



# NATIONAL SHERIFFS' ASSOCIATION

## **DEA may move marijuana to schedule II only, not III.**

### **Introduction**

Marijuana has been in schedule I of the Controlled Substances Act (CSA) since 1970, and this placement has aligned with the scientific and medical reasoning and recommendation of the U.S. Department of Health and Human Services (HHS)—each of the several times the issue has come up. On May 16, 2024, however, the Drug Enforcement Administration announced its intention to move marijuana from schedule I to schedule III. HHS has suddenly changed its scientific and medical reasoning, and the Office of Legal Counsel (OLC) in the U.S. Department of Justice has written an accommodating opinion.

The people in over 3,000 counties across the country elect their sheriffs, and sheriffs are dedicated to public safety. Sheriffs see marijuana's worst effects on people in the streets and in the county jail. Along with other first responders, sheriffs see marijuana's effects on drivers. Sheriffs help pick up the dead bodies. Representing over 3,000 sheriffs, the National Sheriffs' Association (NSA) comments on DEA's proposal:

- At most, DEA may move marijuana to schedule II, not III, because it has a high abuse potential. HHS and DEA have found this to be true repeatedly, and marijuana strains and products have only increased in potency in recent years.
- In its August 2023 recommendation, HHS found that marijuana's abuse potential is less than other drugs in schedule I or II. First, HHS committed the legal error of failing to assess whether marijuana has a high abuse potential. The CSA requires HHS to find that a drug does not have a high abuse potential before it may consider its relative abuse potential. No one should defer to HHS's legal error. Second, HHS changed its method of analysis to put the most weight on marijuana's adverse outcomes compared to drugs like heroin and fentanyl. But HHS offered no reason for this, and certainly no reason that impeached its scientific and medical reasoning in years past. Third, HHS chiefly considered *single-dose* adverse outcomes and, thus, ignored the abundant evidence of marijuana's long-term adverse effects on individual and public health. HHS's 2023 scientific and medical reasoning is contrary to its past reasoning and is faulty. HHS's past scientific and medical reasoning is entitled to deference under the CSA.
- DEA somehow denies that its proposal raises federalism concerns. But the CSA's schedules and restrictions are tied to the states' drug-control laws, and federal and state officials work together to facilitate legitimate drug research, including on medical marijuana, and to prevent diversion. Executive Order 13132 requires DEA to confer with state and local officials.
- DEA may move marijuana only to schedule II for the United States to meet its obligations under the Single Convention on Narcotic Drugs, 1961. OLC's 2024 opinion that the Single Convention itself does not require a particular schedule misses the point. The *CSA itself* requires DEA to place a drug in the most appropriate schedule to comply with international treaties, and the CSA makes I or II the most appropriate schedule for marijuana. DEA's rulemaking authority does not permit it to select a less appropriate schedule intentionally and make up the shortfalls with additional regulations.
- Contrary to HHS's assertion, the 2018 Farm Bill does not support moving marijuana to schedule III.

**Thesis:** At most, the law and evidence support rescheduling marijuana from I to II, not III.

## Background

The CSA regulates various drugs and other controlled substances by placing them in one of five schedules. Schedule I has the most controls and V the fewest. Drugs in schedule I have no currently accepted medical use in the United States (CAMU) and a high potential for abuse. Drugs in schedule II have a CAMU but also a high potential for abuse. Drugs in schedule III have a CAMU; they do not have a high absolute potential for abuse; and their relative abuse potential is less than drugs in schedule I or II.

When it passed the CSA in 1970, Congress put marijuana in schedule I. The Drug Enforcement Administration, however, may move a drug to another schedule in certain circumstances. In scheduling a drug, DEA must confer with the U.S. Dept. of Health and Human Services (HHS) for scientific and medical recommendations, and DEA must defer to HHS's proper recommendations. In 1989, 2001, 2011, and—most recently—2016, DEA rejected petitions to move marijuana from schedule I. Each time, DEA found that marijuana had no CAMU, and this kept the drug in I. In 2001, 2011, and 2016, DEA also found that marijuana had a high abuse potential. DEA's findings concurred with HHS's recommendations each time.

In October 2022, the President asked HHS and DEA to review marijuana's scheduling.

In an August 2023 letter, HHS recommended rescheduling marijuana from I to III—not II. HHS backed its letter with a 77-page *Basis for Recommendation* and over 170 pages of analysis on whether marijuana has a CAMU.

On May 16, 2024, DEA announced its preliminary decision to reschedule marijuana from I to III consistent with HHS's recommendation. DEA published its decision in a Notice of Proposed Rulemaking (NPRM) in the *Federal Register*.

In a 1994 executive order (EO 13132), the President directed executive-branch agencies to confer with state and local officials in the development of regulatory policies that have federalism implications; that is, implications for the relationships between federal, state, and local levels of government. In its 2024 NPRM, DEA asserted that marijuana's proposed rescheduling does not have federalism implications that warrant conferring with state and local officials.

In scheduling drugs, the CSA requires DEA to comply with the nation's international treaty obligations. In a 1972 opinion, the Office of Legal Counsel (OLC) in the U.S. Dept. of Justice said that marijuana must remain on schedule I for the United States to comply with the Single Convention on Narcotic Drugs, 1961. In 2016, DEA believed the same thing—without reference to the 1972 OLC opinion. In its 2024 NPRM, however, DEA asserted that, in fact, it *can* comply with the Single Convention by rescheduling marijuana to III—if it passes additional regulations to make up the shortfall between what the Convention requires and III's existing restrictions.

In an April 11, 2024 opinion, DOJ's OLC answered three questions related to DEA's NPRM. First, OLC said that HHS may use an analysis to decide if marijuana has a CAMU that is different than the one HHS has used in the past. Second, OLC said that DEA must accord HHS's scientific and medical determinations significant deference. Asserting that its reading of the evidence must only be adequate and not the best, DEA will use this part of OLC's opinion to reject comments to its NPRM, which read the evidence as showing that marijuana has a high potential for abuse. Third, OLC said that the Single Convention itself does not require DEA to place marijuana in schedule I or II.

## Summary Table of Contents

|   |    |
|---|----|
| Introduction . . . . .  | 1  |
| Background . . . . .  | 2  |
| Abbreviations & Definitions . . . . .   | 4  |
| 1. At most, the evidence supports rescheduling<br>marijuana from I to II, not III. DEA’s and HHS’s<br>reasoning is contrary to 811 and 812, unsupported, or otherwise faulty. . . . . | 5  |
| 2. The federalism concerns raised by DEA’s NPRM<br>require consultation with state and local gov’ts. . . . .  | 10 |
| 3. DEA has not shown that the United States will<br>be able to meet its international treaty obligations. . . . .   | 13 |
| 4. The 2018 Farm Bill doesn’t justify<br>rescheduling marijuana from I to III. . . . .  | 15 |
| Conclusion: At most, DEA may reschedule marijuana to II, not III. . . . .   | 17 |
| Endnotes . . . . .  | 18 |

## Abbreviations & Definitions

**2018 Farm Bill** – This is the Agricultural Improvement Act of 2018, Pub. L. No. 115-334, which excluded hemp—with only a tiny percentage of delta-9 THC—from the CSA and, thus, expanded domestic production of hemp and hemp-derived products.

**811(c)** – This provision, 21 U.S.C. § 811(c), lists eight factors for analyzing a drug’s scheduling (8FA).

**812(b)** – This provision, 21 U.S.C. § 812(b), sets out the criteria for schedules I, II, III, IV, and V.

***Basis for Recommendation* or *Basis*** – DEA must consult HHS on drug scheduling. In an Aug. 29, 2023 letter, HHS recommended rescheduling marijuana from I to III. HHS’s *Basis for Recommendation* accompanied the letter. DEA refers to the *Basis* in its NPRM.

**CAMU** – This stands for currently accepted medical use. Drugs in schedule I have no CAMU while a drug must have a CAMU to fall in II, III, IV, or V.

**CBD** – Cannabidiols and cannabinols are components of marijuana (cannabis). When the 2018 Farm Bill removed hemp from the definition of marijuana, it removed CBD. Chemists remove CBD from hemp and synthesize delta-8 THC from CBD.

**CSA** – federal Controlled Substances Act, 21 U.S.C. §§ 801, *et seq.*

**DEA** – Drug Enforcement Administration

**Delta-9 THC** – This is marijuana’s chief psychoactive ingredient.

**Delta-8 THC** – Chemists synthesize CBD from hemp, and they derive delta-8 THC from CBD. Although psychoactive, delta-8 THC is less potent than delta-9 THC.

**DOJ** – Some procedural rules, like EO 13132, which requires a federal agency to consult with state and local officials when proposed rulemaking has federalism implications, may apply to the U.S. Dept. of Justice (instead of separately to a component, like DEA).

**HHS** – U.S. Dept. of Health & Human Services

**NPRM** – In its May 16, 2024 Notice of Proposed Rulemaking, DEA proposes to reschedule marijuana from I to III.

**OLC** – DOJ’s Office of Legal Counsel prepared an April 11, 2024 opinion related to DEA’s NPRM.

**UNODC** – United Nations Office of Drugs and Crime tracks the trafficking and use of illicit drugs. It prepares the *World Drug Report* annually.

**WDR** – **World Drug Report** contains information about drug demand and supply trends globally.

**1. At most, the evidence supports rescheduling marijuana from I to II, not III. DEA’s and HHS’s reasoning is contrary to 811 and 812, unsupported, or otherwise faulty.**

### **1.1 Criteria**

**Schedule I** – The drug has a high potential for abuse, no currently accepted medical use in treatment in the United States (CAMU), and a lack of accepted safety for use under medical supervision.

**Schedule II** – The drug has a high potential for abuse, with a currently accepted medical use, and abuse of the substance may lead to severe psychological or physical dependence.

**Schedule III** – The drug has a potential for abuse less than a I or II drug. It has a currently accepted medical use, and abuse may lead to moderate or low physical dependence or high psychological dependence.<sup>1</sup>

### **1.2 The President’s Oct. 2022 Request**

The President asked HHS to “initiate the administrative review process to review expeditiously how marijuana is scheduled under federal law,”<sup>2</sup> and he questioned marijuana’s inclusion on schedule I, which is a higher schedule than fentanyl’s (II). Nonetheless, he did not suggest III over II, and the FDA has approved fentanyl for use as a pain reliever and anesthetic,<sup>3</sup> which is a broader range of uses than FDA has conferred for any marijuana-derived drug.

### **1.3 DEA’s 2016 Determination**

In 2016, HHS recommended that marijuana remain on schedule I because it had a high potential for abuse, no CAMU, and a lack of accepted safety for use under medical supervision.<sup>4</sup> Although the lack of a CAMU was decisive, DEA published HHS’s medical and scientific analysis related to marijuana’s scheduling.<sup>5</sup> HHS’s 2016 analysis is relevant to the scheduling analysis today.

### **1.4 Currently Accepted Medical Use (CAMU)**

The only thing that has changed since 2016 is that some evidence may now suggest that marijuana has a CAMU for anorexia related to a medical condition, nausea and vomiting (*e.g.*, related to chemotherapy), and pain.<sup>6</sup> Nonetheless, HHS’s conclusion is equally consistent with re-scheduling marijuana from I to II because a substance must have a CAMU under both II and III.<sup>7</sup>

### **1.5 Marijuana has a high potential for abuse.**

If a drug has a high potential for abuse and a CAMU, then it belongs in schedule II.<sup>8</sup> In 2016, DEA found that “marijuana has a high potential for abuse.”<sup>9</sup> Today, neither DEA nor HHS points to any flaw in their 2016 reasoning, and neither points to any evidence—much less evidence developed after 2016—that marijuana’s abuse potential has declined in the last seven or eight years.

