IN THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	§	DEA Docket No. 1362
MARIJUANA	§	Hearing Docket No. 24-44
RESCHEDULING	§	
	§	Administrative Law Judge
	§	John J. Mulrooney, II

NON-PARTY DOCTORS FOR DRUG POLICY REFORM'S MOTION TO STAY FORMAL RULEMAKING AND REQUEST TO FILE OUT OF TIME

Doctors for Drug Policy Reform is an organization of medical professionals in support of evidence-based cannabis regulation. The Organization and its President, Bryon Adinoff, M.D., submitted a request to participate in the formal rulemaking hearing on whether marijuana should be moved from schedule I to schedule III, but were denied by the Administrator of the Drug Enforcement Administration. The Organization has petitioned the United States District Court for the District of Columbia Circuit to review the Administrator's denial of the Organization's request to participate. The Organization now moves this tribunal to stay the rulemaking hearing scheduled to commence January 21, 2025 pending the D.C. Circuit's review.

The tribunal should grant the motion to stay because (1) the Organization is likely to succeed on the merits of its petition, (2) the Organization will likely be irreparably harmed absent a stay, (3) others will not be substantially harmed by a stay, and (4) the public interest favors a stay.

BACKGROUND

The tribunal is familiar with the facts giving rise to these proceedings and the Organization's efforts to participate in them. Only the essential facts are summarized below.

I. The Department Of Health And Human Services Recommends Marijuana Be Rescheduled.

In August 2023, HHS sent DEA its evaluation and recommendation that marijuana be

moved from schedule I to schedule III. *See* 21 U.S.C. § 811(b). HHS's evaluation included an analysis of marijuana's abuse potential compared to other controlled drugs, including benzodiazepines in schedule IV. HHS Recommendation at 9, 38 (Aug. 29, 2023).

II. DEA Disagrees With Aspects Of HHS's Evaluation.

An April 2024 memorandum from the Office of Legal Counsel ("OLC") to the Attorney General shows that DEA disagreed with the test underlying HHS'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. OLC Op. at 19 (Apr. 11, 2024) ("DEA's main concern with HHS's two-part inquiry is that it places too much emphasis on state regulatory decisions."). OLC's memo resolved the dispute in favor of HHS. *Id.* at 1.

III. The Attorney General—Not DEA—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 HHS recommended. The notice is historically anomalous because—although the Attorney General long ago delegated his CSA rulemaking authority to the DEA Administrator—the Attorney General clearly initiated this rulemaking on his own authority. *See* 28 C.F.R. § 0.100(b); 21 U.S.C. § 811(a); 89 Fed. Reg. 44597-01 at 44601 ("[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 DEA Administrator, who would ordinarily have all the powers of the Attorney General under § 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.

89 Fed. Reg. 44597-01 at 44598.

The Attorney General reserved "all powers necessary to conduct a fair hearing" to the ALJ. *Id.*

IV. DEA Issues A General Notice Of Hearing, Inviting Requests To Participate.

In August 2024, the Administrator issued a general notice of hearing, announcing that DEA 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." 89 Fed. Reg. 70148-01 at 70149 (quotation marks omitted and alteration adopted). 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." *Id.* The Administrator specified these notices must:

> (1) State with particularity the interest of the person in the proceeding;
>
> (2) State with particularity the objections or issues concerning which the person desires to be heard; and
>
> (3) State briefly the position of the person regarding the objections or issues.

Id.

The Administrator stated: "I will assess the notices submitted and make a determination of participants." *Id.*

V. The Organization Requests To Participate In The Hearing.

In September 2024, the Organization submitted to the Administrator a request to participate in the form specified. *See* Ex. A.

The Organization specifically stated it was interested in participating because it is

"comprised of doctors, nurses, [and] pharmacists—many if not nearly all of whom are [DEA] registrants." *Id.* at 3. It explained that moving marijuana to schedule III would impact its members' ability to recommend, prescribe, and dispense marijuana. *Id.* at 3, n.6.

The Organization identified two issues on which it wanted to be heard: (1) marijuana's abuse potential relative to other controlled drugs, especially benzodiazepines; and (2) whether the definition of "drug abuse" employed by FDA and DEA is generally accepted in the medical community. *Id.* at 3–4.

Finally, the Organization stated its position on these issues: (1) marijuana's abuse potential was lower than other controlled drugs, especially benzodiazepines; and (2) the definition of "drug abuse" employed by FDA and DEA was not generally accepted in the medical community. *Id.* at 4–6. The Organization specifically stated it would support these positions with testimony from two of its members. *Id.* at 1, 4.

VI. DEA Selects 25 Participants, Excluding The Organization.

In October 2024, the Administrator announced a selection of 25 individuals and organizations to participate in the rulemaking hearing. Ltr. from DEA Administrator Milgram to Hon. John J. Mulrooney, II (Oct. 29, 2024). The Organization was not among those selected, and the Administrator gave no reasons for its selections. *Id.* In the same order, the Administrator designated the Honorable John J. Mulrooney, II to preside as ALJ over the hearing. *Id.*

VII. The Tribunal Requests Additional Information And Rules On Standing.

Because the Administrator's selection process left this tribunal without any information about the selected participants apart from their names and email addresses, the tribunal ordered the participants to provide additional information, including "why/how the [participant] would be sufficiently 'adversely affected or aggrieved' by the proposed scheduling action to qualify as an

'interested person' under the regulations" and "whether the [participant] supports or opposes the rescheduling action the DEA seeks in its NPRM." Prelim. Order at 3 (Oct. 31, 2024).

After receiving that information, the tribunal ruled that nine of the selected 25 participants lacked administrative standing. Standing Order at 15–41 (Nov 19, 2024). Nonetheless, the tribunal permitted all but two of those who lacked standing to participate in the hearing. *Id.*

VIII. The Organization Moves To Intervene And Requests A Final Appealable Determination.

In November 2024, the Organization moved to intervene to participate in the rescheduling hearing under 5 U.S.C. § 555(b). It also requested a final appealable decision from the Administrator granting or denying its request to participate.

The tribunal denied the Organization's motion because it lacked authority to review the Administrator's selection decisions, and because it found the Organization's exclusion resulted from a "reasonable" exercise of the Administrator's "discretion in determining the number and nature of participants." Order Denying Mot. to Intervene at 2 (Nov. 11, 2024).

IX. DEA Formally Denies The Organization's Request To Participate.

On November 25, 2024, DEA issued a letter formally denying the Organization's request to participate. Ex. B. 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."

X. The Organization Petitions The D.C. Circuit For Review.

On November 27, 2024, the Organization petitioned the D.C. Circuit to review the Administrator's order selecting 25 participants and order denying the Organization's request to

participate, under 21 U.S.C. § 877. Ex. C.

