No. 22-1568

In The United States Court of Appeals for the Ninth Circuit

ADVANCED INTEGRATIVE
MEDICAL SCIENCE INSTITUTE,
PLLC, ET AL.,

Petitioners,

v.

UNITED STATES
DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

On Petition for Review of a Final Decision
of the United States Drug Enforcement Administration

PETITIONERS' OPENING BRIEF

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DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, the undersigned counsel of record for Petitioners Advanced Integrative Medical Science ("AIMS") Institute, Sunil Aggarwal, MD, PHD, FAAPMR, FAAHPM, Michal Bloom, and Erinn Baldeschwiler hereby certifies that AIMS is a professional limited liability company and does not have any parent companies, subsidiaries, or affiliates that have issued shares to the public.

Date: February 8, 2024

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INTRODUCTION

Over the last decade, a democratic movement swept the nation as a supermajority of states voted to empower terminally ill patients with a "Right to Try" ("RTT") certain unapproved, investigational drugs for therapeutic use. Forty-one states have passed these laws since 2014. In 2018, the federal government followed the states' lead: To "expand[ ] the scope of individual liberty and agency among patients, in limited circumstances," Congress added § 561B to the Federal Food Drug and Cosmetic Act ("FDCA"), "establish[ing] national standards and rules by which investigational drugs may be provided to terminally ill patients" for therapeutic use under specified conditions.

In early 2021, Petitioner Dr. Sunil Aggarwal sought to provide psilocybin, an investigational drug, to his terminally ill patients for therapeutic use under Washington's RTT. Psilocybin has shown enormous promise in early clinical trials in relieving debilitating anxiety and depression suffered by terminally ill patients. It has twice obtained "breakthrough therapy status" from the Food and Drug Administration ("FDA") and is in stage III clinical trials. Yet because it remains a

schedule I controlled substance, no supplier would provide psilocybin to Dr. Aggarwal without the United States Drug Enforcement Administration's ("DEA") consent.

Since then, Dr. Aggarwal has presented DEA with multiple proposals. These proposals would legally permit him limited access to psilocybin for use under state and federal RTT consistent with public health and safety and the requirements of the Controlled Substances Act ("CSA"). DEA has rejected each request but has never addressed the arguments that Dr. Aggarwal has raised in support of them. Indeed, this Court recently granted Dr. Aggarwal's petition for review in a related case, remanding a DEA's denial of Dr. Aggarwal's petition to reschedule psilocybin because DEA failed to address the grounds Dr. Aggarwal presented in the petition. *See Aggarwal v. U.S. DEA*, No. 22-1718, 2023 WL 7101927, at *2 (9th Cir. Oct. 27, 2023) ("*Aggarwal*").

DEA committed the same error here. Dr. Aggarwal made two requests in the petition at issue in this case. *See* Petition, 2-ER-14–15. First, he requested that DEA permit him access to psilocybin for therapeutic use under state and federal RTT without requiring him to

obtain any special registration or a waiver from DEA. 2-ER-14–19. In support of that request, Dr. Aggarwal argued that 21 U.S.C. § 902 required DEA to interpret the CSA to accommodate provisions of the FDCA like federal RTT. 2-ER-19. He also emphasized that, where, as here, (1) no registration classification existing under the CSA or DEA regulations covers the activity at issue and (2) the proposed activity does not constitute "an essential link in the closed distribution system established by the Controlled Substances Act," and DEA has in the past permitted others to access schedule I substances without registering with DEA. 2-ER-18. DEA rejected Dr. Aggarwal's request without responding to his arguments. *See* DEA's Final Decision, 1-ER-6–8.

Second, DEA rejected Dr. Aggarwal's alternative proposal that, in the event that DEA believed registration was required, the agency exercise its established authority to grant a waiver or exemption from those requirements as necessary. 1-ER-7; 2-ER-18–19. Dr. Aggarwal pointed to several instances when DEA has, in the past, granted similar exceptions to the CSA's otherwise-applicable requirements to accommodate requests for far broader access to schedule I substances. 2-

ER-16–17. In light of these DEA precedents, Dr. Aggarwal argued that his more limited request qualified for similar treatment. 2-ER-17.

Once again, DEA rejected his request. 1-ER-6–8. In its view, granting the sort of waiver that Dr. Aggarwal proposed would be contrary to public health and safety. 1-ER-7. But DEA did not explain why that was so, aside from reiterating the general statutory characteristics of schedule I substances. *Id.* Yet, as Dr. Aggarwal pointed out in the petition, the agency has granted such waivers in the past. 2-ER-16–17. DEA did not consider his arguments based on the agency's precedent in this regard, nor did it provide a reasoned explanation for treating his request differently from similar ones it has dealt with in the past.

This Court has already held that DEA's refusal to address the grounds Dr. Aggarwal raised in its denial of a related petition violated the Administrative Procedure Act ("APA") and required a remand. *Aggarwal*, 2023 WL 7101927, at *2. Because DEA committed the same error here, the same result is required. If DEA wants to disclaim authority to grant Dr. Aggarwal access to psilocybin under the CSA and

RTT, it must provide a reasoned explanation for how that decision comports with the CSA and the agency's own precedent.

JURISDICTIONAL STATEMENT

"[A]ny person aggrieved" by a final DEA determination may seek review of the decision in the United States Court of Appeals in the circuit in which his principal place of business is located within thirty days after notice of the decision. 21 U.S.C. § 877. Congress did not define "final" in the CSA or in relation to a DEA determination. *See* 21 U.S.C. § 802; *Advanced Integrative Med. Sci. Inst., PLLC v. Garland,* 24 F.4th 1249, 1256 (9th Cir. 2022) ("*AIMS I*"), 2-ER-20–45.

In *Bennett v. Spear*, 520 U.S. 154 (1997), the Supreme Court articulated a two-element test for determining whether an agency's decision is final: the action complained of must (1) "mark the consummation of the agency's decisionmaking process" and (2) "be one where rights or obligations have been determined, or from which legal consequences flow." *See AIMS I*, 24 F.4th at 1256, 2-ER-35 (applying *Bennett*'s two-part test) (omitting internal quotations).

