THE STORIES WE TELL: NARRATIVE, POLICYMAKING, AND THE RIGHT TO TRY

PROFESSOR CHRISTINE NERO COUGHLIN† & PROFESSOR NANCY M.P. KING††

“Patients tell stories of desperate but unsuccessful efforts to obtain investigational drugs. Families describe loved ones who died without having a chance to try the drugs they were seeking. To lawmakers and the public hearing those stories, it would be cruel to vote against a right to try law.”1

Public health policy, according to the World Health Organization, refers to the “decisions, plans, and actions that are undertaken to achieve specific health care goals” in society.2 When public health policies are enacted into law—whether in state constitutions, state or federal statutes, case law, executive orders, regulations, state and local ordinances, or other governmental policies—they can positively affect the health of the entire population.3 For example, public health policies have reduced child mortality,

† Professor Christine Nero Coughlin, Professor of Law, Wake Forest University School of Law, Wake Forest University Center for Bioethics, Health & Society.
†† Professor Nancy M.P. King, Professor, Department of Social Sciences and Health Policy, Wake Forest School of Medicine, & Co-Director of the Wake Forest University Center for Bioethics, Health, and Society.

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decreased the number of deadly automobile accidents, and virtually eliminated smallpox in the United States.4

However, even though public health laws improve health outcomes, their application must be carefully scrutinized as they often limit and sometimes significantly restrict the public’s freedom of choice, association, or movement. Moreover, in their focus to benefit the population as a whole, the application of these laws may detrimentally affect particular individuals or groups in the population.5 As such, public health laws should be comprehensive, based on empirical research and a sound normative foundation.6

Personal stories that demonstrate public health problems can be a persuasive tool to obtain public support for a legislative, regulatory, or other legally-oriented solution. Personal stories associate an identified life7—a specific, inherently sympathetic person who needs help now—with a problem public action can solve. This association enables us to draw parallels between ourselves and the identified life, the story’s protagonist. These parallels also motivate us to act on behalf of the identified life. The more emotionally charged the story, the more likely we are to credit the narrative as an accurate and representative portrayal of the problem.8 But public health focuses on the health of whole populations, not just the identified lives. Public health policies protect and promote the health of statistical lives, which are both numerous and invisible, and thus lack the immediate appeal of identified lives.9 For these reasons, personal narratives, while a powerful motivating force, can

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5. See, e.g., Hunt Allcott et al., Regressive Sin Taxes, with an Application to the Optimal Soda Tax, 134 Q.J. ECON. 1557, 1558–59 (providing an example of how some public health measures may be described as regressive in their effects on low-income consumers); Lawrence O. Gostin, Public Health Law in a New Century: Part I: Law as a Tool to Advance the Community’s Health, 283 JAMA 2837, 2840 (2000) (discussing how government action to promote community health may detrimentally affect individual private activities).


9. Id. at 1154.
limit appreciation of the complexity of the public health issue and proposed policy to which they draw attention and sympathy.\textsuperscript{10}

The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017\textsuperscript{11} and its forty-one state law counterparts\textsuperscript{12} offer a stark example of how tragic personal stories, rather than sound data and normative justification, created laws that are at best misleading and inefficient, and at worst, dangerous to public health.

This essay examines the history of investigational drugs and expanded access through some of the stories that influenced Food and Drug Administration ("FDA") policy and practice. It then turns its focus to the right to try movement and explores some of the many personal stories that were used to propel the development of right to try laws by focusing exclusively on autonomy and access.

The focus then shifts to those whose personal stories—equally compelling—are \textit{not} being told in the right to try discussions. These untold stories include narratives that highlight the need for careful science and the duties of researchers; stories that illustrate systematic disadvantage and structural injustice and can help demonstrate the demand for a health care system that is meaningfully available to all from the outset; stories about unidentified statistical lives; stories from those who have come to regret the exercise of their right to try; and stories by and about those who have struggled between the do-everything mindset and the desire for a good death. We discuss the concept of identified lives and why the public supports “rescuing” individuals it deems attractive and deserving.\textsuperscript{13} We then address the problems associated with elevating these identified lives over other untold stories and statistical unidentified lives in the context of right to try laws.

\textsuperscript{10} Id. at 1150.


\textsuperscript{12} Leah Lawrence, \textit{The Realities of “Right to Try,”} ASH CLINICAL NEWS (OCT. 1, 2018), https://www.ashclinicalnews.org/spotlight/realities-right-try.

\textsuperscript{13} Randall F. Moore, \textit{Caring for Identified Versus Statistical Lives: An Evolutionary View of Medical Distributive Justice,} 17 ETHOLOGY & SOCIOBIOLOGY 379, 380 (1996) ("Identified lives are those of specific individuals who are explicitly recognized, for example by name or by having met healthcare providers face to face. Identified lives may be helped if care is offered to them, but may be harmed if care is not offered to them."). See generally Scott Burris, et al., \textit{Making the Case for Laws That Improve Health: A Framework for Public Health Law Research,} 88 MILBANK Q. 169, 169–210 (2010).
This essay concludes that personal narrative has a place in public health policy generally, and in the question of access to investigational drugs specifically. Personal stories, used judiciously, can be a powerful tool in advocating for needed change. However, in the context of access to investigational drugs, crafting policy with a sole focus on the primacy of personal choice and autonomy fails to incorporate the public policy mandate to base available choices on at least a minimal amount of safety data and a high degree of information transparency. Where research directed to improving human health is at issue, contributing to generalizable knowledge—the principal purpose of research—should not be minimized because patients with life-threatening illnesses believe that they have nothing to lose by trying. While personal narratives can and should be considered, they should be combined with acknowledgment of the complexities of the investigational drug and clinical trial processes, and with awareness of the perennial and inevitable tension between providing access and collecting data that supports safety and efficacy. Even in the most tragic of circumstances, health care policy in this area deserves to be made collectively, based on careful science, good research, and a fair allocation of resources.

15. Id. at 1637–40 (evaluating the evolving changes in FDA policies following challenges from Abigail Alliance for Better Access to Developmental Drugs, a patient-advocacy organization).
I. A Brief History of Investigational Drugs and Expanded Access

To appreciate how right to try laws originated, it is important to understand at least a few of the background stories woven into its history.17

Modern regulation of investigational drugs began in 193718 after drug company S.E. Massengill, Co. sold “Elixir Sulfanilamide,” a liquid antibacterial drug to which the company’s chemist had added the sweet-tasting, poisonous solvent diethylene glycol,19 along with raspberry flavoring for children.20 As a result, seventy-one adults and thirty-four children died. Congress then enacted the 1938 Food Drug and Cosmetic Act (“FDCA”), which required manufacturers to show that a new drug was safe—but not necessarily effective—before it was marketed.21 The new drug application would become effective sixty days after submission unless the FDA affirmatively disapproved it.22
Clinical trial regulation was strengthened in 1962 through the courage of Frances Oldham Kelsey, a pharmacologist, physician, and medical officer with the FDA who reviewed new drug applications before allowing manufacturers to market them. One of the first applications that Dr. Kelsey reviewed was for Thalidomide, a drug marketed in Europe to alleviate morning sickness in pregnant women. Despite significant pressure from the manufacturer, she refused to approve the application for marketing in the United States and raised concerns about inadequate evidence of safety. Soon thereafter, researchers in Europe linked the drug to severe birth defects. The thousands of children born with severe birth defects as a result of Thalidomide sales outside the United States motivated Congress to pass the Kefauver-Harris Drug Amendments of 1962.

