[NOT YET SCHEDULED FOR ORAL ARGUMENT]

IN THE UNITED STATES COURT OF APPEALS
FOR THE D.C. CIRCUIT

Doctors for Drug Policy Reform, *et al.*, Petitioners, v. Drug Enforcement Administration, *et al.*, Respondents.	No. 24-1365

OPPOSITION TO EMERGENCY MOTION FOR AN INJUNCTION PENDING APPEAL

Earlier this year, the Attorney General issued a notice of proposed rulemaking that contemplates transferring marijuana from schedule I under the Controlled Substances Act to schedule III. 89 Fed. Reg. 44597, 44597 (May 24, 2024). The Department of Justice received 43,564 comments in response to that proposal. Regulations.gov, *Schedules of Controlled Substances: Rescheduling of Marijuana*, https://perma.cc/6JEE-TNYJ.

Consistent with the Controlled Substances Act's requirement for rulemaking "on the record after opportunity for a hearing," 21 U.S.C. § 811(a), a formal hearing has been scheduled to begin January 21, 2025.

Mot. 494.[1] More than 160 individuals and entities asked to participate in that hearing. Add. 2. Due to concerns about administrability, relevance, and the scope of the hearing, the Administrator of the Drug Enforcement Administration (DEA) (the relevant agency within the Department) identified 25 individuals and entities to participate in the live hearing by presenting opening arguments, soliciting testimony from witnesses, submitting evidence, participating in cross-examination, and presenting closing arguments. Mot. 39-41, 490-93. Due to the extensive nature of this evidentiary hearing, the agency currently expects that it will last, at least, from January 21 to March 6. Mot. 494-95.

Petitioners are an individual and entity who were not selected to present live evidence at the hearing, but who did make a written submission in response to the notice of proposed rulemaking, and DEA will consider those comments in the course of the rulemaking. 21 C.F.R. § 1308.43(g). Petitioners seek extraordinary relief: they ask this Court to enjoin the formal rescheduling hearing because they are disappointed that DEA selected other participants to participate in it. While petitioners

[1] Citations to "Mot." refer to petitioners' motion for an injunction pending appeal and the page number of that ECF filing. Citations to "Add." refer to the addendum attached to this opposition.

characterize their request as a motion for a stay, relief in their favor would enjoin Executive Branch rulemaking, and in all events petitioners must satisfy the same stringent substantive standards. *Nken v. Holder*, 556 U.S. 418, 434 (2009).

Petitioners identify no error made by DEA in managing what could easily become an unwieldy hearing lasting months—if not years—if all 163 assertedly interested persons were permitted to participate. Nor do petitioners identify any injury that could not be cured on judicial review of whatever final rule DEA adopts. And the public interest supports a decision without undue delay about how marijuana should be regulated under the Controlled Substances Act. The motion for an injunction should be denied.[2]

STATEMENT

I. Legal Framework and Background

A. Congress established a comprehensive regulatory regime for marijuana and other drugs when it enacted the Controlled Substances Act

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[2] Petitioners separately seek expedition of a merits briefing schedule. The government does not oppose expedition of the briefing schedule or the Court's consideration of the case, so long as the government receives the normal 30 days in which to file a merits brief. But for the same reasons that an injunction is unwarranted, the Court should not impose petitioners' extraordinarily compressed expedition proposal.

in 1970. Pub. L. No. 91-513, title II, part A, 84 Stat. 1236, 1242 (1970) (codified at 21 U.S.C. § 801 *et seq*.). The Act "consolidate[d] various drug laws on the books into a comprehensive statute" that would establish regulation for "legitimate sources of drugs" and "prevent diversion into illegal channels." *Gonzales v. Raich*, 545 U.S. 1, 10 (2005). 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 Controlled Substances Act. *Id*. at 13 (citing 21 U.S.C. §§ 841(a)(1), 844(a)).

The Act divides controlled substances into five schedules "based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body." *Raich*, 545 U.S. at 13-14 (citing 21 U.S.C. §§ 811, 812). Schedule I substances are defined as having "no currently accepted medical use in treatment in the United States" and a high risk for abuse, while schedule II-V substances have currently accepted medical uses and decreasing risks of abuse and dependence. 21 U.S.C. § 812(a)-(b).