XI. The Tribunal Schedules The Rulemaking Hearing.

On December 4, 2024, the tribunal issued a prehearing ruling scheduling the rulemaking hearing to commence on January 21, 2025. The order included a determination that "the time for seeking relief through motion practice has reasonably passed. The time has come to receive evidence and proceed with the hearing. Any further motions must be accompanied by a request to file out of time and supported by a demonstration of good cause that is likely to be narrowly construed." Prehearing Ruling at 8.

ARGUMENT

A stay of agency proceedings pending appeal is appropriate when the "balance" of the following four factors weigh in favor of a stay:

> (1) the likelihood that the party will prevail on the merits of the appeal; (2) the likelihood that the party will be irreparably harmed absent a stay; (3) the prospect that others will be harmed if the court grants the stay; and (4) the public interest in granting a stay.

McCammon v. United States, 584 F. Supp. 2d 193, 197 (D.D.C. 2008).

The tribunal should stay the formal rulemaking hearing scheduled for mid-January 2025 because the balance of these factors favor a stay.

I. The Organization Should Be Granted Leave To File Out Of Time.

As the tribunal's prehearing ruling requires, the Organization requests leave to file this motion out of time. Good cause exists to file the motion now because the Organization did not receive a final decision from the Administrator on its request to participate until November 25, 2024. Two days later, the Organization filed its petition for review with the D.C. Circuit. The Organization has not been dilatory in seeking a stay of the rulemaking hearing, which was officially

scheduled just today.

II. The Organization Is Likely To Prevail On The Merits Of The Appeal.

This factor does not require a showing of "assured [] success on appeal." *Al-Adahi v. Obama*, 672 F. Supp. 2d 81, 83 (D.D.C. 2009). Rather, it is enough for the petitioner to raise "questions going to the merits so serious, substantial, difficult and doubtful, as to make them a fair ground for litigation and thus for more deliberative investigation." *Id.* (quoting *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977)).

The Organization satisfies this standard because its arguments on appeal, set out below, will show that the Administrator lacked authority to unilaterally select participants. Alternatively, the Administrator's selection of participants and exclusion of the Organization was arbitrary and capricious because she (1) failed to adequately explain her reasons, (2) acted outside the zone of reasonableness, and (3) treated the Organization differently from similarly situated applicants.

A. The Administrator Lacked Authority To Unilaterally Select Participants.

The Attorney General has delegated to the DEA Administrator his authority under the CSA 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, 74 S. Ct. 499, 503, 98 L. Ed. 681 (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") (quoting *Heathcote v. Priddis*, No. 93–2–02331–8, 1997 WL 3203, at *4 (Wash. App. Jan. 3, 1997)).

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." 89 Fed. Reg. 44597-01, 44598. These specific instructions would not be necessary if the general delegation remained intact. *See Libby*, 429 F. Supp. 2d at 43.

Critically, the notice of proposed rulemaking did not grant the Administrator independent authority to rule on requests for hearing or to participate without the input of an ALJ. 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 hold conferences to simplify or determine the issues in the hearing or to consider other matters that may aid in the expeditious disposition of the hearing; require parties to state their position in writing; sign and issue subpoenas to compel the production of documents and materials to the extent necessary to conduct the hearing; examine witnesses and direct witnesses to testify; 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).

89 Fed. Reg. 44597-01, 44598.

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."

89 Fed. Reg. 70148-01, 70149. 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.

Even under normal circumstances—when the general delegation is intact and the Administrator initiates rulemaking—the Administrator's selection of participants would have exceeded the bounds of her role and trenched on the "exclusive control of the Agency ALJ" over all "procedural aspects of administrative hearings." John J. Mulrooney II, *Current Navigation Points In Drug Diversion Law: Hidden Rocks In Shallow, Murky, Drug-Infested Waters*, 101 Marq. L. Rev. 333, 425 (2017). As this tribunal has observed, "DEA regulations provide no legal mechanism for administrative litigation to be managed by the Administrator or his staff." *Id.* at 426.

The procedural irregularity of the Administrator's unilateral gatekeeping has been noted by this tribunal. Indeed, the Administrator's adjudication of participants was so shrouded in secrecy that even this tribunal had no record of any "hearing requests, notices of appearance, or correspondence between the Agency and the Designated Participants or those who sought that status." Prelim. Order at 3. As the tribunal noted, the Administrator's failure to serve the tribunal with copies of all participation requests directly flouted the Attorney General's notice of proposed rulemaking. *Id.* at 2; 89 Fed. Reg. 44597-01, 44598. The Administrator's procedural failings compelled the tribunal to order supplemental notices from the selected participants. Prelim. Order at 3. After receiving the supplemental notices, the tribunal essentially redid the work, on the record, that the Administrator presumably did off the record, determining whether the designated participants were "interested persons" with relevant evidence to present. *See* Standing Order.

The Administrator's secretive selection of participants was procedurally improper and

ultra vires. As the tribunal noted in denying the Organization's motion to intervene, the Administrator's decision to select participants before appointing an ALJ renders the Administrator's selections unreviewable—except by the court of appeals. Order at 2. The court of appeals should hold DEA to its purported "commit[ment] to conduct[] a transparent proceeding," 89 Fed. Reg. 70148-01, 70148, and vacate the Administrator's October 29, 2024 order selecting the participants, and remand with instructions to the ALJ to select participants from the entire pool of applicants.

B. The Administrator's Selection Of Participants And Exclusion Of The Organization Was Arbitrary And Capricious.

The APA authorizes courts to overturn agency action when it is arbitrary, capricious, or otherwise contrary to law. 5 U.S.C. § 706(2). 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. v. Fed. Communications Comm'n*, 45 F.4th 406, 411 (D.C. Cir. 2022) (quoting *Fed. Communications Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 423, 141 S. Ct. 1150, 1158, 209 L. Ed. 2d 287 (2021)).

"The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result." *Pub. Citizen, Inc. v. F.A.A.*, 988 F.2d 186, 197 (D.C. Cir. 1993). "[T]he core requirement is that the agency explain 'why it chose to do what it did.'" *Tourus Records, Inc. v. Drug Enf't Admin.*, 259 F.3d 731, 737 (D.C. Cir. 2001) (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.

Further, "[a]n agency must provide an adequate explanation to justify treating similarly

situated parties differently." *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005). "Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld." *Id.*

Even if the Administrator had authority to unilaterally select participants, its selections should be vacated for two reasons. First, the Administrator failed to adequately explain her reasons for rejecting the Organization's request to participate. Second, the Administrator's explanation was substantively unreasonable and treated the Organization differently from other similarly situated applicants.

