

To Try or Not to Try: *Who Decides Is the Question*

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I. INTRODUCTION

Father of three . . . married . . . terminally-ill . . . victim of melanoma at forty-one. Unfortunately, this set of facts is becoming all too common in today's society. Nick Auden, a Colorado resident, died waiting in line for investigational drugs that might have cured his condition.

After learning that the U.S. Food and Drug Administration ("FDA") had not yet approved any drugs or remedies for melanoma, Auden turned a hopeful eye to experimental drugs.¹ One drug in particular demonstrated a fifty-two percent success rate with melanoma patients. Auden's wife expressed the optimism of many Right to Try advocates when she confronted the odds. She conceded that, "[o]f course, there was a chance that Nick would not have been in the fifty second percentile of people who [were] responding to the drug; however, a fifty-two percent chance at life is better than a zero percent chance at life."² Although two drug manufacturers produced the drug for which Auden advocated, neither pharmaceutical company would grant him access.³

¹ See Rosa Prince, *'Right to Try' law will allow Dallas Buyers-Club-style experimental drugs*, THE TELEGRAPH, May 18, 2014, available at <http://www.telegraph.co.uk/news/worldnews/northamerica/usa/10839233/Right-To-Try-law-will-allow-Dallas-Buyers-Club-style-experimental-drugs.html> (last visited June 20, 2015).

² *Id.*

³ See KAISER HEALTH NEWS, *'Right-To-Try' Laws on Experimental Drugs Stir Debate*, The KHN Blog (June 24, 2014), <http://www.khn.org/news/right-to-try-laws-on-experimental-drugs-stir-debate/> (last visited June 20, 2015); see also Brady Dennis & Ariana Eunjung Cha, *'Right to Try' laws spur debate over dying patients' access to experimental drugs*, WASH. POST, May 16, 2014, available at http://www.washingtonpost.com/national/health-science/right-to-try-laws-spur-debate-over-dying-patients-access-to-experimental-drugs/2014/05/16/820e08c8-dcfa-11e3-b745-87d39690c5c0_story.html (last visited June 20, 2015).



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Nick Auden passed away before Colorado passed its Right to Try laws; though there is no indication that even those laws would have compelled the drug companies to supply the drug.⁴ Julie Rovner, a health policy correspondent with Kaiser Health News, reported that this outcome is far from an anomaly. She explained that, in many cases, including Auden's, it is the drug companies – not the FDA – which obstruct a patient's path to experimental drug access.⁵ Quoting the FDA, Rovner expounded that drug companies often hesitate to provide the experimental drugs for fear that granting access would jeopardize a drug's ultimate debut in the national drug marketplace.⁶ Auden's story is just one of many that have brought the "Right to Try" debate to the forefront of national discussion.⁷

The "Right to Try" refers to the right of terminally or seriously ill patients to acquire investigational drugs without waiting for FDA approval.⁸ It grants these patients the right to access certain drugs, specifically those drugs that have completed only phase one of the

⁴ 'Right to Try': States Move to Expand Access to Experimental Drugs, NBC NEWS, ASSOCIATED PRESS, May 18, 2014, available at <http://www.nbcnews.com/health/health-news/right-try-states-move-expand-access-experimental-drugs-n108316> (last visited June 20, 2015) [hereinafter "Right to Try"].

⁵ See Kaiser Health News, *supra* note 3.

⁶ *Id.*

⁷ See Prince, *supra* note 1.

⁸ *Right to Try*, *supra* note 4.



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FDA three-phase drug approval process.⁹ Advocates of the Right to Try contend that the decision to try an investigational drug should be between a patient and his or her physician and, thus, exclude the government, i.e., the FDA. Opponents support the FDA's role in the drug approval and distribution process as it currently stands. Although patients may be most immediately impacted by the outcome of the debate, the implications of the "Right to Try" extend to drug manufacturing companies, physicians, the clinical trial process, and the overall concept of federalism.

The Right to Try debate boils down to one question: Who should decide whether a drug is too risky to try?¹⁰ Currently, the FDA regulates the drug approval process and controls exemptions through which patients may gain access to drugs prior to formal approval. Although the FDA allows for exemptions, advocates of the Right to Try argue that the exemption process is too lengthy and oftentimes results in the passing of terminally ill patients before receiving access. Further, even if the FDA were to grant an exemption, the FDA has

⁹ John-Manuel Andriote, *Who Decides? 'Right-to-Try' Law's Unacknowledged, Deep Roots in AIDS Activism*, HUFFINGTON POST, May 22, 2014, available at: http://www.huffingtonpost.com/johnmanuel-andriote/who-decides-rightto-try-right-to-try-law_b_5373157.html (last visited June 20, 2015).

¹⁰ Dennis & Cha, *supra* note 3.

no authority to compel pharmaceutical companies to offer the drug, as those companies have their own risks to weigh.¹¹ This article will explore some of the liability and related coverage concerns for the drug industry.

Stories like Nick Auden's have been surfacing through social media campaigns organized by dying patients' families in an effort to advocate for expanded access to experimental drugs.¹² Patient advocates are pressuring state legislatures to circumvent the FDA regulations by passing laws that would grant access to any terminally ill patient who meets FDA requirements. Contemporaneous with the wave of social media exposure was the release of the film *Dallas Buyers' Club* in 2013, starring Matthew McConaughey, which captured the real-life story of a patient diagnosed with AIDS who traveled to Mexico for drugs not yet approved in the United States. After his character began to recover as a result of the unapproved drugs, he led a large black market movement to give other dying HIV and AIDS patients access to the same drugs.¹³

This article offers insight into the causes and possible effects of the Right to Try movement. Part II outlines the legal background to date of Right to Try efforts. Part III considers the status quo of the drug approval process and access to experimental drugs in the United States administered by the FDA under its authority granted by the Food Drug and Cosmetic Act of 1938. Part IV begins with a brief introduction of the factors that instigated the Right to Try movement and concludes with a fifty state survey of the Right to Try laws, both passed and pending, at the time of this article. Part V delves into the primary arguments on both sides of the Right to Try Debate. The outcome of the emerging state legislation is yet to be determined until the federal government acts. As such, states will continue to have the floor, as well as the "final" say, for now, in deciding who has the "Right to Try."

II. LEGAL BACKGROUND

The Right to Try debate made its debut in a courtroom in 2006. In *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, the District of Columbia Circuit Court of Appeals declined to recognize a fundamental right to access potentially life-saving investigational new drugs.¹⁴ Similar to Nick Auden,¹⁵ Abigail Burroughs was a young terminally ill patient diagnosed with neck and back cancer who exhausted all available FDA-approved treatments and died fighting for access to two experimental drugs that her

¹¹ *Id.*

¹² *Id.*

¹³ See Prince, *supra* note 1.

¹⁴ *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F. 3d 695, 703-707 (D.C. Cir. 2007) (en banc).

¹⁵ See Prince, *supra* note 1.

physician recommended — Erbitux from Imclone Systems, or Iressa from Astra Zeneca.¹⁶ Although the FDA later approved both of these drugs, the approval did not come quickly enough as Abigail Burroughs passed away without access.

After Abigail's death, her father, Frank Burroughs, together with the *Abigail Alliance for Better Access to Developmental Drugs*, an organization he founded to advocate for expanded access, sued the Commissioner of the FDA to demand access to the potentially life-saving drugs. Frank Burroughs sought access to Erbitux, an investigational drug that had only passed phase one and was only available in clinical trials.¹⁷ He posited that terminally ill cancer patients possessed a fundamental right to access experimental drugs. While the District of Columbia Circuit Court of Appeals initially affirmed that such a fundamental right existed,¹⁸ the court reheard the case, upon petition by the FDA, and reversed.¹⁹

In its analysis, the court confronted the underlying conflict at the heart of the Right to Try debate: “[i]n the realm of reviewing medical products to treat serious and life-threatening diseases, there is inevitable tension between early availability of products to patients . . . and the need to obtain sufficient data to provide a reasonable expectation of benefit and lack of excessive harm.”²⁰ The FDA opposed expanding access because it believed it “would upset the appropriate balance that [it was] seeking to maintain, by giving almost total weight to the goal of early availability and giving little recognition to the importance of marketing drugs with reasonable knowledge for patients and physicians of their likely clinical benefit and their toxicity.”²¹ Accepting the FDA's rationale, the District of Columbia Circuit Court of Appeals declined to recognize the right to access experimental drugs as fundamental. The Supreme Court denied certiorari.²²

While the Supreme Court declined to address a constitutional challenge to the Food Drug and Cosmetic Act (“FDCA”) in *Abigail Alliance*,²³ it rejected similar challenges to

¹⁶ Frank Burroughs, ABIGAIL ALLIANCE, *Our Story*, <http://abigail-alliance.org/story.php> (last visited June 20, 2015).

