No. 21-70544

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC, *et al.*,

Petitioners,

v.

MERRICK B. GARLAND, Attorney General, *et al.*,

Respondents.

On Petition for Review of a Non-Final Action of the Drug Enforcement Administration

BRIEF FOR RESPONDENTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Treaty:

Statutes:

Regulations:

Other Authorities:

INTRODUCTION

The federal Right to Try Act,[1] Pub. L. No. 115-176, 132 Stat. 1372 (2018), clears a new path for patients diagnosed with life-threatening conditions to gain access to certain drugs that have not yet been approved as safe and effective by the Food and Drug Administration (FDA). The law does not provide a right to use any specific treatment. Rather, it permits the distribution of eligible drugs by providing limited exemptions to specified provisions of the Federal Food, Drug, and Cosmetic Act that regulate the labeling, approval, and clinical trials of drugs. The Right to Try Act does not exempt anyone from complying with the Controlled Substances Act, or even mention controlled substances at all.

The petitioners in this case are a medical institute, a doctor, and two patients suffering from cancer who wish to use psilocybin to treat their depression and anxiety. Psilocybin is a hallucinogenic substance found in certain mushrooms. *See* Drug Enf't Admin., *Psilocybin*, https://go.usa.gov/x6yRW (last visited June 24, 2021). When Congress passed the Controlled Substances Act, it placed psilocybin in the most strictly controlled category of drugs based on a conclusion that psilocybin had a high potential for abuse and no accepted medical use in treatment. 21 U.S.C. § 812(c). It is unlawful to manufacture, distribute, or possess any drugs in this category, except as

[1] The full name of the Act is the "Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017." *See* Pub. L. No. 115-176, § 1, 132 Stat. at 1372.

part of a preapproved research study. *Gonzales v. Raich*, 545 U.S. 1, 14 (2005) (citing 21 U.S.C. §§ 823(f), 841(a)(1), 844(a)). This is so regardless of whether a state law would authorize use of the drug or whether a person claims a legitimate medical need. *Id.* at 29.

The petitioners nevertheless wrote to the Drug Enforcement Administration (DEA) seeking guidance on how they might obtain psilocybin under the Right to Try Act. The agency explained that the new statute did not waive the requirements of the Controlled Substance Act or provide the agency with authority to do so. But the agency suggested that the petitioners might consider applying for access under the research exception described above. Dissatisfied with this response, the petitioners have sought judicial review of the agency's advice.

This Court lacks jurisdiction over the petition for review. The Controlled Substances Act limits judicial review to DEA's "final" decisions. 21 U.S.C. § 877. Here, DEA did not make any kind of final decision. It did not create a new rule or grant or deny an application. DEA merely shared its view of the Right to Try Act as a courtesy to members of the regulated community. But even if DEA's letter were reviewable, the petitioners' suit would still fail. The Right to Try Act does not silently limit the federal government's ability to regulate the distribution and use of controlled substances. Nor did DEA categorically and permanently deny the petitioners access to psilocybin under any circumstances or under any conceivable agency authority. Rather, the agency responded to their limited request for guidance by correctly

describing the scope of the exemptions created in the Right to Try Act. This was neither contrary to law nor arbitrary and capricious.

STATEMENT OF JURISDICTION

The petitioners seek review of a letter issued by DEA on February 12, 2021. SER-3. The Controlled Substances Act provides that "any person aggrieved by a final decision" made by DEA "may obtain review of the decision in the United States Court of Appeals . . . for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision." 21 U.S.C. § 877. Petitioners timely filed their petition for review on March 8, 2021. Nevertheless, this Court lacks jurisdiction because, as explained below, the petitioners do not seek review of any final action by DEA.

STATEMENT OF THE ISSUES

The Right to Try Act amended the Federal Food, Drug, and Cosmetic Act to authorize the distribution of certain unapproved drugs for use by patients with life-threatening conditions. The petitioners wish to use psilocybin—a hallucinogenic substance found in certain mushrooms—for the treatment of depression and anxiety in cancer patients. Congress placed psilocybin on Schedule I of the Controlled Substances Act based on a conclusion that the drug had no accepted medical use in treatment. 21 U.S.C. § 812(c). The petitioners sought guidance from DEA as to how they could obtain psilocybin under the Right to Try Act for therapeutic use.

Responding to that request, DEA stated that the Right to Try Act does not permit the agency to waive any requirements of the Controlled Substances Act, and it identified another possible option for the doctor to consider. The questions presented are:

1. Whether DEA's response letter is a final agency action subject to judicial review under 21 U.S.C. § 877.

2. Whether, assuming that judicial review is available, the letter was arbitrary and capricious or contrary to law.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory Background

This case concerns the intersection of three federal laws regulating the distribution and use of drugs in the United States: the Controlled Substances Act; the Federal Food, Drug, and Cosmetic Act; and the Right to Try Act.

1. The Controlled Substances Act

The Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, establishes a comprehensive federal scheme for the regulation of dangerous drugs and similar substances. The law makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance,

"[e]xcept as authorized by [21 U.S.C. §§ 801-904]." 21 U.S.C. § 841(a)(1).[2] It is similarly a crime to possess any controlled substance except as expressly authorized. *Id.* § 844(a). The CSA thus establishes a "closed system of distribution," *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 542 (D.C. Cir. 2007) (quotation marks omitted), authorizing certain transactions "within the legitimate distribution chain and mak[ing] all others illegal." *United States v. Moore*, 423 U.S. 122, 141 (1975) (quotation marks omitted).

To dispense controlled substances lawfully, a physician or other practitioner must "obtain from the Attorney General a registration." 21 U.S.C. § 822(a)(2). Registered physicians or other practitioners may dispense controlled substances only "in the course of professional practice or research," *id.* § 802(21), and only "to the extent authorized by their registration and in conformity with the other provisions of [the CSA]," *id.* § 822(b).

The CSA classifies controlled substances into five separate schedules based on their safety, the extent to which they have an accepted medical use, and the potential for abuse. 21 U.S.C. § 812(b). The Act imposes varying regulatory restrictions on controlled substances depending on the applicable schedule. Substances in Schedule

[2] Under the CSA, the term "dispense" includes the issuance of a prescription by a practitioner as well as delivering a controlled substance directly to a patient. 21 U.S.C. § 802(10). A "controlled substance" is "a drug," as defined under the Federal Food, Drug, and Cosmetic Act, "or other substance, or immediate precursor" listed on one of five schedules. *Id.* § 802.

