No. 22-1718

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION, *et al.*,

Respondents.

PETITIONERS' PETITION FOR PANEL RE-HEARING

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PETITIONERS' PETITION FOR PANEL RE-HEARING

Petitioners Advanced Integrative Medical Science Institute ("AIMS Institute") and Dr. Sunil Aggarwal (collectively, "Petitioners") hereby petition the Court for panel re-hearing on the Court's Memorandum Order ("Order"), ECF No. 82, on Petitioners' Petition for Review ("Petition"), pursuant to Fed. R. App. P. 40.

Petitioners agree with the Court's conclusion to grant the Petition. Petitioners respectfully petition for panel re-hearing, because the Order did not address Petitioners' argument that 21 U.S.C. § 811(b) requires a referral to the Food and Drug Administration ("FDA") for scientific and medical evaluation and scheduling recommendation, and instead ordered a remand to the Drug Enforcement Agency ("DEA"). *See* Order at 5 n.3 (noting that panel chose not to address the referral to FDA). This omission has both legal and practical ramifications for the Petitioners, and Petitioners request that the panel correct this legal error.

I. THE LITIGATION

Petitioners filed the instant action in December 2022, seeking review of a DEA final decision denying their original petition to initiate rulemaking proceedings to transfer psilocybin from schedule I to schedule II (the "Original Petition"). *See* 21 U.S.C. § 811, *et seq*.[1]

[1] Proceedings in the related case, No. 22-1568, seeking review of the DEA's Final Decision regarding psilocybin and the Right to Try, were stayed pending resolution of the instant matter.

On October 27, 2023, the Court entered its Order, granting the Petition for Review and remanding to the DEA to either clarify its pathway for denying the Original Petition to initiate rulemaking proceedings or reevaluate the Original Petition on an open record. Order, ECF No. 82.

II. LEGAL STANDARD

In a civil case where one of the parties is a United States agency, any party may file a petition for re-hearing within 45 days, stating with particularity each point of law or fact that the petitioner believes the court has overlooked or misapprehended. Fed. R. App. P. 40(a)(1), (2). A party may seek panel re-hearing only if, among other reasons, a material point of fact or law was overlooked in the decision. *Id*.

In reviewing an agency action, the Court shall compel agency action unlawfully withheld or unreasonably delayed and hold unlawful and set aside agency action, findings and conclusion that are found to be, among others, without observance of procedure required by law. 5 U.S.C. § 706(1), (2)(D). As relevant here, 21 U.S.C. § 811(b) requires the DEA to make a referral to the FDA for a "scientific and medical evaluation" and scheduling recommendation regarding a schedule I drug. FDA's findings on scientific and medical matters bind DEA, and if the Department of Health and Human Services ("HHS") recommends that DEA not subject a substance to control, DEA "shall not control the drug or substance." 21

U.S.C. § 811(b). Only after the FDA's binding, expert views on scientific and medical considerations are rendered may the DEA assess whether "substantial evidence" exists to warrant initiating a formal rulemaking process. *Id*. Only in "the clear case of a filing that patently is either deficient in form or a substantive nullity" may such a referral to the FDA be not required. *See Nat'l Org. for Reform of Marijuana Laws (NORML) v. Ingersoll*, 497 F.2d 654, 659 (D.C. Cir. 1974) (*NORML I*) (quoting *Municipal Light Boards v. Fed. Power Comm'n.*, 450 F.2d 1341, 1345 (D.C. Cir. 1971)) ("[P]eremptory" rejections are appropriate "only in 'the clear case of a filing that patently is either deficient in form or a substantive nullity'").

III. ARGUMENT

The Order granted the Petition and remanded this matter to the DEA to "either clarify its pathway for denying Aggarwal's petition or reevaluate Aggarwal's petition on an open record." Order at 5. However, the Order specifically stated that it did not address Petitioners' arguments that 21 U.S.C. § 811(b) requires the DEA to refer to the Original Petition to HHS and the FDA. *Id*. at 5 n.3. This is a material point of law that the Order overlooked and the reason why Petitioners submit the instant petition. Petitioners ask the Court to address this legal error.

