



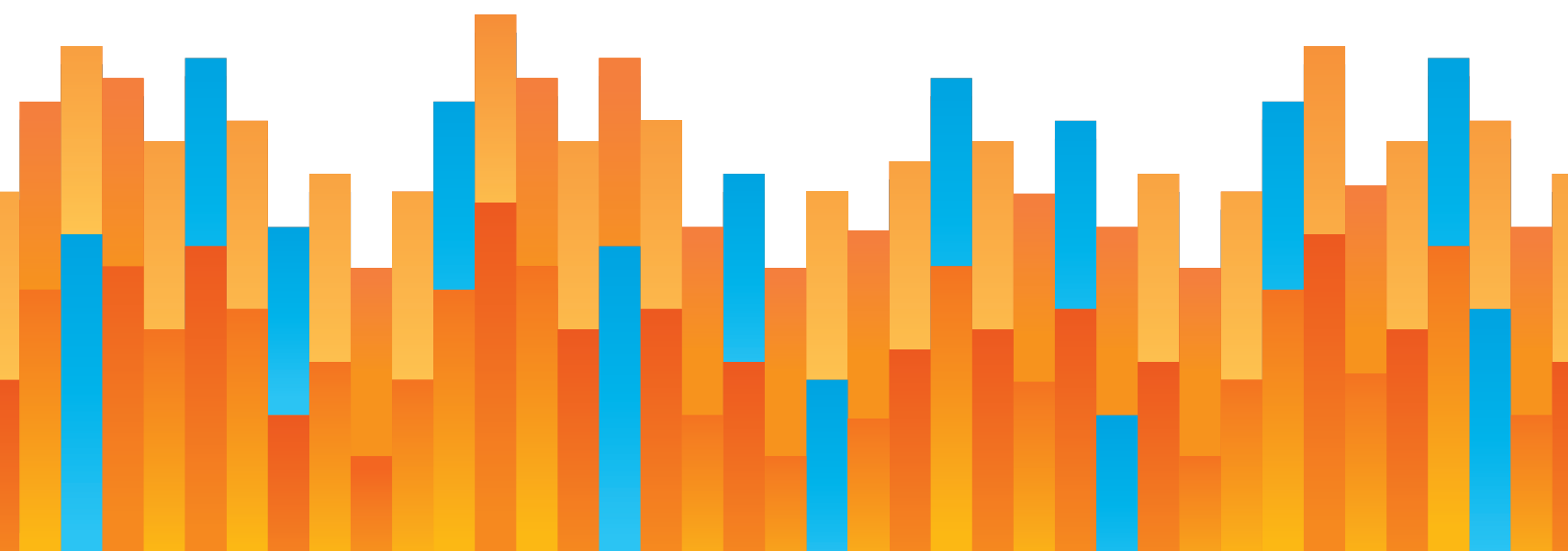
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# THE IMPLICATIONS OF FEDERAL CANNABIS RESCHEDULING

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# EXECUTIVE SUMMARY

In October 2022, President Joe Biden unveiled plans to reevaluate the federal classification of cannabis, aiming to address its restrictive treatment under federal law and the growing conflict between federal and state cannabis law. This move prompted evaluations by the Drug Enforcement Administration (DEA) and the U.S. Department of Health and Human Services (HHS) to potentially alter cannabis's Schedule I status under the Controlled Substances Act (CSA).

Established in 1970, the CSA categorizes drugs into five schedules based on their potential for abuse, medical uses, and other criteria. Since the CSA's enactment, cannabis has held a Schedule I designation, the most restrictive of the five categories, hindering medical research and creating conflicts between state and federal laws. In August 2023 the HHS completed its review and recommended that the DEA reclassify cannabis to Schedule III, a departure from previous opinions issued on the matter, marking a significant shift in federal policy.

This study explores the potential implications of moving cannabis to Schedule III, examining its impact on consumers, businesses, and local markets. Investigating the historical context surrounding cannabis's Schedule I status, the mechanics of the rescheduling process, and the current HHS recommendation, the study also considers possible repercussions for other federally-controlled substances in light of changing perspectives on cannabis.

Should the DEA adopt the HHS recommendation, the cannabis industry and research community stand to gain immediate benefits, including potential relief for medical cannabis patients, reduced barriers to research, and a reduction in federal penalties for cannabis-related crimes. Specifically, the study addresses the financial relief this change might provide to state-authorized cannabis businesses through issues related to taxation and banking.



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Alongside the potential benefits, this study also explores possible drawbacks of moving cannabis to Schedule III, such as the failure to fully address criminal penalties against cannabis users in compliance with state law. Moreover, the study considers the possibility that reclassification may stimulate regulatory interest in the medical cannabis market, possibly subjecting cannabis to greater oversight from the Food and Drug Administration (FDA).

Analyzing potential outcomes, the study delves into the intricate regulatory challenges associated with rescheduling, including the FDA's role, potential pathways for approving state-licensed cannabis-derived medications, and the impact these different approaches may have on existing cannabis markets.

The study concludes that, while the optimal solution would be to remove cannabis from the list of controlled substances entirely, moving it to Schedule III presents both immediate and long-term advantages over its current Schedule I designation. However, challenges would persist were cannabis to remain federally controlled, perpetuating conflicts between state and federal law, and leaving consumers and markets vulnerable to regulatory uncertainty. In particular, an aggressive interpretation of the FDA's regulatory scope

following a shift to Schedule III could impose costs and barriers for existing state-licensed cannabis markets far in excess of the status quo. As federal authorities take this pivotal step, collaborative efforts among policymakers, researchers, and advocates are crucial to ensuring decisions align with evolving scientific understanding, social implications, and the needs of all stakeholders.

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# PART 1

## INTRODUCTION

In October 2022, President Joe Biden announced plans to overhaul federal rules governing cannabis, emphasizing his belief that “no one should be in jail just for using or possessing marijuana.”<sup>1</sup> That announcement prompted the Drug Enforcement Administration (DEA) and the U.S. Department of Health and Human Services (HHS) to assess the appropriateness of cannabis’s current classification under the Controlled Substances Act (CSA). Specifically, these agencies were tasked with considering whether cannabis should be moved to a less-restrictive category or completely removed from the list of federally-controlled substances.

