No. 26-1106 (Consolidated with Nos. 26-1130, 26-1136)

IN THE

United States Court of Appeals for the District of Columbia Circuit

SAM INC., et al.,
Petitioners,

v.

DEPARTMENT OF JUSTICE, et al.,
Respondents.

On Petition for Judicial Review of Attorney General Order No. 6754–2026

REPLY OF NDASA, MMJ INTERNATIONAL HOLDINGS, INC., MMJ BIOPHARMA CULTIVATION, INC., AND MMJ BIOPHARMA LABS, INC. IN SUPPORT OF A STAY PENDING REVIEW OF THE MARIJUANA RESCHEDULING ORDER

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July 16, 2026

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GLOSSARY

Act (or CSA)	Controlled Substances Act of 1970
APA	Administrative Procedure Act
DEA	Drug Enforcement Administration
HHS	Department of Health and Human Services
MRO	Medical Review Officer
MMJ	MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., & MMJ BioPharma Labs, Inc.
NDASA	National Drug and Alcohol Screening Association
Rescheduling Order	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)

This Court should stay the Rescheduling Order pending appeal. The government's standing and zone-of-interests arguments are meritless diversions from its indefensible position on the merits. Movants will suffer irreparable harm, and the balance of equities plainly favors a stay.

ARGUMENT

I. Absent A Stay, Movants Will Sustain Irreparable, Article III Injuries.

The government's standing and irreparable-harm arguments are meritless.

1. NDASA members will suffer at least two forms of irreparable, Article III injury.

First, the Rescheduling Order imposes unrecoverable costs on Medical Review Officer (MRO) practices, which will force some to go out of business. McGuire Decl. ¶¶ 25-28. Because the Order renders marijuana legal for state "medical" use, MROs will need to perform time-intensive checks to determine whether positive THC tests are attributable to licit uses. *See id.* ¶¶ 21-25; Moore Decl. ¶ 10 (Ex. 1). That causes unrecoverable losses—irreparable harm—in two ways. *See In re NTE Conn., LLC*, 26 F.4th 980, 990-91 (D.C. Cir. 2022) (unrecoverable losses are irreparable harm). First, NDASA's MRO members will absorb some of the new costs themselves, incurring unrecoverable losses that cannot be dismissed as mere "voluntary billing decision[s]." Opp. 14. Second, whatever they do not absorb themselves will be passed on through higher prices, which will

cause some clients to drop marijuana testing. *See* Moore Decl. ¶¶ 13-14. It is not "speculative" that some clients will drop more expensive testing; it is the inevitable result of the "commonsense economic realit[y]"—often relied on by courts—that demand falls as prices rise. *See Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 116 (2025); Moore Decl. ¶ 16 ("nearly certain" that employers will cease marijuana testing).[1]

Second, the Rescheduling Order compels the many NDASA members that require employee drug testing either to (1) drop marijuana testing and live with the substantial risk of impaired-employee accidents and diminished productivity, or (2) pay substantially more to test for marijuana and risk Americans With Disabilities Act (ADA) or state-law liability for acting on positive tests.[2] *See* McGuire Decl. ¶ 11; Moore Decl. ¶¶ 15-16. Either way, these members—like Utility Safety &

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[1] Contrary to the government's speculative quibbles (Opp. 13), NDASA's declarant *did* speak with all three NDASA MRO members named in her declaration. *See* McGuire Supp. Decl. ¶ 5 (Ex. 4); *e.g.*, Moore Decl. ¶ 4.

[2] *See* 42 U.S.C. §§ 12112(a), 12112(d)(1) (ADA prohibition on discriminatory use of medical examinations); *id.* § 12114(d)(1) (testing for *illegal* drugs permitted); *id.* § 12114(a)-(b) (similar); *James v. City of Costa Mesa*, 700 F.3d 394, 397, 401 (9th Cir. 2012) (holding that state-legal "medical marijuana use [wa]s not protected by the ADA" because, at the time, marijuana was federally unlawful as a Schedule I drug); *see, e.g.*, Palliative Use of Marijuana Act (PUMA), Conn. Gen. Stat. §§ 21a-408p(b)(3), 21a-408(20) (prohibiting adverse employment action against state "medical" marijuana users); *Noffsinger v. SSC Niantic Operating Co., LLC*, 338 F. Supp. 3d 78, 81, 84 (D. Conn. 2018) (PUMA prohibits "a zero tolerance drug testing policy").