¹⁷ *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 445 F. 3d 470 (D.C. Cir. 2006), *rev'd on rehearing*, 495 F. 3d 695 (D.C. Cir. 2007) (en banc).

¹⁸ *See id.*

¹⁹ 495 F. 3d at 700 (alteration in original).

²⁰ *Id.*

²¹ *Id.*

²² 552 U.S. 1159 (2008).

²³ *See* Michael J. Malinowski, *Throwing Dirt on Doctor Frankenstein's Grave: Access to Experimental Treatments at the End of Life*, 65 HASTINGS L.J. 615, 629 (2014) (citing *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F. 3d 695 (D.C. Cir. 2007))(where plaintiffs argued that an individual had a liberty interest that entitled him to access experimental drugs, comparing to the holding in *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 286-87 (1990), that an individual had a liberty interest in his right to refuse “life-sustaining” treatment even if the resulted in quicker death).

the FDCA and comparable federal statutes.²⁴ In *United States v. Rutherford*, terminally ill patients sued to enjoin the United States from intercepting a shipment of a non-approved drug, Laetrile, in compliance with the FDCA, arguing that the FDCA regulations did not apply.²⁵ The Supreme Court concluded that there was neither an express nor an implied exception under the FDCA for drugs used by the terminally ill, and, as such, the same regulations applied.²⁶ Although the Supreme Court never considered the *Abigail Alliance* case, the District of Columbia Circuit Court of Appeals followed the Supreme Court's holding in *Rutherford* finding no FDCA exception for drugs used by the terminally ill. Thus, to date, no court has recognized a fundamental right to access experimental drugs.²⁷

Fueled by the social media campaigns and Hollywood's depiction of the drug-smuggler trade in *Dallas Buyers' Club*, the Right to Try movement continues to pick up speed across the nation. Currently, more than twenty states, Colorado, Louisiana, Missouri, Michigan, Alabama, Arizona, Arkansas, Florida, Indiana, Minnesota, Mississippi, Montana, Nevada, North Dakota, Oklahoma, South Dakota, Tennessee, Texas, Utah, Virginia, and Wyoming, have passed legislation that relegates the choice to try investigational drugs to terminally ill patients and their physicians, and cuts the FDA mostly out of the picture.²⁸

III. HISTORY

A. *Drug Approval Under the Food and Drug Administration*

Congress passed the Food Drug and Cosmetic Act in 1938 in an effort to protect consumers from unsafe drugs. The act prohibits access to new drugs.²⁹ Investigational new drug means a new drug or biological drug that is used in a clinical investigation, unless and until the FDA has approved it.³⁰ The American public has historically supported and favored

²⁴ See *Abigail Alliance*, 495 F. 3d at 710 (citing *Gonzales v. Raich*, 545 U.S. 1, 11 (2005)); see also *United States v. Rutherford*, 442 U.S. 544, 552 (1979).

²⁵ *Rutherford*, 442 U.S. at 552 (finding that the FDCA contains no exemption allowing terminally ill access to experimental drugs).

²⁶ *Id.*

²⁷ *Abigail Alliance*, 495 F. 3d 695 (D.C. Cir. 2007).

²⁸ Alexander Gaffney, '*Right to Try*' *Legislation Tracker*, REG. AFF. PROFS. SOC'Y, (last updated June 25, 2015), <http://www.raps.org/Regulatory-Focus/News/Right-to-Try/> (last visited July 24, 2015).

²⁹ See 21 C.F.R. § 312.3(b) (2015).

³⁰ 21 U.S.C. § 355 (a) (2015) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection(b) or (j) of this section is effective with respect to such drug.").

increased FDA regulation of new drugs. Recently, however, the same regulations for which the FDA had previously been praised are drawing criticism for obstructing patient access to drugs.³¹

In response to the growing dissatisfaction with the drug approval process, the United States has made many efforts over the last three decades to liberalize access to experimental drugs and promote the efficiency of the approval process. Some of these efforts include creating exemptions to grant individuals or classes of patients access to experimental drugs; promoting transparency by providing access to information about clinical trials to the general public;³² and providing Medicare reimbursement for routine patient care needed as a result of participating in clinical research.³³ As a result of the liberalization of access and focus on efficiency within the clinical research realm, the waiting period for drug approval has decreased.³⁴ However, the efficacy of the experimental drugs and the success of clinics using them have not improved.³⁵ It is estimated that the growth and expansion of clinical research and care will continue to grow at unprecedented rates given the past trend.³⁶

In 1962, Congress passed a wave of amendments that established the “Gold Standard” still in place today. The “Gold Standard” requires drug companies to achieve a requisite level of safety and efficacy for FDA approval.³⁷ First the drug company must submit an Investigational New Drug (“IND”) application to the FDA after completing animal testing.³⁸ Next, upon approval, the FDA allows the drug company to proceed with the other phases before going to market.³⁹ There may be as many as four phases, although there are typically three. Reports indicate that it takes the average experimental drug seven years to pass through all phases.⁴⁰ Phase one consists of testing the drug on a sample population of twenty to eighty people to measure the drug’s safety.⁴¹ Phase two involves a clinical study

³¹ See Linda Katherine Leibfarth, *Giving the Terminally Ill Their Due (Process): A Case for Expanded Access to Experimental Drugs through the Political Process*, 61 *VAND. L. REV.* 1281, 1286 (2008).

³² See Malinowski, *supra* note 23, at 625.

³³ *Id.*

³⁴ See *id.* at 615-69 (comparing the approval waiting time of twenty-seven months in 1997 to fourteen months in 2001).

³⁵ *Id.* at 641 (noting that “the failure rate of new drug candidates in clinical trials exceeds ninety percent, and that is just against a science standard to be better than nothing (beat a placebo) . . .”).

³⁶ *Id.* at 625, 639 (observing that the policy promoting clinical research and the American public’s faith in same coupled with building pressure from investors on drug companies to maintain high performance indicates the trend of liberalization of access will continue).

³⁷ Leibfarth, *supra* note 31, at 1285.

³⁸ 21 U.S.C. § 355 (i)(1) (2015).

³⁹ 21 C.F.R. § 312.20 (2015).

⁴⁰ Abigail Alliance, 495 F. 3d at 698.

⁴¹ 21 C.F.R. § 312.21 (a) (2015).

on a small number of patients with the disease or condition under study to assess the drug's side effects, risks, and overall effectiveness.⁴² In phase three, the testing is implemented on a larger population to gather more information on the effectiveness and safety findings to assess the benefit-risk ratio of implementing the use of the drug.⁴³ Unlike the two previous phases, phase three involves several hundred to several thousand subjects.⁴⁴

After all three phases are completed, drug companies submit the results to the FDA for final approval. This stage of the process can take years. Upon FDA approval, the drug company is permitted to market the drug.⁴⁵ In 1988, in response to the AIDS epidemic of 1981, the FDA agreed to expend efforts to speed up the drug approval process and began to allow patients with AIDS access to unapproved drugs that had only completed phase one of the approval process.⁴⁶ There, like now, suffering patients fought for the right to “be guinea pigs” with hopes for a chance of survival.⁴⁷

B. Exemptions

1. Clinical Trials

Clinical trials represent one avenue by which patients may gain access to experimental drugs. To gain access, however, patients must satisfy the requirements of each clinic, which proves challenging for many.⁴⁸ Further, clinical trials are limited in the number of patients they can accept. Many patients with end-stage diseases, like cancer, may not qualify for clinical trials where the ultimate objective is to monitor a drug's long-term effects.⁴⁹ Clinics are administered by drug companies and overseen by federal regulators, but if a patient does not qualify for a clinical trial, or there is no trial for his or her illness, he or she can try for the expanded access exemption.⁵⁰

⁴² *Id.* § 312.21 (b).

