's practices because he—an electrician, not a physician—was distributing highly toxic and unproven medication to people who did not have physician recommendations. Woodroof was fortunate in his endeavours because he lived significantly longer than the physician estimated life expectancy, but not all terminal patients seeking experimental drugs are as lucky.[105] In the 1980s, in a similar timeframe as Woodroof's HIV diagnosis, an 8-year-old girl named Sheri Beck was undergoing cancer treatment.[106] Sheri was treated with an experimental drug called Mitoxantrone derived from a dye used in ballpoint pen ink and died as a direct result of this treatment.[107] As demonstrated in the tragic example of Sheri Beck, the use of highly toxic drugs is controversial and needs to be closely monitored by physicians and the FDA. The FDA's website clearly states that "under the FD&C Act, the interstate shipment of any prescription drug that lacks required FDA approval is illegal. Interstate shipment includes importation—bringing drugs from a foreign country into the United States" excluding drugs prescribed and intended for personal use.[108] Today, the both the sale and the distribution of unapproved substances or pharmaceutical drugs without prescriptions is illegal for public safety related reasons.[109] When

[105] Jean-Marc Vallée, *Dallas Buyers Club*, Drama/History, 2013.
[106] Ted Gup and Jonathan Neumann, 'Experimental Drugs: Death in the Search for Cures', *Washington Post*, 18 October 1981, https://www.washingtonpost.com/archive/1981/10/18/experimental-drugs-death-in-the-search-for-cures/c85ad468-c91e-4cbc-b02b-6743f00bbbd0/.
[107] *Ibid.*
[108] Center for Drug Evaluation and Research, 'Imported Drugs Raise Safety Concerns', *FDA*, 11 March 2018, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/imported-drugs-raise-safety-concerns.
[109] *Ibid.*

patient autonomy goes too far—like in Woodroof's case—it can put public health at risk and therefore needs to be restricted by the federal government.

A very recent example of how patients may be influenced by the media or misinformation available on the internet is in the case of ivermectin as a preventative measure against COVID-19.[110] Articles published on various websites suggested that ivermectin could mitigate the symptoms of COVID-19, leading patients in the United States to request ivermectin prescriptions from their physicians. In most cases, these patients did not have formal medical education, nor the level of scientific competency required to thoroughly understand the mechanisms of ivermectin and how it may be dangerous, toxic, or ineffective. In the heat of the pandemic when patients were desperate for options, physicians feared facing lawsuits for refusal to prescribe a drug even if they did not believe it to be the best medical decision for their patient. Patients with the means and resources may be able to find a physician who agrees with their medical pursuit without concern of the FDA vetoing their opinion. This is a clear example of how politics interferes with science and medicine. Similar to COVID-19 patients, when cancer patients are able to request access to investigational treatments from their physicians based on their own internet research, it challenges how medicine is practiced in potentially dangerous ways.

In the case of proxy consent and influence from family members, a patient's loved ones often opt for extraordinary measures to be taken to extend their terminally-ill loved one's life. In Abigail Burroughs's case, being a teenager when she was diagnosed meant her parents likely dictated or influenced her healthcare decisions. When patients themselves are unable to express their end-of-life care preferences themselves—either verbally or through advanced directives—it

[110] Joel M. Topf and Paul N. Williams, 'COVID-19, Social Media, and the Role of the Public Physician', *Blood Purification* 50, no. 4–5 (2021): 595–601, https://doi.org/10.1159/000512707.

may add unique stress to their proxies.[111] This requires close communication between patients or proxies and physicians to determine the best next steps that should be taken with regards to their end-of-life care. Patients and their family members alone generally do not have the medical or scientific expertise to determine what experimental drugs are appropriate for their use. Furthermore, the courts have determined that early access to potentially life-saving drugs is not a right protected under the constitution, even for terminally-ill patients. Patients are able to, and should continue to be able to, exercise their autonomy by refusing certain medical treatments. However, as established in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach* 495 F.3d 695 (D.C. Cir. 2007),[112] patients cannot, and should not be able to, demand access to any drug of their choosing due to the safety concerns associated with several drugs.