1. The Administrator failed to adequately explain her reasons for rejecting the Organization's request to participate.

The Organization submitted a request to participate in the rulemaking hearing on September 26, 2024. Ex. A. The Organization learned it had not been selected to participate when the Administrator issued its list of designated participants one month later. DEA Administrator Milgram Ltr. to Hon. John J. Mulrooney, II (Oct. 29, 2024). But the Organization received no direct decision or explanation from the Administrator until November 25, 2024, just over a week before the December 2 preliminary hearing. Ex. B.

The Administrator's proffered reasons for denying the Organization's request are threadbare. Even worse, it is impossible to determine the Administrator's actual reasons because they are couched in an ambiguous "and/or":

> . . . 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. (emphasis added).

This explanation leaves it unclear whether the Organization was not selected because DEA found (1) its request did not sufficiently establish that it was an "interested person," (2) its request did not "sufficiently state with particularity" what evidence it "intended to present during the hearing," (3) the evidence the Organization intended to present was not "relevant evidence on a material issue of fact," or (4) some combination of these reasons. The Agency's "path" to rejecting the Organization cannot "reasonably be discerned." *Pub. Citizen*, 988 F.2d at 197. This alone warrants remand to the Agency for a clearer explanation of reasons.

2. The Administrator's rejection of the Organization was substantively unreasonable and treated the Organization differently from similarly situated applicants.

As explained, the Agency's rejection letter does not allow the Organization to discern the actual reasons it was not allowed to participate. The Organization is left to assume the Administrator found that it (1) had not established it was an "interested person," (2) had not stated with sufficient particularity what evidence it intended to present, and (3) the evidence it intended to present was not relevant to a material issue of fact. Each conclusion was unreasonable and, when considered against the applicants the Administrator selected, strongly suggests the Organization was treated differently from similarly situated applicants.

i. It was unreasonable for the Administrator to conclude the Organization's request did not establish it was an "interested person."

The APA allows "interested person[s]" to "appear before an agency or [one of its ALJs] for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding . . . in connection with an agency function." 5 U.S.C. § 555(b). Although agencies have discretion to deny participation even to "interested persons," they may do so only to maintain

"the orderly conduct of public business." *Id.*; *see also Nichols v. Bd. of Trustees of Asbestos Workers Local 24 Pension Plan*, 835 F.2d 881, 896 (D.C. Cir. 1987). For example, an agency may deny participation to an interested person when "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*, 835 F.2d at 896.

Given the importance of public participation in agency proceedings, *see Bilingual Bicultural Coalition on Mass Media, Inc. v. FCC*, 595 F.2d 621, 624 n.4 (D.C. Cir. 1978), the D.C. Circuit has not shied away from reviewing an agency's rejection of requests to participate, *see Nichols*, 835 F.2d at 896. Such agency action does not get a "rubberstamp . . . based merely upon an assertion of justification." *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 APA does not define the term "interested person." *Animal Legal Def. Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 21 (D.D.C. 2017). Rather, who qualifies as an "interested person"—the so-called "administrative" standing inquiry—is determined with reference to the agency's enabling statute and implementing regulations. *Ritchie v. Simpson*, 170 F.3d 1092, 1095 (Fed. Cir. 1999).

CSA 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 C.F.R. § 1300.01(b). The D.C. Circuit has interpreted similar language in the CSA and APA to call for an inquiry into

(1) what interest the litigant seeks to vindicate, and (2) whether that interest is arguably within the zone of interests to be protected or regulated by the statute." *PDK Labs. Inc. v. U.S. D.E.A.*, 362 F.3d 786, 791 (D.C. Cir. 2004). This test "is not demanding." *Id.* "The court should not inquire whether Congress intended to benefit or regulate the litigant. It is enough that the litigant's interest is arguably one regulated or protected by the statutory provision at issue." *Id.* (quotation marks and citation omitted).

This "lower threshold for participation under § 555(b) comports with 'the important role played by citizens' groups in ensuring compliance with the statutory mandate that agency proceedings serve the public interest." *Vilsack*, 237 F. Supp. 3d at 21 (quoting *Bilingual Bicultural Coalition*, 595 F.2d at 624 n.4) (alterations adopted).

Applying this standard to the facts presented in the Organization's request to participate leaves no doubt that it is an "interested person."

The Organization's request explained its position that "the evidence, properly considered, supports a classification below Schedule III" for marijuana. Ex. A, at 1. The Organization further explained that the "400 physicians and licensed medical practitioners" in its membership would be adversely affected if marijuana were moved to schedule III instead of schedule IV or V because "it may affect how medical marijuana is recommended/prescribed or dispensed, which at present, is done based on recommendations and not prescriptions due to its Schedule I status." *Id.* at 3 & n.6. The Organization noted that moving marijuana to schedule III instead of schedule V would impact "dispensing limits for prescriptions" under 21 U.S.C. § 829. *Id.* at 3, n.6.

The Organization's interest in presenting evidence that marijuana should be moved to a schedule less controlled than schedule III is at least "arguably within the zone of interests to be

protected or regulated by the [CSA]." *PDK Labs.*, 362 F.3d at 791. The CSA is meant not only to "control the legitimate and illegitimate traffic in controlled substances," *Gonzales v. Raich*, 545 U.S. 1, 12 (2005), but also to protect "the public's interest in the legitimate use of controlled substances," *Bonds v. Tandy*, 457 F.3d 409, 414 (5th Cir. 2006). Indeed, the "very existence" of the CSA's "process for reclassifying controlled substances" and obtaining judicial review of reclassification decisions "indicates that . . . Congress intended flexibility and receptivity to the latest scientific information to be the hallmarks of its approach." *United States v. Amalfi*, 47 F.4th 114, 121 (2d Cir. 2022) (quoting *United States v. Kiffer*, 477 F.2d 349, 357 (2d Cir. 1973)). The Organization's participation request sought to fulfill this scientific approach by lending its expertise to the question "whether marijuana should be transferred to Schedule III." 89 Fed. Reg. 44597-01, 44599.

To the extent the Administrator concluded that the Organization's request did not support a finding that it was an "interested person," that decision was unreasonable and not in accordance with law.[1] *See* 5 U.S.C. 706(2)(A).

Further, a comparison of the Organization to applicants the Administrator selected strongly suggests the Administrator applied a more stringent standard to the Organization than it did to other applicants. The Administrator selected the International Academy on the Science and

[1] To the extent the Agency's interpretation of "interested person," set out in § 1300.01(b), categorically excludes persons who would benefit from the proposed rule compared to the status quo—as the tribunal apparently concluded in its Standing Order—that interpretation fails "to preserve the participation opportunities" embodied in § 555(b). *Nichols*, 835 F.2d at 897. The "flexib[le]" and "receptiv[e]" scientific approach Congress intended as the "hallmark" of rescheduling decisions requires participation from both supporters and detractors of a proposed rule. *Amalfi*, 47 F.4th at 121; *see also Vilsack*, 237 F. Supp. 3d at 21 (the "lower threshold for participation under § 555(b) comports with 'the important role played by citizens' groups in ensuring compliance with the statutory mandate that agency proceedings serve the public interest") (quoting *Bilingual Bicultural Coalition*, 595 F.2d at 624 n.4) (alterations adopted).