⁴³ *Id.* § 312.21 (c).

⁴⁴ *Id.*

⁴⁵ Leibfarth, *supra* note 31, at 1285-86.

⁴⁶ Andriote, *supra* note 9.

⁴⁷ *Id.*

⁴⁸ KAISER HEALTH NEWS, ‘Right-To-Try’ Laws on Experimental Drugs Stir Debate, THE KHN BLOG (June 24, 2014), <http://capsules.kaiserhealthnews.org/index.php/2014/06/right-to-try-laws-on-experimental-drugs-stir-debate>.

⁴⁹ *Id.*

⁵⁰ PBS NEWSHOUR, Transcript of “‘Right to try’ law gives terminal patients access to drugs not approved by FDA” (June 21, 2014), <http://www.pbs.org/newshour/bb/right-try-law-gives-terminal-patients-access-non-fda-approved-drugs/> (interviewing Kristina Brogan, a terminally ill patient from Missouri).

2. Expanded Use Exemption a/k/a Compassionate Use Exemption

a. Basic Framework

The Compassionate Use Exemption marks the second path that patients may use to petition for access to experimental drugs when they have no other alternatives.⁵¹ The exemption allows the FDA to grant access to drugs that have completed phase one of the FDA drug approval process to individuals who are excluded from clinical trials or who have already exhausted all FDA-approved treatments.⁵² Specifically, it provides access to unapproved drugs, referred to as investigational new drugs (as identified above, “INDs”), to patients who suffer from “serious or immediately life-threatening disease[s],”⁵³ when there is “no comparable or satisfactory alternative drug or other therapy,”⁵⁴ and where the drug is under investigation and its sponsor is seeking approval.⁵⁵ The FDA acknowledged that the risk-benefit analysis for a patient who suffers from a life-threatening disease should be assessed differently. The FDA considers whether the “potential benefit justifies the potential risks of the treatment used” and explores whether “those potential risks are not unreasonable in the context of the disease or condition to be treated.” Thus, the nature of the disease dictates the amount of risk that is reasonable.⁵⁶

In 2009, Congress amended the expanded use exemption, also referred to as the compassionate use exemption, in an effort to ensure “broad and equitable access to investigational drugs for treatment.”⁵⁷ The amendments clarified the requirements that a patient needed to meet in order to qualify for expanded access. The FDA must determine that:

⁵¹ *Id.*

⁵² Leibfarth, *supra* note 31, at 1289 (Explaining that the Compassionate Use exemption allows the FDA to grant access to experimental drugs that have not completed the four step approval process if: (1) “the drug is intended to treat a serious or life-threatening disease; (2) no satisfactory alternative exists; (3) the drug is already under investigation through FDA-controlled trials; and (4) the drug sponsor is pursuing marketing approval for new drug actively”).

⁵³ See 21 C.F.R. § 312.300(b) (2015).

⁵⁴ See *id.*

⁵⁵ 21 C.F.R. § 312.34 (a), (b)(1)(I)-(II); see also FDA, Access to Investigational Drugs Outside a Clinical Trial (Expanded Access), available at: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm20080392.htm> (Immediately life-threatening disease or conditions means a state of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment; Serious disease or condition means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning; Sponsor means a person who takes responsibility for initiating a clinical investigation).

⁵⁶ See Leibfarth, *supra* note 31, at 1308 (quoting Expanded Access to Investigational New Drugs for Treatment Use, 71 Fed. Reg. 75147, 75149 (proposed Dec. 14, 2006)).

⁵⁷ See FDA, *New Rules for Expanded Access to Investigational Drugs for Treatment Use and Charging for Investigational Drugs*, available at <http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm>.

- (1) The patient or patients to be treated have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;
- (2) The potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated; and
- (3) Providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.⁵⁸

“Expanded use” is awarded by the FDA on a case-by-case basis, and is offered to single patients in non-emergency and emergency settings; small groups of patients; and larger groups of patients under a treatment IND.⁵⁹ Additionally, the expanded access program provides a faster track for individuals in emergency situations.⁶⁰

The FDA established safeguards within the FDCA to guarantee that physicians provide individual patients with fair notice of the risks involved in using an investigational drug. First, the pharmaceutical and medical device manufacturers warn the physician or “learned intermediary” of the appropriate use and possible risks of the product. When the manufacturers warn the physicians, the “learned intermediary” doctrine discharges the manufacturers of their duty to also warn the consumers. Instead, the “learned intermediary” doctrine shields pharmaceutical and medical device manufacturers from tort liability so long as they provide all necessary information to a “learned intermediary” who interacts with his or her patient.

After receiving the warning from the manufacturer, the FDCA requires any sponsor, typically a physician petitioning on behalf of his patient, to make certain that a drug manufacturer is willing to offer the investigational drug upon FDA approval. Additionally, the FDA requires that physicians who apply for INDs are licensed. Upon receiving access to an IND, the FDA requires sponsors to submit IND safety reports.⁶¹ Next, the FDA mandates that all pending applications are reviewed by an Institutional Review Board (“IRB”). The

⁵⁸ 21 C.F.R. § 312.305(a) (2015).

⁵⁹ See FDA, *New Rules for Expanded Access to Investigational Drugs for Treatment Use and Charging for Investigational Drugs*, available at <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/ucm177022.html>.

⁶⁰ See FDA, *Emergency IND Application Timeline*, available at: <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/UCM343024.pdf>.

⁶¹ See 21 C.F.R. § 312.305 (2015).

board evaluates whether the risks of the drug are reasonable in light of the particular patient's conditions versus the potential benefit from the experimental drug. While the FDA may grant access to a drug, it cannot oblige a drug company to distribute the drug.⁶² Further, it is estimated that, on average, the FDA "has approved 99% of all [expanded access] requests since October 2009. On average, the agency has endorsed 932 requests each year since then."⁶³ FDA endorsement of a request for expanded access is tantamount to FDA approval of the drug request. Receipt of the endorsement, however, does not guarantee a patient access to the drug. The manufacturing company still must agree to distribute the drug.

b. Applying for the Expanded Access Exemption

The FDA application requirements demand a lot of information from the requesting patient to ensure that the FDA, by way of the IRB, protects the patients using the experimental drugs.⁶⁴ A physician making a request for an individual patient IND must first verify that the drug manufacturer that produces the experimental drug has agreed to supply it contingent on FDA approval of expanded access.⁶⁵ Next, the physician must submit the IND application to the appropriate board.⁶⁶ Of particular importance in the application packet is the informed consent form. Although the FDA does not provide a template, it offers detailed instructions of what must be included, with special attention placed on the disclosure of both known and

⁶² See *Expanded Access to Investigational Drugs for Treatment Use- Qs & As*, Guidance for Industry, U.S. DEP'T. OF HEALTH AND HUMAN SERVS., May 2013, available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf> (last visited June 20, 2015).

⁶³ See Ed Silverman, *How Compassionate is the FDA? Three Senators Want to Know*, WALL ST. J. PHARMALOT (June 20, 2014 2:09 PM), available at: <http://blogs.wsj.com/pharmalot/2014/06/20/how-compassionate-is-the-fda-three-senators-want-to-know> (last visited June 20, 2015).

⁶⁴ See *Investigational New Drug Application*, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdf> (last visited June 20, 2015).

⁶⁵ See 21 C.F.R. § 312.305 (b) (2015).

⁶⁶ See 21 C.F.R. § 312.305 (b) (2015); see also FDA, *Physician Request for Individual Patient IND under Expanded Access for Non-emergency or Emergency Use*, available at <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigational-newdrugindapplication/ucm107434.htm> (last visited June 20, 2015) (noting the application must include: (1) a statement that this is a request for an individual patient IND for treatment; (2) a brief clinical history of patient including (a) diagnosis, (b) disease status, (c) prior therapy, (d) responses to prior therapy, (e) rationale for requesting the proposed treatment, including a list of available therapeutic options that would ordinarily be tried before the investigational drug or, (f) an explanation of why use of the investigational drug is preferable to use of available therapeutic options; (3) A proposed Treatment Plan with the dose, route, planned duration, monitoring procedures, modifications for toxicity; (4) Chemistry, Manufacturing, and Controls Information and Pharmacology and Toxicology Information describing the manufacturing facility; (5) Informed Consent statement; (6) Investigator Qualification Statement qualifying the physician; (7) FDA Form 1571; and (8) Contact information).

unknown risks.⁶⁷ In its “Guide to Informed Consent-Information Sheet,” however, the FDA prohibits the use of any exculpatory language through which the patient is made to waive his or her rights or release the sponsor, whether physician or drug manufacturer, from liability for negligence.⁶⁸ Beyond liability for negligence, the FDA fails to provide guidance on liability. Although the FDA does not require a patient to waive his or her right to recover from any harm caused by the experimental drug, it has been implied that the informed consent forms shield both sponsors and drug manufacturers from liability.⁶⁹ Otherwise, the FDA remains silent on the issue of liability in the context of the expanded access exemption, allowing the individual informed consent forms submitted by the sponsors and reviewed by the IRB to define the parameters of liability.

