

SAFEGUARDING THE RIGHT TO TRY

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I. INTRODUCTION

When Jenn McNary's son Austin was three and her son Max was just a newborn, both boys were diagnosed with Duchenne's Muscular Dystrophy—an incurable, fatal, degenerative muscle disorder. By the time Jenn learned of a promising treatment undergoing testing in clinical trials, Austin had declined so badly that he was restricted to a wheelchair. Jenn immediately tried to enroll both boys in the trial—only to learn that the trial was limited to ambulatory patients. That meant Max was eligible, but Austin's disease had progressed too far to qualify. Jenn was forced to watch while one son's condition improved significantly under treatment, and her other son's condition worsened until he could no longer dress or use the restroom without help. Thirteen-year-old Max became sixteen-year-old Austin's caregiver.¹

The United States' drug approval system is broken. It blocks Americans from potentially lifesaving medicines and treatments until those treatments receive final approval from the Food and Drug Administration (FDA). And it takes an average of fourteen years and \$1.4 billion for a drug to make its way through the clinical trial process and obtain FDA approval.² But this is

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1. DARCY OLSEN, *THE RIGHT TO TRY: HOW THE FEDERAL GOVERNMENT PREVENTS AMERICANS FROM GETTING THE LIFESAVING TREATMENTS THEY NEED* 30–34 (2015). After three years, the FDA allowed Austin into clinical trials. By then, his disease had progressed to the point that he was unable to regain the ability to walk. *Id.* at 261–62.

2. PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., *REPORT TO THE PRESIDENT ON PROPELLING INNOVATION IN DRUG DISCOVERY, DEVELOPMENT, AND EVALUATION* 13–14 (2012), <https://permanent.access.gpo.gov/gpo32081/pcast-fda-final.pdf>; Tufts Univ., *Cost to Develop and Win Marketing Approval for a New Drug is \$2.6 Billion*, TUFTS CTR. FOR THE STUDY OF DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study. Some organizations have disputed the Tufts estimate. The Federal Trade Commission estimated the cost at \$802 million for approval of a new drug. Jason Millman, *Does It Really Cost \$2.6 Billion to Develop a New Drug?*, WASH. POST (Nov. 18, 2014), <https://www.washingtonpost.com/news/wonk/wp/2014/11/18/does-it-really->

time that dying patients do not have. Patients like Austin and Max—and people like Jenn, who love them—are forced to suffer in limbo, with no say in their own destinies. All of this occurs despite the fact that one of the bedrock principles of medical ethics is *patient autonomy*: decisions about health care are ultimately for the patient to make.³

A new project, called Right to Try, aims to change this. Now law in thirty-seven states, Right to Try statutes protect the right of terminally ill patients to access medicine that has received basic safety approval from the FDA—and that is being given to patients in ongoing clinical trials—but that has not yet received final approval for sale.⁴ This Article looks at some of the legal and ethical implications of these laws, and of the cumbersome, “consistently overconservative,”⁵ and sometimes life-destroying bureaucratic process by which the FDA restricts access to treatments patients need.

II. THE LABYRINTH

At their inception, federal drug regulations focused on ensuring that products marketed to the public at large were safe and correctly labeled,⁶ so that patients had truthful information to make informed decisions about the medicines they were going to take. The law did not require manufacturers to submit information to the FDA as a prerequisite to marketing.⁷ Then, in 1938, Congress passed the Federal Food, Drug, and Cosmetic Act,⁸ requiring manufacturers to prove that a drug was safe *before* marketing.⁹ Still, the law did not require federal evaluation of *efficacy*, only of safety.

cost-2-6-billion-to-develop-a-new-drug/. A 2011 survey of spending by the nation’s twelve leading pharmaceutical companies put the number at \$5.8 billion per drug. See Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/>; see also Avik Roy, *Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials*, MANHATTAN INST. (Apr. 24, 2012), <https://www.manhattan-institute.org/html/stifling-new-cures-true-cost-lengthy-clinical-drug-trials-6013.html>.

3. See, e.g., JANE RUNZHEIMER & LINDA JOHNSON LARSEN, *MEDICAL ETHICS FOR DUMMIES* 138 (2011).

4. *Why We Need Right to Try*, RIGHTTOTRY, <http://righttotry.org/about-right-to-try/> (last visited February 9, 2017).

5. Alexander Volokh, *Clinical Trials: Beating the FDA in Court*, REASON, May 1995, <http://reason.com/archives/1995/05/01/clinical-trials>.

6. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768.

7. Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER MAG., Jan.–Feb. 2006, <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/>.

8. 21 U.S.C. § 301 (2012).

9. Meadows, *supra* note 7.

Gradually, however, federal law shifted from a focus on empowering patients, to a more paternalistic approach—one that in practice is often preoccupied with erecting roadblocks. This reached fruition in the 1962 Kefauver-Harris Drug Amendments to the Federal Food, Drug, and Cosmetic Act,¹⁰ which required manufacturers to “provide substantial evidence of effectiveness for the product’s intended use.”¹¹ These amendments were passed in reaction to the infamous incident involving Thalidomide, a sleep aid sometimes prescribed to pregnant women as a treatment for morning sickness, but was found to cause birth defects.¹² The Kefauver-Harris Act imposed new rules for preapproval of medicines, including new standards for investigating new drugs for both safety and efficacy.¹³

Yet that Act was not matched to the concerns raised by the Thalidomide incident. Thalidomide was a safety problem, not an efficacy problem, and Thalidomide had not been approved in the U.S. due to lingering safety concerns.¹⁴ Only seventeen of the more than 10,000 worldwide cases of children Thalidomide-related birth defects occurred in the U.S.,¹⁵ and American consumers had been protected under the safety rules that were already on the books.

Nevertheless, thanks to the 1962 Amendments, today’s FDA tests are not just for safety, but also for efficacy.¹⁶ And these two things—though often linked—are quite different, both scientifically and ethically. Nobody wants to take an unsafe medicine, but many patients are willing to try one that has not yet been proven to work.

It is not even entirely true that nobody wants to take *unsafe* drugs. Chemotherapy, after all, is not *safe*, in the sense that it is, technically, poison.¹⁷ Even acetaminophen kills more than 400 people per year.¹⁸ In at least five states, terminal patients now have the option of ending their lives

10. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

11. Meadows, *supra* note 7.

12. Matthew R. Madara, *Constitutional Law—Sacrificing the Good of the Few for the Good of the Many: Denying the Terminally Ill Access to Experimental Medication*, 31 W. NEW ENG. L. REV. 535, 560 (2009).

13. *Id.*

14. *Id.*

15. Linda Bren, *Frances Oldham Kelsey: FDA Medical Reviewer Leaves Her Mark on History*, FDA CONSUMER MAG., Mar.–Apr. 2001, https://web.archive.org/web/20090512235601/http://www.fda.gov/fdac/features/2001/201_kelsey.html.

16. 21 U.S.C. § 355(d) (2012) (requiring both safety and efficacy for drug approval).

17. See SIDDHARTHA MUKHERJEE, *THE EMPEROR OF ALL MALADIES: A BIOGRAPHY OF CANCER* 143 (2010) (“[C]hemotherapy [is] poison even at the correct dose.”).

18. See generally W.M. Lee, *Acetaminophen and the U.S. Acute Liver Failure Study Group: Lowering the Risks of Hepatic Failure*, 40 HEPATOLOGY 6 (2004).

with a physician's help, if they choose.¹⁹ The fact that these patients have the right to *end* their lives, but *not* to take medicines that might *cure* them or alleviate their suffering, is just one of the many tragic paradoxes of our overly bureaucratic drug-regulation system.

