

Comments On Notice of Proposed Rulemaking Transferring Marijuana from Schedule I to Schedule III

JULY 22, 2024



COALITION FOR CANNABIS, POLICY, EDUCATION, AND REGULATION

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VIA ELECTRONIC FILING

U.S. Department of Justice Drug Enforcement Administration Diversion Control Division Drug & Chemical Evaluation Section 8701 Morrissette Drive Springfield, VA 22152

RE: Notice of Proposed Rulemaking, Drug Enforcement Administration, Department of Justice; Schedules of Controlled Substances: Rescheduling of Marijuana; 21 CFR Part 1308 (Docket No. DEA-1362) (May 21, 2024)

To Whom It May Concern:

The Coalition for Cannabis Policy, Education, and Regulation (CPEAR) appreciates the opportunity to provide comments on the Drug Enforcement Administration (DEA) Notice of Proposed Rulemaking Transferring Marijuana from Schedule I to Schedule III. (Docket No. DEA-1362) (May 21, 2024)

I. Introduction to CPEAR and the Center of Excellence

The coalition consists of members representing highly regulated industries, academia, think tanks, public safety officials, medical and mental health professionals, and financial services firms, all of whom are eager to support the development of a science-driven regulatory framework. Together, the coalition strives to be a trusted, science-driven resource for policymakers and the larger stakeholder community to rely upon as they develop sound, responsible policies on cannabis regulation. It is important that such policies incorporate CPEAR's core principles, including good governance, youth use prevention, substance use disorder treatment and prevention, criminal justice reform, roadway safety, promoting social equity and inclusion, small business support, patient access, and sound tax policy.¹ We believe

¹ CPEAR: Our Principles



such principles should be the intellectual framework for any future federal regulation of cannabis.

Properly regulating cannabis is a complex exercise and requires a broad array of social, cultural, economic, and scientific expertise as well as lived experiences. To that end, CPEAR is committed to ensuring stakeholders from a variety of fields and disciplines are represented in the most pressing discussions on cannabis policy. Through CPEAR's Center of Excellence (COE), the coalition's research and policy development arm, the coalition can engage a variety of policy experts, ensuring their voices are present in deliberations concerning the development of sound cannabis policy at the federal level.

The COE includes a diverse group of experts from academia, policy think tanks, public health and safety institutions, small and minority business advocates, environmental specialists, and other experts devoted to ensuring cannabis policy reform is done right. Their extensive experience with state-regulated cannabis systems helps inform policy recommendations at the federal level to foster a safe and fair cannabis industry. Since its inception, the coalition's policy experts have engaged in thought leadership to address several policy questions surrounding federal cannabis reform. Several of COE's renowned policy papers are listed below.

- <u>A Science- and Equity-Centered Framework to Reimagine Workplace Cannabis Testing</u>
- <u>Addressing Youth and Cannabis: Solutions to combat and prevent youth misuse through a</u> <u>federal regulatory system</u>
- How Federal Cannabis Legalization Can Restore Police Legitimacy and Enhance Public
 Safety
- <u>Opportunity, Ownership, and Empowerment: A Federal Cannabis Framework for Small</u> and Minority-Owned Businesses
- <u>Prioritizing Mental Health in an Emerging Market: A Framework for Maintaining Public</u> <u>Health and Expanding Knowledge on Cannabis and Mental Health</u>
- <u>Contextualizing the Problem: Driving Under the Influence of Cannabis and Other Drugs</u> <u>in America</u>
- What's in Your Weed?

As such, CPEAR is uniquely qualified to comment on this proposed rule, among other actions the Administration and Congress may be contemplating on cannabis reform.

II. Background on Proposed Rule



The Controlled Substances Act (CSA) is the mechanism that places regulated substances "under existing federal law into one of five schedules… based upon the substance's medical use, potential for abuse, and safety or dependence liability." These substances are placed into one of five schedules and can "be controlled (added to or transferred between schedules) or decontrolled (removed from control)." Factors that are considered when deciding if a substance should be decontrolled or rescheduled include its potential for abuse, and public health effects, among other criteria. ²

Cannabis is currently classified as a Schedule I substance under the CSA, reserved for substances subject to the strictest controls. Under this class, cannabis has the "highest potential for abuse" with "no accepted medical use" in line with other substances in that category, including heroin, lysergic acid diethylamide (LSD), and methylenedioxymethamphetamine (ecstasy). Meanwhile, Schedule V substances have the lowest abuse potential and are considered to have legitimate medical applications.³

On October 6, 2022, President Biden directed the Department of Health and Human Services (HHS) and Department of Justice (DOJ) to review "expeditiously how marijuana is scheduled under federal law."⁴ After scientific review, HHS recommended to the Drug Enforcement Administration (DEA) that cannabis be reclassified from Schedule I to Schedule III under the CSA.⁵ A schedule III classification indicates that cannabis has accepted medical uses and has moderate potential for abuse like Tylenol with codeine, ketamine, anabolic steroids, and testosterone.⁶ Accordingly, the DEA published a proposed rule in the Federal Register rescheduling cannabis from Schedule I to Schedule III under the CSA on May 21, 2024, soliciting public comment for 60 days. At the time of authorship of these comments, the DEA had not granted requests by state officials and stakeholders to extend the comment period.