Instead, DEA changed its analysis—by focusing almost exclusively on narrowly defined adverse outcomes—and asserted “marijuana is not typically among the substances producing the most frequent incidence of adverse outcomes or severity of substance use disorder.”<sup>10</sup> DEA didn’t provide a reason for this change (at least not one that impeaches its 2016 analysis), and, more importantly, DEA didn’t point to any evidence that marijuana’s abuse potential relative to fentanyl or cocaine<sup>11</sup> has changed since 2016.

In short, marijuana has a high potential for abuse, and this fact means that DEA can move it to schedule II only.<sup>12</sup> It cannot reschedule it to III.

## **1.6 HHS committed a legal error in its scheduling analysis.**

The first statutory question is whether marijuana has a high potential for abuse.<sup>13</sup> Here, HHS skipped this step. Instead HHS contends that the issue is only marijuana’s “relative abuse potential compared to other drugs.”<sup>14</sup> This ignores the statute’s structure and text. Drugs in schedules I and II have a high potential for abuse, and drugs in III, IV, and V have a lower abuse potential than the drugs in the preceding schedule.<sup>15</sup> Under this structure, HHS must assess whether a drug’s absolute abuse potential is high, and, if it isn’t, then HHS must assess whether its abuse potential is less than the drugs in I and II in order to go into schedule III. Here, HHS must first find that marijuana does not have a high potential for abuse under 812(b)(2)(A) before it can proceed to assess whether its abuse potential is less than the drugs in I and II under 812(b)(3)(A).

In addition to ignoring 812(b)’s text and structure, HHS ignores the history of its own analysis of marijuana’s high abuse potential and the drug’s scheduling. Congress determined that marijuana had a high abuse potential in 1970, and HHS itself determined the same thing several times,<sup>16</sup> including in 2016.<sup>17</sup> HHS cannot ignore these determinations in favor of a new analysis without justification. HHS’s skipping 812(b)(2)(A)’s criterion about high-abuse potential in the case of marijuana is worse than being arbitrary and capricious or some other APA misstep.<sup>18</sup> It is a strategy to circumvent the CSA. HHS has no evidence that marijuana’s absolute abuse potential or its relative abuse potential or its adverse-outcome potential relative to other I and II drugs has dropped since 2016.

## **1.7 No one should defer to HHS and DEA’s legal error.**

OLC contends that DEA must “accord HHS’s scientific and medical determinations significant deference.”<sup>19</sup> In a June 2024 opinion, however, the U.S. Supreme Court reaffirmed that an administrative agency may not ignore or misread its statute, even to achieve what it thinks is better policy.<sup>20</sup> Here, HHS committed a *legal* error by failing to address the evidence that marijuana has a high potential for abuse, and DEA repeats the error in its NPRM. No one should defer to this.

## **1.8 Even apart from this legal error, HHS’s reasoning about relative abuse potential is suspect.**

First, in 2016, DEA and HHS found that marijuana had a high potential for abuse. Now, HHS points to no evidence that marijuana’s abuse potential compared to that of other schedule I and II drugs has decreased since 2016.

Second, delta-9 THC is marijuana’s chief psychoactive ingredient,<sup>21</sup> and the higher a drug’s potency, the higher its abuse potential.<sup>22</sup> The evidence is overwhelming that the industry has developed marijuana strains with higher delta-9-THC levels and marijuana products, such as vape pens and edibles, with higher delta-9-THC concentrations (HHS calls the increase in potency dramatic<sup>23</sup>).<sup>24</sup> So, although HHS contends that marijuana has a lower “abuse liability” when compared to heroin, oxycodone, hydrocodone, and fentanyl,<sup>25</sup> the fact is that the higher delta-9-THC potency of today’s marijuana strains and products means that its relative abuse potential is *closer* to that of those other drugs than it was in 2016.<sup>26</sup> HHS’s scientific reasoning is faulty.

Third, in 2016, DEA cautioned about the difficulties of comparing marijuana to the diverse array of schedule II drugs because of their pharmacologically dissimilar actions.<sup>27</sup> Thus, DEA considered sociological or epidemiological evidence significant in concluding that marijuana had a high potential for abuse.<sup>28</sup> DEA considered evidence that individuals take marijuana in amounts sufficient to create hazards to their individual or community health, evidence of significant diversion, and evidence that individuals often take marijuana on their own initiative rather than on medical advice.<sup>29</sup> Lastly, DEA considered

evidence that marijuana is so related to other listed drugs, Marinol and Cesamet, that it will likely have the same abuse potential.<sup>30</sup>

An independent source confirms the significance of this sort of evidence. As one of its key missions, the U.N. Office on Drugs and Crime tracks the trafficking and use of illicit drugs. UNODC reports that cannabis is the most-used drug globally.<sup>31</sup> “Most drug use disorders are related to cannabis and opioids, which are also the drugs that lead most people to seek drug treatment, but opioids remain the most lethal drug.”<sup>32</sup> Moreover, of the countries that rank the drugs leading to drug-use disorders, the majority (46%) reported cannabis in first place compared to only 31% who ranked opioids (heroin) in first place.<sup>33</sup> Given its track record in leading to widespread *actual* abuse, marijuana more than meets 812(b)(2)(A)’s standard of high *potential* for abuse.

In contrast to its actions in 2016 or UNODC’s in 2023, however, HHS considered only a slice of this type of evidence in the 2023 *Basis*. HHS put the most weight on evidence about *relative adverse outcomes* associated with the use of marijuana and other drugs in I and II. HHS found “marijuana is not typically among the substances producing the most frequent incidence of adverse outcomes or severity of substance use disorder.”<sup>34</sup> But HHS articulated no reason for focusing on data about comparative adverse outcomes to the exclusion of other epidemiological evidence of abuse potential. In contrast, in 2011, HHS considered that large numbers of persons regularly used marijuana, its use was widespread, and the vast amount of marijuana available for illicit use indicated the drug’s high abuse potential.<sup>35</sup> Also, HHS pointed to no evidence that marijuana’s adverse outcomes compared to heroin’s, cocaine’s, or fentanyl’s are any different, or less severe, today than they were in 2016. These problems cast doubt on HHS’s scientific or medical reasoning.

HHS’s conception of adverse outcomes is unscientifically narrow as well. HHS considered chiefly “serious medical outcomes, including death,” emergency-department visits, hospitalizations, unintentional exposures, and overdose deaths.<sup>36</sup> That is, HHS considered *single-dose* adverse consequences while ignoring or discounting evidence of marijuana’s long-term dangers to individual and public health.<sup>37</sup>

In addition to the evidence of widespread marijuana use globally and domestically and the evidence of its increasing delta-9-THC potency,<sup>38</sup> consider just a sampling of evidence on marijuana’s effects on individual health, driving or motor-vehicle safety, and other adverse outcomes. As to individual health, researchers have connected marijuana use to more-frequent chronic bronchitis episodes and worse respiratory symptoms; increased risks of schizophrenia, other psychoses, social anxiety disorders; and cannabis-use disorder; and it impairs learning, memory, and attention, especially immediately after use.<sup>39</sup> Frequent use may significantly increase the risk of a heart attack and stroke.<sup>40</sup> Among youth and adolescents, marijuana exposure is associated with short- and possibly long-term impairments in cognition, worse academic or vocational outcomes, and increased prevalence of psychotic, mood, and addictive disorders.<sup>41</sup> Some evidence links marijuana to psychosis and violent behavior.<sup>42</sup>

Marijuana use impairs the ability to drive in several ways,<sup>43</sup> and a 2022 NHTSA study found that nearly 56% of roadway users injured or killed tested positive for one or more drugs with cannabinoids as the most prevalent, and another 2023 study found that marijuana’s legalization has caused up to an additional 1,400 road deaths a year.<sup>44</sup>

The evidence is similar with respect to other long-term adverse consequences of marijuana. In a 2020 paper, for example, researchers who reviewed the literature concluded, in part:

“This review indicates that marijuana policy changes have had mixed effects on U.S. adolescent health including potential benefits from decriminalization and negative health outcomes evidenced by increases in cannabis-related motor vehicle accidents, emergency department visits, and hospitalizations. Federal and state legislatures should apply a *public health framework* and consider the possible downstream effects of marijuana policy changes on pediatric health.”<sup>[45]</sup>

Similarly, by early 2023, the number of U.S. workers who are testing positive for marijuana after job accidents or injuries was at a 25-year high.<sup>46</sup>

HHS was the medical and scientific expert on relative abuse potential in 2016, and Congress’s and OLC’s injunction that DEA and others should defer to HHS’s scientific and medical determinations in scheduling marijuana applies in principle to HHS’s 2016 reasoning. Again, HHS pointed to no evidence that marijuana’s potential for abuse has dropped, that its relative potential for abuse when compared to drugs like heroin, cocaine, or methamphetamine has dropped, or that its rates of adverse outcomes compared to those drugs has dropped since 2016.

### **1.9 Marijuana’s Potential to Lead to Physical or Psychological Dependence**

Abuse potential is different from dependence potential.<sup>47</sup> In previous scheduling decisions, HHS and DEA found that marijuana had a high abuse potential, and both I and II require this.<sup>48</sup> But they didn’t study marijuana’s dependence potential because schedule I—marijuana’s schedule—uses a different criterion (lack of accepted safety for use under medical supervision<sup>49</sup>).

In its 2023 *Basis*, however, HHS assessed dependence potential under 812(b)(3)(C) in a similar way to how it assessed abuse potential; that is HHS compared marijuana’s “relative safety or ability to produce physical dependence compared to other drugs,”<sup>50</sup> and it emphasized lack of severe outcomes.<sup>51</sup> HHS found that “abuse of marijuana may lead to moderate or low physical dependence” and that “high psychological dependence does not occur in most people”<sup>52</sup>

Abuse of a schedule II drug may lead to severe psychological or physical dependence.<sup>53</sup> According to the *WRD*, 296 million people worldwide used cannabis in 2021 compared to only 60 million for opioids.<sup>54</sup> Because there is some ambiguity about the distinctions between drug use, drug misuse, and drug abuse, *WRD* uses the neutral term “drug use.”<sup>55</sup> In any event, people “use” cannabis nearly five times as much as they use opioids.

Likewise, in late 2023, *Monitoring the Future* reported that, “past-year use of marijuana and hallucinogens by adults 35 to 50 years old continued a long-term upward trajectory to reach all-time highs in 2022.”<sup>56</sup> In the U.S. in 2022, an estimated 61.9 million individuals aged 12 or older used marijuana in the past year, and 42.3 million reported using it in the past month.<sup>57</sup> This is consistent with other evidence of increased marijuana use by various age groups in the U.S. and by at-risk populations such as depressed persons and pregnant women.<sup>58</sup> Rising use is evidence of a strong dependence potential.

