ORAL ARGUMENT NOT YET SCHEDULED

Nos. 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 Review of Attorney General Order No. 6754–2026

PETITIONERS' OPENING BRIEF

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

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

Counsel for New Directions Addiction Recovery Services, Kenneth Finn, M.D., Elizabeth B. Stuyt, M.D.; Cannabis Industry Victims Educating Litigators, MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., and MMJ BioPharma Labs, Inc.

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

Counsel for Smart Approaches to Marijuana and National Drug and Alcohol Screening Association, Inc.

Cody S. Barnett
Zachary B. Pohlman
Nebraska Department of Justice
1445 K Street, Suite 2115
Lincoln, NE 68508
cody.barnett@nebraska.gov

Counsel for Nebraska

(*Additional counsel on inside cover*)

November 24, 2026

Blake Lanning
Office of the Attorney General
IGC South, Fifth Floor
302 W. Washington Street
Indianapolis, Indiana 46204
(317) 232-1146
blake.lanning@atg.in.gov

Counsel for Indiana

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), Petitioners state as follows:

A. Parties and *Amici*

Petitioners in No. 26-1106 include SAM Inc. (d/b/a Smart Approaches to Marijuana) and the National Drug and Alcohol Screening Association, Inc.

Petitioners in No. 26-1130 include the State of Nebraska and the State of Indiana.

Respondents in Nos. 26-1106 and 26-1130 are the United States Department of Justice, Todd Blanche in his official capacity as Attorney General, the Drug Enforcement Administration, and Terrence C. Cole, in his official capacity as Administrator of the DEA

Petitioners in No. 26-1136 include New Directions Addiction Recovery Services, Kenneth Finn, M.D., Elizabeth "Libby" B. Stuyt, M.D.; Cannabis Industry Victims Educating Litigators; MMJ International Holdings, Inc.; MMJ BioPharma Cultivation, Inc.; and MMJ BioPharma Labs, Inc.

Respondents in No. 26-1136 include President Donald J. Trump, the United States Department of Justice, Todd Blanche in his official capacity as Attorney General, the Drug Enforcement Administration, and Terrence C. Cole, in his official capacity as Administrator of the DEA.

Amici Curiae are David K. Sergi; MedPharm Iowa, LLC, d/b/a Bud & Mary's; Robert Hoban; Tri-Mountain Pure, LLC, d/b/a Bud & Mary's; David C. Holland; and Tyson Daniel.

No party has been granted leave to intervene.

B. RULING UNDER REVIEW

The consolidated petitions for review challenge 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," 91 Fed. Reg. 22714 (Apr. 28, 2026).

C. RELATED CASES

This case has been consolidated with the following petitions for review of the same Attorney General Order: *Nebraska et al. v. DOJ et al.* (26-1130); *New Directions Addiction Recovery et al. v. Donald J. Trump, et al.* (26-1136). At this time, counsel is unaware of any other related cases within the meaning of Circuit Rule 28(a)(1)(C). Out of an abundance of caution, counsel notes that on November 18, 2026, Standard Wellness Utah, LLC, Verde Americano, LLC, and NW Confections OK 241AA LLC filed a petition for review of an order of the Drug Enforcement Administration entitled "DEA Medical Marijuana Timely Applicant Information" (No. 26-1324).

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Petitioners SAM, Inc., the National Drug and Alcohol Screening Association, New Directions Addiction Recovery Services, MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., and MMJ BioPharma Labs, Inc., through undersigned counsel, certify as follows:

SAM, Inc. (d/b/a Smart Approaches to Marijuana) (SAM) is a bipartisan alliance of organizations and individuals dedicated to a health-first approach to marijuana policy headquartered in Washington, D.C. It is a tax-exempt nonprofit corporation organized under the laws of Virginia, has no parent companies, and there is no publicly held company that owns 10% or more of its stock.

The National Drug and Alcohol Screening Association, Inc. (NDASA) represents America's drug and alcohol screening industry. Its members include laboratories, Medical Review Officers, collection sites, third party administrators, drug testing device manufacturers, employers, human resources managers, safety professionals, and substance abuse professionals. NDASA is a 501(c)(6) tax-exempt nonprofit corporation organized under the laws of Arizona. It has no parent corporation and issues no stock, and no publicly held company owns 10% or more of any interest in it.

New Directions Addiction Recovery Services (New Directions) is a substance abuse recovery clinic and retreat center located in McHenry County, Illinois. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Cannabis Industry Victims Educating Litigators (CIVEL) is a marijuana industry victims' advocacy organization that educates lawyers on how to hold the marijuana industry accountable to its victims and enables litigation to protect the rights of cannabis industry victims and to obtain justice for cannabis-related injuries such as psychosis or suicide. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Petitioner MMJ International Holdings, Inc. is a private pharmaceutical cannabinoid development company and the parent of MMJ BioPharma Cultivation, Inc. and MMJ BioPharma Labs, Inc. No publicly held corporation owns 10% or more of the stock of MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc. or MMJ BioPharma Labs, Inc.

November 24, 2026

/s/ *Chase T. Harrington*
Chase T. Harrington

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GLOSSARY

Acronym	Definition
Act (or CSA)	Controlled Substances Act of 1970
ADD	Statutory & Regulatory Addendum
APA	Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*
API	Active pharmaceutical ingredient
CBD	Cannabidiol
CIVEL	Cannabis Industry Victims Educating Litigators
CMC	Chemistry, manufacturing, and controls
CRA	Consumer reporting agency
CUD	Cannabis use disorder
DEA	Drug Enforcement Administration
DOJ	United States Department of Justice
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
HEW	Department of Health, Education, and Welfare (predecessor to HHS)
HHS	Department of Health and Human Services
IND	Investigational New Drug
JA	Joint Appendix

Acronym	Definition
MMJ	MMJ International Holdings, Inc. (MMJIH), MMJ BioPharma Cultivation, Inc. (MMJBC), and MMJ BioPharma Labs, Inc. (MMJBL)
MRO	Medical Review Officer
NDASA	National Drug and Alcohol Screening Association
NPRM	Notice of Proposed Rulemaking
OLC	Office of Legal Counsel, Department of Justice
PAN	Parent Action Network
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)
SA	Standing Addendum
SAM	Smart Approaches to Marijuana
THC	Tetrahydrocannabinol
TPA	Third Party Administrator

INTRODUCTION

This case involves an audacious agency overreach in which the 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 drug in the history of the Controlled Substances Act (CSA).

The CSA regulates harmful drugs by placing them into one of five schedules with varying levels of "controls" or restrictions, Schedule I being the most restrictive. When Congress enacted the CSA, it placed marijuana in Schedule I. Congress also gave the Attorney General limited authority to "reschedule" a substance by moving it from one schedule to another. But Congress carefully constrained that authority by requiring the Attorney General both to secure recommendations from the Secretary of Health and Human Services (HHS) and to make detailed findings on specified criteria through a formal rulemaking on the record. 21 U.S.C. § 811(a). Almost fifty years ago, this Court held that the Attorney General lacks authority to unilaterally decide how marijuana ought to be scheduled and instead must proceed through that detailed process. *NORML v. DEA*, 559 F.2d 735, 750 (D.C. Cir. 1977). Although 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 on moving a drug between two schedules under the CSA, either of which would comply with treaty obligations. *NORML*, 559 F.2d at 750.

The Department of Justice complied with this Court's construction of the CSA for over four decades—until now. Four days after President Trump demanded action on rescheduling marijuana, the Attorney General hastily cancelled a pending formal rulemaking that had been convened to address that issue and, with the stroke of a pen, transferred *some* marijuana—in particular, marijuana in state-licensed medical marijuana programs—from Schedule I to Schedule III under the CSA. There were no public comments, no findings on the record after a hearing to receive evidence, and no consideration of the factors Congress defined to protect the American public from harmful drugs—just a decree from the Attorney General. By eliminating the federal criminal prohibition on the use of so-called "medical marijuana," the Order will vastly increase access to marijuana.

The Order is unlawful for a host of reasons.

First, the CSA permits the Attorney General to move a "drug or other substance" from one schedule to another. 21 U.S.C. § 811(a). It does not allow the Attorney General to divide a single substance—marijuana—into different schedules based solely on whether the substance is marketed pursuant to a state-law licensing scheme. The text and structure of the CSA make clear that a "substance" should be

scheduled based on its chemical and pharmacological properties, not the happenstance of a state licensing regime.

Second, in violation of the plain terms of the CSA and this Court's binding construction of the statute in *NORML*, the Attorney General circumvented the formal rulemaking process that Congress mandated for rescheduling decisions. Nothing in the narrow exception in section 811(d)(1) permitting the Attorney General to ensure compliance with treaty obligations permitted jettisoning all the restrictions Congress placed on the Attorney General's rescheduling authority.

Third, even if section 811(d) allowed the Attorney General to skip formal rulemaking procedures, the Attorney General could invoke that section only to "carr[y] out" U.S. treaty obligations. 21 U.S.C. § 811(d)(1). The Rescheduling Order, however, *violates* U.S. treaty obligations by failing to adhere to multiple restrictions on marijuana imposed by the Single Convention on Narcotic Drugs. As a result, the Rescheduling Order exceeds any statutory authority that could be provided by section 811(d).

Fourth, the Rescheduling Order acknowledges that, if marijuana is moved to Schedule III under the CSA, the standard set of restrictions that apply to Schedule III substances will fall short of complying with some treaty obligations. To fill those gaps, the Order purports to amend existing legislative rules. For instance, the Order imposes import-export permit requirements on Schedule III marijuana. But nothing

in section 811(d) permits the Attorney General to unilaterally issue legislative rules without complying with the ordinary notice-and-comment requirements of the APA. *See* 5 U.S.C. § 553. The new rules are unlawful, and without them the Rescheduling Order even more egregiously violates U.S. treaty obligations (and thus any authority provided by section 811(d)).

Fifth, the Rescheduling Order arbitrarily reverses course on settled positions of the Department of Justice without any rational explanation. *Cf. Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016) (unexplained reversal in course is arbitrary and capricious). For example, the Department of Justice has long acknowledged that, under the CSA and this Court's decision in *NORML*, any rescheduling decision to move marijuana out of Schedule I would require a formal rulemaking. Indeed, the hasty Rescheduling Order is so ill-considered and so poorly explained that, on the *same day* it was issued, the Attorney General issued another order reaffirming the Department's settled view that section 811 of the CSA *requires* formal rulemaking on the record for any decision rescheduling marijuana. 91 Fed. Reg. 22777, 22777 (Apr. 28, 2026). These contradictory assertions highlight the absence of any reasoned explanation for the agency's stark reversal in course.

JURISDICTIONAL STATEMENT

Petitioners seek 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," 91 Fed. Reg. 22714 (Apr. 28, 2026). The Court has jurisdiction under 21 U.S.C. § 877, ADD-69. Petitioners timely sought review on May 4 (No. 26-1106), May 22 (No. 26-1130), and May 29, 2026 (No. 26-1136).

STATEMENT OF THE ISSUES

Whether the Rescheduling Order:

1. Violates the CSA by placing the same substance (marijuana) into different schedules based solely on whether the substance is marketed pursuant to a state-law licensing scheme;

2. Violates the CSA, 21 U.S.C. § 811(a)-(b), by transferring certain marijuana from Schedule I to Schedule III without a formal rulemaking;

3. Exceeds any authority granted under 21 U.S.C. § 811(d)(1) by purporting to reschedule marijuana in a manner that violates U.S. obligations under the Single Convention on Narcotic Drugs;

4. Violates the APA by amending multiple legislative rules without notice-and-comment procedures;

5. Is arbitrary and capricious because it reverses course on settled positions of the Department of Justice without any rational explanation.

STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in a separate addendum.

STATEMENT

A. Statutory And Regulatory Background

The United States acceded to the Single Convention on Narcotic Drugs (Single Convention) in June 1967. *See* Joint Appendix (JA)___[18_U.S.T._1407]. The Single Convention tightly restricts the cultivation and distribution of marijuana.[1] Parties to the Convention must impose quotas on the manufacture of marijuana, JA___[*id.*_art._21], and require that manufacturers obtain a license specifying the "amounts of drugs" they are allowed to manufacture, JA___[*id.*_art._29(2)(c)]. Under Article 28, marijuana is subject to the same controls that govern "the opium poppy," JA___[*id.*_art._28], which means, among other things, that a single government agency must license authorized cultivators, require cultivators to deliver their entire crop to the agency, and purchase and take "physical possession" of the crop within four months of harvest, JA___[*id.*_art._23]. In addition, a "medical prescription" must be required for dispensing marijuana to "individuals," JA___[*id.*_art._30].

Congress passed the Controlled Substances Act of 1970 (CSA), 21 U.S.C. § 801 *et seq.*, ADD-20, to implement the Single Convention. *See*

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[1] The Single Convention uses the term "cannabis" and uses a slightly different definition from the definition of "marijuana" under the Controlled Substances Act, *see* JA__[*id.*_art._1(1)(b)]; 21 U.S.C. § 802(16), ADD-23. The distinctions, however, are immaterial and this brief uses the generic term "marijuana" throughout.

JA___[S._Rep._No._91-613,_at_4_(1969)]. The CSA established a "comprehensive regime to combat the international and interstate traffic in illicit drugs." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005).

The CSA divides controlled substances into five schedules, 21 U.S.C. § 812, ADD-41-46, "based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body," *Raich*, 545 U.S. at 13. Different statutory and regulatory restrictions apply to each Schedule, with Schedule I being the most restrictive. Upon enacting the CSA, Congress placed marijuana in Schedule I. Pub. L. No. 91-513, § 202(c) sched. I(c)(10) (1970). Corresponding restrictions for Schedule I substances—*e.g.*, that the Attorney General must set a quota for production and license manufacturers and distributors of all Schedule I and II substances each year, *see* 21 U.S.C. §§ 823 (licensing), 826 (quotas), ADD-51, 63—ensure that the United States complies with its obligations for restricting marijuana under the Single Convention.

The CSA also established detailed procedural requirements for adding, removing, or transferring substances between Schedules. *See* 21 U.S.C. § 811, ADD-35-40. 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

APA. *Id.* § 811(a) (requiring rulemaking "pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5"), ADD-35. 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." 21 U.S.C. § 811(a)-(b), ADD-35-36. In the on-the-record rulemaking, "outside participants may submit … scientific and medical evidence … that DOJ would need to consider." JA___[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 section 812(b) for the 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 treaty obligations. Section 811(d) provides that "[i]f control 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 requirements of sections 811(a) and (b) described above. 21 U.S.C. § 811(d)(1), ADD-36. Section 811(d)(1) 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 811(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 without regard to the procedures specified in section 811(a). On review, this Court rejected that construction of section 811(d) and held that the truncated process used by DOJ violated the statute. *NORML v. DEA*, 559 F.2d 735, 757 (D.C. Cir. 1977). The Court explained that section 811(d)(1) provides a "limited"

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

[3] The Attorney General has delegated scheduling authority to the Administrator of the DEA. 28 C.F.R. § 0.100, ADD-136.

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 the half 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. 20038; 57 Fed. Reg. 10499; 54 Fed. Reg. 53767. When DEA did cite section 811(d),

[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).

it mentioned the section 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 36123 (same). In fact, over the past 50 years, the Department of Justice and Department of State have concluded numerous times that, given the restrictions that apply to the different schedules under the CSA, the United States can meet its obligations under the Single Convention only by keeping marijuana in Schedules I or II under the CSA. *See, e.g.*, Br. in Opp'n, *Greene v. United States*, No. 89-6753 (U.S. Apr. 1990), perma.cc/4FJY-NNVB; Br. for Respondent at 5, No. 75-2025, *NORML v. DEA* (D.C. Cir. Apr. 1, 1976); 39 Fed. Reg. 23072, 23074 (June 26, 1974) (reprinting letter from State Department Assistant Legal Adviser Charles I. Bevans to DEA); JA___[*Petition_to_Decontrol_Marijuana;_Interpretation_of_Section_201_of_the_Controlled_Substances_Act_of_1970*,_Op._O.L.C._at_12-13_(Aug._21,_1972)].

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* The White House, Statement from President Biden on Marijuana Reform (Oct. 6, 2022), perma.cc/LVF6-344M. Acting under that presidential directive, HHS reversed four

decades of its own conclusions and recommended transferring marijuana to Schedule III. JA___[Memorandum_for_DEA,_from_HHS,_Re:_Basis_for_the_-Recommendation_to_Reschedule_Marijuana_to_Schedule_III_of_the_Controlled_Substances_Act_at_63-66] ("HHS Report").

Eight months later, the Department of Justice's Office of Legal Counsel published an opinion assessing whether transferring marijuana to Schedule III under the CSA would comport with U.S. obligations under the Single Convention. *See* JA___[*Questions_Related_to_the_Potential_Rescheduling_of_Marijuana*,_2024_WL_2412009,_at_*35-36_(O.L.C.-_Apr._11,_2024)]. OLC advised that moving marijuana to Schedule III would be consistent with U.S. treaty obligations only if DEA issued additional rules to address areas where there is a "gap" between requirements under the Single Convention and the existing controls that apply to all Schedule III substances. *Id.* at *3. At minimum, OLC determined that the DEA would need to promulgate new legislative rules imposing import and export permit requirements (to comply with Article 31(4)) and manufacturing quotas (to comply with Article 21) on marijuana in Schedule III. *See id.* at *33-34.

The following month, the Attorney General issued an NPRM proposing to transfer all marijuana to Schedule III. *See* JA___[*Rescheduling_of_Marijuana*,_89_Fed._Reg._44597_(May_21,_2024)]. The Attorney General announced a formal rulemaking proceeding to consider the

rescheduling because "OLC and the United States Court of Appeals for the D.C. Circuit have explained that section 811(d)(1) does not supersede the scheduling procedures set forth in sections 811(a) through (b) and 812(b)" when "more than one schedule" would "satisfy the United States' international obligations" for marijuana under the Single Convention. *Id.* at __[44598-99] (citing JA___[2024_OLC_Op._at_*29 n.8] & *NORML*, 559 F.2d at 747). Instead, the Attorney General acknowledged that "[t]he CSA *requires* that such actions be made through formal rulemaking on the record after opportunity for a hearing." *Id.* at __[44597] (emphasis added).

The public submitted over 43,000 comments and requested a hearing. In the notice scheduling the hearing, the DEA Administrator reiterated that holding a hearing "on the record" was "require[d]" by the CSA. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70148, 70149 (Aug. 29, 2024) (emphasis added). The Administrator designated Nebraska, SAM, NDASA, Dr. Finn, and CIVEL as parties "adversely affected or aggrieved" by marijuana rescheduling. 21 C.F.R. § 1300.01(b), ADD-95. That determination was upheld in a 47-page opinion by the presiding Administrative Law Judge who concluded these parties had "APA standing" to challenge rescheduling. JA___[Order_Regarding_Standing_Scope_And_Prehearing_Procedures,_DEA__Hr'g_Dkt._No._24-44_(Nov._19,_2024) at 4, 18-19, 22-23, 25-26, 30-31, 37-38].

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. JA___[Order,_Hr'g_Dkt._No._24-44_(Jan. 13, 2025)].

The Trump administration did not act on the interlocutory appeal. Twelve months later, 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, 2026, the Attorney General signed an order bypassing formal rulemaking procedures—and any rulemaking procedures at all—

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

and directly transferring two categories of marijuana to Schedule III: (i) FDA-approved drug products containing marijuana; and (ii) marijuana "in any form covered by a state medical marijuana license." JA___[91_Fed._Reg._22714, 22718] (Rescheduling Order).[6] Marijuana that does not fall into one of those two categories remains controlled under Schedule I.

Invoking section 811(d)(1), the Order dispensed with the findings and on-the-record procedures that sections 811(a) and (b) otherwise require. According to the Order, because marijuana is controlled under the Single Convention, the Attorney General can rely on section 811(d) and place marijuana in the schedule "he deems most appropriate to carry out United States obligations" under that treaty. JA___[91_Fed._Reg._at_22714]. The Order acknowledged that, if marijuana is moved to Schedule III, the United States would no longer meet all the requirements of the Single Convention. As a result, the Order also adopted new regulations "to prevent any lapse in compliance." *Id.* at ___[22716, 22719]. For example, the Order amended DEA regulations "to require a permit to import or export" marijuana. *Id.* at ___[22717]. The Order did not set manufacturing quotas for the categories of marijuana moved to Schedule III.

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[6] The first category is a null set because there are no FDA-approved drug products containing marijuana.

The Order also required state-licensed "medical" marijuana businesses to apply for registration with the DEA. *Id.* at ___[22720]. Entities who applied "within 60 days" of the Order could "lawfully operate" while their applications were pending. *Id.* As of November 16, about 3,200 dispensaries, 710 distributors, and 2,100 manufacturers licensed by states were lawfully cultivating, buying, and selling marijuana. DEA, *Medical Marijuana Information*, perma.cc/KKD7-89GB.

Further, as a "consequence of" the Order, state-licensed cannabis businesses buying and selling Schedule III marijuana will be allowed to deduct ordinary business expenses from their federal taxable income. JA___[91_Fed._-Reg._at_22720]. Currently, section 280E of the Internal Revenue Code prohibits taking any federal tax deduction from "carrying on any trade or business" that "consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act)." 26 U.S.C. § 280E, ADD-90. The Order expressly declares that those businesses "will no longer be subject to the deduction disallowance imposed by Section 280E" as a "consequence" of marijuana rescheduling.

The Attorney General also issued two related orders on the same day as the Rescheduling Order. One canceled the pending formal rulemaking hearing on marijuana rescheduling. *See* 91 Fed. Reg. 22778 (Apr. 28, 2026). The other announced a new formal rulemaking to address rescheduling the remaining kinds of

marijuana that are not covered by the Rescheduling Order. *See* 91 Fed. Reg. 22777 (Apr. 28, 2026) (Hearing Order); Preliminary Order, Dkt. No. 26-96 at 2 (June 18, 2026), perma.cc/GMW5-XSZJ ("Importantly, the scope of this hearing is not to discuss the rescheduling of … medical marijuana … , which has already occurred."). Contradicting the Rescheduling Order, the new Hearing Order reiterated DEA's longstanding position that "[t]he CSA *requires* that such actions [*i.e.*, rescheduling] be made through formal rulemaking on the record after opportunity for a hearing." 91 Fed. Reg. at 22777 (emphasis added).

E. Petitioners Seek Review of the Rescheduling Order.

Petitioners timely sought review of the Rescheduling Order.

SUMMARY OF ARGUMENT

This case presents one of the most straightforward violations of the CSA and APA that this Court is likely to see.

I. The Rescheduling Order is contrary to the CSA in at least two respects. First, the Order purported to take a single "substance"—marijuana—and place it into two different Schedules under the Act based not on any differences in chemical composition but based only on existing state regulatory treatment. The CSA does not permit that approach. Second, the Rescheduling Order improperly jettisoned the procedures mandated by sections 811(a) and (b) of the CSA—including formal rulemaking—based on an untenable reading of section 811(d) that is contrary to the text

of the statute and foreclosed by this Court's binding decision in *NORML*. Section 811(d)(1)—the CSA's treaty-control provision—serves a single function that is not applicable here: It enables the Attorney General to ensure that the United States complies with treaty obligations; it does *not* eliminate rulemaking requirements for any drug regulated under the Single Convention. If the scope of section 811(d) is ambiguous (it is not), the major questions doctrine requires any ambiguity be resolved against permitting the novel and unbounded rescheduling power claimed by the Justice Department. Finally, section 811(d) cannot support the Rescheduling Order because the Order repeatedly violates the treaty it purports to carry out.

II. The Rescheduling Order also violates the APA. In addition to transferring state-licensed marijuana to Schedule III, the Order also promulgated no fewer than *five* additional legislative rules without notice-and-comment procedures. The Order's only excuse for skipping notice and comment is that section 811(d)(1) permits scheduling by order. But that provision authorizes, at most, the Attorney General's placement of marijuana in a control schedule under the CSA. It does not give the Attorney General authority to issue *other* legislative rules accompanying such a scheduling change without notice-and-comment procedures.

Moreover, the Rescheduling Order repeatedly departs from the Justice Department's prior position without *any* explanation. It reverses the Department's longstanding view that section 811(d)(1) does not dispense with formal rulemaking

when a drug is moved between treaty-compliant schedules. It ignores completely that DEA has rejected at least nine prior petitions to reschedule marijuana. It reverses *sub silentio* DEA's prior assessment that state medical marijuana programs were a significant source of marijuana diverted to unauthorized recreational use. And it abandons DEA's finding from just two years ago that such state programs have inconsistent product standards and safety requirements. Four unexplained reversals is not reasoned decisionmaking.

STANDING

To establish standing, a petitioner must "demonstrate it has suffered a concrete and particularized injury that is imminent and not conjectural, that was caused by the challenged action, and that is likely to be redressed by a favorable judicial decision." *Del. Dep't of Nat. Res. & Env't Control v. EPA*, 785 F.3d 1, 7 (D.C. Cir. 2015) (quotation omitted). The injury requirement is not daunting: "A dollar of economic harm is still an injury-in-fact for standing purposes." *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 5 (D.C. Cir. 2017). Petitioners here submit declarations detailing the millions of dollars in economic harm that the Rescheduling Order has imposed and will continue to impose on them.[7]

[7] Petitioners here are also well within the CSA's zone of interests. Because Congress authorized "any person aggrieved by a final decision of the Attorney General" under the CSA to "obtain review," 21 U.S.C. § 877, parties "even *arguably* within the zone

A. The State Petitioners Have Standing.

States receive "special solicitude" in the standing analysis where, as here, they invoke a statutory right to challenge agency action and assert "quasi-sovereign interests." *Massachusetts v. EPA*, 549 U.S. 497, 518-20 (2007). Nebraska and Indiana invoke the CSA right of review under 21 U.S.C. § 877, ADD-69, and they seek to protect interests in their tax base, public fisc, and enforcement of state law. Both States readily demonstrate standing, and both fall within the zone of interests that the CSA protects.

1. Nebraska Has Standing Based On Lost Tax Revenue.

The Rescheduling Order will cause Nebraska to lose state income tax revenue because it effectively gives medical marijuana businesses a new federal tax deduction and Nebraska's income tax is tied to federal taxable income. That lost tax revenue easily establishes an injury in fact for Nebraska.

States have standing to sue over a "direct injury in the form of a loss of specific tax revenues" fairly traceable to a change in the law of another sovereign. *Wyoming v. Oklahoma*, 502 U.S. 437, 447-48 (1992) (Wyoming had standing to challenge protectionist Oklahoma law that reduced Wyoming's tax revenue on coal extraction); *see also New York v. Yellen*, 15 F.4th 569, 576 (2d Cir. 2021) (holding

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of interests" may bring a petition. *See FDA v. R.J. Reynolds Vapor Co.*, 606 U.S. 226, 232-36 (2025).

states had standing to challenge new federal cap on state-and-local-tax deductions on ground it would depress state property and real estate transfer taxes).

Here, the Rescheduling Order will reduce federal taxable income for medical-marijuana businesses by giving them access to the deduction for "ordinary and necessary" expenses. 26 U.S.C. § 162(a), ADD-73. Currently, section 280E bars that deduction for those that "traffick[ ] in controlled substances" in Schedule I or II. 26 U.S.C. § 280E, ADD-90. The Rescheduling Order, however, announces that state medical marijuana businesses "will no longer be subject to the deduction disallowance imposed by Section 280E." JA___[91_Fed._Reg._at_22719].

That change, in turn, will reduce Nebraska's state income tax revenue, because Nebraska's state income tax is tied to federal taxable income. *See* Karr Decl. ¶¶ 6-8, Standing Addendum (SA) -2 (citing Neb. Rev. Stat. §§ 77-2716, 77-2734.02(1), 77-2734.04(13), (24); ADD-142, 153, 157–58). The Rescheduling Order will cause Nebraska to incur sizable lost income tax from state licensed marijuana cultivators. Karr Decl. ¶ 11, SA.2; Taddonio Decl. ¶ 7, SA.5. That injury suffices for Article III standing, and it is within the CSA's broad zone of interests. *See Bank of Am. Corp. v. City of Miami*, 581 U.S. 189, 197-201 (2017) (municipal tax-revenue losses are within Fair Housing Act's zone of interests).

2. The Order Imposes Enforcement Costs On Indiana.

The Rescheduling Order will force Indiana to spend additional money to combat the Order's spillover effects, because Indiana prohibits all forms of marijuana. Ind. Code § 35-48-4-11, ADD-141. A State injured when federal action fails to control a harm that crosses its border has standing to challenge that action. *See Massachusetts*, 549 U.S. at 518-26; *see also Del. Dep't of Nat. Res. & Env't Control*, 785 F.3d at 7 (Delaware had standing to challenge EPA rule because of spillover emissions from other states increasing medical costs). Marijuana from States with medical-marijuana programs is regularly diverted to States like Indiana that have no such programs. Sequin Decl. ¶¶ 5-8, SA.14-15. The DEA itself reports that, because of Indiana's proximity to Illinois, Michigan, and Ohio—where marijuana is legal—marijuana from those States often ends up in Indiana. *Id.*, Ex. B, SA.54. Another study found that 44 percent of Indiana residents live within 50 miles of an out-of-state dispensary and that Indiana made more than 13,000 cannabis-related arrests in 2024. *Id.*, Ex. A, at 1, 5, 13-14, SA.25, 29, 37-38. Much of the marijuana illegally diverted to neighboring States comes from licensed establishments. *See In re Schedules of Controlled Substances: Proposed Rescheduling of Marijuana*, DEA Docket No. 1362, Hearing Docket No. 26-96, Hr'g ("DEA Hr'g") Tr. at 2405:22-25, 2406:6-25, 2407:1-17, 2447:20-25, 2448:1-

9 (July 15, 2026), SA.129-31, 133-34 (testimony of Humboldt County Sheriff William Honsal).

The Order here will exacerbate this problem. It encourages production by making medical marijuana far more profitable, and that will predictably increase diversion to Indiana and impose additional enforcement costs—injuries well within the CSA's zone of interests. *See* Sequin Decl. ¶¶ 14, 19, SA.17, 20; 21 U.S.C. §§ 801(3)-(6), 873(a)(6) (recognizing interstate effects of controlled-substance production and distribution). Vacatur would redress that injury by restoring Schedule I restrictions and diminishing enforcement costs. *Cf. Massachusetts*, 549 U.S. at 525.

B. MMJ Has Standing.

MMJ has standing because it has spent millions of dollars attempting to develop an FDA-approved cannabinoid pharmaceutical and the Rescheduling Order suddenly removes restrictions on competitors selling state-licensed medical marijuana. "[I]ncreased competition represents a cognizable Article III injury." *Liquid Carbonic Indus. Corp. v. FERC*, 29 F.3d 697, 701 (D.C. Cir. 1994); *see also La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998) (lifting regulatory restrictions on competitor is Article III injury). Competitors generally have "great success in establishing standing" when they seek "to confine a regulated party within certain statutory guidelines." *Liquid Carbonic*, 29 F.3d at 705. That is so

even when a competitor's interests have "nothing to do with the interests the statute seeks to protect" because "the restriction itself serves the statutory goal." *Id.*; *see also First Nat'l Bank & Tr. Co. v. Nat'l Credit Union Admin.*, 988 F.2d 1272, 1277 (D.C. Cir. 1993) ("competitors have a seemingly unbroken record of success in securing standing in cases involving regulatory systems that restrict entry into a particular field or transaction" (quotations omitted)).

MMJ has competitor standing. *See MD Pharm., Inc. v. DEA*, 133 F.3d 8, 11 (D.C. Cir. 1998) (granting DEA registration to competing drugmaker is an Article III injury). Until the Rescheduling Order, MMJ enjoyed a strong first-mover advantage because of its unbroken track record of federal compliance and significant progress toward an FDA-approved cannabis-based product. Boise Decl. ¶¶ 12-16, SA.66-68. MMJ has spent more than eight years and more than $10 million pursuing the federal FDA-DEA pathway for cannabinoid pharmaceuticals. *Id.* ¶ 10, SA.65-66. Its efforts have included submitting Investigational New Drug materials to the FDA, pursuing orphan-drug status, conducting formulation research and development, seeking DEA laboratory registration, and filing a bulk-manufacturer application. *Id.* ¶ 13, SA.66-67. Meanwhile, MMJ's competitors "have taken few steps"—indeed, *no steps*—toward seeking federal drug approval. *PSSI Glob. Servs., LLC v. FCC*, 983 F.3d 1, 11 (D.C. Cir. 2020); *see* Boise Decl. ¶ 17, SA.68-74. By providing federal authorization for MMJ's competitors, the Rescheduling Order "increase[s]

competition—and thus harm[s] competitors [like MMJ]—as a matter of 'economic logic.'" *PSSI Glob. Servs.*, 983 F.3d at 11 (quoting *Sherley v. Sebelius*, 610 F.3d 69, 72 (D.C. Cir. 2010)); Boise Decl. ¶¶ 23-24, SA.77 (explaining substantial economic harm to MMJ's business).

The Order destroys MMJ's competitive advantage by making federally lawful the products of competitors relying on state medical marijuana programs, an injury that falls within the CSA's broad zone of interests because the CSA "is a quintessential entry-restricting statute." *MD Pharm.*, 133 F.3d at 12-13.

C. The Organizational Petitioners Have Standing.

1. The Order Imposes Costs On NDASA Members.

NDASA is the trade association of the drug screening industry and "may establish standing on behalf of injured members." *Maine Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 70 F.4th 582, 592 (D.C. Cir. 2023). NDASA's members include employers who screen employees for drugs, labs that perform drug screening tests, and companies that provide Medical Review Officer (MRO) services to analyze drug test results. This suit is germane to NDASA's purpose because the Rescheduling Order imposes costs and burdens the operations of its members, McGuire Decl. ¶ 3, SA.81, who are injured in at least two ways.

First, the Order imposes substantial costs on members that provide MRO services. i3screen, for example, provides such services through seven physicians,

who in 2025 reviewed over 100,000 non-negative results related to marijuana. Roys Decl. ¶¶ 3, 10, SA.87, 89. Almost half of i3screen's drug-test revenue comes from marijuana-related tests. *Id.* ¶¶ 5, 10, SA.88-89. Because the Order makes use of marijuana in a state-licensed program legal, i3screen must now spend "significantly more employee hours" determining whether there is a legitimate medical explanation for a positive test result. *Id.* ¶ 12, SA.89-90. That work has raised the time and labor cost of reviewing tests by 20%, forced i3screen to hire at least two additional staff, and cost it at least $20,000. *Id.* ¶¶ 13-14, SA.90. i3screen cannot pass along these costs to customers, because it has determined that raising its prices would result in "los[ing] a substantial amount of … business." *Id.* ¶ 14, SA.90.

