ORAL ARGUMENT NOT SCHEDULED

No. 24-1365

United States Court of Appeals for the District of Columbia Circuit

DOCTORS FOR DRUG POLICY REFORM; BRYON ADINOFF, DR.,

Petitioners

v.

DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondents

On Petition for Review of Orders of the Drug Enforcement Administration (Oct. 28, 2024 and Nov. 25, 2024)

PETITIONERS' OPENING BRIEF

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Certificate as to Parties, Rulings, and Related Cases

I. Parties And Amici

The parties in this court are:

1. Petitioner Doctors for Drug Policy Reform
2. Petitioner Bryon Adinoff, M.D.
3. Respondent United States Drug Enforcement Administration
4. Respondent Derek Maltz in his official capacity as Acting Administrator of the Drug Enforcement Administration[1]

There are no amici or intervenors.

The parties in the agency proceeding below, DEA Docket No. 1362, Hearing Docket No. 24-44, are:

1. United States Drug Enforcement Administration
2. Village Farms International Inc.
3. National Cannabis Industry Association
4. Cannabis Bioscience International Holdings
5. Hemp for Victory
6. Connecticut Office of the Cannabis Ombudsman
7. Ellen Brown

[1] After the petition for review in this case was filed, Administrator Anne Milgram was replaced by Acting Administrator Derek Maltz. Administrator Maltz has been automatically substituted for Administrator Milgram as a party. Fed. R. App. P. 43(c)(2).

8. Massachusetts Cannabis Advisory Board
9. Veterans Initiative 22
10. The Doc App, Inc. d/b/a My Florida Green
11. The Commonwealth Project
12. Dr. Ari Kirschenbaum
13. Cannabis Industry Victims Educating Litigators
14. Community Anti-Drug Coalitions of America
15. Dr. Phillip Drum
16. Dr. Kenneth Finn
17. International Academy on the Science and Impacts of Cannabis
18. National Drug and Alcohol Screening Association
19. Smart Approaches to Marijuana
20. National Transportation Safety Board
21. State of Nebraska
22. International Association of Chiefs of Police
23. Drug Enforcement Association of Federal Narcotics Agents
24. Tennessee Bureau of Investigation
25. National Sheriff's Association
26. United Empowerment Party
27. Saint Michael's College
28. American Academy of Hospice and Palliative Medicine
29. American College of Occupational and Environmental Medicine

II. RULINGS UNDER REVIEW

Petitioners seek review of two orders issued by Respondents in DEA Docket No. 1362, Hearing Docket No. 24-44. No citations for these orders exist:

1. October 28, 2024 order selecting 25 participants in a formal rulemaking hearing on marijuana rescheduling, App.7; and

2. November 25, 2024 order denying Petitioners' request to participate in the formal rulemaking hearing under 21 C.F.R. § 1308.44, App.10.

III. RELATED CASES

The case on review has not previously been before this court or any other court. There is a related case currently pending in this court, *Veterans Action Council v. Drug Enforcement Administration*, 24-1374.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Circuit Rule 26.1, Petitioners Doctors for Drug Policy Reform and Bryon Adinoff, M.D., state as follows: Doctors for Drug Policy Reform is a non-profit organization of medical professionals in support of evidence-based cannabis regulation. There are no parent corporations or publicly held corporations owning 10% or more of the stock of Doctors for Drug Policy Reform.

February 17, 2025

/s/Austin T. Brumbaugh
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GLOSSARY

CSA	"CSA" means the Controlled Substances Act, 84 Stat. 1242, 21 U.S.C. § 801 *et seq.*
DEA	"DEA" means the United States Drug Enforcement Administration
ALJ	"ALJ" means the administrative law judge presiding over the hearings on the proposed rule to reschedule marijuana, the Honorable John J. Mulrooney, II
The Agency	"The Agency" means Respondents Administrator Derek Maltz and the United States Drug Enforcement Administration
The Administrator	"The Administrator" means Respondent Administrator Anne Milgram or her successor, Administrator Derek Maltz
The Secretary	"The Secretary" means the Secretary of the United States Department of Health and Human Services

Statement of Jurisdiction

The Court has original jurisdiction under 21 U.S.C. § 877 to review "final determinations, findings, and conclusions." To be regarded as final, agency action must satisfy the following two-part test:

> First, the action under review must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. Second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow.

John Doe, Inc. v. Drug Enf't Admin., 484 F.3d 561, 566 (D.C. Cir. 2007) (quoting reference omitted).

An agency order is final under this test when it "imposes an obligation, denies a right or fixes some legal relationship as a consummation of the administrative process." *Id.* (quoting reference omitted). An agency's affirmative denial of an application is final action. *Id.*

The Agency's selection of participants and denial of Petitioners' request to participate are final because they mark the consummation of the Agency's decisionmaking process on who may participate in the hearings. The Agency's decisions followed from a factfinding process about whether the applicants were "interested persons" with relevant evidence to present. *See U.S. Army Corps of Engineers v. Hawkes Co.*, 578 U.S. 590, 597 (2016). The Agency has not indicated any

intent to revisit its participant selections, and the ALJ denied Petitioners' motion to intervene on the basis that he was without authority to "overrule" the Agency, underscoring the finality of the decision. App.391–92.

The Agency's actions also definitively denied Petitioners the right to participate in the hearing and all the rights that go along with participation. Had Petitioners been selected to participate, they would have been entitled to present oral testimony and cross examine witnesses, 5 U.S.C. § 556(d); inspect the record, 21 C.F.R. § 1316.46; be heard on relevant matters, *id.* § 1316.50; receive advance summaries of witness testimony, *id.* § 1316.58; submit proposed findings of fact and conclusions of law, *id.* § 1316.64; and make objections to the findings of fact and conclusions of law and the recommended decision, *id.* § 1316.66. The rejection of Petitioners' application therefore had "direct and appreciable legal consequences." *Hawkes*, 578 U.S. at 598 (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)); *see also Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1025 (D.C. Cir. 2016) (agency's "letter [] transmitted legally operative information with a 'legal consequence' sufficient to render the letter final"); *Advanced Integrative Med. Sci. Inst., PLLC v. DEA*, No. 22-1568, slip op. at 17–18 (9th Cir. Feb. 13, 2025) (DEA letter denying request for authorization to dispense psilocybin was final because it "established [petitioner]'s rights—or lack thereof—to access psilocybin").

Statement of the Issues

1. Without any explanation at all, the Agency restricted participation in the formal rulemaking hearings on the proposed rule to reschedule marijuana to 25 participants; was this arbitrary and capricious under 5 U.S.C. § 706(2)(A)?

