[ORAL ARGUMENT NOT SCHEDULED]

Nos. 26-1106, 26-1136 (consol.)

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

SAM, INC., et al.,

Petitioners,

v.

UNITED STATES DEPARTMENT OF JUSTICE, et al.,

Respondents.

NEW DIRECTIONS ADDICTION RECOVERY SERVICES, et al.,

Petitioners,

v.

DONALD J. TRUMP, in his official capacity as President of the United States, et al.,

Respondents.

On Petition for Review of a Final Order
by the Acting Attorney General

OPPOSITION TO MOTION FOR STAY PENDING REVIEW

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Petitioners in No. 26-1106 are SAM, Inc. and National Drug and Alcohol Screening Association, Inc. Respondents are United States Department of Justice; Todd Blanche, in his official capacity as Acting Attorney General; Drug Enforcement Administration (DEA); and Terrance Cole, in his official capacity as DEA Administrator.

Petitioners in No. 26-1136 are New Directions Addiction Recovery Services; Kenneth Finn, M.D.; Elizabeth B. Stuyt, M.D.; Cannabis Industry Victims Educating Litigators; MMJ International Holdings, Inc.; MMJ Biopharma Cultivation, Inc.; and MMJ Biopharma Labs, Inc. Respondents are Donald J. Trump, in his official capacity as President of the United States; Todd Blanche, in his official capacity as Acting Attorney General; United States Department of Justice; DEA; and Terrance Cole, in his official capacity as DEA Administrator.

A motion for leave to intervene in support of respondents has been filed by MedPharm Iowa, LLC, d/b/a Bud & Mary's, and Tri-Mountain Pure, LLC. An amicus brief in support of respondents has been filed by a

group of attorneys representing the cannabis industry: David K. Sergi, David C. Holland, Robert Hoban, and Tyson Daniel. No other amici have appeared in this Court.

B. Rulings Under Review

Petitioners seek review of an order issued by the Acting Attorney General on April 22, 2026, Attorney General Order No. 6754-2026, which places products containing marijuana that have been approved by the Food and Drug Administration and marijuana subject to state-issued licenses in schedule III of the Controlled Substances Act. *See Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana From Schedule I to Schedule III; Corresponding Change to Permit Requirements*, 91 Fed. Reg. 22714 (Apr. 28, 2026). The order is attached to the petitioners' stay motion as Exhibit A.

C. Related Cases

These cases are consolidated with a third petition for review, *Nebraska v. DOJ*, No. 26-1130 (D.C. Cir.). The consolidated cases have not previously been before this Court or any court. Counsel for respondents are unaware of any related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

/s/ *McKaye L. Neumeister*
McKaye L. Neumeister

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GLOSSARY

APA	Administrative Procedure Act
CSA	Controlled Substances Act
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NDASA	National Drug and Alcohol Screening Association, Inc.

INTRODUCTION

In April, the Acting Attorney General issued an order transferring two kinds of marijuana from schedule I under the Controlled Substances Act (CSA) to schedule III: marijuana in drugs approved by the Food and Drug Administration (FDA), and marijuana subject to a state-license for medical use. Because marijuana is required to be controlled by the Single Convention on Narcotic Drugs, the CSA permits the Attorney General to "issue an order controlling" that substance "under the schedule he deems most appropriate to carry out such [treaty] obligations." 21 U.S.C. § 811(d)(1).

Here, the Department of Justice has already concluded that the United States can satisfy its treaty obligations if marijuana were controlled under schedule III. *Questions Related to the Potential Rescheduling of Marijuana*, 48 Op. O.L.C., 2024 WL 2412009, at *3 (Apr. 11, 2024) (OLC Op.). And the Department of Health and Human Services (HHS) has already recommended that marijuana be placed in schedule III. Off. of the Assistant Sec'y for Health, HHS, *Basis for the Recommendation to Reschedule Marijuana Into Schedule III of the Controlled Substances Act* (Aug. 29, 2023), https://perma.cc/U2LB-LZNW (HHS recommendation). Thus, as this Court has explained, the Acting Attorney General was