Second, all drug testing must take place according to a written policy. By changing the legal status of some uses of marijuana, the Rescheduling Order has forced NDASA members to overhaul their now-obsolete drug-testing policies to reflect that new legal status. *See* McGuire Decl. ¶¶ 8-13, SA.82-84. At least two employers have already incurred costs changing their drug-test policies due to the Order. *Id.* ¶ 14, SA.84. Additional employer members plan to spend money

revising their policies upon the completion of DEA's pending rulemaking addressing rescheduling non-medical marijuana. *Id.* ¶ 16, SA.84-85.[8]

2. The Order Causes SAM, CIVEL, And New Directions To Divert Their Limited Resources.

"[A] concrete and demonstrable injury to an organization's activities—with the consequent drain on the organization's resources— … suffices for standing." *PETA v. USDA*, 797 F.3d 1087, 1093 (D.C. Cir. 2015) (quotation omitted); *see Ctr. for Taxpayer Rts. v. IRS*, 190 F.4th 990, 1001 (D.C. Cir. 2026) (reaffirming diversion-of-resources doctrine after *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024)). To be sure, resources spent merely on "litigation," "lobbying," or "pure issue-advocacy" may not qualify for standing purposes. *PETA*, 797 F.3d at 1093-94. But even in cases where parties' activities are "easily … characterized as advocacy," this Court has nonetheless found Article III standing. *See Am. Soc'y for Prevention of Cruelty to Animals v. Feld Ent., Inc.*, 659 F.3d 13, 27 (D.C. Cir. 2011). For instance, when an IRS policy caused a taxpayer advocacy group to "increase[] staffing to focus on education and outreach in light of the … policy change," this Court held that "diverting and redirecting its limited resources to counteract and

[8] Both injuries are also within the CSA's zone of interests because NDASA members' interests in marketing drug-testing devices and services—and their clients' interests in safe, drug-free workplaces—are certainly "consistent with the purposes of the statute." *See Ethyl Corp. v. EPA*, 306 F.3d 1144, 1148 (D.C. Cir. 2002).

offset the effects of the … policy" were "sufficient" injuries for standing purposes. *Ctr. for Taxpayer Rts.*, 190 F.4th at 1001 (quotations omitted).

Like the taxpayer advocacy group, SAM has standing here. The Rescheduling Order has "injured [SAM's] interest," and SAM has "used its resources to counteract that harm." *PETA*, 797 F.3d at 1094. "SAM's core mission is preventative." Niforatos Decl. ¶ 3, SA.92. SAM seeks "to prevent the harms that come from marijuana use" by offering "seminars, trainings, and educational materials." *Id.* SAM's various curricula and materials are premised "in substantial part on the substance's Schedule I designation and the scientific evidence" that the DEA and HHS have long "found supportive of that designation." *Id.* ¶ 11, SA.97. Due to the Order, SAM must "incur significant expenditures outside its ordinary expenses to retool its substantial body of educational materials," *id.* ¶ 12, SA.97—indeed, to the tune of 260 staff hours and a total cost of $30,000 to $50,000. *Id.* ¶ 15, SA.98. In addition, because the Order will stimulate the marijuana industry—increasing addiction and psychosis, among other harms—SAM anticipates substantially increased demand for its less routine activities addressing those harms: addiction treatment placement, victim-care training, and grieving-parent support. *See id.* ¶¶ 16-21, SA.98-100. Increasing attention on these "ancillary," "remedial" activities necessarily diverts SAM's limited resources away from "its core objective of preventing marijuana use and abuse in the first place." *See id.* ¶¶ 16-21, SA.98-100.

New Directions' mission is to provide substance-abuse recovery services, including for cannabis use disorder. Reed Decl. ¶¶ 4-6, SA.102-03. Rescheduling has engendered significant confusion among participants about marijuana's potential for abuse, which has hampered New Directions' mission, requiring substantial "education and outreach" to counteract misunderstandings about "medical" marijuana. *Id.* ¶¶ 11-14, SA.104-05; *see Ctr. for Taxpayer Rts.*, 190 F.4th at 1001 ("increased" efforts focusing on "education and outreach" held "sufficient" for standing).

CIVEL, Dr. Finn, and Dr. Stuyt likewise have standing. The Order makes CIVEL's mission—cannabis-industry victim assistance, attorney education, and case support—harder by giving state-licensed products federal Schedule III status while lacking FDA-approved drug labeling and dosing. CIVEL must now revise materials, educate lawyers and victims about the difference between scheduling and approval, and divert resources from existing services. Evans Decl. ¶¶ 4, 6, 9, SA.108-09. Likewise, Drs. Finn and Stuyt now face substantial difficulty counseling patients because the Order treats marijuana as legitimate medicine while failing to provide any of the critical information that always accompanies rigorous FDA drug

approval, upon which doctors regularly rely. *See* Finn Decl. ¶¶ 6-11, SA.112-13; Stuyt Decl. ¶¶ 5-9, SA.116-18.[9]

ARGUMENT

I. The Rescheduling Order Is Contrary To The CSA

A. The Rescheduling Order Violates The CSA By Purporting To Place A Single "Drug Or Other Substance" (Marijuana) In Two Different Schedules.

The Rescheduling Order is unlawful on its face because it purports to reschedule only marijuana "subject to a state-issued license,"[10] JA___[91_Fed._Reg._at_22714-15], rather than "marijuana" as a unitary "drug or other substance," 21 U.S.C. §§ 811(a), 802(16), ADD-35, 23. Section 811 of the CSA authorizes the Attorney General to "transfer between [CSA] schedules any *drug or other substance*." *Id.* §§ 811(a), 811(d) (emphasis added), ADD-35-36. By its terms, it does not allow the Attorney General to divide a single "drug or other substance" into two artificial categories—marijuana under a state "medical" marijuana program and other marijuana—and reschedule only one of those categories. *See*

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[9] *Compare All. for Hippocratic Med.*, 602 U.S. at 385 (no standing where doctors did *not* prescribe mifepristone on conscience grounds), *with* Finn Decl. ¶ 5 (supporting development and use of cannabis-based medicines, provided "safe, effective, federally compliant products and proper dosing information" are available); Stuyt Decl. ¶ 5 (similar).

[10] The Rescheduling Order also applies to marijuana "included in an FDA-approved drug product"—but that is a null set. 91 Fed. Reg. at 22714.

id. §§ 802(12), 321(g)(1) (definition of "drug"), ADD-23, 9; § 802(16) (definition of "marihuana"), ADD-23. The definition of "drug" does not permit treating the same physical matter as different drugs based merely on a state-law regulatory regime. *See* 21 U.S.C. § 802(12), ADD-23; *id.* § 321(g)(1), ADD-9.[11] Similarly, the ordinary definition of "substance" (which is not defined in the CSA) is "matter of particular or definite chemical constitution." *Webster's Seventh New Collegiate Dictionary* 876 (1963); *Random House Dictionary of the English Language* 1418 (1966) ("a species of matter of definite chemical composition"). That necessarily suggests that, in authorizing the Attorney General to transfer a "substance" between schedules, Congress intended the Attorney General to act upon all matter with the same "chemical constitution" as a single "substance" and transfer *all* manifestations of that substance into a single CSA schedule.

The surrounding text confirms that, for scheduling purposes, the CSA focuses on the physical, chemical, and pharmacological properties of a substance and is designed for a given substance to be placed in a single schedule based on those characteristics. Thus, for example, in listing the factors for the Attorney General to consider in a scheduling decision, section 811(c) points to factors such as the "state of

[11] Section 321(g)(1) defines "drug" as an article recognized in an official compendium, intended to treat or prevent disease, or intended "to affect the structure or any function of the body."

current scientific knowledge regarding the drug or other substance," "[s]cientific evidence of its pharmacological effect, if known," its "actual or relative potential for abuse," and "its psychic or physiological dependence liability." 21 U.S.C. § 811(c)(1), (2), (3), (7), ADD-36. Those factors show that, for purposes of scheduling, the CSA focuses on characteristics that inhere in a given chemical compound, not the happenstance of how the substance might have different treatment under a state licensing regime.

To be sure, some drugs assigned to different CSA schedules contain the same chemical substance at different concentrations.[12] But that proves the point. In such cases, different scheduling is justified because distinct formulations with different concentrations of an active ingredient have different pharmacological effects, different dependence liability, and different potential for abuse.[13] Under the Rescheduling Order, by contrast, the exact same "drug" or "substance" in the exact same concentration—for example, cannabis extract with 60% THC—is treated as a chameleon. If a user buys it under a state medical marijuana program, the Order purports to

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[12] *E.g.*, 21 U.S.C. § 812(c) sched. II (opium derivatives), ADD-43; 21 C.F.R. § 1308.12(b)(1)(i) (Schedule II opium derivatives include codeine), ADD-120.

[13] *See, e.g.*, 82 Fed. Reg. 14815, 14816-17 (Mar. 23, 2017) (placing dronabinol oral solution (Syndros) in Schedule II even though it has the "same pharmacology" as Schedule III drug Marinol because "these formulations differ in their physical and chemical properties," and Syndros "has a greater potential for extraction" and thus "greater abuse potential").

reschedule it. If the same user buys the exact same substance for recreational purposes, the Order does not. That is not how the CSA works. The happenstance of a state-law licensing regime does not make marijuana into two or more different "drugs" or "substances" with different characteristics relevant for scheduling. For this reason alone, the Rescheduling Order is unlawful.

B. Section 811 Does Not Give The Attorney General Power To Transfer Internationally-Controlled Drugs To Any Treaty-Compliant Schedule.

The Rescheduling Order is also unlawful because it flagrantly circumvents the formal rulemaking procedures mandated by section 811(a), which exist to protect stakeholders like Petitioners and to prevent ill-considered, unilateral scheduling decisions by the Attorney General. Nothing in the limited exception from formal rulemaking in section 811(d) permitted the Attorney General's action in this case.

1. Neither Text Nor Context Support The Attorney General's Expansive Reading Of Section 811(d).

In section 811, Congress created a detailed administrative process for substances to be "add[ed]" to, "transfer[red]" between, or "remove[d]" from schedules under the CSA. 21 U.S.C. § 811(a)-(b), ADD-35-36. First, the Attorney General must "gather[ ] the necessary data" and "request from the Secretary [of Health and Human Services] a scientific and medical evaluation," along with HHS's ultimate "recommendations, as to whether such drug or other substance should be so controlled." *Id.* § 811(b), ADD-36. Then, if HHS recommends that it be controlled, the

Attorney General must determine whether there is "substantial evidence of [the substance's] potential for abuse such as to warrant control" in a particular schedule. *Id.* And if there is, "he *shall* initiate proceedings … under subsection (a)." *Id.* (emphasis added).

Under subsection (a), the Attorney General is to reschedule substances "by rule." *Id.* § 811(a), ADD-35. Critically, Congress specified that such "[r]ules … shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II" of the Administrative Procedure Act (APA)—the subchapter that addresses formal rulemaking. *Id.* § 811(a); *see* 5 U.S.C. §§ 556, 557, ADD-3-7. Under those procedures, interested parties are "entitled to present [their] case … by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. § 556(d), ADD-4. And the agency—here, the DEA—may issue a rule only "on consideration of the whole record" based on "reliable, probative, and substantial evidence." *Id.* As this Court has explained, the requirements for formal rulemaking under the APA "represent[ ] the highest degree of administrative protection that Congress believed would be necessary to protect interested parties." *Mobil Oil Corp. v. Fed. Power Comm'n*, 483 F.2d 1238, 1253 (D.C. Cir. 1973).

In addition, Congress further constrained the Attorney General's discretion on scheduling matters by specifying that in any such rulemaking, the recommendations of the Secretary of HHS "shall be binding on the Attorney General as to ... scientific and medical matters." 21 U.S.C. § 811(b), ADD-36.

Here, the Attorney General issued the Rescheduling Order while bypassing the stringent protections of a formal rulemaking process that Congress built into the CSA. His only rationale for doing so was the narrow exception in section 811(d) for international treaty compliance. *See* 21 U.S.C. § 811(d), ADD-36-38. But that exception does not apply here.

Section 811(d)(1) provides that "[i]f control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, 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 subsection (a) ... and without regard to the procedures prescribed by subsections (a) and (b) of this section." 21 U.S.C. § 811(d)(1), ADD-36. That provision serves an obvious and narrow function. It allows the Attorney General to ensure the United States "carr[ies] out [its] obligations" under drug-control treaties even if the criteria and procedures specified in section 811 would ordinarily lead to a different result. *Id.* It provides a failsafe for the Attorney General to ensure

that the United States does not breach a treaty by permitting him to determine the schedule under the CSA that is needed for treaty compliance. *Id.*

If the treaty exemption did not exist, the Attorney General could face conflicting statutory commands. On the one hand, Congress commands that he "*shall* issue an order controlling [the] drug" to comply with U.S. treaty obligations. *Id.* (emphasis added). On the other hand, Congress also commands that he "*shall not* control the drug" if HHS "recommends that [the] drug … not be controlled." *Id.* § 811(b) (emphasis added), ADD-36. Similarly, the various criteria relevant for scheduling substances under the schedules created by the CSA might lead to a result that does not match up with the restrictions the U.S. has agreed to apply under a treaty. Only the subsection (d)(1) exception from "the findings required by subsection (a)" and "the procedures prescribed by subsections (a) and (b)" averts such a clash. The evident purpose for the provision gives context confirming the proper understanding of the section as a narrow exception permitting the Attorney General to make a legal determination about the CSA scheduling assignment that is needed to meet treaty obligations—not an exemption designed to give the Attorney General sweeping policy discretion to choose among CSA schedules when there are "several legally viable scheduling options" that suffice to meet treaty obligations. JA___[91_Fed._Reg._at_22718].

Indeed, what the provision was plainly *not* intended to do was to take all substances that are subject to control under the Single Convention, exempt them from the standards and procedures carefully spelled out in section 811(a) and (b), and give the Attorney General discretionary authority to schedule them (or reschedule them) in any one of various CSA schedules that would meet treaty obligations. The entire structure of section 811 is inconsistent with such an understanding.

Congress clearly took great care in spelling out restrictions that would circumscribe discretion in scheduling substances, including specific criteria to consider, an elaborate rulemaking process, and binding authority for the Secretary of HHS on medical and scientific matters. 21 U.S.C. § 811(a)-(c), ADD-35-36. Congress passed the CSA largely to implement the Single Convention. S. Rep. No. 91-613, at 4 (1969). It is no accident, then, that in crafting section 812's initial drug schedules, the vast majority of nonhallucinogenic substances initially controlled under the Act were also already controlled under the Single Convention. *See NORML*, 559 F.2d at 746 n.53. If Congress had not intended the restrictions that it crafted to apply whenever a substance was subject to control under the Single Convention, the structure of section 811 would make no sense. It would mean that the provision presented as an exception—section 811(d)—would actually swallow the general rule, and all the restrictions that Congress carefully spelled out would be meaningless for most rescheduling decisions, which would simply be assigned to the Attorney General.

But that is not how this Court ordinarily reads a statute. Instead, "[w]hen a clause supplies an exception to a baseline rule, we must read that clause narrowly in order to preserve the primary operation of the provision." *Vanda Pharms., Inc. v. FDA*, 187 F.4th 544, 553 (D.C. Cir. 2026) (quotation omitted); *see also Maracich v. Spears*, 570 U.S. 48, 59-60 (2013) ("exceptions ought not operate to ... contravene the statutory design").

If Congress had really intended the result the Attorney General now claims, it would have straightforwardly stated a general rule permitting the Attorney General discretion to schedule all substances subject to international treaties and then would have provided an alternative procedure narrowly applying to those few substances not subject to international controls. The fact that section 811 is structured in exactly the opposite way strongly confirms that the sweeping discretion the Attorney General purports to find in section 811(d) cannot be correct.

The understanding that section 811(d) is narrowly drawn to permit the Attorney General to make a legal determination about the minimum scheduling required to meet treaty obligations is further buttressed by the general division of responsibilities in the Act. The determination of treaty requirements is squarely within the Attorney General's legal expertise. It does not implicate HHS's medical and scientific expertise, which Congress plainly sought to give a prominent role in most scheduling decisions. 21 U.S.C. § 811(b), ADD-36. Reading section 811(d) as

exempting all substances controlled under the Single Convention from any of the other requirements of section 811 is at odds with the textual command for the Secretary of HHS to play a vital role in policy-based scheduling decisions. Nothing in section 811(d) provides a clear indication that Congress abandoned the policy judgment—clearly expressed in the text of section 811(b)—that the Secretary of HHS should play a central role in policy-based scheduling decisions under the CSA, but that is the import of the Attorney General's sweeping expansion of section 811(d).

2. The Drafting History Of The CSA Confirms That The Attorney General's Reading Of Section 811(d)(1) Is Untenable.

The drafting history of the CSA overwhelmingly confirms that Congress designed section 811 procedures to guard against unilateral rescheduling decisions by the Attorney General and that section 811(d)(1) cannot provide the sweeping exemption from those procedures that the Attorney General claims. That is especially true where, as here, a treaty-controlled substance is moved from Schedule I to III.

Congress was so concerned about constraining scheduling decisions by the Attorney General that the original Senate bill expressly *prohibited* the Attorney General from moving any substance directly from Schedule I to Schedule III under

the CSA without congressional approval.[14] *See* S. 2637, 91st Cong. § 201(d) (1969). Instead, to make such a significant move, the Attorney General would first have to transfer the substance from Schedule I to Schedule II, "and then, in a second step," transfer it from Schedule II to Schedule III. S. Rep. No. 91-613, at 5 (1969). Each time, he would need to "consider," among other factors, the "controls required based on United States obligations under international treaties." S. 2637, 91st Cong. § 201(a)(8). And he would have to conduct an informal notice-and-comment rulemaking under the APA. *See id.* § 201(a). As Michael Sonnenreich, the Deputy Chief Counsel of the Bureau of Narcotics & Dangerous Drugs,[15] explained at the time, it would "require[ ] two separate administrative procedures" or "the consent of Congress" to move a substance from Schedule I to Schedule III. *Drug Abuse Control Amendments—1970: Hearings on H.R. 11701 and H.R. 13743 Before the Subcomm. on Pub. Health & Welfare of the H. Comm. on Interstate & Foreign Commerce*, 91st Cong. pt. 2, at 706-07 (1970).

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[14] Notably, "the Single Convention control[led] almost 90 percent of the 64 nonhallucinogenic substances enumerated in Schedule I of the CSA as originally enacted." *NORML*, 559 F.2d at 746 n.53. The draft Schedule I in S.2637 was almost identical. Thus, the draft prohibition on direct Schedule I-to-III transfers primarily concerned Single Convention drugs.

[15] The Bureau of Narcotics & Dangerous Drugs later became the DEA.

The reason for these procedural hurdles was to prevent "summary type" rescheduling that would relax restrictions on certain sensitive, treaty-controlled drugs like marijuana, heroin, and LSD. *See Narcotics Legislation: Hearings on S. 1895, S. 2590, and S. 2637 Before the Subcomm. to Investigate Juvenile Delinquency of the S. Comm. on the Judiciary*, 91st Cong. 667-69 (1969). As Sonnenreich explained during a hearing on the corresponding House bill, there was a prohibition on moving a drug from Schedule I to Schedule III because, while Congress could make such a move, the general view was that "it should not be in the hands of any administrative official to do it automatically." *Drug Abuse Control Amendments*, 91st Cong. pt. 2, at 707 (1970) (colloquy with Rep. Paul Rogers). In short, both Congress and the DEA's predecessor agency understood that the bills, as originally drafted, would *not* allow "the Attorney General and his staff [to] just arbitrarily say, 'OK, we will put [a Schedule I drug] in schedule III.'" *Narcotics Legislation*, 91st Cong. at 667 (Sen. Hruska).

Many worried that even two layers of informal rulemaking still effectively allowed an end-run around the statutory prohibition on direct transfers from Schedule I to Schedule III. *See Drug Abuse Control Amendments*, 91st Cong. pt. 2, at 707; *Narcotics Legislation*, 91st Cong. at 667. The compromise in the final bill was to require formal rulemaking under the APA for any rescheduling—a stricter

procedure than informal rulemaking, but less onerous than mandating congressional approval. *See* 21 U.S.C. § 811(a), ADD-35.

This drafting history revealing concerns about unilateral Attorney General action confirms that, from the very inception of the legislation, the protections that ultimately developed into a formal rulemaking requirement were intended to apply even to scheduling decisions related to substances controlled under the Single Convention. Nothing in the evolution of the legislation suggests that Congress suddenly decided to abandon those restrictions and give the Attorney General carte blanche to make unilateral rescheduling decisions for any substance controlled under a treaty. While the final bill placed treaty-control considerations in a separate subsection (811(d)(1)) rather than among the subsection (a) factors that the Attorney General was to consider in rulemaking (as in the original draft), Congress sensibly did so to distinguish legal treaty-obligation grounds from the usual scientific grounds for scheduling decisions.[16] And representations to Congress from the Department of Health, Education, and Welfare make clear that the government understood the bill to require any rescheduling of marijuana to proceed based on a factual record—

[16] *See, e.g.*, 116 Cong. Rec. 33316 (1970) (statement of Rep. Boland) ("Considering that the scheduling of a substance is based largely on scientific information," "in the absence of international treaty obligations," "it seems most inappropriate that law-enforcement authorities should have the last word on the content of the schedules.").

not based merely on the Attorney General's authority to pick a CSA Schedule for treaty compliance.[17]

Treating section 811(d) as if it exempts all substances regulated under the Single Convention from the procedural restrictions in section 811(a) and (b) would run completely counter to the evidence in the drafting history that Congress consistently sought to restrict the Attorney General's discretion to make unilateral rescheduling decisions, even with respect to drugs controlled under the Single Convention.

3. The Rescheduling Order Ignores This Court's Binding Interpretation Of Section 811(d)(1) In *NORML.*

While the analysis above fully addresses the correct statutory construction of section 811, the Court need not plow new ground to interpret the section, because it already established a binding interpretation contrary to the Attorney General's approach decades ago. Almost half a century ago, this Court held in *NORML v. DEA* that "to the extent that there is latitude to schedule a substance consistent with treaty obligations, the Attorney General is obliged to follow the prescribed [rulemaking]

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[17] H.R. Rep. No. 91-1444, pt. 1, at 61 (1970) (letter from R. Egeberg, HEW, to Rep. Staggers) (stating that HEW's "recommendation is that marihuana be retained within schedule I at least until the completion of certain studies," and adding: "If *those studies* make it appropriate for the Attorney General to change the placement of marihuana to a different schedule, he may do so in accordance with the authority provided under section 201 of the bill." (emphasis added)).

procedures in" section 811(a) and (b) to make a scheduling determination. 559 F.2d at 747; *see id.* at 754, 757. That binding holding controls here.

NORML addressed a marijuana scheduling order that bypassed "the referral and hearing procedures of [section 811(a)-(b)]" because the government interpreted section 811(d)(1) to dispense with such procedures for any "drugs subject by treaty to international control." 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). JA___[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 nonhallucinogenic substances originally placed under Schedule I of the CSA were controlled by the Single Convention. *NORML*, 559 F.2d 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.* As the Court explained, "Congress never intended to allow the Attorney General to displace the Secretary [of HHS] whenever any international obligations attach to a particular drug." *Id.* at 746.

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.10. Indeed, as recently as 2024, the DEA acknowledged *NORML* as binding. *See* JA___[89_Fed._Reg._44620 n.39]. In an NPRM initiating a rescheduling process, the 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.* (emphases added).

The Rescheduling Order relegates its only mention of *NORML* to a 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 satisfied *NORML*. JA___[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. To the contrary, this Court expressly ordered that, on remand, 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)." JA___[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). JA___[91_Fed._Reg._at_22717] n.19. 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 half a century whenever the agency decides that it no longer agrees with the Court's analysis.

C. The Major-Questions Doctrine Requires Any Ambiguity Over The Scope Of Section 811(d)(1) To Be Resolved Against The Order.

This is a prototypical major questions case. By claiming a right under section 811(d)(1) to reschedule any controlled substance subject to the Single Convention without any process, the Attorney General has claimed a new "unheralded power" based on the "vague language of an ancillary provision of the Act" that was "designed to function as a gap filler and ha[s] rarely been used in the preceding decades." *W. Virginia v. EPA*, 597 U.S. 697, 724 (2022) (quotations omitted). In addition, in claiming that power, the Attorney General has settled a "major social and

economic policy decision[]" in a way that Congress has "conspicuously and repeatedly declined to enact itself." *Id.* at 724, 730. There is no reason to read such a grant of authority into the CSA.

To start, DOJ's interpretation of section 811(d)(1) would grant it an "unheralded" new power and mark a "transformative expansion in [its] regulatory authority." *W. Virginia*, 597 U.S. at 724. As this Court explained in *NORML*, the "almost 90 percent" of the nonhallucinogenic substances listed in Schedule I of the original CSA were already controlled under the Single Convention. 559 F.2d at 746 & n.53. Under the Attorney General's interpretation, section 811(d)(1) would make the detailed procedures mandated in section 811(a) a dead letter for all such substances. DOJ's claim to this sweeping authority is new, and inconsistent with decades of practice. For nearly fifty years, DOJ has repeatedly addressed petitions to reschedule marijuana by following the requirements of sections 811(a) and (b). *See supra* p.10.

DOJ's claim that this newfound authority flows from a "gap filler" provision further requires application of the major questions doctrine. *See W. Virginia*, 597 U.S. at 724. As explained above, section 811(d)(1) serves the narrow purpose of allowing the Attorney General to ensure that the U.S. does not violate treaties. *See supra* pp.8-9, 33-39. It is not a plausible interpretation of the statute to hold that

Congress wrote section 811(d)(1) as a massive, process-free grant of rescheduling authority.

DOJ's interpretation also fails because it grants the agency authority to settle "major social and economic policy decisions." *W. Virginia*, 597 U.S. at 730 (quotations omitted). As the Supreme Court has explained, courts "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies." *Id.* at 723 (internal quotations omitted).

Relaxing restrictions on marijuana is among the biggest social issues currently facing the country. Rescheduling was a major issue in the 2024 election. It was praised in the Democratic Party's platform, and President Trump took a prominent stance on the issue. Niforatos Decl. ¶ 9, SA.95-96; 2024 Democratic Party Platform at 42 (Aug. 19, 2024), tinyurl.com/24DemPlat; Jacob Sullum, *Trump Endorses Federal Marijuana Reforms and Reiterates His Support for Legalizing Pot in Florida*, Reason (Sept. 9, 2024), tinyurl.com/mwbbfjum.[18] Right now, there is a dispute between the House and the Senate on whether to bar DOJ from using funds for rescheduling. *Compare* H.R. 8845, 119th Cong. § 591, *with* S. Comm. on Appropriations, 119th Cong., 2027 Appropriations Act Markup, at 112-41. The economic

[18] Courts may consider publicly available materials and reports when assessing whether the major questions doctrine applies. *See, e.g.*, *Nebraska v. Biden*, 600 U.S. 477, 503 (2023) (citing budget documents and news reports).

impact of the Attorney General's newfound authority further demands the conclusion that Congress did not intend to give the Attorney General absolute, and process-free, rescheduling discretion. The domestic medical marijuana industry reaps over $10 billion in revenue per year, and is projected to grow to almost $25 billion by 2030. Niforatos Decl. ¶ 10 & n.18, SA.96. The Rescheduling Order itself acknowledges that state-licensed marijuana is a "multi-billion-dollar" industry. JA___[91_Fed._Reg._at_22721]. Among many other impacts, the Rescheduling Order will result in at least billions of dollars in tax relief to the medical marijuana industry.[19] These economic effects are almost certainly unprecedented for a single rescheduling decision.

Finally, both the CSA's legislative history and Congress's decades-long refusal to reschedule or legalize marijuana are fatal to DOJ's claim that Congress, in fact, delegated it unchecked and process-free discretion to reschedule marijuana as it sees fit. The CSA created a commission to study "the international control of marihuana" and submit to Congress "recommendations [and proposals] for legislat[ive] and administrative action[ ]," Pub. L. 91-513, § 601, clearly demonstrating Congress's intent to participate in future marijuana scheduling decisions. Senator Dodd explained that, following the Commission's eventual report, "the Congress

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[19] *See* Whitney Economics, *Whitney Economics Refreshes Analysis of Federal Tax Impact on Legal Cannabis Operators* (Apr. 9, 2026), tinyurl.com/224bnMJtax.

will be in a much better position to decide, once and for all, how it wants to handle the many-sided marihuana problem." 116 Cong. Rec. 997 (1970). Since that time, Congress has considered (and declined to enact) rescheduling or legalization multiple times, with at least four such bills currently pending. MORE Act, H.R. 5068, 119th Cong. (2025); Cannabis Administration and Opportunity Act, S. 5022, 119th Cong. (2025); STATES 2.0 Act, H.R. 2934, 119th Cong. (2025); Marijuana 1-to-3 Act of 2025, H.R. 4963, 119th Cong. (2025). The Attorney General's newfound claim to absolute rescheduling authority over Single Convention substances, based on a gap filling provision, simply cannot be squared with the major questions doctrine.

D. Section 811(d)(1) Does Not Authorize The Rescheduling Order Because The Order Violates The Single Convention.

Even if section 811(d)(1) allowed the Attorney General to do without a formal rulemaking under the circumstances of this case, it still would provide no authority for the Rescheduling Order. Section 811(d)(1) authorizes the Attorney General to take scheduling actions to "carry out" the United States' obligations under international treaties, including the Single Convention. In fact, the Rescheduling Order itself acknowledges that the order can "only comport with 21 U.S.C. 811(d)(1) if" it is consistent with the Single Convention. JA___[91_Fed._Reg._at_22719]. The Rescheduling Order, however, conflicts with multiple requirements of the

Single Convention and thus exceeds any statutory authority conveyed to the Attorney General by section 811(d).[20]

First, the Single Convention requires that all producers ("cultivators") of marijuana must be licensed by a single government agency. JA___[18_U.S.T._1407,_art._23(2)(b), art. 28].[21] The United States has implemented that requirement through at least three provisions: (1) 21 U.S.C. § 822(a)(1), ADD-47, requires every person who manufactures or distributes a controlled substance to obtain a "registration" (a license) from the Attorney General; (2) a DEA rule echoes that registration requirement, *see* 21 C.F.R. § 1301.11(a), ADD-99; and (3) a further DEA rule at 21 C.F.R. § 1301.13(a), ADD-100, expressly states that "[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted."

The Rescheduling Order fails to carry out U.S. obligations under the Single Convention because, while it creates a new mechanism for state-licensed medical

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[20] Where Congress has directed an agency to take actions to implement obligations under a non-self-executing treaty, courts may look to the terms of the treaty to determine the boundaries of the authority of the agency under that statute. *See, e.g.*, *NRDC v. EPA*, 464 F.3d 1, 9 (D.C. Cir. 2006) (construing Montreal Protocol, which Congress "implemented … with a direction to EPA to abide by its terms," to determine the bounds of EPA's statutory authority); *Alaska Fish & Wildlife Fed'n & Outdoor Council, Inc. v. Dunkle*, 829 F.2d 933, 938 (9th Cir. 1987).

[21] The restrictions imposed on opium under Article 23 are cross-applied to marijuana by Article 28.

marijuana producers to seek federal registration, it allows any state licensee who applies for federal registration within 60 days of publication of the Rescheduling Order to continue operating *without* a federal license. The revised rules purportedly adopted by the Order, *cf. infra* Part II.A, expressly state that "[n]otwithstanding" the ordinary prohibition in § 1301.13(a) on engaging in any activity for which registration is required until the registration has been granted, any state licensee that applies for registration within the 60-day window "may engage in the manufacture, distribution, and/or dispensing of marijuana ... in conformity with a state-issued license during the pendency of the application." JA___[91_Fed._Reg._at_22722] (amending 21 C.F.R. § 1301.13, ADD-139); *see also id.* at ___[91_Fed._Reg._at_22720] ("[E]arly applicants may lawfully operate under their state-issued licenses during the pendency of review.").

Over 2,100 state-licensed marijuana manufacturers applied for federal registration within the 60-day window, and, as of this filing, over 2,100 state-licensed marijuana manufacturers remain unregistered.[22] As a result, for the last 5 months, these 2,100 state-licensed entities have been producing marijuana under a regime created by the Attorney General but without any federal license. That

[22] DEA, *Medical Marijuana Timely Applicants* (Nov. 24, 2026), perma.cc/6GJM-5L3E.

scheme squarely violates the requirements of Article 23(2)(b) of the Single Convention and thus cannot be authorized by section 811(d).

Second, the Single Convention requires the United States to establish an annual quota for the production of certain controlled substances, including marijuana, to prevent excessive production. JA___[art._21]. Congress implemented that requirement by directing the Attorney General to establish production quotas, but only for Schedule I and II substances under the CSA. 21 U.S.C. § 826(a), ADD-63; *cf.* 91 Fed. Reg. 287, 294 (setting annual quotas for 2026). If marijuana is moved to Schedule III, however, the quota requirement of section 826 will not apply and there is no other extant authority establishing a quota to take its place. In fact, when the Office of Legal Counsel examined moving marijuana to Schedule III, it determined that such a move could be made consistent with the Single Convention only if the government "impos[ed] additional controls" to close the resulting quota "gap." JA___[2024_OLC_Op._at_*4]. This Court has similarly concluded that "several requirements imposed by the Single Convention would not be met if cannabis ... were placed in CSA Schedule III," including specifically "the quota ... requirements" of Article 21. *NORML*, 559 F.2d at 751 & n.71.

The Rescheduling Order conflicts with the Single Convention (and thus with section 811(d)) because it moves marijuana to CSA Schedule III without making any provision for the resulting "gap" in fulfilling the obligations to set quotas for

marijuana production. The Rescheduling Order vaguely promises that, in the future, state-licensed marijuana "*will* be required to meet the quota requirements of the Single Convention," JA___[91_Fed._Reg._at_22718] (emphasis added), but it imposes no quotas on marijuana producers in state-licensed programs and no mechanism to set such quotas.[23] As a result, the Rescheduling Order creates a regime providing federal registration for state-licensed marijuana producers without establishing *any* quota set by the DEA. That squarely violates the Single Convention.