Impact of Cannabis, a doctors' group comparable to the Organization in every material respect except that it advocates against marijuana use and opposes moving marijuana from schedule I. https://iasic1.org/news/.[2] The Administrator also selected a physician who, like the Organization, asserted that marijuana's schedule III status would adversely affect his ability to "competently prescribe or administer the substance as a drug for his patients." Standing Order at 18. The Administrator did not explain why she determined these applicants were "interested persons" but the Organization was not.[3]

ii. It was unreasonable for the Administrator to conclude the Organization had not stated with sufficient particularity what evidence it intended to present.

The Administrator's general notice of hearing required persons requesting to participate to "[s]tate with particularity the objections or issues concerning which the person desires to be heard" and "[s]tate briefly the position of the person regarding the objections or issues." 89 Fed. Reg. 70148-01, 70149.

The Organization's request to participate clearly satisfied this requirement. The Organization identified two specific issues on which it desired to be heard: (1) marijuana's potential for creating physical and psychological dependence relative to drugs in schedules III, IV, and V; and (2) whether FDA and DEA's definition of "drug abuse" is generally accepted in the medical

[2] The International Academy on the Science and Impact of Cannabis has since relinquished its right to participate in the proceedings. *See* Standing Order n.3.

[3] One tempting basis for distinguishing the Organization from these applicants is that the proposed rule would aggrieve the Organization because it does not go far enough in reducing marijuana's controls, whereas these applicants would allegedly be aggrieved because the rule disrupts the schedule I status quo. *See* footnote 1, *supra*. However, the Administrator evidently did not take such a narrow view of "interested person" status. The Administrator selected eight participants who the tribunal later ruled lacked standing because the proposed rule would "benefit" them compared to "the status quo." Standing Order at 14.

community. Ex. A, at 3–4.

The Organization could not have been more specific about the evidence it intended to present on these issues. It explained that two of its members, Drs. Bryon Adinoff and David Nathan, would testify that HHS's analysis "does not properly compare cannabis to the benzodiazepine class in Schedule IV" and that "compared to benzodiazepines, abuse of marijuana leads to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV." *Id.* at 5. It also explained that it would offer testimony showing that the FDA and DEA's definition of "drug abuse" are "not generally accepted by the medical profession" because it includes non-harmful uses of marijuana. *Id.* at 2.

Comparing the Organization to applicants who were selected to participate strongly suggests the Administrator applied more rigorous specificity and relevance standards to the Organization than to other applicants. For example, the tribunal ruled that one selected participant failed to "identify a particular witness or source of expertise that would be particularly knowledgeable" on relevant issues. Standing Order at 27. The Administrator has not explained why it selected these applicants but not the Organization, who clearly satisfied this requirement.

iii. It was unreasonable for the Administrator to conclude the Organization's evidence was not relevant to a material fact.

The Organization explained that its evidence on marijuana's potential for creating dependence compared to drugs in schedules III, IV, and V was relevant because it would show that the analysis underlying HHS's schedule III recommendation was incorrect or, at best, incomplete. This evidence is relevant to "the purpose of the hearing . . . to receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III." 89 Fed. Reg. 44597-01, 44599 (quotation marks omitted and alteration adopted). The Organization's evidence would

show that marijuana's potential for creating dependence is less than drugs in schedule IV, which would support a transfer to schedule III if not schedule IV or V.

The Organization's testimony that DEA and FDA's definition of "drug abuse" is not generally accepted by the medical community is also relevant. HHS evaluated marijuana's "actual or relative potential for abuse" in recommending it be moved to schedule III. HHS Recommendation, at 6. The Organization's testimony would show that HHS's definition of "drug abuse" caused it to overestimate marijuana's abuse potential, which would support a transfer to schedule III if not schedule IV or V.

To the extent the Administrator concluded that the evidence the Organization intended to present was not relevant, that conclusion was unreasonable. Moreover, as shown above, the Administrator's selection of applicants who clearly failed to identify relevant evidence strongly suggests the Organization was held to a stricter relevance standard than other applicants.

III. The Organization Will Be Irreparably Harmed If The Hearing Proceeds Without Its Participation.

The "concept of irreparable harm does not readily lend itself to definition," but at least two "indisputable principles" guide the inquiry. *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985).

First, "the injury must be both certain and great; it must be actual and not theoretical." *Id.* "[T]he party seeking injunctive relief must show that the injury complained of is of such *imminence* that there is a clear and present need for equitable relief to prevent irreparable harm." *Id.* (quotation marks and quoting reference omitted) (alterations adopted).

Second, "[i]t is [] well settled that economic loss does not, in and of itself, constitute irreparable harm." *Id.* "The possibility that adequate compensatory or other corrective relief will

be available at a later date, in the ordinary course of litigation weighs heavily against a claim of irreparable harm." *Id.* (quoting *Virginia Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958)).

The Organization will certainly be irreparably harmed if the rulemaking hearing proceeds without its involvement because its participation rights cannot be vindicated after-the-fact. Once the Administrator decides, without the Organization's oral testimony, whether to issue a rule, the cake has been baked. Even if the rule is promulgated as proposed, the Organization will have been harmed because it will have been deprived of the opportunity to challenge the medical and scientific analysis underlying the judgment that schedule III—rather than IV or V—is appropriate for marijuana.

Further, the Organization's harm could not be prevented by "other corrective relief." The very existence of § 555(b) participation shows notice-and-comment is not a sufficient alternative, especially because the Organization sought to participate in part to respond to other participants' live testimony. *See* Ex. A, at 2. And the Organization's injury could not be vindicated through judicial review after the rulemaking hearing without clearing the prejudicial error hurdle. 5 U.S.C. § 706. The only realistic opportunity to prevent the Organization's injury is before the merits hearing.

IV. A Stay Will Cause No Substantial Harm To Other Parties.

The Organization seeks relief that will benefit all participants. Fundamentally, the petition calls for a fair and transparent process at the first and arguably most critical step in these proceedings: the selection of who may participate and present evidence in the hearing. Any delay caused to the other parties "will not be indefinite but will only last through the pendency of

appeal." *Akiachak Native Cmty. v. Jewell*, 995 F. Supp. 2d 7, 18 (D.D.C. 2014). Such delay "does not outweigh the deleterious effect" of a flawed participant selection process and its impact on the evidence before the Agency. *Id.*; *see also Cuomo v. U.S. Nuclear Regulatory Comm'n*, 772 F.2d 972, 977 (D.C. Cir. 1985) ("[W]e test [harm to others] for substantiality, likelihood of occurrence and adequacy of proof."). The Organization intends to take all reasonable steps to reduce the length of delay, including by seeking expedited consideration in the D.C. Circuit.

