FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC; Doctor SUNIL AGGARWAL, MD, PhD, FAAPMR, FAAHPM; MICHAL BLOOM; ERINN BALDESCHWILER, *Petitioners*, v. UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, *Respondent*.	No. 22-1568 Drug Enforcement Administration OPINION

On Petition for Review of an Order of the
Drug Enforcement Administration

Argued and Submitted August 19, 2024
San Francisco, California

Filed February 13, 2025

Before: Marsha S. Berzon, Daniel A. Bress, and Lawrence VanDyke, Circuit Judges.

Opinion by Judge Berzon

SUMMARY*

Controlled Substances Act

The panel denied a petition for review brought by the Advanced Integrative Medical Science Institute (AIMS) challenging the decision of the Drug Enforcement Administration (DEA) not to exempt AIMS co-director Dr. Sunil Aggarwal from registration under the Controlled Substances Act (CSA) when he sought to provide patients with psilocybin.

AIMS asked DEA to exempt Dr. Aggarwal from registration under the CSA, either by finding that Dr. Aggarwal's proposed use of psilocybin was not covered by the CSA's registration requirement or by waiving the registration requirement. DEA declined to take either action.

The panel held that there was jurisdiction under 21 U.S.C. § 877 to review DEA's letter of August 19, 2022, stating that it would not reconsider its denial of AIMS's request. Under the two-part test set forth in *Bennett v. Spear*, 520 U.S. 154 (1997), the letter constituted final agency action.

The panel rejected AIMS's argument that DEA's denial of its request to exempt Dr. Aggarwal from registration under the CSA was arbitrary and capricious. The DEA articulated several reasons for its denial of AIMS's rulemaking request that, taken together, provided a

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

reasonable explanation as to why it could not or would not exercise its discretion to initiate rulemaking.

COUNSEL

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Illinois, Chicago, Illinois; Dana Nessel, Attorney General of Michigan, Lansing, Michigan; Keith Ellison, Attorney General of Minnesota, St. Paul, Minnesota; Aaron Ford, Attorney General of Nevada, Carson City, Nevada; Ellen F. Rosenbaum, Attorney General of Oregon, Salem, Oregon; Michelle A. Henry, Harrisburg, Pennsylvania; Brian L. Schwalb, Attorney General of District of Columbia, Washington, D.C.; for Amici Curiae the State(s) of Washington, Delaware, Illinois, Michigan, Minnesota, Nevada, Oregon, and Pennsylvania, and the District of Columbia.

OPINION

BERZON, Circuit Judge:

Psilocybin is a hallucinogenic compound found in certain mushrooms. When Congress enacted the Controlled Substances Act (CSA), 21 U.S.C. §§ 801–904, it classified psilocybin under the CSA's schedule I—the statute's most restrictive category for controlled substances. As a schedule I substance, psilocybin may be produced, dispensed, or possessed only in the context of a research protocol registered with the Drug Enforcement Administration ("DEA" or "the Agency") and approved by the Secretary of Health and Human Services.

Since 2021, the Advanced Integrative Medical Science Institute (AIMS) and its co-director Dr. Sunil Aggarwal have sought approval from DEA to provide Dr. Aggarwal's

patients with psilocybin.[1] Initially, AIMS asked DEA for guidance as to how the Agency would accommodate the Right to Try Act (RTT Act), a 2018 amendment to the Food, Drug, and Cosmetic Act (FDCA), that made it easier for patients to gain access to new drugs under certain circumstances. When DEA responded that the RTT Act did not waive any of the CSA's requirements, AIMS petitioned this Court for review. We dismissed AIMS's petition for lack of jurisdiction because DEA's response did not constitute a final decision.

Following the dismissal of its earlier petition, AIMS returned to DEA with a concrete request. AIMS asked DEA to exempt Dr. Aggarwal from registration under the CSA, either by finding that Dr. Aggarwal's proposed use of psilocybin was not covered by the CSA's registration requirement or by waiving the registration requirement. DEA declined to take either action, and AIMS again petitioned for review. Because DEA's response was neither arbitrary nor capricious, we deny AIMS's petition for review.

I. BACKGROUND

A. The Controlled Substances Act

To prevent the illicit and improper use of substances that pose a risk to public health and welfare, *see* 21 U.S.C. § 801, the CSA establishes a "closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). The statute classifies controlled substances under five schedules

[1] We refer to AIMS and Dr. Aggarwal individually when appropriate and collectively as AIMS.

reflecting the government's determination concerning a substance's safety, accepted medical uses, and potential for abuse. 21 U.S.C. § 812(b). Substances in schedule I 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). When the CSA was enacted, Congress initially assigned certain substances to the schedules. *See id.* § 812(c). Congress also authorized the Attorney General to add or remove substances from the schedules and to transfer a drug between schedules, subject to certain statutory criteria. *See id.* §§ 811, 812(c).