Another is the fact that, while the FDA bars patients from taking medicines that have proven safe but have not yet received final approval for sale for treatment for a particular condition, patients *may* take approved drugs for so-called "off-label" uses.²⁰ Off-label refers to the use of medicines to treat conditions other than what the FDA approved that medicine to treat—for example, if a medicine is approved to treat a sleeping disorder, a doctor may prescribe it for Parkinson's Disease, even though the FDA has not evaluated it for treatment for that condition.²¹ Off-label prescriptions are entirely legal,²² and widespread,²³ despite the fact that they are prescriptions *without* proof of efficacy or even full knowledge of proper dosage. In fact, one in five prescriptions today are for "off-label" uses,²⁴ and Medicare even pays for them.²⁵

Thus, our system allows patients to take dangerous medicines, or medicines they expect will kill them, and, under the off-label rule, they may also take medicines that have received approval for safety but *not* efficacy. And in twenty-eight states, patients may even use marijuana with a doctor's prescription, despite the fact that it is a Schedule I prohibited substance under the Federal Controlled Substances Act.²⁶ Yet these same patients are, with

19. California, Oregon, Washington, Vermont, and Colorado have enacted statutes authorizing physician-assisted suicide. CAL. HEALTH & SAFETY CODE § 443 (West 2016); COLO. REV. STAT. § 25-48-103 (2016); OR. REV. STAT. § 127.800 (2016); VT. STAT. ANN. tit. 18, § 5282 (2016); WASH. REV. CODE § 70.245 (2016).

20. 21 U.S. Code § 396 (2012).

21. *Cf.* United States v. Caronia, 703 F.3d 149, 156 (2d Cir. 2012) (lawful to use drug approved for cataplexy and excessive daytime sleepiness for other conditions, including Parkinson's).

22. § 396.

23. James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize.").

24. Kelli Miller, *Off-Label Drug Use: What You Need to Know*, WEBMD, <http://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know> (last visited Mar. 13, 2017).

25. Reed Abelson & Andrew Pollack, *Medicare Widens Drugs It Accepts for Cancer*, N.Y. TIMES (Jan. 26, 2009), <http://www.nytimes.com/2009/01/27/health/27cancer.html?page-wanted=all>.

26. *See* 28 *Legal Medical Marijuana States and DC*, PROCON.ORG, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881> (last updated Mar. 2, 2017).

vanishingly few exceptions, barred from using medicines that have passed basic safety testing and are being administered to patients in FDA-approved clinical trials, but have not yet received final FDA approval for sale. This is the problem Right to Try was designed to fix.

The FDA evaluates potential drugs and treatments under a multi-step process that—after basic research and animal testing have been completed—consists of three phases, and sometimes more. To simplify what is often a complicated system, the first phase consists of basic safety evaluations in a clinical trial consisting of about 100 people.²⁷ Only about 70 percent of drugs pass this phase. The second phase, which can take up to two years, assesses efficacy in addition to safety, and involves about 100 to 300 people. Again, only about a third of medicines survive this stage. The third stage tests the drug against placebos as well as the currently available treatments, and these trials consist of 300 to 3,000 test subjects. These tests can take up to four years, and only about a quarter of drugs survive this round of testing. For some drugs, there is yet another phase of clinical trials.²⁸ Of course, in one sense the testing is never completed, because the FDA continues to monitor drugs for safety as long as they are available on the market, and sometimes withdraws them years after final approval.²⁹ As the FDA admits, “there is never 100% certainty when determining reasonable assurance of safety and effectiveness.”³⁰

Nevertheless, until the multi-stage testing process is completed—until the FDA approves a drug for sale—pharmaceutical manufacturers may not sell it, and doctors may not prescribe it. And because these stages of approval can

27. *The Drug Development Process: Clinical Research*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm#Clinical_Research_Phase_Studies (last visited Feb. 26, 2017) [hereinafter U.S. FOOD & DRUG ADMIN., *The Drug Development Process*].

28. CONG. BUDGET OFFICE, PUB. NO. 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 22–23 (2006), <https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf>; U.S. FOOD & DRUG ADMIN., *The Drug Development Process*, supra note 27.

29. For example, in 1997, the FDA removed fenfluramine from the market after reports associated it with heart conditions. It had been on the market for almost twenty-five years. *Questions and Answers About Withdrawal of Fenfluramine (Pondimin) and Dexfenfluramine (Redux)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm180078.htm> (last updated July 7, 2005).

30. See generally U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: FACTORS TO CONSIDER WHEN MAKING BENEFIT–RISK DETERMINATIONS IN MEDICAL DEVICE PREMARKET APPROVALS AND *DE NOVO* CLASSIFICATIONS (2016), <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm517504.pdf> [hereinafter U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF].

take so long, patients often find themselves blocked from using medicines that have not only passed basic safety but are currently being administered to other patients in Phase 3 or Phase 4 clinical trials. As a result, countless patients suffer and die unable to access medicines that could help them, and that the FDA considers safe enough to administer to those patients fortunate enough to be allowed into clinical trials. People like Jenn McNary and her sons are thus reduced to the helplessness of knowing that a promising and safe treatment is available—but out of reach, because it is sitting on a bureaucrat’s desk.

This deadly delay is a consequence of the FDA’s risk-averse culture, which drives the Agency to focus on preventing unsafe or ineffective drugs from getting to market.³¹ But the FDA “has little incentive to avoid the ‘unseen’ error of blocking new medicines that could ease the suffering of millions of people.”³²

Recognizing the inhumanity³³ of this system, the FDA has made exceptions to its own rules. Under the so-called “compassionate use” or Expanded Access program, some people *can* obtain pre-approval access to medications outside of a clinical trial.³⁴ But these exceptions are applied inequitably, on a case-by-case basis, and the process is extremely cumbersome and time-consuming.³⁵ The paperwork required to seek Expanded Access can take 100 hours to complete³⁶ and requires doctors to obtain information that is often inaccessible, such as technical or proprietary

31. See Henry I. Miller & David R. Henderson, *The FDA’s Risky Risk-Aversion*, HOOVER INST. (Oct. 2, 2007), <http://www.hoover.org/research/fdas-risky-risk-aversion>.

32. AVIK S. A. ROY, MANHATTAN INST., *STIFLING NEW CURES: THE TRUE COST OF LENGTHY CLINICAL DRUG TRIALS* 11 (2012), http://www.manhattan-institute.org/pdf/fda_05.pdf.

33. “Inhumanity” is not too strong a word for it. That, after all, is the very reason the FDA labels its exception “compassionate.”

34. See generally MARK FLATTEN, GOLDWATER INST., *DEAD ON ARRIVAL: FEDERAL “COMPASSIONATE USE” LEAVES LITTLE HOPE FOR DYING PATIENTS* (2016), <http://righttotry.org/dead-on-arrival/>.

35. See generally *id.*

36. Alexander Gaffney, *From 100 Hours to 1: FDA Dramatically Simplifies Its Compassionate Use Process*, REGULATORY AFFAIRS PROF’L SOC’Y: REGULATORY FOCUS BLOG (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/>. The FDA disputes that it takes 100 hours to fill out the application, even though that estimate is published on the form itself and there is nothing on the form or in the agency’s instructions directing doctors to leave any fields blank. See Zachary Brennan, *FDA Officially Dispels ‘100 Hours’ Myth on Time It Takes to Fill Out Compassionate Use Form*, REGULATORY AFFAIRS PROF’L SOC’Y: REGULATORY FOCUS BLOG (May 17, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/05/17/24960/FDA-Officially-Dispels-%E2%80%99100-Hours-%E2%80%99-Myth-on-Time-it-Takes-to-Fill-Out-Compassionate-Use-Form/>.

data on the drug, which may not be available to the doctor.³⁷ And to administer the treatment under Expanded Access, the doctor must abide by burdensome protocols and data-reporting requirements, essentially making him responsible for overseeing (and often funding) a miniature clinical trial for a single patient.³⁸ Additionally, a separate committee at a hospital or medical clinic, called an Institutional Review Board (IRB), must weigh the ethical considerations associated with the patient's use of the treatment.³⁹ Because there are no requirements on how often IRBs must meet or how quickly they must respond to these requests, people in rural areas or without a major university hospital nearby can have few IRB options, which adds more time and delay to the process.⁴⁰ These and other complications mean that only about 1,200 patients per year are even able to submit compassionate use requests to the FDA⁴¹—even though over half a million Americans die annually of cancer alone.⁴² Expanded Access is so riddled with bureaucracy and delay that a patient's chances of obtaining potentially lifesaving treatment in time are practically negligible.