2. The Agency did not explain its criteria for selecting participants in the formal rulemaking hearings or why it chose particular applicants; was this arbitrary and capricious under 5 U.S.C. § 706(2)(A)?

3. The Agency rejected Petitioners' request to participate because it found Petitioners were not "interested persons" and had no relevant evidence to present; were these conclusions arbitrary and capricious under 5 U.S.C. § 706(2)(A), especially considering that the Agency selected applicants who had made a far weaker showing of "interested person" status and relevance than Petitioners had?

4. Through ex parte communications, the Agency assisted anti-rescheduling entities demonstrate they were "interested persons" with relevant evidence to present against the proposed rule, but did not similarly assist Petitioners; does this demonstrate the Agency treated Petitioners differently from other similarly situated entities in violation of 5 U.S.C. § 706(2)(A)?

5. The Attorney General initiated the rulemaking proceedings with a notice of proposed rulemaking issued under his 21 U.S.C. § 811(a) authority; insofar

as the notice of proposed rulemaking specified and limited the Administrator's duties in the proceedings, did it supersede the general powers delegated to the Administrator under 28 C.F.R. § 0.100(b), making the Administrator's selection of participants ultra vires?

INTRODUCTION

Petitioner Doctors for Drug Policy Reform is an organization of medical professionals in support of evidence-based cannabis regulation. Petitioner Bryon Adinoff, M.D., the organization's President, is a board-certified addiction psychiatrist and clinical professor at the University of Colorado School of Medicine.

Petitioners, along with 163 others, requested to participate in the formal rulemaking hearings on the proposed rule to move marijuana to schedule III of the Controlled Substances Act ("CSA"), 84 Stat. 1242, 21 U.S.C. § 801 *et seq.* The Agency denied all but 25 applications. It sent all other applicants, including Petitioners, identical denial letters contending the applicants were not "interested persons" and had identified no relevant evidence they intended to present.

The Agency's selection of 25 participants and exclusion of Petitioners does not withstand arbitrary and capricious review. The Agency gave no reasons for selecting only 25 participants or why it selected particular applicants. The Agency cannot be presumed to have used permissible selection criteria, and there is

substantial evidence that it was motivated by the impermissible goal of creating an evidentiary record that would allow it to reject the proposed rule to reschedule marijuana.

The Agency's failure to explain the reasons for its selections warrants vacatur and remand with instructions to redo the selections.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND

Congress enacted the Comprehensive Drug Abuse Prevention and Control Act to "consolidate the growing number of piecemeal drug laws and to enhance federal drug enforcement powers." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). Title II, the Controlled Substances Act, was intended to "conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Id.* To that end, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Id.* at 13 (citing 21 U.S.C. §§ 841(a)(1), 844(a)).

The Act categorizes controlled substances into five schedules "based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body." *Id.* Congress placed marijuana in schedule I, which is reserved for drugs with "a high potential for abuse, lack of any accepted medical use, and

absence of any accepted safety for use in medically supervised treatment." *Id.* at 14 (citing 21 U.S.C. §§ 812(c); 812(b)(1)).

The Controlled Substances Act empowers the Attorney General to add drugs to the schedules, remove them, or move them between schedules using formal rulemaking "on the record after opportunity for a hearing." 21 U.S.C. § 811(a). These rulemaking proceedings may be initiated by the Attorney General on his own motion, at the request of the Secretary of the Department of Health and Human Services (the "Secretary"), or on the petition of any interested party. *Id.* The Attorney General delegated this authority to the Administrator of the Drug Enforcement Administration. 28 C.F.R. § 0.100(b).

Any "interested person" may submit "a written notice of his intention to participate" in a rescheduling hearing. 21 C.F.R. § 1308.44(b). Such notice must state with particularity "the interest of the person in the proceeding," "the objections or issues, if any, concerning which the person desires to be heard," and "briefly the position of the person with regard to the particular objections or issues." *Id.* § 1316.48.

Any person "entitled to appear in a hearing may appear in person or by a representative in any proceeding or hearing and may be heard with respect to matters relevant to the issues under consideration." *Id.* § 1316.50. A party to the hearing "is

entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. § 556(d).

Before initiating proceedings to reschedule a drug, the Attorney General must first "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." 21 U.S.C. § 811(b). In making an evaluation and recommendation, the Secretary must consider:

> (1) [The drug's] actual or relative potential for abuse.
>
> (2) Scientific evidence of its pharmacological effect, if known.
>
> (3) The state of current scientific knowledge regarding the drug or other substance.
>
> (4) Its history and current pattern of abuse.
>
> (5) The scope, duration, and significance of abuse.
>
> (6) What, if any, risk there is to the public health.
>
> (7) Its psychic or physiological dependence liability.
>
> (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Id. § 811(c). The Secretary's recommendations "shall be binding" as to certain "scientific and medical matters." *Id.* § 811(b).

Once rulemaking proceedings are initiated to reschedule a drug, the Attorney General must consider the same eight factors, and also make the findings required to place the drug in the target schedule. *Id.* § 811(a), (c). To place a drug in schedule III, the Attorney General must find: the drug has a potential for abuse less than the drugs in schedules I and II, has a currently accepted medical use in treatment in the United States, and abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence. *Id.* § 812(b)(3).

II. FACTUAL BACKGROUND

A. The Department of Health and Human Services Recommends Rescheduling Marijuana.

In 2022, President Biden directed the Secretary and Attorney General "to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law." The White House, *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), https://perma.cc/CQF7-V6GZ.

Following that request, the Secretary sent the Agency his evaluation and recommendation that marijuana be moved from schedule I to schedule III. *See* § 811(b). App.11. [2] Underlying the Secretary's recommendation were three key

[2] In accordance with the Court's February 7, 2025 order, Petitioners will identify in footnotes each time an exhibit is cited that is not included in the certified index and which was subject to Petitioners' January 23, 2025 Motion to Supplement Certified Index and for Transmission of Agency Record. The Secretary's recommendation is not included in the certified index and is subject to Petitioners' Motion to

findings: (1) marijuana has a potential for abuse less than the drugs in schedules I and II; (2) marijuana has a currently accepted medical use in treatment in the United States; and (3) abuse of marijuana may lead to moderate or low physical dependence or high psychological dependence. App.73–76.