authorized to "establish[] a minimum schedule or level of control," which here was the same level of control recommended by HHS's "medical and scientific findings." *National Org. for Reform of Marijuana L. (NORML) v. DEA*, 559 F.2d 735, 747 (D.C. Cir. 1977). Accordingly, under 21 U.S.C. § 811(d), the Acting Attorney General was authorized to issue the scheduling order "without regard to the referral and hearing procedures prescribed by [§ 811](a)-(c)." *NORML*, 559 F.2d at 744.

Petitioners are various entities and individuals opposed to the rescheduling of marijuana who have challenged the rescheduling order. A subset of those petitioners now moves for a stay pending appeal, asserting that the order was procedurally defective because the government did not engage in formal rulemaking or notice-and-comment rulemaking procedures. Petitioners come nowhere near satisfying the demanding standard for that extraordinary relief.

The petitioners moving for a stay are an association representing drug screeners and employers who require drug testing, and a pharmaceutical company that "develops cannabinoid therapeutics" that have "yet to see fruition." *Smart Approaches to Marijuana v. Kennedy*, 2026 WL 1453886, at *4 (D.D.C. May 22, 2026) (discussing MMJ petitioners). Petitioners fail to establish Article III standing—the association fails to identify concrete

harm to any of its individual members, and the pharmaceutical company fails to demonstrate competitor standing when it has not yet produced an authorized product to compete in the marketplace. Nor do petitioners' asserted injuries fall within the CSA's zone of interests. Congress enacted the CSA to ensure the proper regulation of substances for research and medical use—it did not enact the CSA to provide drug screeners with a permanent source of income for testing marijuana, nor did it enact the law to protect "market opportunities" for the creation of "cannabinoid-based drugs." Stay Mot. 20 (Mot.).

And petitioners fail to demonstrate a likelihood of success on either of their claims. This Court's decision in *NORML* explains that when the Attorney General can reschedule a drug consistent with international obligations under 21 U.S.C. § 811(d), that scheduling does not require formal rulemaking under § 811(a). 559 F.2d at 744-47. And the notice-and-comment requirements of the Administrative Procedure Act (APA) do not apply to rescheduling orders issued under § 811(d). Petitioners' assertion of irreparable injury is also speculative at best, and the public interest and balance of equities counsel against a stay. The motion should be denied.

STATEMENT

A. Legal Framework and Background

1. Congress established a comprehensive regulatory regime for marijuana and other drugs when it enacted the Controlled Substances Act in 1970. Pub. L. No. 91-513, tit. II, pt. A, 84 Stat. 1236, 1242 (1970). The CSA "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 CSA." *Id.* at 13 (citing 21 U.S.C. §§ 841(a)(1), 844(a)).

The CSA 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 HHS, or on the Attorney General's own motion. *Id.* § 811(a). Rescheduling usually requires the Attorney General to seek scientific and medical recommendations from HHS, *id.* § 811(b), and to engage in formal rulemaking, *id.* § 811(a), that considers 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).

The CSA also ensures that the United States can satisfy its obligations under international treaties, including the Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S 151, which requires the control of cannabis, *id.* arts. 2(1), 28. *See also* 21 U.S.C. § 811(d); *id.* § 801(7) (citing the Single Convention). Congress thus granted the Attorney General authority to schedule substances where "control is required by United States obligations under international treaties" in effect

at the time of the CSA's enactment, *id.* § 811(d)(1), *i.e.*, the Single Convention. In those circumstances, the Attorney General may "issue an order controlling such drug under the schedule he deems most appropriate" for the treaty obligations "without regard to" other requirements, *id.*, including the formal rulemaking procedures in § 811(a) and the procedures to consult with HHS in § 811(b).