There is still another complication for Expanded Access applicants. Even those who can complete the paperwork and qualify must also receive approval from the drug company.⁴³ Nothing requires a pharmaceutical maker to agree to let a person into a clinical trial, and the system provides little incentive for them to do so.⁴⁴ Bad results recorded during treatment under Expanded Access, such as serious negative reactions to the treatment or patient deaths, must be reported to the FDA, and these can damage a company's chances of obtaining final FDA approval, and even destroy the company's financial viability.⁴⁵ Yet data showing that the treatment is successful is not counted in favor of the company.⁴⁶ Because new treatments for terminal illnesses are typically developed by small companies that lack

37. FLATTEN, *supra* note 34, at 9.

38. *Id.*

39. *Id.*

40. *Id.*

41. *See id.* at 5.

42. *See Cancer Facts & Figures 2015*, AM. CANCER SOC'Y, <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2015/index> (last visited Mar. 12, 2017).

43. FLATTEN, *supra* note 34, at 10.

44. *Id.*

45. *Id.* at 11.

46. *Id.* To be clear, patients who receive a "compassionate use" exception are not added to clinical trials; they're simply given the medicine. *Id.* This means they are not part of controlled experiments, and they may have other ailments that hasten their deaths or worsen their conditions. But if that patient experiences a negative outcome from the medicine, that fact can nevertheless be used against the company. *Id.*

the resources necessary for such high-risk philanthropy, the result is that cutting edge medicines are even farther from the reach of patients who need them.⁴⁷ As the Goldwater Institute’s Mark Flatten writes, Expanded Access is “a system of all risks and no rewards” for drug companies.⁴⁸

This regulatory labyrinth is not just a drain on innovation and opportunity. It also clashes with the principle of patient autonomy. Often, in the name of helping the patient, the system undermines individual choice and personal dignity, cedes deeply personal decisions to bureaucrats, and leaves patients to suffer.

III. A NEW WAY

A. *How Right to Try Works*

Decades of trying to change this system from within met with little success.⁴⁹ That changed when the Goldwater Institute took the movement to protect patient autonomy to the states. Now, two years later, over half of the States have passed “Right to Try” laws,⁵⁰ which protect the right of terminally ill patients to try to save their own lives with investigational medicines.

47. *Id.* at 2.

48. *Id.*

49. Frank Burroughs, who lost his daughter Abigail to cancer after she was unable to get access to an investigational drug, worked with members of Congress to introduce the Compassionate Access Act of 2005, but it never became law. OLSEN, *supra* note 1, at 166–68. For a more comprehensive overview of failed attempts to reform the FDA process, visit FDA L. BLOG, <http://www.fdalawblog.net/>.

50. *Right to Try in Your State*, RIGHT TO TRY, <http://righttotry.org/in-your-state/> (last visited Mar. 12, 2017) [hereinafter *Right to Try in Your State*, RIGHTTOTRY]. Thirty-seven states have enacted Right to Try laws: Alabama (ALA. CODE §§ 25-5D-1 to -10 (2016)); Arizona (ARIZ. REV. STAT. ANN. §§ 36-1311 to -1314 (2016)); Arkansas (ARK. CODE ANN. §§ 20-15-2101 to -2011 (2016)); California (CAL. HEALTH & SAFETY CODE §§ 111548, 111548.1–.5 (West 2017)); Colorado (COLO. REV. STAT. §§ 25-45-101 to -108 (2016)); Connecticut (2016 Conn. Acts 214 (Reg. Sess.)); Florida (FLA. STAT. § 499.0295 (2016)); Georgia (GA. CODE ANN. §§ 31-52-1 to -10 (2016)); Idaho (IDAHO CODE § 39-9304 (2016)); Illinois (410 ILL. COMP. STAT. 649 (2016)); Indiana (IND. CODE §§ 16-42-26-1 to -5 (2016)); Iowa (2017 Iowa Legis. Serv. 154 (West)); Kentucky (2017 Ky. Acts 423); Louisiana (LA. STAT. ANN. §§ 40:1169.1–.5 (2015)); Maine (ME. STAT. tit. 22, §§ 2671–2677 (2016)); Maryland (2017 Md. Laws ch. 771); Michigan (MICH. COMP. LAWS §§ 333.26451–26457 (2016)); Mississippi (MISS. CODE ANN. § 41-141-1 (2016)); Missouri (MO. REV. STAT. § 191.480 (2016)); Montana (MONT. CODE ANN. §§ 50-12-101 to -110 (2016)); Nevada (NEV. REV. STAT. § 454.690 (2016)); New Hampshire (N.H. REV. STAT. ANN. §§ 126-Z:1–.5 (2016)); North Carolina (N.C. GEN. STAT. § 90-325 (2016)); North Dakota (N.D. CENT. CODE §§ 23-48-01 to -05 (2016)); Ohio (OHIO ADMIN. CODE § 4729.89–91 (2017)); Oklahoma (OKLA. STAT. tit. 63, § 3091 (2016)); Oregon (OR. REV. STAT. §§ 127.800–.990); South Carolina

Right to Try laws are state laws that allow drug manufacturers to make drugs or medical devices available to eligible patients, and protect manufacturers from liability if a treatment does not work, so long as the company acts with reasonable care. These laws also shield doctors from recrimination if they prescribe investigational medicines, and they forbid state officials from trying to block a patient's access to an investigational treatment.⁵¹

In one sense, these laws represent conservative reform. They simply extend to all terminal patients the same option of trying investigational treatments that the FDA already allows to the fortunate few who are accepted into clinical trials or who are granted Expanded Access.⁵² Right to Try applies only to terminally ill patients and only to medicines that have passed the FDA's Phase 1 safety testing, and that are being administered to patients in FDA-approved clinical trials as part of the subsequent phases of testing.⁵³ If a treatment is withdrawn from FDA-approved clinical trials, it also becomes unavailable under Right to Try.⁵⁴ And if a treatment has not received initial safety approval, it is not eligible.⁵⁵

But in another sense, Right to Try represents a major change. The federal system bars dying patients from potentially lifesaving treatments unless they are willing and able to contribute to a science experiment on terms set by the FDA. Under that system, patients matter, not as individuals in their own right, but only if they contribute to bureaucratically approved testing protocols. Right to Try, by contrast, is premised on the principle that each person owns his or her own life. It respects the principle of medical autonomy—which is not just a cornerstone of medical ethics, but one of the basic principles of

(S.C. CODE ANN. §§ 44-137-10 to -70 (2016)); South Dakota (S.D. CODIFIED LAWS §§ 34-51-1 to -10 (2017)); Tennessee (TENN. CODE ANN. §§ 63-6-301 to -310 (2016)); Texas (TEX. HEALTH & SAFETY CODE ANN. §§ 489.051–.055 (West 2016)); Utah (UTAH CODE ANN. §§ 58-85-101 to -105 (West 2016)); Virginia (VA. CODE ANN. § 54.1-3442.3 (2016)); Washington (2017 Wash. Sess. Laws ch. 212); West Virginia (W. VA. CODE §§ 16-51-1 to -8 (2016)); Wyoming (WYO. STAT. ANN. §§ 35-7-1801 to -1806 (2016)).

51. Model Right to Try legislation is available at <http://scienceblogs.com/insolence/files/2014/10/GoldwaterInstituteRighttoTryModel.pdf>.

52. Of course, even those fortunate enough to be admitted into clinical trials risk being given a placebo instead of treatment. See Gary T. Chiodo et al., *Placebo-Controlled Trials: Good Science or Medical Neglect?*, 172 WEST J. MED. 271, 271 (2000) (questioning the ethics of using placebo controls in clinical research that involves patients who have an active disease for which there is an approved treatment).

53. See Goldwater Inst., *Model Right to Try Legislation*, SCI. BLOGS (last visited May 20, 2017), <http://scienceblogs.com/insolence/files/2014/10/GoldwaterInstituteRighttoTryModel.pdf>.

