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

JOINT MOTION OF NDASA, MMJ INTERNATIONAL HOLDINGS, INC., MMJ BIOPHARMA CULTIVATION, INC., AND MMJ BIOPHARMA LABS, INC. FOR STAY PENDING REVIEW OF THE MARIJUANA RESCHEDULING ORDER

Patrick Kenneally (*admission pending*)
BURKE LAW GROUP, PLLC
205 N. Michigan Ave, Suite 810
Chicago, IL 60601
(832) 987-2214
patrick.kenneally@burkegroup.law

Connor W. Mighell
BURKE LAW GROUP, PLLC
1000 Main Street, Suite 2300
Houston, Texas 77002
(832) 987-2214
connor.mighell@burkegroup.law

Counsel for MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., and MMJ BioPharma Labs, Inc.

Patrick F. Philbin
Chase T. Harrington
TORRIDON LAW PLLC
801 Seventeenth Street NW,
Suite 1100
Washington, DC 20006
(202) 249-6633
pphilbin@torridonlaw.com

Counsel for the National Drug and Alcohol Screening Association, Inc.

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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)

INTRODUCTION

This case involves a brazen agency overreach in which the Acting Attorney General ignored restrictions on his authority set by Congress—and a binding decision of this Court—to carry out one of the most sweeping reductions in restrictions on a dangerous narcotic in the history of the Controlled Substances Act (CSA). Nearly fifty years ago, this Court held that the Attorney General lacks authority to unilaterally decide how marijuana ought to be restricted—that is, which Schedule it should be placed under—pursuant to the CSA. *NORML v. DEA*, 559 F.2d 735, 750 (D.C. Cir. 1977). The Court explained that Congress constrained the Attorney General's authority by requiring him both to secure recommendations from the Secretary of Health and Human Services (HHS) and to make detailed findings through a formal rulemaking on the record. *Id*. While the CSA contains a limited bypass of those procedures to allow the Attorney General to ensure that the U.S. complies with certain treaties, *see* 21 U.S.C. § 811(d)(1), this Court made clear that the bypass cannot be invoked when the Attorney General is simply deciding to move a drug between two Schedules under the CSA, either of which would comply with treaty obligations.

The Department of Justice complied with this Court's construction of the CSA for over four decades—until now. In the Order under review, the Acting Attorney General cancelled a pending formal rulemaking hearing that had been convened to

address rescheduling marijuana and, with the stroke of a pen, transferred marijuana in state-licensed medical marijuana programs from Schedule I to Schedule III under the CSA. There were no public comments, no findings made on the record after a hearing addressing the specific factors Congress defined to protect the American public from harmful drugs, just a fiat from the Acting Attorney General. The Order flouts this Court's binding construction of the CSA, and by eliminating the federal criminal prohibition on the use of so-called "medical marijuana," will vastly increase access to marijuana.

The Court should stay the Rescheduling Order pending review to avoid the devastating effects that will flow from ballooning access to marijuana while this case is pending. The four factors this Court considers all weigh in favor of a stay.

First, Petitioners are likely to succeed on the merits because the Rescheduling Order rests on the same construction of the CSA that this Court squarely rejected in *NORML*. This Court decided nearly fifty years ago that section 811(d)—the very same statutory provision invoked in the Rescheduling Order—simply does not allow the Attorney General to get around the detailed procedural requirements Congress imposed on rescheduling when the Attorney General is selecting between two different Schedules that comply with treaty obligations.

Second, absent a stay, movants will suffer irreparable harm. The National Drug and Alcohol Screening Association (NDASA) is the trade association for the

drug-screening industry. Moving marijuana to Schedule III will cause many employers to stop testing for marijuana altogether and thus will cause unrecoverable losses in revenue for NDASA's members who evaluate drug test results. It will also require NDASA's members who test their employees for drugs (over 700 businesses) to incur unrecoverable costs revamping their drug testing policies. The Rescheduling Order will also inflict irremediable harm on MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., and MMJ BioPharma Labs, Inc.—entities that have invested more than $10 million and nearly a decade lawfully developing Schedule I cannabinoid treatments—by moving competitors' products into Schedule III and enabling them to rapidly enter and flood the market.

