NO. 21-70544

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, et al.,

Petitioners-Appellees,

v.

MERRICK B. GARLAND, et al.,

Respondents-Appellants.

ON REVIEW FROM THE
DRUG ENFORCEMENT AGENCY

AMICUS CURIAE BRIEF OF THE STATES OF WASHINGTON, ARIZONA, DELAWARE, ILLINOIS, MICHIGAN, MINNESOTA, OHIO, AND OREGON, AND THE DISTRICT OF COLUMBIA IN SUPPORT OF PETITIONERS AND GRANTING THE PETITION

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I. INTRODUCTION

Forty-one states have passed "Right to Try" laws. These laws allow access to investigational medical treatments for eligible patients who lack the time to wait for federal approval. Petitioners in this case, residents of Washington, seek access to psilocybin therapy, which is currently in Phase 2 of federal clinical trials. Respondents, representatives of the Drug Enforcement Agency (collectively, "DEA"), have issued a final decision holding that the federal Controlled Substances Act (CSA) prohibits Petitioners' medical treatment, because psilocybin is a Schedule I controlled substance. DEA's decision conflicts with the subsequent and more specific federal Right to Try Act, and with the Supreme Court's admonition that the CSA should not be used to regulate medicine. DEA's interpretation sets a precedent that would allow the federal government to amass undue police power and undermine states' rights. *Cf., e.g.*, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 536 (2012). The Amici States respectfully urge this Court to respect the limits of federalism and to reject DEA's position in favor of Petitioners'.

II. INTEREST OF AMICI CURIAE

Amici are the States of Washington, Arizona, Delaware, Illinois, Michigan, Minnesota, Ohio, and Oregon, and the District of Columbia (States). The States file this brief under Fed. R. App. P. 29(a)(2). They have an interest in avoiding undue federal regulation, particularly criminalization, of the practice of medicine. Several

of the Amici States have enacted Right to Try laws[1] and have an interest in upholding the right of patients with life-threatening illnesses to make intimate medical decisions in consultation with their doctors in accordance with applicable state laws. The States address the federalism implications of Respondents' interpretations of the federal Controlled Substances Act and Right to Try Act.

III. ARGUMENT

A. Background.

1. "Right to Try" in Washington and Other States.

"Right to Try" (RTT) laws allow patients with serious or life-threatening illnesses access to investigational drugs that have not yet received federal approval. More than 80 percent of states have enacted such laws.[2] These states have concluded that any risks associated with the dispensing of unapproved drugs under these circumstances are mitigated by the severity of the patient's illness and outweighed by potential benefits. As the Washington Legislature found, "Patients who have a terminal illness do not have the luxury of waiting until an investigational drug,

[1] *See* Wash. Rev. Code § 69.77; Ariz. Rev. Stat. § 36-11.1; 410 Ill. Comp. Stat. 649; Mich. Comp. Laws § 333.26451; Minn. Stat. § 151.375; Ohio Rev. Code Ann. § 4731.97; Or. Rev. Stat. § 127.990.

[2] *See* Richard Cauchi, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, NCSL (May 3, 2019), https://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx#Right%20 to Try (listing states as of May 2019).

biological product, or device receives final approval from the United States food and drug administration." Wash. Rev. Code § 69.77.010.

Relevant here, Washington's RTT law (Washington RTT), Wash. Rev. Code § 69.77, was passed unanimously by both chambers of the Legislature, and signed into law by the Governor, in 2017. It facilitates access to "investigational products" for patients with a "serious or immediately life-threatening disease or condition." *See* Wash. Rev. Code §§ 69.77.020-.040. An "investigational product" is defined in relevant part as "a drug, biological product, or device that has successfully completed phase one and is currently in a subsequent phase of a clinical trial approved by the United States food and drug administration[.]" *Id.* § 69.77.020(4). This definition does not exclude any categories of substances, such as substances listed under Schedule I of the federal Controlled Substances Act (CSA, 21 U.S.C. § 812). The Washington RTT is therefore broader than the RTT laws of some states that have exempted Schedule I controlled substances from eligibility.[3]

To ensure protection of an eligible patient's rights, the Washington RTT requires written consent from the patient including an explanation of risks and possible outcomes. Wash. Rev. Code § 69.77.050. It also provides that various entities involved in the dispensing of an investigational drug are immune from

[3] *See, e.g.*, Mo. Ann. Stat. § 191.480; Ohio Rev. Code Ann. § 4731.97; Miss. Code. Ann. § 41-131-1.

liability if the law's requirements are met. *Id.* § 69.77.080. These entities, which include the dispensing health care practitioner, are fully immune "from civil or criminal liability and administrative actions [under Washington law] arising out of treatment of an eligible patient with an investigational product, other than acts or omissions constituting gross negligence or willful or wanton misconduct." *Id.*

