
BOOK REVIEWS

THE RIGHT TO TRY

BY DARCY OLSEN

*Reviewed by Evan Bernick**

Note from the Editor:

This book review discusses the controversial concept of the constitutional “right to try” experimental drugs to save one’s own life. The Federalist Society takes no positions on particular legal and public policy matters. Any expressions of opinion are those of the author. Whenever we publish an article that advocates for a particular position, as here, we offer links to other perspectives on the issue, including ones opposed to the position taken in the article. We also invite responses from our readers. To join the debate, please e-mail us at info@fedsoc.org.

- Elizabeth Weeks Leonard, *Right to Experimental Treatment: FDA New Drug Approval, Constitutional Rights, and the Public’s Health*, 37 JOURNAL OF LAW, MEDICINE AND ETHICS 2009 (April 18, 2008), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1208428.
 - Sam Adriance, *Fighting for the ‘Right to Try’ Unapproved Drugs: Law as Persuasion*, 124 YALE L.J. F. 148 (2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2698239.
 - Y. Tony Yang, Brian Chen, and Charles Bennett, “Right-to-Try” Legislation: Progress or Peril?, JOURNAL OF CLINICAL ONCOLOGY (2015), available at <http://jco.ascopubs.org/content/early/2015/07/14/JCO.2015.62.8057.full>.
 - Roger Pilon, M. Edward Whelan, Jonathan H. Adler, Curt Levey, *Abigail Alliance v. von Eschenbach Online Debate*, Federalist Society (2007), available at <http://www.fed-soc.org/publications/detail/abigail-alliance-v-von-eschenbach>.
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Do dying Americans have the right to try to save their own lives and the lives of their children? The question seems absurd because the answer is—or seems as if it should be—obvious. But every year millions of Americans suffering from fatal diseases are denied access to safe, potentially life-saving medicines by the federal government. Darcy Olsen’s *The Right to Try* is a shocking, sometimes heartbreaking, yet ultimately hopeful account of an ongoing tragedy and the growing campaign to put an end to it.

Federal law—specifically, the Food, Drug & Cosmetic Act¹ (FDCA)—generally prohibits marketing and distributing drugs that have not yet been approved by the Food and Drug Administration (FDA). It takes an average of fifteen years to bring a new drug to market (Olsen, 215). Americans suffering from fatal diseases for which there is no FDA-approved treatment have limited options. For all but the very few terminally-ill Americans who are qualified for and able to participate in clinical trials of unapproved drugs, or receive unapproved drugs through the FDA’s “compassionate use” programs (which provide terminally-ill patients with access to drugs on a case-by-case basis), the delay is deadly. As President of the Goldwater Institute, Olsen champions “Right to Try” (RTT) laws—state laws that are designed to expand access to “investigational”

drugs that have passed basic safety trials required by the FDA but have not yet been fully approved.

RTT laws have proven extraordinarily popular. As of this date, they have been approved in 24 states; in 14 of those states, they were enacted by the state legislature without a single dissenting vote in either house (25). Their popularity evinces a widely-held conviction among Americans that we have a right to try to save our own lives from deadly diseases or other fatal conditions. But because federal law trumps conflicting state laws, RTT laws are vulnerable to legal challenges by the FDA, and drug manufacturers face fines and even imprisonment for FDCA violations.² If the right to try is to be secured, federal courts must be prepared to recognize and enforce the constitutional right of self-preservation. Thus far, they have abdicated their responsibility to do so in cases involving investigational drugs.

In this essay, I will summarize Olsen’s book, argue that the Constitution protects the right of terminally-ill patients to try to save their own lives, and sketch the contours of a judicial approach that will ensure that the right to try is consistently enforced in our courts.

I. TRAGEDY AND TRIUMPH: THE RIGHT TO TRY MOVEMENT

Like the movement it chronicles, *The Right to Try* is a story of tragedies and triumphs—tragedies brought about by federally-imposed roadblocks to accessing promising new drugs and triumphs achieved by courageous and determined Americans who are working hard to remove those roadblocks.

Consider Jenn McNary. McNary’s sons, Austin and Max, are both afflicted with Duchenne muscular dystrophy, a fatal disorder for which no FDA-approved treatment was available when McNary received her sons’ diagnoses (30). Only through assiduous research and tireless efforts to identify a clinical trial

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THE RIGHT TO TRY is available for order at <http://www.amazon.com/The-Right-Try-Government-Lifesaving/dp/006240752Xdp/0700619968>.

for a promising drug was McNary able to get her younger son, Max, access to a drug that worked, called eteplirsen (34). But by that time Austin's condition had deteriorated to the point where he could not participate in the eteplirsen trial. Three years later, the FDA allowed the company that developed eteplirsen to expand its trials to include some older, sicker children, and Austin was finally able to get into a trial (261). The drug seems to be helping him—but, owing to the delay, Austin will not walk again (262). “None of this,” Olsen explains, “was to ensure the safety of the drug; it was all to get as close as possible to absolute certainty about the drug’s efficacy before the FDA approved its release” (263).