I—the most restricted schedule—have "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use . . . under medical supervision." *Id.* § 812(b)(1). The CSA prohibits human consumption of Schedule I controlled substances except in a research setting where the research has been allowed to proceed by FDA and the researcher has obtained from DEA a registration authorizing the specific research protocol. *Id.* §§ 355(i), 823(f); *see United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 491 (2001).

When the CSA was enacted in 1970, Congress made an initial assignment of controlled substances to the schedules it found appropriate. 21 U.S.C. § 812(c). Congress placed psilocybin in Schedule I. *Id.* sched. I(c)(15).[3] The CSA authorizes the Attorney General, in consultation with the Secretary of Health and Human Services, to add or remove substances or to transfer substances from one schedule to another based upon statutory criteria that take into account changes in medical and scientific understanding and shifts in patterns of abuse. *Id.* §§ 811, 812. States remain free to enact their own laws relating to controlled substances, such as their own criminal penalties, but state laws are preempted to the extent of any "positive

[3] In 1998, Congress passed a resolution reaffirming that the drugs "listed on Schedule I of the Controlled Substances Act . . . have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision." Pub. L. No. 105-277, div. F, 112 Stat. 2681, 2681-760. Congress also expressed its "continue[d]" "support [for] the existing Federal legal process for determining the safety and efficacy of drugs and oppose[d] efforts to circumvent this process" and to establish legal uses for Schedule I drugs "without valid scientific evidence." *Id.*; 112 Stat. at 2681-761.

conflict" between a provision of state law and the CSA such that the two "cannot consistently stand together." *Id.* § 903.

The CSA implements the United States' obligations under the United Nations Convention on Narcotic Drugs: Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, https://www.unodc.org/pdf/convention_1971_en.pdf (Convention). *See* 21 U.S.C. § 801a(2). Congress recognized that it was "essential that the United States cooperate with other nations in establishing effective controls over international traffic" in psychotropic substances such as psilocybin. *Id.* § 801a(1). Like the CSA, the Convention divides covered substances into schedules, and it lists psilocybin as a Schedule I substance subject to the most rigorous controls. *See* Convention, Appended List of Substances in the Schedules. The Convention obligates the United States to "prohibit all use" of psilocybin and preparations containing it, "except for scientific and very limited medical purposes . . . directly under the control" of or approved by the government. *Id.* arts. 7(a), (f), 12.

2. The Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act (FDCA) imposes substantive restrictions on the distribution of all drugs—not only those designated as controlled substances. *See* 21 U.S.C. § 331. One of the FDCA's "core objectives" is to ensure that any drug used in the United States is "safe and effective for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 134 (2000). To that end, the statute generally prohibits the introduction into interstate commerce of new drugs

unless and until they have been approved by FDA. 21 U.S.C. § 355(a); *see also Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 697 (D.C. Cir. 2007).

To approve a new drug, FDA must determine that the drug is "safe and effective" for each of is intended uses, based on "substantial evidence" gathered from "well-controlled investigations" conducted by scientific experts. 21 U.S.C. § 355(a), (b), (d). Clinical testing on humans is a prerequisite for the approval of a new drug application. But before such testing can even begin, the drug's sponsor must submit an investigational new drug application describing the protocols for planned studies and establishing that human testing is appropriate. *See generally* 21 U.S.C. § 355(i); 21 C.F.R. pt. 312.

FDA regulations prescribe a three-phase process for the clinical testing of a new drug for safety and effectiveness. 21 C.F.R. § 312.21. Phase 1 involves the initial introduction of the new drug into a small number of human subjects (typically twenty to eighty) and is "designed to determine the metabolism and pharmacologic actions of the [new] drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." *Id.* § 312.21(a)(1). Phase 2 involves a well-controlled, closely monitored study of the drug in a small group of patients (usually no more than several hundred) to evaluate "the effectiveness of the drug for a particular indication" and "to determine [its] common short-term side effects and risks." *Id.* § 312.21(b). Phase 3 involves large clinical trials (of several hundred to

several thousand subjects) designed to gather "additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling." *Id.* § 312.21(c).

Throughout the course of the clinical trials, the sponsor is required to notify FDA of any "serious and unexpected" adverse drug experiences. 21 C.F.R. § 312.32. If FDA is concerned about the safety of an investigational drug, it may suspend a trial by issuing a "clinical hold," and if the safety concerns are sufficiently great, FDA may order the termination of the trial. *Id.* §§ 312.40(b)(1), 312.42(b).

That a clinical trial is allowed to proceed from Phase 1 to subsequent phases does not represent a judgment by FDA that the investigational drug is either safe or effective for use in treating diseases. Preliminary expectations of safety and efficacy often prove to be unfounded, and drugs that initially appear to be promising are frequently revealed to be ineffective or even affirmatively harmful. Successful clinical trials are the exception, not the rule, as "the great majority of experimental drugs ultimately provide no benefit." *Abigail Alliance*, 495 F.3d at 708 n.15. For example, only five percent of all cancer drugs that begin clinical testing are ultimately approved for patient use, and even among cancer drugs that successfully complete Phase 1 testing, less than a third proceed from Phase 2 to Phase 3. *Id.* (citing Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. von Eschenbach*, 297 JAMA 205, 206 (2007)).

In some circumstances, when other treatments are unavailing, patients may seek access to investigational drugs outside of the clinical trial process using the FDA "expanded access" program. *See* 21 U.S.C. § 360bbb; 21 C.F.R. pt. 312, subpt. I; *see also Abigail Alliance*, 495 F.3d at 698-99. These expanded access procedures may permit a patient with an "immediately life-threatening" or "serious" disease or condition to gain access to an investigational product outside of a clinical trial when no comparable or satisfactory alternative therapy options are available. 21 C.F.R. §§ 312.300-.305; *see generally* FDA, *Expanded Access*, https://go.usa.gov/x6VPW (last updated Mar. 23, 2021). FDA receives approximately 1,800 requests each year for expanded access to investigational products, and it authorizes 99% of those requests. FDA, *Expanded Access Program Report* 5, 14 (May 2018), https://www.fda.gov/media/119971/download Despite this high volume, emergency requests for single patients are typically reviewed in less than one day, and non-emergency requests for single patients seeking access to investigational drugs are typically resolved in approximately eight days. *Id.* at 14-15. FDA's role in reviewing expanded access requests permits the agency to ensure that patient safety is protected, including by requiring changes to the treatment protocol or strengthening informed consent where necessary.