The Kefauver-Harris Amendments created a more lengthy, complex, and regulated clinical trial process requiring manufacturers to provide preclinical evidence of drug safety and efficacy and submit an investigational new drug (“IND”) application before


25. FDA’s Frances Oldham Kelsey Overview, supra note 23.


beginning clinical trials. When the FDA issued final regulations the following year, an accompanying press release concerning pre-market access to new drugs stated: “There is no bar in the regulations to giving the necessary instructions to and obtaining the necessary commitments from a new investigator by telephone in case this is needed to save a life.”

Using the informal process identified in the FDA’s January 1963 press release, the Agency began to allow patients to petition for access to investigational drugs still in clinical trials. In general, over the next two decades, if a physician believed that a terminally ill patient could benefit from an investigational drug, and there were no other options, the physician could informally ask permission for access. FDA officials would usually approve the request if there was “a manufacturer willing to supply the drug, a physician willing to prescribe it, a patient willing to give informed consent, and some basis for believing that the treatment was not an outright fraud or poison.”

During this time, the court system also began wrestling with the question of whether patients had a right of access to unapproved drugs. In 1975, cancer patients who wanted access to Laetrile, an alternative treatment derived from apricot pits, filed a lawsuit to enjoin the FDA from blocking its shipment and sale. After the lawsuit bounced back and forth between the District Court

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29. The IND identifies investigators and sets forth drug ingredients, the probable mode of action in the body, known interactions, the manufacturing process, the results of animal and laboratory testing, and the study protocol. See, e.g., 21 C.F.R. § 312.20 (2018).
31. EXPANDING ACCESS CONFERENCE SUMMARY, supra note 22, at 7–8.
32. Id.
33. Id.
34. Rutherford v. United States, 399 F. Supp. 1208, 1208–10 (W.D. Okla. 1975). Patients’ quests for the unapproved treatment were publicized after the actor Steve McQueen was diagnosed with a rare form of lung cancer and travelled to Mexico to obtain Laetrile injections; see also Barron H. Lerner, McQueen’s Legacy of Laetrile, N.Y. TIMES (Nov. 15, 2005), https://www.nytimes.com/2005/11/15/health/mcqueens-legacy-of-laetrile.html. As an aside, in 1976, Congress further strengthened the FDA’s authority by creating new pre-market approval requirements with respect to medical devices to ensure that the benefits of any new medical device outweighed the risk. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539-83 (1976).
and the Tenth Circuit Court of Appeals, the United States Supreme Court upheld the FDA’s actions, explaining that an unproven therapy is just as unsafe for terminally ill patients as it is for other patients:

To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner’s authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and “Fountain of Youth” mixtures of spices, oil, and suet. In citing these examples, we do not, of course, intend to deprecate the sincerity of Laetrile’s current proponents, or to imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment. But this historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise.

When the AIDS crisis hit in the 1980s, AIDS patients and their advocates became vocal critics of the FDA, arguing that the agency was more focused on satisfying obscure standards of safety and efficacy for the sake of unknown future patients than in helping currently dying patients. They argued that patients should have the right to incur the risks inherent in experimental drugs rather than waiting years for the clinical trial process to provide more

36. Rutherford v. United States, 542 F.2d 1137, 1142–44 (10th Cir. 1976); Rutherford v. United States, 582 F.2d 1234, 1234 (10th Cir. 1978).
definitive safety and efficacy results. On October 12, 1988, a thousand AIDS activists launched a massive day-long protest at FDA headquarters in Rockville, Maryland, demanding that the FDA speed up the availability of investigational drugs that could help alleviate the epidemic. In his article *AIDS Activists, FDA Regulation, and the Amendment of America’s Drug Constitution*, Professor Lewis Grossman described the scene at FDA headquarters as follows:

Accompanied by whistles and noisemakers, the crowd around the Parklawn Building chanted its demands for pharmaceutical access. “AZT is not enough, give us all the other stuff!” “Release the drugs now!” Most provocatively, the demonstrators, referring to the FDA Commissioner, yelled “Frank Young, you can’t hide, we charge you with genocide!” Their placards and banners were no gentler. “AIDS Doesn’t Discriminate—Our Government Does.” “Federal Death Administration.” Many of the signs displayed a pink triangle, evoking the patch sewn onto the uniforms of gay inmates in Nazi concentration camps.

The action’s theatrical elements captured the attention of cameramen from the television networks and major newspapers. Protestors lay down on the street holding cardboard tombstones bearing epitaphs such as “RIP, Killed by the FDA” and “I Died for the Sins of the FDA.” Others paraded around in “blood”-stained white doctors’ coats.

Although the FDA had formalized an expanded access program in 1987 that provided an alternate pathway for terminally ill patients without meaningful options to request access to

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41. Id. at 689.
unapproved drugs in certain circumstances, advocates viewed this policy change as only one step in the right direction. They pointed out that the paperwork requirements to petition for access using this FDA pathway were time-consuming and burdensome.

II. Right to Try Laws Emerge

At the turn of the twenty-first century, a heart-wrenching case sparked further advocacy around the issue of autonomy and access to investigational drugs by individual patients. In 2000, nineteen-year-old Abigail Burroughs was diagnosed with head and neck cancer and underwent months of ineffective conventional treatments. Her doctor suggested that treating her cancer with either Iressa or Erbitux might benefit her, but neither drug had been approved by the FDA at the time. Because her cancer was so advanced, Abigail was ineligible for clinical trials then underway. Direct requests to pharmaceutical companies for non-trial access to the drugs were denied.

42. U.S. Dep’t of Health & Human Servs., Food & Drug Admin., Expanded Access to Investigational Drugs for Treatment Use, 52 Fed. Reg. 19,466 (1987); see Grossman, supra note 22, at 689–94. However, it was not until 2009 that the FDA clarified criteria for single patient access. 74 Fed. Reg. 40,900 (2009). In 2009, the FDA incorporated the term “expanded access” into its regulatory framework. Food and Drug Administration (FDA) Modernization Act of 1997, Pub. L. 105-115, 111 Stat. 2296 § 402 (1997). Under current FDA regulations there are three categories of expanded access: (1) expanded access for individual patients, including for emergency use; (2) expanded access for intermediate-size patient populations; and (3) expanded access for widespread treatment use through a treatment IND or treatment protocol. 21 C.F.R. §§ 312.310, 312.315, 312.320 (2019).


44. We discuss this case in detail in Regenerative Medicine and the Right to Try, supra note 17, at 609–611 (2017); see also Sam Adriance, Fighting for the “Right To Try” Unapproved Drugs: Law as Persuasion, 124 YALE L.J. F. 148, 150 (2014); Federal Right to Try, supra note 38, at 27.


46. Id. at 2.

47. Id. at 6–7. At the time of the requests, one of the companies provided Erbitux only to patients with colon cancer. Abigail, having been diagnosed with head and neck cancer, did not qualify for this study. The other company denied access because Abigail did not meet the inclusion criteria for its clinical trials. See Caitlyn Martin, Questioning the “Right” in
2020] THE STORIES WE TELL

Abigail’s family and friends embarked on a media campaign to pressure Congress to provide her with access to one of the recommended experimental drugs. For example, her classmates at the University of Virginia secured 6,600 signatures on a petition to Congress demanding access to the drugs. Senators George Allen and John W. Warner, both Republicans from the Burroughs family’s home state of Virginia, wrote to drug companies directly, echoing the family’s pleas for help. These efforts failed and Abigail passed away in 2001.