Understanding the plight of McNary and her sons requires a brief summary of the FDA’s drug approval process. Before any new drug is eligible for full approval and marketing, the Secretary of the U.S. Department of Health and Human Services must find “substantial evidence that the drug will have the effect it purports or is represented to have.”³ Under the authority conferred upon it by the FDCA, the FDA has promulgated regulations that require three phases of government testing on people. In Phase I, drugs are tested on 20 to 80 people to determine “the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.”⁴ Phase II involves targeted, controlled clinical studies of up to several hundred people “to evaluate the effectiveness of the... drug . . . and to determine the common short-term side effects and risks associated with the drug.”⁵ Phase III expanded trials, which can include several thousand people, are “are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug.”⁶

Olsen describes the struggles of dying Americans and those who seek to aid them as they navigate a slow, cruel, costly, confounding regulatory process. The process is slow—as noted above, it can take years to bring a new drug to market. The process can seem cruel—the FDA continues to require “double-blind placebo controlled trials,” which means that parents of terminally-ill children must decide whether to enroll them in a trial that may provide them only with sugar water rather than a life-saving drug—even when it is well-understood what happens to those who do not get treated (223-226). The process is costly—drug manufacturers may not make a profit from emerging drugs and it costs millions of dollars to develop new drugs (206). The process is confounding—the FDA will approve a drug designed to treat a particular disorder on the basis of a short, small-scale study and then require far more complex, lengthier clinical study for follow-on drugs (222-225). And the FDA can, in Olsen’s words, “pull the football back” just when it seems as if approval is near—the FDA will inform companies that it is open to a new drug application after numerous trials demonstrating that the drug is safe and effective, then turn around and demand more data, delaying access for years (55-59).

Few alternatives are available to terminally-ill Americans suffering from diseases for which there is no FDA-approved treatment. They can enter into clinical trials for promising new drugs, but doing so can be very difficult. 40 percent of cancer patients try to get into trials—only 3 percent succeed (184). The

criteria for participants are strict, and they are getting stricter, with eligibility criteria doubling over the past decade (185). As noted above, Austin McNary initially did not qualify because he was too sick; others are rejected because they are too healthy (52). Still others simply live too far away from institutions at which trials are conducted to make the trip.

The FDA and Congress have created “compassionate use” programs to provide early access to unapproved drugs outside of clinical trials. The FDA may approve use of an unapproved drug for the treatment of “serious or immediately life-threatening disease[s]” if there exists “no comparable or satisfactory alternative drug or other therapy,”⁷ if “[t]he drug is under investigation in a controlled clinical trial,”⁸ and if the drug manufacturer “is actively pursuing marketing approval of the investigational drug with due diligence.”⁹ Drug manufacturers may not profit from any approved compassionate use program—they may only “recover costs of manufacture, research, development, and handling of the investigational drug.”¹⁰

These compassionate use programs are wholly insufficient to meet the need for access to emerging drugs. Although about 1,658,370 Americans were diagnosed with cancer in 2015 and 589,430 will die of it, the FDA receives only an average of 1,200 compassionate use requests per year (184). Why? An application for compassionate use requires a willing patient, a willing physician, and a willing drug manufacturer. Doctors rarely bother to apply for compassionate use for their patients because the barriers are overwhelming. The paperwork alone may take up to 100 hours to complete; that amounts to over two work weeks per patient,¹¹ which means, in effect, two weeks off from treating *other* patients. Drug manufacturers cannot be forced to provide drugs and they are reluctant to do so. Expanded use programs are very expensive, and, again, drug manufacturers cannot profit from them. Manufacturers also cite the risk that compassionate use could cause the FDA to delay approval of their new drugs if an adverse event occurs with a patient, and express concern that it will be harder to recruit patients for the large, randomized placebo trials the FDA requires if they make drugs available through a compassionate access program (189).¹² FDA officials contend that they are not standing in the way of access, and argue instead that the drug manufacturers are being overly conservative (190). As Olsen summarizes the situation, “The drug companies blame the FDA. The FDA blames the drug companies. Meanwhile, patients are dying—and no one is doing much of anything to help patients access promising drugs and treatments” (192).

Olsen makes a powerful case that the FDA is in the grip of an “often irrational quest for certainty” and is blind to the reality confronting terminally-ill patients (227). Thus, Dr. Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research, defends the FDA’s restriction on access to drugs that have passed Phase-I safety trials by saying that it “would not be good” “if people who build bridges... or skyscrapers” built them and they fell down eight out of ten times, and that eight of ten drugs that pass Phase-I trials do not prove effective (227). But, to draw upon that rather flippant metaphor, terminally-ill Americans are standing on bridges that are rapidly collapsing, and they must scramble to safety somehow. As Olsen puts it, “[w]hen someone has a terminal illness and has no other op-

tions, he will gladly take a drug with a 50 percent chance of 20 percent effectiveness, over the 100 percent chance that he will die without the drug” (227).

Olsen’s efforts to fix this broken system began in 2012, when a group of oncologists from the Cancer Treatment Centers of America (CTCA), one of the nation’s leading networks of cancer-treatment hospitals and outpatient centers, approached the Goldwater Institute. CTCA had been following Goldwater’s campaign to pass state constitutional amendments that protect the rights of workers to vote by secret ballot in choosing whether their workforce will be represented by a union. Frustrated by Congress’s failure to address a national medical emergency, the CTCA sought advice about whether states could do anything to expand access to investigational drugs that might save cancer patients’ lives (18-19).

