Case No. 21-70544

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ADVANCED INTERGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC; DR. SUNIL AGGARWAL, MD., PhD; MICHAEL BLOOM; and ERINN BALDESCHWILER,

Petitioners,

vs.

U.S. DRUG ENFORCEMENT ADMINISTRATION; MERRICK GARLAND, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL; and D. CHRISTOPHER EVANS, IN HIS OFFICIAL CAPACITY AS ACTING ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

BRIEF OF AMICI CURIAE GOLDWATER INSTITUTE AND CATO INSTITUTE

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INTEREST OF AMICI CURIAE[1]

The Goldwater Institute ("GI") was established in 1988 as a nonpartisan public policy foundation dedicated to advancing the principles of limited government, economic freedom, and individual responsibility through litigation, research, and policy briefings. Through its Scharf–Norton Center for Constitutional Litigation, GI litigates cases and files amicus briefs when its or its clients' objectives are directly implicated.

Among GI's principal goals is defending the vital principle of health care freedom and medical autonomy, and the independent protection for this and other rights in state laws and constitutions. GI has litigated and appeared as amicus curiae in many state courts to promote the enforcement of state legal protections that exceed those provided by the federal constitution. *See, e.g.*, *State v. Hernandez*, 417 P.3d 207 (Ariz. 2018); *Lathrop v. Deal*, 801 S.E.2d 867 (Ga. 2017); *Ladd v. Real Estate Comm'n*, 230 A.3d 1096 (Pa. 2020).

Moreover, GI developed, drafted, and advocated for passage of the 41-state Right to Try laws and federal Right to Try law, which protect terminally ill patients' right to try safe investigational treatments that have been prescribed by

[1] Pursuant to Fed. R. App. P. 29(a)(2), this brief is filed with the consent of all parties. No counsel for any party authored this brief in whole or part, and no person or entity other than amici, their members, or counsel, made any monetary contribution for the preparation or submission of this brief.

their physician but that the federal Food and Drug Administration (FDA) has not yet approved for market. Institute scholars and attorneys have published policy and legal scholarship on federal impediments to health care access. *See, e.g.*, Christina Sandefur, *The FDA's Approach to Off-Label Communications: Restricting Free Speech in Medicine?*, Federalist Society Regulatory Transparency Project (May 10, 2018)[2]; Christina Sandefur, *Safeguarding the Right to Try*, 49 Ariz. St. L.J. 513 (2017); Mark Flatten, *Dead on Arrival: Federal "Compassionate Use" Leaves Little Hope For Dying Patients*, Goldwater Inst. (2016).[3]

The Cato Institute is a nonpartisan public policy research foundation founded in 1977 and dedicated to advancing the principles of individual liberty, free markets, and limited government. Cato's Robert A. Levy Center for Constitutional Studies helps restore the principles of constitutional government that are the foundation of liberty. Toward those ends, Cato publishes books and studies, conducts conferences, produces the annual *Cato Supreme Court Review*, and files amicus briefs.

Cato Institute scholars have long advocated for the Right to Try and, more broadly, general rights to bodily autonomy that are a cornerstone of a free society.

[2] https://regproject.org/paper/fdas-approach-off-label-communications-restricting-free-speech-medicine/
[3] https://goldwaterinstitute.org/wp-content/uploads/2016/02/Dead-On-Arrival-Report.pdf

The Goldwater Institute and the Cato Institute believe their legal and policy expertise will benefit this Court in its consideration of this case.