2. The Federal Right to Try Act.

The federal Right to Try Act (RTT Act, or Act) became law in 2018 after passing with unanimous consent in the Senate and bipartisan support in the House of Representatives. 21 U.S.C. § 360bbb–0a; Pub. L. No. 115–176, 132 Stat. 1372 (2018). The Act's preamble states that its purpose is "[t]o *authorize* the use of unapproved medical products by patients diagnosed with a terminal illness *in accordance with State law*, and for other purposes." Pub. L. No. 115–176, 132 Stat. 1372, 1372 (2018) (emphases added). Under "Sense of the Senate," the Act states that it "establishes national standards and rules by which investigational drugs may be provided to terminally ill patients." *Id.* § 3(7), 132 Stat. at 1375.

The RTT Act amends the Federal Food Drug, and Cosmetic Act (FDAC) to permit eligible patients to request access to investigational drugs that have not yet been approved by the Food and Drug Administration. 21 U.S.C. § 360bbb–0a. It cuts the FDA out of the process for approving such drugs for patients who have "been

diagnosed with a life-threatening disease or condition."[4] *Id.* It expressly exempts the provision of eligible drugs under the Act from various federal requirements directly concerning investigational drugs, such as, for example, labeling and reporting requirements. *Id.* § (b). Information about the use of investigational drugs under § 360bbb–0a is only required to be reported annually. *Id.* § (d). The RTT Act is therefore consistent with the federal government's limited interest in regulating the flow of drugs in interstate commerce. A statutory note states that the law "only expands the scope of individual liberty and agency among patients, in limited circumstances." Pub. L. No. 115–176 § 3(3), 132 Stat. at 1374 (2018).

The Act makes no mention of the Controlled Substances Act or controlled substances generally, including those listed under Schedule I. Instead, an "eligible investigational drug" is defined merely as one for which a Phase 1 clinical trial has been completed, which is unapproved, and which is still under investigation and subject to an active investigational new drug application. 21 U.S.C. § 360bbb-0a(a)(2). As discussed below, in light of the Act's text, structure, and

[4] The original version of the RTT Act introduced in the Senate limited eligibility to patients "with a terminal illness." S. 204, 115th Cong. § 2(a)(1)(A) (1st Sess. 2017), https://www.congress.gov/115/bills/s204/BILLS-115s204is.pdf. According to the original sponsor of the RTT Act, Sen. Ron Johnson of Wisconsin, this language was rejected as too narrow. Sen. Johnson stated that his "aim from the beginning was to be as inclusive as possible such that as many patients as possible who are facing no available alternatives could potentially qualify." 164 Cong. Rec. H4355-01, H4360 (daily ed. May 22, 2018).

purpose, it is evident that the Act supersedes other federal laws, such as the CSA, in the event of any conflict as applied.

A statutory note[5] to the RTT Act under the heading "No Liability" states: "With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to [§ 360bbb–0a] and in compliance with such section, no liability in a cause of action shall lie against" a sponsor, manufacturer, prescriber, dispenser, or other individual entity "unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable state law." 21 U.S.C. § 360bbb–0a, Note, Pub. L. No. 115–176 § 2(b)(1), 132 Stat. at 1374 (Immunity Provision). This broad exclusion of liability is only limited in that it does not "affect the right of any person to bring a private action under any State or Federal product liability, tort, consumer protection, or warranty law." Immunity Provision § 2(b)(3), 132 Stat. at 1374.

The legislative history to the RTT Act reveals that the Immunity Provision was intended largely to ensure that providers of investigational drugs are not discouraged by the threat of liability. As the Chair of Energy and Commerce Committee stated in legislative deliberations, the "provision removes one of the

[5] It is settled that such notes have the force of statutory law. *See, e.g.*, 1 U.S.C. § 112; *U.S. Nat. Bank of Oregon v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 448 (1993); Office of the Law Revision Counsel, *Detailed Guide to the United States Code Content and Features* § VI, http://uscode.house.gov/detailed_guide.xhtml (last visited May 20, 2021).

biggest hurdles patients face, as identified by the Government Accountability Office, in gaining access to experimental therapies: manufacturer hesitancy to participate." 164 Cong. Rec. at H4358 (statement of Rep. Walden). This understanding is consistent with the statement of the law's primary sponsor in the Senate, who stated that the RTT Act is "fundamentally about empowering terminally-ill patients and their doctors." 164 Cong. Rec. at H4360 (statement of Sen. Johnson). He went on: "The bill is not intended to further empower *any federal agency*, including the FDA, to limit *in any way* the ability of an individual facing a life-threatening disease or condition from accessing treatment." *Id.* (emphases added).

