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

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

* Authorities on which Movants chiefly rely are marked with asertisks.

Statutes & Other Legislative Materials

Regulations and Other Administrative Materials

Rules

Other Authorities

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.

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CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) and D.C. Circuit Rule 32(e)(1) because, excluding the parts of the document exempted by Rule 32(f), this document contains 5,169 words.

This document complies with the typeface requirements of Federal Appellate Procedure Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Word O365 in 14-point, Times New Roman font.

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

Exhibit A

is, therefore, being made without notice or public procedure under 5 U.S.C. 553(a)(1). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Executive Order 12866

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

Signing Authority

In accordance with Treasury Order 100–20, the Secretary of the Treasury has delegated to the Secretary of Homeland Security the authority related to the customs revenue functions vested in the Secretary of the Treasury as set forth in 6 U.S.C. 212 and 215, subject to certain exceptions. This regulation is being issued in accordance with Department of Homeland Security Delegation 07010.3, Revision 03.2, which delegates to the Commissioner of CBP the authority to prescribe and approve regulations related to cultural property import restrictions.

Rodney S. Scott, Commissioner, having reviewed and approved this document, has delegated the authority to electronically sign this document to the Director of the Regulations and Disclosure Law Division of CBP, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, and Reporting and recordkeeping requirements.

Amendment to the CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, amend the table in paragraph (b) by revising the entry for Afghanistan to read as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

* * * * *

(b) * * *

State party	Cultural property	Decision No.
*	*	*
Afghanistan	Archaeological material of Afghanistan ranging in date from 50,000 B.C. through A.D. 1747, and ethnological material of Afghanistan ranging in date from the 9th century A.D. through A.D. 1920.	CBP Dec. 22–04, extended by CBP Dec. 26–09.
*	*	*

Robert F. Altneu,

Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2026–08223 Filed 4–27–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1308, and 1312

[AG Order No. 6754–2026]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, which constitutes a final order, the Acting Attorney General of the U.S. Department of Justice places drug products containing marijuana that have been approved by the Food and Drug Administration (FDA) in schedule III of the Controlled Substances Act (''CSA''). This action is required to satisfy the responsibility of the Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States obligations under the Single Convention on Narcotic Drugs, 1961. In general, this final rule applies to marijuana as defined in the CSA, marijuana extracts, and delta-9-tetrahydrocannabinol and other compounds derived from the marijuana plant (other than the mature stalks and seeds) that falls outside the definition of hemp, to the extent that any of these are included in an FDA-approved drug product or are subject to

a state-issued license to manufacture, distribute, and/or dispense marijuana or products containing marijuana for medical purposes (''state medical marijuana license''). Also consistent therewith, this final rule adds such drugs to the list of substances that may only be imported or exported pursuant to a permit. This final rule also establishes an expedited registration process under 21 CFR part 1301 for entities holding state medical marijuana licenses, enabling such entities to engage in the manufacture, distribution, and/or dispensing of marijuana for medical purposes under federal law consistent with the requirements of the Single Convention.

DATES: Effective April 28, 2026.

ADDRESSES: 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Dr. Clara Hellickson, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The United States' Treaty Obligations

The United States is a party to the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151 (''Single Convention''), as amended by the 1972 Protocol. The Single Convention entered into force for the United States on June 24, 1967, after the Senate gave its advice and consent to the United States' accession.[1] The enactment and enforcement of the CSA are the primary means by which the United States carries out its obligations under the Single Convention.[2] Various provisions of the CSA directly reference the Single Convention. One such provision is 21 U.S.C. 811(d)(1), which relates to scheduling of controlled substances.

Under 21 U.S.C. 811(d)(1), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970''—which includes 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 findings required by [21 U.S.C. 811(a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811(a) and (b)].'' [3] This provision is consistent with the Supremacy Clause of the U.S. Constitution, which provides that all treaties made under the authority of the United States ''shall be the supreme Law of the Land.'' [4] In accordance with this constitutional mandate, under section 811(d)(1), Congress directed the Attorney General to ensure that compliance by the United States with our nation's obligations under the Single Convention is given top consideration when it comes to scheduling determinations.[5] Importantly, the Department of Justice's Office of Legal Counsel (OLC) concluded in a 1972 opinion that 21 U.S.C. 811(d)(1) is not limited to those instances where a substance is newly added to an international schedule.[6]

Parties to the Single Convention are required to impose several control measures regarding drugs listed in Schedule I of the Convention.[7] These include the following:

- Limiting exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of such drugs. Article 4.
- Furnishing to the International Narcotics Control Board (INCB) annual estimates of, among other things, quantities of such drugs to be consumed for medical and scientific purposes, utilized for the manufacture of other drugs, and held in stock. Article 19.
- Furnishing to the INCB statistical returns on the actual production, utilization, consumption, imports and exports, seizures, and stocks of such drugs during the prior year. Article 20.
- Requiring that licensed manufacturers of such drugs obtain quotas specifying the amounts of such drugs they may manufacture to prevent excessive production and accumulation beyond that necessary to satisfy legitimate needs. Articles 21 & 29.
- Requiring manufacturers and distributors of such drugs to be licensed. Articles 29 & 30.
- Requiring medical prescriptions for the dispensing of such drugs to patients. Article 30.
- Requiring importers and exporters of such drugs to be licensed and requiring each individual importation or exportation to be predicated on the issuance of a permit. Article 31.
- Prohibiting the possession of such drugs except under legal authority. Article 33.
- Requiring those in the legitimate distribution chain (manufacturers, distributors, scientists, and those who lawfully dispense such drugs) to keep records that show the quantities of such drugs manufactured, distributed, dispensed, acquired, or otherwise disposed of during the prior two years. Article 34.

Because the CSA was enacted in large part to satisfy United States obligations under the Single Convention, many of the CSA's provisions directly implement the foregoing treaty requirements.

Under the Single Convention, cannabis, cannabis resin, and extracts and tinctures of cannabis are listed in Schedule I.[8] The CSA, in implementing

[1] *See* Single Convention, 18 U.S.T. 1407.

[2] *See* S. Rep. No. 91–613, at 4 (1969) (''The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility.''); *Office of Legal Counsel, Control of Papaver Bracteatum,* 1 Op. O.L.C. 93, 95 (1977) (''[A] number of the provisions of [the CSA] reflect Congress' intent to comply with the obligations imposed by the Single Convention.'').

[3] *See also* 21 CFR 1308.46.

[4] U.S. Const., art. VI, sec. 2.

[5] The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration. 28 CFR 0.100.

[6] *Petition to Decontrol Marijuana; Interpretation of Section 201 of the Controlled Substances Act of 1970,* Op. O.L.C. at 7–8 (Aug. 21, 1972) (recognizing that the House Report ''clearly shows that a much broader application was intended''). Consistent with this understanding of the CSA and the Single Convention, on September 28, 2018, DEA issued a final rule under 21 U.S.C. 811(d)(1) placing FDA-approved drug products that contain cannabidiol (CBD) derived from the cannabis plant and no more than 0.1 percent tetrahydrocannabinols (THC) into schedule V of the CSA. *See Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements,* 83 FR 48950 (Sept. 28, 2018).

[7] The text of the Single Convention capitalizes schedules (*e.g.,* ''Schedule I''). In contrast, the text of the CSA generally refers to schedules in lower case. This document will follow this approach of using capitalization or lower case depending on whether the schedule is under the Single Convention or the CSA. It should also be noted that the schedules of the Single Convention operate somewhat differently than the schedules of the CSA. Unlike the CSA, the Single Convention imposes additional restrictions on drugs listed in Schedule IV that go beyond those applicable to drugs listed in Schedule I. All drugs in Schedule IV of the Single Convention are also in Schedule I of the Convention. Cannabis and cannabis resin are among the drugs were also listed in Schedule IV of the Single Convention, but the U.N. Commission on Narcotic Drugs removed cannabis from Schedule IV in 2020.

[8] Under the Single Convention, '''[c]annabis plant' means any plant of the genus Cannabis.'' Single Convention art. 1(1)(c). The Single Convention defines ''cannabis'' to mean ''the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.'' *Id.* art. 1(1)(b). This definition of ''cannabis'' under the Single Convention is slightly less inclusive in certain respects than the CSA definition of ''marijuana,'' which includes all parts of the cannabis plant except for the mature stalks, sterilized seeds, oil from the seeds, and certain derivatives thereof. *See* 21 U.S.C. 802(16). Cannabis and cannabis resin are included in the list of drugs

Continued

these requirements, generally defines marijuana to mean ''the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.'' [9] In 2018, Congress amended the CSA to remove ''(i) hemp, as defined in section [1639*o* of title 7 of the U.S. Code]'' from the definition of marijuana.[10] Section 1639*o*(1) of title 7, in turn, defines hemp as ''the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.'' [11] Delta-9-tetrahydrocannabinol (Δ9–THC) is the major psychoactive intoxicating cannabinoid in marijuana. This exclusion of hemp from the definition of marijuana had the effect of removing many products containing predominantly cannabidiol (''CBD'') derived from hemp and containing no more than 0.3 percent Δ9–THC on a dry weight basis from control as marijuana. Effective November 12, 2026, the definition of hemp in 7 U.S.C. 1639*o*(1) is being amended, with corresponding impact on the definition of marijuana in 21 U.S.C. 802(16)(A).

In addition to the requirements for drugs in Schedule I discussed above, the Single Convention requires the United States to take the following additional measures specific to the growing of marijuana plants within the United States:

- Register and regulate growers, including by designating the land upon which they may grow marijuana plants;
- Limit growing of the marijuana plant to that required for legitimate domestic scientific, medical, and industrial needs, and for legitimate exports;
- Establish the upper limit of marijuana that each grower may grow in a calendar year, as well as the total amount of marijuana that can be grown in the United States annually for legitimate needs;
- Purchase all harvested crops of marijuana and monopolize the wholesale trade in harvested marijuana.[12]

Moreover, the CSA also recognizes that the United States is also a party to the Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175 (Convention on Psychotropic Substances).[13] As with the Single Convention, parties to the Convention on Psychotropic Substances are obligated to take various control measures related to the drugs that are covered by the treaty.[14] Congress implemented the additional authority necessary to comply with the Convention on Psychotropic Substances through various amendments to the CSA.[15] Δ9–THC is a substance covered by schedule II of the Convention on Psychotropic Substances, in addition to being covered by Schedule I of the Single Convention if it is extracted from the cannabis plant. This final rule places in schedule III (i) those FDA-approved drug products that contain Δ9–THC falling within the CSA's definition of marijuana, specifically FDA-approved drug products containing Δ9–THC derived from the plant Cannabis sativa L., other than the mature stalks and seeds; and (ii) marijuana subject to a state medical marijuana license.

Existing State Regulatory Systems

Over the last three decades, forty U.S. states have legalized the sale and use of marijuana for medical purposes as a matter of state law and have established systems to regulate that activity. States that have authorized medical marijuana have done so through a licensing regime that restricts cultivation, manufacture, and distribution to entities approved by a designated state agency—typically a department of health, department of agriculture, or a dedicated cannabis regulatory authority. These agencies conduct application review, perform inspections, and maintain ongoing oversight of licensees. State licensees are required to maintain detailed records of plant counts, harvested quantities, inventory levels, and sales or transfers, and to report that information to state regulators on a periodic basis. State medical licensing regimes oversee permissible uses of medical marijuana, confining distribution to registered patients or caregivers through approved dispensaries or other authorized channels. Registered and licensed physicians oversee patient qualification for medical marijuana based on state specific criteria and qualifying conditions.

Authority To Place Certain Marijuana Products in Schedule III

The Administrator has the authority under Section 811(d)(1) of the CSA to move FDA-approved drug products containing marijuana and marijuana subject to state-issued licenses to Schedule III.