The CSA limits the lawful use of controlled substances. Any person seeking to manufacture, distribute, or dispense a controlled substance must be registered with the Attorney General. *Id.* § 822(a)(1)–(2). The Attorney General has delegated authority to enforce CSA's registration requirements to DEA. 28 C.F.R. § 0.100(a). Because schedule I drugs are classified as having no accepted medical use, they can be dispensed by medical practitioners only in the context of "bona fide research," which requires special registration approved by the Food and Drug Administration (FDA), under authority delegated by the Secretary of Health and Human Services. 21 U.S.C. § 823(f) (2021); *see* Food and Drug Administration; Delegation of Authority, 86 Fed. Reg. 49337 (Sept. 2, 2021).[2] An individual registered to

[2] Following an amendment to the CSA in 2022, the research registration requirement for practitioners is now found at 21 U.S.C. § 823(g)(2)(A). *See* Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. No. 117-215, §§ 101, 103, 136 Stat. 2257, 2258–59, 2261–63 (2022). Because the provision was found at 21 U.S.C. § 823(f) when DEA denied AIMS's request, and was referred to under that subsection by the parties, we refer to that subsection in this opinion.

conduct research with controlled substances may be granted exemption from prosecution under federal, state, or local laws "when acting within the scope of his registration . . . for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his exemption." 21 C.F.R. § 1316.24(a). In addition to handling registration, DEA "may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if [DEA] finds it consistent with the public health and safety." 21 U.S.C. § 822(d).

B. The Food, Drug, and Cosmetic Act

The FDCA protects the public from health risks associated with drugs and other biological products. 21 U.S.C. § 393(b). The statute imposes restrictions on the manufacturing, marketing, and distribution of all drugs, including but not limited to controlled substances. *See, e.g.*, 21 U.S.C. § 331. This Court described the drug approval process under the FDCA in *Advanced Integrative Medical Science Institute, PLLC v. Garland* (*AIMS I*), 24 F.4th 1249 (9th Cir. 2022), a precursor to this case:

> In general, before a new drug can be introduced into the market, the FDA must approve its new drug application or biologics license application, which must include data from clinical trials. 21 U.S.C. § 355. To get this process started, the sponsor of a clinical trial must submit an investigational new drug (IND) application to the FDA for permission to test the drugs on human subjects. *See* 21 C.F.R. § 312.2. Sponsors must provide specified information and comply with a long list of requirements to obtain approval of an

> IND application. *See* 21 C.F.R. § 312.23. If the application is approved, then the sponsor must embark on three phases of clinical trials. An individual may be able to access an investigational new drug through a clinical trial. 21 C.F.R. § 312.300. But in many cases an individual may be unable to do so if (for example) there is no ongoing clinical trial with that drug, any such trial is full, or the patient does not meet the testing criteria.

AIMS I, 24 F.4th at 1252 (footnotes omitted). Outside of the clinical trial process, "a patient may attempt to access an investigational new drug through the FDA's expanded access program." *Id.* The expanded access program provides patients with "serious" or "immediately life-threatening" diseases and conditions access, pursuant to FDA approval, to "investigational" new drugs outside of the clinical trial process where no "comparable or satisfactory alternative therapy" exists. 21 C.F.R. § 312.305. "[B]ut manufacturers are often reluctant to provide experimental drugs that may generate adverse event data." *AIMS I*, 24 F.4th at 1252.

Where a prescription drug is listed as a controlled substance under the CSA, the FDCA and CSA operate in tandem: "[a]ny person or organization that produces or distributes prescription drugs that are also controlled substances must comply with the requirements of both the FDCA and the CSA." *Id.* at 1254.

C. The Right to Try Act

In recognition of the limitations on access to investigational new drugs under both the FDCA and the FDA's expanded access program, Congress passed the RTT

Act in 2018. *See* Pub. L. No. 115-176, 132 Stat. 1372 (codified at 21 U.S.C. § 360bbb-0a); *AIMS I*, 24 F.4th at 1252–53. The RTT Act amended the FDCA to create an "alternative pathway alongside" the FDA's expanded access program for "eligible patients" or their physicians to access "eligible investigational drugs" outside the clinical trial process. Pub. L. No. 115-176, § 3(4), 132 Stat. 1372, 1374 (2018); *see also* 21 U.S.C. § 360bbb-0a(a). An "eligible patient" is a patient who "has been diagnosed with a life-threatening disease or condition," "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. 21 U.S.C. § 360bbb-0a(a)(1). An "eligible investigational drug" is a drug that has not been approved or licensed by the FDA, has completed the first phase of clinical trials, is under active development or production, and is either the subject of a new drug application or under investigation in a clinical trial and the subject of an "active investigational new drug application." *Id.* § 360bbb-0a(a)(2).