3. The Right to Try Act

In 2018, Congress enacted the Right to Try Act, which amends the FDCA to provide a new pathway by which certain patients might be able to access certain unapproved medical products. The Right to Try Act provides that that "[e]ligible

investigational drugs provided to eligible patients in compliance with this section are exempt from" specified statutory and regulatory provisions governing the labeling, approval, and clinical trials of drugs. 21 U.S.C. § 360bbb-0a(b). Such exemptions are contingent, however, on compliance with regulations that forbid promoting, commercially distributing, or test marketing investigational drugs. *Id.* (requiring compliance with 21 C.F.R. 312.7).

An "eligible investigational drug" is a drug that (1) is not approved or licensed by FDA for any use, (2) has been the subject of a phase 1 clinical trial, (3) is the subject of a new drug application filed with FDA (meaning clinical trials have been completed) or is the subject of an active investigational new drug application and is currently under investigation in a clinical trial, and (4) is under active development or production and was not discontinued by the manufacturer or placed on a clinical hold by FDA. 21 U.S.C. § 360bbb-0a(a)(2). An "eligible patient" is someone who has been diagnosed with a "life-threatening disease or condition,"[4] has "exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug" (as certified by a physician), and has provided written informed consent regarding the drug in question. *Id.* § 360bbb-0a(a)(1).

[4] A "life-threatening disease or condition" includes diseases and conditions where "the likelihood of death is high unless the course of the disease is interrupted" and those "with potentially fatal outcomes, where the end point of clinical trial analysis is survival." 21 C.F.R. § 312.81(a). Examples include cancer, heart attack, chronic or active hepatitis, and trauma.

FDA does not review or approve requests for the use of investigational drugs under the Right to Try Act. Rather, the agency's role primarily involves the receipt and posting of certain information that the manufacturers or sponsors of the drugs must submit. *See* 21 U.S.C. § 360bbb-0a(d); *see also* 85 Fed. Reg. 44,803 (July 24, 2020) (proposing regulations regarding the deadline and contents of required submissions). FDA advises that "the sponsor of the investigational drug . . . is in the best position to provide information about whether the drug . . . meets the criteria to be considered an eligible investigational drug." FDA, *Right to Try*, https://go.usa.gov/x6y5r (last updated Jan. 14, 2020).

An uncodified portion of the Right to Try Act limits liability of parties with respect to the provision of investigational drugs under the Act. It provides that "no liability in a cause of action shall lie against" a sponsor or manufacturer of an eligible drug, or against an individual (such as a person who prescribes or dispenses the drug), unless that individual commits reckless or willful misconduct, gross negligence, or an intentional tort under state law. Pub. L. No. 115-176, § 2(b)(1), 132 Stat. at 1374. The Right to Try Act also provides that "[n]o liability shall lie against" any party for "its determination not to provide access to an eligible investigational drug" to a patient. *Id.* § 2(b)(2). In all other respects, the ability to bring a private action is preserved. *Id.* § 2(b)(3).

The Right to Try Act states that it was not intended to "establish a new entitlement" or a "positive right" in any individual. Pub. L. No. 115-176, § 3(1), 132

Stat. at 1374. Rather, the law "only expands the scope of individual liberty and agency among patients, in limited circumstances." *Id.* § 3(3). It was understood that this new access to investigational drugs would be "consistent with, and . . act as an alternative pathway alongside, existing expanded access policies." *Id.* § 3(4).

B. Factual Background

The Advanced Integrative Medical Science Institute "is an integrative oncology clinic located in Seattle." ER-4. Integrative oncology involves the use of "natural and supportive therapies to reduce side effects, to help optimize conventional care and prevent recurrence" of cancer. AIMS Inst., *Integrative Oncology*, https://www.aimsinstitute.net/services/integrative-oncology/ (last visited June 24, 2021). Dr. Sunil Aggarwal is a co-director of the Institute and "a palliative care specialist who treats patients with advanced cancer." ER-4.

In December of 2020, the Institute and Aggarwal approached Organix, Inc., a research and development contractor, seeking to obtain psilocybin for use with seriously ill cancer patients. SER-14. Psilocybin is a hallucinogenic drug obtained from certain kinds of mushrooms. DEA, *Psilocybin*, https://go.usa.gov/x6yRW. While it has no currently accepted medical use in treatment, *see* 21 U.S.C. § 812(b), Schedule I(c)(15), psilocybin has been studied as an investigational drug for the possible treatment of anxiety and depression. ER-26. The petitioners explained that they had been unable to obtain psilocybin from the Usona Institute, the drug's sponsor under an investigational new drug application, and therefore inquired if

Organix would be able to provide it. SER-14, ER-15. A representative explained that Organix "operates under DEA regulations" and could "only ship a DEA Schedule I compound such as psilocybin upon receipt of a copy of the requesting organization's current DEA Schedule I license" and proper paperwork. SER-11.

The Institute and Agarwal next approached DEA to "seek [its] guidance on how DEA will accommodate [the Right to Try Act] so that Dr. Aggarwal and the AIMS Institute can obtain psilocybin for therapeutic use with terminally ill patients." ER-4. In a letter dated January 15, 2021, the petitioners represented that the Institute "intends to purchase psilocybin from Organix, a company which holds an [investigational new drug application] for this drug and is registered as a Distributor of this drug." ER-6; *but see* ER-15, ER-22 (informed consent forms for Aggarwal's patients identifying Usona as the holder of the investigational new drug application for the psilocybin that would be administered). The petitioners explained that they were interested in obtaining the substance "pursuant to the Washington and U.S. Right to Try (RTT) Acts" and conveyed their view that the statutes permit such access because they do not "exclude Schedule I substances from their scope." ER-4, ER-6. They observed that the "existing DEA forms do not appear to accommodate" such access and asked whether Aggarwal should "seek registration as a 'researcher.'" ER-6. The petitioners closed their letter expressing their "hope [that] DEA can promptly advise on how to proceed." *Id.*

Before DEA had responded, the petitioners followed their letter with an email identifying another possible route to obtaining psilocybin. They suggested that the agency could "issue an exemption from prosecution from the CSA," pointing to a regulation that permits such exemptions for individuals who register to engage in research in controlled substances. SER-5 (citing 21 C.F.R. § 1316.24). The petitioners asked for "DEA's guidance on whether it would be preferable to proceed with a Petition for Exemption." *Id.*