Third, the Single Convention requires that all marijuana growers "deliver their total crops" of marijuana to a single government agency (a role fulfilled by the DEA in the U.S.) and requires that the agency "shall purchase and take physical possession of such crops." JA___[art._23(2)(d)]. The Department of Justice has recognized that this treaty language requires "growers licensed under the CSA to transfer the crops to the physical, and not merely legal, control of the federal government." JA___[*Licensing_Marijuana_Cultivation_in_Compliance_with_the_Single_Conve*

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[23] The DEA has belatedly acknowledged that the Single Convention requires quotas for marijuana production and that the Rescheduling Order is *not* in compliance with those treaty obligations. *See Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances*, 91 Fed. Reg. 72566, 72571 (Nov. 10, 2026) (citing JA___[arts._21_&_29]). The DEA's only response, however, is another vague promise of future action, as it notes that the agency is "assessing" "methodologies" for setting marijuana quotas. *Id.* The Court may take judicial notice of this DEA publication. 44 U.S.C. § 1507, ADD-91.

ntion_on_Narcotic_Drugs,_42_Op._O.L.C._63,_72_(June_6,_2018)]. The DEA has implemented that requirement with rules in Part 1318 of Title 21 of the CFR specifying that marijuana growers "shall deliver their total crops" to the DEA, which shall "purchase and take physical possession of such crops." 21 C.F.R. § 1318.04(a), ADD-134. The rules allow for the DEA to "accept delivery and maintain possession of such crops at the registered location" of the grower (to avoid shipping the marijuana to a central location), but only if the DEA "designate[s] a secure storage mechanism at the registered location" over which the DEA must "control access." *Id*.

The Rescheduling Order runs afoul of the Single Convention (and section 811(d)) by exempting state-licensed marijuana distributors from all of these requirements and abandoning any pretense that the DEA will take "physical possession" of their crops. Under new rules adopted by the Order, "Part 1318 ... shall not apply to entities" that have licenses under the new regime for state-licensed marijuana. JA___[91_Fed._Reg._at_22722] (amending 21 C.F.R. § 1301.13(k)(6), ADD-139). Instead, the new rules create a framework of, effectively, sham transactions in which DEA "purchase[s]" the crop on paper at a "nominal price" set by the grower and then immediately "sell[s] the crops back to the entity ... at the same price." JA___[91_Fed._Reg._at_22720, 22722] (amending 21 C.F.R. § 1301.13, ADD-139). Such a transfer of paper title is precisely the "merely legal"

control that OLC found insufficient to satisfy the requirement under the Single Convention that the DEA must take "physical possession" of marijuana crops. *See* JA___[2018_OLC_Op._at_72].

Fourth, the Single Convention obligates the United States to "[r]equire medical prescriptions for the supply, or dispensation" of marijuana "to individuals." JA___[art._30(2)(b)(i)]. In fact, the Rescheduling Order itself acknowledges that the Single Convention requires "medical prescriptions for the dispensing of such drugs to patients." JA___[91_Fed._Reg._at_22715] (citing art. 30). The Rescheduling Order explains that, for "FDA-approved drug products containing marijuana"—which is, in reality, a null set, *see* 89 Fed. Reg. at 44602—that requirement is enforced through the DEA's regulations requiring a prescription that includes "the drug name, strength, dosage form, quantity prescribed, [and] directions for use." JA___[91_Fed._Reg._at_22719] & nn.41, 43 (citing 21 U.S.C. § 829(a)-(b), ADD-66; 21 C.F.R. § 1306.05(a), ADD-106). Indeed, DEA has an entire part of its regulations—part 1306, which is titled "Prescriptions"—dedicated to specifying requirements for prescriptions.

For state-licensed marijuana, the Rescheduling Order conflicts with the Single Convention because it forgoes all of those requirements. Instead, with a sweeping exemption that applies "[n]otwithstanding part 1306 ... or any other provision of these rules," the Order establishes that, for state-licensed marijuana, any

"certification or other document" that "state law deems sufficient" will suffice for dispensing marijuana, as long as it is dated and signed, identifies the user, and identifies the practitioner by state license number. 21 C.F.R. § 1301.13(k)(5), ADD-139. Unlike a prescription, the certification need not name a drug, strength, dosage form, quantity, or directions for use. It need not bear a DEA registration number. That is nothing remotely like a prescription. At the formal rulemaking hearing convened to address the rescheduling of marijuana not covered by the Rescheduling Order, the government's own FDA witness acknowledged that, when it comes to dispensing marijuana in a state-licensed program, "it would be inaccurate to call what doctors or healthcare practitioners do as writing a prescription." DEA Hr'g Tr. 194:2-4 (Dr. Chiapperino); *see also id.* at 1377:8-9 (Dr. Akinfiresoye, DEA) ("a doctor cannot write a prescription for [marijuana]"), tinyurl.com/DEAhrgTr.[24]

II. The Rescheduling Order Violates Basic Administrative Law Principles.

A. The Order Unlawfully Issues Or Amends Legislative Rules Without Notice-And-Comment Procedures.

Even if section 811(d)(1) allowed the Attorney General to reschedule marijuana by revising the provision in the CFR that formally assigns controlled substances to different schedules, *see* 21 C.F.R. §§ 1308.11-.15, ADD-107-30,

[24] The Court can take "judicial notice of the information on" an agency's website even when "the administrative record does not contain" those facts. *Nebraska v. EPA*, 331 F.3d 995, 999 n.3 (D.C. Cir. 2003) (citing Fed. R. Evid. 201).

section 811(d)(1) cannot provide authority for multiple additional actions the Attorney General swept into the Rescheduling Order. Beyond simply changing the scheduling of marijuana, the Rescheduling Order also issued or amended multiple legislative rules to impose additional restrictions on the marijuana moved to Schedule III. Crucially, moreover, it unlawfully bypassed notice-and-comment rulemaking in promulgating those rules.

The Rescheduling Order makes plain on its face that, in some instances, the set of restrictions that comes off-the-shelf with designation under Schedule III of the CSA was not sufficient to satisfy all U.S. treaty obligations under the Single Convention. *See* JA___[91_Fed._Reg._at_22718-19]. As a result, the Order also adds at least five rules imposing new substantive restrictions on marijuana moved to Schedule III.

First, the Order imposed new import-export permit requirements, *id.* at ___[22723] (amending 21 C.F.R. § 1312.30, ADD-140).

Second, the Order created a new category of DEA registration for marijuana manufacturers, distributors, and dispensers that hold state medical-marijuana licenses. *Id.* at ___[22722] (amending 21 C.F.R. § 1301.13, ADD-138-39).

Third, the Order exempted those registrants from the default federal requirements that apply to every other registrant (recordkeeping and reporting, labeling and packaging, physical security, and disposal) and directed that the DEA "shall accept"

compliance with state law to "the maximum extent permissible," *id.* at 22722 (adding 21 C.F.R. § 1301.13(k)(4), (8)-(10))—even though the Attorney General has no authority to waive federal labeling requirements under the Food, Drug, and Cosmetic Act (FDCA). *See* 21 U.S.C. § 902 ("Nothing in this chapter"—including section 811—"shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the [FDCA].").[25] The Order likewise allowed dispensers to dispense on a state-law "certification" rather than a prescription, "[n]otwithstanding part 1306." JA___[91_Fed._Reg._at_22722].

Fourth, the Order displaced DEA's existing crop-purchase regulations and instead created out of whole cloth a 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, ADD-139).

Fifth, the Order waived the registration requirement in the CSA, 21 U.S.C. § 822(a), ADD-47, and allowed thousands of state-licensed marijuana businesses that timely applied for DEA registration to lawfully deal in marijuana. *Id.* at

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[25] The Order kept only "the warning required by 21 U.S.C. 825(c)," 91 Fed. Reg. at 22722, which requires that prescription drug labels "contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient," 21 U.S.C. § 825(c). The Order ignored the FDCA's separate labeling requirements, which the Attorney General has no power to waive. *Id.* § 902; *see* 21 U.S.C. § 352(f) (FDCA provision deeming drugs "misbranded" "[u]nless its labeling bears (1) adequate directions for use; and (2) … adequate warnings" as to contraindications); *see also* 21 C.F.R. § 201.100(c)(1) (requirements for prescription labeling).

___[22722]. Such a waiver is permissible only "by regulation." 21 U.S.C. § 822(d), ADD-48.[26]

The Rescheduling Order is unlawful because it purports to create those new rules by Attorney General order without any notice-and-comment process. It is hornbook administrative law that issuing or amending a legislative rule requires notice-and-comment rulemaking. *See* 5 U.S.C. § 553, ADD-1-2; *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.").[27] There can be no question the new rules outlined above required notice and comment. The new rules impose binding obligations that have "the force and effect of law," *Perez*, 575 U.S. at 96, such as import-export permits and the crop-purchase arrangement, and they confer rights the CSA otherwise withholds, such as the right to distribute a controlled substance before registration and dispensing a Schedule III drug without a prescription. *See* JA___[91_Fed._Reg._at_22722] (adding 21 C.F.R. § 1301.13(k)(5)-(10), ADD-139). Most of them also expressly amend existing legislative rules. They displace

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[26] As to marijuana manufacturers, a waiver would violate the Single Convention, JA___[art._23(2)(b)], and so cannot be authorized by section 811(d)(1).

[27] *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), ADD-71.

DEA's regulations governing registration, prescriptions, labeling, security, disposal, and the purchase of marijuana crops, and "an amendment to a legislative rule must itself be legislative." *Am. Min. Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993).

The only basis asserted in the Order for skipping notice-and-comment procedures is section 811(d). *See* JA___[91_Fed._Reg._at_22721]. But section 811(d)(1) offers no authority for overriding the background restrictions provided by the APA when DOJ promulgates substantive rules that happen to accompany a rescheduling decision. At most, section 811(d)(1) addresses orders placing a drug in "the schedule" the Attorney General "deems most appropriate to carry out [American treaty] obligations," 21 U.S.C. § 811(d)(1), ADD-36, and, for that narrow action, it provides an exemption from "the procedures prescribed by subsections (a) and (b) of this section," *id.* That provision exempts a rescheduling decision from the particularly onerous requirements of a formal, on-the-record rulemaking that would otherwise apply under section 811(a). It does not exempt an Attorney General Order under section 811(d)(1) from the *rest* of the APA or give the Attorney General carte blanche to amend *other* substantive regulations without notice-and-comment rulemaking.

Finally, the government cannot claim that the new rules unlawfully announced in the Rescheduling Order should be severed and the rest of the Order permitted to

stand. The new import-export and sham-transaction rules are "required" to implement the Single Convention and thus to comply with section 811(d). *See* JA___[91_Fed._Reg._at_22715-16]. By DOJ's own admission, without these additional rules, the rescheduling decision itself cannot survive. JA____[Stay_Opp._22-23]. Since the Order cannot "function sensibly" without the additional rules, they cannot be severed. *MD/DC/DE Broads. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001); *accord Dep't of Educ. v. Louisiana*, 603 U.S. 866, 867 (2024).

B. The Rescheduling Order Departs From DOJ's Prior Position On Multiple Points Without Any Adequate Explanation.

The Rescheduling Order also violates elementary administrative law principles by reversing the agency's position on multiple points without adequate explanation. It is black-letter law that when an agency reverses "prior policy," it must—at a minimum—"display awareness that it *is* changing position. An agency may not, for example, depart from a prior policy *sub silentio*." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009) (emphasis original). The agency must also "provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016). "[A] more detailed justification" is required when the new policy is based on "factual findings that contradict those which underlay its prior policy." *Fox Television Stations*, 556 U.S. at 515. The Rescheduling

Order violates these bedrock principles by reversing course without adequate explanation on four points.

First, the Order made an unexplained—and unacknowledged—departure from DOJ's longstanding position that the Attorney General must use the procedures outlined in sections 811(a) and (b) when rescheduling substances that, consistent with the Single Convention, could be placed in more than one schedule. *See supra* Part I.B. In the half century since *NORML*, DEA has received multiple petitions seeking to reschedule marijuana. In each case DEA complied with the procedural requirements of sections 811(a) and (b) by obtaining an HHS recommendation and then either (1) holding a formal, on-the-record rulemaking,[28] or (2) denying formal rulemaking because the HHS recommendation showed there was not "substantial evidence" that the rescheduling criteria listed in section 811(a) and (b) could be met.[29] *See* 21 C.F.R. § 1308.43(e) (allowing administrator to reject rescheduling petitions if there is not "substantial evidence" for a different schedule), ADD-132; *cf.* 21 U.S.C. § 811(b) ("substantial evidence" standard for initiating formal rulemaking to remove substances from schedules or for initial scheduling). Notably,

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[28] *See, e.g.*, 57 Fed. Reg. 10,499 (Mar. 26, 1992); 54 Fed. Reg. 53,767 (Dec. 29, 1989); 44 Fed. Reg. 36,123 (June 20, 1979).

[29] *See, e.g.*, 81 Fed. Reg. 53,767 (Aug. 12, 2016); 81 Fed. Reg. 53,688 (Aug. 12, 2016); 76 Fed. Reg. 40,552 (July 8, 2011).

DEA did not respond to any of those petitions by claiming absolute discretion over rescheduling under section 811(d).

DEA clearly endorsed the traditional reading of section 811(d)(1) just two years ago when it explained in a Notice of Proposed Rulemaking that section 811(d)(1) does *not* give the Attorney General (or Administrator) unilateral authority to transfer marijuana out of Schedule I. *See* 89 Fed. Reg. at 44597. Indeed, on the *same day* that the Attorney General published the Rescheduling Order, he also issued an order reconfirming that "the CSA requires" that any decision rescheduling marijuana "be made through formal rulemaking on the record after opportunity for a hearing." 91 Fed. Reg. at 22777. The Attorney General's newfound position that he can bypass formal rulemaking simply because marijuana is subject to the Single Convention is an unexplained reversal on the scope of his authority.

Second, the Rescheduling Order fails to acknowledge that the DEA Administrator has rejected petitions to reschedule marijuana at least nine times.[30] The Rescheduling Order does not acknowledge a single one of these prior decisions, let alone attempt to explain the change in outcome. The Rescheduling Order therefore fails to satisfy even the basic requirement that the agency must "display awareness that it *is* changing position." *Fox Television Stations*, 556 U.S.

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[30] *See, e.g.*, 81 Fed. Reg. 53767 (Aug. 12, 2016); 81 Fed. Reg. 53688 (Aug. 12, 2016); 76 Fed. Reg. 40552 (July 8, 2011).

at 515 (emphasis in original). Having failed to acknowledge that it was effecting a change in position, the Rescheduling Order necessarily also fails to provide a reasoned explanation for the change. *See Encino Motorcars*, 579 U.S. at 221-22.

Third, the Rescheduling Order reverses the DEA's prior detailed assessment concerning the risk that marijuana may be diverted from state medical marijuana programs and used, instead, for recreational purposes. As recently as the 2024 NPRM, the DEA assessed that there was so much diversion of marijuana from state medical marijuana programs that such programs were "significant additional sources" of marijuana, similar to outputs from "illicit cultivation and production, [and] illicit importation from other countries." 89 Fed. Reg. at 44602.

The Rescheduling Order reverses course on this finding without any explanation. Thus, the Rescheduling Order asserts that, miraculously, state regimes now suddenly have "robust infrastructure for preventing diversion." JA___[91_Fed._Reg._at_22720]. But the Order does not cite any examples, data, or studies to support that conclusion or to explain what has changed since the agency reached the opposite conclusion in 2024.[31] To the contrary, the Order does not even acknowledge that it is departing from the assessment of evidence in the

[31] Nor could the Order invoke any newly developed factual record, because the Attorney General bypassed notice-and-comment procedures that would have created a new record.

2024 NPRM. It simply asserts a new conclusion as an ipse dixit. That in itself renders the Order arbitrary and capricious and warrants vacatur. *E.g.*, *Ctr. for Biological Diversity v. Haaland*, 998 F.3d 1061, 1068 (9th Cir. 2021) (vacating rule that "fail[ed] to offer more than a cursory explanation of why the findings underlying its 2011 [d]ecision no longer apply"); *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (vacating rule that failed to explain "factual findings directly contrary to" findings in prior rulemaking).

Fourth, the Rescheduling Order abandons the 2024 NPRM's findings that state medical marijuana programs show "a lack of unified controls on cultivation and manufacturing" and contain "a patchwork of inconsistent product standards and safety requirements." 89 Fed. Reg. at 44606. Despite DEA's prior findings on these points, the Rescheduling Order ignores them completely and allows state licensees to obtain federal distribution licenses without any discussion of labeling, cultivation, or product standards. *See* JA___[91_Fed._Reg._at_22720, 22722]. Because DOJ abandoned prior factual findings on this point, *Fox* requires both an acknowledgment of the change and, at a minimum, "a reasoned explanation ... for disregarding facts and circumstances that underlay or were engendered by the prior policy." 556 U.S. at 515-16. But the Rescheduling Order does not acknowledge the change in position or cite any evidence that would justify departing from the prior assessment that state programs do not adequately address these issues.

CONCLUSION

The Court should vacate and set aside the Rescheduling Order.

November 24, 2026

Respectfully submitted.

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

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

Counsel for New Directions Addiction Recovery Services, Kenneth Finn, M.D., Elizabeth B. Stuyt, M.D.; Cannabis Industry Victims Educating Litigators, MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., and MMJ BioPharma Labs, Inc.

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

Counsel for Smart Approaches to Marijuana and National Drug and Alcohol Screening Association, Inc.

/s/ *Cody S. Barnett*
Cody S. Barnett
Zachary B. Pohlman
Nebraska Department of Justice
1445 K Street, Suite 2115
Lincoln, NE 68508
cody.barnett@nebraska.gov
Counsel for Nebraska

/s/ *Blake Lanning*
Blake Lanning
Office of the Attorney General
IGC South, Fifth Floor
302 W. Washington Street
Indianapolis, Indiana 46204
(317) 232-1146
blake.lanning@atg.in.gov
Counsel for Indiana

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November 24, 2026

/s/ *Chase T. Harrington*
Chase T. Harrington

CERTIFICATE OF SERVICE

I hereby certify that on November 24, 2026, I caused the foregoing document to be electronically filed with the Clerk and served on the parties using the Clerk's electronic filing system.

November 24, 2026

/s/ *Chase T. Harrington*
Chase T. Harrington

Nos. 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 Review of Attorney General Order No. 6754–2026

STANDING ADDENDUM

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

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

Counsel for New Directions Addiction Recovery Services, Kenneth Finn, M.D., Elizabeth B. Stuyt, M.D.; Cannabis Industry Victims Educating Litigators, MMJ International Holdings, Inc., MMJ BioPharma Cultivation, Inc., and MMJ BioPharma Labs, Inc.

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

Counsel for Smart Approaches to Marijuana and National Drug and Alcohol Screening Association, Inc.

Cody S. Barnett
Zachary B. Pohlman
Nebraska Department of Justice
1445 K Street, Suite 2115
Lincoln, NE 68508
cody.barnett@nebraska.gov

Counsel for Nebraska

(*Additional counsel on inside cover*)

November 24, 2026

Blake Lanning
Office of the Attorney General
IGC South, Fifth Floor
302 W. Washington Street
Indianapolis, Indiana 46204
(317) 232-1146
blake.lanning@atg.in.gov

Counsel for Indiana

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No. 26-1130

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

STATE OF NEBRASKA AND STATE OF INDIANA,

Petitioners,

v.

UNITED STATES DEPARTMENT OF JUSTICE, TODD BLANCHE, IN HIS OFFICIAL CAPACITY AS ACTING ATTORNEY GENERAL OF THE UNITED STATES, DRUG ENFORCEMENT ADMINISTRATION, AND TERRANCE C. COLE, IN HIS OFFICIAL CAPACITY AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

DECLARATION OF AMANDA KARR IN SUPPORT OF PETITIONER STATE OF NEBRASKA'S PETITION FOR REVIEW

I, Amanda Karr, hereby declare as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this Declaration.

2. I am employed by the Nebraska Department of Revenue at its office in Lincoln, Nebraska.

3. The title of my position within Department of Revenue is Attorney III.

4. As a part of my position, I serve as the manager of the Legal section of the Department of Revenue.

5. As a part of my position, I oversee the legal compliance of state tax programs, including interpreting and applying income tax statutes.

6. The starting point to determine state income tax is to calculate state taxable income. The State of Nebraska ties state taxable income to federal taxable income under Neb. Rev. Stat. § 77-2716, § 77-2734.02(1), and Neb. Rev. Stat. § 77-2734.04(13), (24).

7. Once federal taxable income is calculated, state law provides a number of adjustments and deductions that, once applied, yield the taxpayer's state taxable income under, among other statutes, Neb. Rev. Stat. § 77-2716 and § 77-2734.04.02(1).

8. Because state taxable income is tied to federal taxable income, a decrease in a taxpayer's federal taxable income results in a decrease in the taxpayer's state taxable income, which in turn reduces state income tax revenues.

9. Enabling a business to take a federal deduction to federal taxable income amounts that they were not previously entitled to deduct would decrease a state taxpayer's state taxable income, thus decreasing the amount of state income tax a state taxpayer would have paid without the new federal deduction.

10. In my experience, entities typically claim deductions for ordinary and necessary expenses paid or incurred in carrying on a trade or business which lowers their federal taxable income and, thus, ultimately lowers their State tax liability.

11. Based on the foregoing, medical cannabis companies that file Nebraska state income tax returns and are no longer prohibited from deducting business expenses under 26 U.S.C. § 280E as announced in *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. 22,714 (Apr. 28, 2026), will likely elect to deduct ordinary and necessary business expenses on their federal tax return, thus decreasing their federal taxable income, ultimately resulting in lower tax revenues for the State of Nebraska.

12. Aware that cannabis companies will now deduct business expenses, the federal government has stated that the Rescheduling

Order will have "significant positive tax consequences for businesses in the medical marijuana industry." Press Release, *Treasury, IRS Announce Process for Tax Guidance Following DOJ Final Order on Medical Marijuana Rescheduling*, U.S. Dep't of Treasury (Apr. 23, 2026), perma.cc/F9KC-S5TL; see also Press Release, *Whitney Economics Refreshes Analysis of Federal Tax Impact on Legal Cannabis Operators*, Whitney Econ. (Apr. 9, 2026), perma.cc/8YDY-HCP2 (estimating "$2.24 billion in excess cannabis-related federal taxes due to the IRS's 280E tax policy").

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on this 20th day of November, 2026, at Lincoln, Nebraska.

/s/ _____

Amanda Karr

State of Nebraska
County of Lancaster

General Notary - State of Nebraska
SAMANTHA LOWERY
My Comm. Exp. Jan. 13, 2029

Subscribed and sworn before me on November 20, 2026, by the above-named Amanda Karr, known by me to be the person named as the affiant in the above affidavit.

_____

Notary Public
My Commission expires: _____.

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Respondents.

DECLARATION OF MICHAEL A. TADDONIO IN SUPPORT OF PETITIONER STATE OF NEBRASKA'S PETITION FOR REVIEW

I, Michael A. Taddonio, hereby declare as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this Declaration.

2. I am employed by the Nebraska Attorney General's Office and the title of my position is Assistant Attorney General.

3. The Nebraska Medical Cannabis Commission ("Commission") has the "power to regulate all phases of the control of the possession, manufacture, distribution, delivery, and dispensing of cannabis for medical purposes by registered cannabis establishments in the state pursuant to the Nebraska Medical Cannabis Regulation Act." Neb. Rev. Stat. Ann. § 71-24,110.

4. In my role as Assistant Attorney General, I have been assigned to provide legal support to the Commission.

5. The legal support I provide includes reviewing public record requests.

6. In reviewing public record requests, I have reviewed and fulfilled requests about the status of current cultivators licensed by the Commission.

7. The Commission has licensed four medical cannabis cultivators to grow cannabis for medical use in the State of Nebraska.

8. The Nebraska medical cannabis cultivators with active cultivator licenses are:

a. **Midwest Cultivator Group**

i. Licensed Premises: 10710 Sapp Brothers Drive, Omaha, NE 68138

ii. License Number: CL2025 – 1

b. **MahāMotā Cultivation Company**

i. Licensed Premises: 16755 NW 19th St. Raymon, NE 68428

ii. License Number: CL2025 – 2

c. **KRL MED LLC**

i. Licensed Premises: 241 Vista Circle, Tekamah, NE 68061

ii. License Number: CL2026 – 3

d. **Meadowlark Medicinals LLC**

i. Licensed Premises: Parcel #140022701, Parcel # 140020001, Legal: TR In W1/2 27-13-39 121.47A. 1A-O----16 STR(27 13 39), TR In NW1/4 NW1/4 13-13-39 3.76A. 1A-O----16 STR(13 13 39), 69153

ii. License Number: CL2026 – 4

9. To become a licensed medical cannabis cultivator, the putative cultivator must first complete and submit to the Commission a Registered Cannabis Establishment Application Form, attached to this Declaration as **Exhibit A.**

10. The Applicant Attestation attached to the Registered Cannabis Establishment Application Form, which all applicants must sign, requires the applicant to attest that "I have paid all state and local taxes that are due, as well as any additional fees imposed by law," that "any entity associated with my application has paid all state and local taxes that are due, as well as any additional fees imposed by law," that "I am in compliance with any applicable state or local laws, regulations, or ordinances," that "any entity associated with my application is in compliance with any applicable state or local laws, regulations, or ordinances," and that "I understand that failure to comply with all applicable laws or regulations may result in sanctions against my license."

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on November 19, 2026, at Lincoln, Nebraska.

/s/ _____

Michael A. Taddonio

State of Nebraska
County of Lancaster

Subscribed and sworn before me on Jamie Krien, 2026, by the above-named Michael A. Taddonio, known by me to be the person named as the affiant in the above affidavit.

Jamie Krien GENERAL NOTARY COMMISSION EXPIRES March 29, 2027 STATE OF NEBRASKA

_____
Notary Public
My Commission expires: 3-29-2027

Exhibit A

REGISTERED CANNABIS ESTABLISHMENT APPLICATION FORM

License type applying for:

- ☐ Cultivator
- ☐ Dispensary
- ☐ Manufacturer
- ☐ Transporter

Name of proposed Registered Cannabis Establishment

Applicant information:

First Name			Middle Initial
Last Name			
Date of Birth		Social Security Number	
Street Address			Ste #
PO Box			
City, State			
Zip Code			
Telephone Number		Email Address	

If applying on behalf of a business entity:

Name of Entity			
State of Incorporation/Organization			
EIN		Registered Agent	
Street Address			Ste #
PO Box			
City, State			
Zip Code			
Telephone Number		Email Address	

Below, list the name and address of the applicant's officers, directors, managers, or owners, including any minority owner who holds five percent (5%) or more of the financial interests (other than a security interest, lien, or encumbrance) or more than five percent (5%) of the voting interests of an entity, including any parent and subsidiary entities:

Proposed location of Registered Cannabis Establishment:

Street Address				Ste #	
PO Box					
City, State					
Zip Code					
Telephone Number		Email Address			
Do you own the property and building in which the proposed Registered Cannabis Establishment will operate?			Yes ☐	No ☐	
If yes, could you provide proof of ownership upon request by the Commission?			Yes ☐	No ☐	
If no, do you have a rental agreement or lease demonstrating your right to use the property?			Yes ☐	No ☐	
If you do not own the property, provide the name, address, and contact information for the owner of the property:					

Civil and administrative action:

Has the applicant or any members, officers, directors, and managers had a citation, fine, sanction, injunction or court judgment levied against them, or a business owned by them, involving cannabis or cannabinoid related operations or sales?	Yes ☐	No ☐

A completed application requires the following:

- A criminal history record information check submitted to the Commission by the Nebraska State Patrol as required by 238 NAC 1.
- A summary of the applicant's business experience and a business plan meeting the following criteria:
  - Proof of financial capability to build, launch, and sustain cultivation, including access to capital, a detailed budget, and funding sources;
  - Facility design and operational readiness, including compliance with all applicable state laws and regulations and a demonstration of readiness to commence operations;
  - Demonstration of how the applicant meets the residency requirements in this chapter;
  - Any experience in operating a business in a regulated industry;
  - Any experience in cannabis cultivation, cannabis manufacturing, or cannabis retail;
  - Leadership team qualifications; and
  - Financial projections for the next year.
- A signed attestation.

APPLICANT ATTESTATION

By signing, I attest to the following:

- That I satisfy the residency requirements in 238 Nebraska Administrative Code (NAC) 1 and have not been convicted of a disqualifying offense as listed in 238 NAC 1;
- That any entity associated with my application, including any members, officers, directors, or managers of associated entities, satisfy the residency requirements in 238 NAC 1 and have not been convicted of a disqualifying offense as listed in 238 NAC 1;
- That I am a United States Citizen who has been a resident of Nebraska for no less than four (4) years immediately preceding the application;
- That any business entity I am applying on behalf of is majority owned by United States Citizen(s) who has been a resident(s) of Nebraska for no less than four (4) years immediately preceding the application;
- That the location of the proposed Registered Cannabis Establishment is not within 1000 feet of a covered location as defined in 238 NAC 1;
- That I have paid all state and local taxes that are due, as well as any additional fees imposed by law;
- That any entity associated with my application has paid all state and local taxes that are due, as well as any additional fees imposed by law;
- That I am in compliance with any applicable state or local laws, regulations, or ordinances;
- That any entity associated with my application is in compliance with any applicable state or local laws, regulations, or ordinances; and
- That I understand that failure to comply with all applicable laws or regulations may result in sanctions against my license.

☐ By checking this box, I understand that by signing this form, either by handwritten signature or electronic signature, I am attesting that the information in this application form and all additionally submitted documents are true, accurate, and complete.

Signature	
Printed Name	
Date:	

Upon completion, send this document to:

Email: mcc.contact@nebraska.gov

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Respondents.

DECLARATION OF JEFFREY SEQUIN IN SUPPORT OF PETITIONER STATE OF INDIANA'S PETITION FOR REVIEW

I, Jeffrey Sequin, declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am over the age of eighteen (18), and am competent to testify to, and have personal knowledge of, the matters set forth herein.

2. I am currently employed by the Office of the Indiana Attorney General ("OAG") as a special investigator and have served in that position since September 2026.

3. I have worked as a law enforcement professional for over 30 years. Much of my career—nearly 21 years—I have specialized in drug-related enforcement. In particular, I have worked for the Metro

Drug Task Force, the Indianapolis Metropolitan Police Department's ("IMPD") Long Term Narcotics Unit, IMPD's Southeast District Narcotics Unit, IMPD's Gang Unit, the Achilles Task Force of the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives, and IMPD's Northwest Narcotics Unit.

4. I have received extensive law enforcement training specifically related to narcotics and drug enforcement. This training includes attending the U.S. Drug Enforcement Administration's Basic Narcotics Investigation School, the Indianapolis Police Department's ("IPD") Narcotics Detective School, IPD's Drug Interdiction School, and the Georgia LEA Search and Seizure for Drug Cases course. I have also provided instruction and training on the subject of drug enforcement as an instructor with IMPD's Narcotics Detective School.

5. Based on my experience as a law enforcement officer with extensive familiarity with drug-related investigations and enforcement, it is, in my judgment, exceedingly likely that the loosening of federal restrictions on the manufacture, distribution, sale, and consumption of marijuana that is subject to a state-issued license to manufacture, distribute, and/or dispense marijuana or products containing marijuana

for medical purposes will have severe, adverse consequences for public safety in Indiana and place substantial strain on state law enforcement and public health resources.

6. All four states that share a border with Indiana—Michigan, Illinois, Ohio, and Kentucky—have enacted laws that authorize the manufacture, distribution, sale, and consumption of marijuana for medicinal purposes, and they issue licenses for the same. Three of those states—Michigan, Illinois, and Ohio—have also legalized recreational marijuana. Marijuana remains illegal in all its forms, and for any purpose, in Indiana.

7. Indiana's proximity to multiple jurisdictions that have legalized marijuana means that approximately 40 percent of all Indiana residents live within a 50-minute drive of a marijuana dispensary in a neighboring state, and virtually all residents of Indiana live within a 100-mile drive of a dispensary. *See* Ex. A, Rand Research Report at 1.

8. In addition, because many major cities in Indiana are close to the State's borders with Illinois and Michigan, cross-border trafficking of marijuana is widespread and easily facilitated by criminal actors. *See* Ex. B, U.S. Drug Enforcement Administration Report at 4.

9. The availability of marijuana-derived products in jurisdictions bordering Indiana has had significant detrimental consequences for public health and safety in Indiana.

10. In particular, the legalization of medical and recreational marijuana in states bordering Indiana has coincided with a substantial increase in the number of Indiana residents who reportedly use marijuana on a regular basis. For example, Michigan legalized medical marijuana in 2008, and Illinois and Ohio followed suit in 2013 and 2016, respectively. Kentucky legalized medical marijuana in 2023. Michigan, Ohio, and Illinois legalized recreational marijuana in 2018, 2019, and 2023, respectively.

11. Over approximately that same time period, the percentage of Indiana residents who reportedly use marijuana regularly more than doubled. Between 2011 and 2012, approximately 6.2 percent of Indiana residents reported using marijuana in the previous month. By 2023 to 2024, the percentage of Indiana residents who used marijuana in the previous month had increased to 15.5 percent. *See* Ex. B, Rand Research Report at 1.

12. In my professional judgment, it is almost a certainty that the significant increase in regular marijuana users in Indiana over the past decade and a half is driven substantially by increased availability of the drug in states bordering Indiana.

13. The public health and safety implications of the legalization of marijuana in neighboring states and concomitant increase in the number of regular marijuana users in Indiana are stark.

14. For one thing, a higher number of marijuana users in Indiana necessarily places a greater strain on law enforcement because it increases the number of illegal violations on which law enforcement may be called upon to act, the number of investigations law enforcement may be required to undertake, and the number of legal proceedings in which law enforcement may be required to participate.

15. In addition, in my experience, Mexican drug cartels such as CJNG and Sinaloa have shown a propensity to take over licensed dispensaries through force or intimidation of licensed dealers in states that have legalized medical marijuana. The legalization of marijuana thus often increases gang activity, which necessarily has spillover consequences for states like Indiana that, even if they have not

legalized marijuana, share borders with states where this increased cartel activity is occurring. This increased gang activity also drives increases in dangerous criminal activity and places additional strain on law enforcement in Indiana.

16. Data from states that have legalized marijuana demonstrate that greater availability of marijuana leads to more traffic accidents.[1] Every day, hundreds of thousands of drivers transit Indiana's border with neighboring states where medical marijuana is legal.[2] Accordingly, the growing availability and use of marijuana in Indiana and its neighboring states is also creating hazards on Indiana roads.