The RTT Act exempts the drugs provided to eligible patients from specified statutory and regulatory requirements concerning drug labeling, marketing, clinical testing, and approval. *Id.* § 360bbb-0a(b).[3] To access an

[3] 21 U.S.C. § 360bbb-0a(b) provides:

> 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

eligible investigational drug under the RTT Act, an eligible patient or their physician applies directly to the drug's sponsor. The FDA is not involved in approving access. *See* FDA, *Right to Try*, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try; *see also* 21 U.S.C. § 360bb-0a(d) (describing the FDA's role). The RTT Act "does not establish a new entitlement or modify an existing entitlement, or otherwise establish a positive right to any party or individual" nor does it "establish any new mandates, directives, or additional regulations." Pub. L. No. 115-176, § 3(1)–(2), 132 Stat. 1372, 1374. Instead, it "only expands the scope of individual liberty and agency among patients, in limited circumstances." *Id.* § 3(3).

D. Factual Background

Dr. Sunil Aggarwal is the co-founder and co-director of the Advanced Integrative Medical Science Institute, an "integrative oncology clinic" in Seattle, Washington. As part of his medical practice, Dr. Aggarwal treats patients with late stage and terminal cancer, some of whom suffer from anxiety and depression. Dr. Aggarwal is registered with the DEA to prescribe schedule II-V drugs, but not to conduct research with schedule I drugs. Since 2021, Dr. Aggarwal has sought access to psilocybin, a hallucinogen and schedule

> 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.

I controlled substance, for use in treating his patients' anxiety and depression. *See* 21 U.S.C. § 812(c) (listing psilocybin under schedule I). Given his lack of research registration and the schedule I status of the drug, Dr. Aggarwal has been unable to find a supplier willing to provide him with psilocybin.

In January 2021, Kathryn Tucker, counsel to AIMS and Dr. Aggarwal, wrote to DEA seeking the Agency's guidance on "how DEA will accommodate RTT so that Dr. Aggarwal and the AIMS Institute can obtain psilocybin for therapeutic use with terminally ill patients." The letter argued that psilocybin qualified as an eligible investigational drug under the RTT Act and described AIMS's intention to purchase psilocybin from Organix, "a company which holds an [active investigational new drug application] for [psilocybin] and is registered as a Distributor of [psilocybin]."

DEA responded that, as "RTT does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations," DEA had "no authority to waive any of CSA's requirements pursuant to RTT." DEA then noted that Dr. Aggarwal could apply for registration as a schedule I researcher pursuant to § 823(f) of the CSA. AIMS and Dr. Aggarwal sought judicial review of DEA's response in this Court under 21 U.S.C. § 877.[4] *AIMS*

[4] 21 U.S.C. § 877 states:

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the

I, 24 F.4th at 1251. This Court dismissed that action for lack of jurisdiction, holding that DEA's response was an "informational letter of the sort that does not constitute final agency action." *Id.* at 1260.

Following this Court's decision in *AIMS I*, Tucker submitted another letter to DEA on behalf of AIMS and Dr. Aggarwal. In that letter, AIMS again stated that psilocybin qualified as an eligible investigational drug under the RTT Act, and that two of Dr. Aggarwal's terminally ill patients qualified as eligible patients.[5] AIMS asked DEA for "authorization to access psilocybin for therapeutic use under state and federal RTT Acts" and "immunity from prosecution under the Controlled Substances Act." AIMS also asked the Agency, if it determined registration was required under 21 U.S.C. § 823(f), to waive the registration requirement via 21 U.S.C. § 822(d) rulemaking.

In support of its request, AIMS argued that requiring Dr. Aggarwal to obtain schedule I research registration would violate the CSA. AIMS explained that DEA would refer any registration request by Dr. Aggarwal to the FDA for approval, and contended that DEA would thereby "re-impose[] the FDA-approval requirement" for access to an eligible investigational drug that Congress removed via the

> District of Columbia or 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. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

[5] DEA does not contest that psilocybin qualifies as an eligible investigational drug. The Agency describes psilocybin in its brief as having "been studied as an investigational drug for the possible treatment of anxiety and depression."

RTT Act. By so doing, AIMS argued, DEA would be violating the CSA's savings provision, which prohibits DEA from interpreting the CSA "as in any way affecting, modifying, repealing, or superseding the provisions of the [FDCA]." 21 U.S.C. § 902.