INTRODUCTION

State and federal Right to Try laws protect the right of terminally ill patients to try a treatment that has received basic safety approval (Phase 1) from the FDA—and is being given to patients in ongoing clinical trials (typically Phases 2 and 3)—but that has not yet received final New Drug Application approval for sale. These laws declare that people should be able to decide for themselves—in consultation with their doctors—whether to try medicines that could prolong or even save their lives. Right to Try acknowledges that the federal drug approval system, which blocks access to treatments until they receive final approval from the FDA—a process that takes an average of 14 years and $1.4 billion[4]—does not work for dying patients who don't have that time to wait. By providing an alternative pathway to treatments for the most desperate and vulnerable patients,

[4] President's Council of Advisors On Sci. & Tech., Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation, 13–14 (2012), https://permanent.access.gpo.gov/gpo32081/pcast-fda-final.pdf; Tufts Univ., Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion, Tufts Ctr. for the Study of Drug Dev., (Nov. 18, 2014), https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66adc758d46b001a996d6/1522952924498/pr-coststudy.pdf

and by recognizing that the federal government is not empowered to regulate the practice of medicine, Right to Try laws are saving lives today.

The DEA's refusal to accommodate Right to Try not only undermines Congress's goals in adopting that act, but also intrudes on a state-protected right—the right to protect one's own life—and exceeds the DEA's authority.

I. The origin and purpose of state Right to Try laws.

Right to Try laws were adopted out of concern that the federal government has increasingly and improperly interfered with the practice of medicine—quintessentially a matter of state law, *cf. Planned Parenthood of Cincinnati Region v. Strickland*, 531 F.3d 406, 412 (6th Cir. 2008)—by prohibiting doctors from treating patients to the best of their ability and with the full extent of their knowledge. State and federal Right to Try laws protect patients' right to make their own medical decisions, especially patients diagnosed with a life-threatening illness. *See* Sandefur, *Safeguarding*, *supra* at 513–14.

The federal obstructionism that Right to Try sought to redress resulted from "mission creep" by regulatory agencies. The initial round of federal drug regulations adopted a century ago focused on ensuring that patients had truthful information to make their own informed decisions about the medicines they were going to take, by verifying that products marketed to the public were safe and correctly labeled. Pub. L. No. 59-384, 34 Stat. 768 (1906). Manufacturers were not

then legally required to submit information to the federal government as a prerequisite to marketing. Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA Consumer Mag. at 1 (Jan.–Feb. 2006).[5] Then, in 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, requiring manufacturers to prove that a drug was safe *before* marketing. While this expanded federal authority, it still focused on safety, rather than efficacy, and respected patient autonomy.

However, federal law gradually shifted from a focus on providing information to patients and their doctors to a more paternalistic approach—one that in practice blocks patients from accessing medicines they need. This reached fruition in the 1962 Kefauver-Harris Drug Amendments to the FDCA, Pub. L. No. 87-781, 76 Stat. 780, which required manufacturers to "provide substantial evidence of effectiveness for the product's intended use." Meadows, *supra* at 3. These amendments imposed new rules for preapproval of medicines, including new standards for investigating drugs for both safety and efficacy. 21 U.S.C. § 355(d).

This marked a drastic shift because safety and efficacy are quite different, both scientifically and ethically. Nobody wants to take an unsafe medicine, but

[5] https://www.fda.gov/media/110482/download

many patients are willing to try one that has not yet been proven to work. This is especially true of patients battling life-threatening illnesses.

Of course, it is not even entirely true that nobody wants to take *unsafe* drugs. Chemotherapy, after all, is not *safe*, in the sense that it is, technically, "poison even at the *correct* dose." Siddhartha Mukherjee, *The Emperor of All Maladies: A Biography of Cancer* 143 (2010). Even acetaminophen (commonly known as Tylenol) kills more than 400 people per year. *See generally* William M. Lee, *Acetaminophen and the U.S. Acute Liver Failure Study Group: Lowering the Risks of Hepatic Failure*, 40 Hepatology 6 (2004).[6] And in nearly a dozen states, terminal patients even have the option of ending their lives with a physician's help.[7]

Additionally, even under existing law, patients may take approved drugs for so-called "off-label" uses, which means to use a medicine the FDA has approved for condition A, to treat condition B, instead. *See United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012) (discussing "the propriety and potential public value of unapproved or off-label drug use."). Off-label prescriptions are entirely legal, 21 U.S.C. § 396 (2012); 21 C.F.R. § 312.2(d) ("This part does not apply to the use in the practice of medicine for an unlabeled indication of a new drug product