Here, DEA's August 19, 2022, letter (DEA's "Final Decision"), which Petitioners included as an Exhibit to the petition for review, constitutes a "final determination." 1-ER-6–8. In fact, DEA cited *AIMS I* while conceding the finality of its response, writing that the agency's position "constitutes DEA's final decision to deny" Dr. Aggarwal's requests. 1-ER-6.

DEA's Final Decision also fulfills both prongs of *Bennett*'s finality test. First, DEA determined that it had no "authority to waive" the CSA's requirements to accommodate RTT, marking the consummation of the agency's decision-making process. 1-ER-6. Notably, the agency concluded that Petitioners' requests were "not legally feasible." *Id.* Second, this determination squarely adjudicated Petitioners' rights and obligations—blocking Dr. Aggarwal from obtaining or administering psilocybin under RTT. DEA's Final Decision therefore qualifies as final agency action and is ripe for review.

PERTINENT STATUTES AND CONSTITUTIONAL PROVISIONS

Pertinent statutes and constitutional provisions appear in the addendum.

STATEMENT OF THE ISSUE

DEA denied Dr. Aggarwal's Petition without addressing key arguments and reasons he raised, including ones based on the statutory text and DEA precedent. Was DEA's Final Decision arbitrary and capricious?

Yes.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND

In *AIMS I*, this Court described the general statutory background relevant to this case, which remains unchanged. 24 F.4th at 1252–54, 2-ER-24–28 (citations omitted). Regarding FDA and the FDCA, this Court explained:

> The purpose of the FDCA is to protect consumers from various risks associated with drugs and biological products. The FDA enforces the provisions of the FDCA through administrative proceedings, enforcement actions, and civil penalties. 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. 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. Sponsors must provide specified information and comply with a long list of requirements to obtain approval of an IND application. 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. 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. Alternatively, a patient may attempt to access an investigational new drug through the FDA's expanded access program, but manufacturers are often reluctant to provide experimental drugs that may generate adverse event data.

Because of restrictions on clinical investigations and difficulties associated with the expanded access program, Congress passed the RTT Act in 2018 to give certain patients access to investigational new drugs under certain circumstances, outside of a clinical trial setting. The RTT Act's primary function is to relieve qualifying individuals from regulatory requirements that would otherwise be imposed on eligible investigational drugs under the FCPA. The Act specifies that it was not intended to "establish a new entitlement" or a "positive right" in any individual.

Under the RTT Act, the patient or physician must apply directly to the sponsor of the IND, and the FDA is not involved in approving or disapproving the patient's access. The RTT Act applies to "[e]ligible investigational drugs provided to eligible patients in compliance with this section" and exempts them from specified statutory and regulatory provisions otherwise applicable to investigational drugs. An "eligible investigational drug" is an investigational drug that meets several criteria. An "eligible patient" is someone 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 regarding the drug. Under the RTT Act, the sponsor of the drug is responsible for ensuring that the applicable criteria are met.[1]

[1] *AIMS I*, 24 F.4th at 1252–53, 2-ER-25–28 (citations omitted).

As to DEA and the CSA, this Court explained:

> The purpose of the CSA is to prevent the misuse of substances that threaten public health and welfare. To this end, the CSA makes it a crime to manufacture, distribute, or possess a controlled substance without authorization. A "controlled substance" is defined as "a drug or other substance, or immediate precursor" included in a schedule established by the CSA. The CSA categorizes controlled substances into five schedules based on safety, accepted medical use, and potential for abuse. [21 U.S.C.] § 812(b). Schedule I drugs 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." Psilocybin is a hallucinogenic substance obtained from certain mushrooms, and is a Schedule I drug under the CSA.
>
> Controlled substances may be used lawfully under limited circumstances. A person registered with the Attorney General may dispense controlled substances "to the extent authorized by their registration and in conformity with the other provisions of" the CSA. Because substances in Schedule I are deemed to have no accepted medical use under the CSA, they can be produced, dispensed or possessed only in the context of research, and this research requires a special registration. If an individual is registered as an approved researcher in controlled substances, the researcher is exempt 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." The DEA is responsible for enforcing the registration requirements of the CSA.
>
> 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.[2]

While the CSA establishes a "closed regulatory system," it also contemplates exceptions and provides mechanisms for DEA to waive the Act's requirements in certain circumstances. Generally speaking, the statute makes 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). Its various provisions then authorize individuals to handle controlled substances in a variety of ways and in specific circumstances. *See, e.g.*, 21 U.S.C. § 822(b) ("Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances . . . are authorized to possess, manufacture, distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter."); *id.* § 829(a) (barring the dispensing of schedule II prescription drugs without a valid prescription "[e]xcept when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user"); *id.* § 829(c) (barring the

[2] *AIMS I*, 24 F.4th at 1253–54, 2-ER-28–29 (citations omitted).

distribution or dispensing of schedule V controlled substances except when done "for a medical purpose"); *see also United States v. Akinyoyeno*, 199 F. Supp. 3d 106, 113–14 (D.D.C. 2016) (discussing statute's various "cross-referencing exceptions").

In addition to these statutory exceptions, Congress also empowered DEA to waive the Act's requirements to create additional exemptions of its own. *See, e.g.*, *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430 (2006) (holding that a schedule I listing does *not* "preclude[ ] any consideration of individualized exceptions"); *cf. United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 492 n.5 (2001) (noting that "the only *express* exception for schedule I drugs is the Government-approved research project" (emphasis added) (citing 21 U.S.C. § 823(f))). Thus, for example, DEA "may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety." 21 U.S.C. § 822(d). Similarly, DEA "may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in

research," and "[p]ersons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by [DEA]." *Id.* § 872(e).

Put simply, while the CSA's "regulatory system" is "closed," it is also flexible, has exceptions, and empowers DEA to create additional exceptions in various ways when appropriate. The agency has exercised that exception-making authority repeatedly throughout the Act's history. *See* 2-ER-16–17 (discussing several examples of exceptions and waivers DEA has granted in the past).