AIMS also represented that "DEA has permitted access to schedule I substances in similar circumstances throughout its history," citing DEA's "support[ing] physician-initiated therapeutic use of a schedule I cannabis-derived experimental drug," the seizure medication Epidiolex, "by over 300 *children* under FDA's expanded access program" and "DEA's support of single patient [investigational new drugs] in the context of the Federal Medical Marijuana Program." AIMS additionally described DEA's treatment of "reverse distributors," companies that take possession of controlled substances from DEA-registered parties and either return the substances to manufacturers or dispose of them. AIMS maintained that DEA had "permitted [reverse distributors] to handle controlled substances for years without registration because 'they were not considered an essential link in the closed distribution system that the Controlled Substances Act established.'" According to AIMS, the Agency, rather than registering reverse distributors or issuing exemptions via rulemaking, imposed safety measures by entering into memoranda of understanding (MOUs) with the companies. AIMS argued that, like reverse distribution, Dr. Aggarwal's proposed use of a controlled substance to treat terminally ill patients under the RTT was not an "essential link in the closed distribution system" regulated by the CSA. Therefore, AIMS maintained, Dr. Aggarwal should not be required to register under the CSA. Instead, DEA "should impose whatever

diversion controls it deems necessary through an MOU with Dr. Aggarwal."

DEA rejected AIMS's request. DEA first responded to AIMS and Dr. Aggarwal's request with a single-page letter stating that "DEA considers your latest correspondence as a request for reconsideration" of DEA's response to AIMS's 2021 letter. DEA explained that it "finds no basis for reconsideration of its February 12, 2021 letter because the legal and factual considerations remain unchanged." AIMS responded by requesting confirmation that DEA's answer represented the Agency's final decision rejecting their requests.

DEA answered on August 19, 2022, with a letter stating that it was the Agency's final decision concerning AIMS's requests. The Agency informed AIMS that "practitioners who seek to dispense or possess schedule I controlled substances must be properly registered as an approved researcher in accordance with the CSA and its implementing regulations." The Agency explained that the RTT Act does not "provide any exemptions from the CSA or its implementing regulations" or "give the DEA authority to waive CSA requirements." For that reason, DEA explained, "the CSA's requirements to handle psilocybin for research purposes remain in effect."

DEA went on to decline to initiate rulemaking under 21 U.S.C. § 822(d) to exempt Dr. Aggarwal's desired activity from the CSA's registration requirements. The Agency explained that "[as] a preliminary matter, because [AIMS] did not provide DEA with the proposed text, or even the scope, of the regulation [AIMS] purportedly seek[s] pursuant to section 822(d), the Agency is unable to fully assess [AIMS's] proposal." That reason aside, DEA

explained, Dr. Aggarwal's desire to administer psilocybin to patients was "not consistent with public health and safety." In support of this conclusion, DEA relied on Congress's determination, as codified in the CSA, that psilocybin has 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." *See* 21 U.S.C. § 812(b)(1). Given psilocybin's schedule I status, and the conditions for schedule I research set out in 21 U.S.C. § 823(f), DEA concluded that Dr. Aggarwal's proposed therapeutic use of psilocybin was "too great a departure from current law and inconsistent with public health and safety."

Lastly, DEA stated that the "historical scenarios involving schedule I controlled substances" cited by AIMS were "consistent with this 21 U.S.C. [§] 823(f) framework" and therefore did not support AIMS's request. DEA specifically addressed AIMS's reference to the provision of Epidiolex to children with seizure disorders, explaining that "[w]hen that dispensing activity occurred, it was carried out by practitioners who, unlike Dr. Aggarwal, were registered with DEA to conduct research with schedule I controlled substances." The Agency concluded by again inviting Dr. Aggarwal to apply for registration as a schedule I researcher.

On September 19, 2022, AIMS, Dr. Aggarwal, and two patients timely filed a petition for review in this Court pursuant to 21 U.S.C. § 877.[6]

[6] From December 2022 to December 2023, this case was stayed pending this Court's decision in *Aggarwal v. U. S. Drug Enf't Admin.*, No. 22-1718, 2023 WL 7101927 (9th Cir. Oct. 27, 2023). In *Aggarwal*, Dr. Aggarwal challenged DEA's decision denying his petition to initiate

II. DISCUSSION

A. Final Agency Action

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 21 U.S.C. § 877); *see also* 28 C.F.R. § 0.100 (delegating the Attorney General's authority to the Administrator of the DEA). We first consider whether we have jurisdiction under § 877 to review the DEA's letter.