Upon submission, the application is assigned a number, which the physician must provide to the drug supplier. The supplier may then ship the experimental drug to the doctor. Thirty days after the submission of the application, the IND is considered “active” and treatment with the drug may proceed, unless otherwise notified by the FDA.⁷⁰ Where the FDA denies a request, it will promptly notify the sponsor and supply the reasons for its denial. The drug may also be considered active prior to the thirty days upon notification by the FDA.⁷¹

The FDA also provides a streamlined, fast track version of the above process when access to the experimental drug is intended for emergency use.⁷² Unlike the process for non-emergent access, this process allows a physician to start administering treatment with the experimental drug prior to submitting an application. The physician may start administering the drug upon verbal authorization of the FDA, usually by telephone. Such fast-track access, without the paper work and delay for formal approval, allows the patient prompt access to the potentially life-saving drugs. The physician, however, must submit applications and reports within five days of initiating the treatment. The process requires sponsors to verify

⁶⁷ See FDA, *A Guide to Informed Consent - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators*, available at: <http://www.fda.gov/regulatoryinformation/guidances/ucm126431.htm> (noting the informed consent must meet the requirements of 21 C.F.R. § 50.20 and 21 C.F.R. § 50.25(a)-(b) and must gain final authorization from the appropriate IRB) (last visited June 20, 2015).

⁶⁸ See *id.* § 50.20.

⁶⁹ See Access to Experimental Drugs, U.S. PHARMACIST, Mar. 20, 2008, available at http://www.uspharmacist.com/content/t/pharmacy_law/c/10122/ (suggesting that informed consent agreements could pacify drug manufacturers’ fear of liability) (last visited June 20, 2015).

⁷⁰ See 1 C.F.R. § 312.305 (b)(2015); see also FDA, *Physician Request for Individual Patient IND under Expanded Access for Non-emergency or Emergency Use*, available at: <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm107434.htm>.

⁷¹ See *id.*

⁷² FDA, *Emergency IND Application Timeline*, available at <http://www.fda.gov/downloads/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm343024.pdf> (last visited June 20, 2015).

that the drug manufacturer making the requested drug will supply the drug for emergency use. Next, the physician must call the FDA to request opening an emergency IND application.⁷³ Upon receiving verbal authorization, the physician need only obtain informed consent of the patient, rather than wait for IRB approval, to begin administering the drug.⁷⁴

c. Cost of Experimental Drugs

To obtain authorization from the FDA to charge for expanded access use of a drug, a sponsor must (1) provide to the FDA reasonable assurance that charging will not interfere with drug development,⁷⁵ and (2) provide documentation to show that its calculation of the amount to be charged is consistent with the requirements of 21 C.F.R. § 312.8(d). The documentation must be accompanied by a statement that an independent certified public accountant has reviewed and approved the calculation.⁷⁶

An FDA authorization to charge is limited to the number of patients authorized to receive the drug and only applies to certain costs.⁷⁷ Unless a request for an extended authorization is made, the FDA authorization continues for one year.⁷⁸ In an individual patient expanded access case, the sponsor who takes responsibility for initiating the clinical investigation, either the physician or manufacturing company, may recover direct costs associated with providing the patient with access to the drug.⁷⁹ In an intermediate sized expanded access case, where there are several patients, the physician or manufacturing company may recover the cost of making the drug available and the cost of monitoring the access IND and complying with the reporting requirements which are more extensive than in the case of individual patient access.⁸⁰ The FDA does not regulate who may be charged, nor can it mandate that health insurance providers, whether private or public, include coverage for experimental drug access.⁸¹

⁷³ See FDA, Emergency IND Application, Form 1571, available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNew-DrugINDApplication/ucm071098.html> (the Emergency IND application is silent as to liability of both the physician and the drug manufacturer).

⁷⁴ See FDA, Emergency IND Application Timeline, available at: <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/UCM343024.pdf>.

⁷⁵ See 21 C.F.R. § 312.8 (a) (2015).

⁷⁶ See 21 C.F.R. § 312.8 (d)(3) (2015).

⁷⁷ See 21 C.F.R. § 312.8 (c)(3).

⁷⁸ See 21 C.F.R. § 312.8 (c)(4).

⁷⁹ See 21 C.F.R. § 312.8 (d)(1)(i) (2015).

⁸⁰ See 21 C.F.R. § 312.8 (d)(2).

⁸¹ See *Charging for Investigational Drugs Under an IND- Qs & As*, Guidance for Industry, U.S. DEP'T. OF HEALTH & HUMAN SERVS., May 2013, available at: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351264.pdf> (last visited June 20, 2015).

Although many aspects of the Affordable Care Act of 2010 are still making their way through the courts, the language of the act appears to preclude coverage of experimental drugs. Fueled by the agenda of providing affordable health care to many, the act requires all insurance policies to provide “essential health benefits” in order to be sold in the United States health insurance marketplace. These essential health benefits to include service in:

ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.⁸²

None of the definitions of the individual “essential health benefits” enumerate “experimental drug access” as an included service.⁸³ Critics have hypothesized that the act will freeze the advances of experimental drugs by requiring drug manufacturers to provide approved drugs at much lower rates, thereby decreasing revenue needed for research and development. Critics argue that the act misses the forest for the trees by achieving its immediate goal of setting lower prices for drugs, but does so to the “disadvantage of new medications.”⁸⁴

IV. THE RIGHT TO TRY DEBATE

While the FDA provides two well established paths to access experimental drugs, the advocates of the Right to Try contend that the FDA’s process takes too long. A press release from May 2014 noted “patient advocates . . . are frustrated by the years long federal approval process for experimental drugs in the pipeline.”⁸⁵ Other criticisms of the FDA process are that the FDA provides disparate access to treatment use without explaining the rationale for granting the exemptions.⁸⁶

⁸² See HEALTHCARE.GOV, *Essential Health Benefits*, available at <https://www.healthcare.gov/glossary/essential-health-benefits/> (last visited June 20, 2015).

⁸³ *Id.*

⁸⁴ See Paul Roderick Gregory, *Obama Care Will End Drug Advances and Europe’s Free Ride (Unless China Steps in)*, FORBES, July 1, 2012, available at <http://www.forbes.com/sites/paulroderickgregory/2012/07/01/obama-care-will-end-drug-advances-and-europes-free-ride-unless-china-steps-in/> (last visited June 20, 2015).

⁸⁵ See *Right to Try*, *supra* note 4.

⁸⁶ See Leibfarth, *supra* note 31, at 1308 (quoting Expanded Access to Investigational New Drugs for Treatment Use, 71 Fed. Reg. at 75151).

Three U.S. Senators – Lamar Alexander (Republican-Tennessee), Tom Coburn, M.D. (Republican-Oklahoma), and Richard Burr (Republican-North Carolina) – formally requested details about the FDA’s compassionate use program on June 16, 2014, and allotted thirty days for the FDA to respond. While Senator Burr’s office indicated that the FDA has issued a response, it has not yet been disclosed as of the date of this publication. The senators inquired into how access was granted and how the FDA planned to better facilitate individual patient expanded access.⁸⁷ However, the FDA has issued draft guidance on the compassionate use program.⁸⁸

Amidst the national debate, several states are taking initiatives and passing legislation to expand access to experimental drugs. The Right to Try laws proposed thus far generally set forth a process analogous to the FDA’s expanded access program, but strip away safety precautions and regulations imposed by the FDA to protect patients. The state laws offer access to the same drugs, drugs having passed phase one of the FDA approval process, without a guaranteed lower price or faster access rate. The state laws do not require review of patient information or the patient’s consent, although many states require that consent be given in the presence of a witness.⁸⁹ Instead, the decision whether to grant access by way of a prescription resides entirely with a single physician.