54. *Id.*

55. *Id.*

freedom guaranteed by state and federal constitutions.⁵⁶ It is unethical and unconstitutional for government to violate that right—especially when patients are facing certain death. In short, Right to Try reflects the belief that compassionate use should be the rule, not the exception, for terminal patients.⁵⁷

B. A Nationwide Movement

In April 2014, Colorado became the first state to adopt a Right to Try law. Just three years later, Right to Try has been adopted in thirty-seven states, each time with overwhelming bipartisan support in state legislatures.⁵⁸

This movement has been so successful that it has Washington, D.C.’s attention. As California’s Right to Try sponsor, Assemblyman Ian Calderon, told the *Sacramento Bee* in May 2015, “the only way you can get change from the FDA is pressure from the states.”⁵⁹ In June 2014, it inspired an investigation of the FDA’s compassionate use process by Senators Tom Coburn, Richard Burr, and Lamar Alexander, and the introduction of a bill in the House of Representatives to prevent the FDA from blocking implementation of any State Right to Try law.⁶⁰ In May 2016, the U.S. Senate held hearings on the issue of access to investigational drugs,⁶¹ and a Senate bill complementing the House proposal was introduced that same month.⁶²

In addition, because the Right to Try movement has exposed the difficulty—in practical effect, the impossibility—of obtaining a compassionate use exception, the FDA has been forced to acknowledge that its program is too cumbersome and slow. In April 2016, the Agency announced that it was establishing a new position it called a “compassionate use navigator”—meaning, a person who will guide patients through the

56. See discussion *infra* Part IV.

57. In some non-Right-to-Try states like Washington and Vermont, those with a terminal diagnosis can get drugs to end their lives but not to extend or save their lives. Christina White, Comment, *Physician Aid-In-Dying*, 53 HOUS. L. REV. 595, 610, 612 (2015). They can hasten their deaths but not hope for their lives.

58. *Right to Try in Your State*, RIGHTTOTRY, *supra* note 50.

59. Jeremy B. White, “*Right to Try*” Bills Would Let Dying Californians Use Experimental Drugs, SACRAMENTO BEE (May 22, 2015, 5:01 PM), <http://www.sacbee.com/news/politics-government/article21718809.html>.

60. Right to Try Act of 2015, H.R. 3012, 114th Cong. (2015).

61. *Connecting Patients to New and Potential Life Saving Treatments: Hearing Before the S. Comm. on Homeland Sec.*, 114th Cong. (2016).

62. Trickett Wendler Right to Try Act of 2016, S. 2912, 114th Cong. (2016).

FDA's elaborate application process.⁶³ *Regulatory Affairs* credited the Right to Try movement for this change.⁶⁴ Two months later, the FDA announced that it had streamlined its compassionate use process—nearly a year and a half after it had first publicized its intention to do so—purportedly reducing the paperwork burden of filing a compassionate use petition from 100 hours to 45 minutes.⁶⁵ After a quarter-century of FDA intransigence, this was significant progress, at least in the eyes of the *New York Times* and the *Wall Street Journal*, both of which took note of the announcement's importance. The *Times* called it a “breathtaking reduction of red tape.”⁶⁶ But the *Journal* was more insightful. “The decision to expedite access,” it noted, either “means the agency knows its processes are broken or is merely an act of bureaucratic realpolitik.”⁶⁷

These improvements are welcome—and are a clear indication that Right to Try has transformed the national conversation about the rights of patients. But shorter forms and hand-holding bureaucrats do not address the system's fundamental flaw—the rule that bars access to potentially life-saving medicines without a government permission slip.

Recently, there has been further evidence that the state-based Right to Try movement may drive sweeping federal reforms. In February 2017, Vice President Mike Pence, who as governor signed Indiana's Right to Try law, invited terminal patients and their families to the White House to talk about protecting terminal patients' medical autonomy rights.⁶⁸ Shortly after, Vice President Pence announced on Twitter that he and President Donald Trump

63. Zachary Brennan, *FDA's Nonprofit Arm Plots Out New Compassionate Use Navigator*, REGULATORY AFFAIRS PROF'L SOC'Y: REGULATORY FOCUS BLOG (Apr. 7, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/04/07/24721/FDA%E2%80%99s-Nonprofit-Arm-Plots-Out-New-Compassionate-Use-Navigator/>.

64. *Id.*

65. See Press Release, Robert Califf, FDA Commissioner, Statement on the Release of the Final Individual Patient Expanded Access Form (June 2, 2016), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm504579.htm>. The FDA took about fifteen months to finalize its streamlined form. *Id.* While the FDA's announcement is a step in the right direction, it is far from adequate. Patients must still beg the federal government for permission to try to save their own lives—they are just using a shorter form.

66. *Quicker Access to Experimental Drugs*, N.Y. TIMES (Feb. 12, 2015), http://www.nytimes.com/2015/02/12/opinion/quicker-access-to-experimental-drugs.html?_r=0.

67. *The Right-to-Try Revolt*, WALL ST. J. (Feb. 9, 2015, 7:16 PM), <http://www.wsj.com/articles/the-right-to-try-revolt-1423527365>.

68. Maureen Groppe, *Pence Encourages Boy in Fight for Experimental Drugs*, INDY STAR (Feb. 8, 2017), <http://www.indystar.com/story/news/politics/2017/02/08/pence-encourages-boy-fight-experimental-drugs/97652180/>.

support “restoring hope and giving terminally ill patients a fighting chance” with Right to Try.⁶⁹

In the meantime, State Right to Try laws are already saving lives. Within a year of his state’s enacting a Right to Try law, Houston-based oncologist Dr. Ebrahim Delpassand successfully treated seventy-eight terminally ill cancer patients using LU-177 (or Lutetium Dototate), a drug that had successfully completed its three phases of the FDA-approved clinical trials and that has been widely available in European countries for many years, yet it has still not received final FDA approval for sale.⁷⁰ As a result, it has only been available to a small number of Americans who can afford to travel overseas or happen to qualify for clinical trials.⁷¹

Dr. Delpassand administered a successful clinical trial for LU-177 therapy for five years.⁷² In 2015, after the final trial phase was completed, the FDA refused to allow Dr. Delpassand to treat additional patients until the drug received final agency approval.⁷³ But a few months later, Texas lawmakers adopted a Right to Try bill, giving patients a new avenue to access this safe and effective therapy.⁷⁴ Invoking his rights under the new law, Dr. Delpassand continued administering LU-177 to patients suffering from neuroendocrine cancer.⁷⁵ “Many of these patients were only given three to six months to live,” said Dr. Delpassand.⁷⁶ “Now, a year later, many of them are still alive.”⁷⁷

IV. RIGHT TO TRY’S CRITICS

A. Federal Law Is a Floor, Not a Ceiling

The most common criticism of Right to Try is a legal one: do states have constitutional authority to pass laws that appear to sidestep federal law and

69. Vice President Pence (@VP), TWITTER (Feb. 2, 2017, 5:02 PM), <https://twitter.com/VP/status/829133257061056512/photo/1>.

70. *Exploring a Right to Try for Terminally Ill Patients: Hearing before the S. Comm. on Homeland Sec. & Gov’t Affairs*, 114th Cong. (2016) (statement of Dr. Ebrahim Delpassand, Oncologist) [hereinafter *Exploring a Right to Try Hearing*], <http://www.hsgac.senate.gov/hearings/exploring-a-right-to-try-for-terminally-ill-patients>; see also OLSEN, *supra* note 1, at 93.

71. *Exploring a Right to Try Hearing*, *supra* note 70.

72. *Id.*

73. *Id.*

74. H.B. 21, 84th Leg., Reg. Sess. (Tex. 2015).

75. *Exploring a Right to Try Hearing*, *supra* note 70.

76. *Id.*; see also OLSEN, *supra* note 1, at 93.

77. *Exploring a Right to Try Hearing*, *supra* note 70.; see also OLSEN, *supra* note 1, at 93.

FDA policies? But the framing of this question reflects a critical misunderstanding. Right to Try legislation does not seek to nullify federal law but seeks to employ state law to protect individual rights.