Third, the balance of equities and public-interest factors (which merge because the government is the opposing party) overwhelmingly favor a stay. Marijuana has been regulated under Schedule I of the CSA for over 50 years for a reason—it is a dangerous drug that destroys lives. To cite just one major data point: adolescents who use marijuana only occasionally are three times more likely than their peers to attempt suicide. If the Rescheduling Order is not stayed, but the Court decides in eight or ten months that the Order should be vacated, the consequences from lax access to marijuana in the interim could be devastating. On the other side of the balance, the government cannot point to any comparable harm from

maintaining the status quo—which has prevailed for over 50 years—for a few more months until this case is decided.

This is not a close question. The Court should stay the Rescheduling Order.

STATEMENT

A. Statutory and Regulatory Background

Congress passed the Controlled Substances Act of 1970 (CSA), 21 U.S.C. § 801 *et seq.*, to establish a "comprehensive regime to combat the international and interstate traffic in illicit drugs." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). The CSA also implements a treaty known as the Single Convention on Narcotic Drugs, 18 U.S.T. 1407 (Single Convention); *see also* S. Rep. 91st Cong., 1st Sess., No. 91-613, at 4 (1969). The Single Convention (at art. 23, 28, 30) imposes extensive controls on the cultivation, manufacture, distribution, and trade of marijuana.[1]

The CSA divides controlled substances into five schedules, 21 U.S.C. § 812, "based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body," *Gonzalez*, 545 U.S. at 13. Schedule I is the most restrictive and is reserved for substances with no currently

[1] The Single Convention and the CSA use differing definitions of "marijuana" and "cannabis," but the distinctions are immaterial here and the generic term "marijuana" is used.

accepted medical use and a high potential for abuse. Upon enacting the CSA, Congress placed marijuana in Schedule I. 21 U.S.C. § 812(c).

The CSA also established detailed procedural requirements for adding, removing, or transferring substances between Schedules. *Id.* § 811. To change a Schedule designation, section 811(a) requires the Attorney General to make findings about a drug's potential for abuse and the specific criteria set out in section 812(b) for the Schedule in which the drug is being placed—and to do so through a formal, on-the-record rulemaking under the procedures of the Administrative Procedure Act (APA). *Id.* § 811(a). Before initiating that rulemaking, section 811(b) requires the Attorney General to request from the Secretary of HHS a "scientific and medical evaluation," which is then "binding" on all "scientific and medical matters." *Id.* § 811(a)-(b). In the on-the-record rulemaking, "outside participants may submit . . . scientific and medical evidence . . . that DOJ would need to consider." 89 Fed. Reg. 44597, 44599 at n.2 (May 21, 2024). A final drug-scheduling rule must explain why the drug satisfies the criteria in 21 U.S.C. § 812(b) for the particular Schedule in which it is placed.

Congress also included in the CSA an exception to these requirements to ensure that the United States did not violate its obligations under the Single Convention. Section 811(d) provides that "[i]f control is required by United States obligations under [the Single Convention], the Attorney General shall issue an order

controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to" the requirements of sections 811(a) and (b) described above. 21 U.S.C. § 811(d)(1). Section 811(d) has been used repeatedly to add a drug to Schedules I or II following notice that the drug had been newly added to the control regime of the Single Convention.[2]

B. This Court's *NORML* Decision

Shortly after the CSA was enacted, several organizations petitioned to transfer marijuana out of Schedule I. The Drug Enforcement Administration (DEA) determined that marijuana could be transferred to Schedule II under the CSA without violating the Single Convention but nevertheless denied the petition under section 811(d)(1) without making any referral to HHS under section 811(b) and without a formal rulemaking pursuant to section 801(a). 40 Fed. Reg. 44164 (Sept. 25, 1975).[3] The Department of Justice took the position that, because marijuana was subject to control under the Single Convention, section 811(d) gave the Attorney General absolute authority to determine how to schedule—or reschedule—marijuana under the CSA. On review, this Court rejected that construction of section 811(d) and held that the truncated process used by DOJ violated the statute. *NORML*, 559 F.2d at

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[2] *See, e.g.*, 91 Fed. Reg. 1089 (Jan. 12, 2026) (N-pyrrolidino metonitazene); 90 Fed. Reg. 59969 (Dec. 23, 2025) (N-desethyl isotonitazene).