To preserve patient autonomy while also taking systemic constructs into consideration, it is important to have a dynamic policy that clearly outlines the role of all parties involved. For this reason, physicians and pharmaceutical companies, under the close supervision of the FDA, should aid patients in determining whether that terminally-ill patient should request Compassionate Use of an unproven therapy.

[111] 'Advance Care Planning: Health Care Directives'. n.d. National Institute on Aging. Accessed 5 May 2021. http://www.nia.nih.gov/health/advance-care-planning-health-care-directives.
[112] 'Abigail Alliance v. Eschenbach, 495 F.3d 695 | Casetext Search + Citator'.

IMPLICATIONS of COURT RULINGS and THE RIGHT TO TRY ACT

Some of the landmark cases that resulted in RTT are *Abigail Alliance* and the 1980s AIDS crisis or subsequent formation of various buyers' clubs. However, these two cases are outliers from the typical experience of a terminally-ill cancer patient. The research and medical knowledge established currently is far more advanced than the information available during the 1980s AIDS crisis or in 2001 when Abigail Burroughs died. RTT was a response to anomalies—not typical scenarios—in medical history and is therefore not an essential or effective policy with regards to improving access to investigational treatment. Some implications of this Act are that the growing momentum towards expanded access to experimental drugs may place a heavy burden on drug manufacturers and create added pressure for them to make drugs available to patients.

When examining the implications of RTT, it is important to understand the intent behind passing the Act, the precedence that the Act may set, and the ways in which the Act could be applied to different scenarios. The *Abigail Alliance* case, 1980s HIV/AIDS crisis and Woodroof's buyers' clubs, and RTT are all unique situations that have shaped the current law regarding early access to investigational drugs from terminal patients. A vital consideration to note is that the scientific knowledge about HIV/AIDS and the drugs in development to treat it during the 1980s was extremely limited. Likewise, Erbitux was not researched for head and neck cancer at the time when Abigail Burroughs requested access to it. Today, forty years after the HIV/AIDS crisis and twenty years after the death of Burroughs, research on cancer treatments has made immense progress. Furthermore, knowledge on cancer as a disease is significantly more established today than knowledge about HIV/AIDS was in the 1980s. RTT signed into law in 2018 is based on outdated and irrelevant historical examples. Basing a current law on

somewhat obsolescent information can have negative implications due to the untimely nature of the law.

A key implication of supporting *Abigail Alliance* is that it could serve as precedence for all terminally-ill patients to access non-approved drugs which may have serious consequences and is a grave liability for pharmaceutical companies, physicians, hospitals, and other health care providers. It is true that in the case of Abigail Burroughs, it was later determined that Erbitux can in fact be used to treat head and neck cancer; however, there was always the possibility that Erbitux would *not* be found as an appropriate treatment. In retrospect, it would have been fine to grant Abigail access to Erbitux, but the same conclusion cannot be drawn for all terminally-ill patients or for all experimental treatments. When examining the 1980s HIV/AIDS crisis, several of the investigational drugs and clinical trials during that time have been discontinued due to their lack of effectivity or their extremely harmful side effects. Therefore, it cannot be inferred that every drug in development would benefit the patient. Furthermore, early states of research are fickle, and many clinical or pre-clinical trials fail. If patients are taking these drugs that are later found to be harmful, it not only impacts the patients' health, but also opens drug manufacturers to countless lawsuits. When laws like RTT remove the case-by-case approval process, it creates a greater risk factor for most parties involved; however, in defense of Abigail Burroughs whose life may have been extended with access to Erbitux, the permission to access unproven drugs does need to be explored.