V. A Stay Would Further The Public Interest By Ensuring A Fair And Transparent Process.

Open and balanced participation in rulemaking proceedings furthers the public interest by ensuring the Agency considers the most relevant evidence on both sides of the question. *See Vilsack*, 237 F. Supp. 3d at 21. This is especially true when the subject of rulemaking is a drug used as medicine by over six million Americans. HHS Recommendation, at 24. The public has a strong interest in being governed only by rules that emerge from a fair process.

But even actual fairness is not enough. Agency proceedings must also be transparent so the public can see they are fair. *See S.E.C. v. Am. Intern. Group*, 712 F.3d 1, 3 (D.C. Cir. 2013) ("The public has a fundamental interest in keeping a watchful eye on the workings of public agencies.") (quotation marks and quoting reference omitted); *In re Sealed Case*, 971 F.3d 324, 329 (D.C. Cir. 2020) ("Given that the subject matter of the suit is whether the agency has reasonably and evenhandedly applied the statutory and regulatory scheme, the public interest in open and transparent proceedings far outweighs the Refinery's conclusory assertions of factually unsubstantiated economic harms."). The Administrator's cloaked selection process—even assuming it resulted in adequate representation on both sides of the question—harms public perception. Public confidence in these proceedings is especially threatened by the many other

unusual circumstances that have cast on them a shadow of impropriety, including the interagency dispute mediated by OLC, the Attorney General's unprecedented decision to initiate rulemaking on his own, and the evidence of *ex parte* communications between the Agency and an anti-rescheduling participant. A stay is appropriate at least to allow the court of appeals time to dispel any public doubt about the integrity of these proceedings.

CONCLUSION AND PRAYER

The tribunal should stay the formal rulemaking hearing scheduled to commence January 21, 2025 pending the D.C. Circuit's decision on the Organization's petition for review.

Dated: December 4, 2024.

Respectfully submitted,

/s/ Austin T. Brumbaugh

Yetter Coleman LLP
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(713) 457-3099
(713) 632-8002 (fax)

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on December 4, 2024 caused a copy of the foregoing to be delivered to the following recipients: (1) James J. Schwartz, Esq., Counsel for the Government, via email at james.j.schwartz@dea.gov; Jarrett T. Lonich, Esq., Counsel for the Government, via email at jarrett.t.lonich@dea.gov; and S. Taylor Johnston, Esq., Counsel for the Government, via email at stephen.t.johnston@dea.gov; (2) the DEA Government Mailbox, via email at dea.registration.litigation@dea.gov; (3) Shane Pennington, Esq., Counsel for Village Farms International, via email at spennington@porterwright.com; and Tristan Cavanaugh, Esq., Counsel for Village Farms International, via email at tcavanaugh@porterwright.com; (4) Nikolas S. Komyati, Esq., Counsel for National Cannabis Industry Association, via email at nkomyati@foxrothschild.com; William Bogot, Esq., Counsel for National Cannabis Industry Association, via email at wbogot@foxrothschild.com; and Khurshid Khoja, Esq., Counsel for National Cannabis Industry Association, via email at khurshid@greenbridgelaw.com; (5) John Jones and Dante Picazo for Cannabis Bioscience International Holdings, via email at ir@cbih.net; (6) Andrew J. Kline, Esq., Counsel for Hemp for Victory, AKline@perkinscoie.com; and Abdul Kallon, Esq., Counsel for Hemp for Victory, via email at and AKallon@perkinscoie.com; (7) Erin Gorman Kirk for the State of Connecticut, via email at erin.kirk@ct.gov; (8) Ellen Brown for Massachusetts Cannabis Advisory Board, via email at ellen@greenpathtraining.com; (9) Shanetha Lewis for Veterans Initiative 22, via email at info@veteransinitiative22.com; (10) Jason Castro, Esq., Counsel for The Doc App., Inc. d/b/a My Florida Green, via email at jasoncastro@myfloridagreen.com; (11) Kelly Fair, Esq., Counsel for The Commonwealth Project, via email at Kelly.Fair@dentons.com; (12) Rafe Petersen, Esq., Counsel for Ari Kirshenbaum, via email at Rafe.Petersen@hklaw.com; (13) David G. Evans, Esq., Counsel for Cannabis Industry Victims Educating Litigators, Community Anti-Drug Coalitions of America, Phillip Drum, Kenneth Finn, International Academy on the Science and Impacts of Cannabis, and National Drug and Alcohol Screening Association, via email at thinkon908@aol.com; (14) Patrick Philbin, Esq., Counsel for Smart Approaches to Marijuana, via email at pphilbin@torridonlaw.com; and Chase Harrington, Esq., Counsel for Smart Approaches to Marijuana, via email at charrington@torridonlaw.com; (15) Stephanie E. Masker, Esq., Counsel for National Transportation Safety Board, via email at stephanie.masker@ntsb.gov; (16) Eric Hamilton, Esq., Counsel for the State of Nebraska, via email at eric.hamilton@nebraska.gov; and Zachary Viglianco, Esq., for the State of Nebraska, via email at zachary.viglianco@nebraska.gov; (17) Gene Voegtlin for International Association of Chiefs of Police, via email at voegtlin@theiacp.org; (18) Gregory J. Cherundolo for Drug Enforcement Association of Federal Narcotics Agents, via email at executive.director@afna.org; (19) Reed N. Smith, Esq., Counsel for the Tennessee Bureau of Investigation, via email at Reed.Smith@ag.tn.gov; and Jacob Durst, Esq., Counsel for Tennessee Bureau of Investigation, via email at Jacob.Durst@ag.tn.gov; (20) Jim Skinner for National Sheriff's Association, via email at sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org; (21) Sephida Artis-Mills for United Empowerment Party, via email at sephida@unitedempowermentparty.org; (22) Office of the Administrator, DEA via email at DEA.ADDO.attorneys@dea.gov.