Since its inception, the CSA has categorized cannabis as a Schedule I substance, placing it in the most restrictive category alongside heroin, LSD, peyote, and MDMA. This classification has made medical research difficult, hindered the growth and stability of state-sanctioned cannabis markets, and deepened the divide between state and federal cannabis laws. Despite multiple calls for reevaluation of this classification, the federal government has consistently maintained cannabis’s Schedule I status.

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<sup>1</sup> “Statement from President Biden on Marijuana Reform,” White House Press Office Briefing Room, October 06, 2022. [www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform](https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform) (4 Dec. 2023).



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*...the HHS's recommendation this August that DEA reclassify cannabis as a Schedule III drug marks a significant change in federal policy.*

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Against that backdrop, the HHS's recommendation this August that DEA reclassify cannabis as a Schedule III drug marks a significant change in federal policy.<sup>2</sup> This brief delves into the potential ramifications of moving cannabis from Schedule I to Schedule III on consumers, businesses, and local markets. It also examines the broader implications of the Administration's apparent reinterpretation of rescheduling criteria for other federally-controlled substances.

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<sup>2</sup> John Yang, Dorthy Hastings, "U.S. health officials recommend moving marijuana to lower-risk drug classification," PBS.org, PBS Press Hour, August 31, 2023. [www.pbs.org/newshour/show/u-s-health-officials-recommend-moving-marijuana-to-lower-risk-drug-classification](http://www.pbs.org/newshour/show/u-s-health-officials-recommend-moving-marijuana-to-lower-risk-drug-classification) (4 Dec. 2023).

## PART 2

# WHAT THE CONTROLLED SUBSTANCES ACT DOES

Congress enacted the CSA in 1970 as part of the Comprehensive Drug Abuse Prevention and Control Act, proposed in response to concerns over drug abuse and addiction in the 1960s. The CSA established a comprehensive framework for the regulation of controlled substances through the dual lenses of public health and criminal enforcement, with HHS regulating and registering “legitimate” uses of controlled substances and the Department of Justice (DOJ)—through the newly established Drug Enforcement Agency (DEA)—enforcing laws against illegitimate uses or “trafficking.”

Congress constructed the five schedules of controlled substances in statute, setting out specific criteria for placing drugs in each. Schedule I drugs are deemed the most serious, with a high potential for abuse, no accepted medical uses in the U.S., and little or no data regarding safe use. Schedule II through V drugs have accepted therapeutic uses and Schedules III through V have progressively lower potentials for abuse.<sup>3</sup>

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<sup>3</sup> 21 C.F.R. Chapter II pt. 1308 (1973) “Schedules of Controlled Substances.” [www.ecfr.gov/current/title-21/chapter-II/part-1308](https://www.ecfr.gov/current/title-21/chapter-II/part-1308) (5 Dec. 2023).



Penalties associated with each of these schedules depend on the particulars of the case, including the criminal records of defendants, the exact chemicals being used, and the quantities being trafficked.<sup>4</sup> Typically, violations involving Schedule I and Schedule II substances result in substantial fines, mandatory minimum prison sentences, and longer maximum sentences. Violations involving Schedule III, IV, and V substances, meanwhile, typically result in less severe penalties than Schedule I and II drugs, smaller fines, shorter prison sentences, and greater flexibility for judges to consider individual circumstances in sentencing.



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**TABLE 1. SCHEDULE OF CONTROLLED SUBSTANCES (CSA)**

Schedule	Definitions	Examples
I	High potential for abuse, no accepted medical use, and a lack of safety under medical supervision. They are the most tightly controlled and have the highest penalties for offenders.	Heroin, LSD, MDMA (ecstasy), peyote, marijuana.
II	High potential for abuse with severe psychological or physical dependence, but has some accepted medical uses with severe restrictions.	Opioid medications, like oxycodone, fentanyl, and methadone, stimulants such as cocaine, amphetamines, such as Adderall, and methamphetamines. Prescriptions are required for legal use, and there are tight regulations on their production, distribution, and use.
III	Lower potential for abuse than Schedule I and II drugs, as well as currently accepted medical uses. Abuse of these substances may lead to low or moderate physical dependency, but have a high risk of psychological dependence. They require prescriptions but are subject to less stringent controls.	Medications with lower potency opioids, such as Tylenol with Codeine or Buprenorphine (Suboxone), non-narcotic substances like ketamine, and certain anabolic steroids. Practitioners may administer or dispense directly.

<sup>4</sup> Carly Knight, “High Time to Revisit Federal Drug Sentencing: The Confusing Interplay Between Controlled Substances and Career Offender Sentence Enhancements,” *Georgia State University Law Review*, 39 (2023), Georgia State University Law School Reading Room, [readingroom.law.gsu.edu/cgi/viewcontent.cgi?article=3202&context=gsulr](http://readingroom.law.gsu.edu/cgi/viewcontent.cgi?article=3202&context=gsulr) (5 Dec. 2023).

Schedule	Definitions	Examples
IV	Lower potential for abuse compared to Schedule III drugs, accepted medical uses, and limited physical or psychological dependence risk relative to substances in Schedule III	Medications with benzodiazepines, anxiety and sleep medications, such as Xanax and Valium.
V	Lowest potential for abuse among scheduled drugs, accepted medical uses, and limited physical or psychological dependence relative to Schedule IV.	Medications containing very small amounts of controlled substances, such as some cough medicines with codeine.

Source: “Controlled Substances: Alphabetical Order,” Drug Enforcement Administration, *deadiversion.usdoj.gov*, 14 Dec. 2023. [https://www.deadiversion.usdoj.gov/schedules/orangebook/c\\_cs\\_alpha.pdf](https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf) (27 Dec. 2023).

## 2.1

## THE ORIGIN OF CANNABIS'S SCHEDULE I STATUS

The decision to place cannabis in Schedule I occurred almost inadvertently. When Congress created the CSA, it was clear that the initial sorting of drugs into the five schedules was intended to be preliminary. Based in part on recommendations from the HHS, as well as political concerns, Congress initially assigned cannabis to Schedule I with the expectation that the attorney general could and would utilize provisions in the new law to alter a drug’s scheduling as new evidence emerged. But that is not what happened.