Based on a 2024 OLC opinion, if marijuana is listed in schedule III, most of the Single Convention's obligations noted above will continue to be met by CSA statutory authorities and associated regulations.[16] Similarly, the controls available under schedule III are also sufficient to comply with the requirements of the Convention on Psychotropic Substances with respect to Δ9–THC. As discussed in more detail below, this final rule ensures that the United States will continue to meet these obligations without delay or disruption.

As indicated above, Article 31 of the Single Convention obligates parties to require a permit for the importation and exportation of drugs listed in Schedule I of the Convention. This permit requirement applies to drug products containing marijuana because, as further indicated above, such a product is a Schedule I drug under the Single Convention. However, under the CSA [17] and DEA regulations, the import/export permit requirement does not apply to all controlled substances. Rather, a permit is required to import or export any controlled substance in schedule I and II as well as certain controlled substances in schedules III, IV, and V.[18] Thus, in order to control FDA-approved drug products containing marijuana and

in Schedule I of the Single Convention, and cannabis is subject to the same controls as Schedule I drugs as well as additional controls. *See* Single Convention art. 2(6); *id.* art. 28.

[9] 21 U.S.C. 802(16)(A).

[10] Agricultural Improvement Act of 2018, Public Law 115–334, sec. 12619; 132 Stat. 4490, 5018.

[11] As of November 12, 2026, this definition is revised to refer to a ''total a total tetrahydrocannabinols concentration (including tetrahydrocannabinolic acid) of not more than 0.3 percent on a dry weight basis,'' rather than the current reference to the concentration of Δ9–THC. Public Law 119–37, sec. 781.

[12] DEA implemented the requirement to purchase harvested crops of marijuana and to monopolize the wholesale trade in marijuana through regulations pursuant to a 2018 OLC opinion. *See Office of Legal Counsel, Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs,* 42 Op. O.L.C. 1 (June 6, 2018), *https://www.justice.gov/olc/file/1272131/dl?inline* (''2018 OLC Opinion'').

[13] *See also* 21 U.S.C. 801a(2).

[14] *Id.*

[15] *Id.* 801a(2)–(3).

[16] *See Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana,* 45 Op. O.L.C., at *33–34 (Apr. 11, 2024).

[17] The provisions of federal law relating to the import and export of controlled substances—those found in 21 U.S.C. 951 through 971—are more precisely referred to as the Controlled Substances Import and Export Act. However, federal courts and DEA often use the term ''CSA'' to refer collectively to all provisions from 21 U.S.C. 801 through 971 and, for ease of exposition, this document will do likewise.

[18] *See* 21 U.S.C. 952 and 953; 21 CFR 1312.11, 1312.12, 1312.21, 1312.22.

marijuana subject to state-issued licenses in schedule III, DEA must simultaneously amend the regulations to require a permit to import or export such products.

It bears emphasis that where, as here, control of a drug is required by the Single Convention, an order under 21 U.S.C. 811(d)(1) must be issued ''*without regard to* the findings required by [21 U.S.C. 811 (a) or 812(b)] and *without regard to* the procedures prescribed by [21 U.S.C. 811 (a) or (b)].'' Thus, in such circumstances, the plain and unambiguous statutory language does not require the Administrator to request a medical and scientific evaluation or scheduling recommendation from the Department of Health and Human Services (HHS), as is normally done pursuant to rulemaking under section 811(b).[19]

Nonetheless, in a letter dated August 29, 2023, HHS provided DEA with a medical and scientific evaluation and scheduling recommendation that marijuana be controlled in schedule III of the CSA.[20] HHS found, *inter alia,* that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II, and that the abuse of marijuana may lead to moderate or low physical dependence or high psychological dependence.[21] These findings would correspond to the criteria for placement of a substance in schedule III.[22] While each of these findings are discussed briefly below, HHS's scientific and medical evaluation entitled, ''Basis for the Recommendation to Reschedule Marijuana Into Schedule III of the Controlled Substances Act,'' is available in its entirety under the ''Supporting and Related Material'' of the public docket for this final rule at *https://www.regulations.gov* under docket number DEA–1362.

First, HHS found that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II. As noted above, marijuana contains Δ9–THC, the substance responsible for the abuse potential of marijuana. Δ9–THC has agonist properties at CB_1 cannabinoid receptors and produces rewarding responses in animals, as evidenced by its ability to produce self-administration and CPP. When marijuana is administered to humans under experimental conditions, it produces a wide range of positive subjective responses in addition to certain negative subjective responses. Common responses to marijuana when it is used by individuals for nonmedical purposes include euphoria and other positive subjective responses, as well as perceptual changes, sedative responses, anxiety responses, psychiatric, social, and cognitive changes, and physiological changes.[23]

HHS noted that epidemiological data from the 2022 National Survey on Drug Use and Health (NSDUH) show that marijuana is the most frequently used federally illicit drug in the United States on a past-year and past-month basis among the illicit comparator drugs considered. Although 50 percent of respondents in NSDUH reported using marijuana nonmedically fewer than 5 days per month, another 30 percent reported using it nonmedically for 20 days or more per month.[24]

Despite the high prevalence of nonmedical use of marijuana, HHS observed that an overall evaluation of epidemiological indicators suggests that it does not produce serious outcomes compared to drugs in schedules I or II. HHS found this especially notable given the availability of marijuana and marijuana-derived products that contain extremely high levels of Δ9–THC. Due to such availability, the epidemiological data described in HHS's evaluation inherently include the outcomes from individuals who use marijuana and marijuana-derived products that have doses of Δ9–THC that range from low to very high, and yet the data demonstrate that these products overall are producing fewer negative outcomes than drugs in schedules I or II.[25]

HHS compared the rank ordering of selected drugs that are abused for various epidemiological measures and observed that marijuana was among the drugs at the very lowest ranking for a number of measures, including poison center (PC) abuse cases, likelihood that any use would lead to a PC call, accidental or unintentional poisoning, utilization-adjusted rates of unintentional exposure, utilization-adjusted and population-adjusted rates for emergency department visits and hospitalizations, likelihood of being diagnosed with a serious substance abuse disorder, deaths reported to PCs, and overdose deaths when used with other drugs or as a single substance (as total numbers and when utilization-adjusted). In contrast, comparators such as heroin (schedule I), oxycodone (schedule II), and cocaine (schedule II) typically were in the highest rank ordering on these measures.[26]

For the various epidemiological measures evaluated above, HHS noted that marijuana was also compared to controlled substances in schedule III (ketamine) and schedule IV (benzodiazepines, zolpidem, and tramadol), as well as to other schedule II substances (fentanyl and hydrocodone). The analyses were conducted in this manner to provide a comprehensive assessment of the relative abuse potential of marijuana. However, the rank order of these substances regarding harms does not consistently align with the relative scheduling placement of these drugs in the CSA due to the pharmacological differences between various classes of drugs.[27]

There are a number of confounding factors that likely influence the adverse outcomes measured in various epidemiological databases and account for the rank ordering of the drugs evaluated on these measures. For example, a different population abuses each substance, and each substance has

[19] In the House Report to the bill that would become the CSA, this issue is explained as follows:

Under subsection [811(d)], where control of a drug or other substance by the United States is required by reason of its obligations under [the Single Convention], the bill does not require that the Attorney General seek an evaluation and recommendation by the Secretary of Health, Education, and Welfare, or pursue the procedures for control prescribed by the bill but he may include the drug or other substance under any of the five schedules of the bill which he considers most appropriate to carry out the obligations of the United States under the international instrument, and he may do so without making the specific findings otherwise required for inclusion of a drug or other substance in that schedule.

H. Rep. No. 91–1444, at 36 (1970). *See also Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements,* 83 FR 48950, 48952 & n.8 (Sept. 28, 2018). Of note, a 1977 D.C. Circuit decision considered not the plain text of the statute, but rather certain aspects of the legislative history, to conclude that 21 U.S.C. 811(d)(1) still requires DEA to request a scientific and medical evaluation and scheduling recommendation from HHS in certain circumstances, such as when a substance can be placed in more than one schedule under the CSA and still satisfy obligations under the Single Convention. *Nat'l Org. for Reform of Marijuana Laws (NORML)* v. *Drug Enforcement Admin.,* 559 F.2d 735, 746–47 (D.C. Cir. 1977) (stating that the ''language of Section 201(d) is consistent with the clear import of the Act's legislative history,'' including certain floor debates and comments by various congressmen, and ''must be read against this backdrop of intense concern with establishing and preserving [HHS's] avenue of input into scheduling decisions''). Because HHS has provided DEA with a medical and scientific evaluation and scheduling recommendation for marijuana, DEA has met this additional procedural requirement.

[20] *See* Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (Aug. 29, 2023) (''August 2023 Letter''); *see also* Memorandum for DEA, from HHS, *Re:* Basis for the Recommendation to Reschedule Marijuana to Schedule III of the Controlled Substances Act (''HHS Basis for Rec.'').

[21] HHS Basis for Rec. at 62–65.

[22] *See* 21 U.S.C. 812(b)(3).

[23] HHS Basis for Rec. at 62.

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.* at 63.

a different prevalence of abuse and a different profile of severe adverse outcomes in a setting of nonmedical use and abuse. Thus, it is challenging to reconcile the ranking of relative harms associated with the comparators used in this evaluation when the rankings differ across various epidemiological databases and when these rankings often do not align with the scheduling placement of these comparators under the CSA.[28]

To address these challenges, HHS evaluated the totality of the available data and concluded that it supports the placement of marijuana in schedule III. Overall, these data demonstrate that, according to HHS, although marijuana is associated with a high prevalence of abuse, the profile of and propensity for serious outcomes related to that abuse lead to a conclusion that marijuana is most appropriately controlled in schedule III under the CSA.[29]

Second, HHS found that abuse of marijuana may lead to moderate or low physical dependence or high psychological dependence.[30] Regarding physical dependence, as evidenced by its associated withdrawal symptomology upon abrupt discontinuation of use, the most commonly reported marijuana withdrawal symptoms in clinical investigations are sleep difficulties, decreased appetite and weight loss, craving, irritability, anger, anxiety or nervousness, and restlessness. Marijuana withdrawal symptoms typically peak within two to six days and decline over one to two weeks as Δ9–THC is eliminated. Similarly, the drug labels for the FDA-approved drug products Marinol and Syndros state that, following chronic administration of dronabinol, drug discontinuation leads to irritability, insomnia, and restlessness at 12 hours, and by 24 hours the withdrawal symptoms can include hot flashes, sweating, rhinorrhea, diarrhea, and anorexia.[31]

HHS observed that marijuana withdrawal syndrome has been reported in individuals with heavy, chronic marijuana use, but its occurrence in occasional users of marijuana has not been established. Marijuana withdrawal syndrome appears to be relatively mild compared to the withdrawal syndrome associated with alcohol, which can include more serious symptoms such as agitation, paranoia, seizures and even death. Multiple studies comparing the withdrawal symptoms associated with marijuana and tobacco demonstrate that the magnitude and time course of the two withdrawal syndromes are similar.[32]

Based on the evidence, HHS determined that the abuse of marijuana may lead to moderate or low physical dependence, depending on frequency and degree of marijuana exposure. HHS further concluded that marijuana can produce psychic dependence in some individuals, but that the likelihood of serious outcomes is low, suggesting that high psychological dependence does not occur in most individuals who use marijuana.[33]

Although I am not required to consider this HHS recommendation when issuing an order under section 811(d)(1), because I believe there are several legally viable scheduling options that would satisfy the United States' obligations under the Single Convention based on OLC's 2024 opinion discussed above, I exercise my discretion in determining the most appropriate schedule by choosing the option that most closely aligns to HHS's findings and best positions the United States to carry out its obligations under the Single Convention with regard to marijuana crops and other marijuana that has not yet been manufactured into an FDA-approved product or subject to a state medical marijuana license. Namely, I am hereby ordering that FDA-approved drug products containing marijuana, as well marijuana in any form covered by a state medical marijuana license, be placed in schedule III of the CSA.[34]

Additionally, maintaining unlicensed bulk marijuana in schedule I allows the United States to continue to meet two of its obligations under the Single Convention without disruption. First, as indicated above, for drugs listed in Schedule I of the Single Convention, parties are obligated to require that licensed manufacturers of such drugs obtain quotas specifying the amounts of such drugs they may manufacture. The purpose of this treaty requirement is to prevent excessive production and accumulation beyond that necessary to satisfy legitimate needs. Under this scheduling order, the United States will continue to meet this obligation without disruption or delay because unlicensed bulk marijuana, marijuana extract, and Δ9–THC material used to make FDA-approved drug products will remain in schedule I of the CSA and thus be subject to all applicable quota provisions under 21 U.S.C. 826; and because state-licensed marijuana will be required to meet the quota requirements of the Single Convention.