EXHIBIT A

September 26, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152.
Subject: Docket No. DEA-1362, Request for Participation

Dear Sir or Madam:

Doctors for Drug Policy Reform (the "Organization") and the undersigned, Bryon Adinoff, M.D., hereby requests to participate in the matter of "Schedules of Controlled Substances: Rescheduling of Marijuana" (89 Fed. Reg. 44597).[1]

I. Introduction

Doctors for Drug Policy Reform, or D4DPR (formerly known as Doctors for Cannabis Regulation) supports removing cannabis in all its forms from the Controlled Substances Act. In the context of the proposed rule, however, it is the Organization's position that the medical, scientific, and other evidence supports a Schedule V (alternatively, schedule IV) classification for "marijuana," "marijuana extract," and "naturally derived delta-9-tetrohydrocannabinols" and requests to participate in same in support of its position.

First, the 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.

Second, while the Organization agrees with HHS that marijuana should be removed from Schedule I, it contends that the evidence, properly considered, supports a classification below Schedule III. Relative to substances in Schedule III and Schedule IV, marijuana has a low potential for abuse and lower psychological/physical dependence.[2] In support of its position, the Organization intends to present fact and expert testimony/opinion from two of its members with relevant expertise, Drs. Bryon Adinoff and David Nathan, and whose CVs/bios are attached. The HHS analysis failed to fully and properly evaluate the relative abuse potential and psychological/physical dependence of marijuana abuse compared to Schedule III, IV, and V drugs, even though the statute requires this analysis and prior scheduling actions involving other drugs

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[1] The Organization previously submitted a request for hearing. For good measure, it also offers this submission.

[2] The Organization notes that "abuse," "dependence," and marijuana are terms in the statute. The use of statutory terms herein indicates no agreement on the propriety of their use in other contexts. For example, "drug abuse" is no longer a diagnosis in DSM-V and therefore, abuse should not be used by medical professionals.

have done it too. At the requested hearing, the Organization intends to provide testimony and evidence on this matter to assist the agency in its final determination.

The Organization also seeks to offer testimony on the issue of the meaning and application of the statutory term "abuse," particularly as it relates to cannabis use. Both FDA and DEA in the past have applied a definition of "drug abuse" as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect."[3] Accordingly, "abuse potential" abuse potential refers to "the likelihood that abuse will occur with a particular drug product or substance with CNS activity."

These definitions, however, are not generally accepted by the medical profession. Rather, drug or substance abuse, as used in the statute, should be understood to capture use or excessive use of a drug in a way that is harmful or detrimental to self, society, or both.[4] This difference is particularly important in assessing the research and epidemiological evidence. A drug like cannabis that is widely available is often used without a prescription but not in a way that is harmful. Indeed, there is currently no way to "prescribe" cannabis, so all cannabis use is used without a prescription.

The Administrative Procedure Act provides "as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function." 5 U.S.C. § 555(b). It similarly provides that the "agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." 5 U.S.C. § 556.

Because the Organization would adversely affected by the proposed rule, has interests that differ from other potential participants, intends to provide non-cumulative evidence to assist the agency's final determination, and is well-suited to cross-examine evidence put forward by industry and rescheduling opponents alike, it requests a rulemaking hearing or to participate in same in support of its position.[5]

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[3] See, for example, https://www.fda.gov/media/116739/download.

[4] The legislative history and agency precedent indicates that a determination that "potential for abuse" should not "be determined on the basis of isolated or occasional nontherapeutic purposes," but rather "there must exist a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community." 76 Fed. Reg. 77330 at 336. Based on this definition, not all cannabis use, whether medicinal or recreational, would constitute abuse.

[5] See *Animal Legal Defense Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 22-23 (D.D.C. 2017) (citing *Nichols v. Bd. of Trustees of Asbestos Workers Local 24 Pension Plan*, 835 F.2d 881, 896-97 (D.C. Cir. 1987)).

II. Interests of the person in the proceeding.

The Organization is a 501(c)(3) non-profit organization that serves as a global voice for licensed health professionals and scientists advocating for evidence-based drug policies and best practices that advance public health, reduce stigma, and minimize harm. Its website is located at https://www.d4dpr.org/.

In 2015, Dr. David Nathan founded the Organization as Doctors for Cannabis Regulation to bridge the gap between the policy of prohibition and the unregulated legalization of cannabis. The Organization has been dedicated to that mission ever since. Since that time, it has served as the premier national physicians' association committed to the responsible regulation of cannabis in the United States and abroad, a global advocate, and represents the voices of over 400 physicians and licensed medical practitioners, in support of evidence-based cannabis regulation and legalization. The Organization is comprised of doctors, nurses, pharmacists—many if not nearly all of whom are registrants.

The Organization is frequently called upon to provide expert testimony in significant legislative and administrative contexts unaffiliated with the cannabis industry. It provided testimony for the first-ever Congressional subcommittee hearing on cannabis legalization and on dozens state-level initiatives and bills pertaining to medical and adult-use cannabis. The Organization frequently collaborates with other advocacy groups to educate the public, including on rescheduling. The Organization is not affiliated with the cannabis industry.

As noted on its website, the Organization also offers curriculums on cannabis education, each of which has been carefully vetted by our D4DPR Board and Experts.

The Organization and its members not only have a particularized interest and are affected by the proposed rule, but are in the best position to provide relevant, material, and not unduly repetitious evidence sought by the agency.[6]

III. Objections or issues concerning which the person desires to be heard.

As an organization of health care professionals and scientists formed years ago to bridge the gap between the policy of prohibition and the unregulated legalization of cannabis, the Organization is generally interested in participating a hearing central to its longstanding mission.

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[6] The Organization and its members are also interested parties considering the differences between Schedule III and Schedule V substances, for example, in dispensing limits for prescriptions. 21 U.S.C. § 829. These differences directly members of the Organization. The Organization further notes that rescheduling (even from I to III) could adversely impact its members because it may affect how medical marijuana is recommended/prescribed or dispensed, which at present, is done based on recommendations and not prescriptions due to its Schedule I status.

The Organization's participation will ensure that the evidence presented by both industry and rescheduling opponents alike are placed in the proper medical and scientific context.

In addition to general participation, as to specific and particularized issues of interest to the Organization, the Organization wishes to be heard on the following two issues.

a. **Physical and psychological dependence *relative* to Schedule III, IV, and V compounds and relative potential for abuse.** The HHS recommendation states that marijuana was compared to controlled substances in schedule III (ketamine) and schedule IV (benzodiazepines, zolpidem, and tramadol), as well as to other schedule II substances (fentanyl and hydrocodone). Without much additional explanation, the recommendation states that it "evaluated the totality of the available data and have concluded that it supports the placement of marijuana in Schedule III." It is unclear, however, whether and how HHS performed a relative potential for abuse and dependence analysis compared to Schedule III and IV substances.

b. **The meaning of "abuse" / "abuse potential" and its application to marijuana.** Historically, FDA and/or DEA has defined "drug abuse" as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect." But this definition or concept is not generally accepted in the medical community, and what constitutes abuse with a culturally available and sanctioned substance cannot be based on whether, on occasion, an individual consumes the substance on their own initiative rather than based on medical advice. Just like few would consider having a glass of wine with dinner to be alcohol abuse, few medical professionals would seriously consider smoking marijuana once a week on Friday to relax after work to be "abuse." The definition of "abuse" and "abuse potential" is important because it undergirds the HHS findings with respect to marijuana's "potential for abuse." Properly considered, marijuana does not have a "potential for abuse" any greater than drugs in the benzodiazepine class (Schedule IV).