III. Effects of Rescheduling Cannabis from Schedule I to Schedule III Under the CSA

The proposed rule to reschedule cannabis to Schedule III of the CSA, if finalized, undoubtedly yields some policy benefits. This approach would:

² U.S. Drug Enforcement Administration: <u>The Controlled Substances Act</u>

³ U.S. Drug Enforcement Administration: <u>Drug Scheduling</u> (2018)

⁴ The White House: <u>Statement from President Biden on Marijuana Reform</u> (2022)

⁵ Congressional Research Service: <u>Department of Health and Human Services Recommendation to Reschedule</u> Marijuana: Implications for Federal Policy (2023)

⁶ U.S. Drug Enforcement Administration: <u>Drug Scheduling</u> (2018)



- Serve as an initial federal acknowledgment that there are some accepted medical uses of cannabis and as a step towards narrowing existing major gaps between federal and state cannabis policy. Specifically, the reclassification of cannabis to Schedule III would lower barriers to research. Under a less restrictive schedule, researchers would be able to engage in enhanced clinical research and find solutions to difficult questions, including the development of a standard measure of cannabis impairment.
- Provide veterans participating in state medical cannabis programs with a more integrated healthcare experience as U.S. Department of Veterans Affairs (VA) doctors would no longer be prohibited from helping patients with medical cannabis program applications or even answering their questions.
- Enable state licensed cannabis businesses, after meeting new federal regulatory standards for Schedule III, to deduct ordinary normal business expenses on federal tax returns.

Additionally, regulators across all 38 states overseeing existing cannabis programs would implement conforming changes. Some may benefit by utilizing their existing sophisticated compliance and inventory control systems, including track and trace, to collate data and track the movement of newly rescheduled products. More importantly, the vast amount of data points captured by these systems can facilitate the assessment of tax deductions and payments to the Internal Revenue Service (IRS).

However, it is important to note that rescheduling cannabis without establishing a federal regulatory framework and interstate commerce will not fully equip states or the federal government to properly address the plethora of public safety and other issues that exist in the states. The policy issues that will remain include but are not limited to:

- **Criminal Justice**: Cannabis will still be federally illegal as it remains a controlled substance. Rescheduling will not address the criminalization of cannabis or reverse long-standing inequities.
- Interstate Commerce: As cannabis would remain federally illegal under Schedule III, state markets would be prohibited from engaging in interstate commerce. A robust interstate market, underpinned by federal public health regulations along with track and trace systems, is imperative to addressing the illicit markets that currently flourish in the current patchwork system.
- Federal Tax Receipts: IRS recently reaffirmed that "Section 280E disallows all deductions or credits for any amount paid or incurred in carrying on any trade or business that consists of illegally trafficking in a Schedule I or II controlled substance within the meaning of the federal Controlled Substances Act Section." If the proposed rule is finalized, cannabis businesses will be able to deduct their normal business expenses.



While a welcome change for cannabis operators, the change raises significant questions for the IRS including:

- Will an increase in tax returns filed by cannabis operators have a positive or negative impact on revenues to the Treasury?
- Will cannabis operators, who had previously been disallowed from taking deductions under 280E submit amended returns to access deductions for taxes paid in prior years? What will the impact of that practice be for the U.S. Treasury?
- Today, the cost of advertising and promotion is 100 percent deductible as an ordinary business expense. What effect will the rescheduling of cannabis from Schedule 1 to Schedule III have on the ability of cannabis companies to deduct advertising and marketing costs?
- These questions underscore the importance of ensuring there are clear guidelines in place to help operators understand their tax liabilities, and that the Administration and Congress understands the impact of rescheduling to the Treasury. As proposed, the current rule does not provide this much-needed clarity.
- **Federal Assistance Programs**: Rescheduling cannabis without a regulatory framework would not clarify how eligibility for important social programs, including the Temporary Assistance for Needy Families (TANF), or access to public housing would be affected.
- **Product Safety**: Rescheduling cannabis without a regulatory framework and approval process would compound the public health and safety risks in the marketplace today. There are no universal guidelines for cannabis product labels to help consumers understand exactly what, how, and how much to consume.
- Lawful Medical Cannabis Use: While rescheduling cannabis would represent the federal government's acknowledgment of cannabis' accepted medical benefits, cannabis product health claims must be evaluated under the established Food and Drug Administration (FDA) drug approval pathway to be lawfully prescribed to patients, similar to drugs that are formulated with other Schedule III substances. In fact, all but four products—Epidiolex, Marinol, Syndros, and Cesamet—would remain unrecognized by the federal agency.⁷ Therefore, rescheduling cannabis to Schedule III would not fully align federal and state policy on the question of medical cannabis and leave current operators scrambling to comply.⁸