II. FACTUAL BACKGROUND

Petitioner Dr. Sunil Aggarwal is the Co-Founder and Co-Director of Petitioner the AIMS Institute, an integrative oncology clinic based in Seattle, Washington. Declaration of Dr. Sunil Aggarwal ("Aggarwal Declaration"), 3-ER-320. He holds a DEA license to prescribe schedule II–V drugs. *Id.*

In his professional practice, Dr. Aggarwal treats patients with advanced-stage cancer, including some suffering from severe and

debilitating anxiety and depression that do not respond to FDA-approved therapies. 3-ER-321. Based on his professional experience and assessment of (1) the condition and symptoms of his patients and (2) the above-discussed clinical and scientific research on psilocybin therapy, Dr. Aggarwal discussed the possibility of psilocybin therapy, including the risks and rewards, with select patients. *Id.* These patients indicated a desire to try psilocybin treatment and gave informed consent. 3-ER-190.

III. PROCEDURAL BACKGROUND

In January 2021, Dr. Aggarwal sought instructions from DEA on how to obtain permission to acquire psilocybin to provide to his terminally ill patients under RTT statutes which, as discussed above, allow certain investigational drugs to be used with terminally ill patients. *See AIMS I*, 24 F.4th at 1252–53, 2-ER-25–28. In February 2021, DEA sent a letter to Dr. Aggarwal asserting it had no "authority to waive" the CSA's requirements to accommodate RTT. 3-ER-363. That response prompted the *AIMS I* proceedings before this Court. *See* 3-ER-141.

In *AIMS I*, Petitioners sought review of DEA's February 2021 letter determination that "absent an explicit statutory exemption to the CSA, DEA has no authority to waive any of the CSA's requirements pursuant to the RTT." 3-ER-157; 3-ER-363. DEA argued that the letter determination did not constitute a final decision under the 21 U.S.C. § 877. *AIMS I*, 24 F.4th at 1260; 2-ER-111–15. The Court accepted the agency's characterization of its letter, declined to reach the merits, and dismissed the case for lack of jurisdiction. *AIMS I*, 24 F.4th at 1261–62; 2-ER-43–45.

Petitioners then submitted a formal petition to DEA in February 2022. 2-ER-14–19 (the "Petition"). The Petition re-urged arguments previously made in *AIMS I*. 2-ER-19. Petitioners noted, for example, that DEA previously supported physician-initiated therapeutic use of a schedule I cannabis-derived experimental drug by over 300 children under FDA's expanded use, and before that, had supported the Federal Medical Marijuana Program in which the federal government supplied patients marijuana cigarettes under the auspices of Compassionate

Investigational New Drug ("IND") program. 2-ER-16–17.[3] They also discussed DEA's registration of reverse distributors which, as a 2003 DEA rule explains, established an extra-statutory registrant category for entities that dispose of unneeded or outdated controlled substances. 2-ER-18–19 (citing Definition and Registration of Reverse Distributors, 68 Fed. Reg. 41,222 (July 11, 2003), 3-ER-365–79).

The Petition then requested that DEA (a) authorize Dr. Aggarwal to access psilocybin for therapeutic use with his terminally ill patients under the RTT Acts; (b) grant immunity from prosecution under the CSA with respect to the therapeutic RTT use of psilocybin; and (c) to the extent that DEA concludes any registration requirement in the CSA or in DEA's implementing regulations applies to this request, that DEA exercise its authority under 21 U.S.C. § 822(d) to waive or make an exception as necessary to accommodate this request. 2-ER-19.

On June 28, 2022, DEA responded (the "Initial Response"). 2-ER-13. After arguing to this Court in *AIMS I* that the February 2021 letter

[3] *See, e.g.*, Daniel Oberhaus, *The US Government Has Sent This Guy 300 Joints Each Month for 34 Years*, VICE (Sept. 8, 2016), https://www.vice.com/en/article/dp3e4y/the-us-government-has-sent-this-guy-300-joints-each-month-for-34-years.

determination did not constitute a final decision, the Initial Response described Petition as "effectively restat[ing] the grounds that [Petitioners] previously submitted to DEA," construed the Petition "as a request for reconsideration of the agency's letter," and denied reconsideration. *Id*. The next day, Petitioners sent DEA a letter (the "June 29, 2022 Letter") seeking confirmation that "the June 28 letter [wa]s DEA's final decision denying the February 10, 2022, petition" and "a final decision of the agency and therefore subject to judicial review under 21 U.S.C. § 877." 2-ER-12.

In its August 19, 2022 Final Decision, DEA pivoted again. 1-ER-6–8. It maintained that a waiver or exception to permit RTT use was "not legally feasible under the CSA." 1-ER-6. Practitioners that seek to "dispense or possess schedule I controlled substances," it explained, must be registered as schedule I researchers. *Id*. (citing 21 U.S.C. § 823(f)). According to the agency, because Dr. Aggarwal is not so registered, DEA could not permit him to dispense or possess psilocybin. *Id*. DEA therefore disclaimed any authority under the CSA or RTT to authorize the activity Dr. Aggarwal proposed. *Id*.

The Final Decision then denied Petitioners' request on grounds that permitting Dr. Aggarwal to access psilocybin as the Petition requested would not be "consistent with public health and safety." 1-ER-7. As support for that contention, DEA pointed to the statutory characteristics of schedule I drugs and claimed that the proposed activity—permitting psilocybin to be used therapeutically with dying patients under RTT's terms—presented "too great a departure from current law." *Id.*

Petitioners timely petitioned for review in this Court.