2. In *NORML*, a private organization petitioned for marijuana to be removed from the CSA's schedules entirely or moved to schedule V. *NORML*, 559 F.2d at 741. The Department of Justice denied that petition, but this Court remanded for further proceedings, explaining that the Attorney General had failed to meaningfully consider how to both comply with the United States' treaty obligations and meaningful recommendations from HHS based on their scientifical and medical findings. *Id.* at 745-47. The Court explained that 21 U.S.C. § 811(d) permits the Attorney General to schedule a substance "without regard" to other statutory requirements "only to the extent that placement in that schedule is necessary to satisfy United States international obligations." *Id.* at 746. Because marijuana could be placed on a lower schedule consistent with treaty obligations, *id.* at 750-51, and because HHS had not given meaningful medical and scientific recommendations, *id.* at 749-50, the Attorney General could not deny a

rescheduling petition solely under § 811(d), but instead must seek recommendations from HHS under § 811(b), *id*. at 757.

B. Recent Actions Regarding the Rescheduling of Marijuana

1. Following *NORML*, the Attorney General for decades kept marijuana as a schedule I substance. *See Americans for Safe Access v. DEA*, 706 F.3d 438, 439-41 (D.C. Cir. 2013). Scientific and medical research into marijuana has continued, however, and the Department of Justice in recent years has expanded regulatory approval for people who seek to "lawfully manufacture and cultivate cannabis for research purposes." *Craker v. DEA*, 44 F.4th 48, 52, 55 (1st Cir. 2022). In 2022, the President directed the Attorney General and the HHS Secretary to review "how marijuana is scheduled under federal law." Press Release, The White House, *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), https://perma.cc/CQF7-V6GZ. The agencies did so, and in 2023 HHS issued a recommendation that marijuana be moved to schedule III. *See* HHS recommendation.

In response, the Attorney General "sought the legal advice of the Office of Legal Counsel," 89 Fed. Reg. 44597, 44599 (May 21, 2024), including whether marijuana's placement in schedule III would satisfy the United States' obligations under the Single Convention, OLC Op., 2024 WL

2412009. The Office of Legal Counsel concluded that the Attorney General "may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions." *Id.* at *24.

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. A formal evidentiary hearing was initially scheduled but was later postponed indefinitely and ultimately terminated. 91 Fed. Reg. 22778, 22779 (Apr. 28, 2026).

2. In December 2025, the President issued an Executive Order titled *Increasing Medical Marijuana and Cannabidiol Research*. The order directs the Attorney General to "take all necessary steps to complete the rulemaking process related to rescheduling marijuana to Schedule III of the CSA in the most expeditious manner in accordance with Federal law, including 21 U.S.C. [§] 811." Exec. Order No. 14,370, § 2(a), 90 Fed. Reg. 60541, 60542 (Dec. 23, 2025).

3. In April, the Acting Attorney General initiated a new hearing to determine whether marijuana should be placed on schedule III. 91 Fed.

Reg. 22777, 22777-78 (Apr. 28, 2026).[1] Simultaneously, he issued an order under 21 U.S.C. § 811(d) "to move FDA-approved drug products containing marijuana and marijuana subject to state-issued [medical marijuana] licenses to Schedule III." 91 Fed. Reg. 22714, 22716 (Apr. 28, 2026).

The Acting Attorney General explained that "there are several legally viable scheduling options that would satisfy the United States' obligations under the Single Convention." 91 Fed. Reg. at 22718. Accordingly, he chose to "exercise [his] discretion in determining the most appropriate schedule by choosing the option that most closely aligns to HHS's findings" in its 2023 recommendation, "and best positions the United States to carry out its obligations under the Single Convention." *Id.*

The order recognized that certain regulatory amendments were required to ensure that placing these marijuana products in schedule III would comply with the Single Convention. Specifically, the Single Convention requires "permit[s] for the importation and exportation" of marijuana, and "a government agency [to] serve as the exclusive purchaser of cannabis production." 91 Fed. Reg. at 22716, 22720. The Acting Attorney General thus amended the applicable "regulations to require a

[1] The hearing began on June 29, 2026, and is scheduled to conclude by July 15.

permit to import or export" the rescheduled marijuana products, *id.* at 22717; *see* 21 C.F.R. § 1312.30(b)-(d), and further "establish[ed] a new registration pathway for state-licensed medical marijuana entities" to obtain federal approval and to allow the government to "acquire[] and resell[] registered manufacturers' marijuana crops," 91 Fed. Reg. at 22720; *see* 21 C.F.R. § 1301.13(k); *see also Craker*, 44 F.4th at 54 (explaining the treaty requirements).