An April 2024 memorandum from the Office of Legal Counsel to the Attorney General shows the Agency disagreed with the test underlying the Secretary's conclusion that marijuana had a currently accepted medical use in treatment in the United States—a prerequisite for marijuana's transfer out of schedule I. App.263.[3] The Agency also questioned whether it was bound by the Secretary's determination that marijuana has a currently accepted medical use, and whether treaty obligations allowed it to place marijuana in schedule III. App.265–66. The Office of Legal Counsel concluded that (1) the Secretary's test for whether marijuana has a currently accepted medical use was sufficient and that the test historically used by the Agency was "impermissibly narrow"; (2) the scientific and medical determinations that

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Supplement Certified Index and for Transmission of Agency Record. The recommendation is in the record as Exhibit 4 to Petitioners' Emergency Motion for Stay of Formal Rulemaking.

[3] The Office of Legal Counsel opinion is not included in the certified index and is subject to Petitioners' Motion to Supplement Certified Index and for Transmission of Agency Record. The opinion is in the record as Exhibit 5 to Petitioners' Emergency Motion for Stay of Formal Rulemaking.

underlie the Secretary's "currently accepted medical use" recommendation are binding on the Agency, but only until the initiation of formal rulemaking proceedings to reschedule marijuana; and (3) marijuana could be moved to schedule III consistent with treaty obligations. App.263.

B. The Attorney General Issues a Notice of Proposed Rulemaking.

In May 2024, the Attorney General issued a notice of proposed rulemaking to transfer marijuana from schedule I to schedule III, as the Secretary recommended. App.299. The notice is historically anomalous because—although the Attorney General long ago delegated his rulemaking authority under the Controlled Substances Act to the Administrator—the Attorney General initiated this rulemaking on his own authority. App.303 ("[T]he Attorney General is exercising the Attorney General's authority under 21 U.S.C. § 811(a) to initiate a rulemaking that proposes the placement of marijuana in schedule III.").

The Attorney General carved out a narrow role for the Administrator, who would ordinarily have all the powers of the Attorney General under 28 C.F.R. § 0.100(b):

> The decision whether an in-person hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator of the DEA. Upon the Administrator's determination to grant an in-person hearing, DEA will publish a notice of hearing on the proposed rulemaking in the Federal Register.

> If the Administrator determines to grant an in-person hearing to address such matters of fact and law in this rulemaking, the Administrator will then designate an Administrative Law Judge ("ALJ") to preside over the hearing.

App.300.

C. The Administrator Issues a General Notice of Hearing, Inviting Requests to Participate.

In August 2024, the Administrator announced that the Agency would hold a formal rulemaking hearing to "receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III of the list of controlled substances." App.326. The Administrator invited "[e]very interested person … who wishes to participate in the hearing" to "file a written notice of intention to participate for review by the Agency" conforming to 21 C.F.R. § 1316.48. *Id.*

D. Petitioners Request to Participate in the Hearing.

In September 2024, Petitioners submitted a request to participate in the form specified. App.327. Petitioners explained they had a particular interest in the proceeding because Doctors for Drug Policy Reform was "comprised of doctors, nurses, [and] pharmacists—many if not nearly all of whom are [DEA] registrants." App.329. Moving marijuana to schedule III, Petitioners explained, would affect their ability to recommend, prescribe, and dispense marijuana. *Id.* They also stated their intent to present oral testimony that (1) marijuana's potential for creating dependence was less than other controlled substances, including benzodiazepines in

schedule IV, and (2) the definition of "drug abuse" used by the Food and Drug Administration and the Agency was overbroad because it included marijuana use not harmful to self or others. App.328, 330, 331–32. Petitioners explained the testimony would be presented through two board-certified psychiatrists and members of Doctors for Drug Policy Reform: Bryon Adinoff, M.D. and David Nathan, M.D., DFAPA. App.327.

E. The Administrator Selects 25 Participants Without Explanation, Excluding Petitioners.

In October 2024, the Administrator announced her selection of 25 entities to participate in the rulemaking hearing. App.7. She gave no reasons for selecting no more than 25 participants, selecting the applicants she selected, or rejecting the applicants she did not select. Petitioners were not among those selected. In the same order, the Administrator designated an ALJ to preside over the hearings. *Id.*

Because the Administrator's selection process left the ALJ with very little information about the participants, the ALJ ordered the participants to provide additional information, including the basis for claiming they were "interested persons" and whether they supported or opposed the proposed rule. App.333.[4]

[4] The ALJ's order is not included in the certified index and is subject to Petitioners' Motion to Supplement Certified Index and for Transmission of Agency Record. The order is in the record as Exhibit 10 to Petitioners' Emergency Motion for Stay of Formal Rulemaking.

After receiving that information, the ALJ ruled that nine of the selected participants lacked administrative standing. App.357–83.[5] Nonetheless, the ALJ permitted all but two of those who lacked standing to participate in the hearing. *Id.*

F. The Agency Formally Denies Petitioners' Request to Participate.

On November 25, 2024, the Agency issued a letter formally denying Petitioners' request to participate. App.10. The only explanation provided was that "DEA has determined that the request did not sufficiently establish that you are an 'interested person' under DEA regulations and/or the request did not sufficiently state with particularity the relevant evidence on a material issue of fact that you intended to present during the hearing." *Id.* All 138 rejected applicants received identical letters.

G. The ALJ Sets a Hearing Schedule and Excludes All Written Comments.

Although the Agency selected 25 participants, a few voluntarily relinquished their rights to participate and a few were excluded by the ALJ for lack of standing, leaving 20 participants remaining. In early December 2024, the ALJ scheduled the

[5] The ALJ's order is not included in the certified index and is subject to Petitioners' Motion to Supplement Certified Index and for Transmission of Agency Record. The order is in the record as Exhibit 11 to Petitioners' Emergency Motion for Stay of Formal Rulemaking.

rulemaking hearing to commence on January 21, 2025 and to run for 18 days through March 6, 2025. App.399.[6] The ALJ allotted 90 minutes for each participant to present witness testimony, two minutes for opening statements, 10 minutes for closing argument, and 20 minutes of cross examination "for each party on the opposing side of the issue." App.395, 399–400.

The ALJ also ruled that participating in the hearing would be the exclusive way for the public to provide meaningful feedback on the proposed rule, since the over 43,000 comments the Agency received would not be admitted into evidence and "cannot be considered in the recommended decision." App.396–97.

III. PROCEDURAL HISTORY

On November 27, 2024, Petitioners petitioned this Court to review the Administrator's October 28, 2024 order selecting participants and November 25, 2024 order denying Petitioners' request to participate. Petitioners also moved the Court to stay the formal rulemaking hearings scheduled to commence on January 21, 2025.