According to the UNODC, not only does the majority of countries who rank drugs leading to drug use disorders rank cannabis first, but “The ranking in each country is determined mainly by two factors: prevalence of use and *dependence potential*.” (Emphasis added).<sup>59</sup> According to the CDC, “Approximately 3 in 10 people who use cannabis have cannabis use disorder. \* \* \* The risk of developing cannabis use disorder is stronger in people who start using cannabis during youth or adolescence and who use cannabis



more frequently.”<sup>60</sup> Where nearly five times the number of people use marijuana than HHS’s other comparator drugs, like opioids, and three in ten will develop cannabis-use disorder, from a broad perspective, this is evidence that abuse of marijuana may lead to severe psychological or physical dependence. After a young man “battled marijuana addiction and marijuana psychosis” for over five years (his physician had written “THC abuse, severe” in his chart), he took his own life.<sup>61</sup>

### **1.10 Risk to Public Health**

In addition to providing patrol, traffic-enforcement, criminal-investigation, and dispatch services, the nation’s sheriffs supervise most of the nearly 3,000 county jails across the country. “The total annual jail population is *18 times* the annual population of federal and state prisons.”<sup>62</sup> The nation’s sheriffs can confirm that today’s high-potency marijuana and marijuana products present a clear risk to public health.<sup>63</sup>

Although it is anecdotal, the sheriffs’ testimony stands on first-hand experience in responding to 9-1-1 calls from persons in trouble, making traffic stops, responding to traffic crashes and fatalities, investigating crimes, and caring for people in the county jail:

- Although opioids, fentanyl, and methamphetamine are terrible drugs and kill more people, a high percentage of people in a county jail suffer from using marijuana. Marijuana dulls minds, stalls lives, and diverts efforts. A sheriff rarely, if ever, sees marijuana contribute to happiness, well-being, or success.
- Although fentanyl too often kills instantly and methamphetamine wastes a human body, today’s marijuana is not from the 1960s. Today, a sheriff routinely handles persons suffering from extreme THC intoxication. Contemporary marijuana strains and products contain more THC than ever, and the problem is only growing worse. Products are mislabeled, and regulation is struggling to keep up.<sup>64</sup>
- Make no mistake: marijuana impairs the ability to drive, and marijuana use contributes to motor vehicle crashes and deaths.<sup>65</sup>

### **1.11 Conclusion**

At most, the evidence supports rescheduling marijuana from I to II, not III. Most significantly, marijuana has a high potential for abuse—which excludes it from schedule III. Congress found this in 1970, and HHS and DEA found this in 2016.

HHS and DEA now focus on marijuana’s relative abuse potential compared to schedule I and II drugs, like fentanyl and cocaine, and ignore or discount other abuse-potential evidence. But HHS shows no scientific or medical reason for this shift, and it shows no mistake in its 2016 analysis. Instead, HHS changed its analysis in order to avoid putting marijuana in schedule II. Skipping 812(b)(2)(A)’s criterion is a legal error. Moreover, HHS points to no evidence that marijuana’s absolute or relative abuse potential, or its relative adverse outcomes, compared to other I and II drugs, has decreased since 2016. In fact, the industry has produced marijuana strains and products that contain more delta-9 THC than a decade ago, and this means that marijuana’s absolute potential for abuse is higher and its relative abuse potential is closer to other I and II drugs than in 2016.

## **2. The federalism concerns raised by DEA’s NPRM require consultation with state and local gov’ts.**

DEA, or its parent, DOJ, must have “an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.”<sup>66</sup> An agency’s policy or regulation has federalism implications when it has a substantial direct effect on the States, on the relationship between the national gov’t and the States, or on the distribution of power and responsibilities among the various levels of gov’t.<sup>67</sup> Here, DEA asserts, “This rulemaking does not have federalism implications warranting the application of Executive Order 13132.”<sup>68</sup> DEA denies that its NPRM meets any of the criteria to trigger a duty to confer with state and local officials.<sup>69</sup> This defies belief.

“The struggle over marijuana regulation is one of the most important federalism conflicts in a generation.”<sup>70</sup>

— Professor Erwin Chemerinsky, Dean, U.C. Berkeley School of Law

Professor Chemerinsky and his colleagues on marijuana policy surveyed the problems that flow from the “clash” between federal and state marijuana laws, including problems for banks, attorneys, insurance companies, investors, and others.<sup>71</sup> Writing in 2015, they pointed to bills to amend marijuana regulation that had failed to gain traction in Congress.<sup>72</sup> And similar measures are pending today before the 118th Congress.<sup>73</sup> This reflects persistent splits in policy thinking.

Professor Chemerinsky and the others proposed to try to accommodate both sides with an “incremental solution that would allow willing states to experiment with novel regulatory approaches while leaving the federal marijuana prohibition unchanged for the remaining states.”<sup>74</sup> Proponents contend that this sort of cooperative federalism promotes effective government, advances liberty, better handles spillovers and externalities, empowers communities, enhances accountability, and meets diverse needs.<sup>75</sup> EO 13132 touts principles such as recognition of state sovereignty, the states’ role as laboratories of democracy, and a “healthy diversity of public policies.”<sup>76</sup>

In contrast to the professors, DEA proposes far-reaching amendments to marijuana regulation without consulting state and local officials and, thus, proposes to deprive the nation of the benefits of such consultation.

### **2.1 Penalties, Tax Deductions, and Prescriptions**

Moving marijuana from I to II or III will affect penalties for CSA violations where the penalties turn on the schedule.

Moving marijuana to III will render certain producers eligible for tax deductions and credits that would remain unavailable under II.<sup>77</sup>

Moving marijuana from schedule I to III—or from I to II—will pave the way for physicians to prescribe FDA-approved marijuana products. A drug needs a CAMU to be in either.<sup>78</sup> But schedule II drugs have more prescription restrictions and safeguards than IIIs.<sup>79</sup> In a state like Texas, moreover, a schedule II drug may have more safeguards related to prescription drug monitoring.<sup>80</sup>

## 2.2 Research Safeguards

With respect to controlled substances, DEA’s mission is to prevent diversion and abuse of these substances and to ensure that an adequate supply is available for the nation’s medical, scientific, and research needs.<sup>81</sup> Currently, DEA’s *Researcher’s Manual* lists various requirements and standards imposed on those who research schedule I or II substances, and these protect public health and safety.<sup>82</sup> In contrast, the *Manual* lists no comparable requirements or standards for schedule III (although some less-strict controls apply to schedule III research). Also, DEA sets production quotas for schedules I and II, but not III.<sup>83</sup> Thus, re-scheduling marijuana from I to III, instead of II, will remove procedures and standards that protect public health and safety while fostering accountability and integrity in research, and this will affect both federal and state research using marijuana.

DEA’s proposed re-scheduling of marijuana raises related federalism concerns. In fighting diversion and protecting a research supply of controlled substances, DEA works “closely with state and local authorities and other federal agencies”:

Federal controlled substance laws are designed to function in tandem with state controlled substance laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to make certain that pharmaceutical controlled substances are prescribed, administered, and dispensed for a legitimate medical purpose in the usual course of professional practice. Within this framework, the majority of investigations into possible violations of controlled substance laws are carried out by state authorities. DEA focuses its investigations on cases involving violators of the highest level or most significant impact.<sup>84</sup>

Given this relationship between federal and state regulations and officials, any proposal to reschedule marijuana—especially to a schedule lower than II—implicates federalism.

Moreover, HHS’s *Basis for Recommendation* illustrates the size of the underlying research infrastructure.<sup>85</sup> In assessing whether marijuana has a qualifying CAMU, HHS considered “the current widespread medical use of marijuana under the supervision of licensed health care practitioners (HCPs) under state-authorized programs.”<sup>86</sup> HHS found that more than 30,000 health care providers may recommend the use of marijuana for over 6 million registered patients, and HHS reviewed information from these state-authorized programs to evaluate whether evidence supports that marijuana has a CAMU for things like anorexia, anxiety, epilepsy, nausea and vomiting, pain, and PTSD.<sup>87</sup> Proposing to remove guardrails from such a large, multi-state system is no small thing.

In sum, federal and state law—largely turning on a drug’s scheduling—sets up a framework to ensure a supply of a controlled substance for the nation’s research needs and to combat diversion. Federal law enforcement works closely with state and local law-enforcement and public-health officials toward these ends. And the multi-state research system is gigantic. Thus, a re-scheduling decision will have downstream consequences, and DEA’s NPRM requires consultation with state and local officials.

## **2.3 Congress has highlighted the federalism implications in its appropriations riders.**

In a line of appropriations riders, Congress has protected medical-marijuana programs in the states.<sup>88</sup> Section 531 of a 2024 appropriations bill, for example, prohibits DOJ from using federal funds “to prevent any of [a list of 47 states, the District of Columbia, and four territories] from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.”<sup>89</sup>

First, Congress has inserted these provisions in must-pass bills about other topics, and they are merely stopgaps. Congress did not design them to be the next big step in federal marijuana regulation.

Second, this sort of temporary suspension on the use of funds to enforce certain federal laws is not the same thing as an amendment to the CSA itself. Congress hasn’t exempted marijuana from the nation’s larger—federal—framework for research on controlled substances. Congress didn’t remove marijuana from its description of schedule I at 812(c)(10).

Third, with these suspensions, Congress is *practicing federalism* by recognizing the significance of states establishing their own marijuana regulations and medical-marijuana research programs. In contrast, DEA’s NPRM would diverge from Congress’s example and force a result on all other members of our federalist system without state and local consultation.

## **2.4 DEA’s Narrow View of EO 13132**

It’s difficult to imagine a rationale for DEA’s assertion that its proposal to reschedule marijuana from I to III does not have federalism implications warranting consultation with state and local officials. But DEA is apparently prepared to argue something like the NPRM proposes a change in *federal* drug scheduling and won’t change the CSA’s preemptive scope.<sup>90</sup> Rescheduling marijuana to III will probably reduce conflicts between the CSA and the laws of states with medical- or recreational-marijuana laws. Even if these points are accurate, however, marijuana’s scheduling does raise federalism concerns. DEA’s new assertion is inconsistent with its statements that federal controlled-substances laws function in tandem with state controlled-substances laws and that federal, state, and local law enforcement cooperate to combat diversion.<sup>91</sup> “[T]he diversion and abuse of pharmaceutical controlled substances remains a public health concern in the United States.”<sup>92</sup> As noted, Congress has recognized the federalism implications in multiple appropriations riders.

If DEA argues that EO 13132 does not “create any right or benefit, substantive or procedural, enforceable at law,”<sup>93</sup> then the nation’s sheriffs—representing people in over 3,000 counties across the country—submit that it is all the more important for DEA to comply with EO 13132 on its own accord.

## **2.5 Conclusion**

DEA’s assertion that its proposal to reschedule marijuana from I to III does not have federalism implications that justify conferring with state and local officials defies belief. As the professors said, marijuana regulation is one of the most important federalism conflicts in a generation, and policy leaders at all levels of government remain divided. This is precisely when EO 13132 requires a federal agency to confer with state and local officials. Given the significance of the federal regulatory framework over controlled drugs and the related research, law-enforcement, and public-health systems, laws, and officials, rescheduling marijuana will have substantial downstream consequences. If, through a lack of standing, no one can force DEA to comply with EO 13132, then DEA must comply on its own accord.