Design, Inc. (USDI), *see* Landis Decl. ¶ 19 (Ex. 2)—face irreparable injury in the form of substantially increased risk of liability and unrecoverable compliance costs in revising their testing policies. *See NRDC v. EPA*, 464 F.3d 1, 6 (D.C. Cir. 2006) ("[I]ncreases in risk can … be 'injuries in fact' sufficient to confer standing."); McGuire Decl. ¶ 14 ($700,000 in compliance costs for NDASA members); *NTE*, 26 F.4th at 990-91 (unrecoverable economic loss is irreparable harm); *Phang v. Blanche*, 2026 WL 1831251, at *15 (D.D.C. June 25, 2026) (same).

2. MMJ will also sustain irreparable, Article III injury to its competitive position in the market for federally lawful cannabis-based pharmaceuticals. "[I]ncreased competition represents a cognizable Article III injury." *Liquid Carbonic Indus. Corp. v. FERC*, 29 F.3d 697, 701 (D.C. Cir. 1994); *see also La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998) (lifting regulatory restrictions on competitor is Article III injury). Until the Rescheduling Order, MMJ enjoyed a strong first-mover advantage because of its unbroken track record of federal compliance and significant progress toward an FDA-approved cannabis-based product. Boise Supp. Decl. ¶¶ 5-8 (Ex. 3). The Order destroys that competitive advantage—which reflects eight years of hard work and $10 million of investment—by making federally lawful the products of competitors who have long spurned federal law to capitalize on state medical marijuana programs. *See id.* ¶¶ 9-14. That plainly constitutes an irreparable, Article III injury. *See MD Pharm., Inc.*

v. DEA, 133 F.3d 8, 11 (D.C. Cir. 1998) (granting DEA registration to competing drugmaker is Article III injury); *cf. Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1311 (D.C. Cir. 2010) (drugmaker's "loss of the first-mover advantage" was "an injury that [c]ould not be remedied … later on").

These harms cannot be dismissed on the theory that MMJ is "not a current market competitor" while it remains subject to the FDA approval process. Opp. 16. MMJ has jumped through countless hoops over eight years to seek DEA registration and FDA approval, while its competitors "have taken few steps"—indeed, *no steps*—toward seeking federal drug approval. *PSSI Glob. Servs., LLC v. FCC*, 983 F.3d 1, 11 (D.C. Cir. 2020); *see* Boise Decl. ¶¶ 11-21; Boise Supp. Decl. ¶¶ 4-5, 9-11. By welcoming MMJ's competitors as "new entrant[s] into [the] fixed market" for federally authorized drugs, the Rescheduling Order "increase[s] competition—and thus harm[s] competitors [like MMJ]—as a matter of 'economic logic.'" *Id.* (quoting *Sherley v. Sebelius*, 610 F.3d 69, 72 (D.C. Cir. 2010)); Boise Supp. Decl. ¶ 19 (explaining existential threat to MMJ's business).

II. Movants Are Within The Zone Of Interests Of The CSA.

The government's zone-of-interests arguments are meritless. "The [zone-of-interests] test … is not demanding." *PDK Lab'ys Inc. v. DEA*, 362 F.3d 786, 791 (D.C. Cir. 2004); *see also CSL Plasma Inc. v. CBP*, 33 F.4th 584, 593 (D.C. Cir. 2022) (test is "lenient"). Movants need not be "intended beneficiaries of the CSA."

Opp. 18; *see Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012). Nor does it matter that movants have "pocketbook interests" at stake while the CSA has broader objectives aimed at the general welfare. Opp. 18. "Parties motivated by purely commercial interests routinely satisfy the zone of interests test." *Amgen, Inc. v. Smith*, 357 F.3d 103, 109 (D.C. Cir. 2004). What matters is whether a litigant's interests "can be expected to police the interests that the statute protects." *Id.* (quotations omitted). Suit is foreclosed "*only* when a plaintiff's 'interests are *so marginally related to or inconsistent with* the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.'" *Patchak*, 567 U.S. at 225 (quotations omitted) (emphases added). And "the benefit of any doubt goes to the [petitioner]." *Id.*

Under that standard, NDASA is plainly a proper litigant.

First, as the drug-screening industry's trade association, NDASA has an interest in the CSA's formal-rulemaking requirement for rescheduling decisions. *See* 21 U.S.C. § 811(a). That provision protects the ability of interested parties like NDASA to be heard. *See* H.R. Rep. No. 91-1444, at 23 (1970).