B. Psilocybin Treatment May Be an "Investigational Product" Under Washington Law.

Psilocybin is listed as a Schedule I substance under Washington's Uniform Controlled Substance Act (UCSA). Wash. Rev. Code § 69.50.204(c)(28). Until recently, the USCA provided that "[i]t is unlawful for any person to possess a controlled substance unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his or her professional practice." *Id.* § 69.50.4013(1). On February 25, 2021, this criminal prohibition on simple drug possession was struck down by the Washington Supreme Court in *Washington v. Blake*, 481 P.3d 521 (2021). This spring, the Washington Legislature passed, and the Governor approved, a new bill (ESB 5476) that adds a *mens rea* element and downgrades simple possession to a misdemeanor.

Engrossed S.B. 5476, 67th Leg., 2021 Reg. Sess., §§ 8, 9 (Wash. 2021), http://lawfilesext.leg.wa.gov/biennium/2021-22/Pdf/Bills/Session%20Laws/Senate/5476.SL.pdf#page=1.

The immunity provision in the Washington RTT provides a defense against "civil or criminal liability and administrative actions arising out of" treatment with an investigational product in compliance with the law. Wash. Rev. Code § 69.77.080; *cf. State v. Hanson*, 157 P.3d 438, 441-42 (Wash. Ct. App. 2007) (examining similar provision from Washington's Medical Marijuana Act). Therefore, dispensing psilocybin as part of an RTT-compliant treatment would not violate Washington law.[6]

The States take no position on whether the Petitioners would be eligible patients, or whether psilocybin would be an eligible treatment, under the Washington RTT. Primary responsibility for making such decisions does not lie with the government. Rather, as the Washington Legislature found: "The use of available investigational drugs . . . is a decision that should be made by the patient with a terminal illness in consultation with the patient's health care provider[.]" Wash. Rev. Code § 69.77.010. That said, the States understand that psilocybin treatment of terminally ill patients meets the basic requirement that an "investigational drug" be

[6] This brief describes Washington law, which is at issue in this case. State RTT laws vary from state to state, and this brief does not assert that each state law would apply like Washington's law.

one that has successfully completed Phase I clinical trials and is now in a subsequent phase of trials. *See id.* § 69.77.020(4); Pet'rs' Br. at 32–33.

It is well-established that the treatment of a life-threatening illness is not limited to curative treatments that address its etiology, or cause. For example, treatment of cancer need not be limited to interventions that seek to control the division, spread, and effects of cancerous cells. Rather, such treatment often includes palliative approaches that alleviate symptoms, improve quality of life, and which, by doing so, may render curative treatments more effective.[7] According to the World Health Organization (WHO), "[p]alliative care is an approach that improves the quality of life of patients (adults and children) and their families who are facing problems associated with life-threatening illness."[8] And "numerous intervention studies have shown that palliative approaches to care for patients with life-threatening diagnoses foster better physical quality of life and reduce depressive symptoms."[9] One study found that early palliative care can increase survival in some

[7] *See What are Palliative Care and Hospice Care?*, NIH, https://www.nia.nih.gov/health/what-are-palliative-care-and-hospice-care (last visited May 12, 2021).

[8] *Palliative Care*, WHO (Aug. 5, 2020), https://www.who.int/news-room/fact-sheets/detail/palliative-care (last visited May 20, 2021).

[9] Michael Hoerger, *Right-to-Try Laws and Individual Patient "Compassionate Use" of Experimental Oncology Medications: A Call for Improved Provider-Patient Communication*, 40(2) Death Studies 113 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4816436/.

cancer patients by over six months.[10] Palliative care can also significantly reduce treatment costs by, for example, reducing unnecessary hospitalizations.[11]

C. Federal Prohibition of "Right to Try" Treatments Authorized By State Law Intrudes in an Area of Traditional State Concern.

Under our system, states retain "a residuary and inviolable sovereignty" to do all the things that nation-states may do, except as their powers are limited by the Constitution. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461,1475 (2018) (quoting The Federalist No. 39, at 245 (C. Rossiter ed. 1961)). The role of the states in the federal system has been famously compared to that of a laboratory to "try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

The Supreme Court recognizes that states have "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (cleaned up). Although the federal government can set uniform standards in medicine, the "regulation of health and safety is 'primarily, and historically, a matter of local concern[.]'" *Gonzales*, 546 U.S. at 271 (quoting *Hillsborough County v. Automated*

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[10] *Id.*

[11] Peter May et al., *Palliative Care Teams' Cost-Saving Effect Is Larger For Cancer Patients With Higher Numbers Of Comorbidities*, 35(1) Health Affairs 44 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4849270/; Peter May et al., *Economics of Palliative Care for Hospitalized Adults With Serious Illness*, 178(6) JAMA Intern Med. 820 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6145747/.