DEA responded by letter signed on February 12, 2021. SER-3. The agency described its understanding of the petitioners' request: they wished to obtain psilocybin "pursuant to the 'Right to Try Act' (RTT)" and they "ask[ed] DEA for guidance on how DEA will accommodate" their request under that statute. Quoting the statute's operative language, DEA explained that the Right to Try Act "does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations." Accordingly, the agency related its view that it "has no authority to waive any of the CSA's requirements pursuant to the RTT." *Id.*

DEA then addressed the applicability of the specific administrative pathways mentioned in the petitioners' correspondence. The agency confirmed that "[a] potential avenue for Dr. Aggarwal to pursue is to apply for a Schedule I researcher registration with DEA to conduct research with psilocybin," and explained where to find information about such applications. SER-4. With respect to the exemption from prosecution, however, DEA explained that the regulation cited by the

petitioners "only applies to individuals already registered with DEA to engage in research in controlled substances" and "would therefore not be applicable to Dr. Aggarwal at this time." But DEA noted that Aggarwal could "petition the DEA Administrator for a grant of exemption from prosecution" after he obtained a researcher registration. *Id.*

The AIMS Institute and Aggarwal, joined by two patients who wish to take psilocybin to alleviate their depression and anxiety, ER-12, ER-20, seek judicial review of DEA's letter.

SUMMARY OF ARGUMENT

The Right to Try Act creates a pathway by which eligible patients with life-threatening conditions can obtain drugs not yet approved by FDA. Petitioners wrote to DEA seeking "guidance" as to how they could obtain psilocybin "pursuant to the Washington and U.S. Right to Try (RTT) Acts." ER-4. Congress has placed psilocybin on Schedule I of the CSA, and subject to certain exceptions provided in the CSA itself, it may not be distributed, dispensed or possessed legally. DEA explained that the Right to Try Act "does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations." SER-3.

1. The Court lacks jurisdiction over this petition for review because it does not challenge a "final decision" reviewable under the CSA. 21 U.S.C. § 877; *see Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1085 (9th Cir. 2003). The letter does not mark the consummation of a decisionmaking process, *Bennett v. Spear*, 520 U.S. 154, 177-78

(1997); it responds to a request for guidance on how to request a decision. Nor does the letter determine any rights or obligations or give rise to any legal consequences. *Id.* at 178. The guidance letter did not compel the petitioners to do or to refrain from doing anything. Any legal consequences they would face from dispensing or using psilocybin imposed by the CSA and are not affected by DEA's letter noting its view of another statute. "[A]n agency works no legal effect merely by expressing its view of the law." *Valero Energy Corp. v. EPA*, 927 F.3d 532, 536 (D.C. Cir. 2019) (quotation marks omitted); *see also City of San Diego v. Whitman*, 242 F.3d 1097, 1102 (9th Cir. 2001). Permitting judicial review of such documents would only discourage agencies from responding to requests for assistance from members of the regulated community.

2. Assuming that the Court has jurisdiction to review the DEA letter, the petitioners fundamentally misunderstand the interaction of the Right to Try Act, the CSA, and the FDCA. DEA correctly explained that the Right to Try Act "does not waive the requirements of any provision" of the CSA and does not provide the agency with "authority to waive" any of those requirements. SER-3. Indeed, the Right to Try Act makes no reference to the CSA or to controlled substances.

The petitioners urge that psilocybin must be legally available, despite its placement on Schedule I, because the CSA contains a longstanding savings clause stating that its provisions should not be construed to supersede the provisions of the FDCA. But this provision does not call into question any restrictions on Schedule I

drugs. The CSA and the FDCA are separate regulatory schemes with separate protocols and restrictions. Uses of a drug for certain purposes may be permitted by one statute but precluded by the other. Petitioners also rely on a provision in the Right to Try Act that limits the "liability in a cause of action" against parties who comply with the Act. Pub. L. No. 115-176, § 2(b), 132 Stat. at 1374. But this provision is directed at civil litigation by private parties. Had Congress intended to limit federal enforcement of the nation's drug laws, it would have said so explicitly. *See Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("[Congress] does not, one might say, hide elephants in mouseholes.").

The Petitioners are on no firmer ground in criticizing DEA for addressing the effect of the Right to Try Act and not addressing statutory provisions that the petitioners now suggest might allow them to possess psilocybin legally. They urge this Court not only to review informal views set out in a letter responding to a request for guidance regarding the Right to Try Act, but to go further and pass, in the first instance, on the scope of legal authorities that were not the subject of that request for guidance. There is no basis for doing so.

STANDARD OF REVIEW

Judicial review of final decisions made under the CSA is governed by 21 U.S.C. § 877. The agency's findings of fact are conclusive if supported by substantial evidence. *Id.* Because § 877 does not specify a standard of review for the agency's legal reasoning and exercise of discretion, "[t]he narrow parameters of [this Court's]

review are set by the Administrative Procedure Act [(APA)]." *Fry v . DEA*, 353 F.3d 1041, 1043 (9th Cir. 2003); *see also Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001). Thus, this Court "may not substitute its judgment for the agency's" and may only set aside DEA's action if it was "arbitrary, capricious, an abuse of discretion or not in accordance with the law." *Fry*, 353 F.3d at 1043 (citing 5 U.S.C. § 706(2)(A)).

ARGUMENT

I. This Court Lacks Jurisdiction Over This Petition Because The DEA Letter Is Not A Final Decision Subject To Review Under The CSA.

Under 21 U.S.C. § 877, this Court has "original jurisdiction over 'final determinations, findings, and conclusions of the Attorney General' made under the CSA." *Oregon v. Ashcroft*, 368 F.3d 1118, 1120 (9th Cir. 2004) (quoting § 877); *see also* 28 C.F.R. § 0.100 (delegating the Attorney General's authority to DEA). Thus, this Court has recognized that its jurisdiction under § 877 "depends on whether th[ere] is a final determination." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1085 (9th Cir. 2003); *see also John Doe, Inc. v. DEA*, 484 F.3d 561, 565 (D.C. Cir. 2007) (explaining that finality is jurisdictional where "review is sought under a specific statute prescribing finality as a prerequisite of judicial review").

Agency action is final when two conditions are satisfied: first, the action must "mark the consummation of the agency's decisionmaking process," and second, it must be an action "by which rights or obligations have been determined, or from

which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (quotation marks omitted).[5] Here, neither condition is satisfied.

First, the letter at issue here does not mark the consummation of a decisionmaking process. The petitioners asked the agency for guidance as to how they might achieve their objective of obtaining psilocybin, and the agency responded by explaining which of the proposed routes were viable in its view. DEA noted that access pursuant to the Right to Try Act and an exemption from prosecution were not available, but a researcher registration might be a "potential avenue" to access. SER-4. This letter did not begin a decisionmaking process, let alone consummate one.