[3] The Attorney General has delegated scheduling authority to the Administrator of DEA. 28 C.F.R. § 0.100.

757. The Court explained that section 811(d)(1) provides a "limited" exception to prevent "violation of treaty obligations." *Id.* at 746-47. Properly understood, section 811(d)(1) "directs" the Attorney General to decide the "minimum schedule or level of control below which placement of the substance may not fall" and then to evaluate the subset of treaty-compliant schedules with HHS review and formal rulemaking through the procedures spelled out in sections 811(a) and (b). *Id.*

In more than half a century since *NORML*, DEA has received multiple petitions seeking to reschedule marijuana. Each time, the agency has followed the procedures required by sections 811(a) and (b). First, DEA has referred the matter to HHS for a recommendation pursuant to section 811(b). Next, after receiving the HHS recommendation, in each case DEA has either (1) held a formal, on-the-record rulemaking to assess rescheduling in accordance with section 811(a); or (2) because HHS has consistently found that marijuana has, among other things, a "high potential for abuse" and lacked a "currently accepted medical use," DEA has concluded that there is no "substantial evidence" to support rescheduling and thus no basis for initiating a formal rulemaking under section 811(a).[4] In most of those actions, DEA did not mention section 811(d) at all. *See, e.g.*, 76 Fed. Reg. 40552; 66 Fed. Reg.

[4] *See, e.g.*, 81 Fed. Reg. 53767 (Aug. 12, 2016); 81 Fed. Reg. 53688 (Aug. 12, 2016); 76 Fed. Reg. 40552 (July 8, 2011); 66 Fed. Reg. 20038 (Apr. 18, 2001); 57 Fed. Reg. 10499 (Mar. 26, 1992); 54 Fed. Reg. 53767 (Dec. 29, 1989); 44 Fed. Reg. 36123 (June 20, 1979).

20038; 57 Fed. Reg. 10499; 54 Fed. Reg. 53767. The others invoke it only to explain that DEA lacks authority to schedule marijuana below Schedule II due to U.S. obligations under the Single Convention, *see* 81 Fed. Reg. at 53767-68 (HHS letter explaining why analysis is limited to Schedules I and II); 81 Fed. Reg. at 53688-89 (same); 44 Fed. Reg. at 36,123 (same).

C. President Biden and President Trump Push for Rescheduling.

In October 2022, President Biden took the unprecedented step of directing the Attorney General and HHS to, once again, "initiate the administrative process to review" marijuana's status as a Schedule I substance. *See* White House, Statement from President Biden on Marijuana Reform (Oct. 6, 2022), perma.cc/LVF6-344M. Acting under that presidential directive, HHS produced a recommendation that was a 180-degree reversal from its consistent conclusions over the past four decades. Changing the five-part test by which HHS evaluated whether a substance has a "currently accepted medical use," HHS found that marijuana had such a medical use and recommended placement in Schedule III. *See* HHS, *Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act* (Aug. 29, 2023), perma.cc/HDB8-V5P8.

In response, the Attorney General issued an NPRM proposing to transfer marijuana to Schedule III. *See* 89 Fed. Reg. 44597 (May 21, 2024). The public submitted over 43,000 comments, and the DEA Administrator announced a hearing,

explaining that the "CSA *requires* that such actions [*i.e.*, rescheduling] be made through formal rulemaking on the record after opportunity for a hearing." 89 Fed. Reg. 70148, 70149 (Aug. 29, 2024) (emphasis added). NDASA was designated by the Administrator to participate in the hearing and planned to provide expert testimony. After the parties had identified expert witnesses and submitted prehearing statements, the hearing was stayed pending resolution of an interlocutory appeal to the Administrator on an unrelated issue. Order, Hr'g Dkt. No. 24-44 (Jan. 13, 2025).