Second, as also discussed above, pursuant to a 2018 OLC opinion, DEA must buy marijuana crops from registered manufacturers, be the seller of that marijuana to any eligible registered purchaser, and establish prices for such purchase and sale.[35] Marijuana growers must pay DEA an administrative fee for such transactions.[36] These actions are necessary for the United States to meet its obligations under articles 23 and 28 of the Single Convention.[37] By maintaining in schedule I all unlicensed marijuana crops, bulk marijuana, and any marijuana or marijuana extract that has not yet been incorporated into a FDA-approved drug product, and by requiring that state-licensed marijuana satisfy the requirements relating to the purchase and sale of marijuana by DEA, the United States will continue to meet these obligations without disruption or delay.

Placing only FDA-approved products containing marijuana and state-licensed marijuana in schedule III also is consistent with articles 23 and 28 of the Single Convention and 21 CFR 1318.04(b), which specify that the requirement to monopolize the wholesale trade in marijuana does not extend to ''medicinal cannabis.'' Medicinal cannabis is defined in 21 CFR 1318.02(b) to mean ''a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act [(FD&C Act)].'' The final rule exempts marijuana subject to state medical marijuana licenses from the requirement to monopolize the wholesale trade in marijuana.

This final rule rescheduling marijuana contained in FDA-approved products or subject to a state medical marijuana license applies to marijuana as listed in 21 CFR 1308.11(d)(23), as well as marijuana extracts as defined in 21 CFR 1308.11(d)(58) because they meet the statutory definition of marijuana and, prior to 2017, were included in 21 CFR 1308.11(d)(23).[38] In addition, this final

[28] *Id.*

[29] *Id.*

[30] *Id.* at 65.

[31] *Id.* at 64.

[32] *Id.*

[33] *Id.* at 65.

[34] Article 5 of the Single Convention requires parties to take legislative and administrative measures ''to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of'' the substances covered by the treaty. In this order, DEA is carrying out this obligation by limiting the rescheduling to FDA-approved drug products and marijuana covered by licenses issued under state-medical-marijuana regulatory regimes.

[35] *See 2018 OLC Opinion, supra n.12. See also* 21 CFR 1318.06(b).

[36] 21 CFR 1318.06.

[37] *2018 OLC Opinion, supra n.12. See also* Single Convention arts. 23, 28.

[38] *See Establishment of a New Drug Code for Marijuana Extract,* 81 FR 90194 (Dec. 14, 2016).

rule applies to Δ9–THC derived from the marijuana plant (other than the mature stalks and seeds) that falls outside the definition of hemp, because it meets the statutory definition of marijuana.

This final rule does not apply to synthetically derived THC, which is outside the CSA's definition of marijuana. Tetrahydrocannabinols that can be derived only through a process of artificial synthesis (*e.g.,* delta-10-tetrahydrocannabinol) are excluded. HHS provided a scientific and medical evaluation only relating to ''marijuana'' as defined in the CSA. That definition is limited to the plant (other than the mature stalks and seeds) and derivatives of the plant. Therefore, synthetic THC remains in schedule I.

This final rule also does not affect the status of hemp (as defined in 7 U.S.C. 1639*o*), because hemp is excluded from the definition of marijuana. This final rule is not rescheduling any drug product containing marijuana or THC that previously has been rescheduled out of schedule I (*e.g.,* Marinol and Syndros). Nor does it impact the status of any previously scheduled synthetic cannabinoids.

As noted, this order placing FDA-approved drug products containing marijuana and state-licensed medical marijuana in schedule III will only comport with 21 U.S.C. 811(d)(1) if all importations and exportations of products containing marijuana remain subject to the permit requirement. Until now, since all marijuana has been a schedule I controlled substance, any importation has been subject to the permit requirement. To ensure this requirement remains in place (and thus to prevent any lapse in compliance with the requirements of the Single Convention), this order amends the DEA regulations (21 CFR 1312.30) to add FDA-approved drug products containing marijuana and state-licensed medical marijuana to the list of nonnarcotic schedule III through V controlled substances that are subject to the import and export permit requirement.[39]

Tax Implications

The Acting Attorney General further notes that, as a consequence of this rule, state licensees will no longer be subject to the deduction disallowance imposed by Section 280E of the Internal Revenue Code, which applies only to businesses engaged in ''trafficking in controlled substances . . . in a schedule I or II,'' 26 U.S.C. 280E. Nothing in this rule constitutes a determination regarding federal tax liability, and qualifying state licensees should consult with tax counsel regarding the applicability of Section 280E to their specific circumstances.

Requirements for Handling FDA-Approved Drug Products Containing Marijuana

Preliminarily, it should be noted that any form of marijuana other than in an FDA-approved drug product or marijuana subject to a state medical marijuana license remains a schedule I controlled substance, and those who handle such material remain subject to the regulatory controls, and administrative, civil, and criminal sanctions, applicable to schedule I controlled substances set forth in the CSA and DEA regulations.

However, for those who handle marijuana exclusively in the form of an FDA-approved drug product, the following is a summary of the schedule III regulatory requirements that will apply upon the effective date of this final rule:

1. *Registration.* Any person who handles (*e.g.,* manufactures, distributes, dispenses, imports, exports, engages in research, reverse distributes, or conducts instructional activities or chemical analysis with) FDA-approved drug products containing marijuana must be registered with DEA to conduct such activities.[40] That is, persons and entities wishing to distribute or dispense (including prescribe) marijuana in an FDA-approved product must first obtain a DEA registration applicable to schedule III controlled substances. Entities that transfer marijuana to patients, including dispensaries, must register with DEA as ''practitioners'' under 21 U.S.C. 823(g). Registration under that provision does not allow the practitioner to possess or dispense (including prescribe) schedule I controlled substances, including marijuana and marijuana extracts that are in a form other than an FDA-approved drug product or marijuana subject to a state medical marijuana license.

2. *Disposal of stocks.* Schedule III FDA-approved drug products containing marijuana must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Fees.* Each applicant for registration, other than those employed by state or Federal governments, must pay a registration fee. Current fees are: (1) Manufacturers: $3,699 annually; (2) Distributors: $1,850 annually; and (3) Dispensers, including pharmacies: $888 for a registration valid for 3 years.

4. *Prescriptions.* Prescriptions for FDA-approved drug products containing marijuana are required prior to dispensing, except when dispensed directly by a DEA-registered practitioner, such as a physician, dentist, veterinarian, or hospital.[41] Prescriptions must be ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.'' [42] Prescriptions must include ''the drug name, strength, dosage form, quantity prescribed, directions for use,'' among other items.[43] Under DEA's regulations, both the prescribing practitioner and the pharmacist who fills the prescription have responsibility for the proper prescribing and/or dispensing of controlled substances.[44]

5. *Records and Reports.* All DEA registrants must maintain records and submit reports with respect to FDA-approved drug products containing marijuana.[45]

6. *Security.* All DEA registrants must comply with regulatory security requirements.[46]

7. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of FDA-approved drug products containing marijuana must meet all applicable schedule III labeling and packaging requirements.[47]

8. *Inventory.* Any person registered with DEA to handle FDA-approved drug products containing marijuana must make an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances. After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including

[39] It is DEA's intention that the provisions of this final rule shall operate independently of each other. If this final rule, or any portion of this final rule, is ultimately declared invalid or stayed as to a particular provision, it is DEA's intent that the final rule nonetheless be severable and remain valid with respect to those provisions not affected by a declaration of invalidity or stayed. DEA concludes it would separately adopt all of the provisions contained in this final rule.

[40] 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301, 1312, and 1318.

[41] 21 U.S.C. 829(a), (b); 21 CFR 290.1. *See also* Single Convention, art. 30. Dispensing generally refers to the lawful delivery of marijuana by a DEA registrant to an ultimate user. *See* 21 U.S.C. 802(10).

[42] 21 CFR 1306.04(a).

[43] 21 CFR 1306.05(a).

[44] *Id.* 1306.04(a).

[45] 21 U.S.C. 827 and 832(a); 21 CFR 1301.74(b) and (c), and parts 1304, 1312, and 1317.

[46] 21 U.S.C. 821, 823; 21 CFR 1301.71–1301.76; 1301.90–1301.93.

[47] 21 U.S.C. 825 and 958(e); 21 CFR part 1302.

FDA-approved drug products containing marijuana) on hand every two years.[48]

9. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule III controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of FDA-approved products containing marijuana may only be for the legitimate purposes authorized by the FD&C Act and the CSA.

10. *Liability.* Any activity involving FDA-approved drug products containing marijuana not authorized by, or in violation of the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions

Registration of State Licensees

State medical marijuana regulatory systems have matured significantly since California first authorized medical use in 1996, and today the vast majority of States maintain comprehensive licensing frameworks governing cultivation, processing, distribution, and dispensing of marijuana for medical purposes. These state regimes have developed robust infrastructure for preventing diversion, ensuring product safety, maintaining records, and conducting facility inspections—functions that fulfill the objectives of federal registration and recordkeeping requirements. The Attorney General has reviewed the operation of these state systems and finds that, taken as a whole, they demonstrate a sustained capacity to achieve the public-interest objectives that underlie the CSA's registration framework, including protecting public health and safety and preventing the diversion of controlled substances into illicit channels.

In light of that record, the Attorney General has determined that incorporating state licensing systems into the federal registration framework represents the most effective and efficient means of achieving the CSA's objectives with respect to medical marijuana while promoting the medical benefits of marijuana and causing the least disruption for patients and existing state systems. The rule accordingly leverages existing regulatory infrastructure while preserving the Administrator's authority to deny or revoke registration where specific public-interest concerns arise and to ensure compliance with the Single Convention. This approach reflects the Attorney General's considered judgment that cooperative federalism best serves the statutory purposes of the CSA in the context of a well-regulated medical marijuana market.

The proposed amendments to part 1301 establish a new registration pathway for state-licensed medical marijuana entities seeking federal DEA registration as manufacturers, distributors, and/or dispensers. The regulation creates an expedited review process under which applicants holding state medical marijuana licenses may submit their existing state credentials as conclusive evidence of state-law authorization. The Administrator must grant registration unless doing so would be inconsistent with the public interest under the 21 U.S.C. 823 factors or with the requirements of the Single Convention. A DEA registration automatically suspends upon suspension, revocation, or expiration of the underlying state-issued license, ensuring that federal authorization tracks state authorization. To facilitate a prompt transition, the Administrator is directed to process applications submitted within 60 days of publication within six months, and early applicants may lawfully operate under their state-issued licenses during the pendency of review.

The rule contains several provisions designed to reduce regulatory burden on compliant state-licensed entities. Reporting, recordkeeping, and order-form requirements are limited to what is strictly necessary to satisfy federal statutory and treaty obligations, with state-required records accepted to the maximum extent permissible. State-authorized medical marijuana certifications or similar documents are sufficient to permit the dispensing of medical marijuana to users, provided they include the user's name and address, are dated and signed on the day of issuance, and identify the issuing practitioner. Similarly, registrants may rely on state-law labeling, packaging, disposal, and physical-security requirements in lieu of the otherwise-applicable federal requirements, subject to inclusion of the statutory warning label required by 21 U.S.C. 825(c).