According to the Goldwater Institute, RTT opens a new pathway for terminally-ill patients to access investigational drugs when they do not qualify for any existing clinical trials.[113] The intent of this is rooted in the *Abigail Alliance* case and the Dallas Buyers Club Act

[113] 'The Right To Try', *Goldwater Institute* (blog), accessed 29 November 2021, https://goldwaterinstitute.org/article/right-try/.

or similar acts passed by several states prior to RTT. However, there is little evidence to suggest that RTT was necessary let alone useful due to the FDA's existing Compassionate Use programmes. Although the Court determined that patients have no right "to a potentially toxic drug with no proven benefit", RTT now reverses that ruling.[114] A concern with this statute is that RTT may set precedence for other similar but more extreme policies. Allowing access to eligible investigational drugs "for which a Phase I clinical trial has been completed"[115] could open the floodgate to allow for use of experimental drugs during Phase I clinical trials, or that have been approved for Phase I clinical trials, or even earlier. Completion of Phase I clinical trials or success in entering Phase II of clinical trials are poor indicators of overall drug success, since almost two third of drugs entering Phase III clinical trials fail.[116] This exceptionally low safety standard for experimental drug access is a part of the Goldwater Institute's agenda to remove power from the federal government. Surgical Oncologist Dr. David Gorski wrote blog articles while RTT was going through the policymaking process in 2017 and described it as a "cruel sham", stating that "the real purpose of right-to-try laws is not to help patients, but to neuter the FDA's ability to regulate certain drugs".[117] Furthermore, RTT may instil false hope in patients, which in turn may detract from a patient's desired end-of-life practices.[118] While the intent may have been benevolent, the ramifications of this Act seem to be more harmful than productive according to several medical professionals and policy analysts.

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[114] 'Abigail Alliance v. Eschenbach, 495 F.3d 695 | Casetext Search + Citator'.
[115] Right to Try Act 2017.
[116] Gail A. Van Norman, 'Phase II Trials in Drug Development and Adaptive Trial Design', *JACC: Basic to Translational Science* 4, no. 3 (24 June 2019): 428–37, https://doi.org/10.1016/j.jacbts.2019.02.005.
[117] David Gorski, 'Congress Is Back in Session, and Sneaking the Cruel Sham That Is Right-to-Try in a Must-Pass Bill Is on the Agenda', *RESPECTFUL INSOLENCE* (blog), 24 April 2017, https://respectfulinsolence.com/2017/04/24/congress-is-back-in-session-and-sneaking-the-cruel-sham-that-is-right-to-try-in-a-must-pass-bill-is-on-the-agenda/.
[118] Michael A. Carome, 'Right-to-Try Legislation Offers False Hope and Would Endanger Patients', *STAT* (blog), 16 January 2018, https://www.statnews.com/2018/01/16/right-to-try-legislation-patients/.

An alarming implication of RTT is that there is a sudden regulatory vacuum that also removes several protocols and best practices that used to be in place. Without the FDA overseeing and restricting access to experimental drugs, terminal patients are exposed to countless health risks that could potentially have been mitigated if there was broad government oversight over the non-FDA approved drugs. The implication of RTT is that patients have sole autonomy over their medical decisions, even if it results in their own harm. If individuals without a formal medical education are making critical medical decisions, in a worst-case scenario, it can result in public health catastrophes. The Goldwater Institution and conservative supporters claim that the goal of RTT was to give patients autonomy over their medical decisions and give them the freedom to access life-saving treatment. Further, they claim that RTT was never intended to harm individuals or knowingly put already sick patients further at risk. However, when the opinions of medical professionals are no longer essential and the approval of the FDA—the entity responsible for determining the safety of a drug—is no longer necessary, the true purpose of RTT is no longer being served.

Pharmaceutical companies may be in a predicament as the movement towards broader access to investigational drugs gains further momentum. Drug manufacturers are challenged with balancing the expectation to make investigational drugs accessible to eligible patients while also breaking profit after bearing the high cost of drug development. In Ron Woodroof's battle against HIV/AIDS, he sought non-FDA approved drugs from physicians and manufacturers outside the United States. Had Courts sided with Woodroof and allowed the use and sale of non-FDA approved drugs prescribed by international physicians, it could have changed the way pharmaceutical companies research drugs and the way drugs come to market in the United States. Had Courts favoured Woodroof, it could have potentially set precedence for drugs on

foreign markets to be sold in mass to residents of the United States. The harmful implications of this are that it prioritises individuals who are able to access healthcare or physicians overseas and pay the full cost of drugs without the support of insurance over patients who cannot afford the same opportunity. Furthermore, had Courts legalized the use and sale of non-FDA approved drugs obtained overseas, pharmaceutical companies within the United States may have been incentivised to create new programs to bypass the need for FDA approval. RTT—since it cuts out the requirement for FDA oversight or approval—arguably makes dangerous scenarios like those described in this section possible again.