After her death, Abigail’s father founded the Abigail Alliance for Better Access to Developmental Drugs (the “Alliance”), an organization dedicated to reducing access barriers to non-FDA-approved drugs. The Alliance petitioned the FDA to create regulations that would enable manufacturers to market to terminally ill patients investigational new drugs that have successfully completed Phase 1 testing. When the FDA denied the petition, the Alliance sued the agency, arguing that the Due Process Clause should provide terminally ill patients access to investigational drugs that are “promising enough for substantial human testing.”

The district court initially dismissed the lawsuit, but the Alliance successfully appealed. The D.C. Circuit Court ruled in favor of the Alliance, holding that “the right to access potentially life-sustaining medicine” warranted protection under the Due Process Clause. The FDA sought an en banc review by the D.C. Circuit Court, which held that a fundamental right does not exist for...
terminally ill patients to gain access to experimental products. The Supreme Court denied certiorari.

This litigation raised public awareness about problems surrounding individual access to experimental interventions for therapeutic purposes. As a result, the FDA reformed its expanded access program in 2009 to provide three specific avenues for individual patients and groups of patients to acquire and use experimental products outside of the clinical trial process. The individual pathway eased access upon request, especially in emergencies and for the most seriously ill patients. The voluminous paperwork associated with an application, however, represented an administrative burden for physicians and manufacturers.

Because expanded access policy—and right to try laws, for that matter—depends on a willing manufacturer to supply the investigational drug, some of the larger drug manufacturers began to create their own private expanded access programs to help patients. Yet patient advocates, still frustrated by what they perceived as over-regulation by the FDA, turned to state legislatures to authorize non-trial access to investigational drugs. This effort was buoyed by a somewhat unlikely partnership between the Goldwater

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60. See Ginsberg, supra note 48.
62. Regenerative Medicine and the Right to Try, supra note 17, at 606.
63. Id.
Institute (“Goldwater”), a libertarian think tank that supports deregulation, and the Cancer Treatment Centers of America (“CTCA”), a for-profit hospital chain. In 2012, Goldwater coined the phrase “right to try” and the Goldwater-CTCA partnership began advocating for an alternative pathway to gain access to experimental drugs and devices without requiring permission from the FDA. They argued that patients and their physicians should be able to ask manufacturers directly, without any FDA oversight, for drugs and biologics that have completed Phase 1 clinical trials and are actively being tested in Phase 2 or 3 trials.

Goldwater drafted model state legislation with these goals in mind. According to the model legislation, in order to be eligible for access, patients must (1) have a terminal disease; (2) exhaust all FDA-available options, including clinical trials; (3) consult with a physician who recommends the experimental drug; and (4) provide informed consent in writing to use the experimental drug, which must have completed Phase 1 testing. The model legislation also provided limited liability protection for physicians, prohibiting licensure revocation based on recommendation of or treatment with an experimental product.

In 2014, Colorado became the first state to adopt a right to try law; to date, similar laws have been passed in forty-one states. To date, the following states have passed right to try laws: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. See Right to Try in Your State, RIGHT TO TRY, http://righttotry.org/in-your-state (last visited Feb. 20, 2020). As a result of this rapid expansion of state right to try laws, the FDA again revamped its expanded access program in 2016 to make the process significantly less onerous and time-consuming. Currently, the FDA reports that the average time to complete the paperwork is forty-five minutes and 99% of expanded access requests are approved. U.S. FOOD & DRUG ADMIN., EXPANDED ACCESS PROGRAM REPORT 1, 5 (2018), https://www.fda.gov/media/119971/download [hereinafter FDA EXPANDED ACCESS PROGRAM REPORT].
law, with five-year-old Jordan McLinn at his side. Jordan had been diagnosed with Duchenne muscular dystrophy, and at that time, although some promising experimental treatments were being studied, Jordan was not eligible to participate in those clinical trials. When named the Republican Vice-Presidential nominee, Pence placed the right to try issue on the Republican Party’s platform after another young boy asked him at a campaign rally whether the Republican ticket would advocate for the right to try at the federal level if elected. A video of the boy, Zack Mongiello, explaining that his father, Frank Mongiello, was dying of ALS went viral. Frank Mongiello and Jordan McLinn would ultimately be two of the patients for whom the federal Right to Try Act was named.

During this time, although more states were passing right to try laws, they were not being widely used. Right to try advocates asserted that if the right to try became part of a major political party platform, and was ultimately enacted into federal law, state-level


75. Id.

76. Frank Mongiello was diagnosed with ALS in May 2015, after his arm went numb while he was working in his garden. Mongiello, a father of six, worked for the Federal Reserve Board before his diagnosis. He rose to national prominence in 2016, gaining exposure from his aggressive Congressional lobbying campaign for the federal law. Over the course of the year, Mongiello met with over 100 members of Congress, testifying before four congressional hearings regarding the right to try. See, e.g., Exploring a Right to Try for Terminally Ill Patients: Hearing Before the S. Comm. on Homeland Security and Gov’t Affairs, 114th Cong. 251 (2016).

77. See SUSAN THAUL, CONG. RESEARCH SERV., R45414, RIGHT TO TRY: ACCESS TO INVESTIGATIONAL DRUGS 5–10 (2018).
concern about federal preemption would be eliminated, variation among state laws would be limited, and manufacturers would be reassured that expanding access would not put FDA approval of their products at risk.\footnote{78 See Republican Platform, supra note 73.}

In 2016, Senator Ron Johnson (R-Wisconsin) introduced the federal Trickett Wendler Right to Try Act of 2016.\footnote{79 Trickett Wendler Right to Try Act of 2016, S. 2912, 114th Cong. (2016). In addition, in 2015, two representatives introduced a bare bones version of right to try legislation that authorized experimental drug use with state law. H.R. 3012, 114th Cong. (2015). This bill did not incorporate most of the Goldwater Institute’s model legislation, but it did pass the House. See id.} This draft legislation was named for patient Trickett Wendler, a wife and mother diagnosed with ALS.\footnote{80 Brad Hicks, ALS has no treatment, no cure, no survivors: Waukesha mom shares her story: “I hope it helps others”, FOX6, https://fox6now.com/2015/05/20/als-a-disease-with-no-treatment-no-cure-no-survivors-waukesha-mom-shares-her-story-i-hope-it-helps-others (last updated May 21, 2015, 11:32 AM).} Within three months of her diagnosis, Wendler had lost the use of her lower body, and nine months later, she died, leaving her husband and three children behind.\footnote{81 Team Trickett Wendler: Fewell to Fight ALS, FACEBOOK (last visited Mar. 30, 2020) [hereinafter Team Trickett Wendler].}

Between her diagnosis and her death, Wendler gained a substantial following through shared updates of her prognosis on social media.\footnote{82 Id.} Local news stations published regular blog posts—authored by Wendler—detailing the physical and emotional effects of her condition as it progressed.\footnote{83 Hicks, supra note 80.} Wendler and her family created a “Team Trickett” Facebook page, regularly posting photos of Wendler alongside her children.\footnote{84 Team Trickett Wendler, supra note 81.} Team Trickett held fundraisers and awareness events and ran a highly successful crowdfunding site.\footnote{85 Id.}

The Trickett Wendler Right to Try Act of 2016 called for the same changes as many of its state law counterparts: eliminating FDA oversight, allowing terminally ill patients and their physicians to ask drug companies directly for access to drugs that have completed Phase 1 trials, and offering liability protection for “a producer, manufacturer, distributor, prescriber, dispenser, possessor, or user of an experimental drug.”\footnote{86 S. 2912, supra note 79, at § 2(a)(1).} The new bill also prohibited the FDA from...
using outcome data from non-trial access “to delay or otherwise adversely impact review or approval of such experimental drug, biological product, or device.” This bill, along with subsequent House and Senate bills, failed.