To address Single Convention compliance under Article 23, the rule establishes a nominal-price purchase-and-resale mechanism through which the Administration acquires and resells registered manufacturers' marijuana crops, thereby satisfying the Convention's requirement that a government agency serve as the exclusive purchaser of cannabis production. Registered manufacturers must store crops in a facility to which DEA maintains access until that transaction is complete, and each manufacturer registration must specify the areas in which cultivation is permitted. The Administrator is also authorized to require record-keeping and reporting necessary to comply with the Single Convention, and the Administrator must take into account the requirements of the Single Convention, including any quota requirements, in evaluating applications.

Out of an abundance of caution, the Administrator clarifies that researchers who obtain marijuana or marijuana-derived products from a state licensee for use in scientific research shall incur no civil or criminal liability under the Controlled Substances Act solely by reason of having obtained such products from a state-licensed source rather than a separately DEA-registered bulk manufacturer, provided that the researcher is registered with the Administration to conduct research with marijuana under 21 CFR. 1301.13 and the state licensee from whom the researcher obtained the marijuana held a valid federal registration at the time of the transfer. The Administrator shall not treat the use of state-licensed marijuana products in federally registered research as a basis for adverse action against a researcher's registration.

The Administrator further notes that, as a consequence of this rule, holders of state medical marijuana licenses will no longer be subject to the deduction disallowance imposed by Section 280E of the Internal Revenue Code, which applies only to businesses engaged in ''trafficking in controlled substances . . . in a schedule I or II,'' 26 U.S.C. 280E. The Administrator encourages the Secretary of the Treasury to consider providing retrospective relief from Section 280E liability for taxable years in which a state licensee operated under a state medical marijuana license. Nothing in this rule constitutes a determination regarding federal tax liability, and state licensees should consult with tax counsel regarding the applicability of Section 280E to their specific circumstances.

Regulatory Analyses

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols.[49] If control is required pursuant to such international

[48] 21 U.S.C. 827 and 958(e); 21 CFR 1304.03, 1304.04, and 1304.11.

[49] 21 U.S.C. 811(d)(1).

treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, and ''without regard to'' the findings and rulemaking procedures otherwise required for scheduling actions in 21 U.S.C. 811(a) and (b).[50]

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order, as opposed to scheduling by rule pursuant to 21 U.S.C. 811(a). Therefore, DEA believes that the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action.

Executive Orders 12866, 13563, 14192, and 14294

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866, Regulatory Planning and Review, and the principles reaffirmed in E.O. 13563, Improving Regulation and Regulatory Review. DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

While this scheduling action is exempt from review under E.O. 12866, DEA recognizes this action may have unique economic impacts. Marijuana is subject to a number of State laws that have allowed a multibillion-dollar industry to develop. DEA acknowledges that there may be large impacts related to Federal taxes and research and development investment for the pharmaceutical industry, among other things.

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[51] applies to rules that are subject to notice and comment under the APA or any other law. As explained above, this final rule is not subject to the notice-and-comment procedures of the APA. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new or revised ''collection[s] of information'' as defined by the Paperwork Reduction Act of 1995.[52]

Unfunded Mandates Reform Act of 1995

DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995[53] that this final rule would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This order is not a major rule as defined by the Congressional Review Act (CRA).[54] However, DEA is submitting reports under the CRA to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Registration requirements.

21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting requirement.

For the reasons set out above, DEA amends 21 CFR parts 1300, 1301, 1308, and 1312 as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

■ 2. Amend § 1300.01 by adding the definitions of ''Marijuana''and ''State medical marijuana license'' in alphabetical order to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

Marijuana shall have the meaning set forth at 21 U.S.C. 802(16)(A).

* * * * *

State medical marijuana license means a license issued by a state entity (or by a District of Columbia entity or a federal territorial entity) authorizing the licensee to manufacture, distribute, and/or dispense marijuana or products that contain marijuana for medical purposes.

* * * * *

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965.

■ 4. Amend § 1301.13 by adding paragraph (k) to read as follows.

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(k) *Medical marijuana registrations.* The Administration shall establish an expedited review process for entities holding state medical marijuana licenses who seek registration as a marijuana manufacturer, distributor, or dispenser. Such applicants shall submit, along with the applicable DEA form or forms, proof of a state medical

[50] *Id.*

[51] 5 U.S.C. 601 *et seq.*

[52] 44 U.S.C. 3502(3).

[53] 2 U.S.C. 1501 *et seq.*

[54] 5 U.S.C. 804.

marijuana license in the form specified by the Administrator. The Administrator shall register an applicant under this subsection unless the Administrator determines that the issuance of such registration is inconsistent with the public interest, taking into account the factors set forth at 21 U.S.C. 823(e) through (g), as applicable, and the requirements of the Single Convention on Narcotic Drugs, including any quota requirement. In general, registration of an applicant that complies with a state-law regime that contains robust protections against diversion, requirements for record-keeping and reporting, and safety and inspection measures will not be inconsistent with the public interest so long as registration is consistent with the Single Convention.

(1) *Types of registrations.* (i) A registered marijuana manufacturer may cultivate, produce, process, package, label, and transfer marijuana and products containing marijuana to registered distributors or other registered manufacturers, subject to the limitations of its state license.

(ii) A registered distributor may receive marijuana and products containing marijuana from registered manufacturers and transfer marijuana and products containing marijuana to registered dispensers or other registered distributors, subject to the limitations of its state license.

(iii) A registered dispenser may dispense marijuana and products containing marijuana to individuals authorized by state law to possess marijuana and products containing marijuana for medical purposes, subject to the limitations of its state license.

(iv) Registrations under this subpart do not authorize the manufacture, distribution, dispensing, or use of marijuana or products containing marijuana for non-medical purposes.

(v) A single entity may be granted multiple types of registrations.

(2) *State licenses as evidence of State authorization.* For purposes of 21 U.S.C. 823(e) through (g), and for any other purpose, a state license shall constitute conclusive evidence that the applicant is authorized under state law to engage in the activity for which registration is sought.

(3) *Suspension, revocation, or expiration of State license.* A registration issued under this section shall not exceed the scope of the holder's state medical marijuana license. If the state medical marijuana license is suspended, revoked, or expires, the DEA registration is automatically suspended.

(4) *Reports, records, and order forms.* Notwithstanding any other provision of this part, the Administrator shall require registrants under this subsection to submit only such reports and records, and to use only such order forms, as the Administrator concludes are necessary to comply with federal statutory and treaty obligations. The Administrator shall accept state-required reports, records, and forms to the maximum extent permissible.

(5) *Prescriptions.* Notwithstanding part 1306 of this chapter or any other provision of these rules, a certification or other document (including an electronic document) that state law deems sufficient for a user to obtain marijuana or products containing marijuana for medical purposes shall be sufficient to permit dispensing of marijuana or products containing marijuana to a user so long as the certification or other document is dated as of, and signed on, the day when issued; bears the full name and address of the user; and contains the name, address, and state license number of the practitioner who signed the certification or other document and is authorized to do so under state law.

(6) *Compliance with Article 23 of the Single Convention on Narcotic Drugs.* Part 1318 of this chapter shall not apply to entities holding valid licenses under this paragraph (k)(6).

(i) All manufacturers registered under this subsection shall establish a nominal price for the purchase of their marijuana crops. The Administration shall then purchase the entity's crops at that price and sell the crops back to the entity, or a related or subsidiary entity, at the same price with the addition of the administrative fee as calculated under § 1318.06(a) of this chapter.

(ii) All registered manufacturers shall store marijuana crops in a facility to which the Administration maintains access until the transaction set forth in paragraph (k)(6)(i) of this section is complete. The Administration shall have the right to inspect such facilities on demand.

(iii) A registration for a manufacturer under this subsection shall specify the areas in which marijuana cultivation is permitted.

(7) *Expedition.* The Administrator shall make every effort to process all applications submitted within 60 days of the publication of this regulation in the **Federal Register** within six months. Notwithstanding paragraph (a) of this section, any applicant that submits an application within 60 days of the publication of this rule in the **Federal Register** may engage in the manufacture, distribution, and/or dispensing of marijuana or products containing marijuana for medical purposes in conformity with a state-issued license during the pendency of the application.

(8) *Labeling, packaging, and sealing.* A registrant under this subsection is exempt from the labeling, packaging, and sealing requirements under part 1302 of this chapter, and other provisions of these rules so long as they label, package, and seal marijuana and products containing marijuana in conformity with state law and so long as the label includes the warning required by 21 U.S.C. 825(c), where applicable.

(9) *Disposal.* Notwithstanding part 1317 of this chapter. or any other provision of these rules, a registrant under this paragraph may dispose of marijuana and products containing marijuana in conformity with state law.

(10) *Security Requirements.* Notwithstanding any other provision of these rules, a registrant under this paragraph has sufficient physical-security requirements if the registrant meets the requirements of state law.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 5. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 6. Amend § 1308.13 by adding new paragraphs (g)(2) through (5) to read as follows.

§ 1308.13 Schedule III.

* * * * *

(g) * * *

* * * * * * *

(2) Marijuana, as defined in 21 U.S.C. 802(16), in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license	XXXX
(3) Marijuana extract, as defined in 21 CFR 1308.11(d)(58), in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license	XXXX
(4) Naturally derived delta-9-tetrahydrocannabinols in a U.S. Food and Drug Administration approved product or in marijuana subject to a state medical marijuana license	XXXX

(i) Naturally derived delta-9-tetrahydrocannabinols means those delta-9-tetrahydrocannabinols, except as in paragraphs (g)(2) and (3) of this section, that are naturally contained in a plant of the genus Cannabis (cannabis plant)..
(ii) Naturally derived delta-9-tetrahydrocannabinols do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*..
(iii) Naturally derived delta-9-tetrahydrocannabinols do not include any delta-9-tetrahydrocannabinols contained in substances excluded from the definition of marijuana as set forth in 21 U.S.C. 802(16)(B)(ii)..
(5) [Reserved] XXXX

* * * * * * *

* * * * *

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

■ 7. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 821, 871(b), 952, 953, 954, 957, 958.

■ 8. Amend § 1312.30 by:

■ a. Redesignating paragraph (b) as paragraph (e); and

■ b. Adding new paragraphs (b), (c), and (d).

The additions to read as follows:

§ 1312.30 Schedule III, IV, and V non-narcotic controlled substances requiring an import and export permit.

* * * * *

(b) Marijuana, as defined in 21 U.S.C. 802(16), in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license.

(c) Marijuana extract, as defined in 21 CFR 1308.11(d)(58), in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license.

(d) Naturally derived delta-9-tetrahydrocannabinols in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license.

(1) Naturally derived delta-9-tetrahydrocannabinols means those delta-9-tetrahydrocannabinols, except as in paragraphs (g)(2) and (3) of this section, that are naturally contained in a plant of the genus Cannabis (cannabis plant).

(2) Naturally derived delta-9-tetrahydrocannabinols do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*.

(3) Naturally derived delta-9-tetrahydrocannabinols do not include any delta-9-tetrahydrocannabinols contained in substances excluded from the definition of marijuana as set forth in 21 U.S.C. 802(16)(B)(ii).

* * * * *

Dated: April 22, 2026.

Todd Blanche,

Acting Attorney General.

[FR Doc. 2026–08176 Filed 4–27–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1917

[Docket No. OSHA–2025–0007]

RIN 1218–AD51

Open Fires in Marine Terminals

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule.

SUMMARY: OSHA is finalizing the revocation of the agency's Open Fires in Marine Terminals Standard.

DATES: The final rule is effective April 28, 2026.