Congress placed marijuana within schedule I. 21 U.S.C. § 812(c), sch. I (c)(10). But Congress did not expect the schedules to stay forever static, and granted the Attorney General authority to add, remove, or reschedule substances as appropriate based on new scientific and medical evidence.

Id. § 811(a)-(b). Such rescheduling can be initiated on a petition from an interested party, at the request of the Secretary of Health and Human Services (HHS), or on the Attorney General's own motion. *Id.* § 811(a). In making a rescheduling determination, Congress directed the Attorney General to consider a number of statutory factors, such as the drug's potential for abuse, the current scientific knowledge about the drug, risks to the public health, and the drug's psychic or physiological dependence liability. *Id.* § 811(c). Congress also instructed the Attorney General to comply with the United States' obligations to regulate controlled substances as required by "international treaties" then in effect, including the Single Convention on Narcotic Drugs, 18 U.S.T. 1407. *See* 21 U.S.C. § 811(d); *id.* § 801(7) (citing the Single Convention).

B. Soon after the Controlled Substances Act was passed, a private organization petitioned the Attorney General to remove marijuana from the Act's schedules or to move marijuana to schedule V. *National Organization for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 741 (D.C. Cir. 1977). The Department declined to reschedule marijuana and, on review, this Court remanded for further proceedings but concluded that marijuana was likely subject to a "minimum control regime of [] Schedule II" consistent with "the limits authorized by" the Single

Convention. *Id.* at 757. The Department ultimately initiated a formal rulemaking in late 1986, where "[s]even organizations or individuals participated." 54 Fed. Reg. 53767, 53773 (Dec. 29, 1989). The formal rulemaking included multiple prehearing conferences, submitted evidence from all parties, fourteen days of live hearings in three different cities, proposed findings from all parties, responses by the government, and rebuttals by the parties. *Id.* The administrative law judge who presided over the hearing then issued a recommended decision, which the DEA Administrator reviewed. *Id.* The entire process, from first notification of the hearing to final decision of the Administrator (keeping marijuana in schedule I), took three and a half years. *Id.* at 53773, 53784-85.

The parties to that rulemaking sought judicial review and this Court remanded for further proceedings. *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937 (D.C. Cir. 1991). After additional explanation by the DEA Administrator, this Court held that the Department acted reasonably in declining to reschedule marijuana, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1132-33 (D.C. Cir. 1994). The Court has rejected additional efforts to compel the rescheduling of marijuana since then. *See, e.g.*, *Krumm v. DEA*, 739 F. App'x 655 (D.C. Cir. 2018) (per curiam); *Americans for Safe Access v. DEA*, 706 F.3d 438 (D.C. Cir. 2013).

II. Current Proceedings to Reschedule Marijuana

A. Scientific and medical research into marijuana has continued in the intervening decades. *See Craker v. DEA*, 44 F.4th 48, 52, 55 (1st Cir. 2022) (discussing the Department's regulatory approval of researchers who seek to "lawfully manufacture and cultivate cannabis for research purposes"). So too has public discourse about the proper regulation of marijuana. In 2022, the President directed the Attorney General and the HHS Secretary to review "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. The agencies did so, and HHS issued a recommendation that marijuana be moved to schedule III. 89 Fed. Reg. at 44599.

In response, the Attorney General "sought the legal advice of the Office of Legal Counsel," 89 Fed. Reg. at 44599, including whether marijuana's placement in schedule III would satisfy the United States' obligations under the Single Convention, *Questions Related to the Potential Rescheduling of Marijuana*, 48 Op. O.L.C., slip op. 1, 4 (2024) (OLC Opinion), https://perma.cc/6DLD-75W9. The Office of Legal Counsel concluded that the question was "a close one," *id.* at 28, but that marijuana could be placed in schedule III with additional regulations, *id.* at 33. The

Office of Legal Counsel did not address whether marijuana could be placed in schedule IV or V.