[6] https://liberationchiropractic.com/wp-content/uploads/research/2004Lee-Tylenol.pdf
[7] https://deathwithdignity.org/learn/death-with-dignity-acts/

approved [by the FDA].”), and widespread,[8] even though they are prescriptions *without* proof of efficacy or even full knowledge of proper dosage, because they are often the patient’s best option. *See* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 72 (1998). In fact, one in five prescriptions today are for “off-label” uses. Kelli Miller, *Off-Label Drug Use: What You Need to Know*, WebMD.[9]

Yet the ordinary pathway for approval of medicines remained a cumbersome three (sometimes four) stage process, beginning with Phase 1 safety testing, and proceeding through subsequent stages of efficacy evaluation. During this long process, patients’ only opportunity to obtain access to these potentially life-saving or life-improving medicines was to either qualify for participation in a clinical trial—something most patients cannot do, because they are either not sick enough, or are too sick to qualify—or through the “compassionate use” process, a mechanism that requires such burdensome pre-approvals that it is essentially futile in most circumstances. *See generally* Flatten, *Dead on Arrival, supra.*

[8] Medicare even pays for off-label uses. *Amarin Pharma, Inc. v. U.S. FDA*, 119 F.Supp.3d 196, 201 (S.D.N.Y. 2015).
[9] http://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know

In sum, prior to Right to Try, the federal drug approval system allowed patients to take dangerous medicines, or medicines they expect will kill them, and—under the off-label rule—medicines that have received approval for safety but *not* efficacy. Yet these same patients were barred from using medicines that have *passed* basic safety testing and are currently being administered to other patients in FDA-approved clinical trials (for which these patients do not qualify). And because of their conditions, these patients were also frequently ineligible for compassionate use. As a result, countless patients suffered. This is the problem Right to Try was designed to fix—by allowing dying patients to use investigational treatments by working directly with their doctors and pharmaceutical manufacturers, without having to first seek government permission in the form of a compassionate use application.

Right to Try laws also recognize that dying patients face a different risk/benefit calculus than other people. Even before Right to Try, federal law itself recognized this, in the form of "compassionate use" and the "emergency use authorization," which offered (extremely limited) avenues for terminal patients who wish to access to experimental drugs or devices.

Under compassionate use, if (1) their physicians determine that there is no comparable or satisfactory alternative therapy for the patient's serious disease, and that risks of the investigational drug are comparable to the risks of the disease, and

(2) the FDA determines that there is sufficient evidence of safety and efficacy to support the use and that the use will not interfere with completion of clinical trials, and the sponsor submits an appropriate protocol, the patient could obtain the medicine. 21 U.S.C. § 360bbb(b)(1)–(2). Under emergency use authorization, by contrast, the FDCA authorizes general public access to investigational drugs, if the FDA makes findings that the sponsor is proceeding with clinical trials and is actively pursuing marketing approval. *Id.* § 360bbb(c).

Beneficial as these two alternatives are, their applicability is extremely limited. For example, "compassionate use," is so cumbersome that, at the time Right to Try was being developed, the paperwork required to obtain it could take 100 hours to complete. Alexander Gaffney, *From 100 Hours to 1: FDA Dramatically Simplifies Its Compassionate Use Process*, Regulatory Affairs Prof'l Soc'y: Regulatory Focus Blog (Feb. 4, 2015).[10] It also requires doctors to obtain information that is often inaccessible, such as technical or proprietary data on the drug, which may not be available to the doctor. Flatten, *supra*, at 9. And to administer the treatment, the doctor must abide by burdensome protocols and data-reporting requirements, essentially making him responsible for overseeing (and often funding) a miniature clinical trial for a single patient. *Id.*

[10] http://www.raps.org/Regulatory-Focus/News/2015/02/04/21243/From-100-Hours-to-1-FDA-Dramatically-Simplifies-its-Compassionate-Use-Process/