Second, by creating drug-testing devices, testing for drugs, and reviewing drug-test results, NDASA members translate CSA prohibitions into concrete practices that protect the public. McGuire Decl. ¶ 4. Drug testing creates a deterrent that is essential to the CSA's "main objective[ ] of combating drug abuse." *Gonzales*

v. Oregon, 546 U.S. 243, 250 (2006). Thus, NDASA members' interests in marketing drug-testing devices and services—and their clients' interests in safe, drug-free workplaces[3]—are certainly "consistent with the purposes of the statute." *Ethyl Corp. v. EPA*, 306 F.3d 1144, 1148 (D.C. Cir. 2002) ("manufacturer whose [products]" provide "potential means of compliance" is within statute's zone of interests).

Third, NDASA's members who test their employees have a strong interest in ensuring safety for both their employees and members of the public who may be affected by their work. That interest is self-evidently congruent with the purposes of the CSA. *See* H.R. Rep. No. 91-1444, at 29 (highlighting illegal drugs' "substantial detrimental effect on the public's health and general welfare"). Rescheduling marijuana harms that interest by necessitating costly revisions to drug-testing policies; by making marijuana testing itself more expensive, Moore Decl. ¶ 10; and by exposing NDASA members who act on positive marijuana test results to substantial risk of ADA and state-law liability. *See supra* Part I.

MMJ is also indisputably an appropriate litigant. A drug "manufacturer facing potential competition" from a new entrant "falls within the zone of interests of the [CSA]." *See MD Pharm.*, 133 F.3d at 12. This case is no different. MMJ has

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[3] Vendors need "not independently fulfill the 'zone' test … if their customers" do. *See Nat'l Cottonseed Prods. Ass'n v. Brock*, 825 F.2d 482, 490 (D.C. Cir. 1987).

spent nearly eight years and $10 million to comply with federal law in developing a cannabis therapeutic. Boise Decl. ¶ 21. The Rescheduling Order suddenly creates *federally licit* competition from state-legal cannabis drugmakers—which, to date, have made no effort to comply with federal drug laws. *Id.* ¶¶ 7-13. "The [CSA] is a quintessential entry-restricting statute," and "[w]hen a regulatory system 'by its very nature restricts entry,'" companies "operating in the regulated industry have an interest in enforcing the restrictions on potential market entrants." *MD Pharm.*, 133 F.3d at 12-13.

Twin Rivers Paper Co. LLC v. SEC, 934 F.3d 607 (D.C. Cir. 2019), is irrelevant. There, the interests of paper companies (selling more paper) had no alignment whatsoever with the interests behind federal securities laws. Here, by contrast, a company like MMJ policing market-entry restrictions on competing controlled-substance manufacturers, employers who drug test to promote safety, and companies that create the drug-testing ecosystem that translates the CSA's prohibitions into practical measures protecting the public all clearly have interests congruent with the interests protected by the statute. If biofuel producers (whose interest is selling biofuel) are in the zone of interests of the Clean Air Act, *see Energy Future Coal. v. EPA*, 793 F.3d 141, 144-45 (D.C. Cir. 2015) (Kavanaugh, J.), then Movants here are plainly within the zone of interests of the CSA.

III. Movants Are Likely To Succeed On The Merits.

A. The Rescheduling Order Conflicts With This Court's Decision In *NORML*.

NORML held that when more than one CSA schedule satisfies the Single Convention, section 811(d) does not grant the Attorney General discretion to choose among those treaty-compliant schedules. Instead, once the treaty-prescribed level of control is established, subsequent scheduling decisions must proceed through the formal-rulemaking procedures of § 811(a)-(b). *NORML v. DEA*, 559 F.2d 735, 747, 757 (D.C. Cir. 1977). Because the Attorney General promulgated the Rescheduling Order without the formal rulemaking required by § 811(a), it is unlawful.

The government asserts that marijuana can be placed in any of "several" CSA schedules, including Schedule III, and "satisfy the … Single Convention." Opp. 9. Because the government acknowledges its "latitude to schedule" marijuana "consistent with treaty obligations," 559 F.2d at 747, *NORML* precludes its use of § 811(d) to bypass the procedures that Congress prescribed. Instead, as the government *itself* recently explained, it must "comply with the rulemaking procedures outlined in [§ 811](a)-(b)." *NORML*, 559 F.2d at 757; *see* 91 Fed. Reg. 22777, 22777 (Apr. 28, 2026) ("The CSA *requires* that such actions [to transfer marijuana to Schedule III] be made through formal rulemaking on the record after opportunity for a hearing." (emphasis added)).