After receiving that opinion, the Attorney General issued a notice of proposed formal rulemaking to transfer marijuana from Schedule I to Schedule III. 89 Fed. Reg. at 44597. The threshold issue in the rulemaking will be whether marijuana has a "currently accepted medical use in treatment in the United States" because all controlled substances without a currently accepted medical use must be placed in schedule I, while controlled substances with medical uses may be placed on less restrictive schedules. 21 U.S.C. § 812(b)(1)-(5). Whether marijuana has a currently accepted medical use has consistently been the primary focus of all previous rescheduling decisions, *e.g.*, *Alliance for Cannabis Therapeutics*, 930 F.2d at 938; *Americans for Safe Access*, 706 F.3d at 439-41, and the Department of Justice has recently taken a broader view of what may constitute currently accepted medical use, OLC Opinion 16-20.

The public submitted 43,564 comments in response to the Attorney General's proposal, *supra* p. 1, which the Attorney General explained "will be offered as evidence at the hearing" under 21 C.F.R. § 1308.43(g), and considered by the Department if "competent, relevant, material, and not unduly repetitive," 89 Fed. Reg. at 44598. The DEA Administrator later

issued a notice that the rescheduling hearing would begin December 2, 2024, 89 Fed. Reg. 70148, 70148-49 (Aug. 29, 2024). More than 160 individuals and entities asked to participate in that hearing. Add. 2. The Administrator considered those scores of requests and identified 25 persons and entities (in addition to the federal government) who may give live testimony, present argument, and conduct cross-examination as part of the hearing. Mot. 39-41, 490-93.

In an initial hearing on December 2, 2024, an administrative law judge (ALJ) assigned to the rescheduling proceeding conferred with the government and the designated participants. Mot. 489. All of the participants intend to present witnesses and documents. Mot. 490-91. The evidentiary portion of the hearing is currently expected to begin January 21, 2025, and to run through March 6, 2025. Mot. 494-95.

B. Petitioners are an organization, Doctors for Drug Policy Reform, and its president, Dr. Byron Adinoff. Mot. 3. Petitioners submitted a comment in response to the notice of proposed rulemaking, which the Department considered along with the thousands of other submitted comments. Regulations.gov, *Comment on FR Doc # 2024-11137*, https://perma.cc/TRN6-TMXW.

Petitioners also requested to participate in the formal hearing. Mot. 365. Petitioners stated that they believed marijuana has a currently accepted medical use and would "present additional evidence to support that assessment," but petitioners did not identify any evidence they intended to present. Mot. 365-70. Instead, petitioners focused on a different issue—whether marijuana's potential for abuse and dependence was lower than that of other schedule III drugs and therefore warranted placement in schedules IV or V. Mot. 365-66, 368-70.

DEA denied petitioners' request to participate in the hearing. Mot. 43. DEA explained that petitioners had not "sufficiently state[d] with particularity the relevant evidence on a material issue of fact that [they] intended to present during the hearing." *Id.* DEA further noted that petitioners had not sufficiently explained how they might be "adversely affected or aggrieved," 21 C.F.R. § 1300.01(b), by the proposed rescheduling of marijuana to schedule III to qualify as an "interested person" under the relevant statute and regulations. *Id.* (citing § 1300.01).

Petitioners then asked the ALJ overseeing the rescheduling proceeding for permission to intervene. Mot. 541-42. The ALJ denied that request, explaining that DEA "is endowed with the right to place reasonable limits on the number of participants in a given [Administrative

Procedure Act] hearing." Mot. 542. The ALJ recognized that "thousands upon thousands of individuals and entities across the country could add value to the issues to be decided here, but they cannot all be included." *Id.*

Petitioners then asked the ALJ for an "indefinite stay of the [rescheduling] proceedings," Mot. 32, while they sought review in this Court of DEA's decision to select some—but not all—of the 163 requesting parties to participate in the formal hearing, Add. 2. The ALJ denied that request, explaining that "it would be illogical to expect any agency" to admit every possible participant to formal rulemakings, as "[p]roceedings would theoretically never reach a resolution." Mot. 33-34. As a practical matter, not "all can be included, and someone (in this case the Agency) must make that determination." Mot. 34.