In the subsequent months, Olsen and her colleagues created a blueprint for state legislation designed to expand access to investigational drugs and began a campaign to persuade legislators to enact “Right to Try” laws. These laws share several features. All permit drug manufacturers to supply investigational drugs that have passed Phase-I testing to terminally-ill patients who have exhausted all conventional treatment options, but only under certain conditions. The patient’s doctor must have recommended the drug; the drug must remain part of the FDA’s ongoing evaluation and approval process, and the patient must have given informed consent. Finally, all RTT laws bar state licensing boards from taking disciplinary action against physicians for recommending or prescribing drugs under the above conditions (24).¹³

Today, 24 RTT laws have been approved, thanks to a growing coalition of conservatives and liberals, moms and dads, pioneering researchers and former FDA officials—anyone and everyone who has been galvanized by the call to help their fellow Americans save their own lives (24). But, as we will see below, there is a very real question as to whether these laws are, in effect, “placebo legislation” that cannot produce meaningful changes in access to investigational medicine—at least, not unless the courts are prepared to recognize and enforce a constitutional right to try to preserve one’s life.

II. JUDICIAL ABDICATION: DENYING THE RIGHT TO TRY

Olsen depicts the Right to Try movement as a series of “political miracles” (26) and a vindication of federalism—the constitutional distribution of power between the federal government and the states, which guards against the concentration of power in any one governmental entity. And so it is. It is rare to find an issue that is capable of uniting Americans of all ideological persuasions in the service of a common end, and it is inspiring to see politicians setting partisanship aside to address a desperate need. The Right to Try movement offers vivid illustration of how, as Alexander Hamilton put it in *Federalist* 28, “If [the peoples’] rights are invaded by either [states or the federal government], they can make use of the other as the instruments of redress.”

But the FDA’s authority to regulate investigational drugs is conferred by federal law, and it is well-established that federal law (and regulations passed pursuant to federal law) preempts conflicting state laws, rendering them invalid under

the Constitution’s Supremacy Clause.¹⁴ If the FDA decides that the FDCA preempts RTT laws, it could seek to enjoin the states from thwarting its regulatory efforts and subject drug manufacturers who market and distribute unapproved drugs to enforcement actions. While it is true that, as Olsen puts it, “[f]ederal regulations that violate our constitutional liberties can never trump state laws protecting those liberties” (224), that begs the question: Does the Constitution protect the right to try to preserve one’s own life? The answer is yes, yet the courts have disavowed any responsibility to enforce what Olsen calls “the most personal, intimate right of all” (245) in cases involving access to investigational drugs.

It is beyond reasonable dispute that the people who wrote and adopted our Constitution believed that the essential function of any legitimate government was the protection of natural rights—rights that people possess in virtue of being born.¹⁵ For the Framers, the need to secure natural, “unalienable” rights both justified government and limited the scope of its “just powers.”¹⁶ As James Wilson, arguably the leading political theorist among the Framers, put it, government “should be formed to secure and enlarge the natural rights of its members; and every government, which has not this in view, as its principal object, is not a government of the legitimate kind.”¹⁷

This understanding of the function and limits of government is embodied in numerous constitutional provisions that refer to preexisting rights and safeguard people against governmental deprivations of those rights.¹⁸ The most important constitutional provision for our purposes is the Due Process of Law Clause of the Fifth Amendment, which guarantees, in relevant part, that “No person shall be... deprived of life, liberty, or property, without due process of law.” The concept of “due process of law” is drawn from Magna Carta’s “law of the land” clause,¹⁹ which Founding-era lawyers, influenced by seventeenth-century jurist Sir Edward Coke, understood to be a prohibition against arbitrary government actions—unjustified deprivations of natural or common law rights.²⁰ Understood in historical context, the phrase “due process of law” connotes a normative conception of law, according to which government actions that lack certain characteristics are *not law at all*.²¹

One can see this normative conception of law at work in many late eighteenth-century judicial decisions, perhaps most clearly in Justice Samuel Chase’s opinion in *Calder v. Bull*.²² In *Calder*, the Supreme Court considered whether a state statute that vacated a probate court’s invalidation of a will and ordered a new trial of the will, despite the statute of limitations for appeals having run, violated the Constitution’s prohibition of *ex post facto* legislation by the states. Although the Court concluded that the statute was *not ex post facto* legislation, Justice Chase opined that states had no power to pass *ex post facto* legislation even if the Constitution did not specifically prohibit them from doing so: “There are certain vital principles in our free Republican governments, which will determine and overrule an apparent and flagrant abuse of legislative power; as to authorize manifest injustice by positive law; or to take away that security for personal liberty, or private property, for the protection whereof the government was established.”²³ Chase went on to explain that a government action inconsistent with the primary purposes for which “government [is] established”

is not *law*: “An Act of the Legislature (for I cannot call it a law) contrary to the great first principles of the social compact, cannot be considered a rightful exercise of legislative authority.”²⁴ Justice James Iredell famously disagreed, contending that the only limits on government power were those written into the Constitution’s text: “If... a government... were established, by a Constitution, which imposed no limits on the legislative power, the consequence would inevitably be, that whatever the legislative power chose to enact, would be lawfully enacted, and the judicial power could never interpose to pronounce it void.”²⁵ Although Iredell’s positivist understanding of “law” has been embraced by some conservative originalists (perhaps most famously by Judge Robert Bork²⁶), his understanding appears to have been an outlier.²⁷

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.²⁸ James Wilson called the right to self-preservation “the primary law of nature.”²⁹ Alexander Hamilton stated that it was “paramount to all positive forms of government.”³⁰ In a series of decisions spanning the late nineteenth and early twentieth centuries, the Supreme Court consistently acknowledged the existence of a right to self-defense from violent attack, often without citing any constitutional provision.³¹ The Court has held in several cases that the Fourteenth Amendment’s Due Process of Law Clause protects the right to terminate a pregnancy in order to preserve life or health.³² Most recently, the Court in *District of Columbia v. Heller*³³ held that the Second Amendment protects an individual right to bear arms that is rooted in an “inherent right of self-defense.”³⁴

Notwithstanding the above history and case law, the FDA’s restrictions on access to investigational drugs have never been the subject of a successful constitutional challenge. The leading Supreme Court decision in this area remains *United States v. Rutherford*, in which the Court held that the government has an interest in regulating unsafe drugs.³⁵ But the Court in *Rutherford* did not consider whether terminally-ill patients have a right to try investigational drugs. Further, as Olsen notes, the case involved a “highly toxic product” called laetrile that the FDA had identified as a “public health menace” and could cause mental confusion, comas, and even death (246).