C. This Litigation

Several advocacy groups, states, individuals, and organizations have petitioned this Court for judicial review of the rescheduling order. 21 U.S.C. § 877. But only a subset of those petitioners have moved for a stay pending appeal, and we limit our discussion to these movant-petitioners for purposes of this response.

Petitioners are a trade association representing the drug and alcohol screening industry (National Drug and Alcohol Screening Association, Inc. (NDASA)), and a "private pharmaceutical cannabinoid development company" and its subsidiaries (MMJ). Stay Motion (Mot.) 2-3; MMJ Pet. for Review 12 (MMJ Pet.). Petitioners assert that the order was procedurally improper under the CSA and the APA, in excess of statutory

authority, and arbitrary and capricious. NDASA Pet. 2; MMJ Pet. 13-18. They now move for a stay pending appeal.

ARGUMENT

To secure the "exceptional relief" of a stay pending review, "the stay applicant must (1) make a strong showing that it is likely to succeed on the merits; (2) demonstrate that it will be irreparably injured before the appeal concludes; (3) show that issuing a stay will not substantially injure the other parties interested in the proceeding; and (4) establish that the public interest favors a stay." *KalshiEX LLC v. Commodity Futures Trading Comm'n*, 119 F.4th 58, 63 (D.C. Cir. 2024) (alteration omitted) (quoting *Nken v. Holder*, 556 U.S. 418, 434 (2009)). The third and fourth factors "merge when the Government is the opposing party." *Nken*, 556 U.S. at 435.

I. Petitioners Are Not Likely To Succeed On The Merits.

A. Petitioners have not established Article III standing to challenge the rescheduling order.

1. As a trade association proceeding as the representative of its members (Mot. 19), NDASA must satisfy the requirements of associational standing and show that "'at least one of its members would have standing to sue in [their] own right.'" *Animal Legal Def. Fund, Inc. v. Vilsack*, 111 F.4th 1219, 1225 (D.C. Cir. 2024). It has failed to do so. Instead, NDASA's

declaration contains generalized speculation about how the rescheduling order might affect the drug-testing industry rather than particularized allegations about how the order has affected specific members of the association.

a. NDASA asserts that some of its members are "employers that require drug-screening for their employees," and they will "incur costs" in changing their drug-testing policies. Mot. 20; *see* Mot. Ex. B ¶¶ 11-15. Although NDASA purports to have "700 employer members," Mot. Ex. B ¶ 14, it fails to identify a *specific* member who has standing. Consequently, the declaration of NDASA's Executive Director contains only speculation about what a hypothetical employer "may decide" to do in response to the rescheduling order, *id.* ¶ 11, and how much this is estimated to cost employers generally, *id.* ¶¶ 12, 14.

Such allegations are insufficient to establish associational standing. As this Court has explained, "[i]t is not enough to show … that there is a substantial likelihood that at least one member may have suffered an injury-in-fact." *American Chemistry Council v. DOT*, 468 F.3d 810, 820 (D.C. Cir. 2006). Rather, "[a]t the very least, the identity of the party suffering an injury in fact must be firmly established." *Id.*; s*ee Chamber of Com. v. EPA*, 642 F.3d 192, 199 (D.C. Cir. 2011) ("[P]etitioner must

specifically 'identify members who have suffered the requisite harm.'"). Because NDASA offers only generalized speculation and fails to identify a specific member who has been injured, it has not demonstrated standing.

b. NDASA also asserts that, as a result of rescheduling, its members that are drug screeners (medical review officers) will face lost revenue from fewer employers testing for marijuana and "higher costs" required to determine "whether positive results reflect state-licensed medical use." Mot. 19; *see* Mot. Ex. B ¶¶ 23-27.