The government misreads *NORML* as holding that once HHS happens to recommend the same Schedule the Attorney General independently identifies as treaty-compliant, § 811(a)'s rulemaking procedures simply disappear. But *NORML* says no such thing. *NORML* required DEA *both* to obtain HHS's recommendation under § 811(b) *and* to "comply with the [formal] rulemaking procedures" specified in § 811(a). 559 F.2d at 757.

B. The Unlawful Amendments To DEA Rules Made Without Notice And Comment Were Neither Harmless Nor Severable.

As explained in the motion, the Rescheduling Order also issued new rules concerning import-export permit requirements and establishing a sham-transaction regime through which DEA nominally monopolizes the state-regulated "medical" marijuana market. Mot. 17-19. None of those legislative rules was issued with notice and comment, and the government offers no credible excuse for that egregious violation of the APA.

The government cannot claim harmless error. Opp. 23. A case where the government has "evad[ed] altogether the notice and comment requirements" is "the 'most egregious' breach[ ] of notice-and-comment obligations," *NRDC v. Wheeler*, 955 F.3d 68, 85 (D.C. Cir. 2020), and prejudice requires showing only that Movants had "something useful to say" that would permit them to "mount a credible challenge if given the opportunity to comment," *Window Covering Mfrs. Ass'n v. Consumer Prod. Safety Comm'n*, 82 F.4th 1273, 1284 (D.C. Cir. 2023) (quotations omitted);

see also Sugar Cane Growers Co-op. of Fla. v. Veneman, 289 F.3d 89, 96 (D.C. Cir. 2002) ("[A]n utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure."). To put it mildly, NDASA had "something useful to say" about the government's combined rescheduling and rule changes: NDASA submitted over 300 pages of comments, prehearing statements, and exhibits in the rulemaking announced in 2024. All were excluded from consideration here. *See* McGuire Supp. Decl. ¶ 6; *see also* Boise Decl. ¶ 20 (describing MMJ's intended input).

Nor does severability salvage the Rescheduling Order. Opp. 23. The government concedes that the new import-export and sham-transaction rules are "required" to implement "article[s] 23 and 28" of the Single Convention. *Id.* at 22-23. Without those rules, moving marijuana to Schedule III would violate U.S. treaty obligations. The Order thus cannot "function sensibly" without the additional rules, so they cannot be severed. *MD/DC/DE Broads. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001); *accord Dep't of Educ. v. Louisiana*, 603 U.S. 866, 867 (2024).

Section 811(d) provides no authority for the new rules. Opp. 23. It authorizes only an order "controlling" a "drug under" a "schedule"—not promulgating *additional* legislative rules along with the rescheduling decision. The government's theory turns the statute on its head. Section 811(d) permits expedited scheduling decisions by the Attorney General simply to place a substance in the appropriate

Schedule as needed to avoid treaty violations. It does not grant authority to make a scheduling decision that, standing alone, would violate a treaty and then exempt from the APA *additional* rules needed to make that scheduling order treaty-compliant.

IV. The Government Cannot Manufacture An Equitable Interest From An Unlawful Order.

The public interest plainly supports a stay. "There is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016).

The government never argues that a stay here would exceed this Court's power under the APA, 5 U.S.C. § 705, so *Trump v. CASA, Inc.* 606 U.S. 831 (2025) is inapposite. The universal injunctions there caused "irreparable harm" because they "likely exceed[ed] the authority conferred by the Judiciary Act," 606 U.S. at 860, not because they "enjoin[ed] regulatory action," Opp. 25. *See* 606 U.S. at 847 & n.10 (APA presents "distinct question[s]").

Nor does the government dispute that marijuana abuse has dangerous, lifelong consequences—especially for adolescents and pregnant women. Mot. 21-22; *see* Opp. 26. By cutting taxes on cannabis companies, *see* 91 Fed. Reg. 22714, 22719 (Apr. 28, 2026), the Rescheduling Order will stimulate the industry and increase marijuana abuse. That is reason enough to preserve the status quo of the last 50 years.

CONCLUSION

The Court should stay the Rescheduling Order pending review.

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Respectfully submitted.

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July 16, 2026

/s/ *Patrick F. Philbin*
Patrick F. Philbin

CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of July, I caused the foregoing document to be electronically filed with the Clerk and served on the parties using the Clerk's electronic filing system.

July 16, 2026

/s/ *Patrick F. Philbin*
Patrick F. Philbin