Additionally, a separate committee at a hospital or medical clinic, called an Institutional Review Board (IRB), must weigh the ethical considerations associated with the patient's use of the treatment. *Id.* Because there are no requirements on how often IRBs must meet or how quickly they must respond to these requests, people in rural areas or without a major university hospital nearby typically have few IRB options, which adds more time and delay to the process. *Id.* These and other complications mean that at the time Right to Try was being developed, only about 1,200 patients per year were even able *apply* for compassionate use, *id.* at 5—even though over half a million Americans die annually of cancer alone. *See* Cancer Facts & Figures 2015, Am. Cancer Soc'y.[11]

Emergency Use Authorization was similarly cumbersome, and often applied arbitrarily, as indicated by this Court's recent ruling in a years-long FOIA case seeking information about the circumstances under which the FDA granted an authorization to the drug ZMapp in 2014. *Goldwater Inst. v. U.S. Dep't of Health & Hum. Servs.*, 804 F. App'x 661 (9th Cir. 2020).

Thus, in addition to restoring patient autonomy, Right to Try was meant to eliminate the arbitrary and unjustifiable outcomes that resulted from a system that forced patients to undergo a lengthy and complicated process to get government

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11 http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2015/index

permission to try to save their lives. Right to Try added a third option that removes the arbitrariness of requiring federal approval: if a patient with a life-threatening illness wants to try an investigational treatment that has passed Phase 1 safety trials, and is currently being used in a clinical trial, the patient is *legally entitled* to use that medicine even though it may bring serious risks.

II. The power of the states to safeguard the Right to Try.

A. State Right to Try laws are broader in scope than their federal counterpart.

Rather than exempting Right to Try treatments from specific federal regulations, the state versions of Right to Try expressly allow drug manufacturers to make qualifying treatments available to eligible patients.[12] In other words, while the federal Right to Try act places specific limitations on the FDA, *state* Right to Try laws should be interpreted broadly to achieve the goal of protecting the right of terminally ill patients to try to save their own lives with investigational medicines.

State Right to Try laws are the origin and foundation of the Right to Try movement. In April 2014, Colorado became the first state to adopt a Right to Try law. Mere months later—in June 2014—state Right to Try laws inspired a congressional investigation of the FDA's compassionate use process, and the introduction of a bill in the House of Representatives to prevent the FDA from

[12] *See Right to Try in Your State*, http://righttotry.org/in-your-state/

blocking implementation of any state Right to Try law. *See* H.R. 3012, 114th Cong. (2015). In May 2016, the U.S. Senate held hearings on the issue of access to investigational drugs. *See* Connecting Patients to New and Potential Life Saving Treatments: Hearing Before the S. Comm. on Homeland Sec., 114th Cong. (2016).[13] Full federal recognition of the Right to Try was signed into law in 2018, by which time 41 states had enacted their own statutes.[14] But in passing federal Right to Try, Congress emphasized the primacy of the state laws: "To authorize the use of unapproved medical products by patients diagnosed with a terminal illness *in accordance with State law*, and for other purposes." S.204, 115th Cong. (2018) (emphasis added).

State Right to Try laws empowered qualifying patients to receive unapproved treatments years before Congress enacted the federal Right to Try. For example, Houston-based oncologist Dr. Ebrahim Delpassand successfully treated hundreds of terminally ill cancer patients under Texas's Right to Try law by using LU-177 (or Lutetium Dototate), a drug that at the time had successfully completed three phases of the FDA-approved clinical trials and was already available in European countries, but had not yet received final FDA approval for sale. *See* Exploring a Right to Try for Terminally Ill Patients: Hearing before the S. Comm.