POLICY ANALYSIS AND RECOMMENDATIONS

In order to propose appropriate and feasible policy recommendations regarding early access to non-FDA approved drugs for terminally-ill patients, we must first consider a situation in which the Court ruled in favour of *Abigail Alliance*. Had this happened, all terminally-ill patients would be allowed access to investigational drugs that have not been fully approved by the FDA. This hypothetical situation is similar to the current environment, since RTT was passed by United States Congress and signed into law in 2018.

Since the process of overruling a law is inefficient, this thesis recommends that RTT be amended to include FDA oversight and additional protections for patients who use RTT to access experimental drugs. Use of unproven drugs for terminally-ill patients should be legal and accessible, but with strict regulations. The federal government and FDA should create policies and regulations regarding use of experimental or investigational drugs based on ethical standards, legal considerations, and medical 'best practice' protocols. Some factors to consider are the timeline of disease progression, the cost of treatment, misinformation and media influence, accountability and record-keeping, and the impacts of experimental drug use on clinical trials and drug research.

I. Timeline of Disease Progression

An important consideration when creating these policies is the estimated amount of time a patient has remaining to live. Due to all the ethical reasons outlined previously in this paper, access to potentially harmful drugs for cancer patients—even if they are potentially life-saving—should be restricted only to people who are deemed certainly terminal by a qualified medical specialist and have no other medical options. Furthermore, it is crucial to distinguish between

terminally-ill patients and chronically-ill patients and determine if this distinction is relevant to RTT.[119]

The number of estimated days a person has remaining is arguably the most important consideration when it comes to determining whether a terminally-ill patient should be given early access to unproven and non-FDA approved drugs or treatments. If, for example, a cancer patient has less than a month to live, accepting a treatment that may extend their life by several months with the risk that it may be harmful might be a risk that individual is willing to take. However, if a cancer patient has at least one year remaining, it may not be appropriate to administer a potentially harmful drug that could shorten their life when they still have significant time to live. The evaluation of whether experimental drug use is appropriate for a specific patient is a difficult concept to balance and needs to be made on a case-by-case basis between each patient and their physicians. A "cut-off" date—a number of estimated days remaining agreed upon by two different specialists—should be explored by medical ethicists to protect the 'right to life'. General standards to determine whether a patient is 'terminal' require meeting either of the following criterium: Either the patient must have no further treatment options available, or they must be within six months of expected death.[120] Since hospice care standards and guidelines will consider patients with less than six months remaining eligible for hospice care,[121] the same standard could be used in decisions to allow terminally-ill patients access to unproven drugs. If a physician can predict that a patient has less than six months to live, there are no remaining approved treatment options available, and that patient consents to a potentially harmful

[119] Diane C. Robinson, 'Coping with a Chronic or Terminal Illness', accessed 2 December 2021, https://www.orlandohealth.com/content-hub/coping-with-a-chronic-or-terminal-illness.
[120] David Hui et al., 'Concepts and Definitions for "Actively Dying," "End of Life," "Terminally Ill," "Terminal Care," and "Transition of Care": A Systematic Review', *Journal of Pain and Symptom Management* 47, no. 1 (January 2014): 77–89, https://doi.org/10.1016/j.jpainsymman.2013.02.021.
[121] 'What Are Palliative Care and Hospice Care?', National Institute on Aging, accessed 2 December 2021, http://www.nia.nih.gov/health/what-are-palliative-care-and-hospice-care.

treatment, patients should be given the autonomy to take that risk. However, since every patient is unique, it should also be generally accepted that exceptions to the timeline-based guidelines outlined above will be made on a case-by-case basis.