In his 2018 State of the Union address, President Trump revived the federal right to try effort when he stated: “People who are terminally ill should not have to go from country to country to seek a cure—I want to give them a chance right here at home. It is time for Congress to give these wonderful Americans the ‘right to try.’” President Trump signed the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 into law on May 30, 2018, stating at that time: “These are experimental treatments and products that have shown great promise, and we weren’t able to use them before. Now we can use them. And oftentimes they’re going to be very successful. It’s an incredible thing.” However, health care providers, scientists, and bioethics scholars have expressed broad disapproval of the federal Right to Try Act because of its significant curtailment of FDA oversight and limited reporting requirements, as well as its numerous other adverse ethical and safety implications.

87. Id. at § 2(b)(2); see also Letter from Sen. Ron Johnson (RWI) to Commissioner Gottlieb (May 31, 2018), https://www.hsgac.senate.gov/imo/media/doc/2018%205%2031%20RHJ%20to%20Gottlieb%20HHS%20rc%20Right%20to%20Try.pdf (“[T]his legislation is fundamentally about empowering patients to make decisions in cooperation with their doctors and the developers of potentially life-saving therapies” and it “intends to diminish the FDA’s power over people’s lives, not increase it.”).
III. THE RIGHT TO TRY’S SLIPPERY SLOPE?

One of the concerns about right to try laws is that they may become a slippery slope with respect to patients’ requests for access to drugs. For instance, with respect to the COVID-19 pandemic, President Trump remarked,

But this is beyond Right to Try. If treatments known to be safe in Europe, Japan, or other nations are effective against the virus, we’ll use that information to protect the health and safety of the American people. Nothing will stand in our way as we pursue any avenue to find what best works against this horrible virus.93

On this point, however, Jaci Hermstad’s story is instructive, and perhaps surprising.

Jaci Hermstad was a twenty-five-year-old who suffered from a rare form of rapidly advancing ALS.94 Her symptoms started as

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94. Tragically, Jaci’s twin sister died from the same rare form of the disease eight years before Jaci was diagnosed. Nicolas Florko, When ‘right to try’ isn’t enough: Congress wants a single ALS patient to get a therapy never tested in humans, STAT (May 31, 2019) https://www.statnews.com/2019/05/31/when-right-to-try-isnt-enough.
simple backaches and muscle weakness, but quickly escalated into significant pain that prevented her from even walking.\textsuperscript{95}

Following Jaci’s diagnosis, her physician told her family about an experimental form of individualized treatment for ALS—“an antisense oligonucleotide that researchers hoped would prevent the production of proteins suspected to kill motor neurons.”\textsuperscript{96} This treatment, however, had not yet been tested in humans.\textsuperscript{97} After a social media and fundraising blitz, as well as bipartisan Congressional pressure from Speaker of the House Nancy Pelosi, a Democrat, and Senators Chuck Grassley and Steve King, both Republicans, the FDA granted Jaci permission to obtain the drug.\textsuperscript{98} Jaci received twelve infusions of the drug before she passed away on May 1, 2020.\textsuperscript{99}

In this instance, the FDA worked closely with the family, the physician, and the manufacturer to make the drug available with minimal toxicity testing.\textsuperscript{100} Jaci was the first human to receive it.\textsuperscript{101} Her physician acknowledged three important aspects of this widely reported story: (1) the FDA’s helpfulness, (2) the need to make use of a comprehensive drug development process like that used by Columbia researchers to develop an antisense oligonucleotide called Milasen for a single patient, named Mila, with a rare variant of Batten disease,\textsuperscript{102} and (3) the likelihood that this model of extremely early access would itself expand.\textsuperscript{103} Arguably, because the

\textsuperscript{95} Id.

\textsuperscript{96} Id.

\textsuperscript{97} Id.

\textsuperscript{98} Id. Senator King introduced a bill directing the FDA to make an exception for Jaci Hermstad but Congress never formally considered it. H.R. 2855, 116th Cong. (2019).


\textsuperscript{100} Florko, supra note 94.

\textsuperscript{101} Stella Daskalakis, First dose of FDA-approved drug administered to Jaci Hermstad, KTIV (June 11, 2019), https://ktiv.com/2019/06/11/first-dose-of-fda-approved-drug-administered-to-jaci-hermstad. Note that the FDA did not provide premarket approval for this drug.

\textsuperscript{102} Jinkuk Kim et al., Patient-Customized Oligonucleotide Therapy for a Rare Genetic Disease, 381 NEW ENG. J. MED. 1644, 1644–52 (2019); Erika Check Hayden, This girl’s dramatic story shows hyper-personalized medicine is possible—and costly, MIT TECH. REV. (Oct. 9, 2019), https://www.technologyreview.com/s/614522/this-girls-dramatic-story-shows-hyper-personalized-medicine-is-possibleand-costly; Kristina Fiore, Mila’s N-of-1 Trial Detailed in NEJM, MEDPAGE TODAY (Oct. 9, 2019), https://www.medpagetoday.com/genetics/generalgenetics/82648.

\textsuperscript{103} Rose Duesterwald, The FDA, Congress, A Young Woman Dying of ALS, Her Physician, and Her Parents Are All Struggling over Access to an Untested Therapy, PATIENTWORTHY (June 10,
flexibility demonstrated by the FDA in this instance is not available in the federal right to try law or any of the state statutes, all of which require the completion of Phase 1 trials, the FDA’s expanded access program remains a viable pathway to broad and early access that may be scientifically superior to utilizing any right to try statute.  

104. An IND for a first-in-humans use must be submitted, provided the manufacturer is willing to provide a letter of authorization. See Janet Woodcock & Peter Marks, Drug Regulation in the Era of Individualized Therapies, 381 NEW ENG. J. MED. 1678, 1679 (2019); see also Sharon Begley, 5 things to know about the experimental treatment Charlie Gard might receive, STAT (July 17, 2017), https://www.statnews.com/2017/07/17/charlie-gard-treatment (describing how nucleoside bypass therapy had never been tested in a clinical trial but was already being provided to at least one patient through FDA “compassionate use.”); see also Erika Lietzan, The Tradeoffs Involved in New Drug Approval, Expanded Access, and Right to Try, OBJECTIVE INTENT (Mar. 21, 2020) (“For an individual patient, the general criteria for expanded access must be satisfied, and (1) the treating doctor must determine that the probable risk to the patient from the drug is not greater than the probable risk from the disease, and (2) FDA must determine that the patient cannot obtain the drug any other way (for instance, by enrolling in a clinical trial).”). The agency ordinarily looks for completed Phase 1 trials at doses similar to those proposed for the patient, together with preliminary evidence suggesting effectiveness. Id. “In some cases, however, FDA will permit a single patient access based on preclinical (animal) data or even mechanism of action.” (emphasis added). Id. In the COVID-19 pandemic, we have also seen extensive use of the FDA’s Emergency Use Authorization process, whereby unapproved medical products or unapproved uses of approved medical products may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. 21 U.S.C. § 360bbb-3; see also Emergency Use Authorization, FDA, https://www.fda.gov/emergency-preparedness-and-response/cms-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited May 25, 2020) (explaining that the EUA within section 564 of the Food, Drug & Cosmetic Act was amended by the Project BioShield Act of 2004, the Pandemic and All Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), the 21st Century Cures Act, and Public Law 115-92 of 2017); see also 85 Fed. Reg. 13,169 (Mar. 20, 2020), https://www.federalregister.gov/documents/2020/03/06/2020-04630/policy-for-diagnostics-testing-in-laboratories-certified-to-perform-high-complexity-testing-under (describing final guidance, “Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under the Clinical Laboratory Improvement Amendments Prior to Emergency Use Authorization for Coronavirus Disease-2019 During the Public Health Emergency,” whereby laboratories may use tests they develop and validate even before obtaining EUA so as to provide for increased testing capacity in the United States). These public health emergency options are not available to patients under current Right to Try laws. See Liz Richardson, How COVID-19 Patients Can Access Investigational Drugs and Devices, PEW CHARITABLE TR. (Apr. 28, 2020), https://www.pewtrusts.org/en/research-and-analysis/articles/2020/04/28/how-covid-19-patients-can-access-investigational-drugs-and-devices.
IV. WHOSE STORIES DO WE FAIL TO HEAR IN RIGHT TO TRY DISCUSSIONS?