ADDRESSES: *Docket:* The docket for this rulemaking (Docket No. OSHA–2025–0007) is available at *https://www.regulations.gov,* the Federal eRulemaking Portal. Most exhibits are available at *https://www.regulations.gov;* some exhibits (*e.g.,* copyrighted material) are not available to download from that web page. However, all materials in the dockets are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2500 (TDY number 877–889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Contact Frank Meilinger, Director, OSHA Office of Communications, Occupational Safety and Health Administration; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General information and technical inquiries: Contact Andrew Levinson, Director, OSHA Directorate of Standards and Guidance, Occupational Safety and Health Administration; telephone: (202) 693–1950; email: *osha.dsg@dol.gov.*

Copies of this ***Federal Register*** *notice:* Electronic copies are available at *https://www.regulations.gov.* This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's web page at *https://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

This final rule revokes the Open Fires in Marine Terminals Standard, 29 CFR 1917.21 (''Open Fires Standard''). OSHA has determined that this standard is no longer necessary to protect employees working in marine terminals from occupational safety and health hazards. This is a deregulatory action per Executive Order 14192, ''Unleashing Prosperity Through Deregulation'' (90 FR 9065 (Feb. 6, 2025)).

II. Legal Authority

The purpose of the Occupational Safety and Health Act (29 U.S.C. 651 *et seq.*) (''the Act'' or ''the OSH Act'') is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources'' (29 U.S.C. 651(b)). To achieve this goal Congress authorized the Secretary of Labor (''the Secretary'') to promulgate standards to protect workers, including the authority ''to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce'' (29 U.S.C. 651(b)(3); see also 29 U.S.C. 654(a)(2) (requiring employers to comply with OSHA standards), 29 U.S.C. 655(a) (authorizing summary adoption of existing consensus and established federal standards within two years of the Act's enactment), and 29 U.S.C. 655(b) (authorizing promulgation, modification or revocation of standards pursuant to notice and comment)). An occupational safety and health standard is ''. . . a standard which requires conditions, or

Exhibit B

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

SAM, INC., et al., *Petitioners*, v. U.S. DEPARTMENT OF JUSTICE, et al., *Respondents*.	**Case No. 26-1106** Consolidated with Nos. 26-1130 and 26-1136

DECLARATION OF M. JO MCGUIRE

I, M. Jo McGuire, declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am the Executive Director of the National Drug and Alcohol Screening Association, a position I have held since 2019. I have personal knowledge of NDASA's mission, operations, membership, and the impact that the sudden transfer of "medical" marijuana in state-licensed programs from Schedule I to Schedule III will have on NDASA and its members. The facts in this declaration come from my own personal observations and knowledge and I could competently testify to them if necessary.

2. I make this Declaration in Support of the joint motion of NDASA, MMJ International Holdings, Inc., MMJ Biopharma Cultivation, Inc., and MMJ Biopharma Labs, Inc. for stay pending review of the Attorney General's order

entitled "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" that was published by Respondents in the Federal Register at 91 Fed. Reg. 22714 (Apr. 28, 2026) ("Rescheduling Order").

3. I have worked in the drug testing industry for over 17 years. I became the Executive Director of NDASA in 2019.

4. Founded in 2018, NDASA is a 501(c)(6) trade association for the drug and alcohol screening industry. NDASA currently has over 3500 members representing over 450 organizations and businesses. Members include private employers regulated by Department of Transportation (DOT) in the trucking, aviation, and railroad sectors; public employers such as public utilities, city municipalities, and state departments of transportation; private employers not covered by federal transportation regulations, including oil and gas companies, construction companies, and manufacturers; and all sectors of the drug and alcohol screening industry, including drug testing companies, drug testing device manufacturers, drug testing laboratories, medical review officer practices, third-party drug testing administrators, and substance abuse professionals.

5. I also previously worked for 5 years in a medical review officer practice, starting as the Director of Compliance and working as a Medical Review

Officer Assistant, and later I became Corporate Trainer to help set up drug test collection franchisees for the parent company. As Executive Director of NDASA, I am routinely informed of the impact that drug rescheduling will have on medial review officer practices by our medical review officer credentialing associations, who are NDASA members.

A. Drug Test Policy Costs

6. The Order will impact employers nationwide who require employees to undergo drug testing.

7. There are approximately 900,000 employers who are obligated by DOT regulations to drug test their employees. Approximately another 2 million employers not covered by DOT regulations voluntarily choose to pay for drug tests. The vast majority of these non-DOT employers nevertheless adopt federal drug testing guidelines.

8. Employers that administer drug tests to their employees, whether by federal mandate or as a desired business practice, must have in place a drug testing policy before they can administer a drug test to their employees. The majority of states require such policies to give employees pre-test notice of which drugs will be tested for and how the test will be conducted.

9. The notice requirement extends to changes made to an existing drug test policy program. If an employer already has a drug test policy but they decide

to, for example, eliminate marijuana testing or change the consequences for testing positive for marijuana, they will need to revise their drug test policy to give employees sufficient notice.

10. Drug test policies usually contain five sections: (1) timing of the test (*e.g.*, pre-employment, annual, or random); (2) the drugs covered by the test; (3) the test method (*e.g.*, urine or oral fluid); (4) prohibited conduct (*e.g.*, testing positive, being under the influence while on duty, or causing an accident under the influence); and (5) consequences (*e.g.*, termination, reprimand).

11. Rescheduling marijuana from Schedule I to Schedule III under the Controlled Substances Act triggers multiple necessary changes to an employer's drug testing policy. The prohibited conduct and consequences sections of the policy will need to be revised to account for medical use of marijuana, which may be protected by the Americans With Disabilities Act or state law employment protections. To differentiate protected medical marijuana use from improper workplace marijuana use, some employers may decide to change a urine-sample test to a (more expensive) oral-fluid test because the latter provides more precise information about the time of marijuana use. And many employers may simply decide to drop marijuana testing entirely. All of these changes will require revisions to an employer's drug testing policy.

12. Depending on the size of the company and a company's unique drug testing needs, updating a drug test policy to account for the Rescheduling Order will cost $500 to $3,000 per employer. Multiplied across the 2.9 million employers who currently use drug testing, the policy revision costs could easily exceed $1 billion.

13. The Order will require every NDASA member employer to either drop drug testing altogether or pay for a revised drug testing policy that accounts for marijuana's status as a substance that, in some contexts, is under Schedule III of the Controlled Substances Act.

14. For NDASA's 700 employer members, I estimate that the cost of revising drug policies alone will exceed $700,000.

15. I estimate that NDASA members will accrue these costs over the next several months through the end of FY2026 as employers adjust to marijuana's new status.

B. Costs Specific To Medical Review Officer Practices

16. Based on my experience working in a medical review officer practice and as Executive Director of NDASA, the Rescheduling Order will have an irreversible and devastating effect on the medical review officer industry.

17. Medical Review Officers are licensed physicians who interpret and transmit drug test results to end-users such as employers. Medical Review Officers work in a connected chain with collectors who gather biological samples (urine,

typically) and drug testing laboratories, which analyze the samples and provide the results to medical review officers, who verify and interpret the data.

18. Most medical review officer practices derive all or nearly all of their revenue from private employers who drug test their employees. These private employers fall into one of two categories: employers in transportation industries like trucking, aviation, and railroads, who are required by law to screen their employees for certain drugs by the DOT, and all other employers that test their employees for illegal drugs to promote productivity and workplace safety. Employers who are not regulated by DOT comprise about 85% of the business revenue for medical review officer practices.

19. Medical review officer practices derive revenue from the number of positive results received and interpreted.

20. When a patient's drug test reveals a laboratory confirmed positive result for a particular substance, a medical review officer must determine whether there is a legitimate medical explanation. For other Schedule III drugs like benzodiazepines (*e.g.*, Xanax), determining whether the substance was medically authorized requires contacting a pharmacy or prescribing physician, and verifying the existence of the user's prescription and date of medication pickup (to ensure pickup was prior to the drug screening and not after). Based on that information, the medical review officer then determines whether the positive result has a legitimate medical explanation. If

the medical explanation does not hold up to scrutiny, the medical review officer reports their findings to the employer.

21. Delta-9 THC, the primary intoxicating compound in marijuana, is the most common laboratory positive result that Medical Review Officers must analyze and report to employers. Reviewing positive THC results usually accounts for more than 50% of a medical review officer practice's total revenue.

22. Prior to the Rescheduling Order, because marijuana was a Schedule I substance, it had no medical use at the federal level, so Medical Review Officers did not need to attempt to verify whether a positive result for Delta-9 THC was a result of marijuana use in connection with a state-licensed medical marijuana program.

23. If marijuana in state-administered medical marijuana programs is transferred to Schedule III, then medical review officers will have to determine whether a positive result for Delta-9 THC was due to a test subject's use of medical marijuana as authorized under a state program.

24. Assessing whether a positive result for Delta-9 THC comes from a medical use under a state program is very difficult and time consuming. As of today, no state medical marijuana program dispenses cannabis by a standardized prescription where the cannabis is picked up at a pharmacy. Unlike a prescription of traditional medicine, a state-issued recommendation for "medical" marijuana does not provide the name of the recommending physician, let alone their contact

information, or information about the dose and date of pickup. Dispensaries in state programs also do not keep records of purchase that are publicly accessible, and some states have laws against such records being publicly accessible.

25. As a result, a medical review officer will be required to analyze an employee's medical marijuana authorization form and track down their recommending physician. This process will add substantial time and labor, driving up the cost of processing those positive results for Delta-9 THC.

26. While some employers will pay the increased costs, most will drop marijuana from their drug testing panel. Because there will no longer be a complete federal criminal bar on marijuana, many employers will decide that it is no longer worth the expense to test for marijuana. And since marijuana positive results are the largest source of revenue for medical review officer practices, I believe it is likely that the Rescheduling Order will diminish the revenue of the medical review officer industry by up to 35% to 50% over the next six months to a year.

27. That sudden loss in business will have irreversible effects on the more than 25 medical review officer practices that are NDASA members, including i3screen, Cynergy Wellness Inc., and HireRight.

28. Over the next several months through the end of the year, it is likely that many small medical review officer practices that are members of NDASA either

will find it necessary to consolidate with a larger company to stay afloat or will go out of business as a result of the Rescheduling Order.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 9, 2026

M. Jo McGuire

Exhibit C

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

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.*	Case No. 26-1136

DECLARATION OF DUANE BOISE
IN SUPPORT OF PETITIONERS' MOTION FOR STAY PENDING REVIEW

I, Duane Boise, hereby declare under penalty of perjury pursuant to 28 U.S.C. § 1746 as follows:

I. Personal Background and Competence

1. I am over eighteen years of age and am competent to testify as to the matters stated herein. I make this declaration based on my personal knowledge.

2. I am the Chief Executive Officer of MMJ International Holdings, Inc. ("MMJIH") and its subsidiaries, MMJ BioPharma Cultivation, Inc. ("MMJBC") and MMJ BioPharma Labs, Inc. ("MMJBL") (collectively, "MMJ"). In my role, I have personal knowledge of the organizational structure, operations, mission, programs, finances, regulatory history, and the impact of the Marijuana Rescheduling Order on the activities of MMJIH, MMJBC, and MMJBL.

3. I submit this declaration in support of Petitioners' Motion for Stay Pending Review of the Marijuana Rescheduling Order, 91 Fed. Reg. 22714 (Apr. 28, 2026), which

transferred certain categories of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

II. Corporate Structure and Organizational Purpose

4. MMJ International Holdings, Inc. is a Delaware-incorporated life sciences company established for the purpose of developing pharmaceutical cannabinoid therapeutics under the U.S. Food and Drug Administration ("FDA")'s botanical drug development framework, including the Botanical Drug Development Guidance for Industry issued in December 2016. MMJIH serves as the parent company overseeing regulatory strategy, clinical development planning, chemistry, manufacturing, and controls ("CMC") preparation, and Investigational New Drug ("IND") submissions for cannabinoid-based treatments targeting Huntington's disease and multiple sclerosis.

5. MMJIH has assembled a team of nationally recognized scientists and regulatory professionals to support this mission, including Elio Mariani, Ph.D, a pharmaceutical scientist with over forty years of experience across ethical pharmaceutical companies, who serves as VP of Scientific Affairs and has been responsible for FDA submissions; and Terry Plasse, M.D., who previously developed dronabinol (synthetic tetrahydrocannabinol) as an appetite stimulant in AIDS and has over thirty-five years of experience in drug and biologic development from pre-IND through regulatory approval.