[13] https://www.govinfo.gov/content/pkg/CHRG-114shrg22718/pdf/CHRG-114shrg22718.pdf
[14] http://righttotry.org/in-your-state/

on Homeland Sec. & Gov't Affairs, 114th Cong. (2016) (statement of Dr. Ebrahim Delpassand, Oncologist).[15] Dr. Delpassand administered a successful clinical trial for LU-177 therapy for five years. In 2015, after the final trial phase was completed, the FDA refused to allow him to treat additional patients until the drug received final agency approval. *Id.* But a few months later, Texas adopted a Right to Try bill, giving patients a new avenue to access this safe and effective therapy. H.B. 21, 84th Leg., Reg. Sess. (Tex. 2015). Under that new law, Dr. Delpassand continued administering LU-177 to patients suffering from neuroendocrine cancer, many of whom were expected to live only a few months but were still alive a year after receiving treatment under Texas's Right to Try law. Exploring a Right to Try: Hearing, *supra*.

B. State Right to Try laws exercise state authority to protect citizens more than federal law does.

State Right to Try laws shield the treatment of terminally ill patients with investigational drugs independent of federal law. The federal Constitution provides a floor of protection for individual rights, not a ceiling, leaving states free to enact laws that protect those rights more broadly than the federal Constitution does. *Cf. Florida v. Powell*, 559 U.S. 50, 71 (2010) ("'[T]he federal Constitution sets the floor, not the ceiling, and [a state court] retains the ability to interpret [protections

[15] http://www.hsgac.senate.gov/hearings/exploring-a-right-to-try-for-terminally-ill-patients.

for] right[s] … afforded by the [state] Constitution more broadly than that afforded by its federal counterpart.'") (Stevens, J., dissenting); *Kelo v. City of New London,* 545 U.S. 469, 489 (2005) ("[N]othing … precludes any State from placing further restrictions on its exercise of … power … that are stricter than the federal baseline."). The founders envisioned the federalist system providing a "double security … to the rights of the people," *The Federalist* No. 51, at 320 (James Madison) (Clinton Rossiter ed., 1961), by enabling each state to "exercise its police power or its sovereign right to adopt in its own Constitution individual liberties more expansive than those conferred by the Federal Constitution." *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 81 (1980). This enables states to "respond, through the enactment of positive law," to protect the rights of citizens "without having to rely solely upon the political processes that control a remote central power." *Bond v. United States*, 564 U.S. 211, 221 (2011).

Courts have recognized states' powers to provide broader protections than the federal Constitution does, with respect to free speech,[16] private property,[17] and other rights.[18] State Right to Try laws protect the most personal and intimate right of all: the right to one's own life. In *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Supreme Court affirmed the power of states to guarantee medical autonomy more broadly than federal law does, when it upheld Oregon's "right to die" legislation against the objections of the U.S. Attorney General, who argued that it conflicted with federal law. *Id.* at 272 (reasoning that the Controlled Substances Act presumes

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[16] *See, e.g., Coleman v. City of Mesa*, 284 P.3d 863, 872 ¶ 36, n.5 (Ariz. 2012) ("Arizona's [free speech provision] is in some respects more protective of free speech rights than the First Amendment."); *L.A. Alliance for Survival v. City of L.A.*, 993 P.2d 334, 342 (Cal. 2000) ("[T]he California liberty of speech clause is broader and more protective than the free speech clause of the First Amendment."); *Bradburn v. N. Cent. Reg'l Library Dist.*, 231 P.3d 166, 172 ¶ 18 (Wash. 2010) (recognizing that Washington's free speech provision "is more protective of speech than the First Amendment" and that "it is already settled that [the provision] is subject to independent interpretation").

[17] *See, e.g.*, *Bailey v. Myers*, 76 P.3d 898, 903 ¶ 20 (Ariz. App. 2003) ("The federal constitution provides considerably less protection against eminent domain than our Constitution provides."); *Bd. of Cnty. Comm'rs of Muskogee Cnty. v. Lowery*, 136 P.3d 639, 651 (Okla. 2006) ("[Oklahoma's Constitution] provide[s] private property protection to Oklahoma citizens beyond that which is afforded them by the Fifth Amendment to the U.S. Constitution.").