Right to try proponents understandably relate compelling and tragic stories. Hearing these stories, it is easy to identify with these patients and imagine that each of us, if faced with a devastating diagnosis, would act similarly. But like all narratives, each story is no more than a single thread in the fabric of this complex medical, legal, ethical, and social issue. These stories by themselves cannot provide us with a comprehensive understanding of the issue because there are many other stories missing from the fabric. These include, but are not necessarily limited to, stories about research scientists who are working to develop new treatments, stories that illustrate the public health needs of those who cannot as readily be portrayed as “innocent” identified lives, stories from those who regret seeking treatment with experimental drugs, and stories about how the FDA’s stringent regulations ultimately saved lives. These rarely-told stories not only illustrate systematic disadvantage and structural injustice but help to support arguments and data demonstrating the need for a health care system that is meaningfully available to all.

A. Portraying the Duties of Responsible Science

A large part of the success of the right to try movement lies in its portrayal of paternalistic resistance to the autonomous choices of understandably desperate patients, who have nothing to lose—except their lives. Making use of narrative to move beyond this oversimplification and deepen public understanding of the role of responsible science is particularly challenging because, in a sense, it requires starting from a profound deficit of positive stories about science and scientists. Consider how many television and movie portraits of “the good doctor” have been culturally available in the


106. See Annas, Changing Landscape, supra note 16, at 126, 132, 135, 139–140 (asserting that the argument that terminally ill patients have “nothing to lose” is extremely harmful, especially to the most vulnerable patients.); Annas, Questing for Grails, supra note 16; Kolata, supra note 16.
United States, from the 1960s to the present. An attempt to list portrayals of good scientists quickly ends with the realization that mad scientists and evil scientists—from Dr. Frankenstein to Dr. Strangelove to Dr. He Jiankui—are instead distressingly common. What makes good doctors good—devotion to the best interests of their patients—is often depicted as following from a genuinely shared decision-making process, in which the patient’s needs and preferences and the physician’s superior knowledge come together. That the physician’s knowledge is a conclusion built from a foundation of scientific data assembled through careful and systematic research is rarely an explicit part of the picture.

Nonetheless, the duties that researchers have to uphold the scientific process for the safety of current subjects and the benefit of future patients are complementary to, and consonant with, the principles of autonomy, beneficence, and justice that govern the physician-patient relationship. When the research enterprise is approached for access to an unproven intervention, the duty that researchers share to make only fair offers of access to unproven interventions is as fully applicable to patients using the right to try law as it is to potential research subjects being recruited for a clinical trial. The scientist who does not care that the intervention might not be safe enough, or that its likelihood of being at all effective is either very low or completely unknown, is not a good scientist.

107. Consider, for example, the following characters: Dr. Kildaire, Dr. Marcus Welby, Dr. Hawkeye Pierce, Dr. Doogie Howser, the doctors of ER and Chicago Hope, and many more.
109. DR. STRANGELOVE, OR HOW I STOPPED WORRYING AND LEARNED TO LOVE THE BOMB (Columbia Pictures 1964).
112. Id.
clinician who assists a patient with a right to try request but does not care about those things is not a good doctor, either. Clinicians may not fully recognize the limitations of their knowledge about a requested intervention; and right to try laws, by eliminating the role of the FDA, have removed the clinician’s best access to complete information. In short, the skepticism about responsible science that has increasingly characterized public discourse in the United States has made it difficult to generate positive narratives about the role that clinical research plays in improving the public’s health, except when those narratives promise that cures are just around the corner.115

Consider, for example, the FDA’s initial rejection of tissue plasminogen activator (tPA), a drug now used by hundreds of thousands of patients, which breaks up ischemic stroke-causing blood clots.116 Following the initial FDA rejection, the company retested the drug at a lower dose—which was found to be effective, had fewer fatal side effects, and was less expensive.117 At the new lower dose, the FDA approved the drug.118 Powerful examples like this of the benefits of the FDA’s rigorous testing requirements and safety and efficacy controls do not, however, receive much airtime.

One example of narratives about responsible science has, surprisingly, emerged from the chaotic response of the federal government to COVID-19. Dr. Anthony Fauci, who has directed the National Institute for Allergy and Infectious Diseases since the

117. Id.
118. Id. But cf. Stacy Colino, Why Aren’t Stroke Patients Getting Clot-Busting tPA Drug?, AARP (June 16, 2008), https://www.aarp.org/health/conditions-treatments/info-2018/stroke-treatment-tpa-blood-clots.html. According to a recent study, although there are 795,000 strokes per year, about 25% of stroke patients do not receive tPA, in part because many hospitals do not have a stroke team and thus are not prepared to administer tPA. Because of this negative outcome, this tPA story is a call to action for readers.
1980s, seems to be emerging as the personification of the good scientist. Dr. Fauci, who was instrumental in the federal response to Ebola, SARS, anthrax, HIV, and H1N1, has been at the forefront of news about domestic COVID-19 protection, testing, and treatment measures. Although more recently the subject of right-wing conspiracy theories, he has been widely praised in numerous publications, including *The Atlantic*, *The New York Times*, and *The Hill*, and has been a voice of reason amid a cacophony of promised quick fixes and unproven therapies. The recognition his efforts have received as of this writing suggest not only that he is indeed an exemplary public figure and public health leader, but also that many in the American public are more than ready for stories of scientific leadership like his.

119. The National Institute of Allergy and Infectious Diseases is one of the entities that make up the National Institutes of Health (NIH), which is an agency under the ambit of the United States Department of Health and Human Services. See generally National Institute of Allergy and Infectious Diseases, Nat’l Inst. Health, https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-institute-allergy-infectious-diseases-niaid (last updated Apr. 10, 2019).


B. Personifying Statistical Lives

People turn their attention to identified lives for many reasons, but two reasons dominate when it comes to the right to try. Identified lives are, generally, “innocent”—that is, we can view them as not responsible for their medical misfortunes. Identified lives also present us with misfortunes that can be easily remedied by discrete action—in this case, by supporting legislation that appears to provide direct access to potentially lifesaving interventions. Right to try advocates assert that the laws allow many people access to unproven medical interventions, thus potentially making the case that those patients who have given their names to the federal law are personifying statistical lives.127 Yet similar efforts to put a sympathetic face on public health policy have not been as successful.128 When the remedy for an identified misfortune is less immediate and discrete than supporting a short-term rescue like that promised by GoFundMe efforts,129 it can be much harder to garner sympathy.