Another aspect of this topic that should be evaluated and should be considered in legislation is the differentiation between chronic and acute conditions, and between terminally-ill and chronically-ill patients. Chronic conditions like cancer, Alzheimer's disease, obesity, and HIV/AIDS often have long periods of time where a patient is still active, healthy, and able to maintain a close-to 'normal' lifestyle. Acute conditions like certain types of fast-acting viral or bacterial infections including COVID-19 can deteriorate a person's health at a significantly more rapid rate than chronic conditions. This difference in timeline impacts the way physicians approach treatment and the way patients cope with their own mortality. When a patient can see their death approaching, like those with chronic conditions, they have sufficient time to evaluate options, consult other physicians or family members, prepare advanced directives, and make other difficult decisions.[122] On the contrary, when a person is diagnosed with a sudden, acute, and terminal condition, the privilege of time is not always available and may blur decision-making. For these reasons, it is important to establish a timeline for disease progression and life expectancy to better support patients in their end-of-life related decision making. Furthermore, RTT should not discriminate between terminally-ill and chronically-ill patients. To many individuals, their quality of life is equally as important as the concept of being alive. Chronically-ill patients, including cancer patients, often have an equally high degree of suffering and distress as terminally-ill patients and therefore should be given equal access to investigational drugs under RTT.

[122] Gawande, *Being Mortal: Medicine and What Matters in the End*.

In addition to timeline-based protocols, this thesis recommends the inclusion of mandated consultations and waiting periods to help patients take time in making decisions that may shorten or end their life instead of proceeding with rash judgements. Furthermore, policies mandating time lapses before decisions can be reached will also protect hospitals, drug manufacturers, and physicians from liability. In Texas, individuals seeking an abortion are legally required to have a consultation where physicians are required to outline all risks associated with abortion and offer alternative options instead of abortion.[123] This policy is unpopular amongst women's rights activists and many left-of-centre individuals because it creates an additional barrier in abortion access.[124] Although this abortion policy has been heavily criticised for restricting access to healthcare, a policy recommendation regarding RTT is to impose a similar time lapse guideline for making decision. The reason for this policy recommendation that restricts accessibility is because unlike abortion—a procedure that is thoroughly researched and has predictable consequences—using an experimental drug has a high unknown risk. Furthermore, with abortion there is a clear intent to terminate a pregnancy and the risks associated with that medical procedure are clearly known. However, in using RTT eligible drugs that are severely under-researched, the patient is consenting to a concoction of unknown outcomes. If patients seeking investigational cancer therapies under RTT were required to participate in an educational consultation to understand the risks associated with taking a potentially toxic drug followed by a twenty-four-hour contemplation period, it may improve patient satisfaction with their health outcomes. Furthermore, implementing this educational consultation and waiting period as a part of a patient's informed consent reduces liability for physicians, hospitals, and manufacturers.

[123] 'Know Your Rights: Abortion in Texas'. Accessed 29 November 2021. https://www.aclutx.org/sites/default/files/field_documents/abortionkyr_final.pdf.
[124] 'Government-Mandated Delays Before Abortion'.

II. Cost and Finances

Everything comes at price—especially in healthcare. The average cost of cancer treatment per patient in the United States is $150,000.[125] Annually, according to 2018 statistics, approximately $156 billion is spent on cancer care in the United States.[126] The financial burden can be significantly higher depending on the type of cancer, the severity of the diagnosis, and the patient's insurance status. For example, breast cancer is the most expensive type of cancer spending $3.4 billion in total in the United States, followed by lung and colon cancer each costing about $1.1 billion per year.[127] The most expensive component of treatment is paying for medications. Under RTT, it is unclear who is responsible for the cost of investigational drug doses.

In order for patients to access investigational drugs under the Right to Try Act, physicians and their staff are required to request the drugs from manufacturers and provide substantial paperwork. Creating added work for physicians' offices and hospitals poses a question: how will the additional work performed by physicians' offices be appropriately compensated without applying an undue burden on patients, the physicians, or drug manufacturers? Since under RTT pharmaceutical companies cannot directly compensate physicians and requiring patients to pay additional fees makes experimental drug access less feasible, RTT should allocate appropriate funding to offset the cost of additional labour in physicians' offices. Based on the research and issues outlined throughout this paper, recommendations for financial responsibility are as follows:

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[125] Peter Moore, 'The High Cost of Cancer Treatment', AARP, accessed 5 December 2021, https://www.aarp.org/money/credit-loans-debt/info-2018/the-high-cost-of-cancer-treatment.html.
[126] Robert Preidt, 'Cancer Care Costs U.S. $156 Billion Per Year; Drugs a Major Factor', US News & World Report, 13 October 2021, //www.usnews.com/news/health-news/articles/2021-10-13/cancer-care-costs-us-156-billion-per-year-drugs-a-major-factor.
[127] *Ibid.*

First, to continue incentivising and appropriately compensating drug manufacturers, pharmaceutical companies should be allowed to sell doses of investigational drugs with certain restrictions. These restrictions include selling doses at the same price to every individual regardless of their demographic background, not compensating physicians or patients for their use of the drug and setting the drug's price based on retail costs similar to therapies available on the market. The purpose of setting prices to be comparable to retail prices is to treat RTT eligible drugs the same way FDA-approved cancer therapeutics are treated. The intent of these restrictions is to limit the potential for discrimination against patients, to limit bribery or other nefarious behaviours, and to ensure that the cost of each dose of investigational drug is set at a reasonable price for patients. While this does not account for the existing financial barriers to healthcare, it at least reduces the potential for an additional barrier to accessing experimental drugs.

Second, insurance providers including Medicare and Medicaid should financially support patients who request drug access under the Right to Try Act the same way they financially support patients with physician prescriptions for FDA approved drugs.[128] Although drugs accessed under RTT are not FDA approved, it is federally legalised to obtain these drugs with a physician's recommendation. So, since it is a medical treatment intending to save a patient's life, insurance providers should treat it as such. The requirement for insurance providers including Medicare and Medicaid to reimburse for the cost of investigational drugs makes early access of investigational drugs under RTT more equitable for all individuals who may be interested in seeking those options.

[128] David Gorski, 'The Koch Brothers and Vice President Mike Pence Back a Final Push to Pass the Cruel Sham Known as "Right-to-Try"', *RESPECTFUL INSOLENCE* (blog), 22 January 2018, https://respectfulinsolence.com/2018/01/22/the-koch-brothers-and-vice-president-mike-pence-back-a-final-push-to-pass-the-cruel-sham-known-as-right-to-try/.

III. Misinformation, Media, and Education

Since many patients are able to research their medical concerns before consulting a physician and more medically literate patients are able to research drug options, the role of the physician especially with regards to experimental drug access has changed. Physicians are now responsible for not only examining their patients and recommending the best treatment plan available but are now also have a responsibility to discredit unreliable medical information that their patients may discover online. Furthermore, since many patients do not have the medical qualifications or education to truly understand the reliable information available online, medical professionals have a responsibility to educate their patients appropriately. This becomes especially risky in circumstances related to non-FDA approved drugs and drugs that are under-researched. Many of these issues pertaining to information and misinformation could be mitigated with policies that restrict the way information about investigational drugs is delivered and shared. To preserve safety standards for patients, it is important to create policies that manage the way information about unproven and investigational drugs are shared. These policies are intended to prevent misinformation, to promote informed consent, to protect patients' wellbeing, and to uphold standards of medical integrity. Policy recommendations to prevent miscommunication and promote medical research and physician input include the following:

A. Strict regulations on direct-to-consumer television, radio, billboard, or other mass forms of advertisement or promotion specifically for non-FDA approved drugs or medical devices,[129]

[129] Benita Lee, 'How Is Consumer Drug Advertising Regulated in the United States?', GoodRx, accessed 2 December 2021, https://www.goodrx.com/healthcare-access/patient-advocacy/prescription-drug-advertising-regulation-united-states.

a. Including drugs available in overseas markets that are not approved or pending approval in the United States.
b. Including drugs undergoing FDA approved trials.
c. Including drugs that qualify for use under the Right to Try Act.
d. Including non-FDA approved drugs that are not intended for life-saving purposes or emergency use.
e. Not including forms of media or advertisement that are not mass-targeting populations.
f. Not including promotion of non-FDA approved drugs or medical devices by physicians directly to their patients.
g. Not including research publications not intended for advertisement or promotion purposes.