Those assertions appear to be based entirely on speculation by NDASA's Executive Director. *See* Mot. Ex. B ¶ 16 ("Based on my experience working in a [screening] practice and as Executive Director of NDASA … ."). Although the declaration specifically names three of the "25 medical review officer practices that are NDASA members," *id.* ¶ 27, the declaration does not state that the Executive Director actually spoke with those specific members since the rescheduling order was issued, *id.* ¶ 5 (asserting generally that Executive Director is "routinely informed of the impact that drug rescheduling will have on [screening] practices by our [screening] credentialing associations"). Nor does the declaration explain how the actual clients of these specific members have reacted to the rescheduling order in the two months since its issuance. Instead, based on the Executive

Director's past experience working at a drug screener, the declaration speculates about the effects of the order on the "industry" generally, and provides no details specific to any of NDASA's members. *See id.* ¶¶ 16, 26, 28. And the declaration largely predicts how the clients of drug screeners generally might respond to the order, without citing any clients who have changed or intend to change their practices. *Id.* ¶ 26 ("While some employers will pay the increased costs, most will drop marijuana from their drug testing panel."). Given this generalized discussion and unsubstantiated speculation, NDASA fails to establish standing. *See Vilsack*, 111 F.4th at 1225.

Moreover, the future injuries that NDASA fears would be caused either by the decisions of clients to stop testing for marijuana entirely, or the joint decision of its members and their clients for the drug screener to bear the increased costs of testing. *See* Mot. Ex. B ¶ 26; Mot. 19. Petitioners have not shown that it is "'predictable,'" rather than merely "'speculative,'" that third-party employer-clients will choose to stop testing for illegal marijuana use. *See Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 112 (2025). And any increased costs to drug screeners from their clients' continued testing would be traceable to their voluntary billing decisions, not the rescheduling order. *See National Fam. Plan. & Reprod.*

Health Ass'n v. Gonzales, 468 F.3d 826, 831 (D.C. Cir. 2006) ("[S]elf-inflicted harm … does not amount to an 'injury' cognizable under Article III" and "would not be fairly traceable to the defendant's challenged conduct.").

2. MMJ also has not established standing to pursue its petition for review. MMJ asserts a "competitive injury," claiming that its ability to compete in the market for cannabinoid-based drugs is harmed by the fact that the rescheduling order allows state-licensed products into the market that did not go through the "DEA-FDA regulatory pathway." Mot. 20-21; Mot. Ex. C ¶¶ 33-39.

Under the competitor-standing doctrine, this Court recognizes that parties can establish standing to challenge a government action that "directly increase[s] competition in the affected market." *Air Excursions LLC v. Yellen*, 66 F.4th 272, 280 (D.C. Cir. 2023). To successfully invoke that doctrine, however, a litigant must "show that it is in fact 'a *direct* and *current* competitor' in that market," such that its "'bottom line may be adversely affected by the challenged government action.'" *Id.*; *see PSSI Glob. Servs., LLC v. FCC*, 983 F.3d 1, 11 (D.C. Cir. 2020) (rejecting competitor-standing argument where there was no current "actual participation in the relevant market").

Here, MMJ is not a current market competitor. It has two Investigational New Drug applications pending with the FDA, Mot. Ex. C ¶ 20, but acknowledges that its products have not "complete[d] the clinical trial process," *id.* ¶ 34. MMJ thus cannot satisfy the requirements of competitor standing. *See Smart Approaches to Marijuana*, 2026 WL 1453886, at *11-13 (rejecting similar claim of competitor standing by MMJ).