### 3. DEA has not shown that the United States will be able to meet its international treaty obligations.

The DEA must comply with the nation's commitments under international treaties, including the Single Convention on Narcotic Drugs, 1961.<sup>94</sup> In 1972, DOJ's Office of Legal Counsel opined that, "It would appear that full compliance with our obligations under the Single Convention could not be achieved unless marihuana is listed under Schedule I or Schedule II of the Act."<sup>95</sup> DEA still believed this in 2016, *without* reference to OLC's 1972 opinion.<sup>96</sup>

In its 2024 opinion, however, OLC opines, "[W]e believe that the Single Convention does not require DEA to place marijuana in Schedule I or Schedule II."<sup>97</sup> OLC contends that a new request from HHS and the State Dept. about "additional regulations" justifies the change.

DEA and OLC's proposal, however, faces one or two problems.

#### 3.1 OLC's proposal violates the CSA.

"If control is required by United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part, *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) of this section or section 202(b) [21 U.S.C. § 812(b)] and without regard to the procedures prescribed by subsections (a) and (b) of this section." 21 U.S.C. § 811(d)(1)<sup>98</sup>

The CSA is clear. DEA must use the most appropriate *schedule* to meet the nation's Single Convention obligations. In 2016, DEA recognized that 811(d) itself requires it to select the most appropriate schedule.<sup>99</sup> Although the DEA may use its rulemaking authority to supplement a schedule's restrictions to meet treaty obligations when the most appropriate one's fall short, 811(d)(1) doesn't authorize DEA to select an *inappropriate*, or even a less appropriate, schedule intentionally and then make up the difference with "additional regulations."

In its 2024 opinion, OLC asserts that the CSA doesn't state that a drug must be placed in a particular schedule to comply with the Single Convention and that the CSA doesn't expressly foreclose the United States from complying with the Convention with a combination of scheduling and regulation.<sup>100</sup> OLC asserts that 811(d)(1) "directs the Attorney General to 'control' a drug 'under the schedule [the Attorney General] deems most appropriate' (emphasis [OLC's])—language that signals a broad grant of discretion to the Attorney General (and thus DEA)."<sup>101</sup> OLC suggests that this gives DEA the discretion to meet the "CSA's varied, and potentially conflicting," purposes, such as something unspecified about "medical usefulness."<sup>102</sup>

OLC misquotes 811(d)(1). It doesn't direct the Attorney General to control a drug under the schedule the Attorney General deems most appropriate, period. When the United States must control a drug to meet its international obligations, 811(d)(1) requires the Attorney General to control the drug "under the schedule he deems most appropriate *to carry out such obligations*." 811(d)(1) doesn't grant the Attorney General discretion to select a schedule most appropriate to meet *other* CSA purposes.

811(d)(1) goes further. In scheduling, 811(a) requires the Attorney General to consider factors such as a drug's abuse potential, medical usefulness, and dependence potential, and 811(b) requires the Attorney General to solicit a recommendation from HHS on these factors and to defer to HHS's medical and scientific evaluation. 811(d)(1), however, expressly requires the Attorney General to select the most appropriate schedule to meet the nation's international treaty obligations "without regard to the procedures prescribed

by subsections (a) and (b) of this section”; that is, the very provisions that require the Attorney General to consult with HHS.

OLC contends that the CSA grants the Attorney General, or DEA, with the authority to fashion regulations to make up any gap between a schedule’s restrictions and what an international treaty, such as the Single Convention, may require.<sup>103</sup> And this is the case. But what’s decisive here is that 811(d)(1)’s text requires DEA to select the most appropriate schedule to meet international obligations, and it doesn’t permit DEA to select an inappropriate, or less appropriate, schedule intentionally. Also contrary to OLC’s 2024 suggestion,<sup>104</sup> DEA is intentionally avoiding the consequences of placing marijuana in schedule II. It isn’t trying to further the CSA’s other purposes.

In the case of marijuana, the CSA makes schedule I or II most appropriate for the United States to comply with Single Convention. “Many of the provisions of the CSA were enacted by Congress for the specific purpose of ensuring U.S. compliance with the [Single Convention].”<sup>105</sup> For example, article 21 of the Convention requires a signatory to set production quotas for the manufacture of a covered drug<sup>106</sup> (even OLC’s 1972 opinion emphasized this quota provision<sup>107</sup>). The CSA provides for production quotas for I and II drugs in section 826.<sup>108</sup>

OLC argues that 826 “should not be read as implicitly foreclosing the imposition of [manufacturing] quotas for drugs in Schedules III through V.”<sup>109</sup> But this misses the point. 811(d)(1) requires DEA to select the most appropriate schedule to meet Single Convention obligations, and 826 (and the fact that marijuana has a high abuse potential) supports the conclusion that II is more appropriate than III in marijuana’s case. After selecting the most appropriate schedule to meet international obligations, DEA retains rulemaking authority, including to impose quotas, to make up the schedule’s shortcomings in order to meet international obligations fully.

### **3.2 What DEA and OLC are talking about may legally be a schedule II classification.**

OLC contends that the United States can comply with the Single Convention by placing marijuana in schedule III “while ‘adopting such additional regulations *as are necessary for treaty compliance.*’”<sup>110</sup> But if schedule III’s restrictions, together with these new “additional regulations,” essentially make up schedule II’s essential restrictions, then the new hybrid III is a schedule II and all the law associated with marijuana being formally scheduled in II should apply.

Although OLC emphasizes DEA’s rulemaking authority under the CSA,<sup>111</sup> Congress didn’t confer this authority so that DEA can avoid putting a drug in the most appropriate schedule to comply with the Single Convention for the purpose of avoiding that schedule’s CSA restrictions.

### **3.3 Conclusion**

The CSA requires DEA to select the most appropriate drug schedule for the U.S. to meet its international treaty obligations, including those under the Single Convention on Narcotic Drugs, 1961. The CSA makes schedules I and II the most appropriate, and there’s no question that II is more appropriate than III. Although DEA’s rulemaking authority supports regulations to allow the U.S. to meet the Single Convention when the most appropriate schedule falls short, the CSA doesn’t authorize DEA to select an inappropriate, or less appropriate, schedule intentionally and then try to make up the difference by regulation.

#### **4. The 2018 Farm Bill doesn't justify re-scheduling marijuana from I to III.**

Early in its *Basis*, HHS points to two changes as “important difference[s] in the present scientific and medical evaluation” of marijuana’s scheduling: (1) the 2018 Farm Bill amended the definition of marijuana, and (2) the 2018 Farm Bill decontrolled many products containing cannabidiol (CBD).<sup>112</sup> Not only is it hard to see how a farm bill has scientific or medical significance, but HHS’s contentions are misleading.

##### **4.1 Congress’s removal of hemp from marijuana’s definition is irrelevant to scheduling.**

Congress cut out hemp from marijuana’s definition. But its definition limits hemp to parts of the *Cannabis sativa* L. plant “with a delta-9 tetrahydrocannabinol [THC] concentration of *not more than 0.3 percent* on a dry weight basis.”<sup>113</sup> Delta-9 THC is the psychoactive substance in marijuana.<sup>114</sup> So, Congress’s carving out of components that contain practically no delta-9 THC from marijuana’s definition does not justify moving marijuana to schedule III. Instead, the limit of a 0.3 percent on a dry weight basis illustrates the opposite: Congress considered even such a tiny amount of delta-9 THC to be dangerous. Moreover, Congress didn’t remove marijuana from schedule I at 21 U.S.C. § 812(c)(10) even after amending its definition and while it was amending other CSA provisions.

##### **4.2 Congress’s deregulating hemp-derived or CBD-containing products is irrelevant, too.**

Hemp contains CBD,<sup>115</sup> and Congress essentially decontrolled many CBD-containing products in the 2018 Farm Bill. HHS discusses post-Farm-bill developments with CBD products, including the FDA’s approval of Epidiolex for the treatment of a severe form of epilepsy.<sup>116</sup> But legal CBD products, by definition, can contain no more than 0.3 percent of delta-9 THC on a dry weight basis. Therefore, no developments involving legal CBD-containing products even *speaks* to the question of re-scheduling marijuana, much less supports moving it from schedule I to III.<sup>117</sup>

##### **4.3 HHS’s analysis of the 2018 Farm Bill’s significance to scheduling casts doubt on its overall reasoning.**

A brief search of information about products that contain CBD or delta-8-THC raises red flags.<sup>118</sup> Producers remove CBD from hemp and synthesize delta-8 THC from CBD.<sup>119</sup> Like delta-9 THC, delta-8 THC is psychoactive—although it is less potent than delta-9.<sup>120</sup> As of July 2024, FDA warns consumers about delta-8 THC’s “serious health risks.”<sup>121</sup> The manufacturing process uses potentially harmful chemicals,<sup>122</sup> and the chemical industry warns of unknown byproducts, such as strong acids and heavy metals.<sup>123</sup> FDA hasn’t evaluated delta-8-THC products for safe use, and parents should keep delta-8-THC products away from children and animals.<sup>124</sup> FDA has issued dozens of warning letters related to products that reportedly contain CBD.<sup>125</sup> The CDC issued a health advisory listing adverse-event reports related to delta-8-THC products in Sept. 2021.<sup>126</sup> And 11% of 12th-grade students report using delta-8-THC products in 2023.<sup>127</sup>

A search for “delta-8” and “Δ8” in HHS’s August 29, 2023 recommendation and 251 pages of support turns up one use of “delta-8” on page 75 of HHS’s *Basis*. HHS cited a study by Michael Tagen and Linda Klumpers that surveyed studies on delta-8 THC use and warned of gaps in our knowledge of delta-8 pharmacology.<sup>128</sup> Far from citing the paper for this knowledge gap, HHS cited it to suggest that CBD may be less addictive than delta-9 THC because it has a weaker affinity for the relevant receptors in the brain.<sup>129</sup>

Despite contending that developments about hemp and CBD (and, thus, delta-8 THC) are scientifically and medically important,<sup>130</sup> HHS doesn’t cite the abundant evidence of the dangers of products containing CBD or delta-8 THC. Ignoring this evidence calls into question HHS’s review of the evidence behind its recommendation to move marijuana to schedule III. Because delta-8 THC is derived from CBD itself, this

evidence suggests that the 2018 Farm Bill may have de-regulated delta-8 THC too hastily. In fact, some states have prohibited delta-8 THC products,<sup>131</sup> and, pointing to post-2018 evidence, the FDA recommended that Congress develop a new regulatory pathway for CBD products in January 2023.<sup>132</sup>

#### **4.4 Conclusion**

Congress's exclusion of hemp, with no more than 0.3 percent delta-9 THC on a dry-weight basis, from the CSA's definition of marijuana in no way supports re-scheduling marijuana from I to III. Moreover, HHS's assertion to the contrary isn't medical or scientific reasoning, and no one should defer to it. Moreover, whatever the value of HHS's review of post-2018 evidence about the de-regulation of CBD, HHS appears to have overlooked significant evidence of risks posed by products containing CBD or delta-8 THC. Again, the evidence has forced FDA and CDC to caution people about their health risks. These two developments from the 2018 Farm Bill do not support rescheduling marijuana to III.



**Conclusion: At most, DEA may reschedule marijuana to II, not III.**

Marijuana has been in schedule I of the Controlled Substances Act (CSA) since 1970, and the U.S. Department of Health and Human Services has supported this placement several times. As of May 16, 2024, however, the Drug Enforcement Administration intends to reschedule marijuana from I to III. HHS has altered its scientific and medical reasoning to accommodate this, and the Office of Legal Counsel (OLC) is assisting with a new legal opinion that diverts from OLC's past opinions in key ways.