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[1] *See* Charles M. Farmer, et al., *Changes in Traffic Crash Rates After Legalization of Marijuana: Results by Crash Severity*, 83 J. STUD. ON ALCOHOL & DRUGS 494 (July 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9318699/#B15 ("[T]he estimated increase in traffic crash rates after marijuana legalization is consistent with earlier studies: a 5.8% increase in injury crash rates anda 4.1% increase in fatal crash rates."). *See also The Legalization of Marijuana in Colorado*, Rocky Mountain High Intensity Drug Trafficking Area (Aug. 2013), https://www.sheriffs.org/sites/default/files/FINAL%20Legalization%20of%20MJ%20in%20Colorado%20the%20Impact_0.pdf (explaining that after the legalization of medical marijuana in Colorado, marijuana involved traffic "fatalities involving drivers testing positive for marijuana increased 114 percent").

[2] *See* HMB, *Louisville-Southern Indiana Ohio River Bridges Project: Post Construction Traffic Monitoring Study* 11-12 tbl. 3.5 (2018), tinyurl.com/LvilleBrg (98,100 daily vehicle crossings from Kentucky into Indiana at four Louisville-area crossings); Parsons, *I-80/94 Borman Expressway: Preliminary Purpose & Need/Logical Termini* 1 (2022), tinyurl.com/I8094-trfk (204,000 vehicles per day crossing Illinois–Indiana line); RiverLink, *2025 Annual Progress Report* 2 (2026), tinyurl.com/RvrLnk (over 34.9 million crossings on three Kentucky–Indiana toll bridges in 2025).

17. The growing availability of marijuana in Indiana driven to a significant degree by legalization in neighboring states has also placed strain on Indiana's public health system. For example, total cannabinoid and analog exposures reported to poison control centers in Indiana increased by 41 percent between 2022 and 2024, with pediatric exposures of children under age five rising 46 percent and exposures among children aged 6–12 increasing 62 percent. *See* Exhibit C, Indiana Poison Center data, 2022–2025 (on file with the Indiana Department of Health). The increased prevalence of marijuana in the state has thus also likely resulted in more hospital visits and greater expenditures of medical resources.

18. There are other immediate, quantifiable costs to Indiana caused by the growing availability and increased use of marijuana in the state. For example, as marijuana has become more widely available in neighboring states, many companies that sell marijuana in those states have begun to advertise their products within Indiana to entice Indiana residents to cross state borders and purchase marijuana products. To combat this practice of encouraging Indiana residents to break Indiana law, Indiana recently outlawed the advertising of

marijuana products in Indiana. *See* Ind. Code ch. 24-4-26. The Office of the Indiana Attorney General is tasked with enforcing this statute and has estimated that the cost to the State of pursuing investigations and initiating enforcement actions under this statute to combat the spread of marijuana advertising in Indiana will be nearly $250,000 per year.

19. For all these reasons, there is no question in my mind that, as it becomes easier to obtain marijuana in states that neighbor Indiana, as Indiana residents take advantage of the greater availability of the drug in those jurisdictions, and as marijuana use increases, Indiana pays the price of increased traffic accidents, greater strain on law enforcement, increased hospital visits and medical issues, and a variety of other costs that law enforcement and public health authorities in Indiana must shoulder.

20. Rescheduling marijuana that is subject to a state-issued license to manufacture, distribute, and/or dispense marijuana or products containing marijuana for medical purposes has exacerbated—and will continue to exacerbate—all of the costs and challenges that Indiana has already experienced due to the legalization and increased availability of marijuana in neighboring states.

21. The federal rescheduling of marijuana used for medical purposes has almost certainly increased the availability of the drug in states neighboring Indiana. The Rescheduling Order removed federal restrictions on the sale, distribution, manufacture, and use of medical marijuana in the four states bordering Indiana that have medical marijuana programs.

22. With federal restrictions slackened, it has become easier to manufacture, sell, distribute, and use marijuana in neighboring states, creating increased supply of the drug. For example, rescheduling makes various tax benefits available to marijuana businesses, which very likely stimulates the growth of those businesses.[3] Rescheduling marijuana also eliminates the criminal consequences for participating in the manufacture, sale, and distribution of medical marijuana, and thus removes a significant disincentive for people and businesses to engage in these activities.

23. From my experience as an Indiana law enforcement officer who has specialized in drug enforcement, I know the consequences for Indiana that will follow from the further expansion of the availability of

[3] *See* 26 U.S.C. § 280E.

marijuana in neighboring states based on what happened when medical marijuana was legalized at the state level in those jurisdictions. I have outlined those consequences above. Indiana has suffered and will continue to suffer from increased crime, increased gang activity, increased health and safety incidents, and greater strain on public resources because of the federal rescheduling of state medical marijuana programs.

VERIFICATION

I, Jeffrey Sequin, swear and affirm under the penalties of perjury that the foregoing information is true and accurate to the best of my knowledge and belief.

11·23·26
Date

Jeffrey Sequin

See attached notarial certificate.

State of Indiana
County of Marion

I, a Notary Public, hereby certify that Jeffrey Sequin whose name is signed to the foregoing instrument or conveyance, and who is known to me, acknowledged before me on this day that, being informed of the contents of the conveyance, he/she/they executed the same voluntarily on the day the same bears date.

Given under my hand this the 23rd day of November, 2026.

KASEY SCHUERMAN
Notary Public
Hendricks County - State of Indiana
Commission Number NP0000771797
My Commission Expires Jul 12, 2034

Kasey Schuerman
Signature of notarial officer
My commission expires: July 12, 2034

Exhibit A

RAND

Research Report

BEAU KILMER, GREGORY MIDGETTE, ROSANNA SMART, ROLAND NEIL, ELLE WADSWORTH, ANNA NEWELL, BEN SENATOR

Indiana's Cannabis Landscape

Policy discussions about cannabis—also referred to as *marijuana*[1]—and intoxicating hemp products are heating up at the federal level and in many states, including Indiana. Since 2024, Indiana state legislators have introduced more than a dozen bills focused on cannabis-related issues, although none have been signed into law (see Annex II for details). Favorable public support for legalizing cannabis for medical and adult use among Indiana residents (Ball State University, 2024; Brown, 2026) suggests that these policy conversations will continue.

Our main goals in this report are to provide background information and new insights for those who seek to learn more about the cannabis landscape in Indiana. We neither pass judgment on Indi-

KEY FINDINGS

- Indiana has some of the nation's strictest cannabis laws yet allows the largely unregulated retail sale of hemp-derived delta-9 tetrahydrocannabinol (THC)—the primary psychoactive compound in cannabis—to be sold in grocery stores, gas stations, smoke shops, and other outlets.
- In addition to the proliferation of hemp-derived intoxicating cannabinoids throughout Indiana, more than 40 percent of Indiana residents live within a 50-mile drive of a licensed cannabis dispensary in a neighboring state—and nearly all residents reside within a 100-mile drive of a dispensary.
- Indiana had more than 13,000 arrests involving cannabis in 2024. The per capita arrest rate for Black residents in Indiana was approximately four times higher than it was for White residents.
- Approximately 1.3 million Indiana residents ages 12 and older reported using cannabis in the past year. Roughly one-third of these residents reported daily or near-daily use.
- Although cannabis use among adults in Indiana has steadily increased, the Indiana Youth Survey reports that past-month use among 12th graders dropped nearly in half from 2016 to 2024.
- Indiana residents spend approximately $1.8 billion (range: $1.2 billion to $2.6 billion) on cannabis each year. Most of the spending is by daily and near-daily users.
- Uncertainty exists about the extent to which the existing evidence on cannabis legalization will apply to Indiana if it decides to legalize. For example, almost all the existing research is based on states that allowed medical cannabis before legalizing adult use, an important difference in the case of Indiana.

ana's approaches to cannabis and intoxicating hemp nor do we summarize the research on the risks and benefits of using these products (for more information, see National Academies of Sciences, Engineering, and Medicine, 2017; National Institute on Drug Abuse, 2024; Hoch et al., 2025; and Lake et al., 2025).

This report is organized into four topics: cannabis policies throughout the country and in Indiana; cannabis use and size of the market in Indiana; cannabis-related criminal justice indicators for Indiana; and other outcomes related to cannabis use in Indiana. Two annexes to this report—Annex I, containing our review of the more-rigorous studies of legalization and a complete description of the methodology and findings, and Annex II, containing details about the data sources and methods used for the calculations in this report—are available at www.rand.org/t/RRA4439-1.[2]

For those seeking insights about cannabis policy options for the state, please see our companion report, *Considering the Consequences of Changing Cannabis Policy in Indiana* (Kilmer et al., 2026).

The Changing Landscape for Legal Cannabis

Cannabis Laws and Policies in the United States

The supply and possession of cannabis is illegal under U.S. federal law. Within the federal Controlled Substances Act, cannabis is classified as a Schedule I drug, meaning that—according to the federal government—the drug has no medical value and carries a high risk of abuse (Public Law 91-513, 1971). In December 2025, President Trump signed an executive order asking the U.S. Attorney General to expedite the process—which was started under the Biden administration—to reschedule cannabis as a Schedule III drug. Although rescheduling would likely financially benefit licensed cannabis companies in states that have legalized and reduce some federal penalties (see Annex II), rescheduling would neither legalize cannabis at the federal level nor make state-level legalization efforts—for medical and/or adult-use purposes—compliant with federal law.

Abbreviations

CBD	cannabidiol
CI	confidence interval
HHC	hexahydrocannabinol
ICPS	International Cannabis Policy Study
INYS	Indiana Youth Survey
NPDS	National Poison Data System
NSDUH	National Survey on Drug Use and Health
SAMHSA	Substance Abuse and Mental Health Services Administration
THC	tetrahydrocannabinol

When states first started legalizing medical cannabis in the late 1990s and early 2000s, these policy changes continued despite some federal efforts to shut down or stifle these markets (Kilmer and MacCoun, 2017). A 2013 memorandum from the U.S. Department of Justice provided *some* guidance for states legalizing for adult-use purposes but made clear that this activity was still illegal under federal law (Cole, 2013).[3] Beginning in 2014, a budget rider was passed in a federal appropriations bill, which barred the U.S. Department of Justice from using taxpayer funds to prevent states from "implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana" (Lampe, Sacco, and Sheikh, 2024). This policy has remained in effect. Although this budget rider is only specific to medical laws, federal agencies and policymakers have largely opted against interfering in the nearly half of U.S. states that have legalized cannabis production, sales, and possession for adult use (National Academies of Sciences, Engineering, and Medicine, 2024).

A sizable and growing literature exists on the effects of adult-use legalization. Table 1 summarizes the key takeaways from our review of the more-rigorous studies of legalization (see Annex I for a complete description of the methodology and findings). We should note that there is uncertainty about the extent to which this evidence base will apply to Indiana if it decides to legalize. For example, almost all the existing research is based on states that had medical cannabis (sometimes longstanding) before legalizing adult use, an important difference in the

TABLE 1

Summary of Our Review of the Evidence on Adult-Use Legalization

Outcomes of Focus	Findings Generally Point to . . .
Cannabis use and perceptions	
Cannabis prevalence among adults	Increases in past-month use; larger effects after retail opening
Cannabis prevalence among youth/young adults	Mixed; modest increases among young adults, null to small increases among youth
Cannabis initiation	Increases among adults; larger effects with retail access
Perceptions of cannabis harms	Decreases in perceived risk among youth
Modes of consumption	*Limited causal evidence; sales data show shifts toward concentrates and edibles*
Use of other substances	
Opioid analgesic prescribing	Modest reductions that may have attenuated over time; effects may be smaller in settings with lower rates of inappropriate prescribing or misuse.
Tobacco use	Increases in cannabis-tobacco co-use but no increase in tobacco or nicotine use overall
Alcohol use	Small increases in consumption; increases in alcohol-cannabis co-use among adults
Other substance use or distribution	Mixed; some limited evidence of benzodiazepine prescribing reductions
Substance use disorders and poisonings	
Cannabis use disorder	Stable or declining treatment admissions despite increased use prevalence
Cannabis-related poisonings	Large increases, especially pediatric (after edible legalization)
Cannabis-related emergency room and hospital visits	Increases in cannabis-related encounters
Opioid overdose mortality	Mixed and inconclusive, with more-recent studies indicating potential harms; insufficient evidence for causal claims
Other substance disorders and adverse outcomes	Insufficient evidence for causal claims
Other health outcomes	
Mental health	Mixed and inconclusive; heterogeneous effects across populations
Suicide and suicidality	Mixed; some evidence of increases among youth in early-adoption states
Pain	*Limited causal evidence for policy effects; but randomized controlled trials of cannabinoids indicate possible small benefits for improving pain severity*
Traffic crashes and mortality	No consistent effect from legalization alone. Overall increases after retail stores open; appears to be driven by a subgroup of states
Labor market and other economic outcomes	
Labor markets and income support	Small or null overall effects; agriculture employment increases
Tourism	Increases in early-adopting states; likely attenuated for later adopters
Home prices	*Limited causal evidence; studies show mixed local effects depending on jurisdiction and study design*

Table 1—Continued

Outcomes of Focus	Findings Generally Point to . . .
Social outcomes	
Population change	Small positive effects in early-adoption states; may not generalize to late adopter states
Crime and arrests	Large decreases in cannabis possession arrests; null effects on violent and property crime
Homelessness	*Limited peer-reviewed evidence*
State budgets	*Limited causal evidence; significant cannabis tax revenues, but magnitude varies by state; offset considerations apply*

SOURCE: Features information from our comprehensive review of sources listed in Annex I.

NOTE: Italicized categories do not have sufficient peer-reviewed quasi-experimental evidence to establish causal relationships; descriptive or observational findings are summarized for these outcomes.

case of Indiana.[4] Much will also depend on the regulatory regime and many other policy choices.[5]

A recent and major change in federal policy has been referred to as a loophole or accident that inadvertently legalized some forms of intoxicating hemp products.[6] Specifically, new language was added to the 2018 Agriculture Improvement Act (or the 2018 Farm Bill) in an effort to create a bright line between *Cannabis sativa L.* plants used to grow products that will get one high versus those using these plants to produce nonintoxicating hemp products (including cannabidiol [CBD]) (Public Law 115-334, 2018). The 2018 Farm Bill revised the federal definition of *marijuana* to exclude plants and their derivatives that are less than or equal to 0.3 percent delta-9 THC by dry weight. This definition means that these products were no longer illegal under the federal Controlled Substances Act.

The hemp industry—and others who entered the market—saw this new language as a green light to produce intoxicating products from cannabis plants as long as the plants and products did not exceed 0.3 percent delta-9 THC by dry weight. Under this interpretation, a medium-sized 4-gram gumdrop could have 12 milligrams of delta-9 THC—typically enough for occasional users to feel a psychoactive effect (Martin-Santos et al., 2012). The industry also interpreted this rule as exempting intoxicating products that were synthesized from hemp-derived CBD (e.g., delta-8 THC) from the Controlled Substances Act. Intoxicating hemp proliferated in many parts of the country—especially places like Indiana that had not legalized cannabis for medical or adult-use purposes.

Several state attorneys general (including Indiana's attorney general), public health advocates, and some expert panels called for Congress to close this loophole, calls that were heeded in November 2025 (National Academies of Sciences, Engineering, and Medicine, 2024; National Association of Attorneys General, 2025). As part of the federal expenditure bill, Congress added language that any hemp-derived product with more than 0.4 mg of total THC per container would be categorized as marijuana and thus illegal under the Controlled Substances Act. Although the law is scheduled to go into effect on November 12, 2026, Congress could pass other laws to delay, repeal, or adjust it.

Cannabis Laws and Policies in Indiana

It is illegal to produce, distribute, or possess cannabis in Indiana.[7] A person convicted of a cannabis offense can be subject to a fine, community supervision, or a term of incarceration. Anyone convicted of supply offenses can generally face more severe penalties. Even for someone who is not sentenced to incarceration, that person may still spend some time in jail immediately after an arrest. Some of those arrested may also be invited to participate in a diversion program—especially if it is a first offense—which could lead to the charges being dropped after suc-

cessful completion. The availability of this option is at the discretion of the local prosecutor.[8]

The cannabis policy environment in a jurisdiction entails more than only the penalties associated with cannabis supply and possession. A research team, including some authors of this report, developed a state-level *cannabis policy score* based on 17 different policies (Blanchette et al., 2022). Some of these policies were specific to legalization and possession penalties, but others included impaired driving laws, driver's license revocation for underage possession, and clean air and smoke-free laws. Drawing on expert ratings of the strength of state implementation of the policy, as well as the hypothesized effectiveness of the policy for reducing problematic cannabis use, researchers aggregated 17 policies into a composite score reflecting the restrictiveness of each state's cannabis policy environment. Using these composite scores and focusing on 2019, researchers determined Indiana to be the most restrictive state in the nation when it came to cannabis.

Despite being the most restrictive state toward cannabis, the sale of intoxicating hemp products—including delta-9 THC—is ubiquitous throughout most of Indiana. The Indiana Office of the Attorney General has ruled that hemp-derived delta-9 THC is legal under state law (as long as the concentration is less than or equal to 0.3 percent by dry weight), but other semisynthetic intoxicating hemp products, such as delta-8 THC and hexahydrocannabinol (HHC), are not.[9] Nonetheless, enforcing the law against establishments producing or selling these semisynthetic products has not been a priority for most state and local officials.[10] Thus, these products—which are not subject to testing requirements—have proliferated throughout the state.

Distance to Dispensaries in Neighboring States to Indiana

Indiana's geographic position means that the vast majority of residents live within a practical driving distance of licensed cannabis dispensaries in Illinois, Michigan, and/or Ohio. This proximity has significant implications for understanding current consumption patterns, estimating the potential size of a regulated Indiana market, and projecting tax revenues that would accrue under legalization.

To quantify accessibility, we conducted a spatial analysis of driving distances from Indiana census tracts to verified dispensary locations in neighboring states.[11] The results are telling: Approximately 44 percent of Indiana's population—nearly 3 million residents—lives within a 50-mile drive of at least one dispensary in another state. Expanding the radius to 100 miles captures 96 percent of Indiana's population, or approximately 6.5 million residents. In practical terms, almost all Hoosiers who wish to purchase cannabis from a retail store can do so with a roundtrip drive of fewer than four hours.

Access to legal cannabis varies geographically across Indiana in ways that may shape cross-border purchasing patterns and the potential cannabis market (Table 2). Northwest Indiana is in close proximity to multiple legal markets. Lake County—home to Gary, Hammond, and East Chicago—lies within 50 miles of dispensaries in both Illinois and Michigan, providing residents with competitive options

TABLE 2
Indiana Population Within Driving Distance of Dispensaries in Neighboring States

State	Within 50 Miles (in thousands)	Within 100 Miles (in thousands)	Dispensaries
Illinois	1,433 (21.0%)	4,626 (67.9%)	111
Michigan	1,615 (23.7%)	2,447 (35.9%)	114
Ohio	861 (12.6%)	3,246 (47.7%)	33
At least one state	2,991 (43.9%)	6,540 (96.0%)	258

NOTE: Features population estimates drawn from 2017–2021 American Community Survey 5-year estimates at the census-tract level (U.S. Census Bureau, 2022). Distances represent driving distance, not a straight-line distance. The "At least one state" row counts residents within the specified distance of at least one dispensary in any neighboring state (individuals may be counted in multiple state columns but only once in the total.

and short travel times. Residents of northeast Indiana face a different calculus. Allen County, containing Fort Wayne and representing one of the state's largest population centers, falls within 50 miles of Ohio dispensaries and 100 miles of Michigan retailers. Therefore, Fort Wayne residents have relatively convenient access to Ohio's medical and adult-use markets, but these markets are smaller and prices are higher than Michigan's options.

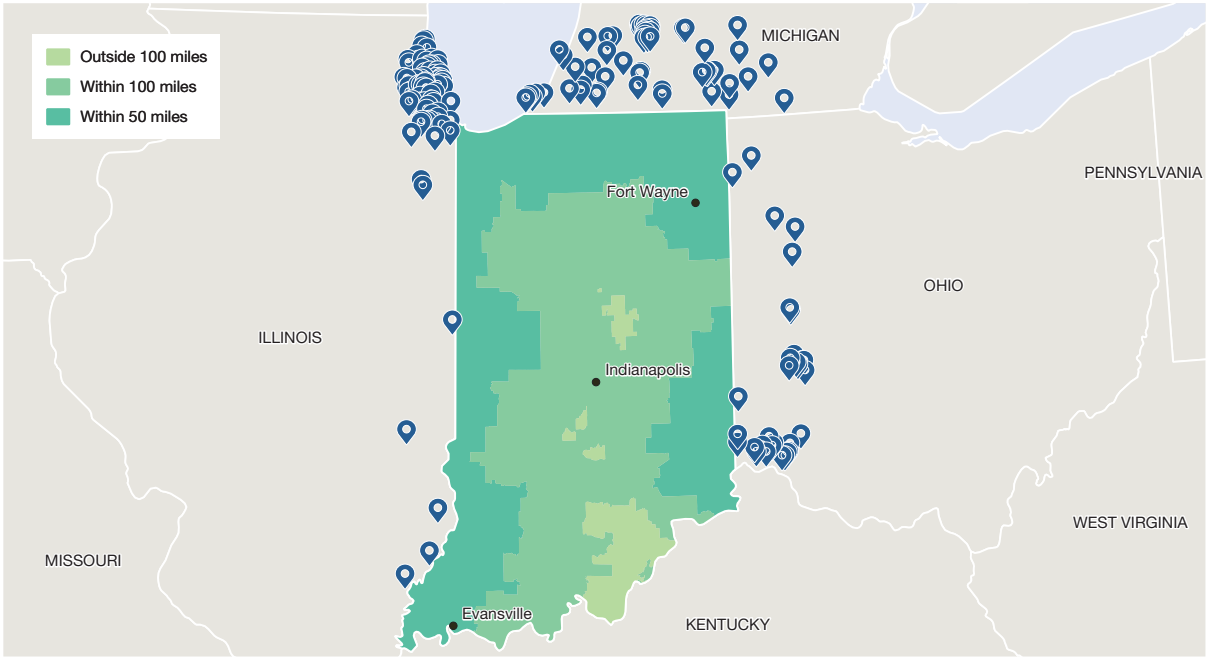
Central Indiana, which includes the Indianapolis metropolitan area (Marion and Hamilton counties), sits beyond 50 miles from any neighboring state's dispensaries. Indianapolis is within 100 miles of retailers in both Illinois and Michigan, with round-trip travel times of three to four hours. This distance probably attenuates but does not eliminate cross-border purchasing, particularly for consumers who are willing to make periodic bulk purchases.

The asymmetry across neighboring states merits attention. When the radius expands from 50 to 100 miles, Illinois provides the most dramatic increase in cannabis access for the Indiana population—from 21 percent to 68 percent. This is because Indianapolis falls within 100 miles of Chicago-area dispensaries. Ohio similarly expands from 13 percent to 48 percent coverage as Indianapolis and surrounding suburbs enter range. Michigan's coverage increases more modestly (24 percent to 36 percent) as Indianapolis remains beyond 100 miles (see Figure 1).

These geographic patterns interact with price differentials between neighboring markets. Michigan's exceptionally low prices (see "The Low Costs of Cannabis in Michigan" box) may make it the preferred destination for price-sensitive Indiana consumers despite longer drive times. Illinois, though geographically more convenient for many Indiana residents, has cannabis prices roughly double those in Michigan because of more restrictive licensing. Ohio's newer market falls between the two. Understanding these trade-offs between distance and price

FIGURE 1

Indiana Population Living within a 50- and 100-Mile Drive of an Adult-Use Cannabis Dispensary in a Neighboring State



SOURCE: Features data drawn from U.S. Census Bureau, 2022.

The Low Costs of Cannabis in Michigan

Michigan voters passed adult-use cannabis legalization in November 2018, and the state's Cannabis Regulatory Agency (CRA) did not impose caps on the number of production and retail licenses they issued. The state has a population of nearly 10 million people, and CRA data from November 2025 indicate that there were more than 900 active grower licenses and 843 active retail licenses for the adult-use market (i.e., excluding businesses that only serve medical patients). To help put this in perspective, Ohio (which has closer to 12 million residents) recently passed a bill capping cannabis dispensaries at 400—fewer than half of the dispensaries currently active in Michigan.

Because of the massive amount of production and competition in the state, prices have plummeted. The average retail price for an ounce in Michigan fell from roughly $250 per ounce in 2021 to $150 per ounce in 2022 (Semmler, 2022), and now average pretax price is about $60 per ounce (State of Michigan, undated). There is a 10 percent excise tax on adult-use cannabis sales and a 6 percent state sales tax.

But those are just the averages. It is not hard to find prices that are half that amount within a short drive of the Michigan-Indiana border. For example, the first author of this report visited a dispensary in Lawrence, Michigan (population about 1,200; about a 50-mile drive from Indiana border) in July 2025 that was selling an ounce for $25, as was the other cannabis retailer across the street. As of January 2026, both establishments are still advertising $25 (pretax) per ounce online.

To put this in perspective, a daily cannabis consumer may use 2 grams of flower a day on average (Caulkins, Pardo, and Kilmer, 2020). Thus, a consumer could drive to Michigan once a month and legally pay roughly $60 total for the two ounces (plus gas money) for their monthly supply. Although Michigan law limits possession in public to no more than 2.5 ounces, getting caught in Michigan with 2.5 to 5 ounces is just a civil infraction and punishable with a fine. If Indiana residents make multiple 2.5-ounce cannabis purchases in Michigan and keep the product in the trunk of their vehicle, their chances of getting caught are quite low.

On January 1, 2026, Michigan imposed a new 24 percent excise tax at the wholesale level. It is unclear how this will affect retail prices, but for the moment let's assume that it all gets passed on to the consumer (and retailers do not use the opportunity to raise the retail prices above and beyond the tax). While evidence on pass-through rates in cannabis markets is limited, one study of Washington estimated that retailers actually passed on more than 100 percent of costs to consumers (Hollenbeck and Uetake, 2021), although pass-through rates are likely lower in a more competitive market, such as Michigan. With the new tax compounded by the existing retail excise and sales tax, the cost to consumers of that advertised $25 per ounce would increase from $29 to $36 after tax. That equates to an additional quarter per gram, or $0.50 per day for the typical daily user.

is essential for modeling how an Indiana market would compete for cannabis consumers who currently purchase across state lines.

Cannabis Use and Size of the Market in Indiana

Characteristics and Number of Indiana Residents Who Use Cannabis

The best source of information on people using cannabis by state is the National Survey on Drug Use and Health (NSDUH). Although this annual survey is designed to produce national estimates, it also produces state-level estimates by combining data from two-year periods (e.g., estimates about the number of people who used cannabis in the past month averaged across 2023 and 2024). Although general cannabis prevalence figures for Indiana are available for the 2023–2024 period (and described below), details about the characteristics of Hoosiers who report using cannabis is publicly available only for 2022 and 2023 (as of March 2026). Table 3 displays these demographic and social-economic characteristics for those who reported using in the past month, those who used in the past year but not the past month, those who used more than a year ago, and those who have never used.

TABLE 3

Characteristics of Indiana Population by Recency of Cannabis Use, 2022–2023

Population Group and Subgroup	Cannabis Use Recency			
	Past 30 Days	Past 31–365 Days	>12 Months Ago	Never Used
Overall	0.134	0.065	0.262	0.539
	(0.013)	(0.007)	(0.017)	(0.021)
Sex				
Female	0.144	0.056	0.264	0.536
	(0.019)	(0.008)	(0.020)	(0.024)
Male	0.125	0.074	0.259	0.543
	(0.015)	(0.009)	(0.026)	(0.029)
Age				
12–17	0.061	0.059	0.026	0.855
	(0.014)	(0.017)	(0.009)	(0.024)
18–25	0.237	0.133	0.138	0.492
	(0.030)	(0.020)	(0.019)	(0.031)
26–34	0.216	0.083	0.260	0.441
	(0.024)	(0.018)	(0.027)	(0.031)
35–49	0.149	0.079	0.299	0.473
	(0.024)	(0.021)	(0.029)	(0.028)
50 and older	0.084	0.031	0.336	0.548
	(0.020)	(0.013)	(0.034)	(0.040)
Race/Ethnicity				
Black	0.156	0.033	0.292	0.520
	(0.034)	(0.007)	(0.056)	(0.066)
Hispanic	0.133	0.095	0.164	0.608
	(0.050)	(0.031)	(0.029)	(0.047)
White	0.131	0.067	0.278	0.523
	(0.014)	(0.008)	(0.019)	(0.023)
Other or multiple	0.151	0.034	0.081	0.734
	(0.040)	(0.014)	(0.023)	(0.055)
Education (18+)				
Less than high school	0.200	0.045	0.272	0.484
	(0.051)	(0.017)	(0.051)	(0.062)
Some college or associate's degree	0.166	0.063	0.317	0.454
	(0.025)	(0.011)	(0.034)	(0.038)
High school graduate	0.127	0.076	0.248	0.549

Table 3—Continued

Population Group and Subgroup	Cannabis Use Recency			
	Past 30 Days	Past 31–365 Days	>12 Months Ago	Never Used
	(0.023)	(0.013)	(0.029)	(0.037)
College graduate	0.115	0.062	0.306	0.517
	(0.016)	(0.013)	(0.020)	(0.025)
Income				
Less than $20,000	0.203	0.073	0.208	0.517
	(0.035)	(0.016)	(0.035)	(0.039)
$20,000–$49,999	0.147	0.073	0.250	0.529
	(0.028)	(0.013)	(0.032)	(0.034)
$50,000–$74,999	0.126	0.048	0.274	0.551
	(0.022)	(0.014)	(0.026)	(0.034)
$75,000–$99,999	0.082	0.040	0.292	0.587
	(0.019)	(0.014)	(0.048)	(0.045)
$100,000 or more	0.107	0.073	0.286	0.534
	(0.020)	(0.016)	(0.029)	(0.043)
Unemployed in Past Year				
Yes	0.263	0.086	0.146	0.506
	(0.045)	(0.023)	(0.035)	(0.058)
No	0.160	0.060	0.306	0.474
	(0.019)	(0.010)	(0.027)	(0.027)

NOTE: Cells show column percentage, the share of each IRMJRC category within each subgroup. Standard errors (in parentheses) show the column percentage standard error. Overall = marginal distribution.

Focusing on those using in the past month (and accounting for most consumption and expenditures), respondents between the ages of 18 and 34, those with lower incomes, or those who were unemployed in the past year were more likely to report use.

NSDUH produces state-level prevalence estimates for different age groups, and Figure 2 plots the past-month prevalence of cannabis use in Indiana from 2002 to 2003 and 2023 to 2024 for five age categories (12 or older; 18 and older; 12 to 17; 18 to 25; and 26 and older).

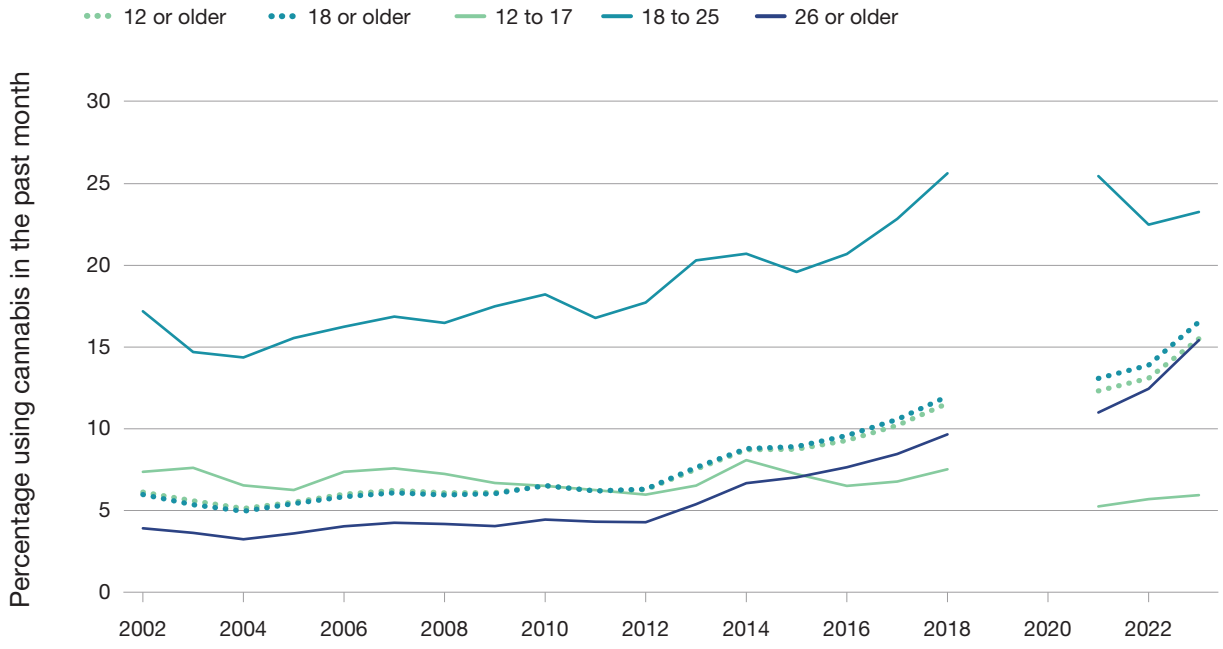
Indiana as a whole has seen a consistent increase in the past-month cannabis prevalence rate since 2011–2012. In 2011 to 2012, 6.2 percent of residents ages 12 and older reported use of cannabis in the past month; by 2023 to 2024, the rate had more than doubled to 15.5 percent. Accordingly, for this most recent period, approximately 900,000 Hoosiers (95 percent confidence interval [CI]: 786,000 to 1.02 million) reported using cannabis in the past month, and approximately 1.3 million reported use in the past year (95 percent CI: 1.17 million to 1.44 million).

However, these trends have varied across age groups, especially since 2021. The sharp increase in the overall prevalence rate in recent years (from 13.1 percent in 2021–2022 to 16.6 percent in 2023–2024) has been driven by the 26-and-older age group. In fact, the past-month prevalence rate for those younger than 18 has been relatively flat since 2021.[12]

Other data from Indiana that allow for trend analyses over time suggest that youth cannabis use has decreased over the past decade. The Indiana

FIGURE 2

Share of Indiana Population Reporting Cannabis Use in the Past Month, by Age Group, 2002–2003 to 2023–2024



SOURCE: Features information from Substance Abuse and Mental Health Services Administration (SAMHSA), 2026.

NOTE: Data for 2019–2020 and 2020–2021 are unavailable because of complications with survey implementation during the coronavirus disease 2019 (COVID-19) pandemic. The pandemic created challenges that led to a revised survey methodology in 2021, meaning that we should not directly compare the survey results before and after the change.