The FDA does not support the efforts in the states. Richard Klein, M.D., who works with the FDA Patient Liaison Program, commented that the FDA pathway:

Seems to work quite well, and [he is] not sure what the state right to try bills really add to that—and in fact I think they might take away some of those safety advantages people have by going through the FDA process where you’ve got Institutional Review Boards, you’ve got somebody checking the informed consent, make sure the patients are fully aware of what they’re getting into, and what’s the balance that we know so far about this particular product.⁹⁰

⁸⁷ See Liz Wolgemuth, *Senators Ask FDA about Expanded Access Program in Response to Patient Concerns*, U.S. S. COMM. ON HEALTH, EDUC., LABOR, & PENSIONS, June 18, 2014, available at <http://www.help.senate.gov/newsroom/press/release/?id=ea9346fb-fa3d-47bd-9c09-5b2893960e7f> (last visited June 20, 2015).

⁸⁸ See Alexander Gaffney, *From 100 Hours to 1: FDA Dramatically Simplifies its Compassionate Use Process*, REG. AFF. PROFS. SOC’Y, (Feb. 4, 2015), <http://www.raps.org/Regulatory-Focus/News/2015/02/04/21243/From-100-Hours-to-1-FDA-Dramatically-Simplifies-its-Compassionate-Use-Process/> (last visited June 20, 2015).

⁸⁹ See, e.g., COLO. REV. STAT. § 25-45-103 (4) (2015).

⁹⁰ PBS NEWSHOUR, *Transcript of “‘Right to try’ law gives terminal patients access to drugs not approved by FDA”* (June 21, 2014), <http://www.pbs.org/newshour/bb/right-try-law-gives-terminal-patients-access-non-fda-approved-drugs/> (interviewing Kristina Brogan, a terminally ill patient from Missouri).

In the same vein, another FDA representative feared such legislation would undermine “congressionally-mandated authority and agency mission to protect the public from therapies that are not safe and effective.” Similarly, bioethicist Arthur Caplan of NYU Langone-Medical Center remarked that the Right to Try laws are “well-intentioned,” but “federal regulation is still necessary to ensure patients are aware of risks.”⁹¹

Despite the expressed concern from the FDA and individuals within the medical community, there has not been any mention of preemption from opponents. As it stands, the state laws that are passed offer a parallel path to access that aims to achieve the same end, yet the laws circumvent federal law by shifting the final say from the FDA to independent patients and their doctors. The current state Right to Try laws follow the federally prescribed path inasmuch as they provide access to experimental drugs that have already passed through phase one of the FDA approval process.

A. Colorado

Introduced by a Democratic General Assembly and signed by a Democratic governor, Colorado’s Right to Try bill became law on May 17, 2014.⁹² Fueled by the story of Nick Auden, a Colorado patient, advocates in Colorado fought to expand access to experimental drugs by cutting the FDA application requirement out of the process. Advocates have promoted the law as a “ray of hope for dying patients trying to navigate the red tape of existing ‘compassionate use’ guidelines for obtaining drugs outside clinical trial,” and even call the law the “Dallas Buyers Club” bill, harkening back to the film that portrayed a journey to expand access to experimental drugs.⁹³ Advocates presented the law as a shortcut to experimental drugs that leaves the right to try experimental drugs in the hands of the patients, rather than a governmental agency. Further, advocates contended that the law would secure and protect the fundamental right to attempt to pursue preservation of a patient’s own life. While many oppose the bill calling it nothing more than a “feel good campaign that won’t help dying patients,” Colorado doctors’ groups, hospitals, and health insurers declined to comment on the law.⁹⁴

The Colorado statute grants access to experimental drugs, or those that have passed phase one of the FDA drug approval process for patients diagnosed with a terminal illness. The law defines terminal illness as “a disease that, without life-sustaining procedures, will *soon* result in death or a state of permanent unconsciousness from which recovery is unlikely.”⁹⁵

⁹¹ *Id.*

⁹² See ‘Right to Try’: States Move to Expand Access to Experimental Drugs, NBC NEWS, ASSOCIATED PRESS, May 18, 2014, available at <http://www.nbcnews.com/health/health-news/right-try-states-move-expand-access-experimental-drugs-n108316> (last visited June 20, 2015).

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ COLO. REV. STAT. § 25-45-103 (3) (2015) (emphasis added).

While the law does not require a sponsor to apply for authorization to use the drug or an IRB approval, it sets forth a few parameters for access. The law requires patients applying for access to provide proof that they have been unable to participate in a clinical trial for their terminal illness within one hundred miles of their home address. It also requires a recommendation from a physician and informed consent signed in the presence of a physician and a witness.⁹⁶ The informed consent requirement seems to serve the same purpose as the IRB review in the FDA process as it ensures that the patient is aware of all possible outcomes, including the risk of unknown side effects. Additionally, the law does not require insurance providers to extend coverage to experimental drugs.

The law also contains a provision shielding physicians and any party involved in the chain of distribution of the experimental drugs, including the manufacturers, from liability within the state unless harm results from a failure to use reasonable care.⁹⁷ Further, the act only protects physicians and manufacturers from liability on a state-level and if they demonstrate good faith compliance with the act's other provisions. Although this law offers a shield from state liability, it proves porous under federal law.

The Colorado law represents a watered-down version of the FDA expanded access program, but with less regulation and a less inclusive class of potential recipients of experimental drugs. Both the FDA and the Colorado law provide access to the same drugs—drugs that have passed through phase one of the FDA process. Thus, the law does not entirely obviate FDA regulation. While the bill removes the FDA's role as regulator, it fails to provide guaranteed access to experimental drugs as the Colorado legislature cannot force drug manufacturers to provide drugs. In fact, the law specifically provides that it does not require a manufacturer to make experimental drugs available.⁹⁸ Under this law, a patient receives authorization from an individual doctor and then asks the drug manufacturer for access. Although the law requires a relatively high standard for proving informed consent, it strips all other safety measures, such as IRB review, by excluding the FDA.

Additionally, the class of patients to which this bill offers access is much more limited than the class to which the FDA's expanded access program provides access.⁹⁹ The Colorado law would exclude someone who is rapidly losing eye-sight or suffering from other serious conditions that are not likely to cause immediate death.¹⁰⁰ Not only is the law under-inclusive,

⁹⁶ COLO. REV. STAT. § 25-45-103 (4).

⁹⁷ COLO. REV. STAT. § 25-45-107.

⁹⁸ COLO. REV. STAT. § 25-45-105.

⁹⁹ Compare 21 C.F.R. § 312.300(b) ("serious or immediately life-threatening disease or condition") with COLO. REV. STAT. § 25-45-103(3).

¹⁰⁰ Arthur Caplan, *Bioethicist: 'Right to Try' Law More Cruel Than Compassionate*, NBC NEWS, May 18, 2014, available at <http://www.nbcnews.com/health/health-news/bioethicist-right-try-law-more-cruel-compassionate-n108686> (last visited June 20, 2015).

it also runs the risk of becoming over-inclusive as well, as it allows independent parties, generally physicians, to determine which patients are “terminally ill” without any government oversight. Allowing for subjective determinations of who qualifies for access can lead to inconsistent application and may result in one physician granting access to patients with certain illnesses in some cases and another physician denying access to people with the same illnesses. Granting broad discretion invites forum shopping and physician misconduct. For instance, if one physician is known for liberally diagnosing patients with terminal illness so that they may qualify for access to experimental drugs, patients from other jurisdictions might flock to the area in which the physician practices. A low supply of experimental drugs and high demand coupled with the lack of a statutory cap on what sponsors, physicians or manufacturers, can charge may lead to price gouging.

The law is silent as to what drug manufacturers can charge patients for the experimental drugs, unlike the FDA which requires sponsors to apply for authorization to charge, and limits the costs for which sponsors can recover. It provides that a drug manufacturer may offer the drugs free of charge or it may require a patient to pay the costs associated with manufacturing the drug. Although the law is well-intentioned, it fails to make up for the holes in the FDA’s expanded access process.