C. In addition to petitioners, more than a dozen individuals and entities have all sought to intervene in the evidentiary hearing for the formal rulemaking. *See* DEA, *Administrative Law Judge Orders*, https://www.dea.gov/administrative-law-judge-orders (last visited December 20, 2024). Like petitioners, David Heldreth and Panacea Plant Sciences also sought a stay of the hearing based on their non-selection to participate in the formal hearing, which the ALJ denied. *Id.*

Heldreth responded by suing in district court and seeking a temporary restraining order of the hearing because he had not been chosen to participate. Order at 1, *Heldreth v. Garland*, 24-1817 (W.D. Wash. Nov. 27, 2024). The district court denied that request, holding that Heldreth failed to establish irreparable harm and that an injunction would do more harm than good. *Id.* at 4-6. Other parties have likewise begun to seek judicial review. Veterans Action Council has filed a petition with this Court, seeking an order to "allow our group to participate in the hearings." Petition at 1, *Veterans Action Council v. DEA*, No. 24-1374 (D.C. Cir. Dec. 5, 2024).

ARGUMENT

An injunction pending appeal—like a preliminary injunction—is "an extraordinary remedy never awarded as of right." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 24 (2008). A petitioner "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Id.* at 20.

Thus, petitioners here "must clear a 'high standard' and demonstrate that their injury is 'both certain and great,'" and that "their injury is

sufficiently serious that there is a 'clear and present need for equitable relief' on an expedited timeline and without the benefit of full factual development and hurried consideration of legal questions." *Alpine Securities Corp. v. FINRA*, 121 F.4th 1314, 1332 (D.C. Cir. 2024). Because petitioners fail to meet these "stringent requirements for an injunction pending appeal," *Archdiocese of Washington v. Washington Metropolitan Area Transit Authority*, 877 F.3d 1066, 1066 (D.C. Cir. 2017) (per curiam), the Court should decline their request to enjoin the pending rescheduling proceeding.[3]

I. Petitioners Fail to Demonstrate Any Irreparable Harm

Petitioners assert that they will be irreparably injured if they cannot "present relevant evidence in support of rescheduling marijuana" at the formal rulemaking hearing. Mot. 21-22. Yet petitioners have already submitted their views to the Attorney General when they commented on the notice of proposed rulemaking, *supra* p. 9, and their comment will be considered as part of the rulemaking, 21 C.F.R. § 1308.43(g). Petitioners express concern about the ALJ's statements regarding the mechanism for

[3] This Court has cast doubt on the "'sliding scale' approach" that petitioners invoke, Mot. 8. *See, e.g.*, *Changji Esquel Textile Co. v. Raimondo*, 40 F.4th 716, 726 (D.C. Cir. 2022).

admitting comments into the record, *see* Mot. 22, but the comments that have been submitted are plainly part of the administrative record and will be before the Administrator for decision, *see* 89 Fed. Reg. at 44598 (citing § 1308.43(g)). That petitioners must present their views only in writing, rather than both in writing and through live testimony, falls far short of the "certain and great" irreparable harm that would be needed to derail DEA's rescheduling proceeding. *Alpine Securities*, 121 F.4th at 1332.

Petitioners cite no authority that a party suffers irreparable injury when—as part of formal rulemaking—it may submit written evidence and comments to the agency but is not selected to give live testimony and argument as part of the hearing. Petitioners are of course free to seek judicial review if they are aggrieved by the eventual final rule that DEA promulgates. 21 U.S.C. § 877 (judicial review provision). In doing so, they can press their apparent arguments concerning the appropriate scheduling of marijuana, whether the rulemaking was prejudiced by any alleged errors in the admission of evidence, 5 U.S.C. § 706, and whether the ultimate scheduling decision is "supported by substantial evidence," *Alliance for Cannabis Therapeutics*, 15 F.3d at 1137. This Court can thus correct any cognizable errors on eventual judicial review of a final rule. Petitioners'

alleged injury—based on the process of the rulemaking—can be reviewed and remedied retrospectively if warranted.[4]

Petitioners' failure to satisfy the irreparable-injury requirement is a sufficient reason to deny the motion. *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 676 (D.C. Cir. 1985) (per curiam).