Youth Survey (INYS) is conducted by the Indiana University Prevention Resource Center among 6th, 8th, 10th, and 12th graders in more than 200 of the state's 1,091 eligible public and charter schools statewide (Jun et al., 2024).[13] According to the INYS, past-month cannabis use among 12th graders dropped from 21.1 percent in 2016 to 11.2 percent in 2024—a reduction of nearly one-half. Declines also occurred across the other grade levels over this period.[14] The 2024 INYS also provides new insight into routes of administration: among past-month cannabis users, vaping was the most common method (endorsed by 68.7 percent of users).

The divergent trends between those younger than 18 and those ages 26 years and older suggest that whatever factors are leading to increased adult cannabis use—be it changing social norms, proximity to legal markets in neighboring states, or the growth of hemp-derived THC products—have not translated into increased prevalence among youth. It is unclear how much of this decline is attributable to students shifting to hemp-derived products and not considering them as "marijuana" when answering the survey questions.

Total Size of the Cannabis Market in Indiana

Although the cannabis-related indicators described above provide useful information on the current cannabis landscape in Indiana, they are insufficient for characterizing the total size of the Indiana cannabis market. Yet, measuring the size of the cannabis market is key for several purposes. Knowing total amount used and expenditures on cannabis helps predict the likely consequences of changing cannabis policies (e.g., for tax revenues) and informs the amount of money going to illegal markets or to legal markets in neighboring states.

Ideally, state-representative surveys would ask respondents about how much consumers spent on cannabis in the past month, and then one could sum

up the responses, multiply by 12, and generate an annual spending estimate (Caulkins and Kilmer, 2013). Although some surveys do ask questions about cannabis expenditures, comprehensive data that would allow us to do this for Indiana do not exist. Therefore, we estimate the total number of cannabis use days in the state and multiply this by an estimate of average spending per use day. This less direct method produces wide CIs for annual spending, but it allows us to understand the order of magnitude.

Table 4 presents our estimates of Indiana past-month cannabis users by frequency category. Of the 896,000 Indiana residents older than age 18 estimated by NSDUH to use cannabis in the past month, daily or near-daily users represent the largest category at approximately 433,000 individuals, followed by frequent users (167,000), infrequent users (158,000), and occasional users (138,000). There were also 33,000 past-month users ages 12 to 17 years old, but less information is available about their frequency of use. Uncertainty around these estimates is captured by the "Standard Error" column in the table. Taken together, roughly 50 percent of past-month cannabis users in Indiana used on a daily or near-daily basis.

Estimates of spending per use day are derived from the International Cannabis Policy Study (ICPS), which asks respondents about their cannabis-related expenditures in the past 30 days. The ICPS is not state representative for Indiana, but its nationally focused surveys collect information from Indiana residents. Using ICPS data from Indiana respondents, we estimate average spending of $9.86 per use day (standard error = $1.44) among respondents who reported purchasing cannabis. This included spending on all cannabis products expressed in 2025 dollars. Estimating total annual expenditure requires pulling in data from multiple sources and adjustments for underreporting in the NSDUH survey, each with its own sources of uncertainty. As is common in cannabis market estimation (Kilmer et al., 2011; Kilmer et al., 2013), we use a Monte Carlo simulation approach to capture the combined implication of uncertainty in various components (parameters) of these calculations (see Annex II for more details). Figure 3 presents the distribution of results after running this simulation 10,000 times. The mean and median of this distribution are $1.8 billion, and 90 percent of predictions fall between $1.2 billion (5th percentile) and $2.6 billion (95th percentile).

An important question is the extent to which this $1.8 billion estimate includes spending on intoxicating hemp products. Although the NSDUH survey has separate questions about hemp and cannabis, it is unclear how those using hemp-derived THC would answer.[15] Thus, this estimate likely includes some spending on intoxicating hemp products in Indiana stores.[16]

Cannabis and the Criminal Justice System in Indiana

Cannabis Arrests in Indiana

Most cannabis arrests in Indiana—and throughout the country—involve individuals possessing small

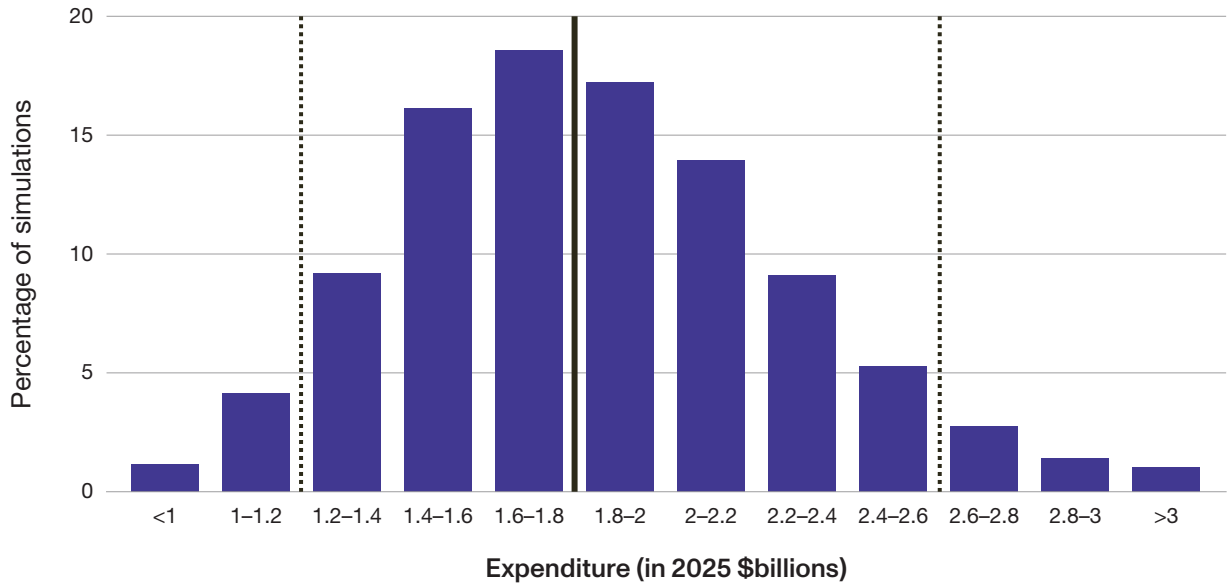
TABLE 4
Estimated Indiana Cannabis Users by Frequency Category, 2024

Category	Days per Month	Estimated Number of Past-Month Users (in thousands)	Standard Error (in thousands)
Infrequent	1–2	158	35
Occasional	3–5	138	35
Frequent	6–19	167	29
Daily/near-daily	20–30	433	65
Ages 12–17 (all frequencies)	15.7	33	5
Total		929	

NOTE: Features estimates based on 2022–2023 use day distributions and 2023–2024 use prevalence. Infrequent, occasional, frequent, and daily/near-daily categories include youth ages 12 to 17 (SAMHSA, 2026; Center for Behavioral Health Statistics and Quality, 2025). See Annex II for our methodology.

FIGURE 3

Distribution of Simulated Indiana Cannabis Expenditure Estimates, 2024



SOURCE: Features information from our simulations; see sources listed in Annex II.
NOTE: Dashed black lines indicate 5th and 95th percentiles; solid black line indicates mean.

amounts of the drug; however, many of these arrests also involve non-cannabis offenses. Those arrests that lead to a criminal conviction can result in criminal sanctions and several collateral consequences for those individuals and their families (Bryan, 2024; Schlussel, 2021). These arrests also generate costs for police departments, courts, jails, prisons, and community corrections agencies, although some of these costs can be (partially) offset by court fees, fines, and pay-to-stay fees for those who are incarcerated. Also, an arrest could be the wake-up call for some people that they need to change behaviors (e.g., using, driving under the influence) and possibly enter a treatment program for a substance use disorder.

According to Indiana's statewide criminal history records data, in 2024, there were 13,250 cannabis arrests in Indiana involving 12,351 unique individuals (some people were arrested more than once). More than 90 percent of these arrests were for possession (versus production or sales), and more than 75 percent of these arrests also involved a non-cannabis charge (e.g., the police also confiscated another illegal drug, or the person was also arrested for theft). There were roughly 166,000 total arrests in Indiana in 2024, meaning that 1 in 12 arrests (8 percent) involved a cannabis offense. Statewide, the overall cannabis arrest rate in 2024 was 191 per 100,000 residents, and the cannabis possession arrest rate was 176 per 100,000 residents.

Cannabis arrests in Indiana are not distributed evenly across demographic groups (see Table 5). Male cannabis arrest rates in 2024 were over twice as high as female rates, and the arrest rate for Black residents was approximately four times larger than the arrest rate for White residents.[17] Some age groups (such as people younger than 15 or older than 64) were rarely arrested for cannabis, whereas rates were the highest for individuals between the ages of 15 and 44.

Cannabis arrest rates also vary across jurisdictions. Figure 4 maps how overall rates of cannabis arrests differ across Indiana's 92 counties, again using data from 2024 arrests. Generally, Indiana counties with the highest rates are in the northern half of the state and those with the lowest rates are in the southern half, but there are strong exceptions to that pattern. The three counties with the highest rates are Posey (806 arrests per 100,000 residents), White (652),

TABLE 5

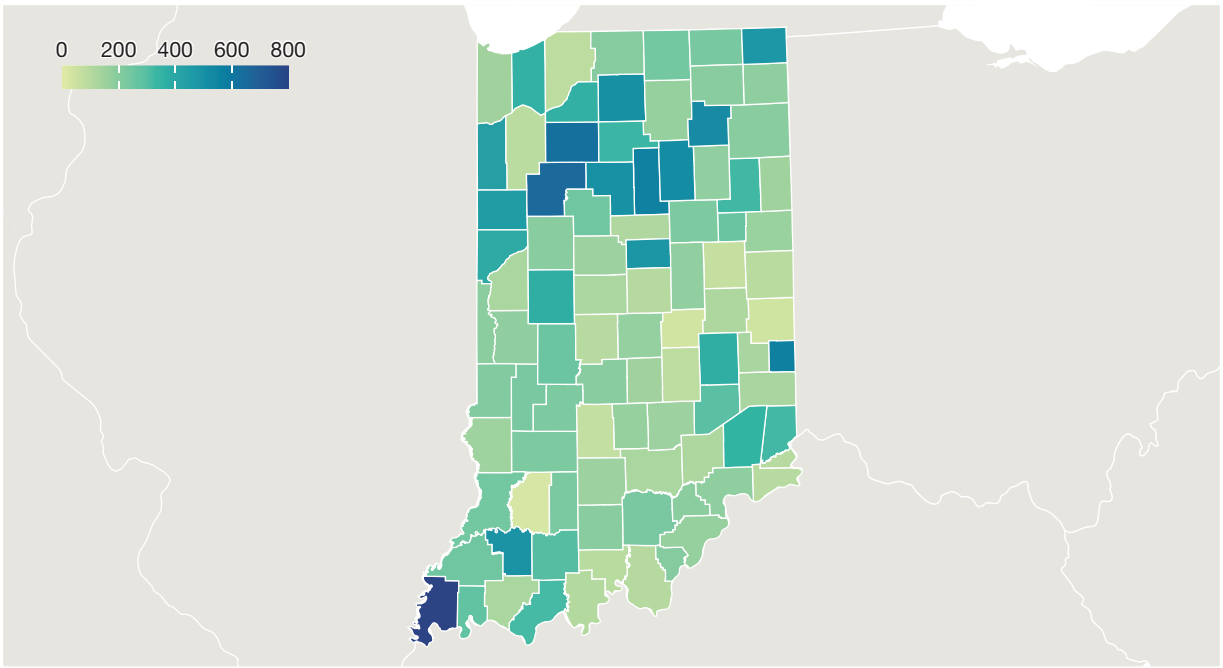
Cannabis Arrest Counts and Rates, by Demographic Group

Group	Population	Overall Cannabis Arrests	Overall Cannabis Arrest Rate	Cannabis Possession Arrests	Cannabis Possession Arrest Rate
Sex					
Male	3,431,764	9,767	285	8,800	256
Female	3,492,511	3,473	99	3,345	96
Race					
Black	631,469	4,617	731	3,971	629
White	5,784,236	8,391	159	7,960	151
Age					
1–14	1,289,705	4	0	4	0
15–24	948,979	3,492	368	3,112	328
25–34	929,702	4,281	460	3,900	419
35–44	889,095	3,041	342	2,825	318
45–54	815,867	1,570	192	1,484	182
55–64	832,526	708	85	681	82
65+	1,218,401	152	12	147	12

NOTE: Rates are per 100,000 state residents of that demographic group.

FIGURE 4

Cannabis Arrest Rates by County in Indiana, 2024



NOTE: Rates are per 100,000 county residents.

and Pulaski (628). The three counties with the lowest rates are Daviess (26), Hancock (34), and Wayne (39).

Cannabis arrests have remained relatively stable over the past decade, with the exception of a sharp increase and then a decrease between 2015 and 2019. Figure 5 describes trends in cannabis arrest counts from 2014 to 2024, for all cannabis arrests (the solid line) and cannabis possession arrests (the short dashed line). Throughout the 11-year period, cannabis possession arrests account for the vast majority of cannabis arrests and, thus, drive the overall trends. Before 2016, overall cannabis arrests were annually between 13,000 to 14,000. Between 2016 and 2018, they increased, peaking at approximately 20,000 in 2018, and then equally steeply declined through 2020. From 2020 to 2024, the number of cannabis arrests was relatively stable, returning to the pre-2016 level at around 13,000 arrests per year. Over time, the fraction of cannabis arrests that only have cannabis charges (i.e., with no charges for other offense types) has dropped, from roughly one-third to one-fifth (not shown in the figure).

What Happens After a Cannabis Arrest in Indiana?

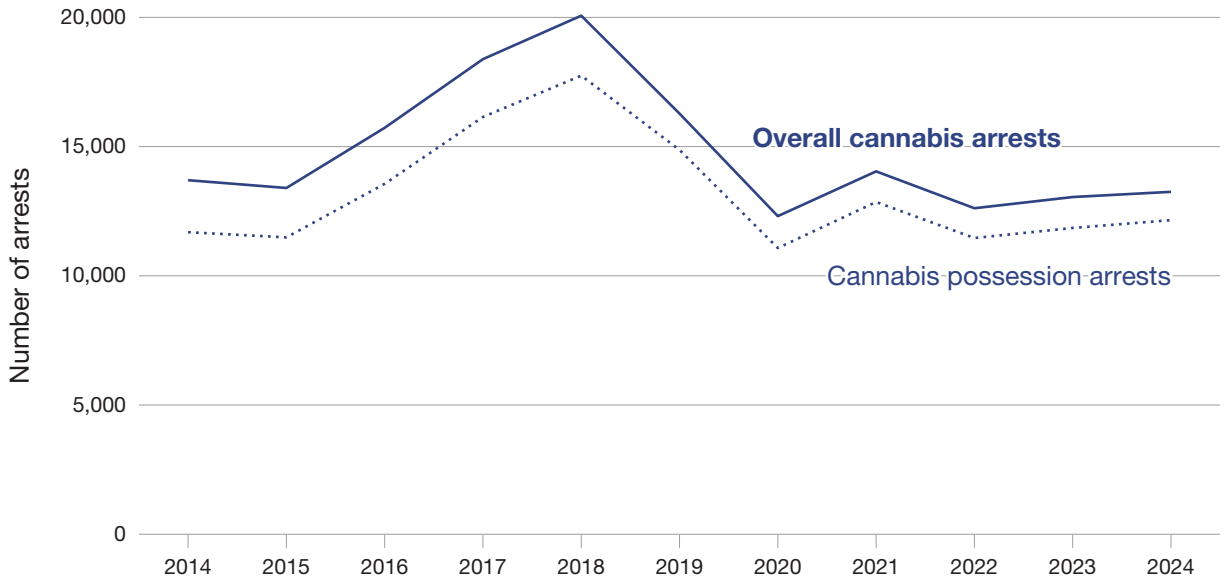
The process after law enforcement apprehends someone for a cannabis offense depends on multiple factors, such as the type of offense (e.g., possession, selling), the amount seized, whether other offenses were involved (e.g., cocaine possession, theft), whether the prosecutor wants to pursue the case, and where the offense took place.

Information in this section was drawn from multiple sources to provide some insights about what happens after law enforcement apprehends someone for a cannabis-related offense. We start with prosecution and the courts and then offer insights into jail stays, which can occur immediately after the arrest or after the person is convicted. In the latter sections, we focus on prisons and community corrections (i.e., parole and probation).

Prosecution and the courts. As is common in other parts of the country, district attorneys in Indiana have tremendous discretion when it comes to cannabis cases, especially for first-time possession offenses. For example, they can decline to prosecute, conditionally discharge the case (meaning the charges will be dropped if the defendant completes certain conditions), reduce the charges in return for

FIGURE 5

Indiana Cannabis Arrests, 2014–2024



a plea deal, or prosecute the case. Using data from 2022,[18] we found that prosecutors declined to file cannabis charges or the charges were eventually dismissed (which includes a mixture of court dismissals or the prosecutors dropping the charges) the majority of the time. It is hard to say if any criminal penalties were imposed after those arrests, since it is possible that a plea deal was reached in which those specific cannabis charges were dropped but penalties were imposed for another offense.

Jail. As noted, individuals may spend time in jail after they are arrested or as part of their sentence if they are convicted. We are unaware of a central entity in Indiana that routinely collects daily data about everyone who is jailed; however, New York University's Jail Data Initiative has gathered information for several years from the daily inmate logs of several county jails (Public Safety Lab, undated). We drew from these data for the 27 Indiana counties that have sufficient information for analyses. Together, these counties cover half of Indiana's population and provide a decent, albeit limited, picture of the share of the jail population with cannabis charges.

The main takeaway is that very few individuals who are only arrested for cannabis spend much time in jail, if any. On July 1, 2024, there were 9,014 inmates in these 27 Indiana county jails. Of these inmates, only 839 (9.3 percent) had a cannabis charge. Of these 839 inmates, almost all of them (98.1 percent) had also been arrested for non-cannabis charges.[19]

Prisons. Most cannabis charges are misdemeanors that, on their own, do not lead to a prison sentence. Of the 8,491 people admitted to Indiana's prisons in 2024, only 22 (0.26 percent) had cannabis charges listed as their most serious offense (Indiana Department of Corrections, undated).

Community supervision. There are generally two types of community supervision: parole (for those being supervised after leaving prison) and probation (which is often an alternative to being incarcerated). Given how few people are sentenced to prison for cannabis offenses, the number of parolees who were only convicted of a cannabis offense would be very small.[20]

At the end of 2024, county probation departments in Indiana were supervising approximately 98,000 adults and juveniles (Supreme Court of Indiana, 2024). There are different levels of probation supervision (high, medium, low, administrative), and the published data do not allow us to determine the level of supervision or how many of these probationers are being supervised because of a cannabis offense. We know that there were roughly 3,700 people convicted with cannabis charges in Indiana in 2022 (and many were also convicted on other charges). This would be the upper limit on the number of people who are placed on probation per year with cannabis charges, and the true number is likely to be less because an unknown share of those people will receive other sentences, such as a fine.

Very few individuals who are only arrested for cannabis spend much time in jail, if any.

Other Outcomes Related to Cannabis Use

Substance Use Disorder Treatment Admissions for Cannabis in Indiana

Although these various surveys provide useful information about the prevalence and frequency of cannabis use in Indiana, they do not provide information about the number of individuals in the state with a cannabis use disorder. There are different severity levels of cannabis use disorder. Although cannabis use disorder is generally not as harmful as use disorders related to methamphetamine or cocaine, frequent cannabis use can create real problems for some people who use and their loved ones.

One way of getting some insight into what is happening with cannabis use disorder is to analyze admissions to substance use disorder treatment when cannabis use is the primary, secondary, or tertiary reason for which the person is seeking treatment. However, one needs to be very careful when making

inferences from treatment data because not everyone entering treatment for cannabis actually has a cannabis use disorder (e.g., the person is referred or ordered to treatment from a criminal justice agency even though they do not have cannabis use disorder). In addition, the available data for Indiana only come from treatment facilities that receive state or public funding; private treatment facilities typically do not report this information to the state (see Annex II for more about SAMHSA's Treatment Episode Data Set).

Figure 6 shows the number of treatment admissions involving cannabis as the primary drug in the admission; as any drug in the admission; as the primary drug in the court-referred admission; and the percentage of all admissions for which cannabis is the primary drug. Note that although there is a substantial spike in treatment admissions involving cannabis in 2018, the proportion of admissions involving cannabis as the primary drug over all of Indiana's treatment admissions did not change.

Figure 7 presents the number of treatment admissions for which cannabis is the primary drug over time from 2015 to 2023, stratifying trends by age group. The 18–29 age group consistently accounts for the highest number of cannabis-primary treatment admissions in Indiana. However, the gap between that age group and the others has decreased in recent years because of declines in the number of admissions for that age group. Other age group trends have remained relatively stable over the same period. The 30–39 age group accounts for the second-highest number of admissions, while youth (ages 12 to 17) account for a far smaller proportion of overall cannabis-primary admissions. The aforementioned spike in admissions in 2018 was primarily driven by two age groups (18-to-29-year-olds and 30-to-39-year-olds) and, in part, by an increase in court referrals at this time. This spike additionally corresponds to the peak in cannabis arrest rates in 2018, suggesting that the increase in treatment admissions during that year was influenced by heightened criminal justice involvement related to cannabis offenses.

There are also substantive age differences in the share of treatment admissions for which cannabis is listed as the primary substance. In 2023, cannabis was the primary drug in almost 20 percent of all treatment admissions (see bars in Figure 6), but among the youngest age group, 12 to 17 years old, the rate was 78 percent. The 18–29 age group was also above the average at 31 percent, while the rate among patients 30 and older was 13 percent. These findings suggest that some age groups, particularly adolescent and young adults, are more likely than others to have cannabis listed as the primary drug in their treatment admission.

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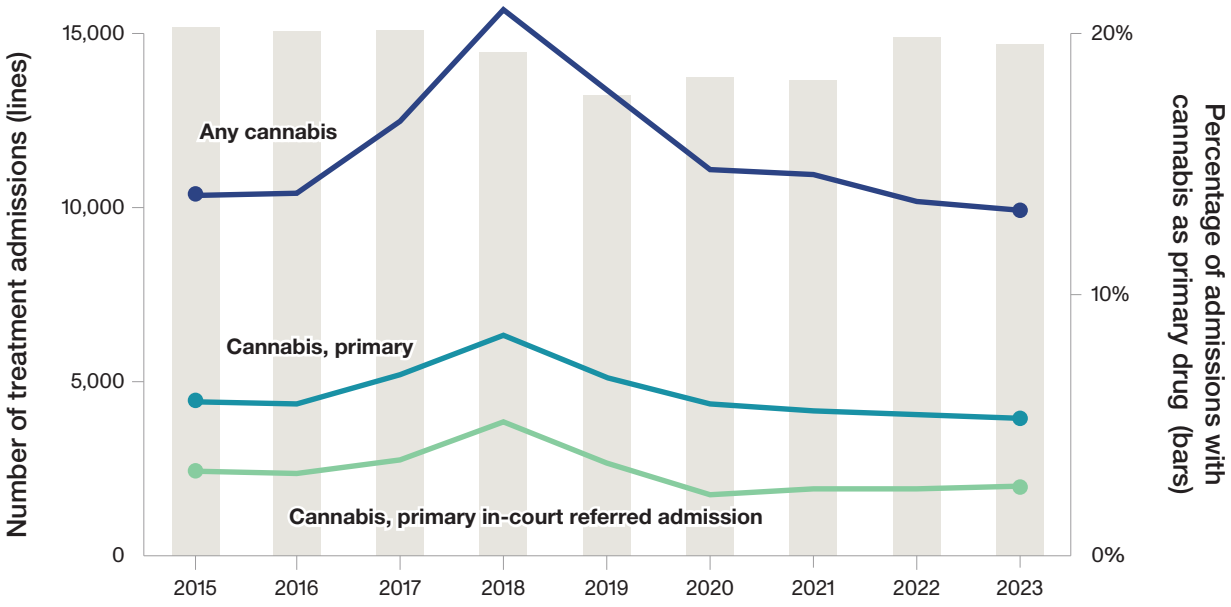
Poison Centers Data

The U.S. Poison Centers National Poison Data System (NPDS) is a useful resource for understanding state-level exposures to cannabis, particularly among younger populations (Dilley et al., 2024). The NPDS collects detailed information on calls to Poison Centers for each state and allows disaggregation of poisoning cases by key demographic groups, such as those ages 0 to 5 years. The NPDS tracks whether the callers report synthetic or nonsynthetic cannabis poisoning cases; however, it is unclear as to whether synthetic cannabis exposures are limited to synthetic cannabinoids (e.g., "spice," which can be much stronger than natural cannabis [Prete et al., 2025]), or whether they also include hemp-derived semisynthetic products, such as delta-8 THC (McConnell, 2025).

In Indiana, cannabis-involved Poison Center cases have increased substantially over the past

FIGURE 6

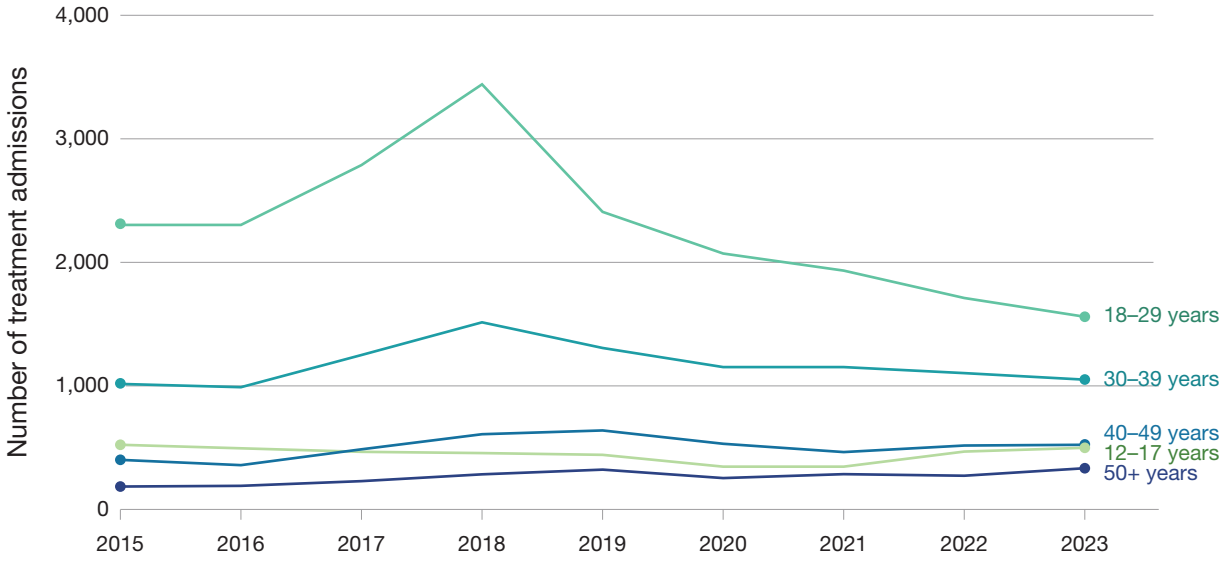
Indiana Cannabis Treatment Admissions and Court Referrals, 2015–2023



SOURCE: Features information from Treatment Episode Data Set drawn from SAMHSA, 2025.

FIGURE 7

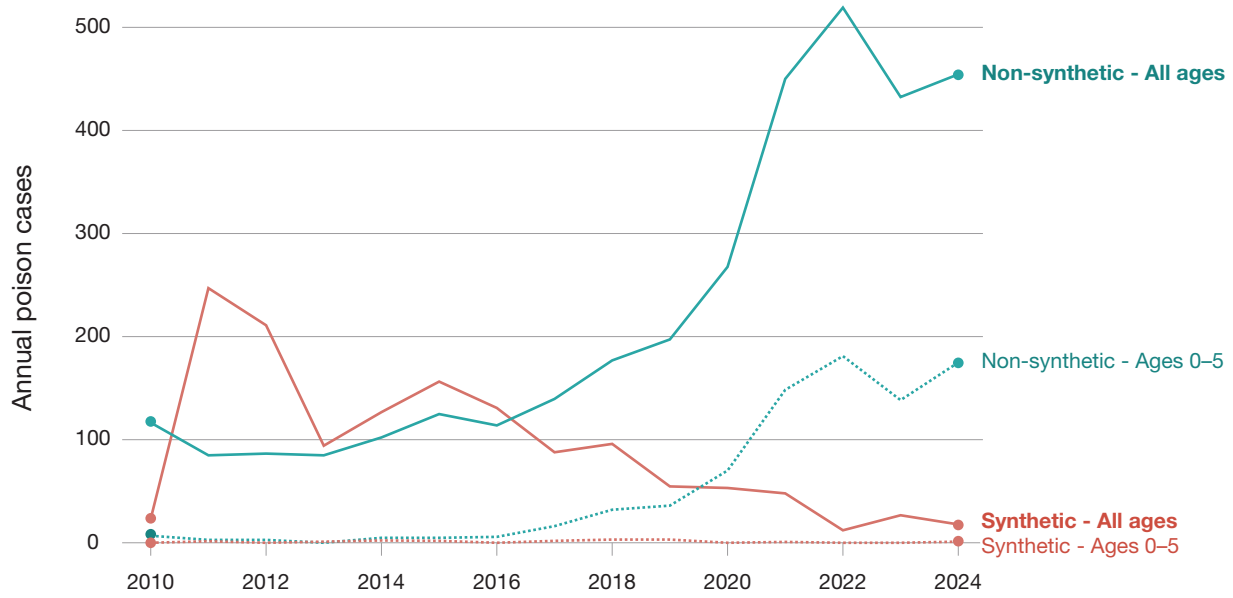
Indiana Treatment Admissions Where Cannabis Is the Primary Drug by Age Group, 2015–2023



SOURCE: Features information from Treatment Episode Data Set drawn from SAMHSA, 2025.

FIGURE 8

Indiana Cannabis-Involved Poison Center Cases, by Age Group and Type of Cannabis



SOURCE: Features data from the NPDS (see America's Poison Centers, undated).

decade, with a more rapid increase seen since around 2019 (Figure 8). Noticeably, cannabis-involved Poison Center cases in Indiana for those ages 5 and younger increased from 4 percent of all cannabis cases in 2015 to almost 40 percent in 2024.

Concluding Thoughts

As policy discussions about cannabis and intoxicating hemp gain prominence in Washington, D.C., and Indiana, it is critical that Hoosiers have reliable data to guide these conversations. In this report, we provided a comprehensive assessment of many indicators and outcomes that feature in these debates, but the assessment is not exhaustive.

Our goal was not only to provide an assessment of the cannabis policy landscape in Indiana but also to highlight the areas in which there is uncertainty. For example, while there are relatively reliable data about the number of people using cannabis in Indiana and how frequently they use, much less is known about the products people are using and the levels of cannabinoids they are consuming.[21] There is also much to learn about the share of delta-9 THC consumed by Hoosiers coming from (1) Indiana stores selling intoxicating hemp products, (2) neighboring states, (3) those illegally growing in Indiana, or (4) illegal products that have been imported from other states. Fortunately, the state could learn more about consumption and sources by augmenting existing surveys, administering its own, or collaborating with other cannabis data collection efforts (e.g., the ICPS) (Hammond et al., 2025).

Another area deserving of more research is the overall effect of cannabis on health outcomes—both negative and positive—and how these relationships may have changed for Indiana residents with the proliferation of intoxicating hemp products. In this report, we included new information about cannabis treatment admissions and calls to Poison Centers, but detailed and rigorous analyses of claims data, hospitalizations, emergency room visits, and pharmacy data could yield additional insights.

Although this report is not the final word on cannabis and intoxicating hemp in Indiana, it serves as a useful primer for those seeking a better view of the existing landscape. We hope these insights and those produced by other researchers will help ground discussions on a topic that is often controversial and always complex.

Notes

[1] For the purposes of this report, we use the term *cannabis* to refer to varieties of the cannabis plant or derived products that contain a high amount of delta-9 tetrahydrocannabinol (THC), the plant's principal psychoactive compound. We distinguish the term *hemp* as varieties of the cannabis plant that, as defined in federal law (as of early 2026) contain less than or equal to 0.3 percent concentration of delta-9 THC.

[2] For this report, statistics and calculations we present were drawn from our review and analyses of secondary sources listed in Annex I and Annex II unless otherwise cited from different sources that will be specifically noted.

[3] The U.S. Department of Justice also published a memorandum in 2009 relaxing federal enforcement policy on medical cannabis and subsequently reversed this position with another memorandum in 2011. For additional information on these memorandums and how they affected youth, see Smart and Doremus (2023).

[4] One might expect the effects of legalization on cannabis use and related outcomes to be larger in Indiana than in the states that adopted adult legalization on top of an existing medical regime. On the other hand, much of the evidence on the effects of legalization draws on policy variation implemented prior to the 2018 Farm Bill and from states more isolated from other states with legal cannabis regimes than Indiana. Access to cannabis products may not change dramatically after legalization for many Indianans because regular retail establishments sell delta-9 THC products and residents have relatively easy access to inexpensive legal cannabis products from bordering states.

[5] For more information, see our companion report on Indiana cannabis policy (Kilmer et al., 2026).

[6] Some argue that this was not a loophole or accident (for example, see Jaeger, 2025).

[7] In general, Indiana does not allow cannabis to be used for medical purposes, although, in April 2017, Indiana Governor Eric Holcomb signed a restrictive bill into law allowing the use of CBD oil (containing no more than 0.3 percent total THC) for those suffering from treatment-resistant epilepsy (Indiana House Bill 1148, 2017). Physicians who are board-certified in neurology can recommend this oil to patients.

[8] Another example of discretion includes Marion County's decision to not prosecute possession cases involving small amounts of cannabis (Hill and Martin, 2019). As displayed in Figure 2, the arrest rate in Marion County is similar to many other counties in the state.

[9] In 2025, Indiana's attorney general wrote:

> As you know, the federal 2018 Agricultural Improvement Act (the "Farm Bill") legalized hemp by defining it as cannabis containing no more than 0.3% total delta-9 THC by dry weight, and **Indiana law allows for the sale and possession of such delta-9 products**. However, the federal law did not address other isomers, such as delta-8 THC, delta-10 THC, or HHC, which have similar chemical structures and, pointedly, have similar psychoactive effects. These products are currently illegal in Indiana. See my Official Opinion 2023-1. Given the illegality of these products and their psychoactive effects, for the last several weeks, my office has engaged in a concerted effort to ensure that the General Assembly is clear-eyed in its consideration of [Senate Bill] 478, which seeks to regulate such isomers (Rokita, 2025; emphasis added).