Indeed, the petitioners did not ask DEA to make a decision—they asked the agency "how to proceed" with requesting one. ER-6. This is clear not only in their opening letter asking about researcher registration, but also in the follow-up email where they asked "whether it would be preferable to proceed with a Petition for Exemption" under 21 C.F.R. § 1316.24. SER-5. Even if DEA's response could somehow be characterized as a determination, finding, or conclusion, it was certainly not a final one. That would come, if ever, only after the petitioners pursued one of

[5] *Bennett* establishes the test for finality under the APA, which provides for judicial review of "final agency action." 5 U.S.C. § 704. As the D.C. Circuit has observed, however, there is "no reason" why "the word 'final' in § 877 should be interpreted differently than the word 'final' in the APA." *John Doe*, 484 F.3d at 566 n.4. This Court has applied *Bennett*'s test under other statutes that provide for judicial review of "final" administrative actions. *See, e.g.*, *Alaska Dep't of Envtl Conservation v. U.S. EPA*, 244 F.3d 748, 750 (9th Cir. 2001).

the available routes to requesting access to psilocybin and their application was granted or denied. *See John Doe*, 484 F.3d at 566 (explaining that an agency action was "definitive" and "not merely tentative" when "the DEA affirmatively denied [a] permit application").

Second, DEA's guidance letter did not determine any rights or obligations or give rise to any legal consequences. It did not order the petitioners do anything or refrain from doing anything; it did not grant or deny a permit or license. The most that could be said is that DEA conveyed its view that the Right to Try Act does not provide an exemption from the CSA or its regulations. But as a general matter, "an agency works no legal effect merely by expressing its view of the law." *Valero Energy Corp. v. EPA*, 927 F.3d 532, 536 (D.C. Cir. 2019) (quotation marks omitted). Thus, this Court has held that there is no final action where an agency's "letter simply responds to [a] request for 'assistance'" on a question of what law the agency would apply to a permit application. *City of San Diego v. Whitman*, 242 F.3d 1097, 1102 (9th Cir. 2001). The D.C. Circuit has likewise repeatedly held that the second prong of the *Bennett* test is not satisfied where a letter "communicates the agency's position on a matter" but "compels action by neither the recipient nor the agency." *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012) (quotation marks omitted); *see also, e.g.*, *Independent Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 427 (D.C.

Cir. 2004) (Roberts, J.) (holding agency "advice letter" nonfinal where it "imposed no obligations and denied no relief" (quotation marks omitted)).

Nor did the DEA letter here "alter the legal regime" to which the petitioners are subject. *Bennett*, 520 U.S. at 178. The letter was provided "simply to *inform* [the petitioners] of what the law, previously enacted or adopted, is." *Golden & Zimmerman, LLC v. Domenech*, 599 F.3d 426, 432-33 (4th Cir. 2010) (addressing a reference guide with frequently asked questions and answers). It "does not itself *determine* the law or the consequences of not following it," *id.* at 433, nor does it have (or claim to have) any independent legal force. *Valero Energy*, 927 F.3d at 537. Rather, the DEA letter "leaves the world just as it found it." *Id.* at 536; *Independent Equip. Dealers*, 372 F.3d at 428. Any restrictions on the petitioners' ability to access and use psilocybin flowed directly from the CSA and its implementing regulations. *See Gonzales v. Raich*, 545 U.S. 1, 13-14 (2005) (describing the statutory scheme and its restrictions on Schedule I substances). An agency action does not have legal consequences where a party's "obligation" to act arises under federal statute and regulations and "any penalty" for not acting "would result from [the party's] disregard of its statutory obligation." *Gallo Cattle Co. v. U.S. Dep't of Agric.*, 159 F.3d 1194, 1199 (9th Cir. 1998); *see also Golden & Zimmerman*, 599 F.3d at 433.

This Court's cases finding other types of agency action to be final underscore what is lacking here. For example, DEA did not "orde[r]" the petitioners to refrain from taking action "on pain of fines and imprisonment." *See San Francisco Herring*

Ass'n v. Department of the Interior, 946 F.3d 564, 577 (9th Cir. 2019) (distinguishing *Golden & Zimmerman* and *Independent Equip. Dealers*). Nor could DEA take action against the petitioners "for failure to comply" with the letter, *see Gill v. U.S. Dep't of Justice*, 913 F.3d 1179, 1184-85 (9th Cir. 2019), or subject them to increased penalties, *see Alaska*, 244 F.3d at 750; *see also Sackett v. EPA*, 566 U.S. 120, 126 (2012). The DEA action at issue here does not "orde[r] sanctions for violations of its provisions." *Ashcroft*, 368 F.3d at 1120; *Hemp Indus. Ass'n*, 333 F.3d at 1085. Nor does it amend the agency's regulations, *Hemp Indus. Ass'n. v. DEA*, 357 F.3d 1012, 1015 (9th Cir. 2004), or adjudicate an application, *Mathew v. U.S. DEA*, 472 F. App'x 453, 454 (9th Cir. 2012).

Agencies issue advice letters "countless times per year in dealing with the regulated community." *Independent Equip. Dealers*, 372 F.3d at 427 (quotation marks omitted). Permitting every recipient of such a letter to sue over its contents "would quickly muzzle any informal communications between agencies and their regulated communities—communications that are vital to the smooth operation of both government and business." *Id.* at 428. The case law "rightly rejects that unwelcome result." *Valero Energy*, 927 F.3d at 538.

II. The DEA Letter Is Consistent With Law And Reasonably Responded To The Petitioners' Request For Guidance.

Assuming that the Court has jurisdiction to review DEA's letter, the petitioners' arguments are without substance.

A. DEA Correctly Described The Scope Of The Right To Try Act.

1. The Right to Try Act amended the FDCA to provide a new pathway by which certain patients can gain access to certain medical products that have not been approved by FDA. The statute provides that "[e]ligible investigational drugs provided to eligible patients in compliance with this section are exempt from" specified statutory and regulatory provisions of the FDCA that govern the labeling, approval, and clinical trials of drugs. 21 U.S.C. § 360bbb-0a(b). An "eligible investigational drug" is a drug that has not been approved by FDA but is at some stage of the review process or is under active development or production and has not been discontinued by the manufacturer or placed on a clinical hold by FDA. *Id.* § 360bbb-0a(a)(2).