STANDARD OF REVIEW

Under the APA, "a reviewing court shall … hold unlawful and set aside agency action, findings, and conclusions found to be … in excess of statutory jurisdiction, authority, or limitations"; "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D). A decision 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 v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

While courts typically afford agencies considerable deference when reviewing refusals to institute rulemaking proceedings, they must still satisfy themselves that an agency's decision making was "reasoned" and applied appropriate legal standards. *See Am. Horse Prot. Ass'n, Inc. v. Lyng*, 812 F.2d 1, 5 (D.C. Cir. 1987). Courts generally review agency interpretations of statutes they administer under *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). "Even under *Chevron*," however, courts "owe an agency's interpretation of the law no deference unless, after 'employing traditional tools of statutory construction,' we find ourselves unable to discern Congress's meaning." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018) (citations omitted).

SUMMARY OF THE ARGUMENT

For the same reasons this Court remanded DEA's inadequate denial letter in *Aggarwal* less than four months ago, it must remand

DEA's Final Decision in this case as well. The APA obligates administrative agencies to provide reasoned explanations when they deny the petitions like the one Dr. Aggarwal presented here. Thus, an agency's decision is arbitrary and capricious if, among other things, it fails to address an important aspect of the problem the petition presents or ignores the agency's own precedent or past practice. Like its inadequate denial letter in *Aggarwal*, DEA's Final Decision in this case simply ignored the grounds Dr. Aggarwal raised in support of his requests.

First, DEA ignored Dr. Aggarwal's argument that the agency should permit him to access psilocybin under RTT because the limited activity he proposes—therapeutic use with terminally ill patients in compliance with state and federal RTT—does not constitute "an essential link in the closed distribution system established by the Controlled Substances Act." As Dr. Aggarwal explained, DEA precedent supports his request. 2-ER-18–19. For years, DEA permitted the entire "reverse distributor" industry to handle schedule I substances without any special registration from DEA. *Id*. DEA

acknowledged that reverse distributors' activity qualified as "manufacturing" schedule I substances under the CSA's broad definition of the term, but permitted the activity to proceed without an exemption and without requiring reverse distributors to register with DEA because their activity did not constitute "an essential link in the closed system of distribution." *Id*. DEA's failure to acknowledge—much less address and distinguish—its reverse-distributor precedent renders the Final Decision arbitrary and capricious.

Second, DEA failed to address Dr. Aggarwal's argument that the agency's attempt to force him to register as a schedule I researcher to access psilocybin under RTT is contrary to law. As this Court recognized in *AIMS I*, part of the purpose of RTT is to permit qualifying patients to access qualifying drugs under certain circumstances *without* obtaining FDA approval first. To obtain a schedule I researcher registration, however, Dr. Aggarwal would have to submit a protocol to FDA for approval. Section 902 of the CSA bars DEA from construing provisions of the CSA, including the schedule I researcher registration requirements of section 823(f), to limit or in any way

modify provisions of the FDCA like federal RTT. DEA's failure to acknowledge or address Dr. Aggarwal's statutory argument also requires remand.

Third, DEA failed to address grounds Dr. Aggarwal raised in support of his alternative proposal that, in the event that DEA concluded that his proposed activity requires special registration, the agency should waive the statute's registration requirements at least temporarily because doing so is consistent with the public health and safety. In support of that proposal, Dr. Aggarwal noted several times in the past when DEA has granted such waivers to facilitate far broader access to schedule I substances than Dr. Aggarwal seeks here. 2-ER-16–17. In its Final Decision, DEA ignored all but one of those examples and offered no support for its conclusion that those past waivers were consistent with the public health and safety but granting the one Dr. Aggarwal seeks would not be. 1-ER-6–7.

Finally, Dr. Aggarwal argued that to the extent that DEA believed that any of the activity he proposed might present abuse or diversion risks, the agency should enter into a memorandum of

understanding ("MOU") with him to impose additional restrictions on his access as necessary to address those concerns. 2-ER-18. In support of that alternative proposal, Dr. Aggarwal noted that DEA had used MOUs in this way in the past to permit even broader access to schedule I substances. *Id*. DEA's failure to address Dr. Aggarwal's alternative proposal or even to attempt to distinguish its own precedent supporting the use of MOUs in this way also requires remand.

ARGUMENT

I. DEA'S REFUSAL TO ACCOMMODATE RTT TO PERMIT DR. AGGARWAL TO ACCESS PSILOCYBIN FOR THERAPEUTIC USE WITH HIS TERMINALLY ILL PATIENTS WAS ARBITRARY AND CAPRICIOUS.

"A fundamental requirement of administrative law is that an agency set forth its reasons for decision; an agency's failure to do so constitutes arbitrary and capricious agency action." *Tourus v. DEA*, 259 F.3d 731, 737 (D.C. Cir. 2001) (Garland, J.) (citations and internal quotation marks omitted). The APA thus "mandates that whenever an agency denies 'a written application, petition, or other request of an interested person made in connection with any agency proceeding,' the agency must provide 'a brief statement of the grounds for denial,'

unless the denial is 'self-explanatory.'" *Id.* (quoting 5 U.S.C. § 555(e)). "This requirement not only ensures the agency's careful consideration of such requests, but also . . . facilitates judicial review." *Id.* Agency action is therefore "arbitrary and capricious if the agency . . . ignores important arguments or evidence." *Nat. Res. Def. Coun., Inc. v. EPA*, 822 F.2d 104, 111 (D.C. Cir. 1987) (citations omitted).

This Court has therefore held that "an agency must, at a minimum, clearly indicate that it has considered the potential problem identified in the petition and provide a 'reasonable explanation as to why it cannot or will not exercise its discretion'" as the petitioner requests. *Compassion Over Killing v. FDA*, 849 F.3d 849, 857 (9th Cir. 2017) (quoting *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007)). Indeed, in its recent opinion in *Aggarwal*, this Court remanded DEA's denial of Dr. Aggarwal's petition to reschedule psilocybin precisely because DEA "failed to 'clearly indicate that it has considered the potential problem identified in the petition.'" *Aggarwal,* 2023 WL 7101927, at *1 (quoting *Compassion Over Killing*, 849 F.3d at 857). DEA committed the same fatal error here, denying Dr. Aggarwal's

petition without considering important grounds Dr. Aggarwal raised in detail.

