No. 21-70544

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC, DR. SUNIL AGGARWAL, MD, PHD, MICHAL BLOOM, AND ERINN BALDESCHWILER,

Petitioners,

v.

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,

Respondents.

BRIEF OF THE AMERICAN CIVIL LIBERTIES UNION OF WASHINGTON AS *AMICUS CURIAE* IN SUPPORT OF THE PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

Amicus is a non-profit organization that does not have a parent corporation or issue stock.

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I. INTEREST OF *AMICUS CURIAE*[1]

The American Civil Liberties Union of Washington ("ACLU-WA") is a statewide, nonprofit, nonpartisan organization with more than 135,000 members and supporters. It is dedicated to the preservation and defense of civil liberties and civil rights, and has long worked to defend constitutional rights including those at issue in this case. ACLU-WA also is committed to drug policy reform, criminal justice reform, and reduction of mass incarceration, and works to promote racial equity in all those contexts.

This appeal presents this Court with an opportunity to consider how the Drug Enforcement Administration ("DEA") has misinterpreted the Controlled Substances Act ("CSA") with the result that terminally ill people suffering from certain conditions that can be ameliorated by use of psilocybin have been precluded from exercising their "Right to

[1] No counsel for a Party authored this brief in whole or in part. No Party, counsel for a Party, or any person other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of the brief.

All Parties consented to the filing of this brief.

Try" ("RTT") under both federal and Washington state law (respectively, the "Federal RTT Act" and "State RTT Act"), increasing their suffering for no valid reason. Underlying the issues presented by this appeal is the fact that doctor and patient access to psilocybin for legitimate treatment purposes is fundamentally a medical issue—not a criminal justice issue—and neither the CSA nor the DEA should foreclose a patient's access to a legitimate treatment regime recognized by both the Federal and Washington state RTT Acts.

II. SUMMARY OF ARGUMENT

In support of Petitioners' position, this brief presents the following arguments to assist the Court's consideration of this appeal:

> 1. The DEA's erroneous interpretation encroaches upon the doctor-patient relationship and infringes upon the rights of doctors and patients to pursue registration and treatment via the Federal and State RTT laws free from criminal prosecution.
>
> 2. The DEA's erroneous interpretation not only obstructs implementation of the Federal RTT Act, but it also violates the rights of Washington residents under the State RTT Act in light of principles of federalism.

For these reasons, along with all those raised in the other supporting briefs, ACLU-WA respectfully submits that Petitioners should prevail.

III. BACKGROUND

A. Federal Controlled Substances Act of 1970

The CSA was enacted in 1970. *See* 21 U.S.C. § 801 *et seq*. "The stated purpose of the CSA is 'to provide increased research into, and prevention of, drug abuse and drug dependence . . . and to strengthen existing law enforcement authority in the field of drug abuse.'" *Oregon v. Ashcroft*, 368 F.3d 1118, 1121 (9th Cir. 2004) (quoting Pub. L. No. 91-513, 84 Stat. 1236 (1970) (preamble)). Importantly, the CSA permits the Attorney General to "waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety." 21 U.S.C. § 822(d).

The legislative history of the CSA makes clear that Congress intended to curb the illegal distribution of controlled substances and *not* to hinder the legitimate practice of medicine by licensed physicians:

- "[Title II of] [t]he bill provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and *makes transactions outside the legitimate distribution chain illegal*." H.R. REP. NO. 91-1444, at 4569 (1970) (emphasis added).

- "The bill is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a 'closed' system of

> drug distribution for legitimate handlers of such drugs. Such a closed system *should significantly reduce the widespread diversion of these drugs out of legitimate channels* into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control." H.R. REP. NO. 91-1444, at 4571-72 (emphasis added).

- "The reported bill combines both the punitive and rehabilitative approaches to the problem of drug abuse. It seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse *except through legitimate channels of trade and for legitimate uses*." H.R. REP. NO. 91-1444, at 4574 (emphasis added).