Indiana's attorney general also stated in 2023:

> [T]HC variants, including but not limited to delta-8 THC, delta-10 THC, THC-O, and THC-P as well as derivatives and isomers of these compounds, fall within the currently defined controlled substance "Tetrahydrocannabinols" as a Schedule I controlled substance within Ind. Code § 35-48-2-4(d)(31). . . . Even as a natural extraction of the cannabis plant, delta-8 THC would still be classified as a controlled substance under the statute (Rokita, 2023, , pp. 1, 11).

[10] There were some exceptions, at least early on (e.g., Dubois County) (Gray, 2023).

[11] Dispensary locations were obtained from the following official state regulatory agencies: the Illinois Cannabis Regulation Oversight Officer, Michigan Cannabis Regulatory Agency, and Ohio Department of Commerce. We identified all licensed dispensaries within 50 miles of Indiana's border and verified their operational status through direct telephone contact, confirming current addresses and business hours. Of 318 licensed locations within 50 miles of Indiana, 258 were verified as actively operating at the time of data collection (October to November 2025). Driving distances from Indiana census tract centroids to dispensary locations were calculated using origin-destination cost matrices constructed in ArcGIS with the ArcGIS World Geocoder (Wang and Xu, 2011). Population data are derived from the 2017–2021 American Community Survey 5-Year Estimates matched by census tract geographic identifiers (U.S. Census Bureau, 2022).

[12] The research community tends to rely more on NSDUH for measuring cannabis use in the general population, but for Indiana, the Behavioral Risk Factor Surveillance System (BRFSS) has a much larger sample size (more than 9,000). Data from the BRFSS show past-month prevalence for those 18 and older increasing from 8.0 percent in 2020 to 10.1 percent in 2023. NSDUH consistently produces higher estimates than BRFSS, with the gap widening by more than 300,000 people circa 2023 and 2024. The persistent gap between estimates reflects fundamental methodological differences. BRFSS is a telephone survey and NSDUH uses computer-assisted self-interviewing for sensitive questions, allowing respondents to enter answers privately rather than reporting drug use verbally to an interviewer (when not conducted online). Theoretically, this should reduce social desirability bias and lead to more accurate answers. NSDUH also covers populations excluded from telephone surveys, including residents of college dormitories, shelters, and rooming houses. As a dedicated substance use survey, NSDUH employs extensive screening questions and probes that improve recall, whereas BRFSS embeds cannabis questions within a general health survey. Thus, we use NSDUH for our calculations instead of BRFSS.

[13] We rely on the biennial random sample of a subset of approximately one-third of participating schools for inference about youth cannabis use and perceptions in the state between 2016 and 2024 (Gassman et al., 2016; Gassman et al., 2018; Jun et al., 2024).

[14] The prevalence in grade 10 fell from 12.1 percent to 8.4 percent over this period; among 8th graders, it declined from 6.3 percent to 4.2 percent.

[15] In the survey section on marijuana, NSDUH notes the following:

> The next questions are about CBD or hemp products made from hemp plants. CBD and hemp products have no or small amounts of THC and are not intended to cause a "high." They come in many forms including oils, lotions, edibles, and isolate. People sometimes use them to relieve pain, to reduce anxiety, or to help them sleep. Have you ever, even once, used any CBD or hemp products? (SAMHSA, 2026).

Next, NSDUH presents the following:

> The next questions are about marijuana and cannabis products, sometimes called pot, weed, hashish, or concentrates. Some of the ways these products can be used are smoking (such as in joints, pipes, bongs, blunts, or hookahs), vaping (using vape pens, dab pens, tabletop vaporizers, or portable vaporizers), dabbing, eating or drinking, or applying as a lotion. **Please exclude your use of CBD or hemp products when answering these questions** (SAMHSA, 2026; emphasis added).

It is possible that some people will classify intoxicating hemp as cannabis, given that hemp is categorized as having no or small amounts of THC in hemp products not intended to cause a high. However, given the emphasized sentence at the end of the survey's cannabis question, they may not.

[16] The national estimates on retail expenditures on intoxicating hemp vary dramatically (Brightfield Group, 2024; Whitney and Wilberding, 2023a; Whitney and Wilberding, 2023b), and the publicly available estimates available for Indiana focus on all hemp-derived cannabinoids, including CBD (Whitney and Wilberding, 2023a; Whitney and Wilberding, 2023b). There are also some questions about spending on different intoxicating hemp products in the ICPS. As discussed in Annex II, our best estimate for annual spending on intoxicating hemp in Indiana ranges from about $175 million to $350 million.

[17] These arrest data do not contain information on ethnicity; and, in terms of race, individuals are classified by law enforcement as Black, White, or Other. For any cannabis arrest, Table 5 suggests that the arrest rate for individuals who are Black is 4.6 times higher than it is for individuals who are White (= 731/159); for possession, it was 4.2 times higher (= 629/151). Given the complexity, we excluded multiracial individuals from the denominators of these calculations. If we assume that every time a multiracial Black individual was arrested that the person was recorded as Black in the arrest data, changing the Black population denominator to include those individuals would result in a slightly smaller Black-White difference of cannabis arrest rates (roughly 3.6 times higher). Thus, we are most comfortable stating that the arrest rate for Black residents was approximately four times larger than it was for White residents.

[18] Because it takes time for charges to be processed before they reach a final disposition—for instance, because of criminal trials—in this section, we focus on data from the 14,235 cannabis charges resulting from 12,625 cannabis-involved arrests made in 2022, which have had more time to reach a disposition.

[19] The missing data mean we cannot precisely count the statewide number of inmates with cannabis charges. However, if we assume that the rate of cannabis inmates per capita (i.e., per county resident) was the same for the remaining counties, there would be 1,698 inmates with cannabis charges on July 1, 2024, for all of Indiana. The arrest rate for cannabis per capita was 19.5 percent higher in the counties for which we do not have jail data. If we assume that this translates into an equivalent (19.5 percent) increase in cannabis bookings per capita for the counties with missing jail data, then 1,841 inmates across Indiana would be in jail with cannabis charges on July 1, 2024.

[20] Because many parolees are subjected to drug testing, those who test positive for cannabis could be violated and returned to prison. It is unclear how often this occurs, and it also applies to probationers and jails.

[21] In 2024, the INYS added past-month frequency questions for different modes of cannabis use (Jun et al., 2024).

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The views presented in the report are ours and should not be interpreted as endorsements by the funders, reviewers, or people with whom we spoke.

About This Report

Policy discussions about cannabis and intoxicating hemp products are heating up at the federal level and in many states, including Indiana. Our main goals in this report are to provide background information and new insights for those who seek to learn more about the cannabis landscape in Indiana. This is a report for educational purposes as to what the current circumstances are in Indiana on this topic.

RAND Drug Policy Research Center

This work was conducted in the RAND Drug Policy Research Center. Since 1989, the center has carried out research to help decisionmakers in the United States and abroad address issues involving alcohol and other drugs. In doing so, the center brings an objective and data-driven perspective to this often emotional and fractious policy arena. For more information, visit www.rand.org/health/centers/dprc.html.

Funding

This research was sponsored by the Richard M. Fairbanks Foundation.

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Exhibit B

U.S. Department of Justice
Drug Enforcement Administration



The Illegal Drug Threat in Indiana

DEA Intelligence Report

SEPTEMBER 2024

DEA-CHI-DIR-024-24
UNCLASSIFIED

Executive Summary

The most significant drug-related threat to Indiana is posed by Mexican drug trafficking organizations (DTO), particularly the Cartel de Sinaloa (CDS) and the Cartel de Jalisco Nueva Generación (CJNG). Mexican DTOs dominate the wholesale supply of illicit opioids (both fentanyl and heroin), cocaine, methamphetamine, and Mexico-grown marijuana in the state. The opioid threat remains dire and is of grave concern. Reporting from the Drug Enforcement Administration's (DEA) offices in Indiana, forensic laboratories, and public health officials confirms that fentanyl has almost completely replaced heroin in the illicit opioid marketplace throughout Indiana. The availability and use of cocaine and methamphetamine are increasing, with seizures increasing and prices decreasing for both. Fake pills manufactured both domestically and outside of the United States are an increasing threat in the illicit drug market. Large volumes of illicit proceeds are laundered throughout the state. While the movement of bulk currency from Indiana to the Southwest Border (SWB) remains the primary method of sending drug proceeds back to Mexico, DTOs increasingly are making use of money transfer tools on the open internet and dark web to launder their illicit proceeds.



MEXICAN DTOs
DOMINATE THE WHOLESALE SUPPLY OF
ILLICIT OPIOIDS

(U) Figure 1. Chicago Division Area of Responsibility

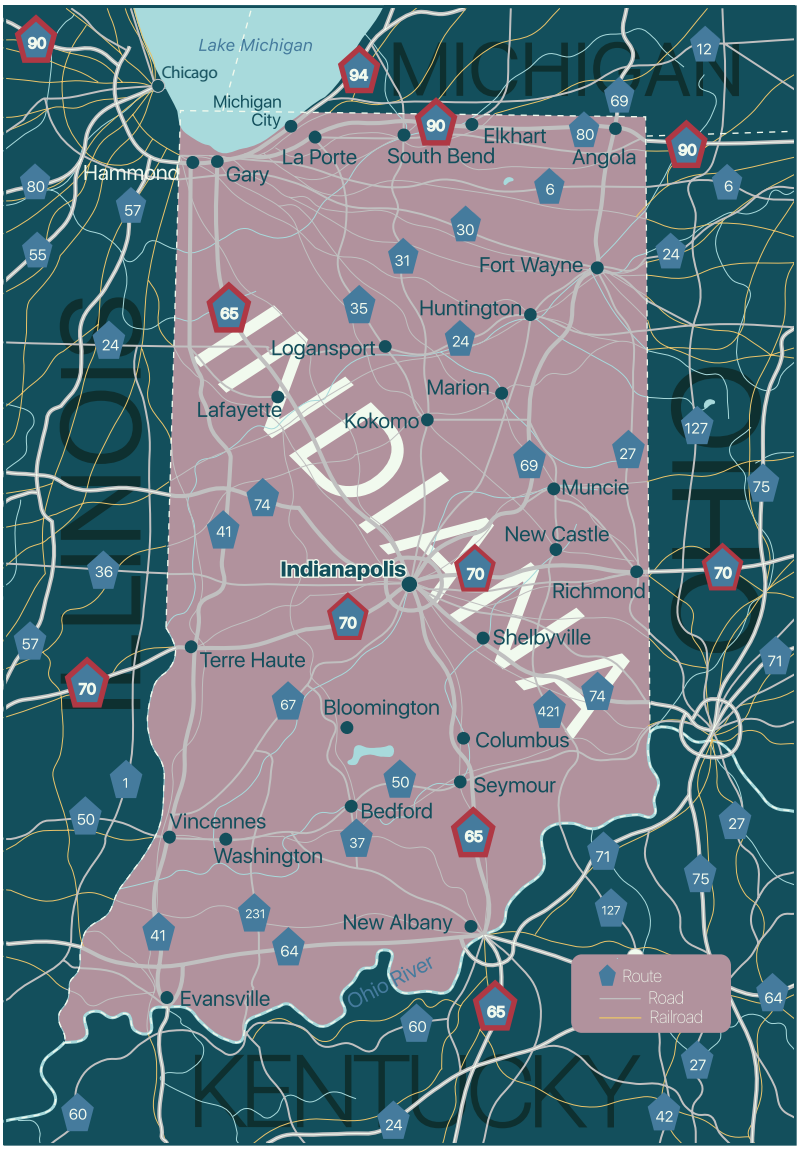


Source: DEA

(U) Indiana is the 38th largest by area (36,418 square miles) and the 17th most populous (6.8 million) of the 50 United States. It is divided into 92 counties and two U.S. Judicial Districts, Northern and Southern. Within Indiana, DEA maintains five offices: the Indianapolis District Office (DO), Terre Haute Post of Duty (POD), and the Evansville Resident Office (RO) in the Southern District, and the Merrillville DO and the Ft. Wayne POD in the Northern District. DEA also maintains one enforcement group in the Indiana High-Intensity Drug Trafficking Area (HIDTA). A DEA Intelligence Supervisor manages the HIDTA Investigative Support Center.

Details

The primary drug trafficking threat to Indiana is posed by Mexico-based DTOs, particularly CDS and CJNG, whose members have close ties to street gangs operating mostly in the northwestern portion of the state. These Mexican DTOs dominate the wholesale supply of fentanyl, heroin, cocaine, methamphetamine, and Mexico-grown marijuana in the state. The drugs are transported either directly to distribution hubs in Indiana or to Chicago, Illinois from strategic points across the U.S.–Mexico border, and subsequently distributed to cells operating across the state. DTOs use a variety of transportation methods, including vehicles outfitted with concealed compartments, or co-mingled with commercial goods, such as produce or furniture. However, the most common transportation method remains by land via tractor-trailer trucks or personal vehicles. The state's extensive highway, train, and mail and parcel delivery services make it an ideal transportation hub to move drugs from the SWB to markets throughout the Midwest. Indiana's highway system, particularly Interstates (I) 65, 70, 90, and 94, also facilitates the transportation of drug proceeds (bulk currency) back to the SWB for further transportation into Mexico.



Fentanyl

Fentanyl and fentanyl-related substances (FRS) pose the biggest drug threat across DEA's Chicago Division (CD) and in Indiana. Availability has increased steadily over the last several years, as evidenced by increasing seizures, overdoses/poisonings, and deaths. The continued practice by DTOs of adulterating other drugs with fentanyl has led to a surge in overdoses/poisonings over the last several years, as users inadvertently consume a dangerous dose of fentanyl. Demand remains high, with continued seizures of fentanyl in both powder and pill form. As the demand for fentanyl has steadily increased in recent years, the price of fentanyl has decreased. In 2018, the median price for a kilogram of fentanyl was around $90,000; by the end of 2023, it was approximately $30,000. Fake pills, manufactured to look like legitimate controlled prescription drugs (CPDs), are increasing in availability and popularity. Locally, drug distributors use pill presses to produce fake pills consisting of fentanyl, FRS, or other



Fake Pills

DEA has reported that seven out of 10 fake fentanyl pills contain a potentially lethal amount of the drug (2 milligrams). The DEA Chicago Division seized 1.9 million fake pills in 2023—twice the amount seized in 2022. The expansion of fake pill production domestically and the illicit sale of these pills via the internet represent a growing threat to the public, who may not be aware that prescription pills cannot be purchased legitimately via social media and that all of these fake pills likely contain fentanyl, methamphetamine, or some other clandestinely produced substance.

Source: DEA

dangerous drugs. Pill presses range from just under $100 for a handheld press to several thousand dollars for automated presses and can be easily ordered over the internet. The ease of obtaining pill presses has created an increase in variations of drug compounds appearing in pill and capsule form.

Heroin

Increasingly, heroin is becoming interchangeable with fentanyl. Some seizure and availability reports are inconsistent, due to the uncertainty of whether law enforcement is encountering heroin or fentanyl, or both. Law enforcement officers have reported that sellers and users may not necessarily distinguish heroin from synthetic opioids in their sales and purchases. Heroin demand remains high at user levels; however, decreasing seizures of heroin indicate decreasing availability.

Methamphetamine

The dangers of methamphetamine continue to rise throughout the state, as availability increases and prices decrease. According to the 2023 Indiana HIDTA Threat Assessment, methamphetamine was ranked as the second most significant drug threat in Indiana, except in parts of southern Indiana, where it ranked first. Indiana has a long history of methamphetamine use, and is one of the top states when ranking the highest number of clandestine laboratories dismantled by law enforcement. While domestic clandestine laboratory seizure numbers have dropped in recent years, Indiana still ranked second nationally for the number of laboratories processed by law enforcement agencies. The increased availability of methamphetamine is a direct result of the control exerted by Mexican DTOs over the production, smuggling, and distribution of the drug. While most methamphetamine appears in crystalline form, methamphetamine in powder form is customarily white in color, but it also has been observed in other colors, such as pink or blue. The increased supply—and the limited but rising instances of it being mixed with fentanyl in the past few years—has led to an increase in the number of drug deaths in Indiana involving methamphetamine.

Cocaine

All indicators of availability show that cocaine remains a significant drug of concern for Indiana. The specific nature and scale of the cocaine threat varies throughout the state, depending on location and other factors. Most of the cocaine reaching Indiana is transported from source countries, primarily Colombia, into Mexico, smuggled into the United States, then distributed through major cities like Indianapolis, Fort Wayne, and Evansville, and finally into smaller communities. Both the supply of and demand for cocaine appear strong in Indiana. Seizures have increased and prices appear to be

trending downward. Substantial supplies seem to be related, at least in part, to increased production in South America. Similar to other drugs, Mexican DTOs transport wholesale volumes of cocaine from the SWB into larger urban areas on a regular basis, using methods similar to those used for the transportation of other illicit drugs.

Marijuana

Marijuana continues to be the most widely used illegal drug used within the state. As of January 2024, Indiana is surrounded by three states, Illinois, Michigan, and Ohio, that have fully legalized, at the state level, the use of marijuana; Indiana remains one of six states where cannabis remains illegal at the state level. Due to Indiana's proximity to states with legal cannabis products, the availability of and demand for marijuana remains high. This includes traditional leaf/bud products, as well as other modalities, like vape cartridges and edibles. The proximity of major cities in Indiana to Illinois and Michigan, where recreational marijuana is legal, makes it very easy to transport the drug across state lines.

Diversion

CPDs continue to be a threat throughout the country, as well as in Indiana; but, due to increased diversion-related enforcement and regulatory actions and lawsuits, CPDs are being more carefully prescribed. One of the primary reasons for the diversion of prescription drugs in Indiana is the high demand for these drugs, particularly opioids. Opioid drugs, like oxycodone and hydrocodone, are highly addictive and can be easily abused, leading to a significant risk of overdose/poisoning and death. The retail sale of CPDs is primarily sourced via prescription fraud, mostly by independent DTOs.

Money Laundering

The primary methods used to move/exchange proceeds generated from drug trafficking are bulk smuggling (generally via commercial and/or personal conveyance), wire transfers, structured bank deposits, money order purchases, and commingling illicit funds with legitimate funds. Money launderers generally operate as part of a DTO, and they may or may not be involved in drug distribution as well. Some money launderers operate legitimate businesses (such as restaurants, car dealerships, towing services, and trucking companies) as a means of laundering or legitimizing drug proceeds. Bulk cash movement is still the preferred method to move large amounts of illicit drug funds; however, seizures of currency have fallen over the past few years in Indiana. One reason for the decrease is that the use of digital currency to move illicit funds is increasing in popularity. Drug trafficking and payment, using web-based applications, are occurring throughout Indiana across urban, suburban, and rural communities. Drug traffickers advertise on social media platforms, using known code words and emojis. Prospective buyers typically respond using encrypted communication applications. After the deal is agreed upon, the buyer will pay using one-click money transfer applications. By their very nature, digital currencies are more difficult for law enforcement to detect and seize.

Outlook

DTOs and money laundering organizations will continue to infiltrate Indiana communities; however, there are some indications that smaller independent DTOs will take over retail distribution that historically has been controlled by larger street gangs and DTOs in open air drug markets. The use of technology—combined with privately owned vehicles and commercial parcel delivery services—make communication, transportation, and distribution of illicit drugs throughout the state more accessible to individuals and smaller organizations.

The opioid crisis in Indiana will continue to be a public health and public safety challenge. The presence of fentanyl or FRSs combined with other drugs, such as heroin, cocaine, and methamphetamine, adds another layer of complexity to the opioid crisis, as does the presence of fentanyl in fake pills that mimic legitimate medications. This will further contribute to the devastating number of fatal opioid overdoses/poisonings in the state. Drug traffickers seeking to maximize profit by either intentional compounding or unintentional contamination of fentanyl with other drugs—and opioid users seeking a more potent high by using fentanyl in combination with other drugs—will continue to be key factors in the overdose/poisoning epidemic. Controlled prescription drugs will continue to be abused in Indiana.

DTOs will continue to take advantage of new technology in an attempt to thwart investigations and enforcement activities. Social media, encrypted communications, digital payment applications, and cryptocurrencies continue to evolve and grow in popularity. DTOs will use these technologies to communicate with their networks and launder drug proceeds. Dark web vendors doing business in Indiana will expand their position in the illicit marketplace to distribute locally sourced drugs, both nationally and internationally.

DEA Intelligence Report

PRB#2024-16

(U) This product was prepared by the DEA Intelligence Program – Chicago Division. Comments and questions may be addressed to the DEA Indicator Programs Section at: DEA.IntelligenceProducts@dea.gov. For media/press inquiries call (571) 776-2508.

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How will you use this report? (Check all that apply)

☐ Policy Formulation ☐ Situational Awareness ☐ Operational Planning

☐ Training ☐ Resource Allocation ☐ Other

Additional Comments:

Exhibit C

Indiana - 2022

	Total Exposures	<= 5 yrs	6-12 yrs	13-19 yrs	>= 20 yrs	Unknown Child	Unknown Adult	Unknown Age	Un-Intnt	Intnt	Other	Adv rxn	HCF	No Effect	Minor Effect	Mod Effect	Major Effect	Death
Stimulants and Street Drugs																		
Cannabinoids and Analogs																		
Cannabidiol (CBD)	343	139	45	45	105	0	10	0	199	99	3	38	131	49	112	59	7	0
eCigarettes: Marijuana Device Flavor Unknown	58	21	4	22	9	0	2	0	25	31	0	1	30	5	18	15	0	0
eCigarettes: Marijuana Device With Added Flavors	11	6	0	2	2	0	1	0	6	3	0	2	6	0	4	2	0	0
eCigarettes: Marijuana Device Without Added Flavors	5	2	0	1	1	0	0	1	2	2	0	1	3	0	3	0	0	0
eCigarettes: Marijuana Liquid Flavor Unknown	2	1	0	1	0	0	0	0	1	1	0	0	1	0	0	1	0	0
eCigarettes: Marijuana Liquid With Added Flavors	1	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0
Marijuana: Concentrated Extract (Including Oils and Tinctures)	38	13	1	9	14	0	0	1	20	17	0	0	19	6	8	13	0	0
Marijuana: Dried Plant	454	224	36	76	95	1	20	3	275	131	8	25	261	29	142	139	10	0
Marijuana: Edible Preparation	1,091	516	183	147	229	0	13	7	709	307	23	39	593	70	422	351	18	0
Marijuana: Oral Capsule or Pill Preparation	8	4	0	2	2	0	0	0	6	2	0	0	4	0	2	1	0	0
Marijuana: Other or Unknown Preparation	36	18	7	5	4	1	1	0	24	8	0	0	26	2	7	15	3	0
Marijuana: Topical Preparation	1	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0
Marijuana: Undried Plant	1	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0
Minor Cannabinoids	17	7	3	4	3	0	0	0	8	8	0	0	6	0	8	5	0	0
Synthetic Cannabinoids, Analogs and Precursors	26	1	1	8	15	0	1	0	6	18	0	0	19	0	6	14	2	1
Category Total:	**2,092**	**953**	**280**	**322**	**480**	**2**	**49**	**12**	**1,283**	**627**	**34**	**107**	**1,099**	**161**	**733**	**615**	**40**	**1**
Total	**2,092**	**953**	**280**	**322**	**480**	**2**	**49**	**12**	**1,283**	**627**	**34**	**107**	**1,099**	**161**	**733**	**615**	**40**	**1**

Indiana - 2023

	Total Exposures	<= 5 yrs	6-12 yrs	13-19 yrs	>= 20 yrs	Unknown Child	Unknown Adult	Unknown Age	Un-Intnt	Intnt	Other	Adv rxn	HCF	No Effect	Minor Effect	Mod Effect	Major Effect	Death
Stimulants and Street Drugs																		
Cannabinoids and Analogs																		
Cannabidiol (CBD)	175	84	31	9	45	0	6	0	132	26	0	15	55	33	48	20	1	0
eCigarettes: Marijuana Device Flavor Unknown	73	31	2	28	11	0	1	0	34	35	0	2	37	4	27	20	1	0
eCigarettes: Marijuana Device With Added Flavors	14	8	2	3	1	0	0	0	8	5	0	0	5	0	8	2	0	0
eCigarettes: Marijuana Device Without Added Flavors	3	1	1	1	0	0	0	0	1	1	0	1	0	0	0	0	0	0
eCigarettes: Marijuana Liquid Flavor Unknown	3	1	0	2	0	0	0	0	1	2	0	0	2	0	0	2	0	0
Marijuana: Concentrated Extract (Including Oils and Tinctures)	67	27	4	13	18	0	4	1	38	22	2	3	30	7	14	21	0	0
Marijuana: Dried Plant	419	201	46	71	81	0	15	5	249	127	3	17	235	27	121	109	18	0
Marijuana: Edible Preparation	1,222	565	197	194	249	1	15	3	764	361	13	63	708	78	435	409	31	0
Marijuana: Oral Capsule or Pill Preparation	8	3	0	0	3	0	2	0	4	3	0	1	5	0	5	2	0	0
Marijuana: Other or Unknown Preparation	82	46	8	14	12	0	1	1	55	17	0	3	64	4	20	38	3	0
Marijuana: Pharmaceutical Preparation	2	1	0	0	1	0	0	0	1	1	0	0	2	1	1	0	0	0
Marijuana: Topical Preparation	3	1	0	0	2	0	0	0	2	0	0	1	0	1	0	0	0	0
Minor Cannabinoids	355	139	43	56	112	0	5	2	183	151	4	18	206	19	147	102	11	0
Synthetic Cannabinoids, Analogs and Precursors	48	7	2	10	28	0	1	0	13	33	0	1	35	0	22	11	4	0
Category Total:	**2,474**	**1,115**	**336**	**401**	**563**	**1**	**50**	**12**	**1,485**	**784**	**22**	**125**	**1,384**	**174**	**848**	**736**	**69**	**0**
Total	**2,474**	**1,115**	**336**	**401**	**563**	**1**	**50**	**12**	**1,485**	**784**	**22**	**125**	**1,384**	**174**	**848**	**736**	**69**	**0**

Indiana - 2024

	Total Exposures	<= 5 yrs	6-12 yrs	13-19 yrs	>= 20 yrs	Unknown Child	Unknown Adult	Unknown Age	Un-Intnt	Intnt	Other	Adv rxn	HCF	No Effect	Minor Effect	Mod Effect	Major Effect	Death
Stimulants and Street Drugs																		
Cannabinoids and Analogs																		
Cannabidiol (CBD)	151	80	20	8	38	0	4	1	115	19	1	15	46	30	38	19	1	0
eCigarettes: Marijuana Device Flavor Unknown	94	46	9	25	11	0	3	0	55	32	3	4	43	8	39	21	4	0
eCigarettes: Marijuana Device With Added Flavors	7	5	1	1	0	0	0	0	6	1	0	0	3	2	3	1	0	0
eCigarettes: Marijuana Device Without Added Flavors	2	1	0	1	0	0	0	0	1	1	0	0	2	0	1	0	0	0
eCigarettes: Marijuana Liquid Flavor Unknown	2	1	0	1	0	0	0	0	1	1	0	0	1	0	0	1	0	0
eCigarettes: Marijuana Liquid With Added Flavors	1	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Marijuana: Concentrated Extract (Including Oils and Tinctures)	75	35	3	11	17	1	6	2	47	19	2	3	28	4	20	18	5	0
Marijuana: Dried Plant	409	205	44	54	88	0	11	7	254	111	6	23	235	24	105	132	12	0
Marijuana: Edible Preparation	1,613	798	291	233	266	1	22	2	1,094	414	14	56	926	85	536	606	50	0
Marijuana: Oral Capsule or Pill Preparation	12	6	1	2	3	0	0	0	8	4	0	0	7	0	4	5	0	0
Marijuana: Other or Unknown Preparation	101	58	13	15	13	0	2	0	66	24	0	3	82	4	26	51	9	0
Marijuana: Pharmaceutical Preparation	1	0	0	0	1	0	0	0	0	0	0	1	1	0	0	1	0	0
Marijuana: Topical Preparation	2	1	0	0	1	0	0	0	2	0	0	0	0	1	0	0	0	0
Marijuana: Undried Plant	1	1	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0
Minor Cannabinoids	439	145	69	74	148	0	5	0	221	199	4	12	273	20	160	155	18	0
Synthetic Cannabinoids, Analogs and Precursors	38	5	2	12	19	0	0	0	10	25	0	1	28	0	13	14	4	0
Category Total:	**2,948**	**1,388**	**453**	**437**	**605**	**2**	**53**	**12**	**1,882**	**850**	**30**	**118**	**1,676**	**178**	**945**	**1,024**	**103**	**0**
Total	**2,948**	**1,388**	**453**	**437**	**605**	**2**	**53**	**12**	**1,882**	**850**	**30**	**118**	**1,676**	**178**	**945**	**1,024**	**103**	**0**

Indiana - 2025 (First Half)

	Total Exposures	<= 5 yrs	6-12 yrs	13-19 yrs	>= 20 yrs	Unknown Child	Unknown Adult	Unknown Age	Un-Intnt	Intnt	Other	Adv rxn	HCF	No Effect	Minor Effect	Mod Effect	Major Effect	Death
Stimulants and Street Drugs																		
Cannabinoids and Analogs																		
Cannabidiol (CBD)	59	29	8	4	17	0	0	1	43	9	0	4	23	8	14	11	0	0
Delta-9 Tetrahydrocannabinol in Combination with Other Psychoactive Substances	3	1	0	2	0	0	0	0	1	2	0	0	2	0	2	0	0	0
eCigarettes: Marijuana Device Flavor Unknown	51	16	4	24	6	0	1	0	18	31	0	2	29	2	29	10	1	0
eCigarettes: Marijuana Device With Added Flavors	5	4	0	1	0	0	0	0	4	1	0	0	2	1	1	0	0	0
eCigarettes: Marijuana Device Without Added Flavors	4	2	0	2	0	0	0	0	2	2	0	0	4	0	2	2	0	0
Marijuana: Concentrated Extract (Including Oils and Tinctures)	39	21	2	5	11	0	0	0	24	14	0	1	22	6	14	11	2	0
Marijuana: Dried Plant	172	86	17	23	36	1	7	2	114	37	4	9	88	8	47	44	6	0
Marijuana: Edible Preparation	913	430	156	126	189	0	11	2	625	246	5	28	536	41	300	347	27	0
Marijuana: Oral Capsule or Pill Preparation	1	1	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0	0
Marijuana: Other or Unknown Preparation	45	27	4	8	5	0	0	1	33	6	2	1	33	0	12	21	2	0
Marijuana: Pharmaceutical Preparation	1	0	0	0	1	0	0	0	0	1	0	0	0	0	1	0	0	0
Marijuana: Undried Plant	1	1	0	0	0	0	0	0	1	0	0	0	1	0	0	1	0	0
Minor Cannabinoids	125	53	19	21	31	0	1	0	65	50	1	7	74	2	40	50	2	0
Synthetic Cannabinoids, Analogs and Precursors	24	6	3	2	13	0	0	0	6	16	0	0	21	1	6	11	4	0
Category Total:	**1,443**	**677**	**213**	**218**	**309**	**1**	**20**	**6**	**937**	**415**	**12**	**52**	**836**	**69**	**469**	**508**	**44**	**0**
Total	**1,443**	**677**	**213**	**218**	**309**	**1**	**20**	**6**	**937**	**415**	**12**	**52**	**836**	**69**	**469**	**508**	**44**	**0**

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** Consolidated with Nos. 26-1106 and 26-1130

DECLARATION OF DUANE BOISE

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

1. I am over eighteen years of age and am competent to testify to the matters stated herein. I make this declaration based on my personal knowledge, my review of MMJ records, and my review of public agency records, including the official hearing transcripts published by the Drug Enforcement Administration in Hearing Docket No. 26-96.

2. I am the Chief Executive Officer of MMJ International Holdings, Inc. ("MMJIH") and President of its subsidiaries, MMJ BioPharma Cultivation, Inc.

("MMJBC"), and MMJ BioPharma Labs, Inc. ("MMJBL") (collectively, "MMJ"). In that role, I have personal knowledge of MMJ's organizational structure, operations, finances, regulatory history, capital-raising efforts, and the effect of AG Order No. 6754-2026 (the "Rescheduling Order") on MMJ.

3. MMJIH is a Delaware-incorporated life-sciences company formed to develop pharmaceutical cannabinoid therapeutics under the FDA botanical drug development framework. MMJIH oversees regulatory strategy, clinical development planning, chemistry, manufacturing, and controls work, and Investigational New Drug submissions for cannabinoid-based treatments targeting Huntington's disease and multiple sclerosis.

4. MMJBC is a Delaware-incorporated subsidiary formed to cultivate and produce pharmaceutical-grade cannabis plant material required for MMJIH's FDA-authorized clinical trials and drug development. On December 27, 2018, MMJBC submitted DEA applications to import and manufacture marijuana for FDA-authorized clinical trials and research. Thereafter, MMJ obtained authorization from both Health Canada and the DEA to ship pharmaceutical cannabinoid materials into the United States for MMJ's FDA-regulated development program to prove cannabis's therapeutic efficacy through rigorous clinical science.

5. MMJBL is a Delaware-incorporated subsidiary formed to perform analytical testing, formulation support, and regulatory-grade characterization of

botanical extracts used in MMJIH's drug development program. MMJBL was issued a DEA Schedule I analytical laboratory registration issued after DEA inspection and approval of physical security systems, recordkeeping controls, and diversion-prevention safeguards.

6. MMJBC's bulk-manufacturing registration application remains pending before DEA after more than seven years of regulatory process. DEA commenced its pre-registration Section 303 investigation on June 22, 2021. DEA conducted a final on-site visit on October 24, 2021, and a further visit at MMJ's Westerly, Rhode Island facility on October 12, 2022. MMJ provided requested supplemental information in full compliance. After DEA filed a show-cause order on October 3, 2023 and the ALJ recommended that MMJ's application be denied, DEA Administrator Terrance Cole rejected that recommendation and remanded on September 15, 2026. Subsequently, DEA dropped its show-cause proceeding, and has now restarted its inspection process. MMJBC is currently preparing its facility to undergo final inspection in early December 2026.