Medical Laboratories, Inc., 471 U.S. 707, 719 (1985)); *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). A state's police powers include regulation of the practice of medicine and of the prescription and administration of drugs. *E.g.*, *Hawker v. New York*, 170 U.S. 189, 191 (1898); *Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921); *Collins v. Texas*, 223 U.S. 288, 297-98 (1912); *Gibbons v. Ogden*, 22 U.S. 1, 114 (1824).

By contrast, the federal government did not enter the field of national drug regulation until the 20th century, with the adoption of The Pure Food and Drug Act in 1906. This law was primarily concerned with adulteration, labeling, and branding. Pub. L. No. 59–384, 34 Stat. 768 (1906). FDA review of new drugs did not begin until the passage of the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938. *See Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 705 (D.C. Cir. 2007) (en banc). With the passage of the RTT Act, Congress determined that FDA approval is not required at all for the use of investigational drugs by eligible patients.

Forty-one states have enacted RTT laws. Some of those states opted to exclude Schedule I substances from eligibility.[12] Others, like Washington, did not. Both approaches are valid exercises of the states' inherent and reserved police powers to regulate the practice of medicine for the public's health and welfare.

[12] *E.g.*, Miss. Code. Ann. § 41-131-1(2)(b).

D. The Federal RTT Act Expressly Precludes Liability in Connection With Eligible Treatments.

DEA incorrectly concluded that the Federal RTT Act does not contain "an explicit statutory exemption" to the CSA's prohibitions. *See* Pet. for Review at 14. DEA's analysis focused entirely on the exemptions listed in 21 U.S.C. § 360bbb–0a(b). *See id.* But the agency misunderstood the structure of the statute and ignores the crucial Immunity Provision. In so doing, it improperly reads the RTT Act "as a series of unrelated and isolated provisions." *See Gonzales*, 546 U.S. at 273 (cleaned up).

Section 360bbb–0a(b) spells out exemptions from regulatory requirements normally applicable to new and investigational drugs *in particular*. *See* 21 U.S.C. § 360bbb–0a(b) (citing "sections 352(f), 353(b)(4), 355(a), and 355(i) of this title, section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations)"). This approach is consistent with the law's purpose of empowering eligible patients by removing federal regulators—primarily but not exclusively the FDA—from playing any role in determining when they may access investigational drugs. The subject of § 360bbb-0a(b) is "[e]ligible investigational drugs." This subsection therefore only addresses exemptions to laws applicable to "drugs," not people or other entities.

The structure of the law is, in relevant part, as follows:

- An "eligible investigational drug" is one that meets the criteria in 21 U.S.C. § 360bbb–0a(a)(2).
- If an eligible drug is provided to an eligible patient (as defined in 21 U.S.C. § 360bbb–0a(a)(1)), it need not meet other specific requirements normally applicable to investigative drugs, provided that the person making the drug available to the patient "is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs." *Id.* § 360bbb–0a(b).
- If an investigational drug is provided pursuant to and in compliance with 21 U.S.C. § 360bbb–0a, including the provisions described in the proceeding paragraphs, then the entities specified in the Immunity Provision have an affirmative defense against most forms of liability, including all federal liability. *See* Immunity Provision, 132 Stat. at 1374.

This last point is important. DEA errs by misunderstanding the difference between an exemption from specific legal requirements applicable to new drugs, as spelled out in § 360bbb–0a(b), and a broader privilege to engage in conduct that could otherwise violate various laws, to the extent provided in the statutory note. The

former specifies what the Department of Health and Human Services may not require with respect to eligible investigational drugs, while the latter describes a statutory immunity. *See, e.g.*, *McKelvey v. United States*, 260 U.S. 353, 357 (1922); Immunity, *Black's Law Dictionary* (11th ed. 2019). The Immunity Provision expressly creates immunity for "any alleged act or omission" in compliance with the RTT Act, with the exception of certain serious conduct in violation of state law.

Affirmative defenses, such as statutory immunities, serve to defeat claims "previously cognizable either at common law or by virtue of another statute." *See Fishman by Fishman v. Delta Air Lines, Inc.*, 132 F.3d 138, 143 (2d Cir. 1998). It is well established that Congress may create affirmative defenses by statute. *See, e.g.*, *Chevron U.S.A. Inc. v. Echazabal*, 536 U.S. 73, 78-79 (2002) (citing a provision (42 U.S.C. § 12112(b)(6)) carving out an affirmative defense to discrimination action); *Taisho Marine & Fire Ins. Co. v. M/V Sea-Land Endurance*, 815 F.2d 1270, 1272 (9th Cir. 1987); 47 U.S.C. § 230; 15 U.S.C. § 1115(b); *In re Stock Exchanges Options Trading Antitrust Litig.*, 317 F.3d 134, 151 (2d Cir. 2003) (statutory immunities are affirmative defenses); *see also Wilson v. City of Chicago*, 758 F.3d 875, 879 (7th Cir. 2014) (describing state law with similar language as providing immunity defense); *State v. Hanson*, 157 P.3d 438, 442 (Wash. Ct. App. 2007) (describing provision of Washington law providing legal immunity for medical use of marijuana). The creation of immunity for conduct in compliance with 21 U.S.C.