II. Petitioners Are Not Likely to Succeed on the Merits

A. The DEA Administrator Appropriately Limited Live Participation in the Formal Rulemaking Hearing

Petitioners are unlikely to succeed on their claims, which, at bottom, contest the DEA Administrator's decision to limit live participation in the formal rulemaking hearing to 25 identified parties.[5] As this Court has recognized, "[n]o principle of administrative law is more firmly established than that of agency control of its own calendar." *City of San Antonio v. Civil Aeronautics Board*, 374 F.2d 326, 329 (D.C. Cir. 1967). In conducting this formal rulemaking, permitting argument, testimony, and cross-examination from 163 different entities on a variety of different topics

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[4] If petitioners seek judicial review of DEA's final rule, they of course will be required to demonstrate standing under Article III—that is, that "they suffer direct and particularized harms due to the misclassification of cannabis." *Sisley v. DEA*, 11 F.4th 1029, 1034 (9th Cir. 2021).

[5] Due to voluntary withdrawals, Mot. 441 nn.1-3, the hearing is scheduled for 20 parties in addition to the federal government, Mot. 494-95.

"could produce a proceeding of virtually unlimited proportions and would seriously delay" DEA's consideration of whether marijuana should be rescheduled, "a matter which is deemed by the President and the [agency] to be one of high priority." *Id.*

This Court applied that reasoning in holding that the Civil Aeronautics Board (in conducting a proceeding to study air flight) acted appropriately in limiting its consideration to evidence and applications from 25 cities. *City of San Antonio*, 374 F.2d at 327-29. Cities that had not been selected petitioned for this Court's review, arguing—like petitioners here—that the agency had "prejudged" the evidence by failing to select them for participation, that in choosing some participants but not others the agency acted "illegal[ly] per se or arbitrarily applied as to them," and that the agency's decision otherwise did not comply with the Administrative Procedure Act. *Id.* at 328. This Court rejected those contentions, holding that the agency acted properly in keeping the proceeding "within manageable limits lest the [agency] be paralyzed in performing its function." *Id.* at 329.

City of San Antonio further rejected the petitioners' argument that "all persons interested in a proceeding have a right to participate as full parties." 327 F.2d at 331. To the contrary, the Court recognized that many

entities had a similar interest in the pending proceeding, and "similar treatment would be required for hundreds of other cities similarly situated." *Id.* at 332. The Court declined to require the agency to make scores upon scores of entities full parties to the proceeding. Instead, the Court explained that agencies "should be accorded broad discretion in establishing and applying rules for public participation, including how many are reasonably required to give the [agency] the assistance it needs in vindicating the public interest." *Id.* (ellipses omitted). Accordingly, the agency acted within its discretion in declining to grant the petitioners party-status. *Id.* at 333.

Consistent with that holding, the DEA Administrator "exercis[ed] her discretion in determining the number and nature of participants," Mot. 542, because it would be impractical to include all 163 individuals and entities who wished to participate in the formal hearing. But the Department ensured that all interested entities could submit their views and any supporting evidence in writing. 21 C.F.R. § 1308.43(g). If any of those entities are dissatisfied with marijuana's scheduling after the proceeding concludes, they may seek judicial review of the final rule, or their arguments can be "heard by the [agency] in a later proceeding," *City of San Antonio*, 374 F.2d at 330, by themselves petitioning DEA to further

reschedule marijuana, 21 U.S.C. § 811(a) (permitting citizen petitions for rescheduling).