One example was thoughtfully analyzed by Georgia State Law Professor Charity Scott130 when an Atlanta newspaper highlighted the story131 of a family whose children benefited from PeachCare, Georgia’s State Children’s Health Insurance

127. See Right to Try Bill Signing Remarks, supra note 91 (“We will be saving—I don’t even want say thousands, because I think it’s going to be much more—thousands and thousands, hundreds of thousands . . . .”).
129. Contributing to a GoFundMe account created to pay high health care costs, including costs incurred for unproven treatments, is a simple, one-time action that may reinforce the prioritization of privatized help for identified lives. For example, in Regenerative Medicine and the Right to Try, we tell the story of Charlie Gard, who was born in August 2016 and, two months later, was diagnosed with infantile onset encephalomyopathic mitochondrial DNA depletion system (MDDS) caused by a mutation in his RRM2B gene. He became paralyzed and suffered brain damage. Charlie’s parents launched a social media campaign to raise awareness and funds to bring him to the United States for an experimental nucleoside treatment that had apparently provided benefit to some infants with a different gene mutation in a small clinical trial. Through a GoFundMe campaign, Charlie’s parents raised millions of dollars to support his travel and purchase right-to-try access to the unproven medical treatment. A protracted legal battle occurred in the United Kingdom and the European Court of Human Rights; the courts found that palliative care and withdrawal of life-prolonging treatment were in Charlie’s best interests. Charlie died in July of 2017. See Regenerative Medicine and the Right to Try, supra note 17, at 592–93 (citations omitted).
131. Id. at 16.
Program. The article’s authors sought to argue in support of maintaining the current level of benefits for children in low-income families that are not quite poor enough for Medicaid, at a time when a legislative proposal to curtail PeachCare eligibility was being considered. Instead, readers nearly universally commented that the parents were not sufficiently innocent; they had too many children and could have found higher-paying jobs, so they were responsible for their own misfortune in not being able to meet their children’s health care needs without PeachCare, and therefore did not deserve to be helped by the continuation of a long-term drain on taxpayers. Professor Scott attributed this response—which is unfortunately less surprising in 2020 than it was in 2008—to belief in a just world. That is, if a person believes that life is essentially fair and good—or prefers that belief because it is easier than facing the challenge of reforming inadequate social structures—then it becomes essential to conclude that those who are unfortunate are at fault, or it at least becomes necessary to determine that “it can’t happen to me” (that is, “I would make better choices, I would be able to avoid needing help from the government”).

Professor Scott’s concept of “belief in a just world” has a specific application in the right to try context. Right to try narratives generally feature patients with whom white, middle-class readers can readily identify and sympathize. Because these patients with whom many identify are not blameworthy, it then becomes easy to blame the FDA. Those patients whose life circumstances have contributed to their conditions, and/or who lack the resources to

132. Id.
133. Id.
134. Id. at 16–17.
136. See Scott, supra note 128, at 18–19 (discussing reader responses). The COVID-19 pandemic continues to demonstrate the strength of this habit of focusing blame and responsibility on individuals, as a growing consciousness of structural inequity competes with a focus on comorbidities and bad habits to explain the disproportionate levels of morbidity and mortality in Black and Latinx patients. See, e.g., Nancy M. P. King, Justice and Domestic Health Research, 42 ETHICS & HUMAN RESEARCH 41–42 (2020); Larry R. Churchill, Nancy M. P. King, & Gail E. Henderson, The Future of Bioethics: It Shouldn’t Take a Pandemic, 50 HASTINGS CENTER REPORT 54–56 (2020).
137. Id. at 16.
mount a social media campaign\textsuperscript{138} or otherwise assert their right to try, simply do not appear in the narratives; they remain statistics.

Perhaps most challenging about these untold stories is the complexity attendant upon addressing their absence from the narrative armamentarium. It is possible to argue persuasively that everyone ought to have the right to try—that it is unfair to exclude those who are not attractive, innocent, wealthy, or socially connected enough to gain access to unproven interventions. A successful argument for equality of access might trouble the most thoroughly libertarian proponents of the right to try, but it entirely fails to address more systematic problems of access. Many of those who seek the right to try have never been denied access to health care before. Indeed, the requirement that all other treatment possibilities be exhausted before a patient can gain access to an unproven intervention strongly implies that access to appropriate treatment has generally been available for those who exercise the right to try.\textsuperscript{139} Therefore, focusing legislative efforts on the most extreme of rescue scenarios runs considerable risk of drawing attention away from the real and substantial needs of statistical lives—that is, all those who lack access to basic health care. When we are willing to provide the last resort, and to encourage private efforts to fund it (such as GoFundMe drives to pay the cost of non-trial access\textsuperscript{140} or public shaming of drug manufacturers to encourage them to reduce or waive charges),\textsuperscript{141} we may become far less willing to identify and address basic health care needs, especially when private generosity and charity cannot substitute for public funding. In

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\item \textsuperscript{138} See Mackey & Schoenfeld, \textit{supra} note 64, at 5 (finding that individuals with cancer typically gain the most social media traction, presumably because most of the population can personally connect to their stories, having known at least one person who has died from cancer).
\item \textsuperscript{139} See Alison Bateman-House, \textit{“Right to Try” Is Law, Now What?: Part I}, \textit{Health Affairs} (Oct. 25, 2018), https://www.healthaffairs.org/do/10.1377/hblog20181024.111856/full (explaining how right to try drugs are those investigational drugs outside of clinical trials, demonstrating that patients have exhausted numerous FDA-approved options; this suggests a continuing patient-physician relationship throughout the trial).
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other words, some untold stories are about those who would not need to be “rescued” if they had not been adversely affected by systemic disadvantage and structural injustice.142 These stories, when heard, illustrate the need for a health care system that is meaningfully available to all from the outset.143

Public health needs are rarely as immune to belief in a just world as is the right to try scenario. Those who seek access to unproven interventions by invoking right to try laws have already shown themselves to be “deserving” by virtue of being able to afford to try everything else available. The right to try argument thus deflects attention from a broad range of genuine, urgent, public health needs that apply to a great many individuals and families and that very probably cannot effectively be addressed solely through the stories of even the most sympathetic lives.

C. No One Has Nothing to Lose

The stories that are most tragically left untold in the shadow of the right to try are not about the responsible scientist or the worthy patient; they are stories about the good death. Before the ascendancy of modern medicine, when death was not only inevitable but was not even susceptible of postponement, what should count as a good death was a subject worthy of discussion.144 After science began to understand and conquer many infectious diseases, and when what was learned in two world wars was applied to all illness and injury, it became necessary at times to invert a popular maxim for the benefit of physicians in training, urging them: “Don’t just do something—stand there!”145 This reminder that doctoring is about curing when possible, but caring for and being with patients always, is increasingly necessary as medical technology advances. When patients and their families believe that the best thing they can do is everything that has any chance of prolonging life, they also

144. In Charles Dickens’ A Christmas Carol, set in Victorian England, it is Ebenezer Scrooge’s reaction to the possible future in which he dies alone and unloved that finally changes the course of his life. CHARLES DICKENS, A CHRISTMAS CAROL (1843).
145. This apocryphal quote has been attributed to many, but the most interesting source is the White Rabbit in the animated Disney film Alice in Wonderland (Walt Disney Productions 1951 at 0:21:00).
tend to believe that a cure is just around the corner, and that their courage and persistence in the face of adversity will be rewarded if they can hold out long enough. That hope is understandable but tragic when it makes staying with and caring for dying patients seem like giving up.

The narratives that are arguably the hardest of all to tell are those about doing everything and regretting that choice, as is illustrated by the story of Joe Malinowski, who at age thirty-seven was diagnosed with advanced hairy cell leukemia, an aggressive form of cancer. Joe’s physicians suggested experimental treatments, which he tried. Joe’s health improved and his cancer went into remission for fourteen years. Eventually, however, Joe began to get sick again. Palliative care options were never discussed, and Joe decided to again turn to experimental treatments to save him.