6. MMJ BioPharma Cultivation, Inc. is a Delaware-incorporated subsidiary formed to support the cultivation and production of pharmaceutical-grade cannabis plant material required for extraction and formulation of the active botanical drug

substance used in MMJIH's IND programs. In December 2018, MMJBC submitted an application to the U.S. Drug Enforcement Administration ("DEA") for registration as a bulk manufacturer of marijuana active pharmaceutical ingredient ("API") specifically for use in FDA-authorized clinical trials and drug development.

7. The State of Rhode Island issued a corresponding bulk manufacturing registration to MMJBC; however, the company remains pending final DEA approval necessary to proceed with federally authorized cultivation operations. MMJBC's cultivation facility in Westerly, Rhode Island was designed to employ state-of-the-art automated growth chambers capable of generating medical marijuana with exacting and repeatable secondary metabolite profiles at production levels consistent with federal research supply requirements.

8. MMJBC also retained Jorge Jimenez, a former DEA Diversion Control Division Section Chief with nearly two decades of federal enforcement experience, as Director of Compliance and Regulatory Affairs to ensure full adherence to the Controlled Substances Act and all applicable federal regulations.

9. MMJ BioPharma Labs, Inc. is a Delaware-incorporated subsidiary established to perform analytical testing, formulation support, and regulatory-grade characterization of botanical extracts used in MMJIH's drug development program. MMJBL obtained a DEA Schedule I analytical laboratory registration, issued following a DEA inspection and approval of the laboratory's physical security systems, recordkeeping controls, and diversion-prevention safeguards, consistent with its Rhode Island state authorization. The laboratory's responsibilities include development of

validated analytical methods supporting identity, purity, potency, stability, and batch reproducibility required under FDA botanical drug development standards.

10. These three entities were intentionally structured to operate as an integrated and interdependent pharmaceutical development platform. MMJBC was established to supply standardized botanical source material required for extraction and formulation. MMJBL was established to perform DEA-authorized analytical testing and regulatory characterization of those materials. And MMJIH was established to manage FDA regulatory submissions, clinical trial planning, and pharmaceutical product development. Each entity depends operationally and strategically on the others to advance the development of standardized botanical cannabinoid drug products through the federal FDA and DEA regulatory pathways. The current principal business address for MMJIH, MMJBC, and MMJBL is 101425 Overseas Highway, Suite 170, Key Largo, Florida 33037.

III. Regulatory History and Investment

11. On December 27, 2018, MMJBC submitted DEA applications to import and manufacture marijuana (drug codes 7350, 7360, and 7370) for the purpose of eventually conducting FDA-approved clinical trials, as well as partnering with other researchers using marijuana in their research.

12. On June 22, 2021, the DEA commenced its pre-registration Section 303 investigation process. The investigation concluded with a final on-site visit on October 24, 2021, during which all DEA questions were satisfactorily answered and all security systems and protocols were reviewed. Thereafter, on October 12, 2022, DEA

representatives conducted a further visit at MMJ's Westerly, Rhode Island facility, during which MMJ was asked to supply supplemental information, which MMJ provided in full compliance.

13. The DEA published a Final Rule in December 2020 establishing a registration pathway for manufacturers and research laboratories not to exceed fifteen applicants. *See* 85 Fed. Reg. 82,333 (Dec. 18, 2020). The Final Rule further provided that any corporation already approved by a state to commercialize CBD and hemp would not be permitted to apply for federal DEA registration. *Id.* at 82,338. MMJ's decision to pursue federal DEA registration rather than operate through state-level cannabis authorization was directly informed by this framework and reflects the company's deliberate commitment to full federal compliance.

14. In parallel, MMJ obtained DEA import permits authorizing shipment of cannabis-derived materials from Canada to support its FDA botanical drug development program while the domestic cultivation registration remained pending.

15. In October 2022, MMJBC submitted a detailed response to the National Institute on Drug Abuse ("NIDA") Request for Proposal No. 75N95022R00058 for the "Production of Cannabis and Related Materials for Research." The University of Connecticut submitted letters of support for MMJ's proposal. On November 16, 2022, NIDA eliminated MMJ's proposal from consideration because MMJ could not provide proof of a finalized DEA registration, which was then pending before the DEA Administrator.

16. As of the date of this declaration, MMJBC's bulk manufacturing registration application remains pending before the DEA Administrator for final determination—a period of over seven years since submission. The DEA issued an Order to Show Cause regarding the application, and the matter proceeded through administrative proceedings before a DEA Administrative Law Judge, who subsequently issued a recommended decision. MMJBC continues to await issuance of a final agency decision.

17. In August 2018, MMJIH initiated formal regulatory engagement with the FDA's Center for Drug Evaluation and Research ("CDER") through submission of Pre-Investigational New Drug meeting requests for its cannabinoid drug candidates MMJ-001, intended for treatment of Huntington's disease, and MMJ-002, intended for treatment of multiple sclerosis. The FDA opened regulatory files, including IND file number 137754 (Huntington's disease) and IND file number 140712 (multiple sclerosis).

18. On January 29, 2019, the FDA granted Orphan Drug Designation for Δ9-tetrahydrocannabinol and cannabidiol for the "treatment of Huntington's disease" pursuant to 21 U.S.C. § 360bb. This designation recognized the seriousness and rarity of the targeted condition and reinforced the regulatory significance of MMJ's pharmaceutical development program.

19. MMJIH developed a standardized botanical drug product consisting of a soft-gelatin capsule containing a defined combination of THC and CBD, consistent with the FDA's Botanical Drug Development Guidance for Industry. The development process encompassed controlled cultivation, comprehensive quality testing, supercritical carbon dioxide extraction, ethanol winterization purification, chromatographic characterization,

stability testing, and final dosage form development. MMJ evaluated seven prototype formulations and selected one consisting of 5 mg CBD and 2.5 mg THC per capsule. MMJ engaged Catalent Pharma Solutions to develop and manufacture prototype soft-gel capsule formulations consistent with IND requirements. Soft-gel manufacturing has been completed.

20. MMJ has submitted two IND applications to the FDA supporting clinical development for Huntington's disease and multiple sclerosis. The FDA issued a Full Clinical Hold letter dated February 7, 2025, addressing clinical and CMC questions associated with IND 140712. MMJ has since submitted a comprehensive Complete Response to Full Clinical Hold, including a revised protocol and supporting materials.

21. Over approximately eight years, MMJIH and its subsidiaries have invested more than $10 million in scientific, regulatory, financial, and manufacturing resources into advancing pharmaceutical cannabinoid therapeutics through the federal FDA and DEA pathways. These investments include: Baker & Hostetler LLP (FDA regulatory counsel); Parexel International (clinical development strategy); Haffner Associates LLC (Investigator's Brochure); Avanti Rx Analytics Inc. (analytical testing); Catalent Pharma Solutions (IND-grade soft-gel manufacturing); Citrin Cooperman (accounting and financial advisory); and construction of a DEA-compliant cultivation and security facility in Westerly, Rhode Island. Additionally, MMJIH engaged Seaport Global Securities LLC as lead financial advisor for a proposed $45 million private placement, and Seaport prepared an IPO investment thesis positioning MMJ as a leading pharmaceutical cannabis company. These investments were undertaken with the clear expectation that

FDA approval would provide the regulatory foundation for coverage by Medicare and other third-party payers.

IV. The Rescheduling Order and Its Impact on MMJ

22. On April 22, 2026 (published April 28, 2026 at 91 Fed. Reg. 22,714), the Acting Attorney General signed an order transferring certain categories of marijuana from Schedule I to Schedule III of the Controlled Substances Act (the "Rescheduling Order" or "Order").

23. The Rescheduling Order invoked Section 811(d) of the CSA, bypassing the formal rulemaking procedures required by sections 811(a) and (b), including the notice-and-comment process and the evidentiary hearing that had been underway since 2024. The Order canceled that pending hearing.

24. The 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." The second category encompasses thousands of products that have never undergone FDA review, have never been tested in clinical trials, and lack standardized dosing, validated manufacturing controls, or regulatory-grade characterization.

25. This Court in *NORML v. DEA*, 559 F.2d 735 (D.C. Cir. 1977), rejected this same interpretation of Section 811(d), holding that the provision does not authorize the Attorney General to reschedule controlled substances outside the formal rulemaking framework. The DEA itself acknowledged *NORML* as binding in its 2024 Notice of Proposed Rulemaking. *See* 89 Fed. Reg. 44,597 n.39.

26. Prior to the Order, state-licensed marijuana remained a Schedule I substance under federal law, and the only lawful pathway to bring cannabinoid therapeutics to the interstate commercial market was through the FDA drug approval process. By moving state-licensed marijuana to Schedule III, the Order eliminates the fundamental regulatory distinction between products developed through the rigorous federal pharmaceutical pathway and products sold through state-regulated dispensaries, granting the latter a federal imprimatur of legitimacy that was previously reserved only for products completing the FDA approval process.

27. The Rescheduling Order directly undermines the commercial premise of MMJ's pharmaceutical development program. MMJ invested over $10 million and eight years on the explicit understanding that only products completing the FDA approval pathway would achieve federal recognition as legitimate medical products. The Order floods the market with products purporting to serve the same therapeutic needs—chronic pain, neurological conditions, appetite stimulation—without any of the regulatory discipline that ensures safety, efficacy, or consistent quality. This creates a textbook competitive injury: MMJ is forced to compete against products that gained market access not through rigorous scientific evaluation, but through a unilateral executive action that bypassed the procedures Congress established for scheduling determinations.

28. The Rescheduling Order also directly impacts MMJ's pending DEA bulk manufacturing registration. By transferring state-licensed marijuana to Schedule III, the Order fundamentally alters the regulatory landscape in which MMJ's application was

submitted and evaluated, potentially rendering moot the regulatory pathway that MMJ has pursued for over seven years before the DEA.

29. The Rescheduling Order further raises unresolved conflicts with the United States' obligations under the 1961 Single Convention on Narcotic Drugs, as amended, which imposes extensive controls on the cultivation, manufacture, distribution, and trade of marijuana. The DEA's December 2020 Final Rule relied upon these treaty obligations to restrict who could apply for federal manufacturing registration, yet the Rescheduling Order simultaneously permits a regulatory framework that treats federally compliant applicants and state-licensed marijuana businesses under fundamentally different standards.

30. The constitutional defects underlying the Rescheduling Order are compounded by the Department of Justice's own formal acknowledgment that the DEA's Administrative Law Judge structure is unconstitutional. On February 27, 2025, the DOJ filed a Notice of Change of Position in *MMJ BioPharma Cultivation Inc. v. Bondi*, Civil Action No. 1:24-cv-127-WES-PAS (D.R.I.), stating that "the multiple layers of removal restrictions for administrative law judges ('ALJs') in 5 U.S.C. § 7521 do not comport with the separation of powers and Article II." Yet the same constitutionally defective administrative system was expected to conduct the rescheduling hearing that the Order canceled. Under the Supreme Court's holding in *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175 (2023), being subjected to an unconstitutionally structured administrative proceeding constitutes a distinct and irreparable legal injury.

31. On May 28, 2026, MMJ filed a formal Notice of Intention to Participate in the DEA's administrative hearing regarding the proposed rescheduling of marijuana, scheduled for June 29, 2026. *See* 91 Fed. Reg. 22,777 (Apr. 28, 2026). In that Notice, MMJ raised objections concerning: (a) the conflict between rescheduling and the United States' treaty obligations under the Single Convention; (b) the impact on pending DEA manufacturer registration applications; (c) competitive injury and administrative fairness to entities that pursued the established federal pharmaceutical pathway; (d) the proper interpretation of scheduling criteria under *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024), without judicial deference to DEA; and (e) Article II constitutional objections to the DEA ALJ structure. MMJ expressly reserved all rights to seek judicial review, declaratory relief, and injunctive relief in federal court.