In pursuit of these objectives, Congress "create[ed] a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act's five schedules."[2] *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006) (quoting *Gonzales v. Raich*, 545 U.S. 1, 12–13 (2005)); *see also* 21 U.S.C. § 841; 21 U.S.C. § 844. That said, Congress provided that "[n]o provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision

[2] By classifying psilocybin as a Schedule I drug, as opposed to listing it on a lesser schedule, the manufacture, distribution, or possession of psilocybin became a criminal offense under federal law. 21 U.S.C. §§ 823(f), 841(a)(1), 844(a); *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 490 (2001).

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.

B. Washington Uniform Controlled Substances Act

Similar to the federal statute, psilocybin is regulated in Washington State according to the Uniform Controlled Substances Act, RCW 69.50, *et seq*., which was enacted a year after the federal CSA in 1971. The state statute was passed due to "[t]he tremendous increase of drug abuse and the desire to control the availability for illicit use of both the raw materials and the actual drugs themselves." Comm. on Soc. and Health Servs., Rep. to Speaker's office regarding House Comm. Amend. to Second substitute Senate Bill No. 146 (1971).

As with the federal CSA, Psilocybin is listed as a Schedule I substance. RCW 69.50.204(c)(28). Physicians may be registered to prescribe Schedule II substances, but there is no explicit provision for them to register to prescribe Schedule I substances. RCW 69.50.308.

C. Federal Right to Try Act

On May 30, 2018, former President Trump signed the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act into law. *See* 21 U.S.C. § 360bbb-0, *et seq.* The Right to Try Act was expressly intended to allow terminally ill, end-of-life patients who have exhausted approved treatments to access other drugs—including controlled substances—which, while still the subject of ongoing studies, might alleviate the primary or secondary effects of illnesses such as cancer or end-of-life treatments. 21 U.S.C. § 360bbb-0a. Indeed, at the time of the Act's passage, the Trump Administration expressly acknowledged "that treatment decisions for those facing life-threatening illnesses are best made by the patients with the support and guidance of their treating physicians" and subsequently characterized this principle as a "fundamental freedom." Statement From the Press Sec'y Regarding Passage of S. 204 - Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act of 2017, 2018 WL 2328462, at *1 (May 22, 2018); Remarks by President Trump at S. 204, "Right to Try" Bill Signing, 2018 WL 2426489, at *1 (May 30, 2018).

D. Washington State's "Right to Try" Act

On July 23, 2017, Washington State enacted its own "Right to Try" law. RCW 69.77, *et seq*. In published findings, the state legislature explained that "[p]atients who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States food and drug administration." RCW 69.77.010. Notably, the legislature declared that the use of such 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." *Id.*

To effectuate this intent, the Washington RTT Act provides that an "eligible patient and his or her treating physician may request that a manufacturer make an investigational product available for treatment of the patient." RCW 69.77.030. As with the Federal RTT Act, Washington's RTT law does not exclude Schedule I drugs from its definition. *Compare* RCW 69.77, *et seq*. *with* Mo. Ann. Stat. § 191.480(2) (Missouri's RTT Act, defining "investigational drug" to not include Schedule I drugs).

IV. ARGUMENT

Petitioners have robustly discussed the troubling statutory issues at play, given how the DEA's interpretation and application of the CSA directly conflicts with both federal and state RTT laws. Pet'r's Opening Br. at 40-46, 57-60.[3] And although Petitioners have also discussed some

[3] *Amicus curiae* wishes to make two brief additional points in support of Petitioner's statutory arguments:

1. We emphasize the simple point that neither the Federal nor State RTT Acts preclude Schedule I controlled substances from classification as EIDs. Indeed, the DEA seemingly ignores that the federal CSA delegates to the Secretary of Health and Human Services matters related to medical judgments, and neither the text of the Federal RTT Act nor the direction of the Secretary excluded Schedule I drugs from the scope of the Federal RTT Act. *See Gonzales v. Oregon*, 546 U.S. at 272 ("This difficulty is compounded by the CSA's consistent delegation of medical judgments to the Secretary and its otherwise careful allocation of powers for enforcing the limited objects of the CSA"). Likewise, the State RTT Act does not exclude Schedule I drugs from the definition of EID. As demonstrated by RTT laws like that of Missouri, legislators are clearly able to make such an exclusion if they elect to do so, *see* Mo. Ann. Stat. § 191.480(2)—and they did not do so with both RTT Acts at issue here.