The nation's sheriffs are dedicated to public safety, and they are concerned with this proposed sea change in national policy. Sheriffs see marijuana's worst effects, including extreme intoxication, derailed plans, and motor-vehicle crashes and fatalities. Representing over 3,000 sheriffs, the National Sheriffs' Association contends:

- At most, DEA may move marijuana to schedule II, not III, because it has a high abuse potential.
- In its August 2023 recommendation, HHS failed to consider the long-standing evidence that marijuana's absolute abuse potential is high. This is a legal error. To ignore this evidence, HHS focused on marijuana's lower rate of single-dose adverse outcomes compared to drugs like heroin or fentanyl. But HHS offered no scientific or medical reason for this change. Abundant evidence illustrates marijuana's long-term adverse consequences. HHS's past scientific and medical reasoning is entitled to deference under the CSA.
- DEA's denial of its proposal's implications for federalism defies belief. In its *Researcher's Manual*, DEA acknowledges the tight relationship between the federal CSA and the states' drug-control laws, and their restrictions turn on a drug's scheduling. DEA's *Manual* also acknowledges the fact that federal and state officials work together to facilitate legitimate drug research and to combat diversion. Therefore, DEA must confer with state and local officials under Executive Order 13132.
- DEA may move marijuana only to schedule II for the United States to meet its obligations under the Single Convention on Narcotic Drugs, 1961. OLC's 2024 opinion that the Single Convention itself does not require a particular schedule misses the point. The *CSA itself* requires DEA to place a drug in the most appropriate schedule to comply with international treaties, and the CSA makes I or II the most appropriate schedule for marijuana. DEA's rulemaking authority permits it to use regulations to make up shortcomings in the most appropriate schedule's ability to meet international obligations. DEA's authority does not permit it to select a less appropriate schedule intentionally and make up the shortfalls with additional regulations.
- Contrary to HHS's assertion, the 2018 Farm Bill does not support moving marijuana to schedule III.

At most, the law and evidence support rescheduling marijuana from I to II, not III.

## Endnotes

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<sup>1</sup> See 21 U.S.C. § 812(b).

<sup>2</sup> See Letter to Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Asst. Sec. for Health, HHS, at 1 & n.1 (Aug. 29, 2023) (citing Statement from President Biden on Marijuana Reform (Oct. 6, 2022), with Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/>), <https://www.hhs.gov/sites/default/files/scheduling-recommendation.pdf>.

<sup>3</sup> See, e.g., DEA, Drug Fact Sheet, “Fentanyl” (Apr. 2020), [https://www.dea.gov/sites/default/files/2020-06/Fentanyl-2020\\_0.pdf](https://www.dea.gov/sites/default/files/2020-06/Fentanyl-2020_0.pdf).

<sup>4</sup> See, e.g., DEA, Docket No. DEA-426, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,688, at 53,689 (Aug. 12, 2016).

<sup>5</sup> See, e.g., DEA, Denial, 81 Fed. Reg. 53,689 (“For the reasons just indicated [that marijuana had no CAMU in 2016], no further analysis beyond this consideration is required. Nonetheless, because of the widespread public interest in understanding all the facts relating to the harms associated with marijuana, DEA is publishing here the entire medical and scientific analysis and scheduling evaluation issued by the Secretary, as well as DEA’s additional analysis. \* \* \* The Food and Drug Administration (FDA) has considered the abuse potential and dependence-producing characteristics of marijuana.”).

<sup>6</sup> See Basis for Recommendation, at 28.

<sup>7</sup> See 21 U.S.C. § 812(b)(2)(B), (b)(3)(B).

<sup>8</sup> See 21 U.S.C. § 812(b)(2).

<sup>9</sup> DEA, Docket No. DEA-426, “Denial of Petition to Initiate Proceedings to Reschedule Marijuana,” 81 Fed. Reg. 53,688 (Aug. 12, 2016) (“The HHS evaluation and the additional data gathered by the DEA show that marijuana has a high potential for abuse.”); see DEA, Docket No. DEA-427, “Denial of Petition to Initiate Proceedings to Reschedule Marijuana,” 81 Fed. Reg. 53,767 (Aug. 12, 2016) (same); DEA, Docket No. DEA-352N, “Denial of Petition to Initiate Proceedings to Reschedule Marijuana,” 76 Fed. Reg. 40,552 (July 8, 2011) (“DHHS concluded that marijuana has a high potential for abuse . . . .”); *id.* at 40,562 (“Marijuana has a high potential for abuse.”).

<sup>10</sup> DEA, NPRM, Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597, at 44,603 (May 21, 2024); see 89 Fed. Reg. at 44,620.

<sup>11</sup> See DEA, NPRM, 89 Fed. Reg. at 44,620 (comparing marijuana’s abuse potential to that of fentanyl and cocaine).

<sup>12</sup> See, e.g., DEA, Docket DEA-352N, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552 (July 8, 2011) (“DHHS concluded that marijuana has a high potential for abuse, has no [CAMU], and lacks an acceptable level of safety for use even under medical supervision. Therefore, DHHS recommended that marijuana remain in schedule I.”); DEA, Notice of Denial of Petition, 66 Fed. Reg. 20,028 (Apr. 18, 2001) (“HHS concluded that marijuana does have a high potential for abuse and therefore recommended that marijuana remain in schedule I.”). Drugs in I and II have a high potential for abuse. See 21 U.S.C. § 812(b)(1)(A), (b)(2)(A). Assuming that evidence suggests that marijuana has a CAMU in 2024, then DEA can reschedule it to II at most because of its high abuse potential.

<sup>13</sup> This is true under schedule I and II. See 21 U.S.C. § 812(b)(1)(A), § 812(b)(2)(A).

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<sup>14</sup> Basis, at 1 (“At the conclusion of an 8FA, three findings need to be made to determine the scheduling recommendation for a substance: its relative abuse potential compared to other drugs, whether it has a currently accepted medical use (CAMU) in the United States . . . , and its relative safety our ability to produce physical dependence compared to other drugs, as provided under 21 U.S.C. § 812(b).”); *id.* at 62 (“Marijuana has a potential for abuse less than the drugs or other substances in Schedules I and II.”).

<sup>15</sup> *See* 21 U.S.C. § 812(b)(1)(A), (b)(2)(A) (I and II, with high abuse potential), (b)(3)(A), (b)(4)(A), (b)(5)(A) (III, IV, and V, with descending abuse potential).

<sup>16</sup> *See, e.g.*, DEA, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552 (July 8, 2011) (“DHHS concluded that marijuana has a high potential for abuse . . . .”); *id.* (“As discussed in the attached analysis, marijuana has a high potential for abuse . . . .”); DEA, Notice of Denial of Petition, 66 Fed. Reg. 20,038 (Apr. 18, 2001) (“HHS concluded that marijuana does have a high potential for abuse and therefore recommended that marijuana remain in schedule I.”); DEA, Marijuana Scheduling Petition; Denial of Petition, 84 Fed. Reg. 53,767, 53,783 (Dec. 29, 1989) (“For purposes of this proceeding, the parties stipulated that marijuana has a high potential for abuse.”). Thus, in 1989, the pro-marijuana petitioners didn’t fail to recognize that marijuana has a high potential for abuse.

<sup>17</sup> DEA, Docket No. DEA-426, “Denial of Petition to Initiate Proceedings to Reschedule Marijuana,” 81 Fed. Reg. 53,688 (Aug. 12, 2016) (“The HHS evaluation and the additional data gathered by the DEA show that marijuana has a high potential for abuse.”); *see* DEA, Docket No. DEA-427, “Denial of Petition to Initiate Proceedings to Reschedule Marijuana,” 81 Fed. Reg. 53,767 (Aug. 12, 2016) (same).

<sup>18</sup> *See, e.g.*, 5 U.S.C. § 706(2).

<sup>19</sup> Memorandum Opinion for the Attorney General from Christopher C. Fonzone, Assistant Attorney General, Office of Legal Counsel, *Re: Questions Related to the Potential Rescheduling of Marijuana*, at 1 (Apr. 11, 2024), <https://www.dea.gov/sites/default/files/2024-05/2024-04-11%20-%20AAG%20Fonzone%20-%20Marijuana%20Rescheduling.pdf>; *id.* at 3 (citing 21 U.S.C. § 811(b) for the proposition that HHS’s recommendations “shall be binding” as to “certain scientific and medical matters”); *id.* at 6 (stating that Congress intended to “place scientific and medical judgments” in HHS’s hands).

<sup>20</sup> *See Garland v. Cargill*, 602 U.S. 406 (2024) (rejecting an ATF rule for failure to comply with the GCA’s definitions, which confined its rulemaking authority).

<sup>21</sup> *See* Basis, at 10 (“Δ9-THC is the major psychoactive intoxicating cannabinoid in marijuana . . . .”); DEA, Denial, 81 Fed. Reg. 53,688, at 53,742 (“Δ9-THC, the primary psychoactive component in marijuana, is an effective reinforcer in laboratory animals . . . .”).

<sup>22</sup> *See, e.g.*, Elizabeth Stuyt, M.D., “The Problem with Current High Potency THC Marijuana from the Perspective of an Addiction Psychiatrist,” 115 *Mo. Med.* 482 (Nov.–Dec. 2018) (“The more potent a drug is, the stronger the possibility of addiction.”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6312155/>.

<sup>23</sup> *See* Basis at 11 (“In the past 30 years, the potency of marijuana with regard to Δ9-THC has increased dramatically.”).

<sup>24</sup> *See* Francesca Vernich, *et al.*, “Trends in Illicit Cannabis Potency based on the Analysis of Law Enforcement Seizures in the Southern Area of Rome,” 11 *Toxics* 648 (July 26, 2023) (“This paper presents data about THC concentration in cannabis resin samples seized by law enforcement from 2015 to 2022 in the southern area of Rome (Italy). From 2015 to 2022, more than 1000 hashish samples were analyzed; the average THC content was 18.0% and dramatically increased from 13.7% (2015) to 27.1% (2022). The potency of THC in some samples characterized by unusual shape and color was higher than 24% and, in a few cases, higher than 40%. The age group most involved in seizures of cannabis resin concerned males aged between 15 and 36 years old. The spread of this phenomenon increases the risk of adverse health outcomes.”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10458633/>; Mahmoud A. ElSohly, *et al.*, “Changes in Cannabis Potency over the Last Two Decades (1995–2014) – Analysis of Current Data in the United States,” 79 *Biol. Psychiatry* 613 (Jan. 19, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987131/>.

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<sup>25</sup> See, e.g., Basis at 9.

<sup>26</sup> Cf. Godfrey D. Pearlson, Michael C. Stevens, & Deepak Cyril D’Souza, “Cannabis and Driving,” *Frontiers in Psychiatry* (2021) (“Furthermore, while the prevalence of alcohol and other drugs in the same population of suspected impaired drivers submitted for testing did not change during this same 5 year period; cannabis was the only drug to increase in frequency.”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8499672/>.