A. DEA Ignored Dr. Aggarwal's Argument That the Activity He Proposed Does Not Constitute an Essential Link in the Closed System of Distribution.

DEA has repeatedly insisted that the only way Dr. Aggarwal can access psilocybin is to apply for a schedule I researcher registration under § 823(f), which, at the time in question and in relevant part, applied to "practitioners wishing to conduct research with controlled substances in schedule I." 1-ER-6–7 (citing § 823(f)); 3-ER-364. Dr. Aggarwal has responded that he does not "wish[] to conduct research with [psilocybin]." 2-ER-18. Rather, he seeks to provide psilocybin to his terminally-ill patients for therapeutic use consistent with state and federal RTT laws. 2-ER-14.

In the Petition, Dr. Aggarwal reiterated and expanded on this point. Specifically, he explained that "[n]one of the registration categories available under current DEA regulations applies to [his] request." 2-ER-18. He proceeded to emphasize that when confronted with a similar dilemma in the past, DEA has either (1) created a new

registration classification that does apply to the overlooked activity or (2) concluded that no registration was necessary and permitted the activity to continue. *Id*. In determining which approach is appropriate in a given case, Dr. Aggarwal explained, DEA has asked whether the activity in question qualifies as an "essential link in the closed system of distribution." *Id*. (citing Definition and Registration of Reverse Distributors, 68 Fed. Reg. at 41,223, 3-ER-366).

To illustrate the point, Dr. Aggarwal described the "development of the reverse distributor industry" in some detail. 2-ER-18. Reverse distributors collect controlled substances, including schedule I substances, from DEA registrants and either return them to the manufacturer or arrange for their disposal. *See* Definition and Registration of Reverse Distributors, 68 Fed. Reg. 41,222, 3-ER-365–79. Because they "process" controlled substances, reverse distributors qualify as "manufacturers" under DEA's broad definition of that term. *Id.* at 41,223 (acknowledging that reverse distributors manufacture controlled substances because they process them), 3-ER-365–67. Nevertheless, DEA permitted these companies to handle controlled

substances for years without registration because "they were not considered an essential link the closed distribution system established by the Controlled Substances Act." *Id.*

Over time, however, the industry grew, and reverse distributors came to play a more vital role in the "closed system." In response, DEA sought to require reverse distributors to register as manufacturers. *Id.* But comments from the industry convinced DEA that the regulations applicable to registered manufacturers were not appropriate or necessary in the reverse distributor context. *Id.* Accordingly, DEA created a new registration category especially for reverse distributors. *Id.* In the meantime, however, it continued to permit the industry to operate sans registration. In doing so, DEA did not ignore security and diversion risks. Rather, it imposed requirements to address those concerns as necessary through MOUs executed with each company. *Id.*

After describing this history, Dr. Aggarwal argued that "[j]ust as reverse distributors in the early days did not constitute 'an essential link in the closed distribution system that the Controlled Substances Act established,' neither do physicians seeking access to controlled

substances to treat terminally ill patients under RTT." 2-ER-18. In fact, "as far as Dr. Aggarwal is aware, he is in a category all his own in this respect." *Id*. Accordingly, he contended that "he should not be required to register under the Act at all," and "[i]nstead, DEA should impose whatever diversion controls it deems necessary through an MOU with [him]." *Id*. If a special registration for practitioners treating patients under RTT became necessary later, DEA could "establish a special registration for [them] at that time, just as it did with reverse distributors." *Id*.

Despite Dr. Aggarwal's detailed explanation of the reverse distributor precedent and careful argument that it supported his request for access to psilocybin for therapeutic purposes under state and federal RTT, DEA denied his request without addressing the arguments and precedent he raised. 1-ER-6–8.

An agency, however, is not free to simply ignore its own precedent. *See, e.g.*, *Andrzejewski v. F.A.A.*, 563 F.3d 796, 799 (9th Cir. 2009) ("An agency's decision is arbitrary and capricious if the agency fails to follow its own precedent or fails to give a sufficient explanation

for failing to do so.") (citations omitted). Nor may it ignore important aspects of the problem a petitioner raises. *Aggarwal*, 2023 WL 7101927, at *1 (quoting *Compassion Over Killing*, 849 F.3d at 857). In refusing to engage with Dr. Aggarwal's detailed argument that the agency's treatment of reverse distributors supported his petition *at all* before denying his request, DEA did both.

Beyond reverse distributors, DEA's authority to establish and apply exceptions to the CSA not expressly stated in statute is established. As with "reverse distributors," DEA also admits exceptions to accommodate the Religious Freedom Restoration Act ("RFRA"). Before 2005, DEA similarly refused to grant exemptions to the CSA to permit religious use, contending the CSA had no exception. In *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, the Supreme Court reversed DEA's misunderstanding of the CSA. 546 U.S. 418, 424 (2006). The Court expressly held that a schedule I listing does *not* "preclude[ ] any consideration of individualized exceptions." *Id.* at 430. The CSA does not "prohibit[ ] *all* use of controlled substances except as authorized by the Act itself." *Id.* (emphasis

added). In support of that notion, the Supreme Court identified 21 U.S.C. § 822(d), which contemplates that exempting certain people from its requirements would be "consistent with the public health and safety." *Id.* at 434. "Put simply," the Court held, "the findings in the Controlled Substances Act do not preclude exceptions altogether." *Id.* DEA's categorical assertion to the contrary in this case is thus contrary to law.

Indeed, three years after *O Centro*, DEA established a process for religious organizations to obtain exemptions from the CSA. The Eleventh Circuit in *Soul Quest Church of Mother Earth, Inc. v. Attorney General, United States* recently described the two-step process that evaluates RFRA rights "within the CSA's regulatory framework." 2023 WL 8714320 (11th Cir. 2023) at *5. DEA invented this process. It has never been subject to notice and comment and is not codified in the Code of Federal Regulation. Importantly, for it to be valid, DEA must have had authority to create it. It did: DEA has the inherent authority to grant exemptions to the Act and the express authority to "enforce any rules, regulations, and procedures which [it]

may deem necessary and appropriate for the efficient execution of [its] functions under this subchapter." 21 U.S.C. § 871(b). That same authority permits DEA to grant exceptions and exemptions not just in the case of reverse distributors and RFRA, but in any case it deems appropriate and consistent with the public health and safety.