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Due to the lack of scientific research, Congress sought input from the HHS on how cannabis ought to be scheduled. Citing “a considerable void in our knowledge of the plant,” the HHS recommended cannabis remain a Schedule I substance, “at least until the completion of certain studies now underway,” noting that the DOJ could reclassify the drug if appropriate based on those studies’ findings.<sup>5</sup>

<sup>5</sup> Jean-Gabriel Fernandez, “In 1972, Nixon Appointees Already Stated the Obvious: Marijuana Should Never Have Been Criminalized,” *Shepherd Express* [Milwaukee], 1 Apr. 2022. [ShepherdExpress.com](http://ShepherdExpress.com). [www.shepherdexpress.com/cannabis/cannabis/in-1972-nixon-appointees-already-stated-the-obvious-marijuan](http://www.shepherdexpress.com/cannabis/cannabis/in-1972-nixon-appointees-already-stated-the-obvious-marijuan) (5 Dec. 2023).

The studies to which the HHS referred were being generated by the National Commission on Marihuana and Drug Abuse—a presidential commission created by the CSA to aid Congress in the initial classification of cannabis.<sup>6</sup> The Commission conducted a comprehensive study, with 50 separate projects, collecting thousands of pages of testimony, and conducting a nationwide survey.<sup>7</sup> The Commission’s final report, “Marijuana: A Signal of Misunderstanding,” took the position that Congress ought to repeal criminal penalties for adult cannabis use or possession, noting that the “the actual and potential harm of use of the drug is not great enough to justify intrusion by the criminal law into private behavior, a step which our society takes only with the greatest reluctance.”<sup>8</sup> But President Richard Nixon expressly wished to keep cannabis illegal, and thus the DOJ under his administration ignored that report and took no action, essentially making cannabis’s Schedule I designation permanent.

## 2.2

### THE RESCHEDULING PROCESS

As both Congress and the HHS noted during the initial scheduling process, the CSA includes two main pathways through which a substance can be rescheduled, up to and including complete removal from the list of controlled substances. The first pathway deals with substances that may be subject to international treaties to which the U.S. is a party. In this case, the attorney general may reassign the substance to the schedule deemed most appropriate to carry out those treaty obligations at his or her own discretion.<sup>9</sup>

If not subject to treaty obligations, the rescheduling process is akin to formal rulemaking. For these substances, the rescheduling process may be initiated by the HHS, the DEA, or any other interested party, including through a citizen’s petition or presidential request. Once initiated, this path requires the participation of both the HHS and the DEA and provides for public input through mandated public comment periods. Unlike with a

<sup>6</sup> David Downs, “The Science behind the DEA’s Long War on Marijuana,” *Scientific American*, April 19, 2016. [www.scientificamerican.com/article/the-science-behind-the-dea-s-long-war-on-marijuana](http://www.scientificamerican.com/article/the-science-behind-the-dea-s-long-war-on-marijuana) (27 Nov. 2023).

<sup>7</sup> “Nixon Tapes Show Roots of Marijuana Prohibition: Misinformation, Culture Wars and Prejudice,” CSDP.org, Center for Common Sense Drug Policy, [www.csdp.org/research/shafernixon.pdf](http://www.csdp.org/research/shafernixon.pdf) (March 2002).

<sup>8</sup> Gabriel G. Nahas, Albert Greenwood, “The first report of the National Commission on marihuana: signal of misunderstanding or exercise in ambiguity,” *Bulletin of the New York Academy of Medicine*, Vol. 50 (1974), National Library of Medicine Online. [www.ncbi.nlm.nih.gov/pmc/articles/PMC1749335](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1749335) (5 Dec. 2023).

<sup>9</sup> 21 U.S. Code § 811 Chapter 13 pt. 811 (1970), “Authority and criteria for classification of substances,” Law.cornell.edu, Cornell Law School Legal Information Institute, <https://www.law.cornell.edu/uscode/text/21/811> (20 Dec. 2023).

substance covered by international treaties, this pathway imposes constraints on how the DEA reaches its determination regarding scheduling.

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Broadly, each of the CSA schedules have specific criteria the DEA must consider when assigning substances to schedules.<sup>10</sup> First, there are the definitions for each category regarding the drug’s potential for abuse, whether it has accepted medical uses, and the risks associated with its use under medical supervision, including physical or psychological dependence. Moreover, the law stipulates eight factors that both the DEA and the HHS must consider in deciding how or if a drug should be controlled.<sup>11</sup>

Once the process of review has been initiated, the DEA then requests from the HHS a scientific and medical evaluation, as well as their recommendation on scheduling. Next, the DEA analyzes all of the evidence it has gathered and tests it against the eight factors stipulated by the CSA to determine if there is “substantial evidence” to alter a substance’s scheduling. Those eight factors are:

1. The substance’s actual or relative potential for abuse;
2. Scientific evidence of its pharmacological effects;
3. The state of scientific knowledge regarding the substance;
4. Its history and current pattern of abuse;
5. The scope, duration, and significance of abuse;
6. The risks, if any, to public health;
7. Its psychic or psychological dependence liability; and
8. If the substance is an immediate precursor of an already-controlled substance.

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<sup>10</sup> 21 U.S.C. Chapter 13 pt. 812 (1970) “Schedules of controlled substances,” Law.cornell.edu, Cornell Law School Legal Information Institute, [www.law.cornell.edu/uscode/text/21/812](http://www.law.cornell.edu/uscode/text/21/812) (20 Dec. 2023).

<sup>11</sup> 21 U.S.C. Chapter 13 pt. 811 (1970) “Authority and criteria for classification of substances,” Law.cornell.edu, Cornell Law School Legal Information Institute, [www.law.cornell.edu/uscode/text/21/811](http://www.law.cornell.edu/uscode/text/21/811) (20 Dec. 2023)

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When considering medical and scientific evidence in the eight-part test, the DEA is bound to the findings provided by the HHS evaluation. However, the DEA is not bound to the HHS’s scheduling recommendation unless it recommends “no control,” in which case the DEA is obligated not to control the substance.<sup>12</sup> Otherwise, the DEA may assign the drug to the category it deems most appropriate based on the evidence provided by the HHS, DEA-gathered data, and the categorical definitions of the schedules under the CSA.

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<sup>12</sup> 21 U.S.C. Chapter 13 pt. 811 (1970), “Authority and criteria for classification of substances.”