DEA took no further action for twelve months. Then, in December 2025, President Trump directed 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 14370, *Increasing Medical Marijuana and Cannabidiol Research*, 90 Fed. Reg. 60541, 60542 (Dec. 23, 2025).

Four months later, during an Oval Office signing ceremony for an executive order expanding access to psychedelic drugs, President Trump expressed frustration with the delay. Pointing toward an administration official, the President asked, "Will

you get the rescheduling done?" and he complained he was getting "slow-walk[ed]" on "rescheduling."[5]

D. The Rescheduling Order

Four days later, on April 22, 2023, the Acting Attorney General signed an order directly transferring certain categories of marijuana to Schedule III. 91 Fed. Reg. 22714 (Apr. 28, 2026) (Rescheduling Order) (Ex. A).[6] As authority for that action, the Rescheduling Order points to section 811(d) and asserts that, because marijuana is controlled under the Single Convention, any order rescheduling marijuana "must be issued 'without regard'" to the "norma[l]" HHS review and formal rulemaking required under sections 811(a) and (b). *Id.* at 22717.

The pending rulemaking hearing was canceled, *see* 91 Fed. Reg. 22778 (Apr. 28, 2026), and a new hearing was set to address rescheduling *all* marijuana (in addition to the two categories of marijuana addressed in the Rescheduling Order). 91 Fed. Reg. 22777 (Apr. 28, 2026) (Hearing Order). Contradicting the Rescheduling Order, the new Hearing Order reiterated DEA's longstanding position

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[5] Devlin Barrett, *Trump Administration Loosens Restrictions on Medical Marijuana*, N.Y. Times (Apr. 23, 2026), tinyurl.com/5pubshed.

[6] The Rescheduling Order transferred to Schedule III two categories of marijuana: (i) FDA-approved drug products containing marijuana; and (ii) marijuana "in any form covered by a state medical marijuana license." 91 Fed. Reg. at 22718.

that "[t]he CSA *requires* such actions be made through formal rulemaking on the record after opportunity for a hearing." 91 Fed. Reg. 22777 (emphasis added).

E. Movants Petition for Review of the Rescheduling Order.

NDASA and MMJ petitioned for review on May 4 and May 29, 2026, respectively. NDASA is the trade association for the drug and alcohol screening industry and has over 3500 members. NDASA's members include businesses that will have to revise their drug-screening policies in light of the Rescheduling Order and Medical Review Officer (MRO) businesses—that is, businesses that review and interpret drug-screening results. As explained below, the Rescheduling Order will have a dramatic impact on MROs, both because some employers will no longer screen for marijuana and because, given the partial federal blessing for *some* uses of marijuana, the costs of interpreting positive screening results will skyrocket. *See* McGuire Decl. ¶6-28 (Ex. B).

MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., and MMJ BioPharma Labs, Inc. (together, MMJ) are entities that have invested over $10 million and eight years developing pharmaceutical Schedule I cannabinoid therapeutics exclusively through the federal FDA and DEA regulatory pathways. Boise Decl. ¶¶4-10, 21 (Ex. C). Left in place, the Rescheduling Order will cause MMJ to lose substantial market share by moving its competitors' products to

Schedule III while it navigates FDA and DEA requirements for its orphan-designated cannabinoid therapeutic. *Id.* ¶¶34-35.

ARGUMENT

The Court should stay the Rescheduling Order to "retur[n] things to the *status quo ante* while this case proceeds." *Coal. for Humane Immigrant Rts. v. Noem*, 805 F. Supp. 3d 48, 74 (D.D.C. 2025); *see, e.g.*, *NFIB v. OSHA*, 595 U.S. 109, 112-13 (2022) (staying already-effective OSHA vaccine mandate); *West Virginia v. EPA*, 577 U.S. 1126 (2016) (mem. op.) (staying final EPA rule that took effect over a month before).