The most substantial treatment of the constitutional status of the right to try arose from a suit by the Abigail Alliance for Better Access to Developmental Drugs, an organization of terminally-ill patients and their supporters. The organization was founded by Frank Burroughs, whose daughter, Abigail, died of cancer before the FDA approved a drug that might have saved her life. The Alliance sought to enjoin the FDA from enforcing its policy of barring the sale of post-Phase I investigational drugs to terminally-ill patients. The Alliance argued that the Fifth Amendment’s Due Process of Law Clause protects the right of terminally-ill patients who have no government-approved treatment options, acting on their doctor’s advice, to procure those medicines (247).

In *Abigail Alliance v. Von Eschenbach*,³⁶ a three-judge panel of the U.S. Circuit Court of Appeals for the District of Columbia initially ruled in the Alliance’s favor. Judge Judith

Rogers, writing for the majority, applied the two-step test set forth by the Supreme Court in *Washington v. Glucksberg*³⁷ for identifying unenumerated “fundamental” rights—rights not expressly listed in the Constitution’s text but nonetheless entitled to heightened judicial scrutiny rather than the highly deferential “rational-basis test” applied to all other unenumerated rights. The *Glucksberg* test requires that the right being asserted 1) be given a “careful description” and 2) be “deeply rooted in this Nation’s history and tradition” to qualify as a fundamental right.³⁸ The majority described the claimed right as “the right of terminally-ill patients, acting on a doctor’s advice, to obtain potentially life-saving medication when no alternative treatment approved by the government is available.”³⁹ Turning to history, the majority found that the right of control over one’s body, including the “right to self-defense and the right to self-preservation” was recognized throughout Anglo-American history and law, whereas regulation of access to new drugs is relatively recent, and requirements that drug manufacturers provide evidence of effectiveness as distinct from mere safety are more recent still.⁴⁰ The majority also drew upon *Cruzan v. Director, Missouri Department of Health*,⁴¹ in which the Supreme Court held that the Fourteenth Amendment’s Due Process of Law Clause protects a terminally-ill patient’s right to *refuse* life-sustaining treatment. In *Cruzan*, the Court stated that “the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment.”⁴² “The logical corollary,” wrote Judge Rogers, “is that an individual must also be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life.”⁴³ The majority concluded that the FDA’s policy burdened a fundamental right and thus was subject to strict scrutiny—the most demanding standard of judicial review.⁴⁴ It remanded the case to the district court to determine whether the FDA’s policy was narrowly tailored to serve a compelling government interest.

This victory proved short-lived. The FDA petitioned the court for a rehearing, and the full circuit court reversed. Judge Thomas Griffith, writing for the court, stressed that the Supreme Court has directed lower courts to “exercise the utmost care” when identifying unenumerated fundamental rights, “lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the [courts’ members].”⁴⁵ Accepting at face value the FDA’s assertions that the drugs were potentially unsafe because post-Phase I tests are also concerned with safety, the court denied that any right of self-preservation was implicated, reasoning that “terminally-ill patients cannot fairly be characterized as using reasonable force to defend themselves when they take unproven and possibly unsafe drugs.”⁴⁶ Thus, the court defined the claimed right as the right to “be free to assume the risk of investigational drugs” “with no proven therapeutic benefit.”⁴⁷ The court, drawing upon drug regulations dating back to the colonial period, found that “[o]ur Nation’s history and traditions have consistently demonstrated that the democratic branches are better certainly suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so.”⁴⁸ Thus, the court determined that no fundamental right was implicated by the FDA’s policy. Applying the rational-basis test, the court easily concluded that the FDA’s policy was constitutional, cit-

ing the Supreme Court's decision in *Rutherford*, and urged the plaintiffs to seek recourse "through the democratic process."⁴⁹

In a vigorous dissent, Judge Rogers, writing for herself and Chief Judge Douglas Ginsburg, took the majority to task for its "flawed conception" of the right claimed by the Alliance and its "stunning misunderstanding of the stakes."⁵⁰ She drew extensively upon the common law doctrines of necessity and self-defense, as well as common law prohibitions against interference with rescue, explaining these doctrines' roots in an underlying right of self-preservation.⁵¹ To the majority's argument that the sought-after drugs *might* not save anyone's life, Judge Rogers responded that although one cannot be certain that the "driver of a car that is hurtling towards a cliff" will "press the brake" in time to save his life, he will *certainly* die if he does not.⁵² "No doubt the deceased members of the Alliance who were denied access to investigational drugs that were subsequently approved by the FDA would have been surprised to learn that these drugs... were unnecessary," she observed.⁵³ Judge Rogers noted that the Supreme Court had recently reaffirmed that the government may not ban abortion procedures if doing so subjects women to significant health risks,⁵⁴ adding as well that "[n]owhere in the Supreme Court's jurisprudence has it intimated that the government may ban procedures that represent a patient's only chance of survival because they might not be successful."⁵⁵ Judge Rogers went on to emphasize the recent lineage of restrictions on access to drugs based upon efficacy and observed that doctors are not prohibited from and often do prescribe drugs for purposes that the FDA has not approved "even if the drug is not deemed safe and effective for that use, such as when a drug studied only for adults is prescribed for a child."⁵⁶ Judge Rogers accused the majority of engaging in "tragic wordplay" in concluding that "the right to save one's life is unprotected notwithstanding the specific protection afforded life in the Fifth Amendment,"⁵⁷ and of neglecting prior decisions recognizing a "right to be free from unwarranted government intrusion."⁵⁸ Judge Rogers wrote, "It is difficult to imagine any context in which this liberty interest would be stronger than in trying to save one's own life."⁵⁹

