

NOT FOR PUBLICATION

OCT 27 2023

UNITED STATES COURT OF APPEALS

MOLLY C. DWYER, CLERK U.S. 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.,

Drug Enforcement Administration

MEMORANDUM*

No. 22-1718

^{*} 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.*

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.