## PART 3

# HHS SCHEDULE III RECOMMENDATION

In a little under a year after the president initiated this most recent review, the HHS transmitted its evaluation of cannabis's scheduling to the DEA in August 2023. Though not yet available to the public in full, the HHS reportedly recommended the DEA move cannabis into Schedule III, alongside drugs deemed to have a lower potential for abuse than those in Schedules I and II, having currently accepted medical uses, and a moderate risk for physical dependency or a high risk of psychological dependency.<sup>13</sup>

Though not entirely unanticipated, the HHS's recommendation represents a significant shift in the agency's perspectives on the evidence surrounding cannabis use. It also raises a number of questions about what happens next, whether the DEA chooses to accede to or divert from the HHS recommendation, and the implications for domestic cannabis markets.

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<sup>13</sup> Natalie Fertig, Paul Demko, "Slightly higher times: Biden administration moves to loosen weed restrictions," *Politico.com*, *Politico Magazine Online*, 30 Aug. 2023. [www.politico.com/news/2023/08/30/marijuana-review-move-to-schedule-iii-00113493](https://www.politico.com/news/2023/08/30/marijuana-review-move-to-schedule-iii-00113493) (5 Dec. 2023).

## 3.1

## PAST RESCHEDULING ATTEMPTS

Marijuana reform advocates and lawmakers from two states have initiated four previous reviews of cannabis’s scheduling.<sup>14</sup> In all cases, the DEA denied the petition, citing a few key factors. In its 2011 denial of a petition filed by a coalition of advocates in 2002, the DEA cited HHS’s declaration that cannabis has a high potential for abuse and no accepted medical use, concluding that “Congress established only one schedule, Schedule I, for drugs of abuse with ‘no currently accepted medical use in treatment in the United States’ and ‘lack of accepted safety for use under medical supervision.’”<sup>15</sup>

In the DEA’s 2016 denial of a petition filed by the governors of Rhode Island and Washington, the DEA again cited the HHS evaluation, which again found that cannabis has a high potential for abuse, no accepted medical uses, and no data regarding safe use under supervision. The DEA also pointed to the nation’s treaty obligations as a reason for maintaining cannabis’s Schedule I status. Specifically, the DEA cited the Single Convention on Narcotic Drugs (Single Convention) of 1961—an international agreement that requires signatory nations to restrict listed drugs, including cannabis, to medical and scientific uses.



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Though the U.S. has been party to the treaty since 1967, it remains an open question of how or if it still applies to U.S. cannabis policy. Much has changed in the five decades since the U.S. became a party to the Single Convention. The American public has shifted dramatically in its opinion on cannabis use, leading to waves of cannabis reform across the

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<sup>14</sup> “A Brief History of Cannabis Rescheduling Petitions in the United States,” NORML.org, National Organization for the Reform of Marijuana Laws, [norml.org/marijuana/fact-sheets/a-brief-history-of-cannabis-rescheduling-petitions-in-the-united-states](https://norml.org/marijuana/fact-sheets/a-brief-history-of-cannabis-rescheduling-petitions-in-the-united-states) (5 Dec. 2023).

<sup>15</sup> “Denial of Petition To Initiate Proceedings To Reschedule Marijuana,” Drug Enforcement Administration, Federal Register Online, 8 July 2011. [www.federalregister.gov/documents/2011/07/08/2011-16994/denial-of-petition-to-initiate-proceedings-to-reschedule-marijuana](https://www.federalregister.gov/documents/2011/07/08/2011-16994/denial-of-petition-to-initiate-proceedings-to-reschedule-marijuana) (5 Dec. 2023).

country.<sup>16</sup> Arguably, the U.S. has been out of compliance with the Single Convention since 1973, when Oregon became the first state to decriminalize cannabis possession.<sup>17</sup> If not then, it has certainly been out of compliance since 2012, when Colorado and Washington became the first states to legalize cannabis for adult-use. The United States has seen 24 states and the District of Columbia legalize recreational cannabis and 38 states and the District of Columbia legalize medical cannabis as of 2023. The U.S. federal government has at points maintained an official policy of non-interference in state cannabis laws in conflict with the Controlled Substances Act.

The U.S. is not alone. Attitudes toward cannabis have shifted around the globe, and leaders in many nations have sought to update cannabis policies in accordance. Today, around a quarter of the countries who are party to the Single Convention are similarly noncompliant with the treaty due to national policies decriminalizing or legalizing cannabis.<sup>18</sup>



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It would be deleterious for countries to merely flout internationally agreed upon treaties, rather than seeking to alter the countries' relationship to the treaty or working with other signatories to amend the treaty in accordance with changing global perspectives on cannabis.<sup>19</sup> But it would be similarly imprudent to continue deferring to treaty obligations as the sole reason for delaying critical reforms to domestic policies.

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<sup>16</sup> "Support for Legal Marijuana Holds at Record High of 68%," Gallup.com, Gallup, 4 Nov. 2021. [www.news.gallup.com/poll/356939/support-legal-marijuana-holds-record-high.aspx](http://www.news.gallup.com/poll/356939/support-legal-marijuana-holds-record-high.aspx) (5 Dec 2023).

<sup>17</sup> Kyle Jaeger, "US Marijuana Research Policy Violated International Law For Decades, DEA Lawsuit Memo Reveals," MarijuanaMoment.com, *Marijuana Moment*, 29 April 2020. [www.marijuanamoment.net/dea-agrees-to-release-secret-document-allegedly-used-to-justify-marijuana-research-delay](http://www.marijuanamoment.net/dea-agrees-to-release-secret-document-allegedly-used-to-justify-marijuana-research-delay) (5 Dec. 2023).

<sup>18</sup> "Single Convention on Narcotic Drugs, 1961," Treaties.un.org, United Nations, [www.treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=VI-15&chapter=6](http://www.treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-15&chapter=6) (27 Dec. 2023).

<sup>19</sup> John Walsh, Martin Jelsma "Regulating Drugs: Resolving Conflicts with the UN Drug Control Treaty System," *Journal of Illicit Economies and Development*, 1 (2019). <https://jied.lse.ac.uk/articles/10.31389/jied.23> (5 Dec. 2023).



According to the DEA's 2016 petition denial, due to cannabis being deemed to have a high potential for abuse, the Single Convention requires it be either Schedule I or Schedule II. The decision to retain its Schedule I status hinged on whether the substance had accepted medical uses which, according to the HHS at the time, it did not.