In deciding whether to issue a stay, this Court considers "four factors: (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (quotation omitted); *see* 5 U.S.C. § 705. The first two factors "are the most critical," *id.*, and may be balanced against each other, thus a "stay may be granted with either a high probability of success and some injury, or *vice versa*."

Cuomo v. U.S. Nuclear Regul. Comm'n, 772 F.2d 972, 974 (D.C. Cir. 1985). Each factor favors a stay here.[7]

I. Petitioners Are Likely To Succeed On The Merits.

A. The Rescheduling Order Rests On An Interpretation Of Section 811(d) That This Court Rejected In *NORML*.

Petitioners are likely to succeed on the merits because the Rescheduling Order skipped the procedures mandated by sections 811(a) and (b) of the CSA—including a formal rulemaking under the APA—based on a reading of section 811(d) that is squarely foreclosed by this Court's binding decision in *NORML*.

NORML addressed a marijuana scheduling order that bypassed "the referral and hearing procedures of [section 811(a)-(b)]"[8] because the government interpreted section 811(d)(1) to dispense with such procedures for any "drugs subject by treaty

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[7] Petitioners did not seek a stay from DEA because it would have been "impracticable." Fed. R. App. P. 18(a)(1)-(2). The Rescheduling Order implements a presidential directive to reschedule marijuana, *see* Exec. Order 14370, 90 Fed. Reg. at 60542, and came as an immediate response to a complaint from the President himself about being "slow walked." The Order was also made effective immediately through a process that circumvented rulemaking procedures. *See* 21 U.S.C. § 811. Under similar circumstances, courts have held that seeking a stay from the agency is unnecessary. *See, e.g.*, *NFIB*, 595 U.S. at 113 (staying already-effective vaccine mandate despite petitioners not seeking an initial stay with agency); *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 503 (6th Cir. 2021) (seeking stay before agency was impracticable where agency order took effect immediately and agency could take months to consider a stay).

[8] *NORML* refers to 21 U.S.C. § 811(d) using its original public-law designation in the CSA, § 201(d).

to international control." *NORML*, 559 F.2d at 743. The government argued that the Attorney General could place marijuana in any Schedule that complied with U.S. treaty obligations without formal scientific and medical review by the Secretary of Health, Education, and Welfare (now HHS) or a formal rulemaking hearing. *Id.* at 738. The Rescheduling Order makes effectively the same argument: that whenever "control of a drug is required by the Single Convention," section 811(d) allows the Attorney General to dispense with the requirements of sections 811(a) and (b). 91 Fed. Reg. at 22717.

But in *NORML*, this Court made clear that it was "rejecting DEA's interpretation of section [811(d)]." 559 F.2d at 747. The Court flatly rejected the idea that section 811(d) granted the Attorney General a broad authority to evade the detailed procedures set by Congress in sections 811(a) and (b). Instead, the Court explained that the "limited purpose of subsection (d)," was to enable the Attorney General to bypass the usual procedures "only to the extent that placement in that schedule is necessary to satisfy United States international obligations." *Id.* at 746. Where "there is latitude to schedule a substance consistent with treaty obligations" in more than one CSA Schedule, any decision to choose between permissible Schedules or to reschedule a substance requires full adherence to sections 811(a) and (b). *Id.* at 747. Based on a detailed examination of the statutory language and drafting history, the Court emphasized that the restrictions set by those sections were

designed by Congress to limit the Attorney General's power and constrain decision-making with specific required findings. By eliminating those constraints, the DEA's "reading of [section 811(d)] would destroy a balance of power created by a deliberate and conscientious exercise of the legislative process." *Id.* at 746.