Under our federalist system, the Federal Constitution provides a floor of protection for individual rights, not a ceiling, leaving states free to enact laws that protect those rights more broadly than the Federal Constitution does.⁷⁸ The founders envisioned the federalist system providing a “double security . . . to the rights of the people”⁷⁹ by enabling each state to “exercise its police power or its sovereign right to adopt in its own Constitution individual liberties more expansive than those conferred by the Federal Constitution.”⁸⁰ As Justice William Brennan wrote nearly forty years ago, “State constitutions, too, are a font of individual liberties, their protections often extending beyond those required by the Supreme Court’s interpretation of federal law.”⁸¹ This system enables states to “respond, through the enactment of positive law,” to protect the rights of citizens “without having to rely solely upon the political processes that control a remote central power.”⁸²

78. See, e.g., *Florida v. Powell*, 559 U.S. 50, 71 (2010) (“[T]he federal Constitution sets the floor, not the ceiling, and [a state court] retains the ability to interpret [protections for] right[s] . . . afforded by the [state] Constitution more broadly than that afforded by its federal counterpart.”) (Stevens, J., dissenting) (quoting *Rigterink v. State*, 2 So. 3d 221, 241 (Fla. 2009)); *Kelo v. City of New London*, 545 U.S. 469, 489 (2005) (“[N]othing . . . precludes any State from placing further restrictions on its exercise of . . . power . . . that are stricter than the federal baseline.”).

79. THE FEDERALIST NO. 51, at 320 (James Madison) (Clinton Rossiter ed., 1961); see also Arthur E. Wilmarth, Jr., *The Original Purpose of the Bill of Rights: James Madison and the Founders’ Search for a Workable Balance Between Federal and State Power*, 26 AM. CRIM. L. REV. 1261, 1294 (1989) (describing how “Madison expected the states to be the most important checks against federal abuses of power”).

80. *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 81 (1980).

81. William J. Brennan, Jr., *State Constitutions and the Protection of Individual Rights*, 90 HARV. L. REV. 489, 491 (1977).

82. *Bond v. United States*, 564 U.S. 211, 221 (2011).

State constitutions already provide broader protections for free speech,⁸³ property rights,⁸⁴ and the right to privacy,⁸⁵ than their federal counterpart. Right to Try seeks to protect the most personal and intimate right of all: our right to our own lives. Eleven years ago, in *Gonzales v. Oregon*,⁸⁶ the U.S. Supreme Court affirmed the power of states to guarantee medical autonomy more broadly than contemplated by federal law, when it upheld Oregon's "right to die" legislation against the objections of the U.S. Attorney General, who argued that it conflicted with federal law.⁸⁷ "[R]egulation of health and safety is 'primarily, and historically, a matter of local concern,'" the Court noted, and, while federal officials can sometimes override state choices,⁸⁸ the *Gonzales* decision saw no reason to interfere with Oregon's "'great latitude . . . to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.'"⁸⁹

Gonzales was not a one-time thing. Almost a decade earlier, the Court had refused to strike down Washington State's prohibition on physician-assisted suicide under the Fourteenth Amendment, in an opinion that emphasized the autonomy of states and the importance of "an earnest and profound debate about the morality, legality, and practicality of physician-assisted

83. See, e.g., *Coleman v. City of Mesa*, 284 P.3d 863, 872 n.5 (Ariz. 2012) ("Arizona's [free speech provision] is in some respects more protective of free speech rights than the First Amendment."); *L.A. All. for Survival v. City of L.A.*, 993 P.2d 334, 342 (Cal. 2000) ("[T]he California liberty of speech clause is broader and more protective than the free speech clause of the First Amendment."); *Bradburn v. N. Cent. Reg'l Library Dist.*, 231 P.3d 166, 172 (Wash. 2010) (recognizing that Washington's free speech provision "is more protective of speech than the First Amendment" and that "it is already settled that [the provision] is subject to independent interpretation").

84. See, e.g., *Bailey v. Myers*, 76 P.3d 898, 903 (Ariz. Ct. App. 2003) ("The federal constitution provides considerably less protection against eminent domain than our Constitution provides."); *Bd. of Cty. Comm'rs of Muskogee Cty. v. Lowery*, 136 P.3d 639, 651 (Okla. 2006) ("[Oklahoma's Constitution] provide[s] private property protection to Oklahoma citizens beyond that which is afforded them by the Fifth Amendment to the U.S. Constitution.").

85. *State v. Garza*, No. 2 CA-CR 2012-0394, 2013 WL 6410445, at *2 (Ariz. Ct. App. Dec. 6, 2013) ("[Arizona's constitutional privacy provision] is both more explicit and more protective than its federal counterpart in 'preserving the sanctity of homes and in creating a right of privacy.'"); *Am. Acad. of Pediatrics v. Lungren*, 940 P.2d 797, 808 (Cal. 1997) ("[T]he scope and application of the state constitutional right of privacy is broader and more protective of privacy than the federal constitutional right of privacy as interpreted by the federal courts.").

86. 546 U.S. 243 (2006).

87. *Id.* at 272 (reasoning that the Controlled Substances Act presumes and relies upon a functioning medical profession regulated under state's police power).

88. *Id.* at 271 (quoting *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985)).

89. *Id.* at 270 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996)).

suicide . . . in a democratic society.”⁹⁰ To impose a single, nationwide rule on the question, the Court declared, would interfere with the states’ “interest in protecting the integrity and ethics of the medical profession.”⁹¹ Washington State later adopted a law allowing physician-assisted suicide, leading a later court to observe that “[i]n the wake of *Glucksberg* and the Death with Dignity Act, it is clear that Washington State can *bar* medical providers from assisting in taking life, and it can *allow* them to participate in taking a life.”⁹²

Courts have been equally protective of state authority to regulate the ordinary course of affairs outside of the medical context. In *United States v. Windsor*,⁹³ the Court struck down a portion of the federal Defense of Marriage Act because it interfered with the traditional state power to define marriage, a matter the justices called “central to state domestic relations law.”⁹⁴ It was unconstitutional for the federal government to interfere with “the State’s broader authority to regulate the subject of domestic relations” by imposing a federal “definition of marriage” in a way that “impose[d] restrictions and disabilities.”⁹⁵ In *Bond v. United States*, the Court interpreted the international chemical weapons treaty narrowly to avoid stepping on the toes of state governments,⁹⁶ and in *National Federation of Independent Business v. Sebelius*, it again adopted a narrow construction of a federal law to prevent the federal government from withholding all Medicaid funds so as to coerce states into radically altering their Medicaid programs.⁹⁷

Even in cases that involve ordinary consumer protection statutes, states have authority to impose greater standards than federal regulation imposes, so long as those standards do not unduly interfere with the flow of interstate commerce. In *Florida Lime & Avocado Growers, Inc. v. Paul*,⁹⁸ the Supreme Court noted that “[f]ederal regulation by means of minimum standards of . . . agricultural commodities, however comprehensive . . . does not of itself import displacement of state control over the distribution and retail sale of those commodities in the interests of the consumers . . . within the State Congressional regulation of one end of the stream of commerce

90. *Washington v. Glucksberg*, 521 U.S. 702, 735 (1997).

91. *Id.* at 731.

92. *Stormans Inc. v. Selecky*, 844 F. Supp. 2d 1172, 1183 (W.D. Wash. 2012).

93. 133 S. Ct. 2675 (2013).

94. *Id.* at 2691. Although the Court later struck down state prohibitions on same-sex marriage in *Obergefell v. Hodges*, it did so on the grounds that such laws fell below the Fourteenth Amendment “floor.” *Obergefell v. Hodges*, 135 S. Ct. 2584, 2604–05 (2015).

95. *Windsor*, 133 S. Ct. at 2691–92.

96. 134 S. Ct. 2077, 2087–88 (2014).

97. 132 S. Ct. 2566, 2608 (2012).

98. 373 U.S. 132 (1963).

does not, *ipso facto*, oust all state regulation at the other end.”⁹⁹ In short, the states’ constitutional power to regulate “all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State,”¹⁰⁰ is not lightly dispensed with, even in cases where Congress has imposed minimum federal regulatory standards.