The Right to Try Act provides no exemption from the CSA. Indeed, as the States' amicus brief recognizes, the statute "makes no mention of the Controlled Substances Act or controlled substances" more generally. States Br. 5. DEA correctly explained that the Right to Try Act "does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations" and does not provide DEA with "authority to waive any of the CSA's requirements." SER-3.

2. In arguing to the contrary, the petitioners rely primarily on 21 U.S.C. § 902, the CSA's longstanding savings provision. That section states: "Nothing in [the CSA]," with some exceptions not relevant here, "shall be construed as in any way

affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act."

Section 902 does not suggest—and has never been understood to suggest—that the restrictions on Schedule I drugs improperly supersede provisions of the FDCA or that the provisions of the FDCA take precedence over the restrictions of Schedule I. While their subject matter overlaps somewhat, each statute establishes its own protocols and prohibitions, and FDA and DEA have complementary spheres of authority. For example, applications to research in drugs that are classified as controlled substances and have not received approval for marketing under the FDCA must be approved by DEA and allowed to proceed by FDA. *See* 21 U.S.C. § 823(f); 21 U.S.C. 355(i); 21 C.F.R. pt. 312. Either agency can act to prevent the research from going forward. But that does not mean that one agency has superseded or interfered with the other's statutory regime.

Nothing in the Right to Try Act alters that analysis. The Right to Try Act exempts eligible investigational drugs from specifically identified requirements in the FDCA. That exemption does not rescind the CSA or modify the restrictions that the law places on Schedule I substances.[6] The limited effect of the Right to Try Act is

[6] The petitioners suggest (Br. 42) that FDA understands the Right to Try Act to displace the CSA because the agency's website answers a question about access to "cannabis or cannabis-derived products for medical use through Right to Try" without referring to the CSA. *See* FDA, *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)* (Jan. 22, 2021),

underscored by a provision explaining that the Act does not "establish a positive right" or any form of entitlement. Pub. L. No. 115-176, § 3(1), 132 Stat. at 1374.

Petitioners' reliance on the Right to Try Act's liability provision is similarly misplaced. That provision states that "no liability in a cause of action shall lie against" various parties involved with giving or denying access to an eligible investigational drug in compliance with the Act. Pub. L. No. 115-176, § 2(b), 132 Stat. at 1374. As an initial matter, it is not clear why the liability provision should have any bearing on the analysis here, given that the Right to Try Act does not rescind the Schedule I prohibitions and does not establish an entitlement to covered substances.

The petitioners and their amici would be wrong, in any event, to construe this provision to bar the United States from enforcing federal law. *See* Br. 40, States Br. 13-15. The provision is directed at civil litigation by private parties, as evidenced by the limits of the protections it provides. The provision shields various actors from liability "unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort." Pub. L. No. 115-176, § 2(b)(1)(B), 132 Stat. at

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https://go.usa.gov/x6VMN But FDA noted earlier on the same website that parts of the cannabis plant are "controlled under the Controlled Substances Act (CSA) since 1970 under the drug class 'Marihuana.'" *Id.* Repetition was unnecessary. Moreover, other parts of the cannabis plant and some cannabis-derived products are not controlled substances, *see id.* (citing Agricultural Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490), making generalization impossible. In any event, as FDA observed, the agency "is not involved" is decisions regarding access under the Right to Try Act, *id.*, and it had no need to weigh in on a matter outside its jurisdiction.

1374. All of these address the scope of tort actions.[7] Similarly, another "[l]imitation" states that "[e]xcept as set forth," the liability provision shall not "be construed to modify or otherwise affect the right of any *person* to bring a *private action* under any State or Federal product liability, tort, consumer protection, or warranty law." *Id.* § 2(b)(3) (emphases added). A broad reading of this provision to exempt the Right to Try Act from all liability under federal law would contravene Congress's express intention that the Act be "consistent with, and will act an alternative pathway alongside, existing expanded access policies." *Id.* § 3(4); *cf.* 21 U.S.C. 377(a) (providing that "proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States," except for certain actions by States related to food).

[7] The amici States argue that "Congress has referred to criminal 'causes,' 'actions,' or 'causes of actions' on many occasions." States Br. 15. But in all of the examples the States cite, Congress used the word "criminal" to make the provisions more broadly applicable. Such usage does not support the States' argument that the natural reading of "causes of action" without such a modifier would include criminal or administrative enforcement. Black's Law Dictionary, in fact, suggests the opposite. *See Cause of Action*, *Black's Law Dictionary* (11th ed. 2019) (defining "cause of action" to mean "[a] group of operative facts giving rise to one or more bases for suing; a factual situation that entitles one person to obtain a remedy in court from another person"). The States' invocation of the rule of lenity (States Br. 15) is similarly unhelpful. As the Supreme Court previously explained in reviewing a conviction under the CSA, that rule "is not an inexorable command to override common sense and evident statutory purpose . . . ; it is satisfied if the words are given their fair meaning in accord with the manifest intent of the lawmakers." *United States v. Moore*, 423 U.S. 122, 145 (1975) (quotation marks omitted).

The consequences of the petitioners' argument also weigh against the atextual construction they advance. They contend that "[s]o long as a drug meets the applicable investigational drug criteria, the drug's source is irrelevant." SER-10. Thus, when the sponsor of clinical research in psilocybin declined to provide them with the drug, they moved on to another company. SER-14. That company held a DEA registration, but on the petitioners' reading of the Right to Try Act, DEA would be powerless to prevent an unscrupulous doctor from obtaining Schedule I substances from an unregistered manufacturer outside the CSA's "closed system of distribution." *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 542 (D.C. Cir. 2007) (quotation marks omitted). Further, the petitioners do not seek psilocybin to treat the life-threatening disease that triggers "eligible patient" status under the Right to Try Act. Rather, they seek to treat depression and anxiety, ER-26, common conditions among the general populace and almost certainly more common among those with life-threatening conditions.

Given the number of possible manufacturers and consumers, the petitioners' theory would "have a significant impact on both the supply and demand sides of the market" for psilocybin. *Raich*, 545 U.S. at 30. The likelihood that production "will precisely match the patients' medical needs during their convalescence seems remote; whereas the danger that excesses will satisfy some of the . . . demand for recreational use seems obvious." *Id.* at 32. And the persistent existence of the narcotics trade despite criminal enforcement efforts "suggests that no small number of unscrupulous

people will make use of [the Right to Try] exemptions to serve their commercial needs whenever it is feasible to do so." *Id.* Application of the CSA to restrict the use of psilocybin by patients with life-threatening conditions thus furthers the CSA's main objectives "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Id.* at 12.