MMJ also suggests that it is currently suffering harm from its competitive injuries because the "erosion of first-mover advantages, exclusivity opportunities, goodwill, and reputation," Mot. 20-21, affect "investor confidence," Mot. Ex. C ¶ 36. But this Court has already explained that allegations that a prospective market entrant "will be [a] less attractive investment[] if [its future competitors] become more profitable" are insufficient to establish standing. *PSSI Glob. Servs.*, 983 F.3d at 12.

B. Petitioners' alleged injuries are not within the zone of interests of the Controlled Substances Act.

Petitioners also cannot demonstrate a likelihood of success on the merits because their asserted injuries fall outside the zone of interests of the CSA.

To have a valid statutory cause of action, a party's injuries must be "'arguably within the zone of interests to be protected or regulated' by the

[statute]." *Twin Rivers Paper Co. v. SEC*, 934 F.3d 607, 616 (D.C. Cir. 2019). The zone-of-interests test limits challengers to the "'intended beneficiaries' of the statute" or "other 'suitable challengers'—*i.e.*, parties whose interests coincide 'systemically, not fortuitously' with those of intended beneficiaries." *Id.* Challengers who fall outside the zone of interests cannot proceed. Thus, the Court has held that waste treatment plants cannot challenge allegedly lax environmental regulations because they "would urge stricter regulation 'whether the effect on health and the environment [were] good, bad, or indifferent.'" *Id.* at 617. Likewise, a paper company could not challenge a federal securities regulation that allowed regulated entities to place reports online and only mail paper copies upon request. *Id.* at 611. "[S]ellers of paper … are not intended beneficiaries of the securities laws," and "[t]here is no reason to think that" "paper disclosure for all shareholders … system[ically] aligns with the interests of shareholders." *Id.* at 617.

That reasoning applies here. Petitioners—drug screeners, employers who screen for drugs, and a hopeful pharmaceutical company—are not suitable challengers for determining whether certain marijuana products are properly scheduled under the CSA.

The "main objectives" of the CSA are "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Raich*, 545 U.S. at 12. Congress's express findings in enacting the CSA focus on protecting "the health and general welfare of the American people," which is served through the use of controlled substances with "legitimate medical purpose," and harmed by "illegal importation, manufacture, distribution, and possession and improper use." 21 U.S.C. § 801(1)-(2). The intended beneficiaries of the CSA are thus the American public and scientists and medical practitioners seeking legitimate access to controlled substances for research and patient treatment.

Petitioners are not the intended beneficiaries of the CSA, nor do their interests systemically align with those beneficiaries. Petitioners invoke the interests of (1) drug screeners in avoiding loss of business and increased costs; (2) employers in avoiding the costs of revising drug-testing protocols; and (3) a pharmaceutical company (MMJ) in preventing market competition. Petitioners thus invoke pocketbook interests served by keeping all marijuana in schedule I. *See Viasat, Inc. v. FCC*, 47 F.4th 769, 779 (D.C. Cir. 2022) (the injury for zone-of-interests purposes "'must be the same'" as the Article III injury).

Thus, even if rescheduling would unquestionably best serve the public health and the interests of the medical community, petitioners' financial interests would render them opposed to that result. They therefore fall outside the statute's zone of interests: petitioners' interest in categorically stricter regulation results in an "unqualified preference" that is misaligned with the CSA, and their suits are "'more likely to frustrate than to further statutory objectives.'" *See Twin Rivers Paper Co.*, 934 F.3d at 616-17.

C. Petitioners have not demonstrated a likelihood of success on their rulemaking claims.

1. Petitioners also have not shown a likelihood of success on the merits. As this Court has explained, 21 U.S.C. § 811(d) permits the Attorney General to schedule a substance "without regard" to other statutory requirements "only to the extent that placement in that schedule is necessary to satisfy United States international obligations" based on the appropriate "minimum schedule or level of control" that the Attorney General determines. *NORML*, 559 F.2d at 746-47. In other words, § 811(d) "directs the Attorney General, as an initial matter, to make a legal judgment as to controls necessitated by international commitments." *Id.* at 747. Here, the Department of Justice has concluded that marijuana can, consistent with the United States' treaty obligations, be placed in schedule III. OLC Op., 2024 WL 2412009, at *24. As contemplated by this Court's

analysis in *NORML* the Secretary of HHS has determined that marijuana may also be appropriately placed in schedule III based on the relevant "medical and scientific findings," and that recommendation "does not cause" marijuana "to be scheduled in violation of treaty obligations." 559 F.2d at 747; *see* HHS recommendation.