The CSA does not define "final" as that term is used in § 877. In *AIMS I*, this Court adopted the Supreme Court's definition of "final" from *Bennett v. Spear*, 520 U.S. 154 (1997). *AIMS I*, 24 F.4th at 1256–57. Under *Bennett*, "two conditions must be satisfied for agency action to be final." 520 U.S. at 177. First, "the action must mark the 'consummation' of the agency's decisionmaking process" and not "be of a merely tentative or interlocutory nature." *Id.* at 177–78 (quoting *Chi. & S. Air Lines v. Waterman S. S. Corp.*, 333 U.S. 103, 113 (1948)). Second, "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Id.* at 178 (quoting *Port of Bos. Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)).

Under *Bennett*'s two-part test, DEA's August 19, 2022, response to AIMS's letter constitutes final agency action.

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rulemaking to transfer psilocybin from schedule I to schedule II. 2023 WL 7101927 at *1. This Court held that DEA's explanation for its action was inadequate and remanded to DEA "to either clarify its pathway for denying Aggarwal's petition or reevaluate Aggarwal's petition on an open record." *Id.* at *1–2.

First, DEA's denial of AIMS's requests constituted the reasoned "consummation" of the agency's decisionmaking process. As opposed to AIMS's letter to DEA in *AIMS I*, which sought the Agency's "guidance" on the interaction between the RTT Act and DEA's regulation of psilocybin, *AIMS I*, 24 F.4th at 1254–55, AIMS's letter here "formally request[ed] the agency's authorization to obtain psilocybin for therapeutic use for [Dr. Aggarwal's] terminally ill patients as well as immunity from prosecution for this authorized therapeutic use." The Agency's response stated that it "constitute[d] DEA's final decision to deny the requests made in [AIMS's] February 10, 2022 letter." That the Agency "treat[ed] the document as its final view on the matter" underscores that "the document reflects 'the consummation of the agency's decisionmaking process' and not a 'merely tentative' position." *U.S. Fish & Wildlife Serv. v. Sierra Club, Inc.*, 592 U.S. 261, 268–69 (2021) (quoting *Bennett*, 520 U.S. at 177–78).

Second, DEA's decision challenged here, unlike the response at issue in *AIMS I*, is one from which rights and obligations flow. *See Bennett*, 520 U.S. at 178. AIMS asked for formal authorization to access psilocybin and immunity from prosecution. DEA denied both requests. The Agency's determination that the RTT Act did not waive the requirements of the CSA was, as in *AIMS I*, a "straightforward statement of [the Agency's] 'view of what the law requires,'" and so would not, standing alone, constitute final agency action. *See AIMS I*, 24 F.4th at 1261 (quoting *Fairbanks N. Star Borough v. U.S. Army Corps of Eng'rs*, 543 F.3d 586, 594 (9th Cir. 2008)). But that interpretation in this instance informed the Agency's decision to deny AIMS's requests for authorization and immunity, including through rulemaking under 21 U.S.C.

§ 822(d). Considered as a whole, DEA's response established AIMS's rights—or lack thereof—to access psilocybin.

We conclude that DEA's response satisfies § 877's requirement of finality. We therefore have jurisdiction to decide whether that action was arbitrary and capricious.

B. DEA's Response

Review of DEA actions is governed by the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq*. *See Fry v. Drug Enf't Agency*, 353 F.3d 1041, 1043 (9th Cir. 2003). Under the APA, an agency's decision may be set aside "only if arbitrary, capricious, an abuse of discretion or not in accordance with the law." *Id.* (citing 5 U.S.C. § 706(2)(A)). Agency action is arbitrary and capricious if the agency:

> has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

Courts "generally must assess the lawfulness of an agency's action in light of the explanations the agency offered for it rather than any *ex post* rationales." *Garland v. Ming Dai*, 593 U.S. 357, 369 (2021). We may affirm "a decision of less than ideal clarity if the agency's path may

reasonably be discerned." *Id.* (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)). When reviewing an agency's denial of a request to engage in rulemaking, our review is "'extremely limited' and 'highly deferential.'" *Massachusetts v. E.P.A.*, 549 U.S. 497, 527–28 (2007) (quoting *Nat'l Customs Brokers & Forwarders Ass'n of Am., Inc. v. United States*, 883 F.2d 93, 96 (D.C. Cir. 1989)).

AIMS argues that DEA's denial of its request to exempt Dr. Aggarwal from registration under the CSA was arbitrary and capricious. We disagree. The Agency articulated several reasons for its denial of AIMS's rulemaking request that, taken together, provide a "'reasonable explanation as to why it cannot or will not exercise its discretion' to initiate rulemaking." *Compassion Over Killing v. U.S. Food & Drug Admin.*, 849 F.3d 849, 857 (9th Cir. 2017) (quoting *Massachusetts v. E.P.A.*, 549 U.S. at 533).