V. Irreparable Harm

32. The Rescheduling Order inflicts irreparable harm on MMJ that cannot be remedied through monetary damages. Because sovereign immunity precludes recovery of damages against the federal government, the substantial and unrecoverable losses caused by the Order constitute irreparable injury as a matter of law. See 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 (D.D.C. 2026).

33. The Order threatens the very existence of MMJ's pharmaceutical development enterprise. *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). MMJ's business model depends entirely upon the integrity of the federal regulatory framework. MMJ chose to pursue pharmaceutical cannabinoid development exclusively through the

FDA-DEA pathway—rather than through state cannabis licensing—precisely because federal approval was the sole legitimate route to interstate commerce and third-party payer coverage. The Order eviscerates that premise.

34. The competitive injury is immediate and compounding. Every day the Order is in effect, state-licensed marijuana products gain market access and consumer and provider acceptance, directly cannibalizing the market share that MMJ's FDA-approved products were designed to capture. Once providers and patients become accustomed to non-FDA-approved cannabinoid products operating under the imprimatur of Schedule III status, the market differentiation that MMJ's eight years of development was designed to achieve will be permanently diminished. The Order damages public perception of the need for, and value of, FDA-approved cannabinoid medicines before MMJ's product even completes the clinical trial process.

35. The economic injury to MMJ is direct and existential. MMJ's bottom line will be obliterated while it proceeds through established FDA and DEA regulatory processes that require years of additional investment. The company cannot compete on equal terms against products that obtained market access through executive fiat rather than through the scientifically rigorous, multi-year approval process Congress designed.

36. Loss of investor confidence compounds the harm daily. The Rescheduling Order signals to current and prospective investors that regulatory discipline will not be rewarded through market exclusivity. MMJ's planned $45 million capital raise and proposed public listing—which Seaport Global Securities was engaged to lead—was premised on MMJ's positioning as a first-mover in FDA-approved cannabinoid

pharmaceuticals, a market in which regulatory compliance would confer competitive advantage and pricing power. The Order eliminates that advantage by granting federal recognition to products that bypassed the very regulatory process that would have justified MMJ's premium market position.

37. The harm to clinical trial recruitment and investigator engagement is similarly irreparable. As state-licensed marijuana products become normalized under Schedule III, the willingness of investigators, institutional review boards, and patients to participate in rigorous, controlled clinical trials of cannabinoid products diminishes.

38. This harm compounds daily and cannot be undone retroactively. Market share lost to state-licensed products cannot be recovered. Provider prescribing habits, once established around non-FDA-approved products, cannot be easily redirected. Investor confidence, once shaken by regulatory inconsistency, cannot be restored by a belated judicial correction. The state-licensed products elevated by the Rescheduling Order gained their competitive advantage through an agency action that this Court's own precedent in *NORML* holds to be unauthorized—the irreparable harm flows directly from the unlawful Order, not from ordinary market competition.

39. The harm is not speculative. It is occurring now. Every day since April 28, 2026, state-licensed marijuana products have operated under the color of Schedule III legitimacy, eroding the market position, investor confidence, and competitive advantage that MMJ has spent eight years and over $10 million to build. Absent a stay, MMJ will suffer irreparable harm that no subsequent legal remedy can adequately address.

VI. Redressability

40. A stay of the Rescheduling Order would prevent the continued accrual of irreparable competitive harm by restoring the status quo ante in which state-licensed marijuana products remain in Schedule I and MMJ's federal pharmaceutical development pathway retains its intended market distinction. With a stay in place, MMJ can continue to pursue its FDA approval process and DEA registration with the assurance that the federal regulatory framework will reward—rather than penalize—its substantial investment in pharmaceutical development and compliance.

41. Conversely, without a stay, the harm will continue to compound daily as state-licensed products further entrench themselves in the market, and MMJ's ability to realize the commercial potential of its eight years of development will be progressively and irreversibly diminished.

I declare under penalty of perjury that the foregoing is true and correct. Executed on June 8, 2026.

Duane Boise

Duane Boise
Chief Executive Officer
MMJ International Holdings, Inc.

Exhibit D

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

SAM, INC., et al., *Petitioners*, v. U.S. DEPARTMENT OF JUSTICE, et al., *Respondents*.	**Case No. 26-1106** Consolidated with Nos. 26-1130 and 26-1136

DECLARATION OF BERTHA MADRAS, PH.D

I, Bertha K. Madras, Ph.D, declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am a Professor of Psychobiology at Harvard Medical School, Department of Psychiatry. My office is located at McLean Hospital in Belmont, MA, an affiliate hospital of Harvard Medical School, Harvard University.

2. I submit this declaration in support of joint motion of NDASA, MMJ International Holdings, Inc., MMJ Biopharma Cultivation, Inc., and MMJ Biopharma Labs, Inc. for stay pending review of the Attorney General's order entitled "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" that was published by

Respondents in the Federal Register at 91 Fed. Reg. 22714 (Apr. 28, 2026) ("Rescheduling Order").

3. My opinions are my own, are grounded in science, and reflect my 50-plus years of education, research, and experience in the relevant field.

4. I have dedicated a significant portion of my career to basic neuroscience research and educational outreach on substance use and substance-use disorders. My ongoing interest in drug policy was further stimulated by two Presidential appointments. Throughout my career, I have extensively studied how various psychoactive and therapeutic drugs affect the brain, including substances such as cocaine, MDMA (ecstasy), methamphetamine, THC (the active constituent in marijuana), other cannabinoids, opioids, anti-psychotic, antiepileptic, anti-hyperactivity, and anti-narcoleptic drugs. I have designed and evaluated medications to treat substance-use disorders and brain-imaging agents to probe the targets of drugs with abuse potential in the brain.

5. I have special expertise in marijuana research. My recent research, supported by a grant from NIDA-NIH, focused on the contrasting molecular and behavioral effects of THC (the psychoactive constituent of marijuana) and cannabidiol on adolescent and adult brains, requiring in depth analysis of the literature on marijuana's effects, the potential (or lack thereof) of isolated cannabinoids as medicine, and the adverse effects of marijuana use. In 2014–2015,

I was the sole expert witness for United States Department of Justice in the Eastern District of California in a case to re- or de-schedule marijuana. The World Health Organization (WHO) commissioned me to write a monograph "6.2 Update of Cannabis and its Medical Uses" which subsequently formed the foundation of another WHO multi-authored paper titled: WHO Report: "The Health and Social Effects of Nonmedical Cannabis Use." Recognition of my expertise in medical and recreational cannabis is also reflected in a 2024 invitation from the National Academy of Medicine to review its report, *Cannabis Policy Impacts on Public Health and Health Equity* (S. Teutsch, Y. Hurd, and E. Boyle, eds.), a report evaluating the effects of changing cannabis policies on health outcomes, public safety, and health equity.

6. The Rescheduling Order purports to transfer two categories of marijuana from Schedule I to Schedule III under the Controlled Substances Act: (i) marijuana in FDA-approved drug products and (ii) marijuana subject to state-licensed medical marijuana programs.

7. The first category—marijuana in FDA-approved drug products—appears to be a null set. There is no FDA-approved drug product containing botanical marijuana itself, a whole-plant marijuana preparation, a smoked marijuana product, a vaporized marijuana product, or a botanical marijuana extract containing a mixture of cannabinoids and terpenes found in dispensary products, let alone one classified

in Schedule I. Although the FDA has approved certain products containing isolated or synthetic individual cannabinoids, those products are not marijuana. As a result, this portion of the Rescheduling Order appears to describe a category that does not presently exist.

8. I oppose transferring state-licensed "medical" marijuana from Schedule I to Schedule III. Abundant evidence shows that the risks associated with marijuana use are substantial and, in my opinion, unacceptably high.

9. Marijuana does not meet the standards typically required of a medicine. The standards governing marijuana sold in dispensaries differ fundamentally from FDA-approved medications sold in pharmacies, in evidence requirements, manufacturing controls, labeling, and post-marketing surveillance. Effective medical treatments have standardized dosing, defined formulations, specific indications, established routes of administration, clear instructions for use, and criteria for discontinuation. In contrast, cannabis products vary widely in THC concentration (from approximately 4% to 90%), in composition and concentrations of other cannabinoids, purity, strain, and route of administration.

10. Marijuana also poses a hazard to public health. According to the 2023 federal Drug Abuse Warning Network (DAWN), cannabis was documented in an estimated 896,418 emergency department visits (an increase of 4% and 11.8% of all drug-related ED visits), slightly exceeding opioid-related visits (881,556; 11.6%).

Although the clinical symptoms of opioid- and cannabis-related presentations differs substantially, cannabis is now among the most frequently cited substances in U.S. emergency department encounters.[1]

11. Safety and health concerns related to marijuana use include depression, anxiety, and suicidality, with acute psychosis and schizophrenia of notable concern. Schizophrenia and psychotic disorders are among the most devastating mental illnesses. They can disrupt a person's ability to think clearly, distinguish reality from delusions or hallucinations, maintain relationships, succeed in school or work, and live independently. The effects often extend beyond the individual, placing significant emotional, social, and financial burdens on families and caregivers. Marijuana use is associated with increased risk of later psychotic disorders. A large body of research has found that use often precedes the development of psychosis and schizophrenia in vulnerable individuals. The risk increases with early onset of use, more frequent and heavier use, and is greatest with today's high-potency THC

[1] Substance Abuse and Mental Health Services Administration. (2024). Drug Abuse Warning Network: National Estimates from Drug-Related Emergency Department Visits, 2023. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from www.samhsa.gov/data.

products.[2,3] Among individuals who develop psychosis, cannabis users tend to experience symptoms two to three years earlier than nonusers. Although dispensary cannabis is commonly recommended and used for mental health-related conditions, systematic reviews failed to identify significant therapeutic benefits for anxiety disorders, anorexia nervosa, psychotic disorders, post-traumatic stress disorder, or opioid use disorder.[4] Another significant concern is cognitive impairment. Prospective longitudinal studies suggest that adolescent-onset cannabis use, especially when sustained over time, is associated with reductions in IQ as well as deficits in attention, memory, learning, and executive function.[5] One recent study found that adolescents who initiate marijuana use show slower cognitive development over time, with reduced improvement in memory, working memory,

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[2] Di Forti M, Quattrone D, Freeman TP, Tripoli G, Gayer-Anderson C, Quigley H, Rodriguez V, Jongsma HE, Ferraro L, La Cascia C, La Barbera D, Tarricone I, Berardi D, Szöke A, Arango C, Tortelli A, Velthorst E, Bernardo M, Del-Ben CM, Menezes PR, Selten JP, Jones PB, Kirkbride JB, Rutten BP, de Haan L, Sham PC, van Os J, Lewis CM, Lynskey M, Morgan C, Murray RM; EU-GEI WP2 Group. The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study. Lancet Psychiatry. 2019 May;6(5):427-436. doi: 10.1016/S2215-0366(19)30048-3. Epub 2019 Mar 19. PMID: 30902669; PMCID: PMC7646282.

[3] Rittiphairoj T, Leslie L, Oberste JP, Yim TW, Tung G, Bero L, Riggs P, Hutchison K, Samet J, Li T. High-Concentration Delta-9-Tetrahydrocannabinol Cannabis Products and Mental Health Outcomes : A Systematic Review. Ann Intern Med. 2025 Oct;178(10):1429-1440. doi: 10.7326/ANNALS-24-03819. Epub 2025 Aug 26. PMID: 40854216.

[4] Wilson J, Dobson O, Langcake A, Mishra P, Bryant Z, Leung J, Dawson D, Graham M, Teesson M, Freeman TP, Hall W, Chan GCK, Stockings E. The efficacy and safety of cannabinoids for the treatment of mental disorders and substance use disorders: a systematic review and meta-analysis. Lancet Psychiatry. 2026 Apr;13(4):304-315. doi: 10.1016/S2215-0366(26)00015-5. Epub 2026 Mar 16. PMID: 41856154.