⁷ U.S. Food and Drug Administration: <u>FDA Approves New Indication for Drug Containing an Active Ingredient</u> Derived from Cannabis to Treat Seizures in Rare Genetic Disease (2020)

⁸ U.S. Treasury Inspector General for Tax Administration: <u>The Growth of the Marijuana Industry Warrants Increased</u> <u>Tax Compliance Efforts and Additional Guidance</u> (2020)



A federal regulatory framework would better address these pressing issues, among others, and would be consistent with President Biden's intentions on federal cannabis reform.⁹

IV. The Case for Establishing a Federal Regulatory Framework for Cannabis

CPEAR commends the Biden administration's efforts to achieve more realistic alignment with both the medical community and states on the question of cannabis. However, stopping short of enacting a federal regulatory framework limits the federal government's ability to effectively achieve that alignment. States will continue to establish their separate, closed-loop, markets with different regulatory frameworks in line with evolving public sentiment. Without a federal regulatory framework to address outstanding policy issues, rescheduling cannabis encourages a regulatory race to the bottom that compromises public health and safety.

To that end, CPEAR suggests several policies that would underpin a comprehensive regulatory system for cannabis. A regulatory system should employ the capabilities of the FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB) as those federal agencies are best suited to oversee an interstate cannabis market. The federal interagency role would address the following issues:

- Cannabis product specifications.
- Good Agricultural and Manufacturing Practices (GAP) (GMP).
- Packaging, labeling, and marketing standards.
- Product testing standards.
- Facilitating scientific research and leadership on key scientific pursuits.
- Regulation of cannabis-derived drugs.
- Policies regarding underage cannabis access prevention.
- Science-based approach for identifying, assessing, and preventing cannabis impaired driving.
- Clearinghouse for nationwide data collection and public health surveillance.

Moreover, an effective regulatory framework must recognize the role of state regulatory systems and rely on their combined experience and capability through:

• Demonstrating a preference to defer to state authority when not in conflict with broader public health and social justice goals.

⁹ The White House: <u>Statement from President Biden on Marijuana Reform</u> (2022)



• Issuing annual reports summarizing best practices from state systems to ensure federal regulators incorporate the learnings of their state peers.

To ensure a unified and effective approach to cannabis regulation, we advocate for the establishment of formal collaborative mechanisms between federal, state, and local regulatory agencies. These partnerships should facilitate information exchange, joint operations, and the sharing of best practices. Furthermore, we recommend fostering relationships with community organizations to develop and implement prevention and intervention programs. Such collaborative efforts will be essential in addressing the complex challenges associated with cannabis regulation and ensuring consistent enforcement across jurisdictions.

An area for a potential partnership between the federal government and states relates to data collection and analysis. A comprehensive federal framework should include provisions to support law enforcement agencies in adapting to the changing cannabis landscape. This should include federal funding for standardized training programs that enhance officers' ability to distinguish between legal and illicit cannabis activities. Additionally, resources should be allocated for law enforcement operations aimed at diminishing illegal cannabis markets, with a particular focus on combating international smuggling operations. These measures will be crucial in maintaining public safety and effectively enforcing cannabis regulations.

We propose the establishment of a national cannabis data clearinghouse that relies on existing track and trace systems across legal states cannabis-related incidents, trends, and impacts. This data will be invaluable for law enforcement agencies, policymakers, and researchers in identifying areas of concern, prioritizing enforcement efforts, and shaping evidence-based policies. Such a system would provide real-time insights into the effects of cannabis legalization on public health and safety.

Public education should be a cornerstone of any federal cannabis policy. We recommend the development and implementation of comprehensive public awareness campaigns focused on cannabis laws, responsible consumption, and harm reduction strategies. These campaigns should be evidence-based, culturally sensitive, and tailored to various demographics, with a particular emphasis on preventing youth use. By fostering an informed public, we can mitigate potential negative impacts associated with cannabis use and promote responsible behavior within the legal framework.