The Administrator's decision further reasonably recognized that petitioners have not specified any evidence they would present on the threshold issue that determines whether marijuana can be moved from schedule I at all: whether marijuana has a currently accepted medical use. *See* 21 U.S.C. § 812(b). Instead, petitioners assert that they would prefer to present evidence and argument about whether—instead of placing marijuana in schedule III as the proposed rule and HHS's recommendation contemplate—marijuana should be placed in schedule IV or V.[6]

"Courts have long accorded agencies broad discretion in fashioning rules to govern public participation and have for the most part permitted denials of requests" to participate when it "would broaden unduly the issues considered, obstruct or overburden the proceedings, or fail to assist the agency's decision-making." *Nichols v. Board of Trustees of Asbestos*

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[6] Whether such a rescheduling would comport with the United States' obligations under the Single Convention is an open question, *see supra* pp. 5-8, and petitioners have not offered any argument on that point. *Compare* John J. Cohrrsen & Lawrence H. Hoover, *The International Control of Dangerous Drugs*, 9 J. Int'l L. & Econ. 81, 95-96 (1974) (describing the Single Convention's requirements), *with* 21 U.S.C. §§ 822-832 (requirements by schedule).

Workers Local 24 Pension Plan, 835 F.2d 881, 897 (D.C. Cir. 1987). DEA acted well within that discretion by providing that petitioners may submit their views in writing instead. Although petitioners erroneously intimate that this decision reflects hostility by DEA, this Court has explained that similar case-management orders were "necessitated by practical management considerations," and fail to demonstrate that the agency "acted irrationally or arbitrarily." *City of San Antonio*, 374 F.2d at 330.

B. Petitioners Do Not Challenge Final Agency Action, and They Fail to Demonstrate a Clear and Indisputable Right to Mandamus Relief

1. Petitioners are further unlikely to succeed on the merits because they fail to demonstrate that they have a "clear and indisputable" right to relief under mandamus. *In re Cheney*, 406 F.3d 723, 729 (D.C. Cir. 2005) (en banc). Under 21 U.S.C. § 877, parties can seek appellate court review of "final decisions" issued by DEA, *i.e.*, decisions that "clearly determine[]" a party's rights and "establish[] legal consequences." *John Doe, Inc. v. DEA*, 484 F.3d 561, 566-67 (D.C. Cir. 2007) (quotation marks omitted). But unlike a party seeking review of a DEA permitting decision, *id.*, a final rule, *Alliance for Cannabis Therapeutics*, 15 F.3d at 1134, a denial of rulemaking, *Americans for Safe Access*, 706 F.3d at 441-42, or an adjudication, *Chein v. DEA*, 533 F.3d 828, 834 (D.C. Cir. 2008), petitioners

here do not challenge any final action that definitively binds their legal rights in a way that would qualify as final agency action.

Instead, petitioners challenge DEA's direction that certain parties, but not others, should participate in a formal hearing to promulgate an eventual rule. But "[i]t is firmly established that agency action is not final merely because it has the effect of requiring a party to participate in an agency proceeding." *Arch Coal, Inc. v. Acosta*, 888 F.3d 493, 503 (D.C. Cir. 2018) (collecting cases). And petitioners cite no authority that a concomitant decision to exclude some parties from a hearing—but not from making written submissions—is so qualitatively different as to constitute final agency action. That makes good sense, as this Court has explained that an agency's decision to "determine the scope of its own proceedings and arrange its business accordingly" does "not impose, deny, or fix any legal right." *Puget Sound Traffic Association v. Civil Aeronautics Board*, 536 F.2d 437, 439 (D.C. Cir. 1976) (quotation marks omitted).

Because petitioners do not challenge final agency action, the only potential basis for petitioners' request would be this Court's mandamus jurisdiction to control and adjust pending proceedings that will eventually result in an order that can be directly reviewed in this Court. *Telecommunications Research and Action Center v. FCC*, 750 F.2d 70, 75-

77 (D.C. Cir. 1984); *accord In re Multidisciplinary Association for Psychedelic Studies*, 2004 WL 2672303, at *1 (D.C. Cir. Nov. 22, 2004) (reviewing pending DEA proceedings under mandamus standards). Petitioners do not affirmatively invoke this Court's mandamus authority, and they fail to demonstrate the necessary predicates to mandamus: that they have a clear and indisputable right to appear in person at the formal hearing, or that there is "no other adequate means to attain" relief, such as "the regular appeals process." *Cheney v. U.S. District Court*, 542 U.S. 367, 380-81 (2004). If petitioners are aggrieved by a final rule, they can seek judicial review and assert that alleged future errors in a final rule were caused by their lack of live participation.