[6] The ALJ's order is not included in the certified index and is subject to Petitioners' Motion to Supplement Certified Index and for Transmission of Agency Record. The order is in the record as Exhibit 12 to Petitioners' Emergency Motion for Stay of Formal Rulemaking.

On January 10, 2025, the Court denied Petitioners' motion for stay. But a few days later, the ALJ stayed the hearings pending disposition of an interlocutory appeal to the Agency by a group of pro-rescheduling participants.[7] App.404. The issue in that appeal is whether the ALJ properly denied the group's motion to disqualify the Agency from acting as the rule's "proponent," and to initiate an investigation into ex parte communications between the Agency and certain anti-rescheduling participants.

Summary of the Argument

Under the Controlled Substances Act, a drug may not be rescheduled without a formal rulemaking hearing. This reflects Congress's judgment that the accuracy of drug classifications is enhanced by the procedural rigors of formal rulemaking, including public participation, live testimony, and cross examination. It also reflects a judgment about the strength of the public interest in accurate drug classifications.

Never in the history of the Controlled Substances Act has the public interest and the need for robust process weighed so heavily. Legal for recreational use in 24 states and for medical use in 39 states, marijuana is the most commonly used federally illegal drug. *Cannabis Facts and Stats*, CDC (Feb. 22, 2024),

[7] This order is not included in the certified index and is subject to Petitioners' Motion to Supplement Certified Index and for Transmission of Agency Record.

https://perma.cc/Q589-C8S9. 88% of Americans believe marijuana should be legal for medical or recreational use[8] and only 27% believe it should remain in schedule I.[9]

Yet, the Agency has failed to treat this momentous rulemaking with the gravity demanded by the circumstances and the law. 163 members of the public requested to present evidence in the hearings. Addendum to Opp'n to Emergency Mot. for an Injunction Pending Appeal (Dec. 20, 2024), Decl. of Heather Achbach at ¶ 3. The Agency rejected all but 25, offhandedly and unreasonably concluding that the rest were not "interested persons" and had no relevant evidence to present. *See, e.g.*, App.10. 43,564 written comments were submitted for the Agency's consideration. Opp'n to Emergency Mot. at 1. None of them will be considered because the ALJ has ruled they will not come into evidence. App.396–97.

The result is that only 20 voices will be heard on whether marijuana should be rescheduled. How and why those voices were chosen is a secret the Agency has not explained. The Agency's secrecy prevents the Court from reviewing whether the decision is based on relevant and permissible criteria, and whether the Agency considered reasonable alternatives.

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[8] *Most Americans Favor Legalizing Marijuana for Medical, Recreational Use*, PEW RESEARCH CENTER (Mar. 26, 2024), https://perma.cc/F9VT-LRGN.

[9] *High Support for Legalizing Marijuana at the Federal Level*, DATA FOR PROGRESS (Apr. 19, 2024), https://perma.cc/8PCT-VZEK.

The circumstances surrounding the Agency's rejection of Petitioners' application is but one weave in a tapestry of evidence indicating the Agency's secret selection process was guided by the improper aim of creating an evidentiary record that will allow the Agency to reject the proposed rule. The Agency's recent document production in this case revealed for the first time that it sent so-called "cure letters" to several anti-rescheduling entities, asking them to supplement their requests to participate with additional information showing they are "interested persons" with relevant evidence to present. The Agency did not send Petitioners or other pro-rescheduling entities similar "cure letters" before rejecting their applications. Moreover, comparing Petitioners' detailed application with the perfunctory applications of entities who were selected confirms that the Agency treated Petitioners differently from other similarly situated applicants.

Finally, the Administrator's selection of participants overstepped the role circumscribed for her by the Attorney General in the notice of proposed rulemaking, which superseded the general delegation under 28 C.F.R. § 0.100(b).

For these reasons, the Court should vacate the Agency's selection of participants and rejection of Petitioners and remand with instructions to redo the participant selection process.

STANDING

Petitioners have individual and associational standing because they were denied the right to participate and present evidence in the hearing on the proposed rule to reschedule marijuana. The denial of the right to participate was a concrete and particularized harm that prevented Petitioners from furthering their organizational mission of promoting evidence-based cannabis regulation. *See Sierra Club v. EPA*, 292 F.3d 895, 900–01 (D.C. Cir. 2002). Petitioners have a particular interest in the accurate regulatory classification of marijuana because their members recommend and dispense marijuana for medical purposes, and marijuana's regulatory classification affects practices for prescribing, recommending, and dispensing marijuana.

STANDARD OF REVIEW

The Administrative Procedure Act ("APA"), 60 Stat. 237, 5 U.S.C. § 1001 *et seq.*, authorizes courts to overturn agency action that is arbitrary, capricious, or otherwise contrary to law. 5 U.S.C. § 706(2). To withstand this review, an agency must act reasonably, adequately explain its decisions, consider the relevant issues, treat similarly situated parties alike, and consider significant alternatives to the course it ultimately chooses. *Intelligent Transp. Soc'y of Am. v. Fed. Commc'ns Comm'n*, 45 F.4th 406, 411 (D.C. Cir. 2022); *Dep't of Commerce v. New York*, 588 U.S. 752, 780 (2019); *Pub. Citizen, Inc. v. F.A.A.*, 988 F.2d 186, 197 (D.C. Cir. 1993);

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 48 (1983); *Tourus Records, Inc. v. Drug Enf't Admin.*, 259 F.3d 731, 737 (D.C. Cir. 2001); *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005). This standard ensures "that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Intelligent Transp. Soc'y of Am.*, 45 F.4th at 411 (quoting *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)).

"The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result." *Pub. Citizen*, 988 F.2d at 197; *see also Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 48 ("We have frequently reiterated that an agency must cogently explain why it has exercised its discretion in a given manner[.]"); *Dep't of Commerce*, 588 U.S. at 780 ("[I]n order to permit meaningful judicial review, an agency must disclose the basis of its action.") (quotation marks and quoting reference omitted). "[T]he core requirement is that the agency explain 'why it chose to do what it did.'" *Tourus Records*, 259 F.3d at 737 (quoting Henry J. Friendly, Chenery *Revisited: Reflections on Reversal and Remand of Administrative Orders*, 1969 DUKE L.J. 199, 222). Agency action is subject to reversal "if the agency's path may [not] reasonably be discerned." *Pub. Citizen*, 988 F.2d at 197.