The notion that a petition for an exemption or exception is "not legally feasible" is therefore baseless and directly contrary to DEA's own practices. 1-ER-6. Indeed, just months ago, the Government elsewhere argued that "under the CSA, it is the Attorney General who is authorized to make exceptions to its application" and confirmed that Congress "expressly granted" authority "to the Attorney General (and delegated to the DEA) to make exceptions to the application of the CSA in a particular case if he determines it would be in the public interest and consistent with the government's obligations under international laws." Brief for Appellees at 27–28, *Iowaska Church of Healing v. Werfel*, No. 23-5122 (D.C. Cir. Dec. 8, 2023).

DEA's failure to acknowledge its authority to except the application of the CSA in this case was an error. And that error was

not harmless. As the Supreme Court recently emphasized in *Calcutt v. FDIC*, the harmless error rule applies only "in cases where there is not the slightest uncertainty as to the outcome of the agency's proceedings on remand." 598 U.S. 623, 629–30 (2023) (quotation omitted). But, the *Calcutt* Court emphasized, this rule applies "*only in narrow circumstances*." *Id.* at 630 (emphasis added). Specifically, "[w]here the agency was *required* to take a particular action, . . . that it provided a different rationale for the necessary result is no cause for upsetting its ruling." *Id.* (emphasis in original) (cleaned up). But where the agency's decision was discretionary, the ordinary remand rule must apply. *Id.* As the *Calcutt* Court put it: The harmless-error "exception does not apply in this case. FDIC was not required to reach the result it did." *Id.* Instead, the agency's decision hinged on "a discretionary judgment." *Id.*

The upshot: APA errors are harmless only where the agency would be required to take the same action no matter what. In all other

cases, an agency cannot avoid remand.[4]

Calcutt controls this case. The question of whether Dr. Aggarwal's proposed therapeutic use of psilocybin under state and federal RTT constitutes an "essential link in the closed system of distribution established by the Controlled Substances Act" demands a discretionary judgment from DEA. As such, DEA's error in failing to address that question was not harmless and requires remand.

Moreover, under longstanding administrative-law principles, the government may not construct new justifications for their final agency action in this litigation. The Final Decision must stand or fall on the reasons DEA gave in support of it at the time. *See Garland v. Ming Dai*, 593 U.S. 357, 369 (2021) ("[J]udges 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 a court can

[4] Of course, an agency cannot demand remand where the law is clear and where it has failed to heed a prior remand order. *See, e.g.*, *Park v. Garland*, 72 F.4th 965, 978 (9th Cir. 2023) ("[R]emand is unwarranted because the law dictates the outcome that the agency must reach"); *Lewis v. United States*, --- F.4th ---, ---, No. 21-30163, 2023 WL 8711318, at *4 (5th Cir. Dec. 18, 2023); *El Paso Elec. Co. v. FERC*, 76 F.4th 352, 366 (5th Cir. 2023). A commonsense principle unites both lines of precedent—namely that an administrative agency cannot evade Article III review by gaming the APA's remand rules.

devise)." (citing *SEC v. Chenery Corp.*, 318 U.S. 80 (1943)).

B. DEA Ignored Dr. Aggarwal's Argument That Forcing Him to Register as a Schedule I Researcher Would Violate 21 U.S.C. § 902.

Dr. Aggarwal also explained why DEA's repeated suggestions that he "apply for registration to conduct research with a schedule I substance . . . would risk violating the CSA itself." 2-ER-18. Specifically, he explained that "[u]nder § 823(f)," the provision that DEA has referenced in support of its efforts to convince Dr. Aggarwal to seek schedule I registration, "DEA would need to refer Dr. Aggarwal's 'research protocol' to FDA for approval before Dr. Aggarwal could be permitted to administer the eligible investigational drug to his eligible patients." *Id.* Yet, "the entire purpose of RTT is to permit a patient, doctor, and drug company to proceed to treatment with an eligible investigational drug without having to seek FDA's permission first." *Id.* (citing *AIMS I*, 24 F.4th at 1254 n.4, 2-ER-27) (noting that RTT exempts administration of eligible investigational drugs from otherwise-applicable FDA-approval requirements of the FDCA). DEA's attempts to require Dr. Aggarwal to register under

§ 823(f) "in this context" would therefore "re-impose[] the FDA-approval requirement that Congress expressly removed from the question through the enactment of RTT." 2-ER-19 (citing *AIMS I*, 24 F.4th at 1253 n.4, 2-ER-27) (emphasizing that RTT exempts dispensing of eligible investigational drugs from FDCA's otherwise-applicable approval requirements). That, Dr. Aggarwal insisted, would violate the CSA, which "prohibits DEA from construing the research-registration requirement of § 823(f) 'as in any way affecting, modifying, repealing, or superseding the provisions of the [FDCA].'" *Id*. (quoting 21 U.S.C. § 902).

Dr. Aggarwal raised this § 902 argument in even greater detail in the briefing before this Court in *AIMS I*. 3-ER-194–200 (*AIMS I* Opening Br. 40–46); 2-ER-70–77 (*AIMS I* Reply Br. 20–27).[5] To this day, however, DEA has never engaged with it in any meaningful way. And in the Final Decision at issue here, DEA ignored it entirely.

Dr. Aggarwal reiterates that § 902 forecloses DEA's attempts to

[5] Dr. Aggarwal incorporates those arguments here by reference and reiterates his still-unrebutted position that § 902 establishes a rule of construction that bars DEA from categorically refusing to accommodate his request for access to psilocybin for therapeutic use with his terminally ill patients under state and federal RTT.

force him into a DEA-registered researcher role that he does not want to take on and that, in any case, would defeat the express purpose of RTT.[6] Moreover, DEA's wholesale failure to acknowledge—much less address—an argument rooted in the concrete text of the statute itself violates fundamental principles of administrative law and requires remand. *Aggarwal*, 2023 WL 7101927, at *1 (quoting *Compassion Over Killing*, 849 F.3d at 857).