§ 360bbb–0a effectuates the broad reach of the law intended by Congress, and in particular, the goal of countering manufacturer hesitancy.

DEA may respond that the Immunity Provision applies only to civil "cause[s] of action." This would be incorrect. The heading "No Liability" indicates a desire to broadly preclude liability except for causes of action expressly exempted from the provision, such as serious violations of state law. The statute therefore evinces the intent to respect rather than hinder state laws. If Congress had meant to limit immunity to civil causes of action it would have said so, particularly given the intrusion on federalism. The plain meaning of "cause" includes *any* "ground for legal action." Cause, *Black's Law Dictionary* (11th ed. 2019). Congress has referred to criminal "causes," "actions," or "causes of action" on many occasions. *See, e.g.*, 15 U.S.C. § 2617(g)(1); 17 U.S.C. § 1204(c); 25 U.S.C. § 3652(2); 16 U.S.C. § 3844(p)(4)(B)(2); 18 U.S.C. § 2320(g); 18 U.S.C. § 1595(b)(2). Finally, even if the language of the Immunity Provision were ambiguous, "the rule of lenity obliges the court to select the least-harsh interpretation consistent with the statutory language."[13] *United States v. Lillard*, 935 F.3d 827, 834 (9th Cir. 2019); *see also Leocal v. Ashcroft*, 543 U.S. 1, 11 & n.8 (2004) (rule of lenity applies where statute has both civil and criminal applications); *United States v. Sheek*, 990 F.2d 150, 153 (4th Cir.

[13] The constitutional avoidance canon would also apply, as discussed *infra* Part III.G.

1993) (applying rule of lenity to interpretation of statutory exception); *United States v. Tucor Int'l, Inc.*, 35 F. Supp. 2d 1172, 1185 (N.D. Cal. 1998), *aff'd*, 189 F.3d 834 (9th Cir. 1999) ("The fact that the ambiguity is contained in a statutory exemption, rather than the statutory definition of the criminal conduct, does not preclude application of this rule.").

Conduct authorized by the RTT Act is immune from any liability, civil or criminal, under the CSA.

E. The CSA Does Not Prohibit Therapeutic Uses of Schedule I Substances Authorized Under the Plain Language of the RTT Act.

Even if the RTT Act did not contain the Immunity Provision, it would be inappropriate to interpret the CSA as continuing to prohibit RTT-compliant treatments.

1. The CSA Was Not Intended to Regulate the Practice of Medicine.

The CSA, enacted in 1970, is a comprehensive regime intended to address the problem of drug abuse by "combat[ting] the international and interstate traffic in illicit drugs." *Gonzales*, 546 U.S. at 269 (quoting *Gonzales v. Raich*, 545 U.S. 1, 12 (2005)). "The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Raich*, 545 U.S. at 12. Congress was particularly concerned about unlawful diversion from lawful to unlawful channels. *Id.* Congress chose to regulate incidents of the intrastate traffic

of controlled substances because such traffic has "a substantial and direct effect upon interstate commerce." 21 U.S.C. § 801(3).

The CSA established five "schedules" of controlled substances. 21 U.S.C. § 812(a). Among the findings required to place a substance on the most restrictive schedule, Schedule I, is that "[t]he drug or other substance has no currently accepted medical use in treatment in the United States." *Id.* § (b)(1).

The first legislative finding in the CSA states that "[m]any of the drugs included within this subchapter have a useful and legitimate medical purpose." 21 U.S.C. § 801(1). The CSA provides that substances in Schedules II through V may be dispensed for medical purposes.[14] *Id.* § 829. Substances in Schedules II through IV that are prescription drugs under the FDCA may generally only be dispensed through a prescription that complies with that statute. *Id.* §§ (a), (b). A prescriber of controlled substances must be registered with the Attorney General. *Id.* § 822(a)(2). The prescription requirement "ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse." *Gonzales*, 546 U.S. at 274.

Under the heading, "Application to State Law," the CSA provides:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that

[14] For purposes of this brief, the States express no position on the placement of psilocybin on Schedule I. The States take such placement as given in this litigation.

> provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. The CSA includes a savings provision stating: "Nothing in this chapter . . . shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the [FDCA]." *Id.* § 902.