The newest review from the HHS recommending cannabis be assigned to Schedule III indicates the agency's understanding of the medical and scientific evidence has changed since its last evaluation, officially recognizing that cannabis has accepted medical uses in the U.S. But, the final decision rests with the attorney general, who must decide whether the DEA should agree with HHS's conclusion that Schedule III is appropriate for cannabis and whether moving cannabis to that schedule contravenes the international obligations of the United States.

## PART 4

# IMPACTS OF MOVING CANNABIS TO SCHEDULE III

Transferring cannabis to Schedule III would have immediate benefits to the cannabis industry, as well as the research community. Unlike Schedule I drugs, Schedule III drugs may be prescribed by physicians under certain circumstances. Researchers hoping to study cannabis would also face significantly less red tape in studying the plant and its effects. Increased research and medical interest may, in turn, decrease hostility toward cannabis among physicians, the public, and lawmakers.<sup>20</sup>

Medical cannabis patients may also receive some relief, because the Schedule III change would exempt those who use medical cannabis from laws blocking their access to public benefits, work opportunities, and certain rights like firearm possession.<sup>21</sup> The change may also decrease penalties for federal cannabis crimes but would not eliminate them.<sup>22</sup> Nor would the change ameliorate the continued conflict between states' recreational cannabis laws and federal statute.

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<sup>20</sup> “Challenges and Barriers in Conducting Cannabis Research,” *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. (Washington, DC: National Academies Press, 2017). [www.ncbi.nlm.nih.gov/books/NBK425757](http://www.ncbi.nlm.nih.gov/books/NBK425757) (20 Dec. 2023).

<sup>21</sup> “Department of Health and Human Services Recommendation to Reschedule Marijuana: Implications for Federal Policy,” Congressional Research Service, [CRSReports.congress.gov](https://crsreports.congress.gov), 13 Sep. 2023. <https://crsreports.congress.gov/product/pdf/IN/IN12240> (5 Dec. 2023).

<sup>22</sup> Fertig, “Slightly higher times: Biden administration moves to loosen weed restrictions.”

**TABLE 2: FEDERAL MARIJUANA TRAFFICKING PENALTIES**

Marijuana plant	≥ 1000 plants	<p><b>First offense:</b> Not less than 10 years or more than life. If death or serious injury, not less than 20 years or more than life. Fine not more than \$10 million if an individual, \$50 million if not an individual.</p> <p><b>Second offense:</b> Not less than 20 years or more than life. If death or serious injury, life imprisonment. Fine not more than \$20 million if an individual, \$75 million if not an individual.</p>
	100-999 plants	<p><b>First offense:</b> Not less than 5 years or more than 40. If death or serious bodily injury, not less than 20 years or more than life. Fine not more than \$5 million if an individual, \$25 million if not an individual.</p> <p><b>Second offense:</b> Not less than 10 years or more than life. If death or serious injury, life imprisonment. Fine not more than \$20 million if an individual, \$75 million if not an individual.</p>
	50-99 plants	<p><b>First offense:</b> Not less than 20 years. If death or serious bodily injury, not less than 20 years or more than life. Fine \$1 million if an individual, \$5 million if not an individual.</p> <p><b>Second offense:</b> Not less than 30 years. If death or serious injury, life imprisonment. Fine \$2 million if an individual, \$10 million if not an individual.</p>
	1-49 plants weighing < 50 kg	<p><b>First offense:</b> Not less than 5 years. Fine not more than \$250,000 if an individual, \$1 million if not an individual.</p> <p><b>Second offense:</b> Not less than 10 years. Fine \$500,000 if an individual, \$2 million if not an individual.</p>
Marijuana mixture	≥ 1000 kg	<p><b>First offense:</b> Not less than 10 years or more than life. If death or serious bodily injury, not less than 20 years or more than life. Fine not more than life. Fine not more than \$10 million if an individual, \$50 million if other than an individual.</p> <p><b>Second offense:</b> Not less than 20 years or more than life. If death or serious injury, life imprisonment. Fine not more than \$20 million if an individual, \$75 million if not an individual.</p>
	100– 999 kg	<p><b>First offense:</b> Not less than 5 years or more than 40 years. If death or serious injury, not less than 20 years or more than life. Fine not more than \$5 million if an individual, \$25 million if not an individual.</p> <p><b>Second offense:</b> Not less than 10 years or more than life. If death or serious injury, life imprisonment. Fine not more than \$20 million if an individual, \$75 million if not an individual.</p>
	50-99 kg	<p><b>First offense:</b> Not less than 20 years. If death or serious injury, not less than 20 years or more than life. Fine \$1 million if an individual, \$5 million if not an individual.</p> <p><b>Second offense:</b> Not less than 30 years. If death or serious injury, life imprisonment. Fine \$2 million if an individual, \$10 million if not an individual.</p>

Hashish	> 10 kg	<p><b>First offense:</b> Not less than 20 years. If death or serious injury, not less than 20 years or more than life. Fine \$1 million if an individual, \$5 million if not an individual.</p> <p><b>Second offense:</b> Not less than 30 years. If death or serious injury, life imprisonment. Fine \$2 million if an individual, \$10 million if not an individual.</p>
Hashish oil	> 1 kg	<p><b>First offense:</b> Not less than 20 years. If death or serious injury, not less than 20 years or more than life. Fine \$1 million if an individual, \$5 million if not an individual.</p> <p><b>Second offense:</b> Not less than 30 years. If death or serious injury, life imprisonment. Fine \$2 million if an individual, \$10 million if not an individual.</p>

Source: "Drugs of Abuse A DEA Resource Guide: 2020 EDITION," Drug Enforcement Administration, DEA.gov, 13 April 2020. [www.dea.gov/sites/default/files/2021-12/Trafficking%20Penalties.pdf](http://www.dea.gov/sites/default/files/2021-12/Trafficking%20Penalties.pdf) (20 Dec. 2023).

It is unlikely that rescheduling would lead to federally sanctioned medical cannabis prescribing in the near future, but the shift to Schedule III could stimulate regulatory interest in the medical cannabis market. Though the Food and Drug Administration (FDA) does and would continue to have the power to apply its regulatory authority on cannabis products, regardless of scheduling, to date the FDA has abstained from applying its powers under the Food Drugs and Cosmetics Act to state-sanctioned cannabis products. This may be largely due to the fact that, as a Schedule I substance, the agency has few regulatory options other than pursuing the politically unpalatable path of enforcing prohibition. Moving cannabis to Schedule III, however, would place cannabis in the realm of drugs that are legal, but subject to strict requirements overseen by the FDA and the DEA, such as premarket approval, registration requirements, and prescribing guidelines.<sup>23</sup>

It is not yet clear if or how the FDA might apply its regulatory authority to medical cannabis should the substance be moved to a different schedule. Were the agency to apply its pharmaceutical drugs model, it would likely devastate local markets and leave consumers with a handful of products produced by the largest companies.