<sup>27</sup> See DEA, Denial, 81 Fed. Reg. at 53,690 (“The petitioners compare the effects of marijuana to currently controlled Schedule II substances and make repeated claims about their comparative effects. Comparisons between marijuana and the diverse array of Schedule II substances is difficult, because of the pharmacologically dissimilar actions of substances of Schedule II of the CSA. For example, Schedule II substances include stimulant-like drugs (e.g., cocaine, methylphenidate, and amphetamine), opioids (e.g., oxycodone, fentanyl), sedatives (e.g., pentobarbital, amobarbital), dissociative anesthetics (e.g., PCP), and naturally occurring plant components (e.g., coca leaves and poppy straw). The mechanism(s) of action of the above Schedule II substances are wholly different from one another, and they are different from tetrahydrocannabinol (THC) and marijuana as well.”); DEA, Denial, 81 Fed. Reg. 53,688, at 53,747 (“The HHS notes that schedule II substances include stimulant-like drugs (e.g., cocaine, amphetamine), opioids (e.g., fentanyl, oxycodone), depressant drugs (e.g., pentobarbital), dissociative anesthetics (e.g., phencyclidine), and naturally occurring plant components (e.g., coca leaves and poppy straw). The mechanism of action of  $\Delta$ 9-THC and marijuana, which act primarily through the cannabinoid receptors (discussed further in factor 2) are completely different from the above-mentioned classes of schedule II substances. Thus HHS concludes that the differences in the mechanisms of action in the various classes of schedule II substances make it inappropriate to compare the range of those substances with marijuana.”).

<sup>28</sup> See DEA, Denial, 81 Fed. Reg. at 53,690–91.

<sup>29</sup> See DEA, Denial, 81 Fed. Reg. at 53,690–91.

<sup>30</sup> See DEA, Denial, 81 Fed. Reg. at 53,691–92.

<sup>31</sup> See UNODC, World Drug Report 2023, Executive Summary, at 14, [https://www.unodc.org/res/WDR-2023/WDR23\\_Exsum\\_fin\\_DP.pdf](https://www.unodc.org/res/WDR-2023/WDR23_Exsum_fin_DP.pdf). Because there is some scientific and legal ambiguity about the distinctions between drug use, misuse, and abuse, *WRD* uses the neutral term “drug use.” See *id.* at 7. HHS acknowledges this point domestically. See Basis at 62 (“Epidemiological evidence from NSDUH show that marijuana is the most frequently abused federally illicit drug in the United States on a past-year and past-month basis among the illicit comparator drugs considered.”).

<sup>32</sup> UNODC, World Drug Report 2023, Executive Summary, at 14, [https://www.unodc.org/res/WDR-2023/WDR23\\_Exsum\\_fin\\_DP.pdf](https://www.unodc.org/res/WDR-2023/WDR23_Exsum_fin_DP.pdf).

<sup>33</sup> See WDR 2023, Executive Summary, at 14; UNODC, World Drug Report 2024, Key Findings & Conclusions, at 40 (“Cannabis remains one of the most harmful drugs on the continent [of Africa] and is the drug for which the highest proportion of people enter drug treatment. In addition, Africa is the region where cannabis use is growing the fastest, according to qualitative data.”), [https://www.unodc.org/documents/data-and-analysis/WDR\\_2024/WDR24\\_Key\\_findings\\_and\\_conclusions.pdf](https://www.unodc.org/documents/data-and-analysis/WDR_2024/WDR24_Key_findings_and_conclusions.pdf).

<sup>34</sup> Basis, at 9. DEA deferred to this. See DEA, NPRM, 89 Fed. Reg. 44,597, at 44,603.

<sup>35</sup> See DEA, Denial, 76 Fed. Reg. 40,552, at 40,562 (“The large number of individuals using marijuana on a regular basis, its widespread use, and the vast amount of marijuana that is available for illicit use are indicative of the high abuse potential for marijuana.”); *id.* at 40,567–68 (discussing such evidence in finding that marijuana had a high potential for abuse).

<sup>36</sup> See, e.g., Basis at 7–9, 39, 45, 57.

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<sup>37</sup> See, e.g., M. Walker, *et al.*, “The effect of recreational cannabis legalization and commercialization on substance use, mental health, and injury: a systematic review,” 221 *Public Health* 87 (2023) (“RCL [recreational cannabis legalization] was associated with increased rates of cannabis-related hospitalizations. RCL and/or RCC [recreational cannabis commercialization] was associated with increased rates of cannabis-related ED [emergency department visits or hospitalizations for cannabis use or alcohol, motor vehicle fatalities or injury, and intentional injury/mental health.”), <https://pubmed.ncbi.nlm.nih.gov/37429043/>.

<sup>38</sup> See, e.g., Jennifer Hassan, “Marijuana surpasses alcohol in daily use for Americans, study finds,” *Washington Post* (May 23, 2024) (“In 2022, about 17.7 million people reported daily or near-daily marijuana use, compared with 14.7 million people who reported drinking at the same frequency, said that report, which was based on more than four decades of data from the National Survey on Drug Use and Health.”), <https://www.washingtonpost.com/wellness/2024/05/23/marijuana-cannabis-alcohol-drinking-daily/>; UNODC, *World Drug Report 2024, Key Findings & Conclusions*, at 44 (“In 2022, cannabis remained the most used drug worldwide, with an estimated 228 million users in the past year, followed by opioids, with 60 million . . .”), [https://www.unodc.org/documents/data-and-analysis/WDR\\_2024/WDR24\\_Key\\_findings\\_and\\_conclusions.pdf](https://www.unodc.org/documents/data-and-analysis/WDR_2024/WDR24_Key_findings_and_conclusions.pdf); Isabella Blackman, “Not Your Grandmother’s Marijuana: Rising THC Concentrations in Cannabis Can Pose Devastating Health Risks,” *Yale Sch. of Medicine* (Aug. 30, 2023) (“As THC potency increases, science fails to keep up.”), <https://medicine.yale.edu/news-article/not-your-grandmothers-marijuana-rising-thc-concentrations-in-cannabis-can-pose-devastating-health-risks/>.

<sup>39</sup> See, e.g., NIH, *News Releases*, “Young men at highest risk of schizophrenia linked with cannabis use disorder” (May 4, 2023), <https://www.nih.gov/news-events/news-releases/young-men-highest-risk-schizophrenia-linked-cannabis-use-disorder>; Marie Stefanie Kejsler Starzer, *et al.*, “Rates and Predictors of Conversion to Schizophrenia or Bipolar Disorder Following Substance-Induced Psychosis,” 175 *Am. J. of Psychiatry* (2017) (“Overall, 32.2% . . . of patients with a substance-induced psychosis converted to either bipolar or schizophrenia-spectrum disorders. The highest conversion rate was found for cannabis-induced psychosis . . .”), <https://psychiatryonline.org/doi/full/10.1176/appi.ajp.2017.17020223>; Nathan A. Kimbrel, *et al.*, “The Impact of Cannabis Use Disorder on Suicidal and Nonsuicidal Self-Injury in Iraq/Afghanistan-Era Veterans with and without Mental Health Disorders,” 48 *Suicide Life Threat. Behav.* 140 (2018) (“As expected, after adjusting for sex, age, sexual orientation, combat exposure, traumatic life events, traumatic brain injury, posttraumatic stress disorder, depression, alcohol use disorder, and noncannabis use disorder, CUD [cannabis use disorder] was significantly associated with suicidal and nonsuicidal self-injury.”), <https://pubmed.ncbi.nlm.nih.gov/28295524/>; National Academies Sciences, Engineering, Medicine, *New Release*, “Health Effects of Marijuana and Cannabis-Derived Products Presented in New Report” (Jan. 12, 2017), <https://www.nationalacademies.org/news/2017/01/health-effects-of-marijuana-and-cannabis-derived-products-presented-in-new-report>; Alejandro Azofeifa, *et al.*, “National Estimates of Marijuana Use and Related Indicators – Nat’l Survey on Drug Use and Health, United States, 2002–14, MMWR Surveillance Summary (2016), <https://pubmed.ncbi.nlm.nih.gov/27584586/>.

<sup>40</sup> See, e.g., Nat’l Institutes of Health, *News Release*, “Smoking Cannabis associated with increased risk of heart attack, stroke.” (Feb. 28, 2024), <https://www.nih.gov/news-events/news-releases/smoking-cannabis-associated-increased-risk-heart-attack-stroke#:~:text=Frequent%20cannabis%20smoking%20may%20significantly,the%20National%20Institutes%20of%20Health>.

<sup>41</sup> See, e.g., Christopher J. Hammond, Aldorian Chaney, Brian Hendrickson, & Prayesh Sharma, “Cannabis use among U.S. adolescents in the Era of Marijuana Legalization: a review of changing use patterns, comorbidity, and health correlates,” 32 *Int’l Rev. Psychiatry* 221 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7588219/>; Marit S. Tweet, Antonia Nemanich, & Michael Wahl, “Pediatric Edible Cannabis Exposures and Acute Toxicity: 2017–2021,” *Pediatrics* (2023), <https://pubmed.ncbi.nlm.nih.gov/36594224/>;

<sup>42</sup> See, e.g., Kat Petrilli, *et al.*, “Association of cannabis potency with mental ill health and addiction: a systematic review,” 9 *Lancet Psychiatry* 736 (2022) (“Overall, use of higher potency cannabis, relative to lower potency cannabis, was associated with an increased risk of psychosis and CUD.”), <https://pubmed.ncbi.nlm.nih.gov/35901795/>; Norman S. Miller, Redon Ipeku, & Thersilla Oberbarnscheidt, “A Review of Cases of Marijuana and Violence,” 17 *Int’l J. of Environ. Res. Pub. Health* 1578 (2020) (“[S]cientifically documented links between certain marijuana users and violence do exist.”), <https://pubmed.ncbi.nlm.nih.gov/32121373/>.

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<sup>43</sup> See, e.g., Brianna Costales, *et. al.*, “Cannabis Effects on Driving Performance: Clinical Considerations,” 6 *Medical Cannabis & Cannabinoids* 8 (Dec. 2022) (“A recent randomized clinical trial found similar levels of acute driving impairment with THC-dominant cannabis and with a combination of THC-CBD equivalent cannabis using on-road driving tests that provided real-world conditions; however, CBD-dominant cannabis did not produce significant cognitive or psychomotor impairment compared with placebo in this trial.”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9940647/pdf/mca-0006-0008.pdf>; Francesco P. Busardo, Manuela Pellegrini, Julia Klein, & Natale M. di Luca, “Neurocognitive Correlates in Driving Under the Influence of Cannabis,” 16 *CNS Neurol. Disord. Drug Targets* 534 (2017) (“Both experimental and epidemiological studies have reveals that TCH affects negatively both psychomotor and cognitive functions. Studies of the acute effects of cannabis on driving have shown that drivers under the influence of this substance are impaired. Indeed, driving under the influence of cannabis doubles or triples the risk of a crash. Specifically, cannabis use impairs critical-tracking tasks, increases lane weaving, decreases reaction time, and divided attention.”), <https://pubmed.ncbi.nlm.nih.gov/28440193/>; Lauren Eadie, *et. al.*, “Duration of Neurocognitive Impairment with Medical Cannabis Use: A Scoping Review,” 12 *Front Psychiatry* \_ (2021) (“In general, cognitive performance declined mostly in a THC dose-dependent manner, with steady resolution of impairment in the hours following THC administration. Does of THC were lower [in cases of medical use] than those typically reported in recreational cannabis studies. In all the studies, there was no difference between any of the THC groups and placebo on any neurocognitive measure after 4 h of recovery.”), <https://pubmed.ncbi.nlm.nih.gov/33790818/>; Alison C. Burggren, *et. al.*, “Cannabis effects on brain structure, function, and cognition: considerations for medical uses of cannabis and its derivatives,” 45 *Am. J. of Drug & Alcohol Abuse* 563, at 569 (2019) (“There is accumulating evidence that regular cannabis use can alter brain function, especially in networks that support working memory, attention, and cognitive control processing.”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7027431/>.