B. *Louisiana*

Louisiana’s Right to Try law was signed on May 30, 2014 and very closely mirrors that of Colorado, although it was passed by a Republican legislature and signed by a Republican governor. Fueled by the same impetus as Colorado, Louisiana advocates espoused a bill that is nearly identical to Colorado’s in that it provides drugs that have passed phase one, and shields physicians from liability and forfeiture of their medical licenses. The law, however, differs from the Colorado statute in a few respects.

First, it defines an eligible patient as someone who has been diagnosed with a terminal illness by two doctors. Next, it defines terminal illness as a “disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely,” as opposed to the Colorado law that requires death be “soon.”¹⁰¹ Further, the law calls on physicians to carry out a probable risk analysis to confirm that the risk is not greater than the risk associated with the patient’s disease.¹⁰² Next, it only offers protection from civil liability to physicians who prescribe experimental drugs, and not the manufacturers.¹⁰³ The law shields the physicians from any civil liability on a state level for any adverse side effects from the experimental drug. There is no exception for negligence, i.e., failure to use reasonable care, nor is there any indication that the liability shield extends to manufacturers.

¹⁰¹ Compare LA. STAT. ANN. § 1300.383(3) (2015) with COLO. REV. STAT. § 25-45-103(3) (2015).

¹⁰² LA. STAT. ANN. § 1300.383(1)(b).

¹⁰³ *Id.* § 1300.385.

Although this law uses language that qualifies the class of potential recipients, it still fails to compel drug companies to supply the drugs once access is granted and, as such, fails to provide a guaranteed fast route to access.¹⁰⁴ Further, it does not limit the fees that drug manufacturers can charge for the experimental drugs, but provides that they may charge for the costs associated with manufacturing the drug.¹⁰⁵ Just like the Colorado law, the Louisiana statute's definition of the class of patients to which drugs may be provided excludes too many forms of illness and includes too many patients by allowing an independent, non-governmental party to choose subjectively which patients may have access.

C. *Missouri*

Missouri's Right to Try law was passed by its General Assembly, controlled by Republicans, and signed into law by a Democratic governor on July 14, 2014.¹⁰⁶ Comparable to Colorado, Missouri also has a local cause that is motivating its advocates to push for expanded access. One of the most vocal advocates is physician and former Missouri representative, Jim Neely, who is also a stepfather to Kristina Brogan, a Missouri resident diagnosed with stage four colorectal cancer.¹⁰⁷ For Neely, and many others, the Right to Try debate is deeply personal.

The Missouri bill is almost identical to the Louisiana law. It defines a terminally ill patient as someone who will die in the near future.¹⁰⁸ It also provides access to FDA-phase-one-drugs and protects physicians and drug manufacturers from liability in the process, except from harm caused as a result of gross negligence or willful misconduct.¹⁰⁹ Here, the law is closer to that of Colorado's in that it offers protection from civil liability to physicians and other parties involved in the manufacturing, importation, distribution, and administering of the drug, i.e., pharmaceutical manufacturers. Like the Colorado law, the Missouri law serves as a shield to civil liability from harm produced by the drug except in cases of gross negligence or willful misconduct.¹¹⁰ In this regard, this law allows for more protection than Colorado's, which allowed piercing of the liability shield where reasonable care was not used, (in other words, it allowed for simple negligence claims).

¹⁰⁴ *Id.* § 1300.384(A)(2) (“nothing in this Section shall be construed to require a manufacturer to make available any drug, product, or device.”).

¹⁰⁵ *Id.* § 1300.384(B)(2).

¹⁰⁶ *See Missouri becomes third state to enact 'Right to Try' Drug law*, KBIA, July 18, 2014, available at <http://kbia.org/post/missouri-becomes-third-state-enact-right-try-drug-law> (last visited June 20, 2015).

¹⁰⁷ *Id.*

¹⁰⁸ MO. ANN. STAT. § 191.480.1(3) (2015).

¹⁰⁹ *Id.* § 191.480.8.2 (2).

¹¹⁰ *Id.*

The Missouri law also allows manufacturers to charge patients the costs associated with the manufacturing of the drug without setting forth any other requirements.¹¹¹ Additionally, the statute requires physicians and pharmaceutical companies to notify patients who are outside clinical trials, but who have taken drugs currently being used in a clinical trial, if drugs that have passed phase one may no longer be used due to lack of efficacy or toxicity.¹¹²

D. *Arizona*

In Arizona, where both the governor and the state legislature are Republican, the citizens voted for and approved a Right to Try law by referendum on November 4, 2014.¹¹³ The law mostly follows the models of the other state Right to Try laws. The Arizona bill, however, aims to promote the success of expanded access by making it a misdemeanor for any state agent to block a patient's access to experimental drugs if authorized by his physician.¹¹⁴ Also differing from the other states' laws, this legislation allows drug manufacturers to compel patients to participate in data collections.¹¹⁵ Unlike the other state laws, the Arizona law is silent as to liability immunity for both physicians and manufacturers. Thus, in Arizona, both physicians and manufacturers could be vulnerable to civil liability as the law is currently drafted.

E. *Michigan*

Similar to Arizona, a Republican Governor signed the state's Right to Try legislation into law on October 15, 2014.¹¹⁶ Unlike the four other state laws, Michigan's law defines a somewhat broader scope of eligible patients. It utilizes the term "advanced illness," rather than terminal and, thus, allows for more patients to qualify for the access.¹¹⁷ The definition, however, still requires that the illness, without treatment, would soon result in death resulting in a still more limited class of eligible patients than allowed under the FDA definition. The law mirrors the other laws as to liability and informed consent provisions.

¹¹¹ *Id.* § 191.480.8.

¹¹² *Id.* § 191.480.7.

¹¹³ See BALLOTPEdia, *Arizona Terminal Patients' Right to Try Referendum, Proposition 303 (2014)*, [http://ballotpedia.org/Arizona_Terminal_Patients'_Right_to_Try_Referendum,_Proposition_303_\(2014\)](http://ballotpedia.org/Arizona_Terminal_Patients'_Right_to_Try_Referendum,_Proposition_303_(2014)) (last visited June 20, 2015).

¹¹⁴ See ARIZ. REV. STAT. ANN. § 36-1314 (2015).

¹¹⁵ *Id.* § 36-1312(B)(3).

¹¹⁶ See Nick Gillespie, *Michigan Gov. Rick Snyder Signs "Right to Try" Law; a Win for Patient Rights*, REASON.COM HIT & RUN BLOG (Oct. 21, 2014 10:59 AM), <http://reason.com/blog/2014/10/21/michigan-gov-rick-snyder-signs-right-to> (last visited June 20, 2015).

¹¹⁷ See MICH. COMP. LAWS ANN. § 333.26451 Sec. 1 (2)(a) ("Advanced illness, for purposes of this section only, means a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with administration of current federal drug administration approved and available treatments, and that, without life-sustaining procedures, will soon result in death").

F. *Proposed U.S. Law: Compassionate Freedom of Choice Act of 2014*

Although the United States Supreme Court declined to consider whether patients have a fundamental right to access experimental drugs, there is a movement in the U.S. Congress pushing for the Right to Try.¹¹⁸ The pending bill, proposed by a U.S. Representative from Virginia, seeks to amend the FDCA so that its provisions do not prevent terminally ill patients from accessing investigational drugs. Further, the bill would “allow for the manufacture, importation, distribution, and sale of investigational drugs and devices intended for use by terminally ill patients who execute an informed consent document.”¹¹⁹ The bill was referred to the Committee on Energy and Commerce on April 11, 2014 and is still pending approval.

Generally, the bill is very similar to the previously discussed state laws in that it provides access to experimental drugs by patients diagnosed with terminal illness. It goes further than the other laws by prohibiting the FDA from requiring physician disclosure and reporting.¹²⁰ The bill also prohibits the FDA from requiring drug companies that grant access to investigational drugs and devices, to disclose, collect, or report information relating to the process or results.¹²¹ It does not, however, prevent patients who receive the drugs from reporting information to the FDA.¹²²

Similar to many of the other states’ laws, the proposed federal law would also limit liability for “any person who manufactures, imports, distributes, prescribes, dispenses, or administers an investigational drug or device.” Thus, similar to Colorado and Missouri, this law would shield both physicians and manufacturers from both state and federal liability from any harm related to the drug except in cases of negligence, gross negligence, or willful misconduct.¹²³

¹¹⁸ See *Right to Try*, *supra* note 4.