IV. <u>Brief Statement on the Issues.</u>

a. **Physical and psychological dependence *relative* to Schedule III, IV, and V compounds and relative potential for abuse.** The HHS recommendation does not appear to do a meaningful comparative analysis in assessing scheduling factor three, even though the statute demands that in determining a final scheduling placement among Schedules III, IV, or V, the agency must compare physical and psychological dependence among them.[7] Notably, both agencies have done this analysis in the past.

[7] For example, Schedule III, factor 3 (21 U.S.C. § 812(b)(3)(C)) is "Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence," while Schedule IV, factor 4 (21 U.S.C. § 812(b)(4)(C)) is "Abuse of the drug or other

For example, the agency concluded in 2013 that Lorcaserin should be placed in Schedule IV (78 Fed. Reg. 26701), based on an abuse potential study comparing lorcaserin to zolpidem (Schedule IV) and ketamine (Schedule III). The agency concluded in 2005 that pregabalin warranted Schedule V placement because "withdrawal effects of pregabalin are less severe than with other substances currently controlled in Schedule IV." (70 Fed. Reg. 43633.)

The HHS analysis on relative abuse potential, reproduced below, is hard to understand:

> *[T]he rank order of these substances regarding harms does not consistently align with the relative scheduling placement of these drugs in the CSA due to the pharmacological differences between various classes of drugs.*
>
> *There are a number of confounding factors that likely influence the adverse outcomes measured in various epidemiological databases and account for the rank ordering of the drugs evaluated on these measures. For example, each substance has associated with it a different population that abuse that substance, a different prevalence of abuse, and a different profile of severe adverse outcomes in a setting of nonmedical use and abuse. Thus, it is challenging to reconcile the ranking of relative harms associated with the comparators used in this evaluation when the rankings differ across various epidemiological databases, and when these rankings often do not align with the scheduling placement of these comparators under the CSA.* ***To address these challenges, we evaluated the totality of the available data and have concluded that it supports the placement of marijuana in Schedule III.***

The Organization does not believe this analysis is sufficient, and it intends to provide detailed testimony from two witnesses on the low physical and psychological dependence of cannabis relative to Schedule III and IV substances.[8] In particular, the analysis does not properly compare cannabis to the benzodiazepine class in Schedule IV, and it is well documented that benzodiazepine abuse results in significant physiological and psychological dependence. The proposed rule similarly recognizes that the public health risk of benzodiazepines is substantially greater than the risk presented by cannabis. The evidence will show that compared to benzodiazepines, abuse of marijuana leads to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

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substance may lead to limited physical dependence or psychological dependence *relative to the drugs or other substances in schedule III*." To determine whether a drug properly is placed in Schedule III or IV, it is therefore necessary to consider the relative dependence of the substance compared to other substances in Schedule III. The same can be said of Schedules IV and V.

[8] One witness has recognized expertise in addiction and substance use disorders. The other has expertise in cannabis policy and psychiatry.

b. **The meaning of "abuse" / "abuse potential" and its application to marijuana.** Marijuana, like most drugs, can be "abused." But what constitutes "abuse" in the context of a culturally available and state-regulated substance cannot be based simply on whether, on occasion, an individual consumes the substance on their own initiative rather than based on medical advice, without any harm to the individual. Few would consider a glass of wine with dinner to be alcohol "abuse." Likewise, occasional marijuana consumption that presents no individual or societal harm is not "abuse." The proposed rule recognizes that "the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others." None of that is "abuse," and in assessing prevalence as part of a potential for abuse assessment, DEA should neither include medical uses of marijuana nor non-problematic non-medical uses.

All notices to be sent pursuant to the proceeding should be addressed to:

Bryon Adinoff
812 S Gaylord St
Denver, CO 80209

David L. Nathan, MD, DFAPA
Princeton Psychiatry & Consulting, LLC
601 Ewing Street, Suite C-10
Princeton, NJ 08540

and

Matthew C. Zorn
Yetter Coleman LLP
811 Main Street, Ste. 4100
Houston, TX 77002

Respectfully yours,

Bryon Adinoff, M.D.
President, Doctors for Drug Policy Reform

EXHIBIT B

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Bryon Adinoff
812 S Gaylord St.
Denver, CO 80209
mzorn@yettercoleman.com
adinoff@d4dpr.org

Dear Bryon Adinoff,

This is in response to your request, for a hearing and/or to participate in a hearing, to the Drug Enforcement Administration (DEA) regarding the notice of proposed rulemaking (NPRM) to transfer marijuana from schedule I of the Controlled Substances Act (CSA) to schedule III of the CSA. See Schedules of Controlled Substances: Rescheduling of Marijuana, 89 FR 44597 (May 21, 2024) and 89 FR 70148 (Aug. 29, 2024).

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. See 21 CFR 1300.01(b), 1308.44(a), 1308.44(b), 1316.47, 1316.48; see also Placement of Lorcaserin Into Schedule VI, 78 FR 26701 (May 8, 2013); Placement of Lacosamide Into Schedule V, 74 FR 23789 (May 21, 2009); Rescheduling of the FDA Approved Product Containing Synthetic Dronabinol From Schedule II to Schedule III, 64 FR 35928 (July 2, 1999); Placement of Pemoline in Schedule IV, 40 FR 4150 (Jan. 28, 1975). Therefore, DEA has decided not to grant your request.

Sincerely,

THOMAS PREVOZNIK

Digitally signed by THOMAS PREVOZNIK
Date: 2024.11.25 14:30:07 -05'00'

Thomas W. Prevoznik
Assistant Administrator
Diversion Control Division

EXHIBIT C

UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT
333 CONSTITUTION AVENUE, NW
WASHINGTON, DC 20001-2866
PHONE: 202-216-7000 | FACSIMILE: 202-219-8530

Case Caption: Doctors for Drug Policy Reform; Dr. Bryon Adinoff

Petitioners,

v. Case Number: 24-1365

United States Drug Enforcement Administration;
Anne Milgram, in her official capacity as
Administrator of the United States Drug Enforcement
Administration

Respondents.