ARGUMENT

I. THE AGENCY'S SECRET SELECTION PROCESS VIOLATES BEDROCK ADMINISTRATIVE LAW PRINCIPLES.

The "ideal of reasoned decisionmaking on the merits" "undergirds all of our administrative law." *Home Box Office, Inc. v. F.C.C.*, 567 F.2d 9, 56 (D.C. Cir. 1977). "[A]n agency must disclose the basis of its action" "to permit meaningful judicial review." *See Dep't of Commerce*, 588 U.S. at 780. Policing this most foundational principle is simple. The Court's inquiry is whether the Agency gave reasons for its actions, and if so, whether those reasons are rational and based on permissible criteria.

Here, the Agency made at least two decisions of great public importance without giving any reasons. First, it decided to limit the most consequential formal rulemaking hearing in the history of the Controlled Substances Act to 25 participants. Second, it decided who out of over 160 applicants those 25 would be. These important decisions determined the scope and substance of the evidence the Agency will consider in deciding whether to reschedule marijuana, but the Agency's failure to show its work prevents the Court from engaging in meaningful review.

A. Because the Agency Gave No Reasons, Its Decision to Limit the Hearing to 25 Participants Was Arbitrary and Capricious.

One bedrock purpose of the APA is to "provide for public participation in the rule making process." ATTORNEY GENERAL'S MANUAL ON THE APA 7 (1947). Of

the four forms of agency action, Congress particularly stressed public participation in formal rulemaking, which is conducted "on the record after opportunity for an agency hearing." 5 U.S.C. § 553(c). The robust procedures required by formal rulemaking "ensure that agencies gather as much relevant information as possible before promulgating final rules that will have the force and effect of law." *United States v. Springer*, 354 F.3d 772, 776 (8th Cir. 2004).

The Controlled Substances Act requires formal rulemaking to schedule or reschedule drugs. 21 U.S.C. § 811(a). Congress's decision to require formal rulemaking reflects the judgment that the public should be permitted to participate robustly in the drug rescheduling process, even at the expense of administrative efficiency and flexibility. *See* 5 U.S.C. § 556(d); H.R. Rep. No. 91-1444, *reprint in* 1970 U.S.C.A.A.N. 4566, 4589.

Of course, formal rulemaking does not obligate the Agency to hear whatever great mass of evidence the public wishes to present. This Court has recognized agency discretion to "fashion[] rules to govern public participation … when, for example, other parties to the proceeding adequately represent the would-be intervenor's viewpoint or intervention would broaden unduly the issues considered, obstruct or overburden the proceedings, or fail to assist the agency's

decisionmaking." *Nichols v. Bd. of Trustees of Asbestos Workers Local 24 Pension Plan*, 835 F.2d 881, 896 (D.C. Cir. 1987).

However, even in contexts demanding less process than formal rulemaking, the Court has refused to "rubberstamp a challenged denial based merely upon an assertion of justification, especially if the agency contends simply that intervention would prove impermissibly dilatory or burdensome." *Id.* "Courts willingly overturn challenged denials when the responsible agency, either by failing to fashion equitable procedures or by employing its power in an unreasonably overbroad or otherwise arbitrary manner, has not acted to preserve the participation opportunities of interested persons." *Id.*

The congressional judgment underlying § 811(a)'s formal rulemaking requirement is more aptly applied to the proposed rule here than to any in the history of the Controlled Substances Act. The public interest in marijuana's federal regulatory status is significant because "[c]annabis is the most commonly used federally illegal drug in the United States." *Cannabis Facts and Stats*, CDC (Feb. 22, 2024), https://perma.cc/Q589-C8S9. And over six million Americans use medical marijuana under the guidance of healthcare practitioners. App.35. Nine former DEA administrators underscored the point in a June 2024 letter to Administrator Milgram:

> [C]hanging marijuana to Schedule III is likely the most consequential rulemaking DEA has ever attempted. … It is undeniable that the

> decision has national and international significance. … It would be the most significant relaxation of narcotics restrictions in the history of the CSA. Such a sweeping change should be undertaken only on a robust administrative record. That is why Congress required that such decisions be made on the record and with opportunity for a hearing. It is hard to imagine a rule more appropriate for formal process than a proposal to loosen federal restrictions on marijuana.

App.536.

As the former administrators observe, "[i]t is hard to imagine" a proposed rule more worthy of formal process and public participation; it is equally hard to imagine agency action more dismissive of those interests. The Administrator limited this "most consequential rulemaking" to 25 participants without providing any reasons at all. App.7. The Agency did not even contend that greater participation "would prove impermissibly dilatory or burdensome," cause evidentiary redundancy, "broaden unduly the issues considered," or "fail to assist the agency's decisionmaking." *Nichols*, 835 F.2d at 896. Limiting participation to a specific number without any explanation is quintessential arbitrary action. *See Tourus Records*, 259 F.3d at 737.

In its silence, the Agency's decision flunks arbitrary and capricious review, which demands the Agency "articulate a satisfactory explanation for its action." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43). The "satisfactory explanation" requirement enables courts to police at least two related limits on agency action: The requirement that agencies

reach rational decisions based on relevant and permissible criteria, *Motor Vehicle Mfrs.*, 463 U.S. at 43, and the requirement that they consider "significant alternatives," *Allied Local & Reg'l Mfrs. Caucus v. U.S. E.P.A.*, 215 F.3d 61, 80 (D.C. Cir. 2000). Because the Agency gave no reasons for limiting participation to 25, it is impossible to determine whether it satisfied these requirements.

For example, the Agency could have judged that, although many of the over 160 applicants were "interested persons" with relevant evidence to present, a long-drawn-out process would upset the summer travel plans of Agency staff. The record silence prevents the Court from ruling out this impermissible basis, and the Agency is not entitled to any presumption that its unexpressed reasons are permissible or rational. *See Home Box Office*, 567 F.2d at 54 ("[A] reviewing court cannot presume that the agency has acted properly ….").

The Agency's silence also makes it impossible to tell whether it considered "significant alternatives to the course it ultimately cho[se]." *Allied Local*, 215 F.3d at 80. For instance, the Agency could have selected more than 25 participants but given each participant less time to present testimony and cross examine witnesses. The ALJ's order gives each participant a generous 90 minutes to present testimony, two minutes for opening statements, 10 minutes for closing argument, and 20 minutes for cross examination—all during the span of 18 hearing days. App.395, 399–

400. "To be regarded as rational," the Agency would have had to consider the very feasible alternatives of more participants but less time per participant or more hearing days. *Allied Local*, 215 F.3d at 80.