First, the Agency concluded that Dr. Aggarwal was required to register under the CSA before providing psilocybin to his patients. In so determining, the Agency rejected AIMS's argument that the RTT Act waived the CSA's registration requirements for Dr. Aggarwal's desired activity.

AIMS contests DEA's rejection of its statutory interpretation argument as violative of the CSA's savings provision. That section directs that nothing in the CSA "be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act." 21 U.S.C. § 902. AIMS is correct that the RTT Act is an amendment to the FDCA. *See* 21 U.S.C. § 360bbb-0a. But AIMS's argument otherwise

misunderstands the relationship between the RTT Act, the FDCA, and the CSA.

The CSA and FDCA together govern access to controlled substances for medical purposes. "Any person or organization that produces or distributes prescription drugs that are also controlled substances must comply with the requirements of both the FDCA and the CSA." *AIMS I*, 24 F.4th at 1254. The RTT Act provides that "[e]ligible investigational drugs provided to eligible patients . . . are exempt from" certain statutory and regulatory provisions concerning the labelling, marketing, approval, and clinical trials of drugs. 21 U.S.C. § 360bbb-0a(b). The CSA and its related regulations are not included in the RTT Act's enumerated exemptions; the RTT Act does not mention the CSA at all. *See id.* Although the RTT Act itself does not require FDA approval for eligible patients to access eligible investigational drugs, it does not exempt such drugs from the FDA's Attorney-General-delegated oversight pursuant to the CSA. *See id.* § 360bbb-0a(d). So DEA's continued enforcement of the CSA's registration requirements does not "affect[], modify[], repeal, or supersed[e]" the FDCA as amended by the RTT Act. *Id.* § 902.

In its final decision letter, DEA explained that the RTT Act amended the FDCA, not the CSA. Quoting from this Court's decision in *AIMS I*, DEA explained that "the RTT 'did not give the DEA authority to waive CSA requirements.'" As a result, DEA explained, "the CSA's requirements to handle psilocybin for research purposes remain in effect." DEA provided a clear and accurate explanation of the interaction of the RTT Act and the CSA as relevant to AIMS's request. The Agency's explanation of the relationship between the two statutes was therefore neither arbitrary nor capricious.

Second, having found that the CSA applied to Dr. Aggarwal's proposed activity, the Agency explained that it was "unable to fully assess" AIMS's request for 21 U.S.C. § 822(d) rulemaking because AIMS "did not provide DEA with the proposed text, or even the scope, of the regulation [AIMS] purportedly seek[s] pursuant to section 822(d)."[7] As AIMS points out, the CSA and DEA regulations do not generally require petitioners to include the proposed text of the regulations they desire under § 822(d). Nevertheless, DEA's reliance on the lack of clarity in AIMS's request here does not render its decision unreasonable or otherwise arbitrary and capricious.

AIMS's letter to the DEA was unclear as to the specific exemption it sought. In some places, AIMS asked the Agency to exempt only Dr. Aggarwal. At other points, AIMS seemed to request a broader exemption for "physicians like Dr. Aggarwal who seek to administer schedule I substances to ultimate users for therapeutic purposes." Similarly, although the letter suggested that DEA could use MOUs to ensure safe provision of psilocybin to patients, AIMS did not explain what conditions would be appropriate under those MOUs. DEA's assertion that the

[7] DEA argues that AIMS has waived its ability to contest this portion of the agency's response as AIMS failed to address it in its opening brief. DEA contends that this Court should affirm its denial of AIMS's petition on this ground alone. Although issues not raised in a petitioner's opening brief are generally waived, this Court retains discretion to decide the merits of an issue where "the government briefed it, and thus suffers no prejudice from [the petitioner's] failure to properly raise the issue." *Mamouzian v. Ashcroft*, 390 F.3d 1129, 1136 n.4 (9th Cir. 2004) (internal quotation marks omitted). Here, the government briefed the issue beyond "merely not[ing] that [petitioner] had failed to raise the issue." *Eberle v. City of Anaheim*, 901 F.2d 814, 818 (9th Cir. 1990). We therefore consider the issue.

vagueness of AIMS's request affected the Agency's ability to determine whether to grant it was not unreasonable.

Third, DEA relied on Congress's determination, as codified in the CSA, that psilocybin has 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." *See* 21 U.S.C. § 812(b)(1). DEA additionally noted the conditions for schedule I research registration under § 823(f) and concluded that Dr. Aggarwal's "proposal to abandon altogether [the CSA's] findings and limitations" with regard to the claimed therapeutic use of psilocybin was "too great a departure from current law and inconsistent with public health and safety."