Indeed, the Court explained that, if section 811(d)(1) really gave the Attorney General carte blanche to reschedule any substance subject to control under the Single Convention, the statute's procedural provisions would be largely a dead letter—because almost 90% of the substances originally placed under Schedule I of the CSA were controlled by the Single Convention. *Id.* at 746 n.53. But that result would be wholly incompatible with the evident care Congress took in crafting the rulemaking procedures that were to play a robust role in scheduling decisions. *See id.*

The Department of Justice has followed the statutory construction set out in *NORML* for at least thirty years as it has repeatedly addressed petitions to reschedule marijuana by following the requirements of section 811(b) and first referring the matter to HHS for a recommendation. *See supra* p. 7 & n.4. Indeed, as recently as 2024, DEA acknowledged *NORML* as binding on this point. *See* 89 Fed. Reg. at 44620 n.39. In an NPRM initiating a rescheduling process, DEA explained that the "D.C. Circuit … ha[s] interpreted [section 811(d)(1)] as *requiring* the Attorney General to identify which schedules would satisfy the international obligations of the United States with respect to a particular drug and, if more than one schedule

would do so, to select among schedules *using the procedures set forth in sections 811(a), 811(b), and 812(b).*" *Id.* (emphasis added).

Shockingly, the Rescheduling Order relegates its only mention of *NORML* to a single footnote. There, the Order asserts that, because HHS provided a recommendation concerning rescheduling marijuana in 2023, the Attorney General complied with section 811(b) and thereby fully satisfied the requirements set out in *NORML*. 91 Fed. Reg. at 22717 n.19. That is obviously not correct. Section 811 requires *both* referral to HHS on scientific and medical matters (section 811(b)) *and* a formal rulemaking on the record (section 811(a))—and *NORML* was not limited to addressing the HHS referral requirements of section 811(b). To the contrary, this Court expressly ordered that, on remand, after receiving a recommendation from HHS (then Department of Health Education & Welfare), the DEA "is directed to comply with the *rulemaking procedures* outlined in [section 811(a)-(b)]." *NORML*, 559 F.2d at 757 (emphasis added). And the Court explained that, where a substance could be placed in more than one Schedule, the issue should be "fully litigated at a DEA rulemaking hearing." *Id.* at 754. Indeed, as noted above, DEA itself has acknowledged that *NORML* requires all "the procedures set forth in sections 811(a), 811(b), and 812(b)." 89 Fed. Reg. 44620 n.39.

Beyond that, the footnote in the Rescheduling Order obliquely suggests that *NORML* was wrongly decided because it was based on legislative history and "not

the plain text" of section 811(d)(1). *Id.* That mischaracterizes the analysis in *NORML*, and in any event, an agency is not permitted to ignore a decision of this Court that has governed construction of a statute for almost half a century whenever the agency decides that it no longer agrees with the Court's analysis.

B. The Rescheduling Order Also Unlawfully Amends Other Legislative Rules Without Notice And Comment.

Petitioners are also likely to succeed because, even if section 811(d) allowed the Acting Attorney General to reschedule marijuana by revising 21 C.F.R. § 1308.13, the Rescheduling Order does far more than that. It also amends other legislative rules to create additional restrictions governing the "medical" marijuana subject to the Order and unlawfully bypasses notice-and-comment rulemaking in doing so. The Acting Attorney General obviously concluded that the standard set of restrictions that come with designation under Schedule III of the CSA were not sufficient to satisfy all U.S. treaty obligations under the Single Convention. *See* 91 Fed. Reg. at 22718-19. As a result, he also added new rules governing "medical" marijuana that, among other things, imposed new import-export permit requirements, *id.* at 22723 (amending 21 C.F.R. § 1312.30), and also created out of whole cloth an elaborate regime of effectively sham transactions whereby the DEA purchases and then sells back to state licensees their entire stock of "medical"

marijuana, *id.* at 22722 (amending 21 C.F.R. § 1301.13).[9] And he purported to create all those new rules by order without any notice-and-comment process.