In the case of Right to Try, the states’ interest in regulating the ordinary course of affairs is particularly important, given that states have always had the primary responsibility for regulating the practice of medicine.¹⁰¹ The FDA is not empowered to regulate medical practice at all.¹⁰² But through its prohibition on medical access, and the unduly complex process for compassionate use, it does something very much like that. Rather than focusing on ensuring that physicians and patients have the information they need to make their own decisions, the FDA has become the decision-maker, prohibiting doctors from treating patients to the best of their ability and the full extent of their medical knowledge.

When states adopt Right to Try laws, they are providing greater protections for a fundamental right than are provided by the federal system. The FDA’s system presumes that patients should not have access to medicine until federal officials certify it as both safe and effective, and it requires patients and their doctors to navigate a complex labyrinth in order to beg the government for permission to make an exception to that rule. By enacting Right to Try laws, states are reversing that presumption, and providing that terminal patients and their doctors should be free to decide whether treatment should include experimental medications, without having to first obtain government permission. Just as they have done with protections for speech and privacy, they are protecting the most personal and intimate right of all: our right to our own lives.

99. *Id.* at 145 (emphasis added).

100. THE FEDERALIST NO. 45, at 289 (James Madison) (Clinton Rossiter ed., 1961).

101. Traditionally, states “have had great latitude under their police powers to legislate as ‘to the protection of the lives, limbs, health, comfort, and quiet of all persons.’” *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (quoting *The Slaughter-House Cases*, 83 U.S. 36, 62 (1872)); *see also* *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (stating that health care has traditionally been matter of a state regulation). Moreover, the Supreme Court has affirmed that regulation of medical practice is a matter of state concern. *See, e.g., Graves v. Minnesota*, 272 U.S. 425, 428 (1926) (holding that the state is primarily the judge of regulations required in the interest of public safety and welfare); *Semler v. Or. State Bd. of Dental Exam’rs*, 294 U.S. 608, 611 (1935) (holding that the state may regulate the practice of dentistry by prescribing the qualifications that are reasonably necessary).

102. The Food, Drug, and Cosmetic Act expressly disclaims any intent by the federal government to regulate the practice of medicine. *See* 21 U.S.C. § 396 (2012).

Some critics point to the 1979 case *United States v. Rutherford*¹⁰³ as evidence that federal law preempts State Right to Try laws. In that case, terminally ill cancer patients challenged the FDA's prohibition on the interstate shipment and sale of an unapproved drug, Laetrile.¹⁰⁴ The trial court had initially permitted the sale to one of the plaintiffs after finding that in proper dosages Laetrile was nontoxic.¹⁰⁵ However, upon remand to the FDA for further determinations, the Commissioner concluded that Laetrile had not undergone satisfactory testing for either safety or effectiveness,¹⁰⁶ and even deemed it "a public health menace."¹⁰⁷ Despite the safety issues, the Tenth Circuit ruled that dying patients should be free to take Laetrile, holding that the FDA standards had "no reasonable application to terminally ill cancer patients" who "die of cancer regardless of what may be done."¹⁰⁸ The court then ordered the FDA to regard Laetrile, when administered through intravenous injection, "as if" it had been found "'safe' and 'effective'" for terminally ill cancer patients.¹⁰⁹

The Supreme Court reversed, holding that there was no evidence that Congress intended to exempt drugs used by the terminally ill from the FDA process.¹¹⁰ This was especially so for an *unsafe* drug, one the Court called a "self-styled panacea[]." ¹¹¹ The Court pointed out that even the decision below "implicitly acknowledged that safety considerations have relevance for terminal cancer patients," because it "restrict[ed] authorized use of Laetrile to intravenous injections for persons under a doctor's supervision."¹¹²

Thus, despite superficial resemblances, *Rutherford* presents a notably different situation from Right to Try. Right to Try does not involve unsafe panaceas; it applies solely to drugs and procedures that have already passed FDA Phase I testing, and are currently being given to patients. The safety concerns addressed in *Rutherford* are therefore not present in the case of Right to Try (except to the extent that all medicines present some inescapable

103. 442 U.S. 544 (1979).

104. *Id.* at 548.

105. *Rutherford v. United States*, 399 F. Supp. 1208, 1214–15 (W.D. Okla. 1975).

106. *Rutherford*, 442 U.S. at 549.

107. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH, EDUC. & WELFARE, PUB. NO. 77-3056, LAETRILE: THE COMMISSIONER'S DECISION, at iii (1978), <http://www.cancertreatment-watch.org/q/laetrile/commissioner.pdf>.

108. *Rutherford*, 442 U.S. at 551.

109. *Id.*

110. *Id.* at 552.

111. *Id.* at 558.

112. *Id.* at 556.

degree of risk,¹¹³ and that, as the FDA has acknowledged, nothing can be one hundred percent safe¹¹⁴).

More relevant to Right to Try is *Abigail Alliance v. Von Eschenbach*.¹¹⁵ After his twenty-one-year-old daughter Abigail died of cancer in 2001, Frank Burroughs founded the Abigail Alliance for Better Access to Developmental Drugs. Abigail had exhausted her FDA-approved options, but her doctors had identified a promising treatment. Unfortunately, Abigail did not qualify for clinical trials because the testing was for patients with colon cancer, and Abigail was diagnosed with cancer in her head and neck. Abigail was unable to get the treatment, and she passed away. But her father kept up the fight on behalf of other terminal patients.¹¹⁶

In 2003, the Abigail Alliance and Washington Legal Foundation filed a petition with the FDA requesting that the FDA adopt a “policy to grant Initial Approval for promising drugs . . . intended to treat life-threatening diseases with unmet needs” and “regulatory changes to permit expanded availability of developmental lifesaving drugs following phase 1 clinical trials.”¹¹⁷ The FDA denied the petition, and Abigail Alliance sued, arguing that terminally ill patients have a constitutionally guaranteed fundamental right to access experimental drugs that have passed basic safety testing.¹¹⁸

A three-judge panel of the D.C. Circuit Court of Appeals initially ruled that the Due Process Clause of the Fifth Amendment guarantees terminally ill patients’ right to use investigational treatments that had passed FDA Phase I safety testing. But the en banc court reversed, and held that the Constitution does not protect a terminally ill patient’s right to use unapproved drugs.¹¹⁹ After determining that the right is not fundamental, the court weighed the interests of the terminal patients against the “value judgment already

113. In fact, the FDA’s inflexible policies may leave terminally ill patients with no option but to seek out dangerous drugs. Today, desperate American cancer patients often seek Laetrile treatments in Mexico because they lack access to better options in the United States. OLSEN, *supra* note 1, at 246.

114. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, *supra* note 30, at 11.

115. *Abigail All. for Better Access to Dev. Drugs & Wash. Legal Found. v. von Eschenbach (Abigail Alliance I)*, 445 F.3d 470 (D.C. Cir. 2006), *rev’d en banc sub nom. Abigail All. for Better Access to Dev. Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

116. OLSEN, *supra* note 1, at 166–68.

117. Washington Legal Foundation, Citizen Petition of the Abigail Alliance and the Washington Legal Foundation (June 11, 2003), <https://www.fda.gov/ohrms/dockets/dailys/03/Jun03/061703/03p-0274-cp00001-01-vol1.pdf>.

118. *Abigail Alliance I*, 445 F.3d at 473–75.

119. *Abigail All. for Better Access to Dev. Drugs v. von Eschenbach (Abigail Alliance II)*, 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc).

determined by the legislature” and deferred to “the collective judgment of the scientific and medical communities expressed through the FDA’s clinical testing process,” to uphold the federal requirement that terminally ill patients obtain permission from the FDA before seeking access to investigational medications.¹²⁰

Right to Try presents a different question than that addressed in *Abigail Alliance*. First, as in *Rutherford*, the plaintiffs in *Abigail Alliance* were seeking authority to access drugs that had not been approved for safe use by the FDA.¹²¹ This proved a critical point for the courts in both cases; the *Rutherford* Court expressing concern about a purported constitutional right to use “panaceas,” and the *Abigail Alliance* court worrying that approving the patients’ constitutional argument would interfere with “our historical tradition of prohibiting the sale of unsafe drugs.”¹²² Right to Try, by contrast, applies only to drugs that have received the FDA’s basic safety approval and are currently being administered in trials.