¹¹⁹ See Compassionate Freedom of Choice Act of 2014, H.R. 4475, 113th Cong. (2014) (The proposed bill defines “investigational drug” as one that (d) (1) has not yet been approved, licensed, or cleared for commercial distribution under section 505, 510 (k), or 515 of this Act [FDCA] or section 351 of the Public Health Service Act, and cannot otherwise be lawfully marketed in the United States; and (2) is or has been the subject of one or more clinical trials;” “informed consent” requires execution of a document that states (3)(A) the known and potential risks and benefits of such drug or device; and (B) any indications of the illness for which a drug or device is lawfully marketed, or for which treatment is otherwise available, in the United States.).

¹²⁰ *Id.* § 561A(c).

¹²¹ *Id.* § 561A(c)(1)(A)-(B).

¹²² *Id.* § 561A(c)(2).

¹²³ *Id.* § 561B(1)-(2).

G. *Proposed U.S. Law: The 21st Century Cures Act*

As of July 10, 2015, the U.S. House of Representatives has approved H.R. 6, the 21st Century Cures Act, by a vote of 344-77.¹²⁴ The purpose of this nonpartisan act is to provide funding to improve medical treatment, and clinical trials, to provide advanced and faster cures to more patients.¹²⁵ The Act will next go to the U.S. Senate for approval.¹²⁶ This Act will not preempt state Right to Try laws.¹²⁷ In fact, the Cures Act will make it easier to access drugs for chronically ill patients; this includes “fast-tracked drugs, . . . novel or breakthrough therapies and qualified infectious disease products, such as chemotherapies and antibiotics.”¹²⁸

V.

ADVOCATES OF THE RIGHT TO TRY

Proponents of the Right to Try present arguments rooted in ethical considerations, efficiency advantages, and constitutional arguments. Although state legislatures and courts have accepted many of the arguments, the Supreme Court has declined to consider whether there is a right to access experimental drugs.

A. *The Right to Try Offers Dying Patients One Last Fighting Chance*

What do the terminally ill have to lose? This is the argument advocates espouse as they fight for expanded access. Access to experimental drugs offers a “new hope to dying patients.”¹²⁹ Frank Burroughs, father to a victim of an untreatable terminal illness, reasoned that, “The risk-benefit is much different than someone who’s waiting for a new allergy medication or a new toe fungus cream.”¹³⁰ Instead, “experimental drugs pose little additional risk

¹²⁴ *House APPROVES 21st Century Cures Act*, U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE (July 10, 2015), <http://energycommerce.house.gov/press-release/house-approves-21st-century-cures-act#sthash.LyQL9MDY.dpuf>. See also MODDERN Cures Act of 2013, H.R. 3116, 113th Cong. (2014).

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ James C. Shehan, *Expansion of Expanded Access? Federal Right to Try Legislation is Introduced*, FDA LAW BLOG HYMAN, PHELPS & MCNAMARA PC, December 10, 2014.

¹²⁸ Lacie Glover, *How Proposed FDA Changes Could Affect You*, U.S. NEWS & WORLD REPORT, June 16, 2015, <http://health.usnews.com/health-news/health-wellness/articles/2015/06/16/how-proposed-fda-changes-could-affect-you>.

¹²⁹ Prince, *supra* note 1.

¹³⁰ Dennis & Cha, *supra* note 3.

to patients facing death, whereas the slightest possibility of improvement or cure provides a great benefit.”¹³¹ Advocates minimize the threat of unknown side effects, contending that, where patients are already expecting to die, they have nothing left to lose.

B. *The Right to Try Caters to the Immediate Needs of Dying Patients*

Advocates assert that expanded access via the FDA requires more time than most terminally patients can afford to wait. Breaking from the historical trend in which the American public supported FDA’s regulation of drugs, advocates for the Right to Try are more focused on access than the risks of the drugs.¹³² Many advocates criticize the FDA’s drug approval process by arguing that the current regulatory scheme would have withheld approval for drugs like penicillin and aspirin.¹³³ Moreover, advocates claim that the intensive review process is not only unnecessary for the population of patients involved in the Right to Try debate, but also detrimental to their health as it impedes consumer access.

Similarly, they find fault with the amount of paperwork required for the FDA’s expanded access program.¹³⁴ As a remedy to the long approval process and lengthy paperwork required for the exceptions to the approval process, advocates propose bypassing the FDA application process completely. They propose that deleting the middleman, i.e., the FDA, will allow a patient and his physician to interact with the drug company and achieve access at a much faster rate as there is no additional approval or review required. Instead, all that is needed is a prescription by the physician and agreement to provide the drug from the drug company.

Although proponents argue that removing the FDA application process will streamline a patient’s access to experimental drugs, no current laws passed or proposed contain provisions compelling drug companies to supply the drugs. Thus, there is still no remedy available to patients like Nick Auden who are denied access to experimental drugs by the drug companies.

C. *The Right to Try Experimental Drugs is a Fundamental Right Rooted in the Due Process Clause of the Constitution*

By drawing parallels to other recognized fundamental rights guaranteed by the due process clauses of the Fifth Amendment of the United States Constitution, advocates posit that the right to try potentially life-saving drugs is a fundamental right. This discussion refers to the Right to Try argument on a national level and, as such, involves the due process clause contained within the Fifth Amendment which concerns the federal government. The Fourteenth Amendment, however, contains a due process clause as well that pertains to the states. Framing the right to try as a fundamental right would afford more protection to the

¹³¹ Leibfarth, *supra* note 31, at 1288, *but see* Malinowski, 65 HASTINGS L.J. at 643 (noting that “the failure rate of new drug candidates in clinical trials exceeds ninety percent”).

¹³² Leibfarth, *supra* note 31, at 1286.

¹³³ *Id.*

¹³⁴ Dennis & Cha, *supra* note 3.

right to try efforts as it would require courts that review any laws regulating drug access to undergo a strict scrutiny analysis. In other words, the government or any entity that attempts to control access to experimental drugs will have to demonstrate that the regulation is narrowly tailored to achieve a compelling interest, which would impose a heavier burden on parties seeking to control access.¹³⁵

Despite attempts to establish the right to try as a fundamental right, as it stands, courts have not recognized such a right. Further, even if courts agreed that it were a fundamental right, there is evidence to indicate that the FDCA would still pass strict scrutiny as the act serves an irrefutably compelling interest, protecting consumers from unsafe drugs.¹³⁶ The advocates for expanded access in the Abigail Alliance litigation set forth many arguments analogizing the Right to Try to other due process rights.¹³⁷ The Court of Appeals for the District of Columbia, however, declined to recognize any such right. Applying the *Glucksberg* test to discern whether a right to try potentially life-saving drugs qualified as a fundamental right, the court determined that it did not because it could not be found in the nation's history or tradition.¹³⁸ Thus, the court could not conclude that the United States demonstrated a long-standing tradition of protecting such a right.¹³⁹ The Honorable Judith Rogers dissented from the majority's holding.¹⁴⁰ Framing the right to experimental drugs as a right to try to save one's life, Judge Rogers compared this right to the existing rights recognized by U.S. courts:

[I]t is startling that the oft-limited rights to marry, to fornicate, to have children, to control the education and upbringing of children, to perform varied sexual acts in private, and to control one's own body even if it results in one's own death or the death of a fetus have all been deemed fundamental rights covered, although not always protected, by the Due Process Clause, but the *right to try to save one's life* is left out in the cold despite its textual anchor in the right to life.¹⁴¹

¹³⁵ See *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 445 F. 3d 470, 486, (D.C. Cir. 2006), *rev'd en banc*, 95 F. 3d 695, 714 (D.C. Cir. 2007) (noting that where right warrants protection under the Due Process clause, the government must demonstrate its policy is narrowly tailored to serve a compelling governmental interest).

¹³⁶ Leibfarth, *supra* note 31, at 1295.

¹³⁷ See Malinowski, 65 HASTINGS L.J. at 629.