The outcome this second time was far different. The drugs caused Joe’s condition to worsen. As described by his son, Professor Michael Malinowski, in *Throwing Dirt on Doctor Frankenstein’s Grave: Access to Experimental Treatment at the End of Life*:

> [Joe] cried into the mirror. The entire side of his face that was operated on drooped; he had to hold a towel to his face constantly to catch drool, which added further humiliation. Joe was too embarrassed about his appearance to ever leave his home again, and even close, life-long friends staggered visits and then eventually stopped visiting altogether.

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148. Id. at 616–17.

149. Id. at 617.

150. Id. at 618.

151. Id.

152. Id.
Joe developed new tumors all over his face and became physically unrecognizable.\textsuperscript{153} He died a painful death fraught with worry and his experience scarred his family.\textsuperscript{154}

In courses addressing the physician-patient relationship, medical students often discuss what counts as a good death and how to help patients make end-of-life decisions.\textsuperscript{155} One example that is recently of common use in teaching is a short essay, “Lisa’s Stories,” in which a physician wonders whether he should have counseled a dying patient more directly.\textsuperscript{156} Lisa was a young mother, so young and upbeat that when she asked, “I’m not that far gone, am I?” he said no, and recommended a new treatment effort.\textsuperscript{157} She died soon after their conversation, without having taken the opportunity to write stories, or even record messages, for her children to remember her.\textsuperscript{158}

Preparing for death, through leave-taking from and creation of a legacy for one’s survivors, is a longstanding, even time-worn practice that may be losing currency as the “do everything” perspective gains ground.\textsuperscript{159} But many modern stories about making unpopular yet rewarding choices about the end of life feature acceptance of death, too.\textsuperscript{160} Stories about accepting death implicitly challenge the belief, often expressed by right to try advocates, that those who are dying have nothing to lose by trying a treatment of last resort. Such stories show clearly—though not as graphically as stories like Joe Malinowski’s—what can be lost by trying. Although both stories about dying well and stories expressing regret about not accepting death are often quite compelling, they are not numerous or prominent, and thus do not have the same public power as right to try stories about striving to triumph over death seem to command. And when the dominant form of narrative is triumphal,

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\textsuperscript{153} Id.

\textsuperscript{154} Id. at 618–19.

\textsuperscript{155} See, e.g., Thomas P. Duffy, \textit{The Medical Student and Care at the End of Life}, 15 AMA J. ETHICS 672, 672–74 (2013) (detailing the evolution of end-of-life care education).


\textsuperscript{157} Id.

\textsuperscript{158} Id.


\textsuperscript{160} See, e.g., Christine Hemp, \textit{My Father Loved Epic Solo Road Trips, But for His Final Journey, We All Came Along}, SALON (Feb. 9, 2020, 12:30 AM), https://www.salon.com/2020/02/08/my-father-loved-epic-solo-road-trips-but-for-his-final-journey-we-all-came-along.
the fear of being regarded as quitters rather than fighters can significantly influence the choices that patients and families make about the end of life. Too many terminally ill patients may find themselves unable to take advantage of existing support for those with life-threatening illnesses because the stories that accept dying and help families to deal with grief and guilt are drowned out by “trying for the cure” stories.

V. ANALYSIS AND CONCLUSIONS

Looking back, it is quite understandable how narratives helped right to try laws become reality. Right to try narratives publicly “offer heartrending accounts of terminally ill patients seeking investigational drugs and deceased patients who were denied such drugs.”161 It is easy to see how vivid stories, highlighting both the certainty of death and the profound hope that access to unproven interventions could forestall it, made politicians more inclined to act immediately.162

The personal stories that were used to promote the right to try pathway have provided some valuable insights. Indeed, the right to try movement spurred reform of the FDA’s Expanded Access pathway in both 2009 and 2015; today, physicians can complete the necessary paperwork in approximately forty-five minutes, and 99% of requests for access are granted.163 And as we have seen most recently in the case of Jaci Hermstad, FDA’s mechanisms may provide a more permissive option than right to try laws can offer.164

Nonetheless, right to try advocates still see the FDA as an agency that promises to help future patients but cares little for individual patients suffering today.165 Without a doubt, the clinical trial process can be frustrating for patients and their advocates, and it may be particularly discouraging to desperately ill patients who have run out of conventional treatment options. In reality, however, although some investigational drugs do provide therapeutic benefit

161. Dresser, supra note 14, at 1632.
163. FDA EXPANDED ACCESS PROGRAM REPORT, supra note 70, at 5.
164. See Florko, supra note 94.
165. See Corieri, supra note 43; Right To Try Opens Door For Innovation In Coronavirus Crisis, supra note 93.
for patients, the main purpose of clinical research is obtaining generalizable knowledge. The process of obtaining data about safety and efficacy is necessarily time-consuming and expensive, with far more investigational drugs failing than proceeding to market. Specifically, the time from inception to clinical application takes years—usually seven to eight years for the small fraction—approximately 13.8%—of drugs that successfully complete the clinical trial process and receive marketing approval. Moreover, this success rate varies significantly across types of drugs. Vaccines for infectious diseases, for instance, have an approximate 33.4% success rate, while only 3.4% of investigational cancer treatments successfully advance through the clinical trial process. In short, although modern medicine has produced some highly effective drugs, most investigational drugs fail to live up to their pre-market hype and hope.

While personal stories of individuals who are denied access to investigational drugs are emotionally charged and heart-wrenching, the impulse to rescue identifiable victims with tragic stories through right to try laws is fraught with negative consequences. Health policy analysts predict that right to try legislation is unlikely to improve access to investigational therapies to a meaningful extent, primarily because the laws were structured to work outside of, and run parallel to, the FDA’s existing expanded access program. Because these laws do not affect the FDA’s authority to grant marketing approval, they likewise do not directly address concerns about the speed with which new drugs come to market. In fact, widespread use of right to try laws may have the opposite effect, slowing down the development of investigational drugs by diverting

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166. See BELMONT REPORT, supra note 113; see also Nancy M.P. King, Defining and Describing Benefit Appropriately in Clinical Trials, 28 J. L. MED. & ETHICS 332, 332–43 (2000).
169. Wong et al., supra note 168, at 277.
170. Federal Right to Try, supra note 38, at 27 (citing J. Puthamuana et al., Availability of Investigational Medicines through the US Food and Drug Administration’s Expanded Access and Compassionate Use Programs, 1 J. AM. MED. ASS’N NETWORK OPEN 1, 5–6 (2018)).
patients and resources from clinical trials. Moreover, because access under right to try laws is outside of the FDA’s oversight, unscrupulous companies could prey on vulnerable patients by selling them investigational drugs that are neither safe nor effective. Finally, right to try laws are inherently misleading, encouraging patients to regard as effective treatments drugs that have only completed basic safety trials, and leading people to believe they have a right of access to those drugs, when in reality, the right is simply to ask the manufacturer for access. In reality, patients already have the right to ask under the FDA’s expanded access pathway, which, while not perfect, grants 99% of all requests. And according to both the FDA pathway and right to try laws, the manufacturer is free to grant or deny access, and to charge patients the cost of the investigational drug (which is generally provided at no cost to patient-subjects in early-phase clinical trials).