Second, the plaintiffs in *Abigail Alliance* could point to no state legal protections such as Right to Try provides. This is important because the judges who rejected the constitutional argument in *Abigail Alliance* nevertheless called upon the “democratic branches . . . to decide the proper balance between the uncertain risks and benefits of medical technology.”¹²³ The en banc court was understandably reluctant to decide “arguments about morality, quality of life, and acceptable levels of medical risk,”¹²⁴ and they echoed Justice Sandra Day O’Connor’s separate opinion in *Glucksberg*, which argued that the democratic process was the proper way to strike proper balance between the interests of terminal patients and of officials devoted to protecting the public.¹²⁵ “[T]he . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the ‘laboratory’ of the States . . . in the first instance,” she wrote.¹²⁶ Right to Try laws being passed by states nationwide obviously answer that call to action. If, as the *Abigail Alliance* en banc court asserted, “the democratic branches” of government “are entitled to deference” when they seek to “decide the

120. *Id.* at 708–09.

121. *Id.* at 697.

122. *Id.* at 706.

123. *Id.* at 713.

124. *Id.*

125. *Washington v. Glucksberg*, 521 U.S. 702, 736–37 (1997) (O’Connor, J., concurring).

126. *Id.* at 737 (quoting *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 292 (1990) (O’Connor, J., concurring)). The majority in *Glucksberg* also implicitly recognized that protecting a terminal patient’s dignity and independence is a policy issue and should be left to the state to decide. *Id.* at 717–19.

proper balance between the uncertain risks and benefits of medical technology,¹²⁷ then Right to Try laws provide the democratic support that was lacking in the earlier case.

But to the extent that *Abigail Alliance* appeared to reject the idea that people have a constitutional right to defend their lives, it was simply wrong. The right to try to save one's own life is deeply rooted in the nation's history and tradition, and is among the crucial rights protected by the principle of due process of law.¹²⁸ At the turn of the twentieth century, the Supreme Court

127. *Abigail Alliance II*, 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc).

128. The *Glucksberg* Court described the test for substantive due process protection as follows:

First, . . . the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed. Second, we have required in substantive-due-process cases a careful description of the asserted fundamental liberty interest. Our Nation's history, legal traditions, and practices thus provide the crucial guideposts for responsible decisionmaking that direct and restrain our exposition of the Due Process Clause.

Glucksberg, 521 U.S. at 720–21 (citations and quotation marks omitted). Some scholars have argued that the right to patient autonomy is a relative novelty, and that historically, physicians operated on a “paternalistic” model, instead. *See, e.g.*, Thomas L. Hafemeister & Richard M. Gulbrandsen, Jr., *The Fiduciary Obligation of Physicians to “Just Say No” if an “Informed” Patient Demands Services that are not Medically Indicated*, 39 SETON HALL L. REV. 335, 338–47 (2009). This is debatable, given that even in ancient days, the patient was ultimately responsible for choosing whether to submit to a physician's care. *Cf.* PLATO, *Gorgias*, in PLATO: THE COLLECTED DIALOGUES 229, 239 (Edith Hamilton & Huntington Cairns eds., 1961) (discussing the necessity of rhetoric to persuade a patient to allow himself to be treated). But it must also be remembered that the medical profession, more than any other, was revolutionized beginning in the Enlightenment, when the scientific method was gradually adopted. It was roughly during this same period that the theory of individual rights that forms the basis of our constitutional system was devised by political philosophers such as John Locke (who, incidentally, was himself a physician, and who thought it obvious that a person “might . . . innocently change . . . his Physician.”). JOHN LOCKE, *First Treatise of Civil Government*, in TWO TREATISES OF GOVERNMENT 141, 203 (Peter Laslett ed., Cambridge Univ. Press 1988) (1690). The right of patient autonomy is thus a contemporary with other individual rights such as freedoms of speech or religion—neither of which existed in the days of Hippocrates—and both are contemporaries of modern medical science itself. It is unsurprising that the doctrine of patient autonomy would parallel the progress of medical science. *Cf.* Jay Katz, *Informed Consent—Must it Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69, 76 (1994) (“[F]or the first time in medical history it is possible, even medically and morally imperative, to give patients a voice in medical decisionmaking.”). In any event, by the time the American constitutional system was being formalized, it was well established that medical practice is—in the words of Benjamin Rush, a physician and signer of the Declaration of Independence, “[t]he most important *contract* that can be made.” BENJAMIN RUSH, *The Vices and Virtues of Physicians*, in THE SELECTED WRITINGS OF BENJAMIN RUSH 293, 298 (Dogobert D.

confirmed that “[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law,”¹²⁹ and the Illinois Court of Appeals referred to the patient’s right to informed consent, in words many other courts would repeat, as “the free citizen’s first and greatest right, which underlies all others—the right to the inviolability of his person, in other words, his right to himself.”¹³⁰

As the original *Abigail Alliance* panel observed, the right to try to save one’s life using investigational medicines is part of the broader “long-standing tradition of the right of self-preservation,”¹³¹ which is reflected in such legal doctrines as the common law right to lethal self-defense¹³² and liability for interference with rescue.¹³³ One might add the legal doctrine of privilege to violate property rights in cases of emergency.¹³⁴ If one has a right to kill another or destroy another’s property to safeguard one’s life and freedom,¹³⁵ then one should have the same right to avail herself of available medications—which pose no risk of harm to others—to combat a lethal disease. And when government bars a terminal patient’s access to an investigational treatment, it prevents her from pursuing the only known and available means to rescue her own life.¹³⁶ This is troubling enough on ethical grounds; as bioethicist Julian Savulescu writes, “[t]o delay by 1 year the development of a treatment that cures a lethal disease that kills 100,000

Runes ed., 1947) (emphasis added); see also 1 WILLIAM BLACKSTONE, COMMENTARIES *125, *130 (citing among the rights of personal security the right to “the preservation of a man’s health from such practices as may prejudice or annoy it”).

129. *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

130. *Pratt v. Davis*, 118 Ill. App. 161, 166 (1905), *aff’d*, 79 N.E. 562 (Ill. 1906); see also Evan Bernick, *Book Review: The Right to Try*, 17 ENGAGE 52, 55 (2016) (“It is difficult to think of a government action more hostile to the purposes for which government is established than one that prevents people from preserving their own lives and thus makes the exercise of any other rights impossible.”).

131. *Abigail Alliance I*, 445 F.3d 470, 483 (D.C. Cir. 2006), *rev’d en banc sub nom. Abigail Alliance II*, 495 F.3d 695 (D.C. Cir. 2007).

132. *Id.* at 480.

133. *Id.*

134. See generally John Alan Cohan, *Private and Public Necessity and the Violation of Property Rights*, 83 N.D. L. REV. 651, 657 (2007).

135. See, e.g., *Montana v. Egelhoff*, 518 U.S. 37, 56 (1996) (noting that “the right to have a jury consider self-defense evidence . . . is fundamental” and supported by the “historical record”).