The Supreme Court considered the extent of the CSA's regulation of medicine in *Gonzales*. The Oregon Death With Dignity Act exempted physicians who provided a lethal dose of drugs to terminally ill patients from civil or criminal liability. *Gonzales*, 546 U.S. at 249. The drugs were listed in Schedule II. They were available only by prescription under the CSA. *Id.* at 250. The Attorney General issued an interpretive rule stating that physician-assisted suicide was not a legitimate medical purpose. Under this interpretive rule, the drugs could not be lawfully prescribed. *Id.* at 249.

The Supreme Court held that "the CSA's prescription requirement does not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct." *Gonzales*, 546 U.S. at 274-75. It described the CSA as "as a statute combating recreational drug abuse." *Id.* at 272. To the extent the statute permits medical judgments at the federal level, these are to be made by the Secretary of Health and Human Services. *Id.* at

265-66. Congress was "unwilling[] to cede medical judgments to an executive official who lacks medical expertise." *Id.* at 266. After a close analysis of the text and structure of the CSA, the Court determined that the statute "regulates medical practice [only] insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Id.* at 270. The Court found this approach consistent with "the structure and limitations of federalism." *Id.* The Court emphasized that the CSA defers to state law in key respects including the registration of physicians. *Id.* The Court found only "one area" where Congress intended to set national standards of medical practice. This area concerned the treatment of narcotics addictions. *Id.* at 271. The Court concluded that "when Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute." *Id.* at 272.

2. Congress Did Not Intend for the CSA to Prohibit Any Treatment Authorized Under the RTT Act.

As discussed above, the CSA was intended to combat drug trafficking and abuse. Moreover, the RTT Act does not exclude Schedule I substances, even though the law is very similar to analogous, previously-enacted state RTT laws, some of which do exempt Schedule I substances from eligibility. Under the plain language of the Act, psilocybin meets the standard for an "eligible investigational drug." It is worth re-emphasizing that the law's stated purpose is to "authorize the use of unapproved medical products by patients diagnosed with a terminal illness *in*

accordance with State law." Pub. L. No. 115–176 (emphasis added); *see, e.g.*, *Price v. Forrest*, 173 U.S. 410, 427 (1899) (statutory preamble may shed light on ambiguous statute); *Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008) (same with respect to title (citation omitted)).

DEA may point to the fact that Schedule I substances have been found to have "no currently accepted medical use" as evidence that Congress never intended such substances to be used in a medical context, with the sole exception of authorized research. *Cf.* 21 U.S.C. §§ 812, 872(e). There would be several problems with this argument.

First, the meaning and purpose of the RTT Act are clear, and point in the same direction: that the Act removes federal obstacles to treatments with *any* RTT-eligible drug.

Second, it is well-settled that a more recent and specific statute controls over an earlier and broader one. *See, e.g.*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000). "The classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *Id.* (cleaned up). "[A] specific policy embodied in a later federal statute should control [the Court's] construction of the earlier statute, even though it has not been expressly amended." *Id.* (cleaned up); *In re Partida*, 862 F.3d 909, 912 (9th

Cir. 2017). Here, it is easy to make sense of both the CSA and the later, more specific RTT Act: neither law facilitates traffic in illicit substances, both laws emphasize the primacy of states in the regulation of medical practice, and the RTT Act includes broad immunity from liability.

Third, it is irrelevant whether a Schedule I substance has a "currently accepted medical use" under the CSA in the context of uses authorized by the RTT Act. The RTT Act's purpose is to provide a unique, targeted exemption from such requirements.

DEA uses a five-factor test to determine accepted medical use:

1. The substance's chemistry is known and reproducible;

2. There are adequate safety studies;

3. There are adequate and well-controlled studies proving efficacy;

4. The substance is accepted by qualified experts; and

5. The scientific evidence is widely available.

57 Fed. Reg. 10,499, 10,506 (Mar. 26, 1992); *see* Answering Br. for the Fed. Respondents at 39, *Sisley v. DEA*, No. CV20-71433, (9th Cir. Nov. 30, 2020), ECF No. 37. An investigational drug will almost by definition not meet the third factor, and perhaps other factors as well. Nonetheless, Congress decided that the inability to meet this standard should not be a hurdle for treatment under the RTT Act.

Fourth, courts including the U.S. Supreme Court require a clear statement for interpretations of federal statutes that would intrude on traditional areas of state concern. *See Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) ("Congress may legislate in areas traditionally regulated by the States. This is an extraordinary power in a federalist system. It is a power that we must assume Congress does not exercise lightly."); *Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172-73 (2001) (federalism concerns are "heightened" where an "administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power"); *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989) ("[I]f Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its intention to do so unmistakably clear in the language of the statute." (cleaned up)); *United States v. Bass*, 404 U.S. 336, 349 & n.16 (1971) ("[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance."); *Bond v. United States*, 572 U.S. 844, 858-59 (2014) (quoting *Bass* and stating that "[p]erhaps the clearest example of traditional state authority is the punishment of local criminal activity"); *cf., e.g.*, *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.").