In *NORML*, the Department of Justice conceded that cannabis "could be rescheduled to CSA Schedule II consistent with the Single Convention," and other parts of the marijuana plant could likewise be placed on a less restrictive schedule. 559 F.2d at 750-51, 757. Thus, there were several different "minimum schedule[s]" that would be consistent with treaty obligations, and this Court concluded that "the decision whether to impose controls *more restrictive* than required by treaty implicates the same medical and scientific considerations" that the HHS Secretary usually evaluates in making a recommendation under the CSA. *Id.* at 747 (emphasis added). Accordingly, the HHS Secretary was "manifestly more competent to make these nonlegal evaluations," and the Attorney General was required to seek the Secretary's recommendation before deciding whether to reschedule marijuana. *Id.* But that had not happened in *NORML*—instead, HHS had provided a one-page letter asserting that marijuana did not have a currently accepted medical use based on

"conclusory statements without providing a basis for or explanation of its findings." *Id.* at 742-43, 749. The Court held that this single letter "was not an adequate substitute for the procedures enumerated in" § 811(a)-(c). *Id.* at 749-50.

Here, however, the HHS Secretary for the first time has recommended that marijuana be placed in schedule III, based on a 65-page explanatory memorandum supported by extensive supporting analysis, bibliographies, and statistics. *See* HHS recommendation. HHS's recommendation of schedule III is the same "minimum schedule" the Attorney General has concluded under 21 U.S.C. § 811(d) will also satisfy the United States' treaty obligations. *NORML*, 559 F.2d at 747. Accordingly, the plain text of § 811(d)(1) applies, and the Attorney General may "issue an order controlling" marijuana "under the schedule he deems most appropriate to carry out [treaty] obligations." 21 U.S.C. § 811(d)(1). And the Attorney General may do so "without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section." *Id.*

Petitioners are thus fundamentally mistaken in asserting that the "Rescheduling Order skipped the procedures mandated by sections 811(a)

and (b)." Mot. 13. As they appear to acknowledge (Mot. 5-6), § 811(d) explicitly provides a process for issuing a scheduling order consistent with the Single Convention that does not require the additional rulemaking and referral processes in § 811(a)-(b). And, contrary to their suggestion (Mot. 14), the government does not contend that the requirements in § 811(a)-(b) never apply to drugs covered by our treaty obligations. Rather, when the Attorney General established a "minimum schedule" for a substance, *NORML*, 559 F.2d at 747, and when the HHS Secretary recommends a schedule consistent with those minimum legal obligations, then the Attorney General may follow the procedures in § 811(d) to "issue an order controlling such drug … without regard to [§ 811(a)-(b)]," 21 U.S.C. § 811(d)(1). That process was not followed in *NORML*, and so § 811(d) did not apply; but because that process was followed here, the Acting Attorney General properly exercised his authority under § 811(d).

2. Petitioners separately challenge the parts of the rescheduling order that "impose[] new import-export permit requirements" and provide a system whereby the government can take possession of lawfully grown marijuana for purposes of the Single Convention's article 23 and 28. Mot. 17-18; *see also Craker*, 44 F.4th at 54. Petitioners assert that these requirements must go through notice-and-comment rulemaking, Mot. 18-

19, but petitioners fail to identify any harm caused by that alleged error, which in all events would not warrant a stay of the rest of the rescheduling order, as the order makes clear that it is severable. *See* 91 Fed. Reg. at 22719 n.39.