<sup>44</sup> See, e.g., F.D. Thomas, *et. al.*, NHTSA, “Alcohol and Drug Prevalence Among Seriously or Fatally Injured Road Users,” at Abstract, 3–5 (Dec. 2022) (“Overall, 55.8% of the injured or killed roadway users tested positive for one or more drugs (including alcohol) on this study’s toxicology panel. The most prevalent drug category detected was cannabinoids (active THC) with 25.1% positive, followed by alcohol (23.1%), stimulants (10.8%), and opioids (9.3%). Overall, 19.9% of the roadway users tested positive for two or more categories of drugs.”), [https://www.nhtsa.gov/sites/nhtsa.gov/files/2022-12/Alcohol-Drug-Prevalence-Among-Road-Users-Report\\_112922-tag.pdf](https://www.nhtsa.gov/sites/nhtsa.gov/files/2022-12/Alcohol-Drug-Prevalence-Among-Road-Users-Report_112922-tag.pdf); Kusum Adhikari, Alexander Maas, & Andres Trujillo-Barrera, “Revisiting the effect of recreational marijuana on traffic fatalities,” 115 *Int’l J. Drug Policy* \_ (2023) (“Traffic fatalities increase by 2.2 per billion miles driven after retail legalization, which may account for as many as 1400 traffic fatalities annually.”), <https://pubmed.ncbi.nlm.nih.gov/36965303/>; see also Christopher J. Hammond, Aldorian Chaney, Brian Hendrickson, & Prayesh Sharma, “Cannabis use among U.S. adolescents in the Era of Marijuana Legalization: a review of changing use patterns, comorbidity, and health correlates,” 32 *Int’l Rev. Psychiatry* 221 (2020) (stating that marijuana-policy changes have led to increases in “cannabis-related motor vehicle accidents”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7588219/>;

<sup>45</sup> Christopher J. Hammond, Aldorian Chaney, Brian Hendrickson, & Prayesh Sharma, “Cannabis use among U.S. adolescents in the Era of Marijuana Legalization: a review of changing use patterns, comorbidity, and health correlates,” 32 *Int’l Rev. Psychiatry* 221 (2020) (emphasis in original), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7588219/>.

<sup>46</sup> See Julia Shapero, “Americans test positive for marijuana after workplace accidents at highest rate in 25 years,” *The Hill* (May 18, 2023) (reporting on a study released by Quest Diagnostics in May 2023), <https://thehill.com/policy/healthcare/4010934-americans-test-positive-for-marijuana-after-workplace-accidents-at-highest-rate-in-25-years/>; see also Quest Diagnostics, News Releases, “Workforce Drug Test Cheating Surged in 2023, Finds Quest Diagnostics Drug Testing Index Analysis of Nearly 10 Million Drug Tests” (May 15, 2024) (“The percentage of employees in the general U.S. workforce whose drug test showed signs of tampering increased by more than six-fold in 2023 versus the prior year, the highest rate ever in more than 30 years of annual reporting.”), [https://newsroom.questdiagnostics.com/2024-05-15-Workforce-Drug-Test-Cheating-Surged-in-2023.-Finds-Quest-Diagnostics-Drug-Testing-Index-Analysis-of-Nearly-10-Million-Drug-Tests](https://newsroom.questdiagnostics.com/2024-05-15-Workforce-Drug-Test-Cheating-Surged-in-2023.-Finds-Quest-Diagnostics-Drug-Testing-Index-Analysis-of-Nearly-10-Million-Drug-Tests;);

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<sup>47</sup> See, e.g., U.S. Dept. of Health & Human Services, “Assessment of Abuse Potential of Drugs: Guidance for Industry,” at 3 (Jan. 2017) (discussing the differences between abuse and dependence potential), <https://www.fda.gov/media/116739/download>.

<sup>48</sup> Compare 21 U.S.C. § 812(b)(1)(A) with § 812(b)(2)(A).

<sup>49</sup> Compare 21 U.S.C. § 812(b)(1)(C) with § 812(b)(2)(C).

<sup>50</sup> Basis, at 1–2.

<sup>51</sup> See, e.g., Basis at 65 (“It can produce psychic dependence in some individuals, but the likelihood of serious outcomes is low . . .”).

<sup>52</sup> Basis, at 65–65 (“It can produce psychic dependence in some individuals, but the likelihood of serious outcomes is low, suggesting that high psychological dependence does not occur in most individuals who use marijuana.”).

<sup>53</sup> See 21 U.S.C. § 812(b)(2)(C).

<sup>54</sup> See UNODC, World Drug Report 2023, Special Points of Interest, at 4, [https://www.unodc.org/res/WDR-2023/Special\\_Points\\_WDR2023\\_web\\_DP.pdf](https://www.unodc.org/res/WDR-2023/Special_Points_WDR2023_web_DP.pdf).

<sup>55</sup> WDR 2023, Executive Summary, at 7.

<sup>56</sup> Nat’l Inst. on Drug Abuse, News Release, “Marijuana and hallucinogen use, binge drinking reached historic highs among adults 35 to 50” (Aug. 17, 2023), <https://nida.nih.gov/news-events/news-releases/2023/08/marijuana-and-hallucinogen-use-binge-drinking-reached-historic-highs-among-adults-35-to-50>.

<sup>57</sup> See HHS, Press Release, “HHS, SAMHSA Release 2022 National Survey on Drug use and Health Data” (Nov. 13, 2023), <https://www.hhs.gov/about/news/2023/11/13/hhs-samhsa-release-2022-national-survey-drug-use-health-data.html#:~:text=In%202022%2C%2070.3%20million%20people,it%20in%20the%20past%20year..>

<sup>58</sup> See, e.g., Benjamin H. Han & Joseph J. Palamar, “Trends in Cannabis Use Among Older Adults in the United States, 2015–2018,” 180 JAMA Intern. Med. 609 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7042817/>; Alejandro Azofeifa, et. al., “National Estimates of Marijuana Use and Related Indicators – National Survey on Drug Use and Health, United States, 2002–2004,” 64 MMWR Surveill. Summ. 1 (2016), <https://pubmed.ncbi.nlm.nih.gov/27584586/>; Michelle Rotermann & Ryan Macdonald, “Analysis of trends in the prevalence of cannabis use in Canada, 1985 to 2015,” 29 Health Rep. 10 (2018), <https://pubmed.ncbi.nlm.nih.gov/29465739/>; Daniel J. Corsi, et. al., “Trends and correlates of cannabis use in pregnancy: a population-based study in Ontario, Canada from 2012 to 2017,” 110 Can. J. Public Health 76 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6335373/>; Lauren R. Pacek, Andrea H. Weinberger, Jiaqi Zhu, & Renee D. Goodwin, “Rapid increase in the prevalence of cannabis use among people with depression in the United States, 2005–17: the role of differentially changing risk perceptions,” 115 Addiction 935 (2020), <https://pubmed.ncbi.nlm.nih.gov/31797462/>.

<sup>59</sup> WDR 2023, Executive Summary, at 14.

<sup>60</sup> CDC, “Cannabis and Public Health” (visited July 17, 2024), [https://www.cdc.gov/cannabis/health-effects/cannabis-and-teens.html#:~:text=Approximately%203%20in%2010%20people,in%20favor%20of%20using%20cannabis; see also Deborah S. Hasin, et. al., “Prevalence of Marijuana Use Disorders in the United States between 2001–2002 and 2012–2013,” 72 JAMA Psychiatry 1235 \(2015\), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5037576/](https://www.cdc.gov/cannabis/health-effects/cannabis-and-teens.html#:~:text=Approximately%203%20in%2010%20people,in%20favor%20of%20using%20cannabis; see also Deborah S. Hasin, et. al., “Prevalence of Marijuana Use Disorders in the United States between 2001–2002 and 2012–2013,” 72 JAMA Psychiatry 1235 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5037576/).

<sup>61</sup> See Isabella Blackman, “Not Your Grandmother’s Marijuana: Rising THC Concentrations in Cannabis Can Pose Devastating Health Risks,” Yale Sch. of Medicine (Aug. 30, 2023), <https://medicine.yale.edu/news-article/not-your-grandmothers-marijuana-rising-thc-concentrations-in-cannabis-can-pose-devastating-health-risks/>.

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<sup>62</sup> National Association of Counties, “Reinstate Federal Health Care Benefits for Non-Convicted Justice-Involved Individuals,” at 2 (2020) (emphasis added), [https://www.naco.org/sites/default/files/documents/Medicaid-One-Pager\\_3-11-20.pdf](https://www.naco.org/sites/default/files/documents/Medicaid-One-Pager_3-11-20.pdf).

<sup>63</sup> See 21 U.S.C. § 811(c)(6) (listing the risk to public health as scheduling factor 6).

<sup>64</sup> See, e.g., Statement from Janet Woodcock, M.D., Principal Deputy Commissioner, “FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward” (Jan. 26, 2023),

<https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol>;

Walter B. Wilson, Aaron A. Urbas, & Frances Scott, Nat’l Inst. of Justice, “Study Reveals Inaccurate Labeling of Marijuana as Hemp,” (Oct. 17, 2022),

<https://nij.ojp.gov/topics/articles/study-reveals-inaccurate-labeling-marijuana-hemp>;

Johns Hopkins Medicine, “Study Shows Widespread Mislabeling of CBD Content Occurs for Over-the-Counter Products” (July 20, 2022),

<https://www.hopkinsmedicine.org/news/newsroom/news-releases/2022/07/study-shows-widespread-mislabeling-of-cbd-content-occurs-for-over-the-counter-products>.

<sup>65</sup> See, e.g., Boston Univ., School of Public Health, “Car Crash Deaths Involving Cannabis on the Rise,” (Nov. 10, 2021) (“Between 2000 and 2018, the percentage of car crash deaths in the United States involving cannabis have doubled—and the percentage of deaths involving both cannabis and alcohol have more than doubled . . . .”),

[https://www.bu.edu/sph/news/articles/2021/car-crash-deaths-involving-cannabis-on-the-rise/#:~:text=The%20percent%20of%20crash%20deaths,levels%20below%20the%20legal%20limit.](https://www.bu.edu/sph/news/articles/2021/car-crash-deaths-involving-cannabis-on-the-rise/#:~:text=The%20percent%20of%20crash%20deaths,levels%20below%20the%20legal%20limit.;);

Godfrey D. Pearlson, Michael C. Stevens, & Deepak Cyril D’Souza, “Cannabis and Driving,” 12 *Frontiers in Psychiatry* (2021)

(“As more and more states in the U.S. legalize recreational and medicinal cannabis, rates of driving under the influence of this drug are increasing significantly. Aspects of this emerging public health issue potentially pit science against public policy. The authors believe that the legal cart is currently significantly ahead of the scientific horse.”),

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8499672/>.

<sup>66</sup> Executive Order No. 13132, Federalism, § 6(a), 64 Fed. Reg. 43,255, 43,257 (Aug. 4, 1999).

<sup>67</sup> Executive Order No. 13132, § 1(a), 64 Fed. Reg. 43,255.

<sup>68</sup> See DEA, NPRM, 89 Fed. Reg. 44,597, at 44,621.