DEA's reasoning, albeit brief, meets the "low burden" for denials of rulemaking petitions, especially given the vague content of AIMS's petition. *See Compassion Over Killing*, 849 F.3d at 857. AIMS proposes to do exactly what Congress via the CSA identified as neither safe nor accepted by the medical community: provide psilocybin to patients for medical use. The CSA "reflects a determination that [schedule I substances have] no medical benefits worthy of an exception (outside the confines of a Government-approved research project)." *United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 491 (2001). That § 823(f) limits the use of schedule I substances by practitioners to only "bona fide research" underscores Congress's view that these substances are unfit for regular medical use.

Despite the CSA's treatment of schedule I drugs—and as DEA's concern about the "scope" of AIMS's request implies—AIMS did not demonstrate in its letter to the Agency how its proposed use of psilocybin was consistent

with public health and safety. AIMS's letter stated, "psilocybin has shown enormous promise in early clinical trials in relieving the debilitation [sic] anxiety and depression suffered by terminally ill patients." AIMS provided no further information regarding the efficacy of psilocybin and none regarding its safety. Nor did AIMS describe the treatment plan Dr. Aggarwal envisioned or the safety controls he would implement. Given AIMS's threadbare proposal, DEA's substantive response was not arbitrary and capricious.

Contrary to AIMS's submission, *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006), does not foreclose DEA's reliance on Congress's findings regarding schedule I drugs. *O Centro* involved the Religious Freedom Restoration Act's strict scrutiny test for government actions that burden sincere religious exercise, a heightened standard not at issue here. *See* 546 U.S. at 430. *O Centro* held that "*[u]nder the more focused inquiry required by RFRA* . . . the Government's mere invocation of the general characteristics of Schedule I controlled substances, as set forth in the Controlled Substances Act, cannot carry the day." *Id.* at 432 (emphasis added). As AIMS and Dr. Aggarwal raise no claim here requiring any form of heightened scrutiny, *O Centro* is inapposite.

Fourth, DEA did not, as AIMS argues, "fail[] to follow its own precedent or fail[] to give a sufficient explanation for failing to do so." *See Andrzejewski v. F.A.A.*, 563 F.3d 796, 799 (9th Cir. 2009). "Where the petitioner challenges the agency's action as inconsistent with the agency's own policies, we examine whether the agency has actually departed from its policy and, if so, whether the agency has offered a reasoned explanation for such departure." *Bahr v.*

U.S. Env't Prot. Agency, 836 F.3d 1218, 1229 (9th Cir. 2016).

None of the three past practices identified by AIMS in its letter to DEA—(1) DEA's "support" for physicians' use of the drug Epidiolex, a seizure medication derived from the schedule I drug cannabis, (2) DEA's "support of single patient [investigational new drugs] in the context of the Federal Medical Marijuana Program," and (3) DEA's treatment of "reverse distributors"—sanctioned departure from the CSA's registration requirements.

As to its treatment of Epidiolex, DEA explained that Epidiolex was dispensed "by practitioners who, unlike Dr. Aggarwal, were registered with DEA to conduct research with schedule I controlled substances." That explanation was consistent with the 21 U.S.C. § 823(f) registration regime under which DEA advised Dr. Aggarwal to apply. AIMS does not contest the sufficiency of that explanation.

The remaining two examples raised in AIMS's letter do not constitute past practices from which DEA improperly departed. *See Bahr*, 836 F.3d at 1229. In neither example did the Agency exempt parties from the CSA's registration requirement. Nothing in the record indicates that the physicians involved in the Federal Medical Marijuana Program, also known as the "compassionate use" program, were exempted from the CSA's registration requirement via DEA's rulemaking authority under 21 U.S.C. § 822(d). The testimony of a Federal Medical Marijuana Program participant offered by AIMS describes the participant's administering physicians as being "licensed by FDA to evaluate marijuana's use as a glaucoma control drug." This description is in accord with DEA's explanation in its response that the "historical scenarios" cited by AIMS "were

consistent with [the] 21 U.S.C. [§] 823(f) framework." *See James v. City of Costa Mesa*, 700 F.3d 394, 402 (9th Cir. 2012) (describing the Federal Medical Marijuana Program as "presumably authorized by the CSA's limited experimental research provision" and citing 21 U.S.C. § 823(f)).