PETITION FOR REVIEW OF AN AGENCY, BOARD, COMMISSION, OR OFFICER

Notice is hereby given this the 27th day of November 2024, that petitioners Doctors for Drug Policy Reform and Dr. Bryon Adinoff hereby petitions the United States Court of Appeals for the District of Columbia Circuit for review of the orders of the respondents United States Drug Enforcement Administration and Anne Milgram, entered the 28th day of October 2024 and the 25th day of November 2024, respectively.

Attorney for Petitioners,

Matthew C. Zorn
Yetter Coleman LLP
811 Main Street, Suite 4100
Houston, Texas 77002
(713) 632-8077

Certificate of Service

I certify that a copy of the foregoing was served on all counsel of record and parties entitled to receive notice though the Court's CM/ECF system on this November 27, 2024.

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Michelle Rutter Friberg, Director of Government Relations
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/s/ Matthew C. Zorn
Matthew C. Zorn

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

October 28, 2024

Hon. John J. Mulrooney, II
Chief Administrative Law Judge
Office of Administrative Law Judges
8701 Morrissette Drive
Springfield, VA 22152

Dear Chief Judge Mulrooney,

On May 21, 2024, the Department of Justice published a notice of proposed rulemaking (NPRM) to transfer marijuana from schedule I of the Controlled Substances Act (CSA) to schedule III of the CSA. *See* *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 FR 44597 (May 21, 2024). Upon review of the requests for hearing on the NPRM, I authorized a hearing to be conducted in accordance with the Administrative Procedure Act (APA), the CSA, and the Drug Enforcement Administration (DEA) regulations. *See* *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 FR 70148 (Aug. 29, 2024).

Pursuant to my authority under the CSA and DEA regulations, I reviewed the requests for a hearing under 21 CFR 1308.44(a) and 1316.47, and the requests to participate under 21 CFR 1308.44(b) and 1316.48, and I have determined that the following will be participants at the hearing:

1. Village Farms International Inc.
   Shane Pennington of Porter Wright, spennington@porterwright.com

2. National Cannabis Industry Association
   Aaron Smith, CEO and Co-Founder, and Michelle Rutter Friberg, Director of Government Relations, aaron@thecannabisindustry.org and michelle@thecannabisindustry.org

3. American Academy of Hospice and Palliative Medicine
   Dr. Chad Kollas, MD, wchill@aahpm.org

4. Cannabis Bioscience International Holdings
   John Jones, Treasurer and Director, ir@cbih.net

5. Hemp for Victory
   Robert Head, Dr. Corey Burchman, Dr. Darinia Douchi, and Victor Bohm, robert@bluecordfarms.com

6. Cannabis Ombudsman, State of Connecticut
   Erin Gorman Kirk, Erin.Kirk@ct.gov

7. Massachusetts Cannabis Advisory Board
   Ellen Brown, Research Subcommittee Chair, ellen@greenpathtraining.com

8. Veterans Initiative 22
   Shanetha Lewis, Executive Director, info@veteransinitiative22.com

9. The Doc App. Dba, My Florida Green
   Nicholas Garulay, President and CEO, and Jason Castro, Inhouse Counsel, jasoncastro@myfloridagreen.com

10. The Commonwealth Project
    Katy Green, kag@platinumadvisors.com

11. Saint Michael's College
    Ari Kirshenbaum, PhD, Professor of Psychology, mslade@cannabispublicpolicyconsulting.com

12. National Drug and Alcohol Screening Association (NDASA)
    Jo McGuire, jomcguire@ndasa.com

13. Smart approaches to Marijuana (SAM)
    Patrick Philbin, pphilbin@torridonlaw.com

14. International Academy on the Science and Impact of Cannabis
    Roneet Lev, roneetlev@gmail.com

15. Cannabis Industry Victims Educating Litigators
    David Evans, Sr. Counsel, thinkon908@aol.com

16. Kenneth Finn, MD, kfinn@springsrehab.net

17. National Transportation Safety Board (NTSB)
    Jennifer Homendy, Chair, ExecutiveSecretariat@ntsb.gov and correspondence@ntsb.gov

18. Phillip Drum, Pharm D, phillipdrum@comcast.net

19. State of Nebraska
Attorney General Mike Hilgers, zachary.viglianco@nebraska.gov

20. International Association of Chiefs of Police (IACP)
voegtlin@theiacp.org

21. Drug Enforcement Association of Federal Narcotics Agents (DEAFNA)
marshallfisher@rocketmail.com

22. American College of Occupational and Environmental Medicine (ACOEM)
Natalie P. Hartenbaum, occumedix@comcast.net cc: craig@acoem.org

23. Community Anti-Drug Coalitions of America (CADCA)
Sue Thau, cdoarn@cadca.org

24. Tennessee Bureau of Investigation (TBI)
kim.litman@tbi.tn.gov

25. National Sheriff's Association
sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org

Further, an Administrative Law Judge (ALJ) is now designated to preside over the hearing. The ALJ's functions commence upon this designation. *See* 21 CFR 1316.52. The designated ALJ will have powers necessary to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. *Id.* The ALJ's authorities include the power to hold conferences to simplify or determine the issues in the hearing or to consider other matters that may aid in the expeditious disposition of the hearing; require parties to state their position in writing; sign and issue subpoenas to compel the production of documents and materials to the extent necessary to conduct the hearing; examine witnesses and direct witnesses to testify; 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. *Id.*

Sincerely,

Anne Milgram
Administrator

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Bryon Adinoff
812 S Gaylord St.
Denver, CO 80209
mzorn@yettercoleman.com
adinoff@d4dpr.org

Dear Bryon Adinoff,

This is in response to your request, for a hearing and/or to participate in a hearing, to the Drug Enforcement Administration (DEA) regarding the notice of proposed rulemaking (NPRM) to transfer marijuana from schedule I of the Controlled Substances Act (CSA) to schedule III of the CSA. See Schedules of Controlled Substances: Rescheduling of Marijuana, 89 FR 44597 (May 21, 2024) and 89 FR 70148 (Aug. 29, 2024).

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. See 21 CFR 1300.01(b), 1308.44(a), 1308.44(b), 1316.47, 1316.48; see also Placement of Lorcaserin Into Schedule VI, 78 FR 26701 (May 8, 2013); Placement of Lacosamide Into Schedule V, 74 FR 23789 (May 21, 2009); Rescheduling of the FDA Approved Product Containing Synthetic Dronabinol From Schedule II to Schedule III, 64 FR 35928 (July 2, 1999); Placement of Pemoline in Schedule IV, 40 FR 4150 (Jan. 28, 1975). Therefore, DEA has decided not to grant your request.

Sincerely,

THOMAS PREVOZNIK

Digitally signed by THOMAS PREVOZNIK
Date: 2024.11.25 14:30:07 -05'00'

Thomas W. Prevoznik
Assistant Administrator
Diversion Control Division