Finally, and for the same reasons discussed in Part I.A. *supra*, DEA's error in failing to consider *this* important aspect of the problem Dr. Aggarwal's Petition presented was not harmless error and therefore requires remand.

II. DEA'S REJECTION OF DR. AGGARWAL'S REQUEST FOR A WAIVER OR EXEMPTION WAS ARBITRARY AND CAPRICIOUS.

In addition to arguing that DEA should not require him to register with the agency to access psilocybin under RTT, Dr. Aggarwal also argued that, in the event DEA concluded that registration should be required, DEA should waive the statute's registration requirements at

[6] The excellent amicus briefing in *AIMS I* is pertinent here, and Petitioners invite the court to consider it as well.

least temporarily to permit him to use psilocybin for therapeutic purposes with his patients. 2-ER-18–19. He emphasized that DEA had granted far broader waivers to accommodate other requests for access to schedule I substances in the past. He discussed some of those precedents in detail. 2-ER-16–17. Finally, to the extent DEA believed any risk of security or diversion existed, Dr. Aggarwal urged that DEA could address those risks by imposing security requirements and limitations on his access to psilocybin through an MOU as it has done in the past. 2-ER-18.

DEA rejected Dr. Aggarwal's request. The agency concluded that granting it would not be "consistent with public health and safety." Final Decision at 2. 1-ER-7. That was so, according to DEA, for two reasons. First, by placing psilocybin in schedule I in 1970, "Congress determined that the drug 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.'" *Id.* (quoting 21 U.S.C. § 812(b)(1)). Second, "Congress further set forth in 21 U.S.C. § 823(f) explicit conditions for practitioners seeking to dispense schedule I controlled substances to research subjects." *Id.*

As for Dr. Aggarwal's discussion of even broader waivers DEA had granted in the past, the agency concluded that because those "historical scenarios . . . were consistent with th[e] 21 U.S.C. 823(f) framework," they "d[id] not support [Dr. Aggarwal's] request." *Id.* To illustrate its point, DEA noted that "the dispensing activity" that facilitated expanded access to the investigational cannabidiol drug, Epidiolex, which was listed in schedule I at the time, "was carried out by practitioners who, unlike Dr. Aggarwal, were registered with DEA to conduct research with schedule I controlled substances—not practitioners who were only authorized to handle schedule II-V controlled substances." *Id.*

DEA's analysis violated deeply rooted APA principles for two reasons. First, it marked an unexplained departure from the agency's past practice and precedent. Second, it failed to consider important alternative approaches that Dr. Aggarwal raised.

A. In Rejecting Dr. Aggarwal's Proposed Waiver or Exemption, DEA Departed From Its Own Precedent and Past Practice Without Explanation.

DEA's threadbare rationale for concluding that granting Dr. Aggarwal's proposed waiver would be inconsistent with public health

and safety falls far short of the APA's requirements. DEA's entire justification consists of listing the characteristics of schedule I substances and the restrictions Congress placed on use of those substances by DEA-registered researchers operating in the general course. *Id.* In *O Centro*, however, the Supreme Court emphasized that the very fact that § 822(d) contemplates that "exempting certain people from its requirements would be 'consistent with the public health and safety' indicates that congressional findings with respect to Schedule I substances should not carry . . . determinative weight" for purposes of assessing whether a specific waiver or exemption from those requirements would be appropriate. 546 U.S. at 432–33; *id.* at 432 ("[T]he Government's mere invocation of the general characteristics of Schedule I substances, as set forth in the Controlled Substances Act, cannot carry the day."). *O Centro*'s holding that the fact that a substance is listed in schedule I does *not* "preclude[ ] any consideration of individualized exceptions" forecloses DEA's attempt to dismiss Dr. Aggarwal's proposed exemption simply because it involves a schedule I substance. *Id.* at 430 (the CSA does not

"prohibit[ ] *all* use of controlled substances except as authorized by the Act itself" but instead permits exceptions) (emphasis added).

Moreover, as *O Centro* emphasized, DEA's authority to permit proscribed uses of schedule I substances outside the normal scope of medical practice and research is as old as the CSA itself. *Id.* at 433. 21 C.F.R. § 1307.31, for example, states that "listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration." That regulation codified an understanding that existed around the time of the CSA's enactment that use of peyote in religious ceremonies by the Native American Church did not constitute "drug use." *See* Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 Fed. Reg. 7,802 (Apr. 24, 1971).

Dr. Aggarwal made the same point in the Petition, discussing several additional exceptions to the CSA's registration requirements that DEA has permitted over the years to accommodate otherwise-prohibited

uses of schedule I substances. 2-ER-16–17. DEA claimed that these "historical scenarios" "d[id] not support [Dr. Aggarwal's] request" because they "were consistent with th[e] 21 U.S.C. 823(f) framework," requiring schedule I researchers to register with DEA. 1-ER-7. That is simply untrue. As already discussed, DEA permitted reverse distributors to handle schedule I substances for years without *any* registration. *See* Part I.A. *supra*. It never once attempted to force them to register as schedule I researchers as it has Dr. Aggarwal. Nor has DEA ever attempted to explain its apparent insistence on treating Dr. Aggarwal differently. The APA forbids this sort of arbitrariness. *See, e.g.*, *Andrzejewski*, 563 F.3d at 799 ("An agency's decision is arbitrary and capricious if the agency fails to follow its own precedent or fails to give a sufficient explanation for failing to do so.") (citations omitted).