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

and relies upon a functioning medical profession regulated under state's police power). "[R]egulation of health and safety is 'primarily, and historically, a matter of local concern,'" the Court noted, and, while federal officials can sometimes override state choices, *id.* at 271 (citation omitted), the *Gonzales* decision saw no reason to interfere with Oregon's "'great latitude … to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" *Id.* at 270 (citation omitted).

Gonzales was not an outlier. Almost a decade earlier, the Court refused to strike down Washington State's prohibition on physician-assisted suicide under the Fourteenth Amendment, in an opinion that emphasized the autonomy of states and the importance of "an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide … in a democratic society." *Washington v. Glucksberg*, 521 U.S. 702, 735 (1997). To impose a single, nationwide rule on the question, the Court declared, would interfere with the states' "interest in protecting the integrity and ethics of the medical profession." *Id.* at 731. Washington State later adopted a law allowing physician-assisted suicide, leading a later court to observe that "[i]n the wake of *Glucksberg* and the Death with Dignity Act, it is clear that Washington State can *bar* medical providers from assisting in taking life, and it can *allow* them to participate in taking a life." *Stormans Inc. v. Selecky*, 844 F.Supp.2d 1172, 1183 (W.D. Wash. 2012).

Courts have been equally protective of state authority to regulate the ordinary course of affairs outside of the medical context. In *United States v. Windsor*, 570 U.S. 744 (2013), the Court struck down a portion of the federal Defense of Marriage Act because it interfered with the traditional state power to define marriage, a matter the justices called "central to state domestic relations law." *Id.* at 766.[19] It was unconstitutional for the federal government to interfere with "the State's broader authority to regulate the subject of domestic relations" by imposing a federal "definition of marriage" in a way that "impose[d] restrictions and disabilities." *Id.* at 766-68. Similarly, in *Bond v. United States*, 572 U.S. 844, 856 (2014), the Court interpreted the international chemical weapons treaty narrowly to avoid stepping on the toes of state governments, and in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 587 (2012), it again adopted a narrow construction of a federal law to prevent the federal government from withholding all Medicaid funds so as to coerce states into radically altering their Medicaid programs.

Even in cases that involve ordinary consumer protection statutes, states have authority to impose greater standards than federal regulations impose, so long as those standards do not unduly interfere with the flow of interstate commerce. In

[19] Although the Court later struck down state prohibitions on same-sex marriage, it did so on the grounds that such laws fell below the Fourteenth Amendment "floor." *Obergefell v. Hodges*, 135 S.Ct. 2584, 2604–05 (2015).

Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963), the Court noted that "[f]ederal regulation by means of minimum standards of ... agricultural commodities, however comprehensive … does not of itself import displacement of state control … Congressional regulation of one end of the stream of commerce does not, *ipso facto*, oust all state regulation at the other end." *Id.* at 145 (emphasis added). In short, the states' constitutional power to regulate "all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State," *The Federalist* No. 45, *supra* at 289 (James Madison), is not lightly dispensed with, even where Congress has imposed minimum federal regulatory standards.

C. This Court should be skeptical of DEA actions that effectively override state Right to Try laws.

In the case of Right to Try, the states' interest in regulating the ordinary course of affairs is particularly important, given that states have always had the primary responsibility for regulating the practice of medicine. Traditionally, "the State is primarily the judge of regulations required in the interest of public safety and welfare," *Graves v. Minnesota*, 272 U.S. 425, 428 (1926), particularly in medicine. *See also Semler v. Or. State Bd. of Dental Examiners*, 294 U.S. 608, 611 (1935) (holding that the state may regulate the practice of dentistry by prescribing the qualifications that are reasonably necessary).

When states adopted Right to Try laws, they provided greater protections for a fundamental right than were provided by the federal system. These state laws provide that terminal patients and their doctors should be free to decide—without government interference—whether treatment should include experimental medications. The DEA's refusal to accommodate Right to Try not only undermines congressional goals, but also exceeds its authority and intrudes on a state-protected right: the right to protect one's own life.