As discussed above, the medical profession and medical treatment are core areas of traditional state responsibility. *See, e.g.*, *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 643 (1986) ("The need for a proper evidentiary basis for agency action is especially acute in this case because Congress has failed to indicate, either in the statute or in the legislative history, that it envisioned federal superintendence of [medical] treatment decisions traditionally entrusted to state governance."); *Gonzales*, 546 U.S. at 272, 274; *Oregon v. Ashcroft*, 368 F.3d 1118, 1125 (9th Cir. 2004), *aff'd sub nom. Gonzales v. Oregon*, 546 U.S. 243 (2006) ("Unless Congress' authorization is 'unmistakably clear,' the Attorney General may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care." (quoting *Gregory,* 501 U.S. at 460–61)). Even if the CSA could once have been read to prohibit the dispensation of Schedule I investigational drugs to terminally ill patients, under controlling authority such a reading is no longer tenable, at least with respect to states that have authorized such treatment, and especially where Congress has already separately and subsequently authorized the same. *Cf. Williamson Tobacco Corp.*, 529 U.S. at 143.

Read in conjunction with the later and more specific RTT Act, as required, the CSA does not prohibit any treatments that are otherwise in compliance with 21 U.S.C. § 360bbb–0a; *cf.* 21 U.S.C. § 902.

F. There is No Valid Federal Interest in the Regulation of State RTT Treatments.

The Federal Government is one of enumerated powers. Every law passed by Congress must derive from a power specifically delegated in the Constitution. *See, e.g.*, *United States v. Comstock*, 560 U.S. 126, 133 (2010). "The Tenth Amendment thus directs [courts] to determine . . . whether an incident of state sovereignty is protected by a limitation on an Article I power." *New York v. United States*, 505 U.S. 144, 157 (1992).

Congress's discretion in adopting legislative means is broad, but not limitless. *See Comstock*, 560 U.S. at 135. For example, the means must be "really calculated to attain the end." *Id.* (quoting *Burroughs v. United States,* 290 U.S. 534, 547-48 (1934)). The existence of "a longstanding history of related federal action" may shed light on whether the means chosen by Congress are rationally related to the end. *Id.* at 137-38 (noting that federal statutory framework had been in place since 1855). The Supreme Court recognizes "as-applied" challenges to the reach of federal statute based on a "class of activity" regulated by the statute. *Raich*, 545 U.S. at 9, 15, 17; *see also United States v. Kebodeaux,* 570 U.S. 387, 399 (2013) (considering as-applied challenge under Necessary and Proper Clause). Commerce Clause cases like *Raich* require "a tangible link to commerce, not a mere conceivable rational relation," unlike other constitutional contexts where courts apply the similarly-worded, but substantively different, "rational basis" test. *See Comstock*, 560 U.S. at

152 (Kennedy, J., concurring) (citing *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 487-88 (1955)).

In *Raich*, the relevant class of activities was the "intrastate cultivation and possession of marijuana for medical purposes based on the recommendation of a physician[.]" 545 U.S. at 21. The Supreme Court acknowledged that Congress never made particularized findings on this issue. *Id.* It nonetheless held that, given the CSA's central concern with the diversion of controlled substances into illicit channels, "Congress had a rational basis for believing that failure to regulate the intrastate manufacture and possession of marijuana would leave a gaping hole in the CSA." *Id.* at 22. The Court reasoned that the "subdivided class of activities . . . was an essential part of the larger regulatory scheme." *Id.* at 27. The Court noted that marijuana had been found to have no medically accepted use, and even if such use existed, its dispensation would be subject to FDA approval. *Id.* Therefore, cultivation of medical marijuana could not be distinguished "from the core activities regulated by the CSA." *Id.*at 28. In dicta, the Court opined that plaintiffs' theory could create a "nationwide exemption" for a "vast quantity of marijuana (or other drugs) locally cultivated for personal use." *Id.* It rejected the contrary argument that California "ha[d] surgically excised a discrete activity that is hermetically sealed off from the larger interstate marijuana market." *Id.* at 30. Finally, the Court said that

Congress could have rationally found that the "aggregate impact" of medical marijuana was "unquestionably substantial." *Id.* at 32.

The differences between this case and *Raich* are illuminating, and dispositive. Here, Congress *itself* has "surgically excised a discrete activity that is hermetically sealed off from the larger interstate . . . market," through the passage of the RTT Act. *See* 545 U.S. at 30. Under the narrow exception created by that subsequent law, the use of investigational drugs expressly does *not* require a medically accepted use, or FDA approval. There is no reasonable argument that prohibiting use of Schedule I substances consistent with the Federal RTT Act would further any purpose of the CSA. In particular, it is not reasonable to believe that the use of an investigational drug that is subject to ongoing clinical trials, by a subset of patients with "serious or immediately life-threatening diseases" that could potentially be treated by such drugs under the careful supervision of a doctor, will substantially affect any interstate market in such substances or otherwise contribute to illicit use, even in the aggregate. Nor is there any longstanding history of the kind of federal interference with medical practice DEA advocates here. *Cf. Comstock*, 560 U.S. at 137.