136. See, e.g., *Ross v. United States*, 910 F.2d 1422, 1433 (7th Cir. 1990) (holding that deputy sheriff committed a constitutional tort by interfering with efforts to rescue drowning boy); *Sneider v. Hyatt Corp.*, 390 F. Supp. 976, 980 n.2 (N.D. Ga. 1975) (“[D]eliberate interference with rescue efforts by third parties is a traditional basis for imposing liability.”).

people per year is to be responsible for the deaths of those 100,000 people, even if you never see them.”¹³⁷ But it is also problematic on legal grounds. Indeed, courts have specifically held government liable when it prevents others from attempting a rescue and takes no action itself.¹³⁸

Yet the en banc court rejected Abigail Alliance’s argument, holding that “our Nation has long expressed interest in drug regulation” and “determin[ing] the risks associated with both drug safety and efficacy.”¹³⁹ The court found that “our Nation’s history evidences increasing regulation of drugs,” and rejected what it characterized as a “right to procure and use experimental drugs” or “to assume any level of risk without regard to the scientific and medical judgment expressed through the clinical testing process.”¹⁴⁰

Abigail Alliance, however, was not asking the court to abandon the clinical trial process, or asserting an historical right to access and use experimental drugs. Instead, it was asserting a fundamental right to medical autonomy—the right to make one’s own medical decisions.¹⁴¹ As a matter of principle, if not of history, the right to try to save one’s life is implicit in the concept of ordered liberty. The Supreme Court has already acknowledged that the individual has a constitutionally protected liberty interest in *refusing* lifesaving medical treatment when it is not wanted,¹⁴² and that unjustified

137. Julian Savulescu, *Bioethics: Why Philosophy is Essential for Progress*, 41 J. MED. ETHICS 28, 31 (2015); see also Ian Chalmers, *Regulation of Therapeutic Research Is Compromising the Interests of Patients*, 21 INT’L J. PHARMACEUTICAL MED. 395, 395 (2007).

138. *United States v. Lawter*, 219 F.2d 559, 562 (5th Cir. 1955) (affirming liability against government for negligence during sea rescue operations).

139. *Abigail Alliance II*, 495 F.3d 695, 703 (D.C. Cir. 2007) (en banc).

140. *Id.* at 711.

141. By characterizing the right at issue as merely the “right to procure and use experimental drugs,” the en banc court committed the same error as the Supreme Court in *Bowers v. Hardwick*, 478 U.S. 186 (1986), when it rejected what it called “a fundamental right to homosexuals to engage in acts of consensual sodomy.” *Bowers*, 478 U.S. at 192. In his dissent, Justice Blackmun argued that the *real* right at issue was the right to *privacy*, which “[w]e protect . . . not because [it] contribute[s] . . . to the general public welfare, but because [it] form[s] so central a part of an individual’s life . . . [and] embodies the ‘moral fact that a person belongs to himself and not others nor to society as a whole.’” *Id.* at 204–05 (Blackmun, J., dissenting) (citation omitted). In overturning that ruling, the Court later admitted that *Bowers* had “fail[ed] to appreciate the extent of the liberty at stake,” and had “misapprehended the claim of liberty there presented” in such a way as to focus on history instead of philosophy. *Lawrence v. Texas*, 539 U.S. 558, 567–68 (2003). The *Lawrence* Court recognized that it “need not . . . reach a definitive historical judgment,” because “history and tradition are the starting point but not in all cases the ending point of the substantive due process inquiry.” *Id.* at 567–68, 572 (quoting *County of Sacramento v. Lewis*, 523 U.S. 833, 857 (1998) (Kennedy, J., concurring)). Unfortunately, the *Abigail Alliance II* court misapprehended the nature of the liberty at stake, in precisely the same way.

142. *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 278–79 (1990).

intrusions into the body violate due process.¹⁴³ The right to medical privacy—the protection of “the special relationship between patient and physician”¹⁴⁴—and the right “to care for one’s health and person and to seek out a physician of one’s own choice,”¹⁴⁵ are also rooted in the law’s basic respect for a patient’s fundamental right to decide for himself or herself what medical procedures one undergoes. The Due Process Clause even protects a person’s right to cut or not cut his own hair.¹⁴⁶ It strains credulity to imagine it does not also protect a patient’s autonomy when she wants to take a safe, legal, investigational treatment—a treatment the government is already allowing other patients to take—in an effort to save her own life.

Autonomy is the core of liberty. Whatever else might be disputed about rights, it is at least clear that they refer to a realm of free choice within which a person has mastery over his or her actions.¹⁴⁷ The most basic of all rights is the right to one’s own body.¹⁴⁸ And there is no stronger liberty interest than a person’s right to choose actions in an effort to save one’s own life—even if that attempt is ultimately unsuccessful. As Judge Judith W. Rogers, dissenting in *Abigail Alliance*, put it, “[w]hile the potential cures may not prove *sufficient* to save the life of a terminally ill patient, they are surely *necessary* if there is to be any possibility of preserving her life.”¹⁴⁹ To deny someone the opportunity, even if a last-ditch effort, to choose for herself whether or how to fight a deadly disease, “would display a lack of understanding of the meaning of the individual’s rights in free society.”¹⁵⁰ As Brian Clark put it in his now-classic play, *Whose Life Is It Anyway?*, dignity starts with choice.¹⁵¹

143. *Rochin v. California*, 342 U.S. 165, 172–74 (1952) (stating that people cannot be subjected to medical procedures against their will).

144. *Cruzan*, 497 U.S. at 281, 340 n.12.

145. *Doe v. Bolton*, 410 U.S. 179, 218 (1973) (Douglas, J., concurring).

146. *Griffin v. Tatum*, 425 F.2d 201, 203 (5th Cir. 1970).

147. See Tom G. Palmer, *Saving Rights Theory from Its Friends*, in *INDIVIDUAL RIGHTS RECONSIDERED* 35, 66 (Tibor Machan ed., 2001) (“To have mastery over one’s own actions, that is, *dominium* . . . is, in effect, what allows us to ‘own’ our actions.”).

148. See *id.* at 74–84.

149. *Abigail Alliance II*, 495 F.3d 695, 715 (D.C. Cir. 2007) (en banc) (Rogers, J., dissenting).

150. *Suenram v. Soc’y of Valley Hosp.*, 383 A.2d 143, 148 (N.J. 1977).

151. BRIAN CLARK, *WHOSE LIFE IS IT ANYWAY?* 74 (Heinemann Educ. Publishers, 1993) (1978).

V. CONCLUSION

“Having a child that’s dying is the most painful thing in the world,” said Jenn McNary, mother of the two boys with Duchenne’s Muscular Dystrophy. “The only thing that is more painful is having a child that is dying and having a drug that could help him, and not being able to have access to it.”¹⁵²

Yet the FDA system presumes that the public should not have access to medicine until federal officials certify it as both safe and effective to their satisfaction.¹⁵³ But dying patients face a different risk/benefit calculus than other people.¹⁵⁴ Right to Try recognizes that if they want to try an investigational treatment that may bring serious risks, but might also save their lives, that choice should be theirs.

Right to Try is not a call to ignore research or undermine science, or for doctors to abandon obligations to patients, or for drug companies to disregard complex ethical questions such as how to distribute limited supplies of drugs. And obviously Right to Try is not a guarantee that investigational medications will work, or that patients and doctors will have perfect information to inform their decisions. But the current FDA system is none of these things, either. As the FDA admits, no system will ensure against all risks. But that isn’t the question. The question is who should ultimately decide what level of risk is acceptable to a patient—federal officials or patients themselves, in consultation with their doctors? Terminally ill patients have a basic human right to try to save their own lives by using promising medicines.

Today’s obsolete federal drug regulation process rewards delay and prioritizes bureaucracy over the interests of patients who are now suffering from terminal diseases. That must change. Terminal patients have enough on their hands fighting for their lives. They should not have to fight the government too.

152. OLSEN, *supra* note 1, at 38.

153. *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last visited Feb. 25, 2017).

154. Indeed, the Federal Food, Drug, and Cosmetic Act (FDCA) *itself* recognizes this. The FDCA provides avenues for terminal patients who wish to access to experimental drugs or devices if (1) their physicians determine that there is no comparable or satisfactory alternative therapy for serious diseases and that risks of the investigational drug or device are comparable to the risks of the disease or condition; and (2) the FDA determines that there is sufficient evidence of safety and efficacy to support the use and that the use will not interfere with completion of clinical trials, and the sponsor submits an appropriate protocol. 21 U.S.C. § 360bbb(b)(1)–(2) (2012). Section 561 of the FDCA further authorizes widespread access to investigational drugs where the FDA makes findings that the sponsor is proceeding with clinical trials and is actively pursuing marketing approval. § 360bbb(c).