2. In its initial response to Petitioners, the DEA asserted that "[a]s is made clear in 21 U.S.C. 360bbb-0a(b) . . . the RTT does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations." ER-9. But the DEA's reliance upon 21 U.S.C. § 360bbb-Oa(b) is misguided, as a review of the sections referred to in this statutory provision reveals that they relate to misbranding and labeling requirements—rather than defining the intersection or lack thereof between the CSA and the Federal RTT Act.

constitutional concerns with the DEA's response, Pet'r's Opening Br. at 50-57, *amicus curiae* will further explore the fundamental individual liberty interests that are in jeopardy as a result of the DEA's disregard for legitimate channels of psilocybin use.

A. The DEA's Erroneous Interpretation Infringes the Rights of Patients and Doctors to Pursue Registration and Treatment via the RTT Laws Free from Criminal Prosecution

A long line of Supreme Court cases stresses the sanctity of the doctor-patient relationship and recognizes that the joint decision-making process with respect to treatment should be accorded heightened protection. *See, e.g.*, *Whalen v. Roe*, 429 U.S. 589, 598-600 (1977) ("The cases sometimes characterized as protecting 'privacy' have in fact involved at least two different kinds of interests. One is the individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of important decisions."); *Doe v. Bolton*, 410 U.S. 179, 198 (1973) (holding a Georgia statute requiring committee approval of abortion unconstitutionally restricted a woman's right to receive medical care in accordance with her licensed physician's best judgment). It is also well-settled that doctors should be permitted to practice medicine in

accordance with their best professional judgment without undue interference from the government. *See Bolton*, 410 U.S. at 186; *Bering v. SHARE*, 106 Wash. 2d 212, 227 (1986) ("The right of privacy dictates protection of the private relationship between a woman and her physician . . . , and the physician's right to freely practice medicine . . . without coercive outside restraints) (citations omitted); *cf. also Conant v. Walters*, 309 F.3d 629, 636-37 (9th Cir. 2002) ("The Supreme Court has recognized that physician speech is entitled to First Amendment protection because of the significance of the doctor-patient relationship. . . . This Court has also recognized the core First Amendment values of the doctor-patient relationship.").

DEA interference with a licensed physician's exercise of her or his professional judgment when treating terminally ill patients squarely implicates these rights. The DEA's misinterpretation of the intersection between the CSA and the RTT encroaches on this special doctor-patient relationship and essentially "criminalizes the provision of medical assistance to patients in need." Indeed, the federal government's proliferation of this erroneous interpretation "could create conflicts with the doctors' professional obligations and make covert criminals out of

honorable, dedicated, and compassionate individuals." *Compassion in Dying v. State of Wash.*, 79 F.3d 790, 827 (9th Cir. 1996), *rev'd sub nom. Washington v. Glucksberg*, 521 U.S. 702 (1997); *Conant*, 309 F.3d at 639–40 (Kozinski, J., concurring) ("By speaking candidly to their patients about the potential benefits of medical marijuana, they risk losing their license to write prescriptions, which would prevent them from functioning as doctors. In other words, they may destroy their careers and lose their livelihoods.").

In enacting the CSA, Congress intended to criminalize diversion, not legitimate medical use prescribed to a patient receiving end-of-life care. In fact, "there is no indication that Congress, in classifying [psilocybin], considered the harms posed by the particular [palliative] use at issue here." *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 420 (2006). And as the Supreme Court has emphasized, the government's "mere invocation of the general characteristics of Schedule I substances, as set forth in the Controlled Substances Act, cannot carry the day." *Id.* at 432. "Congress' determination that [psilocybin] should be listed under Schedule I simply does not provide a categorical answer that relieves the

Government of the obligation to shoulder its burden under [the Federal RTT]." *Id.*

The enactment of the Federal RTT Act (and the State RTT Act as well) was intended to create a legal pathway allowing physicians to provide access to investigational drugs that they would otherwise be criminally barred from providing to terminally ill patients. However, the DEA's erroneous understanding of the intersection between the CSA and the Federal RTT Act expressly frustrates this purpose. Physicians have a right to practice medicine as properly regulated under federal and state law, and to do so free from unlawful criminal prosecution. Likewise, eligible patients have a right to seek use of EIDs—which should encompass approved Schedule I controlled substances—from physicians free from unlawful criminal prosecution. And the DEA has no place in interfering in this doctor-patient relationship and criminalizing its lawful expression.

