FILED

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U.S. COURT OF APPEALS

NOT FOR PUBLICATION

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.

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Information Regarding Judgment and Post-Judgment Proceedings

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate electronic filing system or, if you are a pro se litigant or an attorney with an exemption from the electronic filing requirement, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1) Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) Purpose

A. Panel Rehearing:

- A party should seek panel rehearing only if one or more of the following grounds exist:
  - A material point of fact or law was overlooked in the decision;
  - A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
  - An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Rehearing En Banc

- A party should seek en banc rehearing only if one or more of the following grounds exist:
  - Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
  - The proceeding involves a question of exceptional importance; or

- The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing must be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- See Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- An answer, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or answer must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms*.
- Attorneys must file the petition electronically via the appellate electronic filing system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms*.

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at www.ca9.uscourts.gov under *Forms* or by telephoning (415) 355-8000.

Petition for a Writ of Certiorari

- The petition must be filed with the Supreme Court, not this Court. Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov.

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published opinion, please send a letter **in writing within 10 days** to:
    - Thomson Reuters; 610 Opperman Drive; PO Box 64526; Eagan, MN 55123 (Attn: Maria Evangelista, maria.b.evangelista@tr.com);
    - **and** electronically file a copy of the letter via the appellate electronic filing system by using the Correspondence filing category, or if you are an attorney exempted from electronic filing, mail the Court one copy of the letter.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 10. Bill of Costs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form10instructions.pdf

9th Cir. Case Number(s)

Case Name

The Clerk is requested to award costs to *(party name(s))*:

I swear under penalty of perjury that the copies for which costs are requested were actually and necessarily produced, and that the requested costs were actually expended.

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