[5] *See, e.g.*, Morin JG, Afzali MH, Bourque J, Stewart SH, Séguin JR, O'Leary-Barrett M, Conrod PJ. A Population-Based Analysis of the Relationship Between Substance Use and Adolescent Cognitive Development. Am J Psychiatry. 2019 Feb 1;176(2):98-106. doi: 10.1176/appi.ajp.2018.18020202. Epub 2018 Oct 3. PMID: 30278790.

processing speed, attention/inhibitory control, language, and visuospatial abilities compared with non-users. The findings suggest that THC exposure during adolescence may contribute to lasting alterations in brain-related cognitive maturation, particularly affecting memory development.[6]

12. Marijuana use in adults can adversely affect health and safety through increased risks of addiction, impaired driving, cognitive impairment, psychiatric illness, compromised heart and lung function, workplace impairment, and harms to others arising from intoxication-related episodes. The frequency of marijuana use, THC content, age of onset, and cumulative cannabis exposure can all contribute to these adverse outcomes in individuals without a pre-existing medical condition or psychiatric disorder.[7] The risk to adolescents is especially acute. Adolescents who use marijuana only occasionally are three times more likely to attempt suicide.[8] Even one or two instances of adolescent marijuana use can alter the volume of grey matter in the brain.[9]

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[6] *See* Natasha E. Wade et al., *Longitudinal Neurocognitive Trajectories in a Large Cohort of Youth Who Use Cannabis: Combining Self-Report and Toxicology*, Neuropsychopharmacology (2026), https://doi.org/10.1038/s41386-026-02395-1.

[7] Sorkhou M, Bedder RH, George TP. The Behavioral Sequelae of Cannabis Use in Healthy People: A Systematic Review. Front Psychiatry. 2021 Feb 16;12:630247. doi: 10.3389/fpsyt.2021.630247. PMID: 33664685; PMCID: PMC7920961.

[8] Jesse D. Hinckley et al., *Cannabis Use Is Associated With Depression Severity and Suicidality in the National Comorbidity Survey–Adolescent Supplement*, 1 JAACAP Open 24 (2023).

[9] Catherine Orr et al., *Grey Matter Volume Differences Associated with Extremely Low Levels of Cannabis Use in Adolescence*, 39 J. Neuroscience 1817 (2019).

13. The Court should not operate on the assumption that the rescheduling accomplished under the Order is neatly cabined so that it will have only a narrow impact on those using "medical" marijuana under state licensing programs and will not raise risks of harm to adolescents and others. Investigation of marketing practices and regulatory compliance among U.S. marijuana retailers in 2025 identified substantial noncompliance with regulations governing youth-appealing marketing, unsubstantiated health claims, and restrictions on promotional discounts. Deficiencies were also observed in adherence to state-mandated warning signage requirements. These findings underscore persistent gaps between regulatory standards and retail practice, reinforcing the need for stronger oversight, enforcement, and refinement of cannabis retail regulations.[10]

14. It is well established that State licensing regimes inevitably result in adolescent use of marijuana. State medical marijuana programs do not prohibit marijuana for those under 18 and, in any event, abundant evidence shows that marijuana in state medical licensing regimes is diverted to illicit uses by adolescents at an alarming rate. The opening of medical cannabis dispensaries was associated with a significant 52.3% increase in accidental cannabis-related exposure rates

[10] Berg CJ, LoParco CR, Rossheim ME, Speer MB, Platt E, Davie C, Amdeta H, Mihelich D, Ndisebuye DM, Cui Y, Cavazos-Rehg PA, Yang YT, Burris S. Cannabis retailers' marketing practices and compliance with state regulations: a 2025 point-of-sale audit in 5 U.S. cities. Addict Behav. 2026 May 7;181:108733. doi: 10.1016/j.addbeh.2026.108733. Epub ahead of print. PMID: 42202488.

among children aged 2–6 years, highlighting the heightened risk of accidental exposure in this vulnerable population. Cannabis exposures among adolescents aged 12–17 years and young adults aged 18–20 years were primarily intentional.[11]

15. One cohort study of 463,000 adolescents (ages 13 to 17) found that, after controlling for demographic factors and other substance use, adolescents who used cannabis had more than double the risk of psychotic disorders.[12]

16. One survey in Massachusetts in 2022 found that 44% of youth reported using someone else's "medical" cannabis.[13] Ilicit direct sale to minors from dispensaries is also a significant issue: state-level data from Arizona shows that "[d]ispensaries, just like drug dealers, sell to thousands of minors every year."[14] While minors in Arizona "can legally purchase marijuana from a dispensary with a doctor-approved medical marijuana card," "according to the Arizona Department of Public Health, there were only 105 medical marijuana patients below the age of 18 in June 2022."[15]

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[11] Steuart SR, Bethel V, Bradford WD. Cannabis and pediatric cannabis exposure - evidence from America's Poison Centers. J Child Psychol Psychiatry. 2026 Mar;67(3):400-412. doi: 10.1111/jcpp.70058. Epub 2025 Oct 12. PMID: 41077545.

[12] Kelly C. Young-Wolff et al., *Adolescent Cannabis Use and Risk of Psychotic, Bipolar, Depressive, and Anxiety Disorders*, 7 JAMA Health F. e256839 (2026), https://doi.org/10.1001/jamahealthforum.2025.6839

[13] Maddie O'Connell et al., *Trends in Cannabis-Related Attitudes and Behaviors among Cannabis-Using Adolescent and Young Adult Outpatients following Medical Cannabis Legalization in Massachusetts*, 43 Substance Abuse 328 (2022) ("In 2016, 44% of youth reported using someone else's medical cannabis").

[14] Connor Kubeisy, *The Drug Review: Marijuana Dispensaries Sell to Thousands of Minors Every Year*, Foundation for Drug Policy (Mar. 11, 2024), https://perma.cc/9DJN-UBJ4.

[15] *Id.*

17. In other words, currently available data shows that, when the Rescheduling Order creates a predictable surge the use of medical marijuana under state licensing schemes (by eliminating federal restrictions), it will also create a corresponding surge in adolescent use of marijuana as marijuana is diverted from the authorized uses under those schemes.

18. Marijuana use among adolescents was associated with a broad range of adverse mental health, behavioral, and academic outcomes.[16] Compared with teens who did not use marijuana, those who used marijuana, even without having a use disorder, were 2 to 4 times more likely to experience a range of mental health, behavioral, and academic problems (depression, suicidal thoughts, school problems, and behavioral difficulties than nonusers).[17]

19. Risks also arise from the authorized use of marijuana within state-authorized medical marijuana parameters. For example, a 2018 survey found that 69% of Colorado dispensaries recommended marijuana to pregnant women.[18]

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[16] Li R, Tao F. Effects of Cannabis Exposure on Adolescent Health and Development: A Narrative Review. Curr Drug Res Rev. 2025;17(2):160-169. doi: 10.2174/0125899775273727231224185028.

[17] Sultan RS, Zhang AW, Olfson M, Kwizera MH, Levin FR. Nondisordered Cannabis Use Among US Adolescents. JAMA Netw Open. 2023 May 1;6(5):e2311294. doi: 10.1001/jamanetworkopen.2023.11294. PMID: 37133862; PMCID: PMC10157425.

[18] Betsy Dickson et al., *Recommendations From Cannabis Dispensaries About First-Trimester Cannabis Use*, 131 Obstetrics & Gynecology 1031, 1031 (2018). See also Young-Wolff KC, Does MB, Negusse R, Ogden SN, Nugent JR, Silver LD, Soroosh AJ, Metz TD. Cannabis Retailer Advice on Blunt, Tobacco, and Cannabis Use During Pregnancy. JAMA Netw Open. 2025 Dec 1;8(12):e2548373. doi: 10.1001/jamanetworkopen.2025.48373. PMID: 41370076 and Wymore EM, Wagner K, Gold C, Halmo LS. High Stakes: Exploring the Impact of Cannabis Use in Pregnancy and Lactation. Neoreviews. 2025 Apr 1;26(4):e247-e263. doi: 10.1542/neo.26-4-006. PMID: 40164212.

20. Marijuana use can harm pregnant women. Preconception and prenatal marijuana use were associated with increased odds of both mild and severe nausea and vomiting during the first trimester, with the highest risks among individuals using marijuana daily before or during early pregnancy.[19]

21. It can also harm children in utero. THC passes the placental barrier,[20] resulting in fetal blood concentrations that closely resemble those found in the mother's blood.[21] A growing number of reports have found that marijuana use during pregnancy is associated with a higher risk of low birth weight, premature birth, admission to a neonatal intensive care unit, and poorer newborn health scores at birth (Apgar scores). Long-term studies also suggest that children exposed to cannabis before birth may have changes in brain development that can affect memory, attention, learning, and decision-making skills later in life.[22] Exposure to marijuana in utero is linked with poorer cognitive outcomes for children.[23] The

[19] Young-Wolff KC, Chi FW, Campbell CI, Alexeeff SE, Ansley D, Vanderziel A, Lapham GT. Frequency of Preconception and Prenatal Cannabis Use and Nausea and Vomiting in Pregnancy. Obstet Gynecol. 2025 May 1;145(5):519-522. doi: 10.1097/AOG.0000000000005884. Epub 2025 Mar 13. PMID: 40080822; PMCID: PMC12005968.

[20] J. Idanpaan-Heikkila et al., *Placental transfer of tritiated-1-delta-9-tetrahydrocannabinol*, 281 New Eng. J. of Med. 330 (1969).

[21] Rebecca Thompson et al., *Marijuana Use in Pregnancy: A Review*, 74 Obstetrical & Gynecological Survey 415 (2019).

[22] Thayyil B, Yusuf K. Evidence on the effect of in-utero cannabis exposure in neonates. J Perinatol. 2025 Nov;45(11):1503-1512. doi: 10.1038/s41372-025-02383-1. Epub 2025 Aug 13. PMID: 40797024.

[23] Baranger DAA, Paul SE, Colbert SMC, Karcher NR, Johnson EC, Hatoum AS, Bogdan R. Association of Mental Health Burden With Prenatal Cannabis Exposure From Childhood to Early Adolescence: Longitudinal Findings From the Adolescent Brain Cognitive Development (ABCD) Study. JAMA Pediatr.

Rescheduling Order can be expected to produce an increase in negative outcomes for the children of mothers who are encouraged under state licensing regimes to use marijuana while pregnant.

22. In a prospective cohort study of 250 children, researchers found that prenatal cannabis exposure was associated with significantly poorer executive functioning—particularly attention and inhibitory control—and increased aggressive behavior at age five, even after adjusting for numerous confounding factors. The authors concluded that these deficits are relevant to long-term academic and adaptive functioning and support counseling pregnant women to avoid cannabis use during pregnancy.[24]

23. As marijuana legalization and nonmedical adult use expand, public health policy discussions have focused primarily on ample evidence of marijuana effects on the user. Far less attention has been paid to the potential harms experienced by others. Marijuana use may adversely affect nonusers through several pathways, including interpersonal violence, workplace problems, childhood abuse and neglect, motor vehicle crashes, adverse pregnancy and infant outcomes, and secondhand cannabis smoke exposure. The cumulative impact on public health can

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2022 Dec 1;176(12):1261-1265. doi: 10.1001/jamapediatrics.2022.3191. PMID: 36094599; PMCID: PMC9468940.

[24] Sarah A. Keim, Peter Fried, Keith Owen Yeates et al., *Prenatal Cannabis Exposure and Executive Function and Aggressive Behavior at Age 5 Years*, 178 JAMA Pediatrics 1316 (2024).

be substantial. These potential harms to others should be considered when developing marijuana regulations and evaluating the broader public health consequences of rescheduling botanical marijuana and its myriad products.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 9, 2026

Bertha Madras, Ph.D