B. The DEA's Erroneous Interpretation Violates the Rights of Washington State Residents Under the State RTT Act

1. Principles of Federalism Protect Not Only States' Rights But Also Individual Rights

The Tenth Amendment provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. CONST. amend. X. Thus, "the Tenth Amendment confirms that the power of the Federal Government is subject to limits that may, in a given instance, reserve power to the States." *New York v. United States*, 505 U.S. 144, 157 (1992). But although the concept of federalism protects the sovereignty of the individual states, the Supreme Court has made it clear that "[f]ederalism is more than an exercise in setting the boundary between different institutions of government for their own integrity." *Bond v. United States*, 564 U.S. 211, 221 (2011). Federalism also protects the "liberty of all persons within a State by ensuring that laws enacted in excess of delegated governmental power cannot direct or control their actions." *Id.* at 222. In other words, federalism also concerns individual freedom. *See id.*; *New York*, 505 U.S. at 181

("[F]ederalism secures to citizens the liberties that derive from the diffusion of sovereign power.").

The Supreme Court further explored this dimension of federalism in the *Sebelius* case, in which it emphasized that "[b]ecause the police power is controlled by 50 different States instead of one national sovereign, the facets of governing that touch on citizens' daily lives are normally administered by smaller governments closer to the governed." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 536 (2012). Accordingly, the Framers "ensured that powers which 'in the ordinary course of affairs, concern the lives, liberties, and properties of the people' were held by governments more local and more accountable than a distant federal bureaucracy." *Id.* (quoting the Federalist No. 45, at 293 (J. Madison)). In this way, "[t]he independent power of the States also serves as a check on the power of the Federal Government: 'By denying any one government complete jurisdiction over all the concerns of public life, federalism protects the liberty of the individual from arbitrary power.'" *Id.* (quoting *Bond*, 564 U.S. at 222).

In short, individual liberty is protected not just by courts recognizing substantive rights, but also by structural constraints, the

diffusion of power, and the political process—*i.e.*, federalism, separation of powers, and democracy. *See Bond v. United States*, 572 U.S. 844, 880 (2014) (Scalia, J., concurring) ("The distinction between provisions protecting individual liberty, on the one hand, and 'structural' provisions, on the other, cannot be the explanation, since structure in general—and especially the structure of limited federal powers—is designed to protect individual liberty."). And, therefore, when a federal executive agency like the DEA claims that a federal statute supersedes a democratically enacted expression of the police powers of a state, not only are principles of federalism, separation of powers, and democracy at risk, but so are individual liberties.

The Supreme Court also explored this important consequence of federalism in *United States v. Windsor*, 570 U.S. 744 (2013). At issue in *Windsor* was the Defense of Marriage Act ("DOMA"), a federal statute which infringed upon certain marital rights conferred upon a same-sex couple by the state of New York. 570 U.S. at 749-53. Put differently, the federal government "s[ought] to injure the very class New York s[ought] to protect." *Id.* at 769. The Court struck down DOMA under a two-step approach. First, the Court recognized that "[w]hen the State used its

historic and essential authority to define the marital relation in this way, its role and its power in making the decision enhanced the recognition, dignity, and protection of the class in their own community." *Id.* at 768. The Court discussed at length the "history and tradition" of states having the power to define and regulate marriage. *Id.* at 766-68. Second, after recognizing New York's authority to do this, the Court held that the federal government's "resulting injury and indignity is a deprivation of an essential part of the liberty protected by the Fifth Amendment." *Id.* at 768.

Similar principles apply here. The state of Washington exercised "its historic and essential authority" to regulate health and safety by enacting the State RTT Act. *See id.* In doing this, Washington "enhanced the recognition, dignity, and protection" of a class of people in its own community—terminally ill patients who have exhausted other options and seek to try potentially ameliorative yet presently unapproved investigational drugs. *See id.* The DEA should not be permitted to quash these state-conferred rights.