In *NORML I* and *NORML v. DEA*, 559 F.2d 735, 737 (D.C. Cir. 1977) (*NORML II*), DEA denied a petition to initiate proceedings to remove a substance

from schedule I without "gather[ing] necessary data" and "request[ing] from the Secretary a scientific and medical evaluation, and his recommendations." 21 U.S.C. § 811(b). Specifically, in *NORML II*, DEA insisted that FDA approval is a "prerequisite" to transferring a substance out of schedule I. *Compare NORML II*, 559 F.2d at 743-44 & n.44 *and* Denial, ER-4.

Here, the Court has granted the Petition but refused to refer the matter to the FDA. This is an error of law. In ordering a remand to the DEA (without conditions, detail, or instructions),[2] the Order appears to conflate DEA's explanation for denying the Original Petition as relevant to assessing whether DEA erred in ignoring its referral obligation to HHS. However, the decision on whether to refer a petition to HHS is different than the decision to grant or deny the petition altogether. As the *NORML I* and *NORML II* courts held, whether DEA erred in failing to refer a petition to HHS depends on whether the petition is a "substantive nullity" or patently deficient in form. *See NORML I*, 497 F.2d at 659; *NORML II*, 559 F.2d at 749.

DEA has not attempted to argue that the Original Petition was either a substantive nullity or patently deficient, and the Order forecloses that possibility. Because the Original Petition warrants further consideration and review from DEA, it satisfies the FDA-referral requirements under *NORML I*, *NORML II*, and 21

[2] For example, the Court could have considered whether it has the authority, under 21 U.S.C. § 811(b), to remand to DEA with the instruction that the Petition be referred expeditiously (e.g., within 30 days of the Order) to FDA.

U.S.C. § 811(b), and the Court should have addressed this issue in the Order. When addressed, Petitioners contend that the Original Petition should be referred promptly to FDA for consideration.

Separately, the Court, under 5 U.S.C. § 706(1) and (2)(D), is required to compel agency action unlawfully withheld if the agency action, findings, and conclusions are without observance of procedure required by law. The clear language of 21 U.S.C. § 811 indicates that referring a petition the FDA is a mandatory, non-discretionary duty. Specifically, 21 U.S.C. § 811(b) states that the "Attorney General *shall*, *before* initiating proceedings under subsection (a) to control a drug or other substance entirely from the schedules, and *after* gathering the necessary data; request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance" (emphasis added).

DEA has not shown that the Original Petition was either a substantive nullity or patently deficient (nor can it), and there is no dispute that the Original Petition does not fail as a matter of law. Under the clear language of 21 U.S.C. § 811(b), DEA has a mandatory, non-discretionary duty to refer the Original Petition to the FDA for a scientific and medical evaluation. Therefore, to not refer the Original Petition to the FDA is without observance of procedure required by law, specifically

21 U.S.C. § 811(b). By not compelling DEA to refer the Original Petition to the FDA, the Court has thus committed an error of law.

Finally, and more broadly, the policy implications of not ordering an FDA referral fly in the face of *NORML I* and *II* and public policy. If agencies could simply procure naked remands (as the Court ordered here) in response to substantive petitions, such a precedent would embolden agencies to avoid making decisions on the merits. In other words, such a precedent would incentivize agencies to say *less*, not more, in initial decisions, multiplying judicial workload and delaying decisions on the merits. For this additional reason, the Court should have ordered a referral to the FDA, rather than a remand to DEA.

IV. CONCLUSION

For the reasons set forth above, the Court should grant re-hearing on the issue to address the legal error arising from the omission of discussion as to the remand under 21 U.S.C. § 811(b).

Date: December 11, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2023, I caused to be filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

Doctor SUNIL AGGARWAL, MD, PhD, FAAPMR, FAAHPM,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondent,

END OF LIFE WASHINGTON; EVERGREEN HEALTH; A SACRED PASSING; PANCREATIC CANCER NORTH AMERICA; PSYCHEDELICS & HEALING INITIATIVE OF THE GLOBAL WELLNESS INSTITUTE; Professor KATHY CERMINARA; Professor DAVID HOFFMAN, J.D.; JILL SIMONIAN, PharmD; MICHAEL FRATKIN, M.D.,