To accomplish the above, the executive branch should work with Congress to develop a framework, especially in light of the recent decision by the U.S. Supreme Court striking the *Chevron* doctrine. Members of Congress from both sides of the aisle recognize the importance of



debating a robust regulatory system. One such example is the bipartisan Strengthening the Tenth Amendment Through Entrusting States (STATES) 2.0 Act¹⁰ led by Congressman Dave Joyce (R-OH) (HR 6673). The bill would implement much-needed safeguards to improve the state of the market and improve economic outcomes for its participants, respecting the leadership of states on the issue and attempting to partner with them regardless of how they decide to regulate the product. The legislation has notably been one of the first cannabis bills endorsed by the law enforcement community, along with other important stakeholders.¹¹ Senate Leader Chuck Schumer (D-NY), Ron Wyden (D-OR), and Cory Booker (D-NJ) have introduced S.4226 the Cannabis Administrative and Opportunity Act (CAOA) this congressional session. The bill establishes a comprehensive regulatory system for cannabis and address a number of externalities related to cannabis reform.¹²

V. A Federal Regulatory Framework for Cannabis Must Address Intoxicating Hemp Derived Cannabinoids

The federal legalization of hemp in 2018 without an accompanying regulatory framework has created a massive, largely unregulated marketplace of hemp-derived intoxicating products. This thriving multibillion dollar industry faces significantly less regulatory burden than state-legal marijuana. Industrial hemp, as defined by the 2018 Farm Bill, is any part of the cannabis plant with not more than 0.3 percent delta 9 THC on a dry weight basis. The law, however, did not contemplate nor create guidelines to address the existence of delta 8 THC and other intoxicating cannabinoids, either as a naturally occurring substance, or a synthetically derived product. As a result of the lack of clarity in the federal statute, hemp derived products can be found virtually anywhere—from gas stations to vape shops. These products are untested, and potentially unsafe for human consumption. Current estimates put the size of the hemp derived cannabinoid market more than \$28 billion, with a workforce of 328,000. However, those estimates do not capture the true size of the market as most of them do not account for the economic activity in the gray market such as gas stations and grocery stores.¹³

States have had widely varying responses to the prevalence of intoxicating cannabinoids. Some have opted to limit or outright ban the substance, such as in South Dakota, which banned the sale of intoxicating delta-8, and other intoxicating products. Meanwhile, other states like Minnesota have integrated hemp derived products into their regulated cannabis market and

¹⁰ Congress.gov: <u>H.R.6673</u> - Strengthening the Tenth Amendment Through Entrusting States 2.0 Act (2023)

¹¹ CPEAR: PORAC ORCOPS STATES 2.0 Act Support Letter (2024)

¹² Congress.gov: <u>S.4226 - Cannabis Administration and Opportunity Act</u> (2024)

¹³ Whitney Economics: <u>U.S. National Cannabinoid Report - Executive Summary</u> (2023)



limited retail sales to state-licensed operators. States taking such vastly different actions have created confusion for national regulators, consumers, and businesses.¹⁴

As a result, Congress is considering ways to close the Farm Bill loophole. There is language banning the commercial production, sale, and distribution of most intoxicating hemp derivatives and products in the House Agriculture Committee's H.R. 8467, the Farm, Food, and National Security Act of 2024 which passed out of the House Agriculture Committee on May 24, 2024. The FY2025 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations bill contains similar language.¹⁵ CPEAR finds it prudent to mention that a federal regulatory framework for cannabis could also address these lawmakers concerns and their likely underlying intent to create safer markets. CPEAR notes that a federal regulatory framework for cannabis would be an alternative approach to addressing lawmakers' concerns about creating a safer marketplace for consumers and communities. The critical need for regulations and standards for all intoxicating cannabinoids is outlined with policy recommendations in the Center of Excellence's paper entitled "<u>What's in Your Weed</u>." As it stands, most intoxicating cannabinoid products, hemp or cannabis derived, are unlikely to meet current FDA product safety standards. A comprehensive federal regulatory framework would ensure a safe and regulated marketplace.

VI. Conclusion: Regulation Must Follow Rescheduling to Ensure a Safe, Legal Marketplace

CPEAR urges the federal government to consider establishing a comprehensive regulatory system to address the downstream effects of reform and provide regulatory clarity and product safety standards for consumers, businesses, and state regulators. Stakeholders, including hardworking employees and employers, veterans, and patients in states with legal cannabis, deserve clarity regarding the federal legality of cannabis. A robust federal regulatory framework would provide consistency, enhance safety, support research, boost the economy, streamline law enforcement, and promote social equity.

¹⁴ MJBizDaily: Where Delta-8 THC Is Legal in the United States (2024)

¹⁵ Congressional Research Service: <u>Hemp Provisions in the House Farm Bill and FY2025 Agriculture</u> <u>Appropriations Bill</u> (2024)