This codification of these patients' liberty interests only serves to enhance fundamental interests like those that members of the Supreme

Court have already recognized. *See Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 287-89 (1990) (finding fundamental right to refuse life support by exercising personal control of medical treatment); *Washington v. Glucksberg*, 521 U.S. 702, 745 (1997) (Stevens, J., concurring) ("Avoiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly '[a]t the heart of [the] liberty . . . to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life.'") (citing *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992)); *id.* at 782 (Souter, J., concurring) ("In my judgment, the importance of the individual interest here, as within that class of 'certain interests' demanding careful scrutiny of the State's contrary claim . . . cannot be gainsaid.").[4] The liberty interests that are at stake here are those of

[4] *Id.* at 736-37 (O'Connor, J., concurring) (emphasizing that the holding would be different if not for the fact that "a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death."); *id.* at 789 (Ginsburg, J., concurring) (concurring in Justice O'Connor's opinion); *id.* at 792 (Breyer, J., concurring) ("Were the legal circumstances different–for example, were state law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life–then the law's impact upon

dying patients who seek nothing more than to relieve themselves of unimaginable pain and suffering. *Seeley v. State*, 132 Wash. 2d 776, 831 (1997) (Sanders, J., dissenting) ("Offensive, in the extreme, is the proposition that the government may restrict ingestion of a substance found by a licensed physician to be medically advisable to comfort a terminal patient. Such right is as fundamental as any."). Because the DEA "seeks to injure the very class [Washington] seeks to protect," its erroneous interpretation cannot stand. *Windsor*, 570 U.S. at 769.

2. Regulation of Health and Medicine Is Generally Left to the States and the DEA Should Not Intervene

Throughout the history of the United States, the "several States have exercised their police powers to protect the health and safety of their citizens." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). "States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Metro. Life Ins. Co. v. Mass.*, 471 U.S. 724, 756 (1985) (quoting *Slaughter-House Cases*, 16 Wall. 36, 62 (1873)). This is

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serious and otherwise unavoidable physical pain (accompanying death) would be more directly at issue. And as Justice O'Connor suggests, the Court might have to revisit its conclusions in these cases.")

because the "regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719 (1985).

Cognizant of this traditional federal-state balance, the Supreme Court has been hesitant to read into federal laws an ability to regulate the practice of medicine where no such intent is explicit. For this very reason, in *Gonzales v. Oregon*, the Court rejected an attempt by an executive officer of the federal government to use the CSA to regulate a state's practice of medicine. 546 U.S. at 275. The Court explained:

> The [CSA] and our case law amply support the conclusion that Congress regulates medical practice 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. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.

Id. at 269-70 (internal quotation marks omitted).

In the instant case, the DEA is interfering with a state's ability to regulate the practice of medicine, as well as preventing individuals from receiving the medical care their health providers recommend. The State RTT Act clearly regulates health and safety in a way that is "without

doubt a proper exercise of its sovereign authority within our federal system, all in the way that the Framers of the Constitution intended." *Windsor*, 570 U.S. at 769; *see also* RCW 69.77.010. The CSA, on the other hand, only regulates "medical practice 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." *Gonzales v. Oregon*, 546 U.S. at 270; *see also Conant*, 309 F.3d at 639 (Kozinski, J., concurring) ("At the same time, the burden of the federal policy the district court enjoined falls directly and personally on the doctors: By speaking candidly to their patients about the potential benefits of medical marijuana, they risk losing their license to write prescriptions, which would prevent them from functioning as doctors.").

Yet, the DEA erroneously claims that the CSA prohibits any use of psilocybin for medicinal purposes pursuant to the Federal RTT. This is especially egregious considering the billions of dollars in medical marijuana transactions that now occur every year around the country even though marijuana remains a Schedule I drug.[5] And in its Final

[5] *See* Eli McVey, *Exclusive: US retail marijuana sales on pace to rise 40% in 2020, near $37 billion by 2024*, MJBIZDAILY (June 30, 2020),

Agency Decision the DEA did not even acknowledge Washington's RTT despite the fact that the CSA "explicitly contemplates a role for the States in regulating controlled substances, as evidenced by its pre-emption provision." 546 U.S. at 251; *see also* 21 U.S.C. § 903 ("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 provision operates . . . 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 . . . and that State law so that the two cannot consistently stand together.").[6]

Far from being the arbiters of proper medical procedures, the DEA's role in this arena is limited to "prohibiting a doctor from acting as a drug pusher instead of a physician." *Gonzales v. Oregon*, 546 U.S.