7. MMJIH initiated formal regulatory engagement with FDA's Center for Drug Evaluation and Research in August 2018 to kick off the Investigational New Drug (IND) process through pre-IND meeting requests for MMJ-001 (to treat Huntington's disease) and MMJ-002 (to treat multiple sclerosis). FDA opened regulatory files including IND 137754 and IND 140712. On January 29, 2019, FDA

granted Orphan Drug Designation for Δ9-tetrahydrocannabinol and cannabidiol for the treatment of Huntington's disease.

8. Consistent with FDA's Botanical Drug Development Guidance, MMJ developed a standardized botanical cannabinoid soft-gel capsule containing defined quantities of cannabis-derived THC and CBD. MMJ evaluated seven prototype formulations, selected a formulation consisting of 5 mg CBD and 2.5 mg THC per capsule, and engaged Catalent Pharma Solutions to develop and manufacture a soft-gel capsule formulation consistent with FDA IND and CMC requirements.

9. MMJ has submitted two IND applications to FDA supporting clinical development for Huntington's disease and multiple sclerosis. FDA has issued clinical holds, including a Full Clinical Hold letter dated February 7, 2025, addressing clinical and chemistry, manufacturing, and controls (CMC) questions associated with IND 140712. MMJ has submitted responses and supporting materials.

10. Over about eight years, MMJ has invested more than $10 million in scientific, regulatory, financial, and manufacturing resources to advance pharmaceutical cannabinoid therapeutics through the federal FDA and DEA pathways. These investments include FDA regulatory counsel, clinical development strategy, an investigator's brochure, analytical testing, IND-grade soft-gel

manufacturing, accounting and financial advisory services, and construction of a DEA-compliant cultivation and security facility.

11. In addition, MMJ engaged Seaport Global Securities LLC as lead financial advisor for a proposed $45 million capital raise and proposed public listing. That capital-markets strategy depended on MMJ's position as a federally compliant first mover in FDA-approved cannabinoid pharmaceuticals.

12. MMJ has structured its operations to comply with federal law governing both controlled-substance handling and pharmaceutical drug development. MMJBL obtained a DEA Schedule I analytical laboratory registration after DEA inspection and approval of its physical security systems, recordkeeping controls, and diversion-prevention safeguards; MMJBC applied for DEA bulk-manufacturer registration to cultivate and produce marijuana as its active pharmaceutical ingredient (API) for FDA-authorized clinical trials; and MMJ has used federally supervised import and supply-chain procedures to support its FDA botanical drug development program. These controls are designed so that, once MMJ's product is approved, it can be prescribed by physicians, dispensed through lawful pharmaceutical channels, and used by legitimate patients as medicine according to FDA-approved directions.

13. MMJ competes directly against a burgeoning group of businesses that supply federally unapproved cannabis-based products for therapeutic use under state

medical-marijuana programs. Until the Rescheduling Order, MMJ's critical competitive advantage was its rigorous compliance with federal law: MMJ filed FDA IND applications, obtained orphan-drug designation, pursued DEA registration, constructed DEA-inspected laboratory systems, engaged in rigorous formulation development, undertook stability studies and analytical testing, and instituted full pharmaceutical manufacturing controls—all for the purpose of bringing federally compliant and therapeutically effective cannabis-based medicine to market. Meanwhile, to reach states' medical marijuana markets faster and to secure substantial market share, MMJ's competitors have skipped these important steps: Their products have not undergone the same DEA registration process, FDA IND review, CMC review, clinical trials, stability studies, controlled-formulation analysis, or FDA labeling that MMJ has assiduously pursued.

14. Because MMJ has consistently followed federal law—unlike its corner-cutting competitors—MMJ can deduct business expenses in filing its taxes. This constitutes a substantial advantage over MMJ's competitors, who—until the Rescheduling Order—have not been permitted to deduct business expenses, and were instead taxed on gross profits under Section 280E of the Internal Revenue Code, because their businesses "consist[ed] of trafficking in controlled substances (within the meaning of schedule I … of the Controlled Substances Act) which is prohibited by Federal law." 26 U.S.C. § 280E.

15. The Rescheduling Order directly harms MMJ's competitive advantage by granting legal Schedule III status to state-licensed products without requiring the companies producing them to satisfy the same federal pharmaceutical-development requirements that MMJ has meticulously observed. It eliminates the compliance-based market distinction that MMJ spent more than eight years and $10 million building. It also harms MMJ's competitive advantage by granting MMJ's competitors relief from the Internal Revenue Code's Section 280E deduction disallowance for trafficking in a Schedule I controlled substance. *See* 91 Fed. Reg. at 22720.

16. MMJ competes against companies that market cannabis-based products for therapeutic use under state medical-marijuana programs. State-licensed products can be marketed or dispensed for therapeutic use in capsule, edible, vape, concentrate, flower, and other forms. The Order gives those competitors federal Schedule III legitimacy without requiring them to prove safety, efficacy, formulation consistency, or manufacturing controls through FDA review.

17. MMJ's direct competitors include:

- **Trulieve Cannabis Corp.** (Trulieve), a multistate cannabis operator that markets cannabinoid products for therapeutic use, including its Momenta brand in a soft-capsule (gelcap) format directly analogous to MMJ's soft-gelatin capsule. Trulieve advertises that its "Momenta

Ratio Capsules offer a balanced 1:1 CBN:THC formulation in a simple, familiar capsule format,"[1] sold in 30-count, 300 mg bottles and promoted as "precisely dosed" and offering "consistent, controlled relief."[2] Trulieve is the largest single beneficiary of the tremendous market momentum already generated by the Rescheduling Order: On June 5, 2026, it announced an uplisting to the New York Stock Exchange, and on June 10, 2026, it became the first U.S.-operating cannabis company to trade on a major U.S. exchange, under the ticker symbol "TRLV."[3] Trulieve describes itself as "the largest cannabis retailer in the United States."[4] Shortly after the Order, Trulieve announced that it had filed applications with the DEA to register certain state-licensed medical cannabis operations under the Order's expedited registration pathway,[5] and on November 2, 2026, received DEA

[1] Trulieve, Momenta Capsules Ratio 30ct 300mg product page, tinyurl.com/Mmenta (last visited Nov. 23, 2026).

[2] Trulieve, THC Capsules category page, tinyurl.com/TrlvCaps (last visited Nov. 23, 2026).

[3] *See Trulieve Announces Uplist to NYSE*, Investing News (June 5, 2026), tinyurl.com/TRLV-list; *Trulieve Is First US Cannabis Company to Trade on NYSE*, MJBizDaily (June 11, 2026), tinyurl.com/TRLV-nyse.

[4] Trulieve Cannabis Corp., Quarterly Report (Form 10-Q), at 18 (May 7, 2026) (period ended Mar. 31, 2026)

[5] *Trulieve Announces Applications Filed for DEA Registration of State Licensed Medical Marijuana Businesses*, Investing News (Apr. 29, 2026), tinyurl.com/TRLV-dea.

registrations for certain retail facilities.[6] Trulieve's products are dispensed for therapeutic use without IND application and FDA approval; without clinical-trial data; without chemistry, manufacturing, and control (CMC) review; and without demonstrating controlled formulation and stability. Trulieve's products thus do not have proven therapeutic efficacy.

- **Cresco Labs Inc.** (Cresco), a multistate operator whose Remedi brand is expressly positioned as a pharmaceutical-style medical product. In May 2026, Cresco announced that it had registered its state-licensed medical cannabis operations with the DEA under the expedited registration pathway created by the Rescheduling Order.[7] Cresco states that "Remedi products are specifically tailored to meet the needs of medical patients, and they come in precise doses and form factors similar to other health and wellness products," and that "Remedi was originally created for patients with existing medical conditions in medical cannabis states."[8] Remedi's capsule line includes formulations

[6] *Trulieve Receives DEA Registrations for State-Licensed Medical Marijuana Operations*, Cannabis Bus. Times (Nov. 2, 2026), tinyurl.com/TRLV-reg.

[7] *Cresco Labs Marks Historic Step Forward with Medical Cannabis Facility DEA Registration* (May 27, 2026), tinyurl.com/Cresco-dea.

[8] Cresco Labs / Remedi brand materials, crescolabs.com/brands; Leafly, Remedi by Cresco Labs.

comparable to MMJ's, such as Relief 1:1 Capsules (2.5 mg CBD + 2.5 mg THC per capsule) and Rest 1:5 Capsules (1 mg CBD + 5 mg THC per capsule).[9] Cresco's Chief Commercial Officer, Greg Butler, has publicly marketed these "category-specific … capsules" to medical patients.[10] Remedi capsule products are dispensed for therapeutic use without IND application and FDA approval; without clinical-trial data; without chemistry, manufacturing, and control (CMC) review; and without demonstrating controlled formulation and stability. Cresco's products thus do not have proven therapeutic efficacy.

- **Verano Holdings Corp.** (Verano), through its Avexia brand, markets microdosing THC/CBD tablets for "pain relief" and other therapeutic uses. In May 2026, Verano filed applications with the DEA to register its state-licensed medical cannabis operations under the expedited registration pathway created by the Rescheduling Order.[11] Verano's products include 1:1 tablets (2.5 mg THC + 2.5 mg CBD) and 4:1

[9] Leafly, Remedi Relief 1:1 Capsules (last visited Nov. 23, 2026), tinyurl.com/leaflycaps; Remedi Rest 1:5 Capsules (last visited July 2026), tinyurl.com/leaflycaps-2.

[10] Press Release, Cresco Labs, *Cresco Labs Launches Remedi Cannabis Brand Into New York* (Oct. 14, 2020), tinyurl.com/Rmedi-2.

[11] *Verano Submits DEA Registration Applications for State-Licensed Medical Cannabis Businesses Following Landmark Federal Rescheduling Order*, Globe Newswire (May 13, 2026), tinyurl.com/VeranoDEA.

tablets (10 mg CBD + 2.5 mg THC),[12] distributed through Verano and affiliated dispensaries. Avexia tablets are dispensed for therapeutic use without IND application and FDA approval; without clinical-trial data; without chemistry, manufacturing, and control (CMC) review; and without demonstrating controlled formulation and stability. Verano's products thus do not have proven therapeutic efficacy.

- **Green Thumb Industries Inc.** (Green Thumb or GTI), a Chicago-based multistate operator, manufactures and sells cannabinoid products for medical and adult use in precisely dosed oral formats. These products include tinctures marketed for therapeutic use under GTI's health-and-wellness brand, Doctor Solomon's.[13] In May 2026, Green Thumb announced that it had filed applications with the DEA to register certain state-licensed medical cannabis operations under the expedited registration pathway created by the Rescheduling Order.[14] None of

[12] Verano/Avexia product listings (last visited July 2026), leafly.com/brands/avexia/catalog; Columbia Care, VE 1:1 Avexia Microdose Tablets (last visited July 2026), tinyurl.com/Avexia; Columbia Care, VE 4:1 Avexia Microdose Tablets (last visited July 2026), tinyurl.com/Avexia-2.

[13] *Our Ingredients*, Green Thumb Industries (last visited July 2026),tinyurl.com/DrSlmn .

[14] Green Thumb Industries Inc., *Green Thumb Industries Files Applications for DEA Registration Following Historic Rescheduling of Medical Cannabis* (May 4, 2026), tinyurl.com/GrnThDEA.

Green Thumb's cannabinoid products has undergone FDA IND review, clinical trials, CMC characterization, or the stability and controlled-formulation requirements MMJ has satisfied, yet its state-licensed products now receive Schedule III treatment and its operations are positioned for expedited federal registration—the same registration that MMJ has diligently sought since December 2018. Green Thumb's products do not have proven therapeutic efficacy.

- **TerrAscend Corp.** (TerrAscend) manufactures and distributes cannabis products for oral administration, including medical-cannabis capsules sold under its Ilera brand.[15] Shortly after the Order, TerrAscend announced that it would be "following all the steps dictated by the DOJ and DEA to register [its] state-licensed medical facilities."[16] TerrAscend's cannabis capsules are dispensed for therapeutic use without IND application and FDA approval; without clinical-trial data; without chemistry, manufacturing, and control (CMC) review; and

[15] Press Release, TerrAscend Corp., *TerrAscend's Award-Winning Apothecarium to Debut Its First Two Pennsylvania Dispensaries* (March 30, 2020),tinyurl.com/Terr-Ilera .

[16] Margaret Jackson, *How Cannabis MSO TerrAscend Is Responding to Federal Marijuana Rescheduling*, MJBizDaily (Apr. 30, 2026), tinyurl.com/TerrAscDEA.

without demonstrating controlled formulation and stability. TerrAscend's products thus do not have proven therapeutic efficacy.

18. Each of these competitors markets a precisely dosed, orally administered cannabinoid product for therapeutic use in the same format that MMJ has developed. Yet none of them has followed the federal pharmaceutical-development pathway that MMJ has pursued: DEA registration, FDA IND application, CMC review, clinical trials, and stability studies. The Rescheduling Order confers Schedule III legitimacy to these competitors' state-licensed products without requiring compliance with this well-established federal pathway.

19. The state-licensed marijuana products covered by the Rescheduling Order include products that have never undergone FDA review, have never been tested in clinical trials to prove efficacy, and lack standardized dosing, validated manufacturing controls, or regulatory-grade characterization. The Order thus opens the floodgates to MMJ's competition: Their products may now be marketed or dispensed for therapeutic use without having followed the same requirements—DEA registration, FDA IND application, CMC review, clinical trials, and stability / controlled-formulation analysis—that MMJ has scrupulously followed. In effect, the Order rewards MMJ's competitors who built their position through federally unsanctioned state medical-marijuana regimes rather than by proceeding through the established federal pharmaceutical pathway. In this way, the Order substantially

erodes the critical market distinction that MMJ carefully built for itself through strict federal compliance.

20. Prior to the Rescheduling Order, many of MMJ's direct competitors candidly acknowledged in filings with the Securities & Exchange Commission that their medical marijuana businesses were subject to substantial legal risk due to marijuana's Schedule I status and their unabashed violation of federal law. These competitors also acknowledged that their illicit trafficking in a Schedule I controlled substance subjected them to a heightened tax burden and a substantial risk-premium to obtain financial services, among other things.

21. For example, Verano's 2025 Annual Report lists as the company's very first risk factor, "the current illegality of cannabis under federal law, the U.S. federal regulatory landscape and enforcement related to medical … use cannabis." Verano Holdings Corp., Annual Report, at 1, 30 (Form 10-K) (Mar. 12, 2026). Verano also highlighted potential liability under federal "money laundering laws and the Racketeer Influenced and Corrupt Organizations Act" (RICO), "the impact of Section 280E" of the tax code, the "limited intellectual property protection available for cannabis products," their "lack of access to federal bankruptcy protections" as a vendor of contraband under the CSA, and "the difficulties cannabis businesses face accessing and maintaining banking or financial services due to federal regulations," among other things. *Id.* at 1–2, 30–33, 53–54, 56, 58–59, 67. Trulieve's 2025

Annual Report identified the same Schedule I related risks. *See* Trulieve Cannabis Corp., Annual Report, at 18–19, 22–25, 27 (Form 10-K) (Feb. 26, 2026). Similarly, Cresco's 2025 annual SEC filing (as a foreign private issuer) likewise identified risks flowing from its trafficking in a Schedule I substance. *See* Cresco Labs Inc., Annual Information Form, at 82–88, ex. 99.4 to Form 40-F (Mar. 14, 2025). Cresco also warned that cannabis businesses like it had "limited, if any, access to credit card processing services" and therefore were "largely cash-based," which "complicates the implementation of financial controls and increases security issues." *Id.* at 27, 36.

22. The Rescheduling Order relieves MMJ's competitors like Verano, Trulieve, and Cresco of these serious risks attendant to their marketing of non-FDA-approved cannabis-therapeutics through state medical marijuana programs. The Order absolves these competitors of falsely marketing their products as having proven medical benefits despite lacking any clinical-trials proof of efficacy. And already, these competitors have begun to reap the substantial financial benefits of the Order's tax relief under Section 230E. *See, e.g.*, Trulieve Cannabis Corp., Quarterly Report, at 25 (Form 10-Q) ("The decrease in provision for income taxes was primarily driven by the Company not applying IRC Section 280E for the 2026 taxable year, where the prior period included the impact of IRC Section 280E.").

23. MMJ's injury is immediate and compounding. Every day the Order remains in effect, state-licensed marijuana products gain market access, consumer acceptance, provider familiarity, investor confidence, and perceived federal legitimacy. That erodes the market position and capital-raising value MMJ built by pursuing FDA approval and DEA compliance. MMJ estimates the economic damage to its business totals $38 million, based on pro-rated sales data in cannabis capsule-category sales.[17]

24. The Order has already harmed MMJ's access to capital. In February 2026, a long-time investor who had previously invested approximately $1 million in MMJ advised me that he would not invest further because of uncertainty created by federal rescheduling efforts and the resulting competitive harm to MMJ. Prospective institutional investors have questioned why Schedule III economic benefits and federally recognized market access are being extended to state-licensees while MMJ's federally compliant pharmaceutical program remains delayed by agency processes.

25. MMJ cannot avoid this injury by abandoning its federal pathway. MMJ has sunk substantial investment into FDA and DEA compliance, its DEA bulk-

[17] *See* Headset, *Cannabis Capsules Product Category*, tinyurl.com/HdstCaps (last visited Nov. 23, 2026) (reporting approximately $72.3 million in U.S. cannabis capsule-category retail sales for October 2025 through September 2026); *see also* Headset, *Insights Sampling Process & Analytical Methods*, tinyurl.com/HdstMthd (last updated Mar. 4, 2024).

manufacturer application remains pending, and the new Schedule III state-licensee pathway is directed to operators holding state medical-marijuana licenses rather than to an applicant already awaiting action under DEA's existing registration process.

26. The Order also injured MMJ procedurally. If MMJ had had the opportunity to participate in a formal rulemaking on the record or otherwise offer comment on the Order before it took effect, MMJ would have submitted evidence that, among other things, reproducible chemistry, standardized dosing, CMC manufacturing controls, stability data, FDA clinical review, DEA registration, and FDA labeling are critical controls for drugs available for medical use outside of Schedule I. These controls, MMJ would have explained, distinguish legitimate, scientifically-grounded pharmaceutical products from merely state-licensed retail products, which do not bear any of the hallmarks of science-based medicine, and so, do not deserve the federal imprimatur conveyed by this Order.

27. A favorable decision vacating the Order would redress MMJ's injury by removing Schedule III status from state-licensed products unless and until the agency lawfully completes the required process. That relief would restore the regulatory distinction between FDA-DEA compliant pharmaceutical development and state-licensee products that have not undergone that process.

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

Dated: November 23, 2026

Duane Boise

Duane Boise
Chief Executive Officer
MMJ International Holdings, Inc.

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

SAM, INC. and NATIONAL DRUG AND ALCOHOL SCREENING ASSOCIATION, INC., *Petitioners*, v. U.S. DEPARTMENT OF JUSTICE; TODD BLANCHE, in his official capacity as acting Attorney General; DRUG ENFORCEMENT ADMINISTRATION; TERRANCE C. COLE, in his official capacity as Administrator of the Drug Enforcement Administration, *Respondents*.	**Case No. 26-1106** Consolidated with Case 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 (NDASA), a position I have held since 2019. NDASA is the national trade association for the drug and alcohol testing industry, representing laboratories, MROs, collection sites, third party administrators and employers. I have personal knowledge of NDASA's mission, operations, and the impact that the sudden transfer of marijuana in state-licensed programs from Schedule I to Schedule

III has had and will continue to have on NDASA's members. The facts in this declaration come from my knowledge and information provided to me by members in the course of my role and I could competently testify to them if necessary.

2. I make this Declaration in support of the petitions in the consolidated cases (Nos. 26-1106, 26-1130, 26-1136) challenging 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"). I previously submitted a declaration in support of the joint motion for a stay pending review on June 9, 2026 and in support of the reply brief in support of a stay on July 14, 2026.

3. This lawsuit is germane to NDASA's purposes because the Rescheduling Rule imposes costs and operational burdens on its members.

A. Background

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

5. 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 700 organizations and businesses. Members include private

employers regulated by the Department of Transportation 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, 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.

B. Drug Test Policy Costs

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

7. There are approximately 2 million employers who voluntarily choose to pay for drug tests to ensure workplace safety and productivity.

8. Employers that administer drug tests to their employees must have in place a written drug testing policy before they can administer a drug test to their employees. Many 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, 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 raise questions under 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.

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

14. Since the Rescheduling Order has come out, I know of at least two NDASA members (both businesses with many employees) who have incurred costs revising their drug test policies to account for marijuana's hybrid schedule designation following the Rescheduling Order.

15. Based on my years of training and experience in the drug testing industry, companies are reluctant to publicly disclose changes made to their drug test policy (beyond giving their employees notice), especially when the changes concern marijuana. Such companies are concerned about, among other things, inviting litigation challenging their company's restrictions on employee use of marijuana.

16. I have also spoken with a dozen other employer members of NDASA who have told me they intend to revise their drug test policies as a result of the Rescheduling Order. Most of them plan to make that change within months and have said they are holding off only until the Drug Enforcement Administration

concludes its pending rulemaking proceeding on rescheduling the remainder of marijuana, so that they do not have to pay to revise their policies twice. Once marijuana rescheduling is finished, these employers will incur costs ranging from $500 to $3,000 each to make necessary updates to their company drug test policies.

17. For NDASA's 700 employer members who are not covered by federal drug testing regulations and nevertheless require their employees to submit to drug tests, I estimate that the final cost of revising drug policies will exceed $700,000.

18. I estimate that NDASA members will accrue these costs—indeed, some already have—as employers adjust to marijuana's new status and DEA's parallel rulemaking proceeding ends.

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



Dated: November 24, 2026 M. Jo McGuire

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

SAM, INC. and NATIONAL DRUG AND ALCOHOL SCREENING ASSOCIATION, INC., *Petitioners*, v. U.S. DEPARTMENT OF JUSTICE; TODD BLANCHE, in his official capacity as acting Attorney General; DRUG ENFORCEMENT ADMINISTRATION; TERRANCE C. COLE, in his official capacity as Administrator of the Drug Enforcement Administration, *Respondents*.	**Case No. 26-1106** Consolidated with Case Nos. 26-1130 and 26-1136

DECLARATION OF MYRANDA ROYS

I, Myranda Roys, declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am the Senior Vice President of i3screen, a position I have held since 2021. I have personal knowledge of i3screen's operations, products, pricing, and customer relationships, and of the effects of the transfer of state-licensed "medical" marijuana from Schedule I to Schedule III of the Controlled Substances Act has had on i3screen's business. The facts in this declaration come from my own observations

and knowledge, and from i3screen's business records, which are maintained in the ordinary course of business. I could testify competently to them if called to do so.

2. I make this Declaration in support of the petitions in the consolidated cases (Nos. 26-1106, 26-1130, 26-1136) challenging 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. i3screen is a member of the National Drug and Alcohol Screening Association (NDASA), the national trade association for the drug and alcohol testing industry.

4. Workplace drug testing involves several participants, each with a separate function. Specimen collectors obtain a biological sample, such as urine or oral fluid. A laboratory analyzes it. A Medical Review Officer (MRO), a licensed physician, evaluates non-negative laboratory results, determines whether there is a legitimate medical explanation, validates any medical explanation to confirm its legitimacy, and reports a verified result to the employer. A Third Party Administrator (TPA) in simplest terms acts as a coordinator for these services to be completed and facilitated.

5. i3screen is a technology company that provides software and drug-testing services for managing drug and alcohol testing and occupational health screening programs for TPAs, Credit Reporting Agencies (CRAs), and MROs. i3screen's services include drug and alcohol testing program management software; MRO services; random testing program management; compliance support and management of laboratory and collection networks; and several additional services related to the occupational health screening industry (for instance, credentialing employees).

6. i3screen's network includes over ten thousand collection sites and approximately twenty-five laboratory partners.

7. i3screen's customers include CRAs, TPAs, and employers. Approximately 90% of i3screen's revenue comes from CRAs or TPAs that resell i3screen's drug testing services to their own clients. Approximately 10% of i3screen's revenue comes from direct employer customers, and other MRO providers. i3screen's CRA and TPA clients include employers subject to federal drug-testing regulations, such as those in transportation industries, and employers that drug test voluntarily.

8. In 2025, approximately 65% of i3screen's drug-testing revenue came from testing programs not subject to federal regulation.

9. i3screen earns revenue from fees per completed test. These may include the fee for MRO review, the laboratory testing fee, collection fees, random program administration fees, and platform subscription or licensing fees.

10. i3screen employs seven licensed physicians as MROs, including a Chief Medical Review Officer. In 2025, i3screen's MROs reviewed approximately 236,000 non-negative drug test results, of which approximately 106,000 were non-negative for delta-9 tetrahydrocannabinol (THC). Almost half of i3screen's drug-test revenue is derived from non-negative tests involving THC. These figures reflect only internal reviews conducted by i3screen's employed MRO team.

11. Based on my experience in the drug testing industry and direct feedback from i3screen's customer base, the Rescheduling Order has created severe operational and financial burdens for i3screen, depending on how i3screen's employer customers choose to adapt their drug test policies.

12. Many i3screen employer customers have continued testing for marijuana, which creates additional costs on i3screen that we are unable to pass on to our customers. Now that marijuana is no longer a Schedule I substance but instead is dual classified in Schedules I and III—depending on whether it was obtained in a state-licensed program—reviewing non-negative tests for THC now requires our physicians and support staff to spend significantly more employee hours investigating whether a donor possesses a valid, legitimate medical explanation.

Where the donor has a state-authorized medical marijuana card, this requires contacting third parties to determine, among other things, whether the card is authentic (and not a forgery) and that it was issued prior to date of the donor's drug test.

13. Since the Rescheduling Order, i3screen has had to hire at least two additional staff members that we would not have had to hire if the Rescheduling Order had not issued last April.

14. Since the Rescheduling Order, the time and labor cost required to review a non-negative THC test has increased 20%. It is difficult to quantify the precise dollar amount of added costs that this 20% figure represents, but based on my review of i3screen's business records and the fact that we have had to hire additional staff in response to the Rescheduling Order, I am confident that i3screen has incurred at least $20,000 in additional costs, and it may be much more than that. Based on my training and experience, if i3screen passed these additional costs to our customers, we would lose a substantial amount of drug testing business as employers would opt to remove marijuana from their drug test program altogether.

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

Signed by:
Myranda Roys 11/24/2026 | 4:16 PM EST
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Dated: November 24, 2026 Myranda Roys

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

SAM, INC. and NATIONAL DRUG AND ALCOHOL SCREENING ASSOCIATION, INC., *Petitioners*, v. U.S. DEPARTMENT OF JUSTICE; TODD BLANCHE, in his official capacity as acting Attorney General; DRUG ENFORCEMENT ADMINISTRATION; TERRANCE C. COLE, in his official capacity as Administrator of the Drug Enforcement Administration, *Respondents*.	**Case No. 26-1106**

DECLARATION OF LUKE NIFORATOS

I, Luke Niforatos, declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am the Executive Vice President of SAM Inc. (Smart Approaches to Marijuana), one of the Petitioners in this case. I make this Declaration in Support of Petitioners' Petition for 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. 22,714 (Apr. 28, 2026) (Rescheduling Order).

2. SAM is a 501(c)(3) organization. I have personal knowledge of SAM's mission, operations, programs, services, finances, involvement in prior rulemakings, and the impact that the sudden transfer of medical marijuana subject to state-issued licenses from Schedule I to Schedule III under the Controlled Substances Act will have on SAM's ability to carry out its core activities. The facts in this affidavit come from my own personal observations to the best of my recollection, and I could competently testify to them if necessary.

3. SAM's core mission is preventative: Through seminars, trainings, and educational materials, SAM seeks to spread understanding of the many dangers that marijuana presents and so to prevent the harms that come from marijuana use, including addiction and its consequences.

4. Marijuana is more addictive than ever. Its psychoactive component, delta-9-tetrahydrocannabinol (THC), is responsible for its addictive properties. The average THC concentration in marijuana seized by DEA rose from about 3% in 1991

to 17.1% in 2017.[1] Dispensary marijuana flower now averages over 15% THC and even reaches 35%.[2] Concentrates such as oils and dabs reach 99% THC.[3]

5. Physical dependence occurs in up to 40–50% of regular marijuana users, and 90% of those diagnosed with cannabis use disorder (CUD) report physical dependence.[4] About three in ten past-year marijuana users have a marijuana use disorder.[5] In 2022, 5.7 million young adults (ages 18–25) and 1.3 million adolescents (ages 12–17) had a marijuana use disorder.[6] Daily marijuana users numbered over 15 million in 2022, up from 5.35 million in 2012.[7] Higher-potency products are associated with higher rates of addiction.[8]

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[1] Memorandum from Rachel L. Levine, Assistant Sec'y, HHS, to Anne Milgram, Adm'r, DEA, Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act 11-12 (Aug. 29, 2023) (HHS Recommendation); *see also* Nat'l Inst. on Drug Abuse, *Cannabis Potency Data* (Nov. 3, 2022), perma.cc/ZFP9-GSFS (average potency rose from 3.96% THC in 1995 to 15.34% in 2021).

[2] Mary Catherine Cash et al., *Mapping Cannabis Potency in Medical and Recreational Programs in the United States*, 15 PLOS One e0230167, at 5, 14 (2020).

[3] Isabella Backman, *Not Your Grandmother's Marijuana: Rising THC Concentrations in Cannabis Can Pose Devastating Health Risks*, Yale Sch. of Med. News (Aug. 30, 2023), perma.cc/LK4N-LSR3.

[4] HHS Recommendation, *supra*, at 61.

[5] Deborah S. Hasin et al., *Prevalence of Marijuana Use Disorders in the United States Between 2001–2002 and 2012–2013*, 72 JAMA Psychiatry 1235, 1235 (2015).

[6] Substance Abuse & Mental Health Servs. Admin., *Results from the 2022 National Survey on Drug Use and Health: Detailed Tables* tbl. 5.1A (2023).

[7] *Id.* tbl. 8.3A; Substance Abuse & Mental Health Servs. Admin., *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables* tbl. 7.19A (2013).

[8] Kat Petrilli et al., *Association of Cannabis Potency with Mental Ill Health and Addiction: A Systematic Review*, 9 Lancet Psychiatry 736 (2022).

6. Cannabis use is strongly and consistently associated with the later development of psychosis and psychotic disorders.[9] Daily users of marijuana with 10% THC or more are nearly five times more likely to develop a psychotic disorder than non-users.[10] About one-fifth of schizophrenia cases among young men could be prevented by averting CUD.[11] In Colorado, emergency department visits for psychosis rose 24% after legalization.[12] Adolescent marijuana use is associated with depression and suicidality in young adulthood.[13] Among young adults without depression, nondaily marijuana users have more than double the rate of suicidal ideation of non-users, and those with CUD have more than four times the rate.[14]

7. Given these and other harms caused by marijuana, SAM expended substantial resources in presenting the scientific and medical bases for marijuana's continued status as a Schedule I drug in response to the Drug Enforcement Agency (DEA) Notice of Proposed Rulemaking to reschedule marijuana in 2024. SAM

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[9] NASEM, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* 295 (2017).

[10] Marta Di Forti et al., *The Contribution of Cannabis Use to Variation in the Incidence of Psychotic Disorder Across Europe (EU-GEI): A Multicentre Case-Control Study*, 6 Lancet Psychiatry 427 (2019).

[11] Carsten Hjorthøj et al., *Association Between Cannabis Use Disorder and Schizophrenia Stronger in Young Males than in Females*, 53 Psychol. Med. 7322 (2023).

[12] George Sam Wang et al., *Impact of Cannabis Legalization on Healthcare Utilization for Psychosis and Schizophrenia in Colorado*, 104 Int'l J. Drug Pol'y 103685 (2022).

[13] Gabriella Gobbi et al., *Association of Cannabis Use in Adolescence and Risk of Depression, Anxiety, and Suicidality in Young Adulthood: A Systematic Review and Meta-analysis*, 76 JAMA Psychiatry 426 (2019).

[14] Beth Han et al., *Associations of Suicidality Trends with Cannabis Use as a Function of Sex and Depression Status*, 4 JAMA Network Open e2113025 (2021).

submitted 149 pages of comments and exhibits for the agency's consideration. The then-Administrator designated SAM an interested party to participate at the formal rulemaking hearing (Hr'g Dkt. 24-44), and the presiding ALJ independently determined that SAM had standing to participate. 91 Fed. Reg. 27778, 27779 (Apr. 28, 2026). SAM submitted a 15-page prehearing statement, proffered 96 pages of exhibits, and designated an expert witness.

8. The Acting Attorney General cancelled the 2024 formal rulemaking hearing because of the present Rescheduling Order, which he issued at the President's directive that marijuana be rescheduled "in the most expeditious manner" possible. Executive Order (E.O.) 14370; *see* 91 Fed. Reg. 27778, 27778-79 (Apr. 28, 2026). Because the Acting Attorney General canceled this formal rulemaking hearing in favor of the procedurally truncated Order at issue here, SAM's exhibits were never entered into evidence, and SAM's expert witness never had the opportunity to give on-the-record testimony.

9. Marijuana policy is among the most salient social issues in American politics today. During the 2024 election, both the Democratic and Republican parties vigorously discussed the issue, with the Democratic Party platform touting the fact that President Biden had taken "a major step to reschedule cannabis" in his first term, and President Trump openly endorsing federal rescheduling and state-level

legalization.[15] More recently, Congress has split over marijuana policy, with the House Appropriations Committee reporting out a bill that would defund DOJ's current rescheduling efforts, and the parallel Senate committee conspicuously stripping out that same provision.[16] Because of the marijuana's social and political salience, millions of dollars are spent annually—especially in election years—to urge each side of the marijuana policy debate.[17]

10. In legalizing state "medical" marijuana, the Order is intended to—and inevitably will—spur significant growth in the booming, multi-billion-dollar cannabis industry.[18] A significant increase in the availability of legal "medical" marijuana will predictably and significantly increase the prevalence of marijuana abuse and addiction, both through its nominally "medical" use and through its

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[15] Jacob Sullum, *Trump Endorses Federal Marijuana Reforms and Reiterates His Support for Legalizing Pot in Florida*, Reason (Sept. 9, 2024), tinyurl.com/mwbbfjum; '24 Democratic Party Platform, at 42 (2024), tinyurl.com/24DemPlat.

[16] *Compare* H.R. 8845, 119th Cong. § 591 (as reported by H. Comm. on Appropriations, May 15, 2026) ("None of the funds appropriated under this Act or otherwise made available by this Act may be used to reschedule marijuana"), *with* S. Comm. on Appropriations, 119th Cong., *Commerce, Justice, Science, and Related Agencies Appropriations Act, 2027* 112-41 (Comm. Print 2026) (markup dated Nov. 12, 2026, omitting the House rescheduling rider while retaining protections for state medical-marijuana programs in § 531); *see also* Tom Angell, *Congressional Committee Votes To Block Marijuana Rescheduling, Even As Trump Administration Moves Forward With The Reform*, Marijuana Moment (May 14, 2026), tinyurl.com/2sv9fju3.