To be marketed legally in the United States, drugs—classified as substances making explicit or implicit claims about preventing, treating, or mitigating disease—must first receive premarket authorization from the FDA.<sup>24</sup> Bringing new drugs to market is neither fast nor cheap, taking on average around 12 years and over \$1 billion. Moreover, applications for new drugs typically focus on the efficacy and safety of a single molecule or active

<sup>23</sup> "New Drug Applications," Food and Drug Administration, FDA.gov, 21 Jan. 2022. [www.fda.gov/drugs/types-applications/new-drug-application-nda](http://www.fda.gov/drugs/types-applications/new-drug-application-nda) (5 Dec. 2023).

<sup>24</sup> Ibid.

ingredient, typically produced synthetically for the sake of purity, which once approved may then be studied in combination with other already-approved ingredients.<sup>25</sup> It is not impossible for cannabis-derived medications to succeed through this pathway; one cannabis-derived drug (Epidiolex) and two synthetic cannabis drugs (Marinol and Syndros) have received FDA authorization.

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But, while it may be theoretically possible for a cannabis company to synthesize specific cannabis chemicals—like tetrahydrocannabinol (THC) or cannabidiol (CBD)—and prove to the FDA these ingredients are safe and can be manufactured according to pharmaceutical standards, few companies will have the funding to complete this process. According to financial reports filed with the Securities and Exchange Commission, no publicly traded cannabis company currently holds enough liquid assets to meet the average cost of shepherding a new drug application through the FDA’s drug approval process. Additionally, products brought to market through this single-molecule pathway may have less therapeutic utility than whole-plant cannabis products that contain hundreds of other naturally-occurring phytocannabinoids, terpenoids, and flavonoids. The interplay of all these constituents is thought to contribute to cannabis’ therapeutic benefits, and this synergy is called the “entourage effect.” This entourage effect and its potential benefits would be difficult, if not impossible, to standardize for new drug approvals.<sup>26</sup>

Alternatively, companies might seek FDA approval for cannabis-derived therapeutics as new botanical drugs. Botanical drugs are formulated with extracts of biological materials, including plants. Because of their natural source, botanical drugs can be less pure or standardized, more closely resembling the chemical makeup of the natural plant. Botanical

<sup>25</sup> Marcel Bonn-Miller, Mahmoud A Elsohly, Mallory Loflin, Suman Chandra, “Cannabis and cannabinoid drug development: evaluating botanical versus single molecule approaches,” *International Review of Psychiatry*, 30 (2018), Taylor&Francis Online. [www.tandfonline.com/doi/abs/10.1080/09540261.2018.1474730](http://www.tandfonline.com/doi/abs/10.1080/09540261.2018.1474730) (5 Dec. 2023).

<sup>26</sup> Catalina Christensen, Martin Rose, Claus Cornett, Morten Allesø, “Decoding the Postulated Entourage Effect of Medicinal Cannabis: What It Is and What It Isn’t,” *Biomedicines* 11 (2023) MDPI.com. [www.mdpi.com/2227-9059/11/8/2323](http://www.mdpi.com/2227-9059/11/8/2323) (5 Dec. 2023).

drugs submitted to the FDA as investigational new drugs can also substitute evidence on historical human use of the drug in place of preclinical animal studies, shortening the estimated timeframe-to-approval to between six and eight years. However, botanical drugs must still be fully characterized, defined, and standardized, and are held to the same standards of safety and efficacy as pharmaceutical drugs. For cannabis companies, this would require tightly controlled agricultural practices to maintain the chemical consistency of final products. This, along with the costs of gaining FDA approval, make the botanical pathway unviable for most companies.<sup>27</sup>

Alternatively, the FDA may choose to create a separate pathway for cannabis products, modify and streamline existing pathways for cannabis-derived products, or offer multiple pathways for different categories of cannabis products where requirements for approval depend on risk level.<sup>28</sup> One approach the FDA might consider, but ought to avoid, is regulating cannabis similarly to how it regulates nicotine. As the Agency's attempt to implement pre-market approval for e-cigarettes demonstrates, this approach would essentially freeze the marketplace, halting innovation and slowing the introduction of new products to a trickle. For example, since Congress granted the FDA regulatory authority over tobacco in 2008, the agency has reviewed more than 26 million applications for e-cigarettes and approved just 23 products.<sup>29</sup>

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The FDA may also choose to share oversight responsibilities with other agencies. For example, the FDA could prescribe certain parameters for allowable ingredients,

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<sup>27</sup> Daniel L. Flint, Deborah M. Shelton, “Cannabis-Derived Botanical Drugs: A Viable Regulatory Pathway for Marketing Medical Edibles?” *Food and Drug Law Journal* 74 (2019) FDLI.org. [www.fdpi.org/wp-content/uploads/2019/07/2-Flint-Shelton-Final.pdf](http://www.fdpi.org/wp-content/uploads/2019/07/2-Flint-Shelton-Final.pdf) (5 Dec. 2023).

<sup>28</sup> “Adapting a Regulatory Framework for the Emerging Cannabis Industry,” National Cannabis Industry Association, 2019. [www.thecannabisindustry.org/wp-content/uploads/2019/09/RegulatoryFramework-WhitePaper-Final-9.30-2.pdf](http://www.thecannabisindustry.org/wp-content/uploads/2019/09/RegulatoryFramework-WhitePaper-Final-9.30-2.pdf) (5 Dec. 2023).

<sup>29</sup> “FDA Makes Determinations On More Than 99% of the 26 Million Tobacco Products For Which Applications Were Submitted,” Food and Drug Administration, FDA.gov, 15 March 2023. [www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted](http://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted) (5 Dec. 2023).

manufacturing, and marketing, while leaving day-to-day enforcement to an agency like the Alcohol Tax and Trade Bureau, similar to the regulation of interstate alcohol sales.