Had Congress meant to limit federal enforcement of the Controlled Substances Act, it would have said so explicitly. The Right to Try Act's liability provision plainly does not accomplish that extraordinary result. The Supreme Court has repeatedly emphasized that Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468, (2001). It did not do so here.

3. The petitioners and their amici go astray when they argue that the Right to Try Act should be read to rescind portions of the CSA in the absence of a clear statement by Congress to preserve them. They urge (Br. 46-49, 51-55; States Br. 22-23; ACLU-W Br. 13-25) that principles of federalism require a clear statement to preserve existing restrictions on Schedule I substances because the regulation of medicine is traditionally the province of state governments. But federal law, including the CSA and the FDCA, has long regulated drugs for use in medical treatment. *See, e.g.*, *Raich*, 545 U.S. at 27 ("[T]he CSA is a comprehensive regulatory regime specifically designed to regulate which controlled substances can be utilized for medicinal purposes, and in what manner."). While this inevitably affects the options

available to physicians, it does not mean that these statutes impermissibly regulate the practice of medicine as traditionally understood. *See, e.g.*, *United States v. 9/1 Kg. Containers*, 854 F.2d 173, 176-77 (7th Cir. 1988) (explaining that phrases like the practice of medicine have "never meant more than that medical licensure and discipline would continue to be the states' business"); *United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981) ("[W]hile the [FDCA] was not intended to regulate the practice of medicine, it was obviously intended to control the availability of drugs for prescribing by physicians."); *see also United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1320 (D.C. Cir. 2014) (refusing to construe the FDCA in a manner that "would allow states to gut the FDCA's regulation of doctors, and thereby create an enormous gap in the FDCA's coverage, by classifying the distribution of drugs by doctors as the practice of medicine").

Indeed, even where state laws expressly authorize medicinal use of controlled substances—creating the strongest possible federalism concerns—the CSA supersedes them. *See, e.g.*, *Raich*, 545 U.S. at 5 (holding that Congress could properly "prohibit the local cultivation and use of marijuana in compliance with California law"); *United States v. Canori*, 737 F.3d 181, 184 (2d Cir. 2013) ("Marijuana remains illegal under federal law, even in those states in which medical marijuana has been legalized."). The petitioners get matters exactly backwards when they contend (Br. 48-49) that "DEA must respect the varying lines states have drawn regarding access to schedule I substances under RTT laws."

Petitioners' reliance (Br. 46-48) on *Gonzales v. Oregon*, 546 U.S. 243 (2006), further illustrates the errors of their analysis. In that case, the Supreme Court set aside an interpretive rule issued by the Attorney General that purported to bar the (otherwise lawful) prescription of controlled substances under Oregon's assisted suicide law because, in his view, "[a]ssisting suicide is not a 'legitimate medical purpose.'" *Id.* at 254 (quoting 66 Fed. Reg. 56,607, 56,608 (Nov. 9, 2001)). Here, in contrast, the petitioners seek an exemption from a Schedule I prohibition with regard to a substance placed on Schedule I by Congress itself. This is a category reserved for those drugs that have "no currently accepted medical use in treatment in the United States" and for which all access is denied except for specifically approved research projects. 21 U.S.C. §§ 812(b)(1), (c), 823(f); *see United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 489-90 (2001). It was therefore "clear from the text of the [CSA] that Congress has made a determination that [psilocybin] has no medical benefits worthy of an exception." 532 U.S. at 493. Given the longstanding restrictions Congress has imposed on such substances—not to mention its subsequent affirmation that drugs listed in Schedule I should remain there, *see* Pub. L. No. 105-277, div. F, 112 Stat. at 2681-760 to -761—the petitioners' insistence that Congress was required to "clearly state" (Br. 51) that it was not setting aside those restrictions when it amended a different statute is difficult to understand.

The canon of interpretation most clearly implicated by this reasoning is not any federalism principle but the "cardinal rule" that "repeals by implication are not favored." *Morton v. Mancari*, 417 U.S. 535, 549 (1974) (quoting *Posadas v. National City Bank*, 296 U.S. 497, 503 (1936)). Courts presume that "Congress will specifically address preexisting law when it wishes to suspend its normal operations in a later statute." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1624 (2018) (quotation marks omitted). Congress did so in the Right to Try Act, which carefully identifies the legal provisions it suspends but does not mention the CSA. "When two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *FCC v. NextWave Pers. Commc'ns, Inc.*, 537 U.S. 293, 304 (2003) (brackets and quotation marks omitted). It is therefore not DEA's interpretation that would require a clear statement, but the petitioners'.

Petitioners are equally wide of the mark in invoking principles of constitutional avoidance (Br. 55-57), on the ground that preserving an existing restriction infringes on protected liberty interests. This canon has "no application" where, as here, a statute is unambiguous. *Oakland Cannabis Buyers' Coop.*, 532 U.S. at 494 (declining to apply the canon to the CSA). In any event, courts have consistently rejected the claim that "the Constitution provides an affirmative right of access to particular medical treatment reasonably prohibited by the Government." *Abigail Alliance for Better Access*

to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 710 & n.18 (D.C. Cir. 2007) (collecting examples).

B. The DEA Letter Did Not Address Other Matters And Was Not Arbitrary Or Capricious.

When the petitioners wrote to DEA, they explained that they sought psilocybin "pursuant to the Washington and U.S. Right to Try (RTT) Acts" and sought the agency's "guidance" on how they could obtain the drug under those statutes. ER-4. In response, DEA explained that the Right to Try Act "does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations." SER-3. Thus, the agency stated that it "has no authority to waive any of the CSA's requirements pursuant to the RTT." *Id.*

The petitioners urge (Br. 57-58) that DEA has other authorities to waive certain statutory or regulatory requirements. Even if that were the case, it would have no bearing on DEA's statement regarding the scope of its authority under the statute that generated the petitioners' inquiry. The agency did not opine on any other potential statutory or regulatory authority. There is no basis for this Court to consider in the first instance the potential merits of arguments regarding agency authorities not addressed in a letter responding to a request for guidance regarding the Right to Try Act.