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https://mjbizdaily.com/exclusive-us-retail-marijuana-sales-on-pace-to-rise-40-in-2020-near-37-billion-by-2023/.

[6] *See also* Letter from Attorney General Janet Reno to Sen. Orrin Hatch, on DEA's ability to take adverse action against physicians for prescribing controlled substances pursuant to Oregon state law (June 5, 1998), Hearing 5–6 ("There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice.").

at 269 (internal quotation marks omitted). And here, like in *Gonzales v. Oregon*, there is a very limited potential for diversion because the RTT scheme by its terms is carried out only through licensed physicians. *See id.* at 252; RCW 69.77.020(7). There is certainly no more risk of diversion than when the Supreme Court granted members of a religious group access to hoasca despite its status as a Schedule I drug. *See O Centro*, 546 U.S. at 437. Beyond this limited job regarding diversion, the DEA has no role left to play under the circumstances.

3. The DEA's Erroneous Interpretation Offends the Democratic Process

Adherence to the principles of federalism is also critically important to the democratic process. Federalism allows states to enact laws answering to "the initiative of those who seek a voice in shaping the destiny of their own times without having to rely solely upon the political processes that control a remote central power." *Bond*, 564 U.S. at 221. Because of federalism, local government can be "more sensitive to the diverse needs of a heterogenous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a

mobile citizenry." *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991). These dynamics further "allow the formation of consensus respecting the way the members of a discrete community treat each other in their daily contact and constant interaction with each other." *Windsor*, 570 U.S. at 769. The state of Washington did exactly what is contemplated by principles of federalism and heeded its voters' calls for RTT legislation.

But when the DEA acts in a way that prevents the residents of Washington from exercising and recognizing those rights conferred upon them by Washington state, those residents are effectively deprived of the benefits which federalism is intended to promote. The DEA as a federal agency of unelected officials serves not only as a figurative arm of a "remote central power," *Bond*, 564 U.S. at 221, but it is also less attuned to the desires of a local constituency. As such, it is unable to respond to the needs of that constituency which are expressed through the democratic process. One of the main tenets of the Tenth Amendment is to "promote political accountability," through the ballot box. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1477 (2018); *see also FTC v. Ticor Title Ins. Co.*, 504 U.S. 621, 636 (1992) ("Federalism serves to assign political responsibility, not to obscure it.").

However, no such political accountability exists to address the decisionmaking of unelected federal officials who refuse to acknowledge the rights of state residents.[7] *See New York*, 505 U.S. at 169 ("Accountability is thus diminished when, due to federal coercion, elected state officials cannot regulate in accordance with the views of the local electorate in matters not pre-empted by federal regulation."); *United States v. Lopez*, 514 U.S. 549, 576–77 (1995) (Kennedy, J., concurring) ("If, as Madison expected, the Federal and State Governments are to control each other . . . and hold each other in check by competing for the affections of the people . . . those citizens must have some means of knowing which of the two governments to hold accountable for the failure to perform a given function . . . . Were the Federal Government to take over the regulation of entire areas of traditional state concern, areas having nothing to do with the regulation of commercial activities, the boundaries between the spheres of federal and state authority would blur and political responsibility would become illusory"). Moreover, the DEA's actions here are doubly

[7] This concern is doubly applicable here, where terminally ill constituents do not necessarily have the luxury of sufficient time to seek redress at the voting booth.

offensive since its interpretation also stands as an obstacle to the realization of rights conferred by legislation enacted by a centralized government. Neither of the RTT Acts dictate any role for the DEA to play, and the self-serving role asserted by the agency inflicts a patently undemocratic result.

V. CONCLUSION

For these reasons, as well as those set forth in the other briefs supporting Petitioners' position, *amicus* requests that the Court grant the Petition for Review, vacate the Final Determination, and instruct the DEA to promptly accommodate RTT and provide directions to licensed practitioners on how to obtain approval from the DEA necessary to obtain Schedule I drugs for therapeutic use consistent with RTT laws.

Date: May 21, 2021

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

9th Cir. Case Number(s) 21-70544

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s/ Nicholas Peterson
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