It is hornbook administrative law, however, that amending a legislative rule requires notice-and-comment rulemaking. *See* 5 U.S.C. § 553; *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 101 (2015) ("[T]he APA … mandate[s] that agencies use the same procedures when they amend … a rule as they used to issue the rule in the first instance.").[10]

The only asserted legal basis in the Order for the government's failure to use standard notice-and-comment procedures is section 811(d). *See* 91 Fed. Reg. at 22721. But section 811(d) offers no authority for the Attorney General to unilaterally promulgate additional, substantive regulatory amendments. At most, it addresses orders placing a drug in "the schedule" the Attorney General "deems most appropriate to carry out [American treaty] obligations." Nothing about section

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[9] This requirement still does not satisfy the Single Convention because it does not require DEA to take physical possession of "medical" marijuana. 21 C.F.R. § 1301.13(k)(6)(ii) (DEA need only have "right to inspect" manufacturers' storage facilities); *but see* 42 Op. O.L.C. 63, 71-73, 76 (2018) (discussing the Single Convention's physical-possession requirement).

[10] *See also* 21 U.S.C. § 952(a) (authorizing the Attorney General to "prescribe" importation "regulations" without exempting such regulations from notice-and-comment rulemaking).

811(d) gives the Attorney General carte blanche to amend other substantive regulations without notice-and-comment rulemaking.

II. Movants Will Suffer Irreparable Harm Without A Stay.

NDASA and MMJ will be irreparably harmed absent a stay.

NDASA's members will suffer at least two forms of irreparable harm.[11] First, the Rescheduling Order will impose unrecoverable costs on Medical Review Officer (MRO) practices—and will likely threaten the existence of some. *See* McGuire Decl. ¶¶16-28. MROs are physicians who interpret drug test results. By reclassifying certain medical marijuana under Schedule III and formally recognizing lawful uses for it under federal law, the Order will lead many employers to stop testing for marijuana as no longer worth the expense. *Id.* ¶26. Because marijuana-positive results are the largest source of MRO revenue, the Order is likely to cause at least a 35% decline in revenue over the next 6-12 months. *Id.* Even for employers who continue testing for marijuana, MROs will face higher costs to assess whether positive results reflect state-licensed medical use, and this combination of reduced revenue and increased costs will likely force some smaller practices out of business. *Id.* ¶¶27-28.

[11] A trade association such as NDASA may establish irreparable harm through harm to its members. *See, e.g., Chamber of Com. v. EPA*, 577 U.S. 1127 (2016) (mem.).

Second, many of NDASA's members are employers that require drug-screening for their employees. They will be forced to incur costs to revise their drug testing policies to account for the new status of some forms of medical marijuana as a Schedule III substance. *See id.* ¶¶6-15. Rescheduling marijuana triggers multiple necessary changes to an employer's drug-testing policy. *See id.* ¶11. The total cost for NDASA's members will likely exceed $700,000. *See id.* ¶14.

MMJ will also suffer irreparable harm. MMJ has invested $10 million and eight years of research and development to create cannabinoid-based drugs. *See* Boise Decl. ¶¶4-10. Since then, FDA has granted MMJ Orphan Drug designation for its treatment of Huntington's Disease and multiple sclerosis. *See id.* ¶18. Throughout that period, MMJ undertook the substantial expense, delay, and uncertainty associated with following the DEA-FDA regulatory pathway. *Id.* ¶¶11-21.

The Rescheduling Order threatens the loss of market opportunities that MMJ spent years creating. Once physicians, patients, and distributors adopt competing cannabis-based products, those relationships and market positions will be permanently altered. The Order also undermines the value of MMJ's regulatory investments and competitive advantages derived from years of compliance with the prior legal regime. The erosion of first-mover advantages, exclusivity opportunities,

goodwill, and reputation as a pioneer in cannabinoid therapeutics is a competitive injury that cannot readily be measured or restored. *Id.* ¶¶32-36.