DEA's treatment of reverse distributors similarly did not involve the Agency exempting those companies from applicable registration requirements. Importantly, reverse distributors do not engage in the activity for which Dr. Aggarwal sought an exemption: the provision of controlled substances to patients by a physician who lacks DEA registration. *See* Definition and Registration of Reverse Distributors, 68 Fed. Reg. 41222, 41223 (July 11, 2003) (describing the activities of reverse distributors). Reverse distributors are DEA-registered companies that take controlled substances from DEA-registered distributors and practitioners and either return them to DEA-registered manufacturers or destroy them. *Id.*; 21 C.F.R. § 1300.01(b). At no point in the reverse distribution process are controlled substances permitted to be possessed by non-DEA-registered parties. *See* 21 C.F.R. § 1300.01(b); Definition and Registration of Reverse Distributors, 68 Fed. Reg. at 41226–27.

Contrary to AIMS's argument, DEA did not "permit[] [reverse distributors] to handle controlled substances for years without registration because 'they were not considered an essential link [in] the closed distribution system established by the Controlled Substances Act.'" In fact, the Agency initially "opposed granting DEA registrations to firms solely or primarily engaged in the disposal . . . of controlled substances because they were not considered an essential link in the closed distribution system that the

Controlled Substances Act established." Definition and Registration of Reverse Distributors, 68 Fed. Reg. at 41223. In other words, the "not considered an essential link" language on which AIMS relies was provided as a reason for *denying* reverse distributors the ability to obtain DEA registrations, not as a reason that no registration was required for the distributors.

Furthermore, contrary to AIMS's contention, DEA did not use MOUs to facilitate reverse distributors' access to controlled substances without registration, but as a means "through which [reverse distributors were] granted DEA registrations." *Id.* Following the increased demand for reverse distribution services, DEA first required reverse distributors to register under the existing registration requirements for distributors and subsequently registered reverse distributors through MOUs that "specifie[d] conditions which the reverse distributor must follow in addition to the regulations that apply to distributors." *Id.* In 2003, the Agency codified a new registration category for reverse distributors, under which all reverse distributors are required to register with the DEA. *See id.* (codified at 21 C.F.R. §§ 1300, 1301, 304, 1305, 1307).

The difference between DEA's prior actions and AIMS's requested exemption from any registration requirement distinguishes this case from those in which this Court has found an agency improperly departed from its past practices. In *Andrzejewski*, for example, this Court held that the National Transportation Safety Board's (NTSB) failure to give an Administrative Law Judge's (ALJ) "implicit credibility determination the requisite level of deference" without explanation was "contrary to NTSB precedent and, therefore, arbitrary and capricious." 563 F.3d at 800. Critical to that holding was the fact that NTSB had ignored its

established precedent of deferring to ALJ's determinations of credibility in similar circumstances. *Id.* at 799. Here, on the other hand, AIMS points to no example of DEA having granted an exemption from registration—or using MOUs as substitute for registration—for activity similar to that which it proposes.[8] So the Agency was not required to further distinguish its decision from the examples cited by AIMS.

Aside from providing adequate reasons for rejecting AIMS's requests in its letter, DEA did not arbitrarily and capriciously ignore the argument raised in AIMS's letter concerning whether Dr. Aggarwal's desired use of psilocybin constituted an "essential link in the closed system of distribution" established by the CSA. Agency action is arbitrary and capricious where the agency has "entirely failed to consider an important aspect of the problem." *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 807 F.3d 1031, 1043 (9th Cir. 2015) (quoting *Pac. Coast Fed'n of Fishermen's Ass'ns, Inc. v. Nat'l Marine Fisheries Serv.*, 265 F.3d 1028, 1034 (9th Cir. 2001)). As we have explained, DEA has never adopted any "essential link" standard regarding registration exemptions. The potential application of such a standard was therefore not a pertinent

[8] In its briefing, AIMS points to two past exemptions from registration granted by DEA: a regulation exempting "nondrug use of peyote in bona fide religious ceremonies of the Native American Church" and a settlement in which DEA agreed to permit a church to "import and use a Schedule I drug for religious purposes." AIMS did not raise these precedents in its letters to DEA. As a general matter, a party "forfeits arguments that are not raised during the administrative process." *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010). Further, these arguments fail because both, like *O Centro*, involve religious uses and so trigger different legal standards.

consideration, and failing to discuss it was not arbitrary and capricious.

In sum, DEA's response explained that "practitioners who seek to dispense or possess schedule I controlled substances must be properly registered as an approved researcher in accordance with the CSA and its implementing regulations." The Agency also ably explained why it was declining to exempt AIMS from the registration requirement. Having considered and discussed the relevant factors underlying its decision, DEA provided a "path" to its decision that "can reasonably be discerned." *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1251 (9th Cir. 2013). The Agency was not required to do more. *See id.*

CONCLUSION

DEA's decision to deny AIMS's requests was neither arbitrary nor capricious. We therefore deny AIMS's petition for review of the DEA's decision.

PETITION DENIED.