2. Even if a more forgiving standard of review applied, petitioners' assertions of error would still fail. They assert that the DEA Administrator lacks authority to select participants for the hearing and that only the ALJ can do so. Mot. 11-13. Petitioners cite no precedent so holding, and there is no serious dispute that the ALJ retains all authority necessary to conduct the hearing and issue a recommended decision under 5 U.S.C. §§ 553(c), 556-557. Agencies, of course, regularly initiate proceedings that determine which parties must participate without delegating that question exclusively to the ALJ. *See, e.g.*, *Arch Coal*, 888 F.3d at 497-98.

Petitioners likewise err in claiming that the Attorney General somehow deprived the DEA Administrator of authority to manage participation in the hearing. Mot. 13-15. The Attorney General has generally delegated all his functions under the Controlled Substances Act to the DEA Administrator, 28 C.F.R. § 0.100(b), which includes overseeing rescheduling hearings. Petitioners note that the notice of proposed rulemaking contemplated that there may be an in-person hearing and that an ALJ might preside, Mot. 14-15 (quoting 89 Fed. Reg. at 44598-99), but nothing in the notice purported to deprive the Administrator of any of her authority. To the contrary, the Administrator made clear in the Department's later order scheduling the hearing that she would "make a determination of participants," 89 Fed. Reg. at 70149, and petitioners identify nothing suggesting that the Attorney General disapproved of that necessary exercise of judgment to make the hearing logistically feasible.

Petitioners are also incorrect in asserting that the agency "provided no explanation" for its decision to limit participation in the hearing. Mot. 17. To the contrary, in addition to the logistical reasons explained above—that formal rulemaking with hundreds of participants would be impractical—the agency explained that petitioners "did not sufficiently state with particularity the relevant evidence" petitioners would present "on a

material issue of fact." Mot. 43. In their motion, petitioners urge that they would seek to demonstrate that (1) marijuana's potential for creating dependence is less than drugs in schedules III and IV drugs, and (2) DEA's "definition of 'drug abuse' [is] overbroad because it included marijuana use not harmful to self or others." Mot. 21. Petitioners fail to explain how this evidence is relevant to the threshold issue that determines whether marijuana can be moved from schedule I at all—whether marijuana has a "currently accepted medical use." 21 U.S.C. § 812(b). It was thus entirely appropriate for the agency to consider this information in written form rather than through live testimony.

Petitioners further err in claiming that they have been treated differently from similarly situated entities who were selected to participate. Mot. 19-21. Petitioners compare themselves to Kenneth Finn, a physician who was selected to participate at the hearing and asserts that the "lack of satisfactory research into cannabis and the absence of any dosing guidelines * * * render him unable to competently prescribe or administer the substance as a drug for his patients." Mot. 458. Regardless of whether the agency ultimately agrees with those assertions, that proposed evidence is surely relevant to the threshold question of whether marijuana has "a currently accepted medical use in treatment in the United States," 21 U.S.C.

§ 812(b), and is qualitatively different from the evidence proposed by petitioners.

The agency also informed petitioners that their papers did not "sufficiently establish that" they were "an 'interested person' under DEA regulations," Mot. 43, meaning a person who would be "adversely affected or aggrieved by" the proposed rule, 21 C.F.R. § 1300.01(b). Although petitioners assert that they believe marijuana might be better placed in schedule IV or V, they do not explain how they would be harmed if, under the proposed rule, it were placed in schedule III. And to the extent that such rescheduling decisions concern legal questions, those issues "can be addressed, as a matter of law, without conducting a fact-finding hearing." 64 Fed. Reg. 35928, 35929 (July 2, 1999).