As Olsen notes, the D.C. Circuit is only one of twelve circuits, and no other circuit courts are bound by *Abigail Alliance* (247). Nonetheless, the decision reveals a broken jurisprudence. The right to self-preservation is not merely a fundamental right but *the* fundamental right.⁶⁰ There is no sensible principle that justifies recognizing (as the Supreme Court has) a right to save one's own life by killing an attacker or undergoing a procedure that kills a viable fetus—but *not* a right to save one's own life by using a medical procedure that does not involve killing.⁶¹ And yet, the *Abigail Alliance* court failed to either grasp the right at stake or offer meaningful protection to it.

III. JUDICIAL ENGAGEMENT: SECURING THE RIGHT TO TRY

Abigail Alliance both discloses the need for effective judicial enforcement of the right to try and demonstrates that our prevailing approach to judicial review cannot fulfill that need. The D.C. Circuit's decision was the product of a deeply flawed approach to identifying "fundamental" rights and a default standard of judicial review—the rational-basis test—that is, as former Justice John Paul Stevens once put it, "tantamount to

no review at all."⁶² Fortunately, a treatment for what ails our jurisprudence is readily available.

How did we get to *Abigail Alliance*? Following the Civil War, state courts and, later, the Supreme Court used the Due Process of Law Clauses of the Fifth and Fourteenth Amendments to protect both enumerated rights, like freedoms of speech and of the press,⁶³ and unenumerated natural and common law rights, like the right to earn a living⁶⁴ and the right to raise and guide the upbringing of children.⁶⁵ But in the seminal case of *United States v. Carolene Products*,⁶⁶ a Court that had come to accept longstanding Progressive criticism of its use of the Due Process of Law Clauses to protect economic liberty set forth a new framework for judicial review. This framework was designed to preserve judicial protection for some individual rights deemed particularly important while allowing the government a wide berth to regulate "ordinary commercial transactions."⁶⁷ Justice Harlan Fiske Stone, writing for the Court, stated that regulatory legislation ought to be upheld "unless in the light of facts made known or generally assumed it is of such a character to preclude the assumption that it rests upon some rational basis."⁶⁸ But in a famous footnote (today known simply as "Footnote Four") the Court left open the possibility that "more searching judicial inquiry" might be called for when legislation appears on its face to be within a specific prohibition of the Constitution, such as those of the first ten amendments, "interferes with the political process, or targets 'discrete and insular minorities.'"⁶⁹

The "more searching scrutiny" contemplated by Footnote Four anticipated the development of "heightened scrutiny," which (in both its intermediate and strict forms) places the burden on the government to demonstrate, with reliable evidence, that its actions are calculated to achieve a proper governmental end. By contrast, the rational-basis test requires challengers to demonstrate the *unconstitutionality* of the government's actions and does not require the government to either offer any evidence or establish a factual nexus between its choice of means and its purported ends. Lower courts following the Supreme Court's lead have understood the rational-basis test to require judges *not* to seek out the government's true ends, disregard evidence concerning those ends, and even invent justifications for the government's actions that have no support in the record.⁷⁰ Often, the difference between heightened scrutiny and rational-basis review is the difference between meaningful judicial review and a charade with a predetermined outcome.

Although the Court initially applied heightened scrutiny only to burdens on textually enumerated rights, it later conferred "fundamental" status upon certain unenumerated rights on an *ad hoc* basis, including the right to bodily integrity, the right to associate, the right to private sexual intimacy, and the right to marry.⁷¹ It distinguished these "personal" rights from "economic" rights that were associated with a discredited line of precedent—and one might add, were simply regarded as less important.⁷² The "restrained methodology" articulated in *Glucksberg* and applied in *Abigail Alliance* was devised to prevent the "liberty" protected by the Court's Due Process of Law from being "subtly transformed into... [judges'] policy preferences."⁷³

As the result in *Abigail Alliance* demonstrates, *Glucksberg* has been interpreted to oblige judges to avoid recognizing

any new unenumerated rights, lest they engage in judicial policymaking. Courts have read *Glucksberg's* requirement of a "careful description" to mean a *narrow* description, and it is more difficult to argue that narrowly described rights are deeply rooted in our nation's history and traditions.⁷⁴ Thus, a "right to procure and use investigational drugs" fares more poorly than the right to self-preservation.

Together, the *Glucksberg* framework and the rational-basis test have produced a jurisprudence of unenumerated rights that is constitutionally unjustifiable and fundamentally unprincipled.⁷⁵ There is no constitutional basis for distinguishing between "fundamental" rights and other exercises of constitutionally protected freedoms and subjecting burdens on the latter to a less rigorous (indeed, often toothless) standard of review.⁷⁶ Further, an approach that encourages narrow rather than accurate descriptions of rights claims and gives judges cover to fail to vindicate genuine rights is no less an invitation to judicial policymaking than an *ad hoc* approach that (according to critics) gives judges cover to vindicate counterfeit rights.