DEA, of course, retains the authority to set rules ensuring that investigational drugs are not somehow "diverted" on their way to patients. Petitioners have described some of this authority. *See* Pet'rs' Br. at 13, 20–22 Moreover, the DEA could implement procedures similar to what is required for the distribution of

Schedule I substances for other authorized purposes such as research. 21 C.F.R. 1305.01-.07. But what it may not do, consistent with the system of enumerated federal powers, is ban such treatments entirely. Congress would have no constitutionally-valid basis to apply the CSA's general prohibitions to RTT-eligible patients.

G. At a Minimum, DEA's Interpretation Raises Serious Constitutional Doubts.

Even if federal law were merely ambiguous on the related issues of whether the CSA continues to prohibit the state-authorized use of a controlled substance in the Right to Try context, or whether the RTT Act provides immunity for acts or omissions related to such treatment, the Court would then need to apply the canon of constitutional avoidance. Under this canon, if one of two plausible interpretations of a statute would raise constitutional problems, the other interpretation must prevail. *E.g.*, *Clark v. Martinez*, 543 U.S. 371, 381 (2005); *see Sebelius*, 567 U.S. 519, 536 (2012) (enumerated powers must be "read carefully to avoid creating a general federal authority akin to the police power"). The alternative interpretation need not even be the most natural one, it need only be "fairly possible." *Sebelius*, 567 U.S. at 563 (cleaned up). The avoidance canon rests "on the reasonable presumption that Congress did not intend the alternative which raises serious constitutional doubts." *Clark*, 543 U.S. at 381. The canon is not only applied when a court definitively concludes that an interpretation would be unconstitutional, but also when it raises

serious doubt on that score. *E.g.*, *id.*; *Nielsen v. Preap*, 139 S. Ct. 954, 971 (2019); *Rust v. Sullivan*, 500 U.S. 173, 191 (1991).

DEA's interpretation raises at least a serious doubt. It intrudes on intimate medical decisions of traditional state concern, without any substantial connection to interstate commerce. To effectuate congressional intent, this Court should recognize that the CSA does not preclude use of any eligible investigational drug pursuant to the RTT Act, which also provides immunity for such use.

H. The Harm to the States Is Substantial, and This Issue Is Likely to Recur.

The potential harm to states that choose to broadly authorize RTT treatments and their citizens is substantial. There are thousands of patients with serious or terminal diagnoses that could possibly be alleviated through investigational therapies. Such therapies could have the potential to prolong life and render curative treatment more effective. They could also help reduce the strain on state medical systems.

Psilocybin is likely not the last Schedule I controlled substance that could be eligible under state and federal RTT laws. For example, the Schedule I substance methylenedioxy-methylamphetamine (MDMA) is the subject of ongoing studies to evaluate possible efficacy in the treatment of anxiety associated with life-threatening illnesses. *See* Philip Wolfson, *MDMA-assisted Psychotheraphy for Anxiety Associated With a Life-threatening Illness*, Multidisciplinary Association for

Psychedelic Studies, Study: NCT02427568 (last updated June 25, 2020), https://clinicaltrials.gov/ct2/history/NCT02427568?V_10=View#StudyPageTop.[15]

DEA's refusal to recognize accommodation for state RTT laws in the face of the clear intent of Congress poses a threat to state sovereignty. This threat is especially acute because it comes from a federal executive agency rather than Congress itself. *See Solid Waste Agency*, 531 U.S. at 172-73; *Virginia v. EPA*, 108 F.3d 1397, 1410 (D.C. Cir. 1997). If accepted, DEA's interpretation would ratify federal involvement in some of the most wrenching decisions a person can make, based on the most "attenuated" relationship to any conceivable federal interest. *Raich*, 545 U.S. at 38 (Scalia, J., concurring). Congress did not intend such a result, and this Court should not validate it.

IV. CONCLUSION

The Amici States urge the Court to rule in favor of the Petitioners in this case.

[15] It was reported in the journal *Nature Medicine* earlier this month that MDMA, when combined with talk therapy, demonstrated a remarkable 67 percent effectiveness in treating severe PTSD. Jennifer M. Mitchell et al., *MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study*, Nature Medicine (2021), https://www.nature.com/articles/s41591-021-01336-3.

RESPECTFULLY SUBMITTED this 21st day of May, 2021.

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