While the federal government can supersede state law in appropriate circumstances, courts are usually reluctant to infer that an administrative agency has power to override a state law absent clear evidence that such was Congress's intent. *Hillsborough Cnty. v. Automated Med. Labs, Inc*., 471 U.S. 707, 717 (1985) ("We are … reluctant to infer pre-emption from the comprehensiveness of regulations than from the comprehensiveness of statutes. … [To do so] is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive [which] … would be inconsistent with the federal-state balance."). Here, the federal Right to Try statute makes quite clear that Congress did *not* intend for federal agencies to effectively override or make unenforceable the states' Right to Try laws.

In *Hillsborough County,* the County adopted an ordinance imposing a license fee and various information gathering requirements on blood donation

centers. These were challenged on the grounds that they were preempted by the FDA's regulation of blood donation centers. The Court rejected that argument because "[i]n the absence of express pre-emptive language," there was no reason to believe that Congress intended to "[leave] no room' for supplementary state regulation." *Id*. at 713 (citation omitted). Here, the fact that Congress expressly declared in federal Right to Try that it was intended to supplement, not displace, state Right to Try laws shows that federal policy cannot excuse actions by the DEA that would frustrate the application of state Right to Try laws. Right to Try was designed in part to create a third and more accessible alternative to the FDA's existing process for seeking access to investigational treatments. The purpose of Right to Try is to extend to every patient with a life-threatening illness the same permission to use treatments that was already enjoyed by those fortunate enough to possess the time and resources to get a special exception from the government. The DEA's refusal to make an accommodation for medical practice under Right to Try laws undermines that purpose.

D. The DEA can easily accommodate Right to Try patients.

As Petitioners have noted, the DEA has authority to waive its CSA requirements and regulations, 21 U.S.C. §§ 822(d), 871(b), and has exercised that authority in the past. Pet'rs' Br. at 20–22. It can easily accommodate treating physicians who do not hold a Schedule 1 registration, by issuing guidance for

Right to Try treatments. For example, the DEA could allow a physician seeking access to a Right to Try-eligible treatment for a Right to Try patient to apply for a waiver from the Schedule 1 registration requirement, which would entitle the physician to order and receive the treatment from a registered manufacturer and distributor. The applicant would attest in writing that he or she:

- Is a physician holding a DEA registration to possess, dispense, and administer substances on Schedules II-V;
- Is treating a patient with a life-threatening illness who suffers conditions not relieved with conventional therapy;
- Holds the professional opinion that the patients could benefit from therapy facilitated with the EID;
- Will take possession of the EID to be used solely for treatment under RTT, hold it in a secure facility, and administer it to the patient in a supervised therapeutic setting;
- Will comply with all applicable state and federal RTT requirements; and
- Practices in a state that does not prohibit the use of Schedule 1 substances for Right to Try treatments.

So as not to undermine the purpose of Right to Try, the DEA would need to issue or deny the waiver within seven days, or the waiver would be deemed granted so

long as the application was complete, thus enabling the applicant to order and receive the EID from any registered manufacturer and distributor.

This solution would be consistent with the purpose of Right to Try without undermining the DEA's core mission, which is the "field of drug abuse." *Oregon v. Ashcroft*, 368 F.3d 1118, 1125, 1128 (9th Cir. 2004).

CONCLUSION

Right to Try laws institutionalize the principle that compassionate use should be the rule, not the exception, for terminal patients. They establish for patients a return to a system that recognizes and respects the rights of individuals to make their own decisions about their health care—especially people whose lives hang in the balance—without being subject to lengthy processes that yield arbitrary results. The DEA's refusal to accommodate Right to Try needlessly undercuts this goal and the state laws that safeguard this autonomy for patients. This Court should grant the Petition for Review and rule in favor of Petitioners.

Date: May 21, 2021

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify that:

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 4,984 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in proportionately spaced typeface using Microsoft Word 2016 Times New Roman 14-point font.

Date: May 21, 2021

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I hereby certify that on May 21, 2021, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ *Christina Sandefur*
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