No. 22-1718

Drug Enforcement Administration

MEMORANDUM*

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

F.A.A.H.P.M.; VETERAN MENTAL HEALTH LEADERSHIP COALITION, INC.; REASON FOR HOPE, INC.; NATIONAL ORGANIZATION FOR THE REFORM OF MARIJUANA LAWS; MANISH AGRAWAL, M.D.; ANTHONY BACK, M.D.; YVAN BEAUSSANT, M.D.; ROLAND R. GRIFFITHS, Ph.D.; ROBERT JESSE; ETHAN NADELMANN, JD, Ph.D.; DAVID NUTT, DM, FRCP, FRCPsych, FSB, FMedSci; BILL RICHARDS, Ph.D.; ALDEN DOERNER RINALDI, M.D.; ZACHARY SAGER, M.D.; PAUL THAMBI, M.D.; CAREY TURNBULL,

Amici Curiae.

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

Argued and Submitted October 20, 2023
Phoenix, Arizona

Before: IKUTA, BADE, and BRESS, Circuit Judges.

Dr. Sunil Aggarwal petitions for review of the Drug Enforcement Administration's (DEA) denial of his petition to transfer psilocybin from schedule I to schedule II, *see* 21 U.S.C. § 812(b), pursuant to its authority under 21 U.S.C. § 811(a). We have jurisdiction under 21 U.S.C. § 877, and we grant the petition.

We must "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "[W]here the agency has failed to provide [a] minimal level of analysis, its action is arbitrary and capricious and so cannot carry the force of law." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). In denying Aggarwal's petition, the DEA failed to provide analysis sufficient to allow its "path" to "reasonably be discerned." *Gill v. U.S. Dep't of Just.*, 913 F.3d 1179, 1187–88 (9th Cir. 2019) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). It also failed to "clearly indicate that it has considered the potential problem identified in the petition." *Compassion Over Killing v. U.S. Food & Drug Admin.*, 849 F.3d 849, 857 (9th Cir. 2017). The DEA's denial letter failed to define "currently accepted medical use with severe restrictions," 21 U.S.C. § 812(b)(2)(B), the standard applicable to transferring a drug from schedule

I to schedule II on which Aggarwal relied.[1] The denial letter did not expressly state that a substance could not meet that standard unless it met the DEA's five-part test for "currently accepted medical use," as defined in Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53767, 53793 (Aug. 12, 2016).[2] Even if we inferred that the DEA does require a substance to meet the five-part test for "currently accepted medical use" in order to be transferred to schedule II, the DEA failed to explain why Aggarwal's submission did not show that psilocybin met the five-part test. Nor did the DEA's letter explain its reasoning for any such conclusion. Although the DEA addresses some of these issues on appeal, "*[p]ost hoc* explanations of agency action by appellate counsel cannot substitute for the agency's own articulation of the basis for its decision." *Arrington v. Daniels*, 516 F.3d 1106, 1113 (9th Cir. 2008).

Our review of agency action is limited to "the grounds that the agency invoked when it took the action," *Dep't of Homeland Sec. v. Regents of the Univ.*

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[1] Moreover, the denial letter's statement that "[a] prerequisite to transferring a substance from schedule I to schedule II under the CSA is for the Food and Drug Administration (FDA) to determine that a substance has a currently accepted medical use in treatment in the United States" is contrary to 21 U.S.C. § 812(b)(2)(B), which sets as a prerequisite to transfer to schedule II *either* "a currently accepted medical use in treatment in the United States" *or* "a currently accepted medical use with severe restrictions."

[2] We therefore do not decide whether the five-part test for "currently accepted medical use" is a lawful interpretation of 21 U.S.C. § 812(b)(2)(B).

of Cal., 140 S. Ct. 1891, 1907 (2020) (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)), and where those grounds are inadequate, we may remand for either a "fuller explanation of the agency's reasoning at the time of agency action," *id.* (quoting *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 654 (1990)), or for the agency to "'deal with the problem afresh' by taking new agency action," *id.* at 1908 (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 201 (1947)). We thus remand for the DEA to either clarify its pathway for denying Aggarwal's petition or reevaluate Aggarwal's petition on an open record.[3]

PETITION GRANTED.

[3] Given the inadequacy of the DEA's denial letter, we do not address Aggarwal's argument that 21 U.S.C. § 811(b) requires the DEA to refer Aggarwal's petition to the Department of Health and Human Services.