¹³⁸ *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F. 3d 695, 711 (D.C. Cir. 2007) (en banc); see also *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 445 F. 3d 470 (D.C. Cir. 2006), *rev'd en banc*, 495 F. 3d 695, 714 (D.C. Cir. 2007) (citing *Washington v. Glucksberg*, 521 U.S. 702, 710 (1997)) (The *Glucksberg* test requires (1) a careful description of the asserted liberty interest; (2) a long-standing tradition in the U.S. protecting said right; and (3) that the right is implicit in the concept of ordered liberty) (internal citations omitted).

¹³⁹ *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F. 3d 695, 711.

¹⁴⁰ *Abigail*, 495 F. 3d 695, 715 (Rogers, J., dissenting).

¹⁴¹ *Abigail*, 495 F. 3d at 715 (Rogers, J., dissenting) (emphasis added).

The Supreme Court denied certiorari and, therefore, left the Court of Appeals' ruling intact.¹⁴²

While the *Abigail* court declined to recognize the right to access potentially life-saving drugs as fundamental, there is still some judicial support.¹⁴³ Proponents have attempted to shoehorn the right to try into already established fundamental rights.¹⁴⁴ For example, alluding to *Roe v. Wade*,¹⁴⁵ advocates contend that the same recognized right to privacy should enable terminally ill patients the right to use potentially life-saving experimental drugs.¹⁴⁶ Advocates have also utilized the “right to decline life-saving treatment” by drawing an inverse conclusion. In other words, they argue that if there is a fundamental right or a liberty interest in choosing death by refusing treatment, so too must there be a fundamental right to choose the drug.”¹⁴⁷

VI.

OPPONENTS TO THE RIGHT TO TRY

A. *The FDA's Current Infrastructure Already Provides Two Paths to Experimental Drugs*

Opponents argue that in many cases, like that of Nick Auden in Colorado, the delay in access does not stem from the FDA application process, but instead the “hold-up” is the reluctance on the part of drug companies to issue the investigational drugs before they are thoroughly tested.¹⁴⁸ Drug companies may be hesitant to release unapproved drugs for a host of reasons, including “high costs, lack of adequate supplies and worries over liability.”¹⁴⁹ In the same way that the FDA lacks the power to compel drug companies to provide experimental drugs, so too do the states lack authority to compel.¹⁵⁰

¹⁴² Leibfarth, *supra* note 31, at 1293-94.

¹⁴³ *Abigail*, 495 F. 3d 695.

¹⁴⁴ *But see* Leibfarth, *supra* note 31, at 1300 (citing *Gonzalez v. Raich*, 545 U.S. 1, 9 (2005) (discussing how the U.S. Supreme Court has already declined to recognize a right to access experimental drugs when it denied the right to access medical marijuana in *Raich*).

¹⁴⁵ 410 U.S. 113 (1973).

¹⁴⁶ Leibfarth, *supra* note 31, at 1293.

¹⁴⁷ *Id.* at 1297.

¹⁴⁸ *Prince*, *supra* note 1.

¹⁴⁹ *Dennis & Cha*, *supra* note 4.

¹⁵⁰ *See* PBS NEWSHOUR, Transcript of “‘Right to try’ law gives terminal patients access to drugs not approved by FDA” (June 21, 2014), <http://www.pbs.org/newshour/bb/right-try-law-gives-terminal-patients-access-non-fda-approved-drugs/> (interviewing Kristina Brogan, a terminally ill patient from Missouri) (last visited June 20, 2015).

B. *State Regulation of Access Will Yield Inconsistent Results*

From the definition of “terminally ill” to the physician deciding to write a prescription, state regulation of the access to non-approved drugs will yield different and possibly arbitrary outcomes. Although the current Right to Try laws, as well as those still pending, all provide access to “terminally ill” patients, their definitions differ.¹⁵¹ For example, the Colorado law defines a terminal illness as “a disease that, without life-sustaining procedures will *soon* result in death or a state of permanent unconsciousness from which recovery is unlikely.”¹⁵² Upon a prognosis that an individual will “soon” die or suffer a permanent state of unconsciousness, a Colorado physician may unilaterally decide to grant a patient access. In contrast, the Louisiana law defines terminal illness a little differently as “a disease that, without life-sustaining procedures, will result in death *in the near future* or a state of permanent unconsciousness from which recover is unlikely. This diagnosis shall be confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty.”¹⁵³ Whether an individual will gain access to an experimental drug will turn on the physician’s interpretation of “in the near future,” just as in Colorado it will depend on how that physician unilaterally defines the term “soon.”¹⁵⁴

Further, in Louisiana, the patient’s fate also hangs on a second physician’s interpretation of the term as well. While “soon” and “in the near future” connote the same general meaning, there is no way to assure that physicians across state lines will interpret them the same. Allowing the outcome of such a critical decision to depend on individual physicians’ interpretations fails to serve the underlying cause of the Right to Try debate. Still, only some patients would be gaining access to these drugs. While Congress defers to the medical community, it did not intend for the regulation of access to be relegated to individual doctors entirely.¹⁵⁵ Such inconsistent results could incentivize forum shopping and could undermine the federal government’s purported attempt to protect the public by regulating access. Both states and federal governments would then have to address whether it is illegal for citizens to bring experimental drugs into a forum where they were not given such access. An FDA representative expressed that he feared state Right to Try laws would undermine “congressionally-mandated authority and [the] agency mission to protect the public.”¹⁵⁶

¹⁵¹ Compare LA. STAT. ANN. § 1300.383(3) (2015) with COLO. REV. STAT. § 25-45-103(3) (2015).

¹⁵² COLO. REV. STAT. § 25-45-103(3) (2015).

¹⁵³ LA. STAT. ANN. § 1300.383(3) (2015) (emphasis added).

¹⁵⁴ COLO. REV. STAT. § 25-45-103(3) (2015).

¹⁵⁵ Leibfarth, *supra* note 31, at 1298.

¹⁵⁶ Prince, *supra* note 1.

C. *State Regulation of Access May Lead to Higher Drug Prices*

Unlike states, the FDCA enabled the FDA to regulate who could charge fees, when they could charge fees, and for what costs sponsors could recover as fees.¹⁵⁷ No such provisions exist within the current and pending Right to Try state laws. Where there are inadequate regulations and requirements, the costs of access to experimental drugs might increase. Many opponents of the Right to Try laws have termed the laws “right to beg,” because (1) the laws do not compel drug companies to provide the drug, and (2) the drug companies may impose higher prices.¹⁵⁸

VII.

CONCLUSION

When the Supreme Court declined to consider whether ill patients had a fundamental right to access potentially life-saving non-approved drugs, it closed the door on the Right to Try argument only to leave a window open for the states to enter. Without federal guidance, states are taking the lead in proposing Right to Try legislation. The outcome of the state legislation is yet to be determined, but, until the federal government interjects, Right to Try advocates will continue to plead their case to state legislatures.

Frustrated with the amount of time the FDA’s expanded access program requires, advocates of the Right to Try urge removing the FDA completely from the equation. They argue that the decision to try an investigational drug should be between a patient and his or her physician and should not involve the government. In support of this argument, advocates assert that the Right to Try is a fundamental right rooted in the Constitution. Opponents to the Right to Try claim that the FDA’s current infrastructure already provides access to experimental drugs. Further, opponents assert that the FDA’s regulations may better guarantee a patient’s safety and produce more consistent outcomes in terms of who is granted access to experimental drugs. The application and implications of these new Right to Try laws are far from known, tested, or proven.

Despite the growing success of the Right to Try movement, the legislation does not appear to improve upon the FDA’s expanded use exemptions. Instead, the Right to Try legislation removes many safeguards without adding any guarantees that pharmaceutical companies will provide drugs. Moreover, the recent wave of Right to Try legislation amongst states reflects a well-intentioned effort to provide dying patients with “one last hope,”¹⁵⁹ but it is unlikely that these laws will provide a method more efficient than that already provided by the FDA.

¹⁵⁷ See *supra* Part B. (iii); see also *Charging for Investigational Drugs Under an IND- Qs & As*, Guidance for Industry, U.S. DEP’T. OF HEALTH AND HUMAN SERVS., May 2013, available at: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351264.pdf>.

¹⁵⁸ Caplan, *supra* note 100.

¹⁵⁹ See Prince, *supra* note 1.