III. The Equities Counsel Against an Injunction

Petitioners fundamentally misunderstand the equities[7] when they insist that the Court should enjoin the rescheduling hearing now, lest the Court review a final rule at the end of the proceeding. Mot. 23. The public interest supports a decision on rescheduling marijuana without undue

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[7] The final factors for whether to issue an injunction pending appeal (the balance of harms and the public interest) "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009).

delay. Multiple entities are already seeking judicial intervention based on their desire to participate in the formal hearing, notwithstanding their opportunity for written submissions. *Supra* pp. 11-12. Each of the 138 applicants to participate who were not selected could equally claim that a court should resolve whether they too can participate before rescheduling goes forward. It is not in the public interest to derail this proceeding while individuals and entities litigate the format of their participation. To the contrary, the "public's interest [is] in certainty and prompt decision," *Windmoller v. Laguerre*, 284 F. Supp. 563, 564-65 (D.D.C. 1968), not in permitting litigants to halt this proceeding indefinitely, *accord* Order at 5-6, *Heldreth v. Garland*, 24-1817 (W.D. Wash. Nov. 27, 2024) (declining to enjoin the rescheduling hearing).

CONCLUSION

The Court should deny the emergency motion for an injunction pending appeal.

Respectfully submitted,

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DECEMBER 2024

CERTIFICATE AS TO PARTIES

Respondents certify the following information regarding the parties in this petition for review. D.C. Cir. R. 8(a)(4), 28(a)(1).

A. Parties

All parties, intervenors, and amici appearing before the agency and in this Court are listed in the motion for petitioners.

CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with the requirements of Fed. R. App. P. 27(d)(1)(E), 32(a)(5), and 32(a)(6) because it has been prepared in 14-point Georgia, a proportionally spaced font. I further certify that this motion complies with the page limitations of Fed. R. App. P. 27(d)(2)(A) because it contains 5,118 words, according to the count of Microsoft Word.

/s/ Daniel Aguilar
Daniel Aguilar

CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2024, I electronically filed the foregoing with the Clerk of the Court by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

/s/ Daniel Aguilar
Daniel Aguilar

ADDENDUM

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Doctors for Drug Policy Reform, *et al.*, Petitioners, v. United States Drug Enforcement Administration, *et al.*, Respondents.	No. 24-1365

DECLARATION OF HEATHER ACHBACH

I, Heather Achbach, pursuant to 28 U.S.C.§ 1746, and based upon my personal knowledge and information made known to me in the course of my employment, hereby make the following declaration with respect to the above-captioned matter:

1. I currently serve as the Acting Section Chief of the Diversion Control Division's Regulatory Drafting and Policy Support Section (DPW). In my role as Acting Section Chief of DPW, I have been designated to act as a DEA Federal Register Liaison Officer to the Office of the Federal Register. In that capacity, I am authorized to sign and submit documents to the Office of the Federal Register as official documents of DEA. The Regulatory Drafting and Policy Support Section is also responsible for receiving all public comments in response to a notice of proposed rulemaking (NPRM) and posting those comments received on public view at Regulations.gov. During the most recent Hearing Notice period the section also received all requests for hearing through a specially designated email box monitored by DPW staff, who then transmitted the requests to the appropriate legal office in DEA.

2. Earlier this year, the DEA Administrator issued a notice that the agency "will hold a hearing with respect to the proposed rescheduling of marijuana into schedule III of the Controlled Substances Act." 89 Fed. Reg. 70148, 70148 (Aug. 29, 2024). The notice directed interested persons who wished to participate in the hearing to "file a written notice of intention to participate" for DEA's review by September 30, 2024. *Id.* at 70149.

3. In response to this notice, DEA received 123 separate requests to participate in the hearing from 163 total individuals and entities. Out of these requests, the DEA Administrator selected 25 entities to participate in the hearing.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on December 13, 2024

/s/ HEATHER ACHBACH Digitally signed by HEATHER ACHBACH Date: 2024.12.13 09:34:01 -07'00'

Heather E. Achbach
Acting Section Chief
Regulatory Drafting and Policy Support (DPW)
Diversion Control (DC)
Drug Enforcement Administration