In sum, the Agency's decision to limit the hearings to 25 participants without any explanation was arbitrary and capricious because it prevents the Court from determining whether the decision was reasonable, based on relevant and permissible criteria, and followed from consideration of significant alternatives.

B. The Agency's Selection of Participants Was Arbitrary and Capricious.

The Agency's second decision of great public importance was who among the over 160 applicants would be permitted to present evidence at the formal rulemaking hearings. The applicants included a broad array of public and private entities, including individuals, educational institutions, states, corporations, trade associations, nonprofit organizations, political parties, veterans' groups, law enforcement associations, and doctors and scientists. Picking the participants was tantamount to picking the evidence, so it was crucial that the Agency use a rational and evenhanded selection process, favoring neither pro-rule nor anti-rule applicants.

Once again, however, the Agency did not explain how it exercised its discretion to make the critical, potentially outcome determinative, participant selections. Instead, the Administrator announced merely that she had "review[ed]"

the requests and "determined" the 25 who would be permitted to participate. App.7. The Agency's order was so threadbare that the ALJ felt compelled to seek information from the selected entities themselves, including what made them "interested persons," whether they supported or opposed the proposed rule, and what evidence they intended to present. App.333.

The Agency's stunningly casual treatment of such an important decision fueled charges of anti-rule bias that had first been ignited by the Office of Legal Counsel opinion and the aberrant proposed rulemaking initiated by the Attorney General. *See, e.g.*, App.404. The selections themselves only fanned the embers. For instance, the Agency inexplicably selected the state of Nebraska to offer evidence against the rule but rejected other states' detailed requests to present pro-rule evidence, including New York's Office of Cannabis Management and the state of Colorado. App.7, 1163, 1427, 1631, 1649. The rejection of Colorado is particularly puzzling because Colorado had offered to contextualize data about traffic fatalities in the state that the Attorney General specifically discussed in the notice of proposed rulemaking. App.316, 1427. The Agency also rejected leading drug policy organizations like Petitioners and the National Organization for the Reform of Marijuana Laws (NORML), App.1120, 1630, in favor of organizations and individuals who submitted barebones requests failing to identify their particular

interest in the proposed rule or any evidence they intended to present. Even a casual comparison of the requests the Agency granted with the ones it denied reflects, at best, arbitrary decisionmaking. *See* Part II.A, *infra*.

Evidence of ex parte communications between the Agency and anti-rule applicants, emerging only recently, has heaped logs on the fire. Documents produced by the Agency in this case reveal that a Deputy Assistant Administrator within the Agency followed up in private correspondence with twelve applicants requesting "additional information establishing that you are a 'person adversely affected or aggrieved by' the proposed rule,"—*i.e.*, an "interested person" under 21 C.F.R. § 1300.01(b)—and "additional information describing the relevant evidence on a material issue of fact that you intend to present during the hearing." App.1509–1520. Of the twelve who received these self-styled "cure letters," nine were strongly against the proposed rule,[10] two had unclear positions,[11] and only one supported the

[10] These were the Association of Federal Narcotics Agents, App.411, 507, 723–43, 1440, Khurshid Khoja, App.418, 1077, Aubree Adams, App.431, 758–70, Heidi Anderson-Swan, App.432, 775, Bryn Spejcher, App.466, 691, Phillip Drum, App.540, 715, Lori Robison, App.597, the Tennessee Bureau of Investigation, App.542, 1444, and Michael Rountree, App.1472.

[11] These were the Minority Cannabis Business Association, App.538, and Darwin Richardson, App.511.

proposed rule.[12] For the one entity who supported the proposed rule, it was unclear from its initial request whether it supported or opposed the proposed rule. App.611. It became clear only in its supplement in response to the Agency's cure letter that it favored moving marijuana to schedule III over keeping it in schedule I. App.902.

The Agency's silence, facially arbitrary participant selections, and ex parte assistance almost entirely to anti-rule applicants, are strong evidence that the Agency acted with an impermissible purpose of creating an evidentiary record supporting its preferred outcome—rejection of the proposed rule. The Agency's silence alone would be enough to warrant remand, at least for "a fuller explanation of the agency's reasoning at the time of the agency action." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 20–21 (2020). But the affirmative evidence of improper motive supports the second remedy outlined in *Regents*: a remand to "deal with the problem afresh by taking new agency action." *Id.* The fundamental unfairness caused by the ex parte communications in particular cannot be cured by mere explanation. Ordering the Agency to redo the selections will not unduly delay the rulemaking hearings, which are currently stayed pending the interlocutory appeal by pro-rule participants.

[12] This entity was the University of California San Diego Center for Medicinal Cannabis Research. App.611, 902.

II. THE AGENCY'S REJECTION OF PETITIONERS WAS ARBITRARY AND CAPRICIOUS.

The Agency sent identical rejection letters to all applicants who were not selected to participate in the rulemaking hearings, including Petitioners. The letters stated:

> Upon review and careful consideration, DEA has determined that the request did not sufficiently establish that you are an "interested person" under DEA regulations and/or the request did not sufficiently state with particularity the relevant evidence on a material issue of fact that you intended to present during the hearing. … Therefore, DEA has decided not to grant your request.

App.10.

In its response to Petitioners' motion for stay, the Agency tried to supplement this sparse reasoning, explaining that Petitioners had been rejected because they did not intend to present evidence on whether marijuana has a currently accepted medical use in treatment in the United States. Opp'n to Emerg. Mot. for an Injunction at 18 (Dec. 20, 2024). This, of course, contravenes the "foundational principle of administrative law that judicial review of agency action is limited to the grounds that the agency invoked when it took the action." *Regents*, 591 U.S. at 20 (quotation marks and quoting reference omitted).

Whether the Court considers the Agency's contemporaneous reasons or Agency counsel's post hoc reasons, the conclusion is the same: The Agency's rejection of Petitioners was irrational and shows Petitioners were treated differently

than other similarly situated applicants. And, if more evidence were needed, the Agency's ex parte communications assisting anti-rule applicants places the Agency's bias beyond doubt.

A. The Agency's Contemporaneous Reasons Are Irrational.

The Agency explained in its rejection letter that Petitioners had not been selected because their request either had not "sufficiently establish[ed]" that they were "interested persons" or had not "sufficiently state[d] with particularity the relevant evidence on a material issue of fact that [they] intended to present during the hearing." App.10. Both conclusions were unreasonable, particularly when Petitioners' request to participate is compared to requests the Agency granted.