B. Mandated educational information provided by the physician recommending an investigational drug prior to the patient being granted use of investigational drug, abiding by the following criterion:
    a. Written and verbal information of all potential risks of investigational drug use including:[130]
        i. Any expected or potential side effects.
        ii. The extent to which the drug is expected to improve the patient's condition or extend life expectancy.
    b. Written and verbal information about the research available on the drug including:
        i. Phase I clinical trial results provided by the drug manufacturer.

[130] Shah et al., 'Informed Consent'.

ii. Information on all comparable or alternative drug options.

The policy recommendations outlined above are intended to protect patients and promote safety while still preserving patient autonomy and physician discretion. It is important to provide guidelines for media advertisement and promotion of non-FDA approved drugs to ensure patient safety and proper use of drugs.

IV. Records, Liability, and Accountability

A concern with RTT is the ability to maintain thorough records and hold entities accountable in the event that drugs are misused or cause a high degree of harm. In 2020, a revision to RTT was proposed to require manufacturers to submit an annual summary of use to the FDA.[131] The policy recommendation regarding record-keeping is in line with the proposed rule to add a requirement to section 561B of the FD&C Act which was added by RTT to require manufacturers to submit annual reports to the FDA.[132] These reports should include:

A. An annual summary of any use of experimental drug supplied under section 561B of the FD&C act.
B. The number of doses supplied.
C. The number of patients treated.
D. The number of physicians involved in recommending access to the drug.
E. The intended use for which the drug was made available.
F. Any known serious adverse side effects.[133]

[131] 'Annual Summary Reporting Requirements Under the Right to Try Act', Federal Register, 24 July 2020, https://www.federalregister.gov/documents/2020/07/24/2020-16016/annual-summary-reporting-requirements-under-the-right-to-try-act.
[132] *Ibid.*
[133] *Ibid.*

It is important for the FDA to retain their role as the preeminent entity in order to limit ethical concerns associated with RTT including discrimination or other illegal behaviour, to preserve safety standards, and to keep comprehensive records of unapproved drug release. In addition to the proposed regulations to increase accountability and keep better records, RTT should include language to protect patients from adverse consequences of the experimental drugs they use.

Since RTT broadly immunises physicians advising or administering experimental therapeutics and companies providing experimental therapeutics, there are few protections for patients. An example that Dr. Gorski uses in his blog is a hypothetical case where an elderly patient may be exploited for financial gain by their physician, which can also apply to patients who are less educated or medically illiterate. In these cases, RTT does not truly serve its purpose to expand access to necessary experimental drugs but rather puts patients at added risk of harm. Policy recommendations to mitigate these harms for terminally-ill cancer patients include consent from at least two board certified physicians who specialise in the relevant subfield of oncology, funding allocations to support patients using RTT eligible drugs in the treatment of potential adverse side effects, and records to be kept of every dose of an experimental drug that is administered to a RTT eligible patient. By requiring consent from at least two physicians, there is a higher standard of accountability, so the risk of patient exploitation is reduced. Providing financial support—whether it be through government programs or mandates on insurance companies—supports terminally-ill patients not only through their pursuit of accessing an experimental drug but also through the management of the potential side effects they incur by taking the experimental drug. Mitigating the harm that a patient suffers helps to satisfy patients' desires to sue pharmaceutical companies and allows a more ideal outcome for all parties involved. Lastly, sending thorough records of experimental drug use under RTT provides checks

and balances to reduce the probability of physician or pharmaceutical company misconduct. The policies recommended in this section of the paper aims to address concerns with RTT and to propose effective and feasible solutions to those concerns.

CONCLUSION

There is no single system that will satisfy every individual's needs. Neither Abigail Burroughs nor Ron Woodroof got the outcome they wanted with regards to experimental drug access. Although the FDA was unable to support patients in both those cases, those cases are both anomalies in history. Ron Woodruff lived with and died of HIV/AIDS in a time where the disease was highly stigmatised, under-researched, and without any form of approved treatment. Abigail Burroughs sought access to a drug that was undergoing research for a different form of cancer than what she was diagnosed with, and therefore the FDA could not in good conscience offer her access to it. The Right to Try Acts and Dallas Buyers Club Acts passed in individual states and by United States Congress base their logic primarily on these two cases instead of on the needs of the masses. This challenges the role of the FDA by compromising the drug safety and efficacy standards that the FDA strives to uphold. The challenge society and policymakers are faced with is finding the balance between promoting patient autonomy and preserving safety standards, which becomes especially difficult when applied to terminally-ill cancer patients.