Instead of marking out "fundamental" rights for special treatment and reflexively deferring to the government in the vast majority of constitutional settings, judges should consistently seek to determine whether restrictions on constitutionally protected freedoms are justified by a proper governmental end. Doing so requires consistent judicial engagement—genuinely impartial judicial review in which judges require the government to affirmatively demonstrate the constitutionality of its actions with reliable evidence.⁷⁷

What would this approach look like in the context of a constitutional challenge to the FDA's restrictions on investigational drugs? Certainly, protecting people from potentially unsafe drugs and ensuring that they are not duped by quacks are proper ends. We have seen, however, that the FDA's restrictions on drug access prevent terminally-ill patients from exercising the right of self-preservation. The government must therefore be required to demonstrate with reliable evidence that this burden is necessary to achieve concededly proper ends. Such judicial engagement is the rule in heightened scrutiny cases involving burdens on "fundamental" rights. It ought to be the rule in every constitutional case.

How would engaged review of the FDA's policies differ from the rational-basis review applied by the *Abigail Alliance* court? An engaged judge would not simply defer to the FDA's policy choices without making any effort to evaluate whether medicine that passed Phase-I testing is in fact unsafe or whether there is any credible evidence of fraud, but would conduct a factual review of the record. She would be cognizant of the fact that patients are acting on the advice of licensed physicians who have knowledge of their specific needs. She would distinguish medicine that has been identified as highly toxic from medicine that has passed basic safety tests. She would consider whether there is a public safety interest that counsels against denying access to medicine, as well as in favor of its regulation. Olsen recounts the horrific story of a clinic called "Oasis of Hope" that continues to offer laetrile—the "highly toxic product" at issue in *Rutherford*—to American patients across the border in Mexico (246). Instead of protecting terminally-ill patients from quack cures, the FDA's policies may be driving them to seek

out treatments that are not only ineffective but dangerous, for lack of other options. In summary, judicial engagement would ensure that the FDA makes a compelling showing of necessity when it denies people access to drugs that could save their lives.

IV. CONCLUSION

The Right to Try is at heart an optimistic book. It is optimistic about the American people; it is optimistic about the future of medicine; it is optimistic about the success of the Right to Try movement. But the right to try will never be secure if federal courts are unwilling to act as the "bulwarks of a limited Constitution" that the Framers envisioned.⁷⁸ The judiciary has a responsibility to ensure that the most fundamental of all rights "retained by the people"⁷⁹ is not extinguished by their servants in Washington or in their state capitals (245).

Olsen concludes her book with a comparison first suggested by Tracy Seckler, whose son Charley suffers from Duchenne and who has raised millions of dollars for Duchenne research. Seckler compares the plight of terminally-ill children to that of passengers on the *Titanic*. "We know it's going down with 100% certainty," Seckler says. "Let's work together to get more lifeboats in the water" (58). For Olsen, this comparison captures not only the urgency of her cause but the reason it will ultimately triumph: "On the one hand, Americans see drowning kids. On the other, they see the government and the pharmaceutical industry making excuses for why we can't rescue them" (276).

Judges, too, have been making excuses when it comes to recognizing and protecting our natural rights. *Abigail Alliance* lays bare the human costs of doing so. The choice between judicial engagement and judicial abdication is not a mere academic debate—it can be a matter of life and death. It is time for judges to choose life.

Endnotes

1 21 U.S.C. §§ 301 *et seq.*

2 *See* 21 U.S.C. § 333.

3 21 U.S.C. §355(d).

4 21 C.F.R. § 312.21(a).

5 *See* § 312.21(b).

6 *See* §312.22 (a).

7 21 C.F.R. § 312.34(a), (b)(1)(i)–(ii).

8 *Id.*, § 312.34(b)(1)(iii).

9 § 312.34(b)(1)(iv).

10 § 312.7(d)(3).

11 Brittany La Couture, *Right to Try*, AMERICAN ACTION FORUM (August 11, 2014), available at <http://americanactionforum.org/insights/right-to-try>.

12 Drug manufacturers are required to notify the FDA of "[a]ny adverse experience associated with the use of the drug that is both serious and unexpected," 21 C.F.R. § 312.32(c)(1)(A), and the FDA may order a "clinical hold" halting the trials if it determines that safety concerns so warrant, *id.* § 312.42.