1. It was unreasonable for the Agency to conclude Petitioners were not "interested persons."

Agency regulations permit "[a]ny interested person" to submit "a written notice of his intention to participate" in a rulemaking hearing. 21 C.F.R. § 1308.44(b). The regulations define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 C.F.R. § 1300.01(b).

Petitioners plainly qualify as interested persons because their membership of "over 400 physicians and licensed medical practitioners" recommend marijuana for treatment of patients, and marijuana's schedule status affects "how medical

marijuana is recommended/prescribed or dispensed" and "dispensing limits for prescriptions." App.329. *See PDK Labs. Inc. v. U.S. D.E.A.*, 362 F.3d 786, 791 (D.C. Cir. 2004) (asking "what interest the litigant seeks to vindicate" and "whether that interest is arguably within the zone of interests to be protected or regulated by the statute"); *Animal Legal Def. Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 22 (D.D.C. 2017).

Comparing Petitioners to applicants who were selected shows that the Agency applied a more stringent standard to Petitioners than to other applicants. For example:

- The Agency selected a doctors' group, the International Academy on the Science and Impact of Cannabis, that could fairly be described as the anti-rescheduling counterpart to Doctors for Drug Policy Reform. App.415, 625, 1539. The only statement in the group's request about why it was an "interested person" was that "[w]e have an interest in the proceeding as physicians and concerned citizens of the United States of America who believe that re-scheduling will have immediate and irreparable harm to the public health." App.415.
- The Agency selected a pharmacist, Phillip Drum, who opposes the proposed rule and, until the Agency sent him a "cure letter" asking for "additional information," had not explained why he was an "interested person." App.540, 1554. In his supplement following the cure letter, he explained he was an "interested person" because he was a pharmacist and the proposed rule would affect "the dispensing of marijuana for medical purposes." App.715. This is the same explanation Petitioners gave to show that the pharmacist members of Doctors for Drug Policy Reform made it an "interested person." App.329.

- The Agency selected a physician, Kenneth Finn, M.D., who gave no explanation why he was any more interested than anyone else with the personal opinion that marijuana is harmful and insufficiently studied for medical use. App.1468, 1545.

- The Agency selected Community Anti-Drug Coalitions of America, which stated merely that its "particularity of interest in the hearing is that rescheduling marijuana would greatly exacerbate the public health harms it causes, especially as they relate to youth." App.635, 1530.

- Finally, on the pro-rule side, the Agency selected Shanetha Lewis, who did not explain why she was an interested person beyond stating she has a degree in medical cannabis science, is a disabled veteran, and is the executive director of a nonprofit focused on veterans' mental health issues. App.1505, 1558.

The Agency's conclusion that Petitioners had not shown they were "interested persons" cannot be reconciled with its selection of these entities, who provided no or clearly deficient explanations that they were "interested persons." The rejection of Petitioners was arbitrary and capricious because the Agency treated Petitioners differently from other similarly situated applicants, without explanation. *See Burlington N.*, 403 F.3d at 776.

2. It was unreasonable for the Agency to conclude Petitioners had not identified relevant evidence they intended to present.

Petitioners explained in their request to participate that they intended to present oral testimony through Drs. Bryon Adinoff and David Nathan that: (1) marijuana's potential for creating dependence was less than other controlled substances, including benzodiazepines in schedule IV, and (2) the definition of

"drug abuse" used by the Food and Drug Administration and the Agency was overbroad because it included marijuana use not harmful to self or others. App.328, 330, 331–32. The Agency cannot plausibly deny this evidence is relevant because the Attorney General discussed marijuana's potential for creating dependence relative to other drugs in his notice of proposed rulemaking. App.301, 305, 312, 315, 317.

Again, comparing Petitioners' request with the requests of entities who were selected to participate shows the Agency treated Petitioners differently from other similarly situated entities. For example:

- Cannabis Industry Victims Educating Litigators submitted only a vague list of general topics on which it intended to offer testimony, such as "Section 280E of the Internal Revenue Code," "There Is No Reason to Change Marijuana's Scheduling Based on the Science or Law," "Marijuana Exposures Among Children, Veterans With PTSD, Older Adults," "Marijuana Use Causes Mental Illness and Violence," and "The Department of Justice States That Marijuana Users Are Dangerous." App.508–09.
- The International Association of Chiefs of Police did not identify evidence it actually intended to present, but merely identified "areas" where it was "concerned with the impact that the proposed change could have," including "Public Safety Risks," "Youth and Health Impacts," "Workplace Safety," "Impaired Driving," "Challenges in Implementation," "Policing Challenges," "Potential Impact on Current Firearms Regulations," and "Diversion Potential." App.631.
- Dr. Finn's request contained a welter of legal and factual assertions about the requirements for FDA approval, the state of the scientific research into medical marijuana, and various marijuana-related harms. App.1468–71. But Dr. Finn did not indicate which of these issues, if any, he intended to testify about. *Id.*

It was irrational for the Agency to conclude that these applicants had identified specific relevant evidence they intended to present but Petitioners had not. The only conclusion is that the Agency unjustifiably treated Petitioners differently from other similarly situated entities.

B. The Agency's Post Hoc Reasons Underscore its Arbitrary Treatment of Petitioners.

In an apparent gloss on the Agency's conclusion that Petitioners had "not sufficiently state[d] with particularity the relevant evidence" they intended to present, the Agency asserted in its response to the motion for stay that Petitioners had been rejected because they did not intend to present evidence on whether marijuana has a currently accepted medical use. Opp'n to Emergency Mot. for an Injunction Pending Appeal at 22–23. Because "'post hoc' rationalizations" are "an inadequate basis for review," the Court should disregard the gloss. *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). But to the extent it is relevant at all, the Agency's post hoc reasoning is additional evidence that the Agency acted arbitrarily in excluding Petitioners.

First, it is simply untrue that Petitioners did not intend to present evidence on currently accepted medical use. They plainly expressed their intent to do so in their request to participate:

> [T]he Organization agrees that marijuana has a currently accepted medical use in treatment in the United States and should be removed from Schedule I. As the premier organization of health professionals and scientists specifically organized to provide expert evidence related to the responsible regulation of cannabis, the Organization is best positioned to present additional evidence to support that assessment and to contextualize evidence and argument to the contrary.

App.327.