Because sovereign immunity precludes Movants from seeking monetary damages, these "substantial, unrecoverable losses" constitute irreparable injury. *Nat'l Lifeline Ass'n v. FCC*, No. 18-1026, 2018 WL 4154794, at *1 (D.C. Cir. Aug. 10, 2018); *see also Adya LLC v. DEA*, 2026 WL 797339, at *10 (Mar. 23, D.D.C. 2026). Indeed, the Rescheduling Order "threatens the very existence of" MMJ and some NDASA members' businesses. *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985).

III. The Balance Of Equities And The Public Interest Favor Staying The Rescheduling Order.

Where, as here, the government is the opposing party, the public-interest and balance-of-equities factors merge. *See Nken*, 556 U.S. at 435. The public interest overwhelmingly favors a stay to ensure that restrictions on access to marijuana are not reduced under the Rescheduling Order only for this Court to vacate the Rescheduling Order a few months from now. The hard fact underlying this case is that marijuana and marijuana addiction destroys lives. Adolescents who use marijuana only occasionally are three times more likely to attempt suicide. *See* Madras Decl. ¶12 (Ex. D). Even one or two instances of adolescent marijuana use can alter the volume of grey matter in the brain. *Id.* Marijuana now exceeds opioids as the substance most involved in drug-related emergency department visits. *Id.* ¶10.

That the rescheduling is limited to "medical" marijuana provides no protections. State licensing regimes do not prohibit medical marijuana for those under 18, and in any event, it is well established that marijuana in state medical licensing regimes is diverted to illicit uses at an alarming rate. *Id.* ¶¶13-14. And risks also arise from authorized uses of "medical" marijuana: A 2018 survey found that 69% of Colorado dispensaries recommended marijuana to pregnant women—despite the fact that there is evidence that exposure to marijuana in utero is linked with poorer cognitive outcomes for children. *Id.* ¶21; *see also* 81 Fed. Reg. at 53775. Given all these harms, the cost of an error prematurely reducing restrictions on marijuana can be extremely high.

On the other side of the scale, there is no comparable countervailing harm if the status quo regulating marijuana stays in place for a few more months while this case is decided. Marijuana has been regulated under Schedule I of the CSA for more than 50 years and the government cannot point to any credible irreparable harm from maintaining that longstanding status quo.

That is particularly the case given that, throughout this regulatory process (which began over three years ago), the government has shown no urgency whatsoever—at least until it rushed through the Rescheduling Order and made it effective immediately. The DEA issued an NPRM on May 21, 2024, but the hearing established under that NPRM languished for 15 months during an interlocutory

appeal that the DEA Administrator never bothered to rule upon. President Trump waited almost a year to issue the Executive Order that re-started this process, and even then, DEA did nothing for months. Where the government has shown no need for expedition, it cannot suddenly claim now that immediate implementation of the Rescheduling Order is vital.

Preserving for a few more months the status quo that has prevailed for over half a century will not cause irreparable harm.

CONCLUSION

The Court should stay the Rescheduling Order pending review.

June 9, 2026

Respectfully submitted.

/s/ *Patrick F. Philbin*
Patrick F. Philbin
Chase T. Harrington
TORRIDON LAW PLLC
801 Seventeenth Street NW,
Suite 1100
Washington, DC 20006
(202) 249-6633
pphilbin@torridonlaw.com

Counsel for the National Drug and Alcohol Screening Association, Inc.

Patrick Kenneally (*admission pending*)
BURKE LAW GROUP, PLLC
205 N. Michigan Ave, Suite 810
Chicago, IL 60601
(832) 987-2214
patrick.kenneally@burkegroup.law

/s/ *Connor W. Mighell*
Connor W. Mighell
BURKE LAW GROUP, PLLC
1000 Main Street, Suite 2300
Houston, Texas 77002
(832) 987-2214
connor.mighell@burkegroup.law

Counsel for MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., and MMJ BioPharma Labs, Inc.

CERTIFICATE OF COMPLIANCE

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June 9, 2026 /s/ *Patrick F. Philbin*
Patrick F. Philbin

CERTIFICATE OF SERVICE

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

June 9, 2026 /s/ *Patrick F. Philbin*
Patrick F. Philbin