Nor were reverse distributors the only example of DEA's past practice that Dr. Aggarwal identified in support of the exemption he proposed. He also discussed DEA's long support of single-patient INDs in the context of the Federal Medical Marijuana Program. 2-ER-17. DEA permitted "physicians and pharmacists . . . to dispense schedule I

marijuana to [Robert] Randall and the other patients who participated in that program for years." 2-ER-17. There is thus "no reason Dr. Aggarwal ought not be permitted to administer psilocybin to his terminally ill patients under RTT." *Id*. Nor were those physicians and pharmacists registered as schedule I researchers throughout the time they were dispensing schedule I marijuana under that program. Testimony of Robert C. Randall, Food & Drug Admin., Public Hearing on Marijuana, Dkt. No. 82N-0162 (n.d.), 3-ER-380–89. Yet, as with the reverse distributors, DEA simply ignored this "historical scenario" as well.

DEA may not simply ignore or mischaracterize its past practice under the CSA. *Andrzejewski*, 563 F.3d at 799 ("An agency's decision is arbitrary and capricious if the agency fails to follow its own precedent or fails to give a sufficient explanation for failing to do so.") (citations omitted). Many of the examples of DEA's past practice that Dr. Aggarwal identified involved exemptions and waivers that accommodated far broader use of schedule I substances than the limited therapeutic use that Dr. Aggarwal seeks. If DEA now contends that its longstanding practice of permitting access to schedule I substances outside the strict

confines of the CSA's registration requirements is somehow forbidden by the statute or otherwise contrary to law, it must acknowledge that change in position and provide a reasoned explanation for it. *FCC v. Fox Television Stations*, 556 U.S. 502, 514-15 (2009). Its failure to do so here renders this Final Decision arbitrary and capricious.

B. DEA's Refusal to Consider Alternatives to Rejecting His Requested Waiver or Exemption Was Arbitrary and Capricious.

As already mentioned, DEA's only basis for distinguishing the examples of agency precedent that Dr. Aggarwal identified—its claim that the people dispensing schedule I substances in those instances were registered with DEA as schedule I researchers under § 823(f)—is not borne out by the facts. 1-ER-7. Yet, even if DEA were correct about that, it is not clear how that distinction would support its conclusion that granting Dr. Aggarwal's proposal would be inconsistent with public health and safety. DEA made no attempt whatsoever to explain why or how Dr. Aggarwal's lack of a schedule I researcher registration made his proposed access to psilocybin the least bit riskier from a security or diversion perspective than the many historical examples discussed in the

Petition—much less so much riskier as to render his proposal contrary to public health and safety. Put simply, DEA's conclusory reasoning draws no "rational connection between the facts found and the choice made." *State Farm Mutual Auto. Ins. Co.*, 463 U.S. at 44.

Finally, to the extent DEA did have concrete—though unspoken—concerns underlying its conclusion that granting Dr. Aggarwal's requested exemption would be contrary to public health and safety, its failure to explain why it could not address those concerns through an MOU would still render its Final Decision arbitrary and capricious. Dr. Aggarwal repeatedly emphasized his willingness to enter into an MOU placing additional restrictions on his access to psilocybin as necessary to address any security or diversion concerns DEA might have. 2-ER-18. He also pointed to DEA's past use of MOUs in similar situations to facilitate access without compromising the statute's emphasis on preventing abuse and diversion. *Id.* (citing Definition and Registration of Reverse Distributors, 68 Fed. Reg. at 41,222–23, 3-ER-365–67). Yet DEA denied his request without identifying any such risks or concerns *and*

without explaining why the MOU alternative was insufficient to address them if they did, in fact, exist.

DEA's failure to address Dr. Aggarwal's proposed alternative to denying his Petition outright "repeat[s] the error [the Supreme Court] identified in one of [its] leading modern administrative law cases." *See Dept. of Homeland Security v. Regents of the Univ. of Calif.*, 140 S. Ct. 1891, 1912 (2021) (citing *State Farm Mutual Auto. Ins. Co.*, 463 U.S. at 29). In *State Farm*, the National Highway Traffic Safety Administration ("NHTSA") required motor vehicles produced after 1982 to be equipped with one of two passive restraints: airbags or automatic seatbelts. 463 U.S. at 37–38. Before the requirement went into effect, however, NHTSA concluded that automatic seatbelts, the industry's preferred restraint option, would not provide sufficient protection. On that basis, NHTSA rescinded the passive-restraint requirement in full. *Id.* at 38.

The Supreme Court concluded that the total rescission was arbitrary and capricious. It explained that while the agency's justification supported "disallow[ing] compliance by means of" automatic seatbelts, it did "not cast doubt" on the "efficacy of airbag technology" or

on "the need for a passive restraint standard." *Id.* at 48. Given NHTSA's prior judgment that "airbags are an effective and cost-beneficial lifesaving technology," the Court held that "the mandatory passive restraint rule [could] not be abandoned without any consideration whatsoever of an airbags-only requirement." *Id.* at 51.

DEA committed precisely the same error here. Even if DEA's unexplained conclusion that granting Dr. Aggarwal's proposed exemption would be contrary to public health and safety is correct, that conclusion would support only a refusal to grant the request in full. It would "not cast doubt" on DEA's ability to address any unspoken security or diversion risks Dr. Aggarwal's proposal might raise through an MOU imposing additional security and diversion requirements DEA deemed necessary. Thus, given DEA's earlier uses of MOUs to facilitate far broader access to schedule I substances—even by entities that, unlike Dr. Aggarwal, were not registered with DEA *at all*—DEA could not deny Dr. Aggarwal's request for an exemption outright "without any consideration

of whatsoever" of the exemption-plus-MOU alternative that he proposed. *Id.* at 51.[7]

CONCLUSION

The Court should grant the petition for review, declare DEA's Final Decision unlawful, set it aside, and remand this matter to the agency with instructions either to grant Dr. Aggarwal's Petition or provide the reasoned explanation for denying it that the APA requires.

[7] For the same reasons discussed in Part I.A., *supra*, DEA's errors discussed here were not harmless and therefore require remand.

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/s/ James F. Williams
James F. Williams

February 8, 2024

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I certify that on February 8, 2024, I electronically filed the foregoing document with the United States Court of Appeals for the Ninth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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February 8, 2024