- 13 See, e.g., ARIZ. REV. STAT. ANN. § 36-1313 (West Supp. 2014). Some RTT laws also limit clinicians' and manufacturers' civil liability for providing drugs to patients. See, e.g., COLO. REV. STAT. ANN. § 25-45-107 (West Supp. 2014).
- 14 "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI. See *Pacific Gas & Elec. Co. v. State Energy Comm'n*, 461 U.S. 190, 203 (1983) ("Even where Congress has not entirely displaced state regulation in a specific area, state law is preempted to the extent that it actually conflicts with federal law.").
- 15 Even scholars who deny that natural rights are a source of enforceable legal claims acknowledge this. See, e.g., Phillip A. Hamburger, *Natural Rights, Natural Law, and American Constitutionalism*, 102 YALE L.J. 907 (1993).
- 16 See THE DECLARATION OF INDEPENDENCE, para. 1 (U.S. 1776). See also TIMOTHY SANDEFUR, THE CONSCIENCE OF THE CONSTITUTION: THE DECLARATION OF INDEPENDENCE AND THE RIGHT TO LIBERTY 7 (2013) (in the view of the Founders, "[f]reedom is more basic than government power, and it sets the terms that rulers must respect").
- 17 James Wilson, "Of the Natural Rights of Individuals," in THE WORKS OF JAMES WILSON 307 (1896).
- 18 See Sandefur, *supra* note 17 at 10 ("The Constitution promises to 'secure' liberty—not create it. It provides that no laws shall be passed 'impairing' contractual agreements; that Congress shall have no power to 'abridge the freedom of speech or to 'violate' the people's 'right' against unreasonable searches"); Randy Barnett, *The Ninth Amendment: It Means What It Says*, 85 TEX. L. REV. 1, 82 (2006) (amassing evidence that the Ninth Amendment is properly read to protect "unenumerated, natural, and individual rights").
- 19 See MAGNA CARTA (1215 & 1225), reprinted in RALPH V. TURNER, MAGNA CARTA THROUGH THE AGES app. at 226, 231 (2003). ("No free man shall be taken or imprisoned or disseised or outlawed or exiled, or in any way ruined, nor will we go or send against him, except by the lawful judgment of his peers and by the law of the land.").
- 20 See generally Frederick Mark Gedicks, *An Originalist Defense of Substantive Due Process: Magna Carta, Higher-Law Constitutionalism, and the Fifth Amendment*, 58 EMORY L.J. 585 (2009).
- 21 See Sandefur, *supra* note 17 at 72 ("[F]or a government act to qualify as law, it must comply with certain preexisting principles.").
- 22 3 U.S. (3 Dall.) 386 (1798).
- 23 *Id.* at 388.
- 24 *Id.*
- 25 *Id.* at 398.
- 26 See ROBERT H. BORK, THE TEMPTING OF AMERICA (1990) (criticizing Chase for "claiming a power beyond any written law," and crediting Iredell with having "resisted" "the impulse to judicial authoritarianism").
- 27 See Gedicks, *supra* note 22 at 651 (finding that "Iredell's position... was largely rejected by state constitutional decisions of the period, which generally held that the 'law of the land' signified natural and customary rights that constrained legislative action and could not be altered by the exercise of ordinary legislative power.").
- 28 John Locke derived *all* natural rights from the right to self-preservation. See John Locke, "The Second Treatise," in TWO TREATISES OF GOVERNMENT § 6 (Peter Laslett ed., Cambridge Univ. Press 1960) (1698) ("Every one ... is bound to preserve himself, and not to quit his Station wilfully; so by the like reason when his own Preservation comes not in competition, ought he, as much as he can, to preserve the rest of Mankind, and may not unless it be to do Justice on an Offender, take away, or impair the life, or what tends to the Preservation of the Life, the Liberty, Health, Limb or Goods of another."). See also Samuel Adams, The Rights of the Colonists: The Report of the Committee of Correspondence to the Boston Town Meeting, 7 OLD SOUTH LEAFLETS 417 (No. 173) (Burt Franklin 1970) (1772) ("Among the natural rights of the Colonists are these: First, a right to life; Secondly, to liberty; Thirdly, to property; together with the right to support and defend them in the best manner they can. These are evident branches of, rather than deductions from, the duty of self-preservation, commonly called the first law of nature.").
- 29 Wilson, *supra* note 18 at 336.
- 30 THE FEDERALIST No. 28 (Alexander Hamilton).
- 31 See, e.g., *Gourko v. United States*, 153 U.S. 183 (1893); *Thompson v. United States*, 155 U.S. 271 (1894); *Allison v. United States*, 160 U.S. 203 (1895); *Brown v. United States*, 256 U.S. 335 (1921). Surveying these cases, Professor Nicholas Johnson observes that the Court has acknowledged a right to self-defense "in the same straightforward way it would acknowledge that crops need rain." Nicholas Johnson, *Self-Defense?*, 2 J.L. ECON. & POL'Y 187, 204 (2006).
- 32 See *Roe v. Wade*, 410 U.S. 113, 163-64 (1973); *Casey v. Planned Parenthood*, 505 U.S. 833, 846 (1992); *Stenberg v. Carhart*, 530 U.S. 914, 931 (2000). It is worth noting that Justice William Rehnquist, dissenting in *Roe*, stated that "[i]f the Texas statute were to prohibit an abortion even where the mother's life is in jeopardy, I have little doubt that such a statute would lack a rational relation to a valid state objective" and thus fail the rational-basis test. *Roe*, 410 U.S. at 173 (Rehnquist, J., dissenting).
- 33 128 S. Ct. 2783 (2008).
- 34 *Id.* at 2817. See David Kopel, *The Natural Right of Self-Defense: Heller's Lesson for the World*, 59 SYRACUSE L. REV. 999, 1012 (2008) (arguing that "Heller has made it clear that self-defense is part of the Constitution").
- 35 *United States v. Rutherford*, 442 U.S. 544 (1979).
- 36 445 F.3d 470 (D.C. Cir. 2006).
- 37 521 U.S. 702 (1997).
- 38 *Id.* at 720-21.
- 39 *Abigail Alliance*, 445 F. 3d at 478.
- 40 *Id.* at 482.
- 41 497 U.S. 261 (1990).
- 42 *Abigail Alliance*, 445 F. 3d at 484 (citing *Cruzan*, 497 U.S. at 281).
- 43 *Id.*
- 44 *Id.* at 486.
- 45 *Abigail Alliance v. Eschenbach*, 495 F.3d 695 (2007).
- 46 *Id.* at 710.
- 47 *Id.*
- 48 *Id.* at 703.
- 49 *Id.* at 714.
- 50 *Id.* at 714 (Rogers and Ginsburg, JJ., dissenting).
- 51 *Id.* at 717-720.
- 52 *Id.* at 720.