172. Consider, for example, high-dose chemotherapy followed by autologous bone-marrow transplantation, a treatment for metastatic breast cancer (abbreviated as HDCT-ABMT). In the early 1990s, anecdotal evidence showed that patients were obtaining better results with HDCT-ABMT than with lower dose chemotherapy. Although randomized clinical trials were being conducted to see if HDCT-ABMT was, in fact, optimal, many physicians started prescribing HDCT-ABMT outside of trials, and it became increasingly difficult to get patients to enroll in the trials. When an adequate number of women finally enrolled, the clinical trials determined that low dose chemotherapy was more effective with far fewer side effects than HDCT-ABMT. See Jerry Menikoff & Edward P. Richards, What the Doctor Didn’t Say: The Hidden Truth About Medical Research 124–35 (2006); Sertkaya et al., Examination of Clinical Trial Costs and Barriers for Drug Development, OFF. OF THE ASSISTANT SECRETARY FOR PLAN. & EVALUATION (July 25, 2014), https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development/43-difficulties-recruiting-and-retaining-participants (discussing major obstacles to recruitment and retention of clinical trial participants).


175. FDA EXPANDED ACCESS PROGRAM REPORT, supra note 70, at 2, 5.

176. Id. at 19. See, for example, Gilead Science, Inc.’s (Gilead) proposed drug for COVID-19, remdesivir. The drug has been in development for over ten years, first used with hepatitis C treatment in 2009 and resurfacing during the Ebola outbreak in 2014. After COVID-19 patients were enrolled without charge in clinical trials, positive results regarding remdesivir’s efficacy were formally announced by Gilead in late April. Gilead then
Because narratives have the power to mobilize public opinion to support rescuing identified individuals, when used in public health policy they need to exhibit features that can support application beyond identified lives, including generalizability and complexity. In addition, they should not stand alone, but must be used in combination with empirical research and a sound normative foundation in order to illustrate and justify the broad public health goals at which they aim. As one scholar commented, “Compassionate rationality as well as rational compassion must come into play when we work with problems of both identified and unidentified lives.”178 Patients’ stories can and do go beyond the simplistic right to try narrative model, even illustrating the need to streamline the clinical trial process and find more efficient translational models.179 Compelling narratives, when combined with sound science and moral reasoning, can thus support the development of improved research policy that blends safe and careful science with caring about and for patients who are research subjects.

Ultimately, the United States needs to expand access to health care, including access to novel and costly treatments, but that expansion must serve the public as a whole.180 Stories must be announced the wholesale price of the course of the drug: developed governments will be charged $2,340 for a five-day course and U.S. insurers will pay $3,120. This angered patient advocates and some legislators, who argue that with Gilead’s net worth at more than $15 billion, it should not be profiting from the pandemic. See Matthew Herper, Gilead announces long-awaited price for Covid-19 drug remdesivir, STAT (June 29, 2020), https://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19; Bret Stephens, The Story of Remdesivir, N.Y. TIMES, Apr. 17, 2020, https://www.nytimes.com/2020/04/17/opinion/remdesivir-coronavirus.html.

177. See Dresser, supra note 14.


179. For example, David Fajgenbaum, who was diagnosed with a rare disease when he was in medical school, studied his condition, found an effective treatment, and went on to develop a highly promising new clinical research model, has promoted this kind of study design innovation through his book CHASING MY CURE (Random House 2019); see also Dresser, supra note 14, at 1633 (2014) (“Experts should use stories and other information on patients’ experiences to describe the full range of effects that investigational drugs can produce. Such information is essential to developing access policies that truly promote patients’ interests.”).

deployed to illustrate the need and the effort required, but in a different way—to highlight individual and group access needs rather than to facilitate judgments about the deservingness or worthiness of patients.181 Stories need to be told to foster public health goals.

It is possible that COVID-19 will teach us exactly how to do that. As medical journalists strive to make sense of conflicting information and rapidly changing data, attempts to make statistical lives vivid and memorable through stories fill the popular, scientific, and scholarly press.182 Quarantined cruise ship passengers have detailed their ordeals and the measures taken (both effective and ineffective) to prevent transmission and test for infection, as have individuals living in China, Italy, Spain, and elsewhere who describe life under lockdown and those in America who have first-hand knowledge of life while sheltering in place.183 A feature in the online magazine Slate, called Coronavirus Diaries, has been publishing a wide variety of first-person accounts of the effects of the pandemic on individuals, families, businesses, and social institutions.184

Significantly, in the face of this viral infection, each of us is one of the enormous number of statistical lives affected, and each of us is both innocent (because no one deserves an infection) and guilty (because each of us can potentially infect others). The plights of those who are, for socioeconomic reasons, vulnerable to either the infection or to the adverse effects of prevention efforts have been widely addressed in news reports, and political discussion has highlighted attention to the health needs of people as of equal or more importance than the economic consequences of the pandemic.185

184. See Pandemic Journal, supra note 182.
We are all familiar with rescue narratives that focus on one or a handful of identified lives, and on the massive and heroic volunteer efforts undertaken to save them. One of the most noteworthy recent examples is that of twelve young boys and the assistant coach of their soccer team who were trapped in an underground cave in Thailand.\(^{186}\) They entered the beautiful cave system for a short celebration after a practice, but an early-arriving monsoon deluge flooded their exit route.\(^{187}\) Over the next few weeks, the world watched as many thousands of volunteers and officials debated options, amassed supplies and equipment, devised rescue strategies, and ultimately succeeded in bringing all thirteen to safety.\(^{188}\) One rescuer died during that time; another died a year later of an infection acquired during the rescue.\(^{189}\)

While some argue that the size and strength of efforts like this rescue seem profoundly disproportionate,\(^{190}\) it is possible to make use of identified-life efforts like these to affect public policy change. After the rescue, the Thai government promised enhanced safety protections for tourists and better training for rescue squads.\(^{191}\) Perhaps even more important, three of the boys and the assistant coach were stateless—a stigmatized status assigned to members of some ethnic minorities in the country, who, though born in Thailand, are not permitted to vote, work legally, own land, or travel

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\(^{187}\) Id.


52  WAKE FOREST JOURNAL OF LAW & POLICY  [Vol. 11:1

freely. After the rescue, they were granted Thai citizenship. The government has stated its intention to end statelessness by 2024, and is a leader in UNHCR-sponsored efforts to end statelessness worldwide—a problem affecting hundreds of thousands of statistcal lives.

Similarly, as we have noted, the global COVID-19 crisis is currently making extensive use of narratives from identified lives to help drive both public health practice and public policy change. Health care providers, celebrities, and individual storytellers are deeply engaged in attempting to shape public behavior, change current practice, and help drive medical progress and policy-level reforms. Linking stories from vulnerable and underserved individuals with stories from essential personnel, many of whom are low-wage workers, and stories from medical and scientific experts on the front lines of prevention and treatment, this modern coupling of sympathetic narrative and responsible information is precisely the right form of narrative-inflected policymaking. Even in the era of smartphone-screen-sized attention spans, it is possible to convey stories with enough depth and nuance to resonate and help us to craft and implement policies that reflect more than individual autonomy and personal charity.

The right to try essentially valorizes consumer choice. In contrast, using narrative in responsible policymaking reminds us that science and government play key roles in promoting solidarity and the best interests of the public as a whole. Braiding narrative together with good science and good data could serve as a model for successful public health policymaking—as long as it becomes a lesson that we actually learn and remember.


193.  Id.


195.  To give just one example, on March 26, basketball great Steph Curry and Dr. Tony Fauci engaged in a live coronavirus question and answer session on Instagram, which was widely publicized, broadly available, and extensively covered by news outlets. See, e.g., Mark Medina, Opinion: Stephen Curry’s coronavirus interview with Dr. Anthony Fauci is most significant move of his career, USA TODAY (Mar. 26, 2020), https://www.usatoday.com/story/sports/nba/columnist/mark-medina/2020/03/26/stephen-curry-coronavirus-interview-anthony-fauci-most-significant-move/2922652001; Mangan, supra note 126.