[17] *See, e.g.*, *Who Funds Marijuana Legalization?*, Learnaboutsam.com (last visited Nov. 19, 2026), tinyurl.com/SAM-MJmoney; *Follow the Money: How Big Tobacco, Big Alcohol and Big Pharma Are Bankrolling Big Marijuana*, WRD.news (Oct. 8, 2026), tinyurl.com/hd2mmb4d.

[18] Grand View Research, U.S. Medical Marijuana Market Size & Outlook, 2023–2030 (last visited Nov. 19, 2026) (estimating U.S. medical marijuana revenue at $10.6 billion, burgeoning to $24.8 billion by 2030).

frequent diversion from "medical" to recreational use. This will, in turn, cause increased marijuana-linked psychosis, depression, and suicide.

11. SAM offers educational programming services about the dangers of marijuana. SAM personnel travel across the country to provide educational seminars and trainings for doctors, lawmakers, law enforcement, and drug prevention abuse organizations. These programs generally cover the science and abuse-liability profile of marijuana. In these presentations, SAM explains that marijuana has no safe or commonly accepted medical use, relying in substantial part on the substance's Schedule I designation and the scientific evidence that the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) have—for decades—consistently found supportive of that designation.

12. The Order will require SAM to incur significant expenditures outside its ordinary expenses to retool its substantial body of educational materials. SAM's current educational materials are premised on the longstanding regulatory treatment of marijuana as a Schedule I narcotic. That regulatory treatment is interwoven throughout myriad materials that SAM uses to explain the dangers of marijuana. The Order will require SAM to overhaul its entire curriculum, written resources, PowerPoint presentations, video resources, and educational activities.

13. These resources include at least seven (7) presentation decks of approximately ninety (90) slides each, eleven (11) short-form primers and other templates, and thirteen (13) substantive pages on SAM's homepage (learnaboutsam.org). All of these will require substantial staff time and attention to revise or recreate.

14. SAM also spent $5,000 creating a professional training video explaining marijuana's designation as a Schedule I substance and why the drug belonged in Schedule I. The Order makes that video resource obsolete and SAM will need to create a new video resource.

15. This effort will require rewriting, redesigning, and fundamentally altering the entire process and delivery of SAM's educational services. I estimate that SAM will need to devote about 260 staff hours to revamping its educational and training materials, and at a total cost of between $30,000 and $50,000.

16. In addition to SAM's core educational offerings that advance its primarily preventative mission, SAM also occasionally provides free remedial services to organizations and individuals harmed by marijuana addiction.

17. These free remedial services, historically provided on an ad hoc basis, have involved matching individuals addicted to marijuana with capable treatment providers. Because of SAM's extensive contacts with such providers who support SAM's mission, SAM is able to help place people suffering from marijuana

addiction with rehabilitation facilities or other counselling providers, upon request. But these occasional remedial services are ancillary to SAM's core mission of marijuana-abuse prevention.

18. By substantially reducing restrictions on access to marijuana and removing the federal criminal bar on marijuana use for state "medical" marijuana programs, the Order will dramatically increase marijuana use under state "medical" marijuana programs and predictably increase marijuana addiction as a consequence. Increased addiction, in turn, will increase demand for SAM's free placement and referral services. This will necessarily divert more of SAM's limited resources towards remediating the effects of marijuana addiction, leaving fewer resources remaining for SAM's core activities that are focused on its mission of preventing marijuana abuse and addiction ex ante.

19. SAM also runs a nationwide program called the Parent Action Network (PAN) that serves parents of children who are addicted to marijuana or who tragically died in connection with marijuana abuse and its consequences (*e.g.*, marijuana-induced psychosis and suicide, incapacitated driving). PAN's mission is to equip these parents with the tools and resources they need to tell their stories in the public square. PAN does so by offering them various educational resources and briefings, and by coaching them on giving testimony, writing letters to the editor, meeting with legislators, and similar advocacy opportunities.

20. In addition to these core activities, PAN provides occasional remedial services to these parents. Specifically, during weekly meetings, SAM connects these parents with peer-recovery support specialists and intervention professionals. These remedial services are ancillary to PAN's core mission of helping families afflicted by marijuana abuse tell their stories publicly, and operating the Parent Action Network itself is ancillary to SAM's core preventative mission.

21. I anticipate that the Order will divert SAM's limited resources by requiring more SAM staff-hours—indeed, more full-time personnel—to operate the Parent Action Network. That is so because the Order will predictably increase the number of adult and minor children addicted to marijuana or who die in connection with marijuana abuse. This too will force SAM to take resources away from its core mission of preventing marijuana use in the first place.

22. In sum, the more SAM has to expand services that address the after-the-fact consequences of marijuana use (addiction-therapy placement, grief counseling, etc.), the less SAM can devote itself to its core objective of preventing marijuana use and abuse in the first place. For this reason, the Order will impair SAM's core mission.

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



Dated: November 20, 2026 Luke Niforatos

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

Consolidated with Nos. 26-1106 and 26-1130

DECLARATION OF CHRIS REED, PRESIDENT, NEW DIRECTIONS ADDICTION RECOVERY SERVICES

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

1. I am over eighteen years of age and am competent to testify to the matters stated herein. I make this declaration based on my personal knowledge and my review of New Directions Addiction Recovery Services' business, program, and participant records, which are kept in the ordinary course of its operations.

2. I am the founder and President of New Directions Addiction Recovery Services ("New Directions"). In that role, I have personal knowledge of New Directions' mission, programs, staff, participants, and the impact of AG Order No. 6754-2026 (the "Order" or "Rescheduling Order") on New Directions' substance-use-disorder recovery services.

3. New Directions is a registered 501(c)(3) nonprofit organization based in McHenry County, Illinois. Its mission is to inspire recovery, foster community, and save lives. New

Directions is funded through private donations, grants from the McHenry County Mental Health Board, and, for the A Way Out Program, drug asset forfeiture funds of the McHenry County State's Attorney's Office. A Way Out charges participants no fees. An increase in the number of participants, or in the time each participant requires, therefore brings New Directions no additional revenue.

4. New Directions provides recovery support through programs including sober-living housing, The Other Side sober bar, Connect to Recovery, and the A Way Out Program.

5. Since September 2020, New Directions has operated the A Way Out Program on behalf of the McHenry County State's Attorney's Office. A Way Out serves McHenry County residents seeking a way out of substance dependence, connects participants to resources aligned with their recovery goals, and uses peer-support Community Navigators with lived experience in substance-use-disorder recovery. Community Navigators, including bilingual staff, work one-on-one with participants and their families. They provide peer support, help participants develop safety plans, support participants while they wait for treatment placement, help them move between levels of treatment, and connect them to community-based recovery support. The A Way Out hotline is staffed seven days a week, and New Directions staff are present in the Emergency Department of Northwestern Medicine Woodstock Hospital three days a week. In 2024, A Way Out served 2,462 participants.

6. Counseling people in recovery from substance-use disorders, including cannabis use disorder, has been part of New Directions' core work since well before the Order. A Way Out is open to any McHenry County resident seeking a way out of substance dependence, whatever the substance. New Directions' relapse-prevention work also addresses cannabis use by

participants recovering from other substances, because cannabis use is a relapse risk for those participants.

7. Relapse-prevention counseling depends on participants accepting accurate information about the risks of the substances they use. When a participant takes a medication, New Directions' staff ordinarily rely on the product's FDA-approved labeling, prescribing information, and the participant's prescriber to discuss dosing, interactions, contraindications, and dependence risk. Those sources allow staff to tell participants, with confidence, what is and is not medically supported.

8. I understand that, to place a drug in Schedule III, the federal government must find that the drug has a currently accepted medical use in treatment in the United States and a lower potential for abuse than drugs in Schedules I and II. 21 U.S.C. § 812(b)(3). Before the Order took effect on April 22, 2026, all marijuana was in Schedule I, which reflects findings that it has no currently accepted medical use and a high potential for abuse. The Order moved marijuana subject to a qualifying state medical-marijuana license, along with FDA-approved drug products containing marijuana, to Schedule III.

9. In my experience, participants and families associate Schedule III with prescription medicines such as testosterone, ketamine, and acetaminophen with codeine. Those medicines are FDA-approved and come with labeling, standardized dosing, package inserts, interaction and contraindication information, and a prescriber.

10. The Rescheduling Order places marijuana subject to state medical-marijuana licenses into Schedule III without any of those features. State-dispensary marijuana has no FDA-approved labeling, dosing protocols, package inserts, contraindication information, drug-interaction data, monitoring guidance, or standardized formulation information of the kind that

clinicians and recovery providers ordinarily use when counseling patients about medicine. As a result, the federal designation tells participants that marijuana is accepted medicine with a lower potential for abuse, but nothing stands behind that message that a counselor can point to or rely on.

11. Illinois has had a medical cannabis program since 2014 and has permitted adult-use marijuana since January 1, 2020. Before the Order, participants who raised marijuana with our staff typically said that it was legal under state law. Our staff could respond that legal is not the same as safe or medically approved, and that the federal government classified marijuana as having no accepted medical use and a high potential for abuse. Since the Order, that response is no longer available for state-licensed medical marijuana, and participants and families do not distinguish between medical and adult-use products. They now cite the federal government's own findings to dispute what our staff tell them.

12. Since the Order, participants and family members have regularly told New Directions staff that marijuana is now federally recognized medicine, or have cited the Order or federal rescheduling, when discussing cannabis use and relapse risk.

13. In those conversations, staff cannot point to FDA labeling, a package insert, or prescribing information to show participants why the federal designation does not mean that state-dispensary marijuana is safe or medically appropriate for them. Instead, staff must use counseling sessions to explain the difference between Schedule III status and FDA approval, and some participants reject that explanation because it contradicts the federal government's own findings.

14. This interferes with the counseling service itself. Sessions that would otherwise address relapse triggers, safety planning, treatment placement, and family support are now spent

disputing the federal government's message. In my experience, participants who do not accept the counselor's information are less likely to keep cannabis abstinence in their recovery plans.

15. Because A Way Out charges no fees and New Directions' funding does not increase with demand, the additional counseling time the Order requires comes at the expense of other services. Since the Order, New Directions has diverted approximately 20% of its staff time, including the time of its Community Navigators, sober-living staff, and program leadership, to cannabis-specific relapse-prevention counseling, participant and family education, and related work responding to the Order's federal designation.

16. That time would otherwise have been used for sober-living support, peer navigation, participant follow-up, overdose-prevention training, and family support. More demand for counseling does not bring New Directions more resources; it spreads the same resources over more need.

17. These harms arise from New Directions' existing counseling and recovery services, which it provided well before the Order. They are operational costs and service impairments, not costs of lobbying, public advocacy, or opposing the Order. The staff time described above does not include time spent on this litigation or on public advocacy concerning the Order.

18. The interference described above comes from the federal designation, not from Illinois law. Participants' and families' statements since the Order refer specifically to federal recognition of marijuana as medicine and to its reduced federal classification, which are findings that only the Order makes.

19. A favorable decision vacating the Order would redress New Directions' injuries by returning state-licensed medical marijuana to Schedule I while the Drug Enforcement Administration ("DEA") follows the procedures required by the Controlled Substances Act

("CSA"). New Directions staff could again tell participants and families accurately that the federal government has not found marijuana to have a currently accepted medical use, and participants could no longer cite a federal finding to the contrary.

20. New Directions also lost the opportunity to present evidence on these harms to the agency before the Order became effective. If given notice and an opportunity to comment or participate in a hearing, New Directions would have submitted evidence concerning cannabis use disorder, relapse risk among people in recovery, patient counseling, the absence of FDA-approved labeling and dosing information for state-dispensary marijuana, and the effect of a Schedule III designation on recovery-service providers.

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

Dated: November 10, 2026

Chris Reed

Chris Reed
President
New Directions Addiction Recovery Services

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

Consolidated with Nos. 26-1106 and 26-1130

DECLARATION OF DAVID G. EVANS

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

1. I am over eighteen years of age and am competent to testify to the matters stated herein. I make this declaration based on my personal knowledge, my work for Cannabis Industry Victims Educating Litigators ("CIVEL"), and my review of CIVEL records.

2. I am Senior Counsel for CIVEL. CIVEL provides concrete programmatic and litigation services to marijuana victims. It develops and distributes legal and scientific guides, assists attorneys in recognizing and preparing cannabis-injury cases, connects victims with interested attorneys, provides public education, and creates and maintains materials used by litigators and victims.

3. CIVEL participated in the prior DEA rescheduling proceeding. CIVEL filed 512 pages across 17 documents as comments prior to the proceeding. Chief Administrative Law Judge John J. Mulrooney II recognized CIVEL as having associational standing in the DEA proceeding,

observing that CIVEL was engaged in the active representation of individuals claiming harmful effects from marijuana and equipped trial attorneys and the public with legal citations and tactical approaches for anti-marijuana litigation.

4. The Rescheduling Order directly impairs CIVEL's core programmatic litigation activities. As a result of the Order, CIVEL's litigation materials and services will now depend on explaining the distinction between FDA-approved medicine and state-commercial marijuana products that have not undergone ordinary federal drug approval.

5. The Order blurs that distinction by placing state-licensed marijuana products into Schedule III without requiring FDA approval, standardized dosing, FDA clinical-trial proof of efficacy and safety, validated manufacturing controls, or FDA approved labeling or proper medical prescriptions or warnings about cannabis and other dangerous drug interactions.

6. Because of the Order, CIVEL must divert staff time and resources from existing victim litigation assistance, attorney education, and case-preparation programs to monitor the Order's implementation, update its legal guides, address new defenses based on Schedule III status, educate attorneys about the difference between federal scheduling and FDA approval, and respond to increased inquiries from victims, lawyers, and the public.

7. These burdens are operational and programmatic. They are not merely ordinary litigation expenses or policy advocacy. The Order makes CIVEL's day-to-day litigation services more difficult because lawyers and victims must now confront the argument that state-licensed marijuana products carry federal medical legitimacy even when they lack FDA-approved labeling, dosing, and safety and effectiveness and other drug interaction information.

8. The Order also caused procedural injury. CIVEL had already been recognized as having standing to participate in the prior DEA hearing and was prepared to present evidence and

expert testimony. The Order terminated that process and deprived CIVEL of the opportunity to present evidence before state-licensed marijuana products received Schedule III status.

9. If given notice and an opportunity to comment or be heard before the Order took effect, CIVEL would have submitted evidence concerning cannabis-injury litigation, victim harms, contamination, high-potency products, psychosis and suicide injuries, the need for FDA safeguards, and the practical effect of federal Schedule III treatment on victims' claims and legal education.

10. A favorable decision vacating the Order would redress CIVEL's injuries by removing the Schedule III imprimatur for state-licensed products unless and until the agency follows lawful procedures and accounts for the harms CIVEL addresses in its programs.

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

Dated: November 20, 2026

David G. Evans
Senior Counsel, CIVEL

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

Consolidated with Nos. 26-1106 and 26-1130

DECLARATION OF KENNETH FINN, M.D.

I, Kenneth Finn, M.D., hereby declare under penalty of perjury pursuant to 28 U.S.C. § 1746 as follows:

1. I am over eighteen years of age and am competent to testify to the matters stated herein. I make this declaration based on my personal knowledge, professional experience, and review of relevant records.

2. I am a physician practicing comprehensive pain medicine in Prescott, Arizona. I am board-certified in Physical Medicine and Rehabilitation, Pain

Medicine, and Pain Management. I am certified in Cannabis Science through the University of Colorado.

3. I am former President of the American Board of Pain Medicine and have served on that Board's Exam Council for more than 25 years. I serve on the Board of Directors of the International Academy on the Science and Impacts of Cannabis. I edited *Cannabis in Medicine: An Evidence-Based Approach* (Springer 2020). I also served on the Colorado Governor's Task Force on Amendment 64 and for four years on the Colorado Marijuana Scientific Advisory Council.

4. I have testified to the Canadian Senate on their marijuana bill in 2018, to the New York General Assembly, and to many other state legislators considering whether to legalize marijuana for medical and recreational use. I have testified to the United Nations and other international organizations as well on public health and safety concerns related to marijuana.

5. My clinical practice, academic work, and policy work place me in direct and recurring contact with patients and providers affected by inadequate marijuana regulatory frameworks. Patients ask about cannabis for pain management. I am not categorically opposed to prescribing or recommending cannabinoid therapies where safe, effective, federally compliant products and proper dosing information exist. In fact, I support appropriate and standardized drug development of cannabinoids which have met the rigor of scientific study. Currently, the FDA has not approved a

single indication for the medical use of raw cannabis, which does not meet the definition of a medicine, despite the amount of research into it and its current schedule.

6. My injury arises because the Rescheduling Order treats state-dispensary marijuana as Schedule III without providing the medical infrastructure that would allow me to counsel or prescribe safely.

7. In ordinary medical practice, a Schedule III drug is accompanied by standardized formulation, dosage strength, FDA-approved labeling, package inserts, warnings, contraindications, drug-interaction information, and directions for use. Those materials allow physicians to assess risks, counsel patients, document informed consent, and meet the standard of care.

8. The Rescheduling Order does not provide those materials for state-licensed marijuana products. It allows state-licensed dispensary products to operate under Schedule III status even though state certifications may omit the drug name, strength, dosage form, quantity, and directions for use that a physician would need to evaluate patient safety.

9. This creates a direct clinical injury in my practice. Without standardized dosing or labeling, I cannot reliably determine whether a patient is using low-potency cannabis flower, a high-potency concentrate, a 15% THC smoked product,

a 95% THC wax or shatter product, an edible, a vape, or another preparation with materially different risk profiles.

10. I also cannot reliably assess drug-drug interactions, cardiovascular risks, pulmonary risks, cognitive risks, psychiatric risks, impairment risk, or monitoring needs for dispensary products that have not undergone ordinary FDA review. Patients may present those products as federally recognized medicine because of Schedule III status, but I do not receive the physician-facing information that federal approval would normally supply.

11. The Order exposes me to professional and legal risk. If I decline to advise a patient, the patient may understand that refusal as inconsistent with the federal government's new Schedule III treatment. If I advise the patient, I must do so without the standardized labeling, dosing, drug interaction, monitoring information, and safety guidelines typically known with standard medication.

12. The Order also injured me procedurally. In the prior DEA rescheduling proceeding, Chief Administrative Law Judge John J. Mulrooney II found that I established standing to participate. I was prepared to present evidence concerning my pain-medicine practice, patient safety, dosing, labeling, drug interactions, and medical standards. The Order terminated that process and deprived me of the opportunity to present that evidence before state-licensed marijuana products received Schedule III status.

13. If given the required opportunity to participate before the Order took effect, I would have explained why medical marijuana cannot be treated as an ordinary Schedule III medicine unless physicians receive indications, standardized formulations which are free of contaminants, dosing guidelines, labeling, contraindication warnings and precautions typically seen with medicines, drug-interaction, monitoring, and adverse-event information.

14. A favorable decision vacating the Order would redress my injury by removing the federal Schedule III treatment of state-licensed marijuana products unless and until the agency follows the procedures required by law and supplies a lawful basis for treating those products as medicine.

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

Dated: November 23, 2026

Kenneth Finn, M.D.

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** Consolidated with Nos. 26-1106 and 26-1130

DECLARATION OF ELIZABETH "LIBBY" B. STUYT, M.D.

I, Elizabeth "Libby" B. Stuyt, M.D., hereby declare under penalty of perjury pursuant to 28 U.S.C. § 1746 as follows:

1. I am over eighteen years of age and am competent to testify to the matters stated herein. I make this declaration based on my personal knowledge, professional experience, and review of relevant records.

2. I am a board-certified psychiatrist with Added Qualifications in Addiction Psychiatry from the American Board of Psychiatry and Neurology. I hold a Colorado medical license. I have served as Medical Director of the Circle Program

at the Colorado Mental Health Institute at Pueblo and as Senior Instructor in the Department of Psychiatry at the University of Colorado Health Sciences Center.

3. I serve on the Board of Directors and as Secretary of the International Academy on the Science and Impacts of Cannabis. I have served on the SAMHSA Drug Testing Advisory Board, the Colorado Retail Marijuana Public Health Advisory Committee, and the Johnny's Ambassadors Scientific Advisory Board. I have written and presented extensively on high-potency THC, cannabis use disorder, psychosis, violence, suicide, youth risk, and addiction psychiatry.

4. My practice and professional work have placed me in direct contact with the consequences of marijuana being presented as medicine without the ordinary scientific and clinical safeguards that physicians rely on when counseling patients. I have treated and counseled patients with substance-use and mental-health conditions for whom high-potency THC has been clinically significant. Although I retired from clinical practice in 2021 and no longer see patients directly, I am doing a great deal of consulting and education for other health care providers who are dealing with patients for whom high-potency THC is causing concerns.

5. The Rescheduling Order directly injures my medical practice because it gives state-licensed marijuana products Schedule III status without providing standardized dosing, formulation, package inserts, FDA-approved labeling, drug-interaction data, contraindication information, adverse-event guidance, or

monitoring protocols. I am not opposed to prescribing or recommending cannabinoid therapies where safe, effective, federally compliant products and proper dosing information exist. However, no such dosing information currently exists, and no such safe, effective, and federally compliant cannabinoid products exist.

6. As an addiction psychiatrist, I need reliable medical information to inform providers and counsel patients who use or ask about cannabis. Many of the health care providers I consult with treat patients who are vulnerable to substance-use disorder, psychiatric destabilization, cannabis-induced psychosis, suicidality, impaired judgment, or relapse.

7. The Order increases the likelihood that patients will treat state-dispensary products as federally recognized medicine while I remain without the prescribing information that would normally accompany a medicine.

8. The lack of standardized information creates concrete clinical burdens. I cannot responsibly counsel providers as well as their patients as though all state-dispensary marijuana products are medically equivalent. Potency, route of administration, product type, contaminants, dose, frequency, and psychiatric history all matter. The Order's Schedule III status does not supply the information needed to assess those risks.

9. The Order also exposes me to professional risk. Providers or their patients may ask me to advise them about state-dispensary marijuana products or

may interpret federal Schedule III status as a medical endorsement. If I counsel them, I must do so without ordinary FDA labeling and dosing information. If I decline, patients may view that decision as inconsistent with the federal government's new classification.

10. The Order injured my procedural interests because it took effect without giving me a meaningful opportunity to present evidence on addiction psychiatry, high-potency THC, psychosis, youth risk, patient counseling, informed consent, and the medical information physicians need before marijuana products can be treated as Schedule III medicine.

11. If given the opportunity to comment or testify before the Order took effect, I would have provided evidence from my clinical experience, publications, and presentations regarding the psychiatric and addiction-related risks of high-potency THC and the need for standardized medical information before physicians are asked to treat state-dispensary products as medicine.

12. A favorable decision vacating the Order would redress my injury by removing the federal Schedule III treatment of state-licensed marijuana products unless and until the agency complies with the required procedures and supplies a lawful record addressing the medical and psychiatric risks that directly affect my practice.

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

Dated: November 23, 2026

Libby Stuyt

Elizabeth "Libby" B. Stuyt, M.D.

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

Hearing

IN THE MATTER OF:	:	DEA Docket No. 1362
Schedules of Controlled Substances: Proposed Rescheduling of Marijuana	:	Hearing Docket No: 26-96

Wednesday,
July 15, 2026

700 Army Navy Drive
Arlington, Virginia

The above-entitled matter came on for hearing, pursuant to notice, at 9:00 a.m. EDT

BEFORE: THE HONORABLE DEREK C. JULIUS,
Chief Administrative Law Judge

APPEARANCES:

On Behalf of the Government:

JARRETT T. LONICH, ESQ.
DAVID C. MALEY, ESQ.
ALEXIS B. ATTANASIO, ESQ
KAYLA L. KREINHEDER, ESQ
Office of Chief Counsel
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
[redacted]

On Behalf of Smart Approaches to Marijuana:

CHASE T. HARRINGTON, ESQ.
JOHN M. MCNICHOLS, ESQ.
Torridon Law PLLC
[redacted]

On Behalf of the States of Nebraska, Idaho, and Indiana:

CHASE T. HARRINGTON, ESQ.
JOHN M. MCNICHOLS, ESQ.
T. ZACHARY HORTON, ESQ.
Torridon Law PLLC
[redacted]

ALSO PRESENT:

GRAYSON E. PHILLIPS, ESQ., Law Clerk
DECLAN HURLEY, Torridon Law summer associate

C-O-N-T-E-N-T-S

WITNESS	DIR	CROSS	REDIR	RECROSS
Deepak D'Souza				
By Mr. Lonich		2369		
By Mr. Harrington			2379	
William Honsal				
By Mr. Horton	2389,2437		2494	
By Mr. Maley		2490		

EXHIBITS	MARK	REC'D
Opposed States		
22 Witness CV	2388	
23 Slide Deck	2437	2437

P-R-O-C-E-E-D-I-N-G-S

9:01 a.m.

JUDGE JULIUS: We are on the record. Today is July 15, 2026. This is day 11 in the matter of Schedules of Controlled Substances, Proposed Rescheduling of Marijuana Hearing Docket No. 26-96, DEA Docket 1362. First order of business will be to state appearances for today. Mr. Lonich on behalf of the government, who do we have?

MR. LONICH: Yes, Your Honor. For the government, Jarrettd Lonich, David Maley, Alexis Attanasio, and Kayla Kreinheder.

JUDGE JULIUS: Welcome, Counsel. And on behalf of the Opposed States?

MR. ~~McNICHOLS~~HARRINGTON: Chase Harrington and John McNichols on behalf of the Opposed States, Your Honor, accompanied by Declan Hurley and Yousef Ya~~c~~qub (Phonetic.) with my law firm.

JUDGE JULIUS: Welcome, Counsel. And on behalf of Smart Approaches to Marijuana?

MR. ~~McNICHOLS~~HARRINGTON: Also Chase Harrington and John McNichols, Your Honor. And I'll note that Zach Horton is also here on behalf of the Opposed States. He happens to be out of the

staff --

MR. HARRINGTON: Yeah.

JUDGE JULIUS: Advised of what's going on.

MR. HARRINGTON: And we'll keep you appraised as to where he is, and if we need more time, I'll let you know.

JUDGE JULIUS: Sounds good.

MR. HARRINGTON: All right.

JUDGE JULIUS: We'll be in recess for at least five minutes.

(Whereupon, the above-entitled matter went off the record at 9:21 a.m. and resumed at 9:37 a.m.)

JUDGE JULIUS: Mr. Harington, are you ready to call him?

MR. HARRINGTON: Yes, he is, Your Honor. The States would like to call for our next witness, Sheriff William Honsal.

JUDGE JULIUS: Okay.

SHERIFF HONSAL: Good morning.

JUDGE JULIUS: Good morning, sir.

MR. HARRINGTON: Good morning, sir.

JUDGE JULIUS: Before you have a seat, if I could ask you to please raise your right

hand if you're able.

WHEREUPON,

WILLIAM F. HONSAL

was called as a witness by Counsel for the Opposed States and, having been first duly sworn, assumed the witness stand, was examined and testified as follows:

JUDGE JULIUS: Thank you so much. You may be seated.

THE WITNESS: Thank you.

JUDGE JULIUS: And before we begin with questions, I just want to give you a few quick pointers, instructions about the process of testifying to make sure our record is clear. Please wait until the entire question is asked before you begin your answer. Please pause for a second or two before beginning your answer to see if the question draws an objection.

If you hear the word "objection," just pause, sit tight. I will address the objection, and then I'll instruct you whether you should answer the question or not. If you need repetition of the question, feel free to ask for repetition.

If at any time you get a question you

don't understand, please say that you don't understand the question before you try to answer it. We'll make sure the question is phrased in a way that you do understand so that you can answer. And if you go ahead and answer a question without saying you don't understand it, we'll assume you understood the question. Make sense?

THE WITNESS: I understand.

JUDGE JULIUS: Sounds good.

THE WITNESS: Thank you.

MR. HORTON: Good morning, Your Honor.

JUDGE JULIUS: Mr. Horton.

MR. HORTON: Zach Horton for the Opposed States. Good morning.

JUDGE JULIUS: Direct exam whenever you're ready, sir.

MR. HORTON: Well, I have a couple of preliminary housekeeping matters --

JUDGE JULIUS: Oh, sure.

MR. HORTON: -- if you don't mind. I recently obtained the our witness's CV, and I shared it with opposing counsel last night and would like to proffer it as States Exhibit Number 22 and move it into evidence,

understanding that there is no objection.

MR. MALEY: That is correct, Your Honor.

JUDGE JULIUS: Okay. States Exhibit 22 will be admitted without objection.

(Whereupon, the above-referred to document was marked as States Exhibit No. 22 for identification.)

MR. HORTON: And as

JUDGE JULIUS: And can you give a copy to Mr. Phillips, please? Thank you.

MR. HORTON: And as a second matter, the Sheriff has some slides that he has used as demonstratives, and we were we may refer to them during this examination. The Government has indicated no objection, and if we can boot them up to have them at the ready, that would be most convenient.

MR. MALEY: That is correct as well.

JUDGE JULIUS: Excellent. Mr. Phillips, if you want to pull those slides up, just have them ready.

Any other preliminary matters?

MR. HORTON: That is all.

JUDGE JULIUS: Excellent.

DIRECT EXAMINATION

BY MR. HORTON:

Q Good morning. Thank you for making the trek out here, Sheriff. Could you please state your full name for the record?

A My name is William Frederick Honsal, III.

Q And what is your current occupation?

A I am currently the Humboldt County Sheriff in Northern California.

Q And about how long have you served as sheriff?

A I have been sheriff since May of 2017.

Q So about eight years?

A Eight years.

Q And how long have you been in law enforcement generally?

A I've been in law enforcement for 31 years.

Q Since approximately?

A June of 1995.

Q But who's counting?

A Yes.

Q Now, could you tell us why you went into law enforcement?

A I went into law enforcement because --

experts that fly in helicopters that survey different lands that have been historically grown for -- or trespassed and grown. And so we rely on that technology.

We've also explored different other technology, you know, using different -- like LIDAR and those kind of things through through different overflights to try and detect historic drug trafficking organizations grow sites. And that's been effective, you know, in California.

But, essentially, we just use that that overflight. Occasionally, we have foresters that find illegal grow sites on their their timber surveying. And they come across these grow areas, and they know immediately to get out because of -- potentially, you know, they could be harmed by being there. And they give us a tip, and at that point in time, we go and follow up on that tip and and go into that private land and take out the marijuana.

Q Now, on the topic of crimes associated with marijuana, what is diversion?

A Diversion is diversion is what happens within within California right now.

We like we like to. Okay. So --

JUDGE JULIUS: Just for the record, there was a loud motorcycle going by the window, so there was a pause.

THE WITNESS: There was a pause. Okay.

So diversion happens in in California right now, and diversion can be looked at ast two things. One is we have illegal marijuana currently being grown in in California and grown without regulation, without oversight.

And and that marijuana is being introduced into the legal market because our track and trace system ihas failed, and it hasn't it hasn't done its job into truly knowing all the different marijuana that's coming into our system in California.

We also see that because marijuana is widely grown across the United States, is the price per pound has gotten so low that a lot of these legacy farmers believe that they can't make it, you know, when marijuana is only being sold for $300, $400 a pound and -- but the black market is still alive and well all over.

The the market for Humboldt's

marijuana is still very lively, especially here on the East Coast. And and so we see that our marijuana can go for up to $1,000 a pound. And so we have these legal growers that have what they call a back door, and where they're growing it legally, but yet they can still make a profit a better profit -- by selling it illegally in these other market out of state markets, including out of country markets. And our marijuana currently is being sold all over the world for for thousands -- or $1,000 a pound.

BY MR. HORTON:

Q So under California's legal regime, how often is marijuana diverted?

A Oh, I think it's diverted a whole lot now because the market is flooded. And especially in Northern California, we have, you know it's it's not the ideal place to grow marijuana, right? Because we're far away from the distribution sites.

The -- Los Angeles has a demand for marijuana, and that's where a lot of the marijuana is being sold. And we are we are 12 hours away from from Los Angeles. And so

to transport our marijuana all the way down there, the shipping costs, everything else it's just -- there's a lot of money that they can that they can lose by by doing this.

So I believe that there's a lot of farmers that are choosing to to go this route, and we are we have our confidential informants, we have our people, our witnesses that are telling us this, and we're actually seeing it as well that this is this is going on, and they are diverting, you know, legal marijuana to these illegal channels.

Q We'll get into that a little bit --

A Okay.

Q -- in greater depth in a bit. But all told, on an annual basis, how many major marijuana cases do you see every year?

A We see 100 to 120 marijuana cases a year.

Q And those include what kinds of cases?

A Drug sales, transportation, cultivation, those are the you know, labor trafficking. Those are the type of cases that we see.

Q Now, as sheriff, do you study crime

scale we're talking about as far as a pound of marijuana is about that much.

Q And in terms of usage, that generates about how many joints?

A Well, I mean, it's about -- what is it? About 50 joints per ounce. And there's 16 ounces in a pound, and so I guess you'd have to do the math on that. It's a lot.

Q I won't subject you to math on the stand.

A Thank you. I appreciate that.

Q Now suffice to say, it's a lot of marijuana?

A It's a lot of marijuana.

Q And just to confirm, under Prop 215 in Humboldt County, one person could grow 99 plants bearing several pounds of marijuana each for medical use. Is that right?

A Yes.

Q And was it all used for medical purposes?

A Well, I don't think so. You know, I think what we saw, the evidence showed that the people coming into Humboldt County weren't concerned about someone's medical status or

providing medicine to people. A vast majority of these individuals were using Proposition 215 as a cover to grow illicitly and to send their illegal marijuana all over the country.

Q How big of a problem was this diversion?

A It was huge. It created such a crime problem for us that it had influence on every part of our policing within Northern California.

Q And under 215, was there any system of accountability to track marijuana from grows to dispensaries?

A No, there was not. There was -- I mean, let me just backtrack by saying we had -- there were certain cities that did govern licensed dispensaries. They were growing on site and they were dispensing marijuana, and those dispensaries were regulated by the cities and some counties actually did that as well. But those were the minority. Those were providing medicine to patients, so to speak, because they were regulated. The ones in the hills were not.

Q Understood. Now, a few moments ago, you referred to the Medical Marijuana Program