53 *Id.*

54 See *Gonzales v. Carhart*, 127 S. Ct. 1610, 1635 (2004) (quoting *Ayotte v. Planned Parenthood of Northern New Eng.*, 546 U.S. 320, 328 (2006)) (stating that a congressional ban on certain procedures used to perform abortions “would be unconstitutional... if it ‘subject[ed] [women] to significant health risks.’”).

55 *Abigail Alliance*, 495 F.3d. at 721.

56 *Id.* at 726.

57 *Id.* at 728.

58 *Id.*

59 *Id.* at 727.

60 Nelson Lund, *The Second Amendment, Political Liberty and the Right to Self Preservation*, 39 ALA. L. REV. 103, 117 (1987). (“[I]n liberal theory, the right to self-defense is the most fundamental of all rights—far more basic than the guarantees of free speech, freedom of religion, jury trial and due process of law.”).

61 See Eugene Volokh, *Medical Self-Defense, Prohibited Investigational Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007) (“American legal traditions properly recognize people’s right to protect their lives, even when that protection involves killing. The law ought to do the same when a dying person simply seeks an opportunity to risk shortening her already short remaining life in order to have the chance of lengthening it.”).

62 *FCC v. Beach Communications, Inc.*, 508 US 307, 323 n.3 (1993) (Stevens, J., dissenting).

63 See *Gitlow v. New York*, 268 U.S. 652 (1925); *Near v. Minnesota ex. rel. Olson*, 283 U.S. 697 (1931).

64 See *Lochner v. New York* (1905); *Meyer v. Nebraska*, 262 U.S. 390 (1923).

65 See *Pierce v. Society of Sisters*, 268 U.S. 510 (1923).

66 304 U.S. 144 (1938).

67 *Id.* at 152.

68 *Id.*

69 *Id.* at 152 n. 4.

70 See, e.g., *Bruinooge v. United States*, 550 F.2d 624, 625 (Ct. Cl. 1977) (claiming the court is obliged to “resort to our own talents and those of counsel to discern what legitimate purpose Congress assigned to this statute”); *Shaw v. Or. Pub. Emps.’ Ret. Bd.*, 887 F.2d 947, 948 (9th Cir. 1989) (explaining that “[a] court may even hypothesize the motivations of the state legislature to find a legitimate objective”); *Starlight Sugar, Inc. v. Soto*, 253 F.3d 137, 146 (1st Cir. 2001) (“Even if Soto’s stated justification for enforcing Market Regulation No. 13 is insufficient... this Court is obligated to seek out other conceivable reasons.”); *Powers v. Harris*, 379 F.3d 1208, 1217 (10th Cir. 2004) (“[W]e are not bound by the parties’ arguments as to what legitimate state interests the statute seeks to further.”).

71 See *Rochin v. California*, 342 U.S. 165 (1952); *NAACP v. Button*, 371 U.S. 415 (1963); *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Loving v. Virginia*, 388 U.S. 1 (1967).

72 See *United States v. Carlton*, 512 U.S. 26, 41-42 (Scalia and Thomas, J.J., concurring) (observing that “[t]he picking and choosing among various rights,” together with the “categorical and inexplicable exclusion of so-called ‘economic rights’... unquestionably involves policymaking rather than neutral legal analysis”).

73 *Glucksberg*, 521 U.S. at 720.

74 See Randy Barnett, *Scrutiny Land*, 106 MICH. L. REV. 1479 (2008) (discussing this problem in the context of *Raich v. Gonzalez*, 500 F.3d 850 (2007)).

75 Importantly, *Glucksberg* may no longer be good law. See *Obergefell v. Hodges*, 135 S. Ct. 2584, 2602 (2015) (acknowledging and pointedly declining to apply the *Glucksberg* framework in determining whether same-sex couples have a right to marry). Dissenting in *Obergefell*, Chief Justice John Roberts stated that “the majority’s position requires it to effectively overrule *Glucksberg*.” *Id.* at 2621 (Roberts, C.J., dissenting). Some scholars have interpreted *Obergefell* as greatly diminishing *Glucksberg*’s strength and perhaps paving the way for its demise. See, e.g., Kenji Yoshino, *A New Birth of Freedom?: Obergefell v. Hodges*, 129 HARV. L. REV. 147, 162 (2015) (“After *Obergefell*, it will be much harder to invoke *Glucksberg* as binding precedent.”); Jack Balkin, *Bye Bye Glucksberg*, BALKINIZATION (June 27, 2015) <http://balkin.blogspot.com/2015/06/bye-bye-glucksberg.html> (“*Glucksberg* is clearly no longer the leading case on substantive due process, if it ever was.”).

76 Professor Randy Barnett has pointed out that Court’s substantive due process jurisprudence contradicts the express command of the Ninth Amendment by “disparaging” unenumerated rights. See RANDY BARNETT, *RESTORING THE LOST CONSTITUTION: THE PRESUMPTION OF LIBERTY* 253 (2004).

77 See generally CLARK NEILY, *TERMS OF ENGAGEMENT: HOW OUR COURTS SHOULD ENFORCE THE CONSTITUTION’S PROMISE OF LIMITED GOVERNMENT* (2013) (defining judicial engagement).

78 See *FEDERALIST* No. 78 (Hamilton).

79 See U.S. CONST. amend. IX.