Regardless of how the FDA might choose to assert its regulatory authority over cannabis, such a move is not something the FDA currently has the funding or statutory discretion to execute. Likely, such oversight would require Congressional action, similarly to what the FDA is now requesting with regard to hemp-derived cannabinoid products since their removal from the CSA in 2018.<sup>30</sup> At the very least, FDA action in this realm would likely be preceded by a budget request to Congress and a formal rulemaking process, giving citizens and lawmakers at all levels of government an opportunity to weigh in on federal oversight.

In the immediate term, the greatest impact of rescheduling cannabis to Schedule III would be the financial relief state-authorized cannabis business would gain through access to the same banking, financing, and tax deductibility of expenses available to other legal businesses.



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## 4.1

### INTERNAL REVENUE CODE 280E

Currently, businesses “trafficking” in Schedule I and Schedule II substances are barred by Internal Revenue Code 280e from deducting business expenses from their gross receipts under the “ordinary and necessary” standard. This standard is what applies to most businesses under the federal corporate income tax and stipulates that if an expense is ordinary and necessary to carry on the trade in which the taxpayer is engaged, it is

<sup>30</sup> Janet Woodcock, “FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward,” Food and Drug Administration, 26 Jan. 2023. [www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol](https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol) (5 Dec. 2023).

deductible. These expenses may include rental payments for facilities or equipment, employee wages, utilities, insurance costs and other expenses. Because Section 280e disallows these deductions, cannabis companies must pay federal corporate income tax based more on gross receipts rather than net income. This has resulted in state-sanctioned cannabis businesses paying an effective tax rate that is up to four times higher than taxes on non-cannabis companies<sup>31</sup> In the worst cases, even a business that has operated at a loss may face a sizable income tax burden for the tax year. This has significantly hampered local cannabis markets. Only around a quarter of cannabis businesses posted profits in 2022.<sup>32</sup>

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While a number of states have sought to address the problem by allowing state-sanctioned cannabis businesses to deduct expenses from their state corporate income taxes, the federal tax penalty resulting from IRC 280e remains. Moving cannabis to Schedule III would automatically enable such deductions by legal cannabis businesses.

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<sup>31</sup> Andrew Larson, “Effective tax rate on cannabis companies ‘can be fatal’; proposed bill would offer relief,” Harfordbusiness.com, *Hartford Business Journal*. 6 Feb. 2023. [www.hartfordbusiness.com/article/effective-tax-rate-on-cannabis-companies-can-be-fatal-proposed-bill-would-offer-relief](http://www.hartfordbusiness.com/article/effective-tax-rate-on-cannabis-companies-can-be-fatal-proposed-bill-would-offer-relief) (accessed 5 Dec. 2023).

<sup>32</sup> MJBiz Staff, “Marijuana industry overpaid \$1.8 billion in federal taxes in 2022, analysis shows,” MJBizDaily.com, *Marijuana Business Daily*. 8 May 8, 2023. [mjbizdaily.com/marijuana-industry-overpaid-1-8-billion-in-federal-taxes-in-2022-analysis-shows](http://mjbizdaily.com/marijuana-industry-overpaid-1-8-billion-in-federal-taxes-in-2022-analysis-shows) (5 Dec. 2023).



## 4.2

**BANKING**

The PATRIOT Act and other federal anti-money laundering laws prohibit the proceeds of commerce in any substance listed under Schedule I or Schedule II of the federal Controlled Substances Act from being converted into a financial instrument. These laws further conscript financial institutions chartered in the United States into assisting law enforcement by monitoring the activity of account holders to determine whether the account holder may be engaged in this type of activity. Financial institutions that do not comply with stringent criteria prescribed by the federal DOJ to implement an effective anti-money laundering policy can face steep penalties, including the loss of a charter, fines, and prison time for officers.<sup>33</sup>

Often, financial institutions respond to these incentives by implementing policies more stringent than are actually required by the DOJ to ensure they do not run afoul of anti-money laundering directives. As a result, few financial institutions have been willing to offer accounts to state-licensed cannabis businesses even though the Justice Department has promulgated rules that technically allow for this type of activity.<sup>34</sup>

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*Moving cannabis to Schedule III may thus reduce some financial institutions’ discomfort in servicing state-licensed cannabis businesses, opening new banking opportunities for cannabis businesses operating in compliance with state law.*

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Moving cannabis to Schedule III may thus reduce some financial institutions’ discomfort in servicing state-licensed cannabis businesses, opening new banking opportunities for cannabis businesses operating in compliance with state law. These changes would enhance the financial transparency of state-licensed cannabis businesses because banking records create an audit trail that is often missing within cash-based businesses. Moreover, public

<sup>33</sup> Geoffrey Lawrence, “Marijuana Industry Financial Services: The Obstacles and the Policy Solutions,” Reason Foundation, 2019. [reason.org/policy-brief/marijuana-industry-financial-services-the-obstacles-and-the-policy-solutions](https://reason.org/policy-brief/marijuana-industry-financial-services-the-obstacles-and-the-policy-solutions) (5 Dec. 2023).

<sup>34</sup> Ibid.

safety may be enhanced by removing the physical presence of cash from licensed cannabis facilities. Finally, the operational efficiency of cannabis companies would likely be improved by lowering the steep transaction costs that these companies often face when they are forced to either transport large sums of physical cash or pay high fees in order to convert that cash into electronic funds. This efficiency may allow cannabis companies to remain as going concerns and continue to generate public tax dollars through excise and income taxes.

## PART 5

# IMPLICATIONS FOR OTHER CSA SUBSTANCES

When the DEA denied the petition from governors of Rhode Island and Washington to remove cannabis from the CSA, the agency relied on the HHS determination that cannabis had a high potential for abuse and no medically accepted uses.<sup>35</sup>

To be determined to have “medically accepted uses” in the United States, a substance must either be approved as a drug by the FDA or meet the DEA’s own five-part test.<sup>36</sup> Historically however, both the HHS and the DEA have used the short-hand of FDA approval as proof that a drug has medically accepted uses. Thus, in previous reviews of cannabis’ scheduling, both agencies have determined that only those FDA-approved drugs with cannabis components may be moved into a lower schedule under CSA, not the entire plant. The HHS’s most recent recommendation signals a shift in that understanding. If accepted by the DEA, it may open the door to rescheduling other Schedule I substances, in addition to cannabis. Of note, the FDA has recently awarded “breakthrough therapy” status to two psychedelic substances listed under schedule I—MDMA and psilocybin.<sup>37</sup>

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<sup>35</sup> Drug Enforcement Administration, “Denial of Petition To Initiate Proceedings To Reschedule Marijuana.”