Second, whether marijuana has a currently accepted medical use is only one issue material to the proposed rule. Also relevant are the eight factors under 21 U.S.C. § 811(c), at least five of which concern marijuana's abuse or dependence potential.[13] To place marijuana in schedule III, the Agency must find not only that

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[13] The § 811(c) factors are:

> (1) [The drug's] actual or relative potential for abuse.
>
> (2) Scientific evidence of its pharmacological effect, if known.
>
> (3) The state of current scientific knowledge regarding the drug or other substance.
>
> (4) Its history and current pattern of abuse.
>
> (5) The scope, duration, and significance of abuse.
>
> (6) What, if any, risk there is to the public health.
>
> (7) Its psychic or physiological dependence liability.
>
> (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

marijuana has a currently accepted medical use, but that it "has a potential for abuse less than the drugs or other substances in schedules I and II" and that "[a]buse of [] [marijuana] may lead to moderate or low physical dependence or high psychological dependence." *Id.* § 812(b)(3). The Attorney General invited evidence on these issues in his notice of proposed rulemaking. App.301, 305, 312, 315, 317. Petitioners' testimony is relevant to these issues because it would show that marijuana has a potential for abuse and dependence risk less than other scheduled drugs, particularly benzodiazepines, App.312–11, and marijuana's potential for abuse does not include uses not harmful to self or others, App.318.

To the extent the Agency denied Petitioners' application because they intended to present evidence on one aspect of the problem (dependence and abuse potential) but not another (currently accepted medical use), bedrock administrative law renders that decision arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

Third, at least 11 of the entities selected by the Agency did not state they intended to present evidence on currently accepted medical use.[14] Many of the

[14] These entities include: Village Farms International, App.1452; Erin Kirk, Connecticut Cannabis Ombudsman, App.983; Ellen Brown, Massachusetts Cannabis Advisory Board, App.982; Shanetha Lewis, Veterans Initiative 22, App.1505; Nicholas Garulay, The Doc App (d/b/a My Florida Green), App.756; The Commonwealth Project, App.913; Cannabis Industry Victims Educating

entities selected are political, business, or law enforcement entities with no expertise in marijuana's medical applications. If the Agency wishes to condition participation on the presentation of evidence on currently accepted medical use, it must apply that condition to all entities, not just to Petitioners.

The irrationality of the Agency's post hoc reasons is yet more evidence that the Agency excluded strong pro-rule applicants like Petitioners to manipulate the evidentiary record against the proposed rule.

C. The Agency Impermissibly Assisted Anti-Rule Applicants Submit Requests to Participate Without Similarly Assisting Petitioners.

The most undeniable instance of differential treatment in the record is the Agency's "cure letters," sent almost exclusively to applicants who intended to offer evidence against the proposed rule. These cure letters invited anti-rule applicants another bite at the apple to show they were "interested persons" who intended to present relevant evidence. Petitioners received no similar assistance from the Agency. This is a quintessential case of treating similarly situated applicants differently without just cause. *See Burlington N.*, 403 F.3d at 776.

Litigators, App.508; National Transportation Safety Board, App.599; Phillip Drum, App.540, 715; International Association of Chiefs of Police, App.631; and the Tennessee Bureau of Investigation, App. 542, 1444.

The ALJ—aware only of the Agency's cure letter to the Tennessee Bureau of Investigation—described the letter as "an apparent effort by the [Agency] to enhance the [the Bureau's] chance of selection as a designated participant above others who applied." App.406. The ALJ was "appall[ed]" and "disturb[ed]" by the allegations. *Id.* According to the ALJ, the Agency's "failure to acknowledge in any way the gravity of the highest levels of its organization allegedly reaching out to help one of the potential [participants] fortify its application to ease the task of justifying its apparently pre-made determination for appeal [] demonstrates an arrogant overconfidence." App.407.

The Agency's ex parte assistance to anti-rule applicants made the selection process fundamentally unfair, particularly because Petitioners and others were denied for failure to make the very showing the Agency assisted others to make. App.10. The only way to cure this unfairness is to vacate the order selecting participants and remand with instructions to redo the selections.

III. THE ATTORNEY GENERAL HAS NOT DELEGATED TO THE ADMINISTRATOR THE POWER TO SELECT PARTICIPANTS IN THESE HEARINGS.

The Attorney General has delegated to the Administrator his authority under the Controlled Substances Act to schedule drugs using formal rulemaking. 28 C.F.R. § 0.100(b); 21 U.S.C. § 811(a). Ordinarily, this general delegation prevents the

Attorney General from interfering with the Administrator's exercise of her delegated authority. *See United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 266 (1954). But what the Attorney General gives, he can also take away—either by expressly revoking a delegation or by issuing a narrower delegation in the same subject area. *See United States v. Libby*, 429 F. Supp. 2d 27, 43 (D.D.C. 2006) (a "broad grant of authority is generally limited by a more specific grant").

The Attorney General's notice of proposed rulemaking implicitly rescinded the Administrator's general authority over marijuana rescheduling and replaced it with a narrow grant of specific functions: (1) deciding whether "an in-person hearing will be needed to address [] matters of fact and law in the rulemaking"; (2) publishing "a notice of hearing on the proposed rulemaking in the Federal Register"; and (3) "designat[ing] an ALJ to preside over the hearing." App.300

Critically, the notice of proposed rulemaking did not grant the Administrator independent authority to rule on requests to participate. Rather, the Attorney General clearly contemplated that, in the event the Administrator determined an in-person hearing was necessary, the ALJ would exercise powers encompassing the determination of participants:

> The ALJ will have all powers necessary to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. The ALJ's authorities include the power to … consider other matters that may aid in the expeditious disposition of the hearing; require parties to state

> their position in writing; … receive, rule on, exclude, or limit evidence; rule on procedural items; and take any action permitted by the presiding officer under DEA's hearing procedures and the APA.
>
> Comments on or objections to the proposed rule submitted under 21 CFR 1308.43(g) will be offered as evidence at the hearing, but the presiding officer shall admit only evidence that is competent, relevant, material, and not unduly repetitive. 21 CFR 1316.59(a).

Id.

The Administrator exceeded the bounds of the Attorney General's specific delegation by taking it upon herself to "assess the notices submitted and make a determination of participants." App.326. Instead, the Administrator was obliged, upon concluding that an in-person hearing was necessary, to appoint an ALJ who, incident to exercising the powers outlined by the Attorney General, would rule on all requests to participate.

CONCLUSION

The Court should vacate the Agency's orders selecting participants and excluding Petitioners and remand with instructions for the Agency to redo the selections.

Dated: February 17, 2025

Respectfully submitted,

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Austin T. Brumbaugh

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