In any event, the CSA provides that scheduling under 21 U.S.C. § 811(d) is accomplished by "an order," in contrast to scheduling accomplished "by rule" under § 811(a). Accordingly, "the notice-and-comment requirements of the [APA] do not apply to this scheduling action," 91 Fed. Reg. at 22721 (citation omitted), because orders are not rules, *see* 5 U.S.C. § 551(4)-(6) (defining rule, rulemaking, and order).

The order elsewhere explains these requirements were necessary aspects of the rescheduling action, required to ensure that "the United States will continue to meet [its treaty] obligations without delay or disruption." 91 Fed. Reg. at 22716. They are thus part and parcel of the "order controlling such drug under the schedule [the Attorney General] deems most appropriate to carry out such obligations." 21 U.S.C. § 811(d)(1), which Congress intended to be accomplished through specialized, streamlined procedures that did not involve notice-and-comment rulemaking.

II. The Equitable Factors Disfavor A Stay Pending Review.

The remaining equitable factors likewise disfavor a stay pending review.

A. Petitioners fail to show irreparable harm, which is "a necessary prerequisite for a stay." *KalshiEX*, 119 F.4th at 64. Under the "high standard" for irreparable injury, petitioners must establish that, absent relief, they will suffer "certain and great" harm that is "of such *imminence* that there is a 'clear and present' need for equitable relief." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (quotation marks omitted). For largely the same reasons that petitioners' allegations are insufficient for purposes of Article III standing, *supra* pp. 11-16, they have not demonstrated irreparable harm.

NDASA complains that, absent a stay, its members would incur "unrecoverable costs" and lose revenue, which could "threaten the existence of some" members' businesses. Mot. 19-20. But NDASA has not identified any instance of actual harm suffered by an identified member. That failure demonstrates a lack of irreparable harm. NDASA's declaration is consistent with that lack of concrete harm; it is based on generalized conjectures about how members and their clients *might* react to the rescheduling order and the estimated consequences that *might* occur at

some point. *See* Mot. Ex. B ¶¶ 11-15, 22-28. That speculation is insufficient to demonstrate irreparable injury "'of such *imminence*' that equitable relief is urgently necessary." *Chaplaincy*, 454 F.3d at 298.

MMJ asserts harm to a future competitive position it might have in the market for cannabinoid-based drugs. Mot. 20-21. That is not a legally cognizable harm for standing (*supra* pp. 15-16), or for irreparable harm. Moreover, MMJ cannot demonstrate that this alleged harm is "beyond remediation." *Chaplaincy*, 454 F.3d at 297. If petitioners ultimately prevail, MMJ will be in the same position as before the rescheduling order with respect to its various "competitive advantages" and "market opportunities," none of which have yet materialized. Mot. 20. And although petitioners offer the bare assertion that the rescheduling order "'threatens [MMJ's] very existence,'" Mot. 21; *see* Mot. Ex. C ¶ 33, they provide no support for the notion that MMJ is at imminent risk of ceasing operations during this appeal.

B. The government and the public suffer a form of irreparable injury whenever a court enjoins a regulatory action duly undertaken by the people's representatives. *See Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025) ("'Any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable

injury.'" (alteration omitted)). And a stay would interfere with the Acting Attorney General's important efforts to administer the CSA consistent with the Nation's treaty obligations.

Petitioners contend (Mot. 21-22) that the public interest requires a stay due to the harms caused by marijuana use and addiction. But as the rescheduling order recognizes, 40 States have already "legalized the sale and use of marijuana for medical purposes." 91 Fed. Reg. at 22716; *see id.* at 22720. In light of the existing state-level practice, there is no basis for concluding that the limited rescheduling action here would materially contribute to those harms during this appeal.

CONCLUSION

The motion should be denied.

Respectfully submitted,

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JULY 2026

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,198 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 27(d)(1)(E) because it was prepared using Word for Microsoft 365 in Georgia 14-point font, a proportionally spaced typeface.

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CERTIFICATE OF SERVICE

I certify that on July 2, 2026, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

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