<sup>36</sup> “Schedule of Controlled Substances: Maintaining Marijuana in Schedule I of the Controlled Substances Act,” Drug Enforcement Administration, DOJ.gov, July 2016. [deaddiversion.usdoj.gov/schedules/marijuana/Maintaining\\_Marijuana\\_in\\_Schedule\\_I\\_of\\_the\\_Controlled\\_Substances\\_Act.pdf](https://deaddiversion.usdoj.gov/schedules/marijuana/Maintaining_Marijuana_in_Schedule_I_of_the_Controlled_Substances_Act.pdf) (5 Dec. 2023).

<sup>37</sup> Madison Carlino, “Research showing the tremendous therapeutic potential of psychedelics,” Reason Foundation, 7 July 2023. [www.reason.org/commentary/research-showing-the-tremendous-therapeutic-potential-of-psychedelics](https://www.reason.org/commentary/research-showing-the-tremendous-therapeutic-potential-of-psychedelics) (27 Dec. 2023).

**TABLE 3: FEDERAL TRAFFICKING PENALTIES**

Drugs (Schedule)	Quantity	Penalty	Quantity	Penalty
Cocaine (II)	500-4999 grams	<p><u>First Offense:</u> Not less than 5 or more than 40 years. If death or serious injury, not less than 20 or more than life. Fine of not more than \$5 million if an individual, or \$25 million if not an individual</p> <p><u>Second Offense:</u> Not less than 10 years, not more than life. If death or serious injury, life imprisonment.</p> <p>Fine of not more than \$8 million for individuals or \$50 million if not an individual</p>	≥ 5 kgs	<p><u>First Offense:</u> Not less than 10 years, not more than life. If death or serious injury, not less than 20 years or more than life. Fine of not more than \$10 million if an individual, \$50 million if not an individual.</p> <p><u>Second Offense:</u> Not less than 20 years, and not more than life. If death or serious injury, life imprisonment. Fine of not more than \$20 million if an individual, \$75 million if not an individual.</p> <p><u>2 or More Prior Offenses:</u> Life imprisonment. Fine of not more than \$20 million if an individual, \$75 million if not an individual.</p>
Cocaine Base (II)	28-279 grams		≥ 280 grams	
Fentanyl (II)	40-399 grams		≥ 400 grams	
Fentanyl Analogue (I)	10-99 grams		≥ 100 grams	
Heroin (I)	100-999 grams		≥ 1kg	
LSD (I)	1-9 grams		≥ 10 grams	
Methamphetamine (II)	5-49 grams pure or 50-499 grams mixture		≥ 50 grams pure or ≥ 1 kg mixture	
PCP (II)	10-99 grams pure or 100-999 grams mixture	≥ 100 grams pure or ≥ 1kg mixture		
Other Schedule I & II drugs or any drug containing GHB	Any amount	<p><u>First offense:</u> Not more than 20 years. If death or serious injury, not less than 20 years or more than life. Fine \$1 million if an individual, \$5 million if not an individual.</p> <p><u>Second offense:</u> Not more than 30 years. If death or serious injury, life imprisonment. Fine \$2 million if an individual, \$10 million if not an individual.</p>		
Other Schedule III drugs	Any amount	<p><u>First offense:</u> Not more than 10 years. If death or serious injury, not less than 20 years. Fine \$1 million if an individual, \$5 million if not an individual.</p> <p><u>Second offense:</u> Not more than 30 years. If death or serious injury, life imprisonment. Fine \$2 million if an individual.</p>		
All other Schedule IV	Any amount	<p><u>First Offense:</u> Not more than 5 years. Fine not more than \$250,000 if an individual, \$1 million if not an individual.</p> <p><u>Second Offense:</u> Not more than 10 yrs. Fine not more than \$500,000 if an individual, \$2 million if other than an individual.</p>		
All Schedule V drugs	Any amount	<p><u>First offense:</u> Not more than 1 year. Fine not more than \$100,000 if an individual, \$500,000 if not an individual.</p> <p><u>Second offense:</u> Not more than 4 years. Fine not more than \$200,000 if an individual, \$500,000 if not an individual.</p>		

## PART 6

# CONCLUSION

While removing cannabis from the list of controlled substances would be the most rational and desirable approach to federal cannabis law, moving cannabis to Schedule III would also produce immediate and long-term benefits. Not only would the move provide immediate relief to businesses, stimulate scientific research, and reduce stigma around the use of cannabis, but it may also pave the way for more balanced and progressive approaches to the regulation of other schedule I substances, in addition to cannabis. Yet, rescheduling cannabis to Schedule III does not address the ongoing conflict between state and federal law, continues to leave citizens following state law vulnerable to federal prosecution, and raises a host of new complexities surrounding regulatory oversight of cannabis. The most significant and uncertain of these complexities centers around how the FDA will choose to regulate cannabis products. Indeed, an aggressive interpretation of the FDA's regulatory scope could impose costs and barriers for existing state-licensed cannabis markets far in excess of the status quo.

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*The path to untangling the knot of state and federal laws, societal perceptions, and international coordination will not be simple.*

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The path to untangling the knot of state and federal laws, societal perceptions, and international coordination will not be simple. But, the HHS's new stance on cannabis's medicinal value and its potential for abuse represent a big—if long-delayed—first step on that road by federal authorities. In this pivotal moment, it is imperative for policymakers, researchers, and advocates to collaborate, ensuring that decisions made reflect evolving scientific understanding, the social implications of drug policy, and the needs of patients and entrepreneurs alike. With careful consideration and cooperation, the reevaluation of cannabis scheduling could mark a significant step towards a more enlightened, equitable, and informed federal approach to cannabis policy.

# ABOUT THE AUTHOR

**Michelle Minton** is a senior policy analyst at Reason Foundation, where she focuses on issues related to consumer freedom and drug policy. With expertise spanning various domains, she has authored studies exploring policies concerning cannabis, nicotine, gambling, alcohol, nutrition, and science-based public health. Minton holds an undergraduate degree from Johns Hopkins University and a master's of science from the University of New England.