Regardless, the provisions cited by the petitioners do not support their arguments. The statutory provisions the petitioners cite provide DEA with

rulemaking authority. *See* 21 U.S.C. § 822(d) (permitting waiver "by regulation" of registration requirements); *Oregon*, 546 U.S. at 259 (describing 21 U.S.C. §§ 821 and 871(b)). But the agency has not undertaken a rulemaking, and the petitioners did not ask them to do so. The petitioners also point to a DEA regulation that permits a person to apply for an exception to any DEA regulation. 21 C.F.R. § 1307.03. But they did not request any such exception, and this provision does not permit DEA to waive any statutory prohibition. The petitioners urge that "[p]ermitting use of a schedule I drug under RTT amounts to treating it as a schedule II substance for that discrete purpose." Br. 53. But the CSA requires that any rescheduling follow "a detailed set of procedures," including an evaluation and recommendation from the Secretary of Health and Human Services and a formal rulemaking on the record. *Oregon*, 546 U.S. at 260.

The petitioners' argument (Br. 60-63) that DEA departed from prior practice is equally unavailing. DEA has not previously addressed the Right to Try Act or taken (or declined to take) any action under it, so there is no relevant past practice here. And because DEA did not grant or deny any specific relief under the CSA, any previous history with respect to such actions was not relevant to the matters addressed in the advice letter.

The petitioners' argument (Br. 63-66) that DEA has inconsistently relied on the FDCA to determine "currently accepted medical use" presents another variation on an unsuccessful theme. In 1992, the agency explained its understanding of that

phrase—a requirement under the CSA for placement of a drug in Schedule I—and laid out a five-factor test for determining whether a drug has such a use. *See* 57 Fed. Reg. 10,499, 10,503-04, 10,506 (Mar. 26, 1992); *see also Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1134-35 (D.C. Cir. 1994) (rejecting a claim that DEA had unreasonably interpreted the statute). DEA had no cause to reconsider or to apply that interpretation in response to a letter seeking advice on the scope of the Right to Try Act. That Act provides limited exemptions to specific provisions of the FDCA governing the distribution of investigational drugs. It did not approve any medical treatment, nor did it affect the scheduling of any controlled substances.

If the petitioners believe that psilocybin should be moved to another schedule so that doctors may prescribe it as a therapeutic treatment, they are free to seek legislative action, *see, e.g.*, Pub. L. No. 115-334, § 12619, 132 Stat. at 5018 (removing hemp from the CSA), or to petition the agency for a rescheduling, *see, e.g.*, *Alliance for Cannabis Therapeutics*, 15 F.3d at 1131 (describing the history of such petitions for marijuana). But nothing in the Right to Try Act disturbed the restrictions on Schedule I substances or Congress's judgment placing psilocybin in that category. DEA did not err in saying so.

CONCLUSION

For the foregoing reasons, the petition for review should be dismissed for lack of jurisdiction or denied.

Respectfully submitted,

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STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, respondents state that they know of no related case pending in this Court.

s/ Thomas Pulham
Thomas Pulham

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 9,134 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Thomas Pulham
Thomas Pulham

ADDENDUM

TABLE OF CONTENTS

21 U.S.C. § 360bbb-0a

§ 360bbb-0a. Investigational drugs for use by eligible patients.

(a) Definitions

For purposes of this section—

(1) the term "eligible patient" means a patient—

(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—

(i) is in good standing with the physician's licensing organization or board; and

(ii) will not be compensated directly by the manufacturer for so certifying; and

(C) who has provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent;

(2) the term "eligible investigational drug" means an investigational drug (as such term is used in section 360bbb of this title)—

(A) for which a Phase 1 clinical trial has been completed;

(B) that has not been approved or licensed for any use under section 355 of this title or section 351 of the Public Health Service Act;

(C)(i) for which an application has been filed under section 355(b) of this title or section 351(a) of the Public Health Service Act; or

(ii) that is under investigation in a clinical trial that—

(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 355 of this title or section 351 of the Public Health Service Act; and

(II) is the subject of an active investigational new drug application under section 355(i) of this title or section 351(a)(3) of the Public Health Service Act, as applicable; and

(D) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 355(i) of this title; and

(3) the term "phase 1 trial" means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

(b) Exemptions

Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from 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), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section 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.

(c) Use of clinical outcomes

(1) In general

Notwithstanding any other provision of this chapter, the Public Health Service Act, or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of such drug under section 355 of this title or section 351 of the Public Health Service Act unless—

(A) the Secretary makes a determination, in accordance with paragraph (2), that use of such clinical outcome is critical to determining the safety of the eligible investigational drug; or

(B) the sponsor requests use of such outcomes.

(2) Limitation

If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of such determination to the sponsor, including a public health justification for such determination, and such notice shall be made part of the administrative record. Such determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

(d) Reporting

(1) In general

The manufacturer or sponsor of an eligible investigational drug shall submit to the Secretary an annual summary of any use of such drug under this section. The summary shall include the number of doses supplied, the number of patients treated, the uses for which the drug was made available, and any known serious adverse events. The Secretary shall specify by regulation the deadline of submission of such annual summary and may amend section 312.33 of title 21, Code of Federal Regulations (or any successor regulations) to require the submission of such annual summary in conjunction with the annual report for an applicable investigational new drug application for such drug.

(2) Posting of information

The Secretary shall post an annual summary report of the use of this section on the internet website of the Food and Drug Administration, including the number of drugs for which clinical outcomes associated with the use of an eligible investigational drug pursuant to this section was—

(A) used in accordance with subsection (c)(1)(A);

(B) used in accordance with subsection (c)(1)(B); and

(C) not used in the review of an application under section 355 of this title or section 351 of the Public Health Service Act.

21 U.S.C. § 812 (excerpts)

§ 812. Schedules of controlled substances.

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended1 pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Schedule I

…

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

…

(15) Psilocybin.

…

…

Pub. L. No. 115-176 (excerpts)

…

§ 3. Sense of the Senate.

It is the sense of the Senate that section 561B of the Federal Food, Drug, and Cosmetic Act, as added by section 2—

(1) does not establish a new entitlement or modify an existing entitlement, or otherwise establish a positive right to any party or individual;

(2) does not establish any new mandates, directives, or additional regulations;

(3) only expands the scope of individual liberty and agency among patients, in limited circumstances;

(4) is consistent with, and will act as an alternative pathway alongside, existing expanded access policies of the Food and Drug Administration;

(5) will not, and cannot, create a cure or effective therapy where none exists;

(6) recognizes that the eligible terminally ill patient population often consists of those patients with the highest risk of mortality, and use of experimental treatments under the criteria and procedure described in such section 561A involves an informed assumption of risk; and

(7) establishes national standards and rules by which investigational drugs may be provided to terminally ill patients.