This thesis recommends that there be a timeline of disease progression established by oncologists specializing in the relevant form of cancer to guide patients in determining whether they want to pursue experimental drugs with unknown risk factors. Furthermore, this thesis advocates for the implementation of mandated consultations and waiting periods to ensure informed consent and thoughtful deliberation. Since the goal of the Right to Try Act is claimed to be improved access to investigational drugs, a significant consideration is how patients are expected to pay for the drugs in question. To improve accessibility and remove financial burdens, this paper promotes requirements for insurance companies and Medicare and Medicaid to cover the expenses associated with experimental drug use in the same ways they cover

prescribed FDA-approved drugs. Since RTT legalizes the use of eligible non-FDA approved drugs for eligible patients, these drugs should be treated in the same way that other approved cancer therapeutics are treated. To account for the influence of media and advertising on patient autonomy, this paper recommends strict regulations to limit the public advertisement of non-FDA approved drugs. Promoting physicians as the primary source of information on experimental drugs supports patient autonomy and informed consent by improving the likelihood that the information delivered to patients is the most up-to-date and medically accurate data. Furthermore, the FDA should at the very least be aware of every release and use of experimental drug doses under RTT to supervise pharmaceutical company and physician behaviours. Finally, since the risk associated with using RTT eligible drugs is so high and cannot be accurately measured before drug administration, there need to be protections and resources available to patients who choose to pursue experimental treatments. When Congress passed RTT, they placed a responsibility on the patients who will be impacted by it, and that should include a guarantee of financial support to access the drug and to manage any adverse reactions caused by the drug. While it would be equally as unfair to hold physicians or drug manufacturers liable due to the under-researched nature of the drug and the fact that the patient is requesting it with informed consent, it is not appropriate or compassionate to leave a terminally-ill patient without medical support. The policy recommendations in this paper aim to create a system that is fair and equitable to all individuals, physicians, and pharmaceutical companies affected by the Right to Try Act.

When issues like racial discrimination, prejudice, financial and other inequities, and forms of systemic discrimination exist, it is more difficult for patients to trust the medical establishment. But, in order for real change to be impacted on a wide scale, it is essential for the

federal government to retain decision-making autonomy over the access to experimental drugs. Although the system is imperfect, the path to perfection is through improvement rather than to uproot the system entirely. In a world where every individual acted ethically and in good conscience, the Right to Try Act could be in the best interest of all chronically-ill and terminally-ill patients. However, in the world in which this thesis is written, patients depend on a joint effort from the government, policymakers, the medical establishment, drug manufacturers, physicians, and patients to create the best possible outcome for the holistic wellbeing of each patient.

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BIOGRAPHY

Ashka Dighe was born in Mumbai, India as a citizen of the United Kingdom and has lived in Brazil, Singapore, Indonesia, Malaysia, and the United States of America. At the University of Texas at Austin, Ashka completed degrees in BA Plan II Honours, BA Health & Society, and BSA Neuroscience alongside a minor in History and a minor in Government. Her passion for interdisciplinary studies motivates her academic and career-related pursuits. Throughout her time at UT Austin she has assisted in the Plan II Modes of Reasoning class to encourage and guide students in their medical research and problem solving skills. As a member of Texas 4000, the longest annual charity bike ride in the world, she has individually raised over $15,000 in the fight against cancer to promote cancer research and support services. In her senior year, she won the Sharon H. Justice and Texas Exes President's Leadership scholarships. She focused extensively on medical law as it relates to cancer, autonomy, and sexual violence. During her time in Washington, D.C. with the Bill Archer Fellowship Program, she interned with the Eleanor Crook Foundation doing policy research for solutions to global malnutrition. As President of the Friar Society and the Vice President of It's On Us, she has shaped her campus culture to be more inclusive and empathetic. Ashka is an advocate for her peers through all the work she does. She intends on attending law school to further her career in advocacy and the promotion of healthcare and human rights.