<sup>69</sup> See DEA, NPRM, 89 Fed. Reg. 44,597, at 44,621.

<sup>70</sup> Erwin Chemerinsky, Jolene Forman, Allen Hopper, & Sam Kamin, *Cooperative Federalism and Marijuana Regulation*, 62 *UCLA L. Rev.* 74 (2015).

<sup>71</sup> See Chemerinsky, *Cooperative Federalism and Marijuana Regulation*, 62 *UCLA L. Rev.* at 190–100.

<sup>72</sup> See Chemerinsky, *Cooperative Federalism and Marijuana Regulation*, 62 *UCLA L. Rev.* at 113–14 & nn.149–56 (citing, e.g., to States’ Medical Marijuana Patient Protection Act, H.R. 689, 113th Cong. (2013)); see also States’ Medical Marijuana Patient Protection Act, H.R. 1983, 112th Cong. (2011); Medical Marijuana Patient Protection Act, HR. 5842, 110th Cong. (2008) (proposing to re-schedule marijuana from I to II).

<sup>73</sup> See, e.g., S. 326, VA Medicinal Cannabis Research Act of 2023, 118th Cong. (2023) (requiring the VA to study cannabis for veterans with PTSD); HR 2682, Veterans Medical Marijuana Safe Harbor Act, 118th Cong. (2023) (authorizing veterans to possess medical marijuana as well as various research activities); HR 394, Veterans Cannabis Use for Safe Healing Act, 118th Cong. (2023) (prohibiting the VA from denying benefits to veterans who participate in a state-approved marijuana program); HR 610, Marijuana 1-to-3 Act, 118th Cong. (2023) (rescheduling marijuana to III); HR 8454, Medical Marijuana and Cannabidiol Research Expansion Act, 117th Cong. (2022) (establishing a new registration process for marijuana research); HR 5601, Marijuana Opportunity Reinvestment and Expungement Act, 118th Cong. (2023) (removing marijuana from the CSA’s schedules); HR 2891, Secure and Fair Enforcement Banking Act of 2023, 118th Cong. (2023) (easing restrictions on state-authorized businesses to introduce money into the banking system).



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<sup>74</sup> See Chemerinsky, Cooperative Federalism and Marijuana Regulation, 62 UCLA L. Rev. at 80; *id.* at 115–16, 118–22 (proposing an amendment to the CSA’s preemption provision, 21 U.S.C. § 903); Phil Weiser, Colorado Attorney General, “Prepared remarks: Attorney General Phil Weiser on the State of our Federalism” (Jan 26, 2021) (“Our current challenge is to develop and fortify respect for and understanding of federalism as a feature of American governance that can transcend and perhaps even diffuse the toxic effects of political polarization. To the extent that states can provide more latitude and respect for one another’s policy decisions—whether to legalize cannabis, for example—perhaps differences can be accommodated rather than fought over.”), <https://coag.gov/blog-post/prepared-remarks-attorney-general-phil-weiser-on-the-state-of-our-federalism-jan-26-2021/>.

<sup>75</sup> See, e.g., Erwin Chemerinsky, Enhancing Government: Federalism for the 21st Century, 117–25 (2008).

<sup>76</sup> Executive Order No. 13132, § 2, 64 Fed. Reg. 43,255–56 (Aug. 4, 1999).

<sup>77</sup> See 26 U.S.C. § 280E (prohibiting a deduction or credit for any amount paid or incurred in carrying on a business if it consists of trafficking in “controlled substances (within the meaning of schedule I and II) of” the CSA).

<sup>78</sup> See 21 U.S.C. § 812(b)(2)(B), § 812(b)(3)(B).

<sup>79</sup> See, e.g., Charles V. Preuss, Arun Kalava, & Kevin C. King, “Prescription of Controlled Substances: Benefits and Risks,” Continuing Education Activity, Nat’l Library of Medicine (updated Apr. 29, 2023) (“Schedule II drugs have the tightest regulations when compared to other prescription drugs. \* \* \* Schedule III drugs are prescribable verbally over the phone, with a paper prescription, or via EPCS.”), <https://www.ncbi.nlm.nih.gov/books/NBK537318/>.

<sup>80</sup> See, e.g., Texas Health & Safety Code, §§ 481.002(47), 481.0755 (requiring official prescription forms for schedule II drugs). See generally PDMP TTAC, Technical Assistance Guide, “History of Prescription Drug Monitoring Programs,” Brandeis U. (Mar 2018) (discussing, for example, the historical role of official prescription forms for schedule II drugs in drug-monitoring programs but noting that only Texas and New York continue to use state-issued forms), [https://www.pdmpassist.org/pdf/PDMP\\_admin/TAG\\_History\\_PDMPs\\_final\\_20180314.pdf](https://www.pdmpassist.org/pdf/PDMP_admin/TAG_History_PDMPs_final_20180314.pdf).

<sup>81</sup> DEA, Researcher’s Manual: An Informational Outline of the Controlled Substances Act, Preface at 8 (rev. 2022), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-057\)\(EO-DEA217\)\\_Researchers\\_Manual\\_Final\\_signed.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-057)(EO-DEA217)_Researchers_Manual_Final_signed.pdf).

<sup>82</sup> See, e.g., DEA, Researcher’s Manual, 14–21 (rev. 2022) (listing application, certification, research protocol, tracking, and reporting requirements for schedule I and II researchers) (citing 21 CFR Part 1301); see also 21 U.S.C. § 828; 21 CFR Part 1305.

<sup>83</sup> See 21 U.S.C. § 826.

<sup>84</sup> Researcher’s Manual at 8.

<sup>85</sup> See Lisa N. Sacco, Joanna R. Lampe, & Hassan Z. Sheikh, Cong. R. Serv., In Focus, “The Federal Status of Marijuana and the Policy Gap with States” (May 2, 2024) (stating that as of May 2, 2024, 38 states, the District of Columbia, and several territories have comprehensive medical marijuana laws and nine other states allow for limited access medical cannabis).

<sup>86</sup> Basis for Recommendation, at 1–2; see *id.* at 24–28.

<sup>87</sup> See Basis for Recommendation, at 24–25.

<sup>88</sup> See Joanna R. Lampe, Cong. R. Serv., LSB10694, “Funding Limits on Federal Prosecutions of State-Legal Medical Marijuana” (May 14, 2024).

<sup>89</sup> Consolidated Appropriations Act, 2024, Pub. L. No. 118-42, \_ Stat. \_ (Mar. 9, 2024) (HR 4266—150).

<sup>90</sup> The CSA’s preemption provision is 21 U.S.C. § 903.

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<sup>91</sup> See, e.g., Researcher’s Manual at 8.

<sup>92</sup> Researcher’s Manual at 7.

<sup>93</sup> EO 13132, § 11, 64 Fed. Reg. at 43,259.

<sup>94</sup> See 21 U.S.C. § 801(7), § 811(d)(1).

<sup>95</sup> Memorandum for John E. Ingersoll, Director, Bureau of Narcotics & Dangerous Drugs, from Mary C. Lawton, Deputy Assistant Attorney General, Office of Legal Counsel, *Re: Petition to Decontrol Marijuana: Interpretation of Section 201 of the Controlled Substances Act of 1970*, at 12–13 (Aug. 21, 1972), <https://www.justice.gov/olc/media/1359191/dl?inline>.

<sup>96</sup> See DEA, Denial, 81 Fed. Reg. 53,688 (“[I]n view of United States obligations under international drug control treaties, marijuana cannot be placed in a schedule less restrictive than schedule II.”) (referring to the Single Convention). The word “Lawton,” for example, doesn’t appear in DEA’s 2016 Denial. In contrast, DEA referred to the Lawton Memo in 2024, see 89 Fed. Reg. 44,597, at 44,620, and OLC referred to it as “the Lawton Memo,” OLC Opinion, at 27, 28, 29, 31.

<sup>97</sup> Memorandum Opinion for the Attorney General from Christopher C. Fonzone, Assistant Attorney General, Office of Legal Counsel, *Re: Questions Related to the Potential Rescheduling of Marijuana*, at 28 (Apr. 11, 2024), <https://www.dea.gov/sites/default/files/2024-05/2024-04-11%20-%20AAG%20Fonzone%20-%20Marijuana%20Rescheduling.pdf>.

<sup>98</sup> 21 U.S.C. § 811(d)(1) (emphasis added).

<sup>99</sup> DEA, Denial, 81 Fed. Reg. 53,688, at 53,688–89 (“Thus, the DEA Administrator is obligated under section 811(d) to control marijuana in the schedule he deems most appropriate to carry out the U.S. obligations under the Single Convention.”). DEA further acknowledged that 811(d) requires DEA to select the most appropriate schedule to meet the Single Convention in rescheduling decisions as well. 81 Fed. Reg. 53,689.

<sup>100</sup> Fonzone Memo., at 28 (“To begin, nothing in the Single Convention requires the United States to comply with its international obligations by placing a drug in a statutory ‘schedule’ that specifically authorizes all the necessary restrictions.”); *id.* at 29 (“Nothing in the CSA, however, states that a drug must be placed into Schedule I or II, or any other particular schedule, to comply with the Single Convention.”); *id.* (“Nor does the CSA expressly foreclose DEA from satisfying the United States’ international obligations with a combination of scheduling and regulatory actions.”); *id.* (“Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific controls that follow from a drug’s placement on a particular schedule.”).

<sup>101</sup> Fonzone Memo., at 29 (“Rather, section 811(d)(1) directs the Attorney General to ‘control’ a drug ‘under the schedule [the Attorney General] deems most appropriate’ (emphasis added)—language that signals a broad grant of discretion to the Attorney General (and thus DEA).”).

<sup>102</sup> Fonzone Memo., at 28 (“Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific controls that follow from a drug’s placement on a particular schedule.”); *id.* at 29–30 (The CSA’s varied, and potentially conflicting, purposes further show why it is appropriate to read section 811(d)(1)’s broad grant of authority in this way. Consider a hypothetical case in which the Single Convention imposes obligations that DEA determines would, absent regulatory action, require placement on Schedule I or Schedule II, but DEA has also determined that the same drug’s abuse potential, medical usefulness, and health effects warrant placing the drug in Schedule III.”); *id.* at 29 (“referring to “even relatively minor gaps”).

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<sup>103</sup> Fonzone Memo., at 28 (“To begin, nothing in the Single Convention requires the United States to comply with its international obligations by placing a drug in a statutory ‘schedule’ that specifically authorizes all the necessary restrictions.”); *id.* (“Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific controls that follow from a drug’s placement on a particular schedule.”); *id.* at 29 (referring to “even relatively minor gaps”).

<sup>104</sup> *See, e.g.*, Fonzone Memo., at 29–30 (noting that DEA could select a schedule for a drug, supplement the schedule’s shortcomings with respect to treaty obligations with new regulations, “while furthering the CSA’s other purposes,” which are “varied and potentially conflicting”).

<sup>105</sup> DEA, Denial, 81 Fed. Reg. 53,688 (“Many of the provisions of the CSA were enacted by Congress for the specific purpose of ensuring U.S. compliance with the [Single Convention].”); *see Craker v. DEA*, 714 F.3d 17, 20 (1st Cir. 2013) (“Among the international treaties, conventions, or protocols referred to in section 823(a), the CSA implements the provisions of the Single Convention on Narcotic Drugs, 18 U.S.T. 1407 (Single Convention), in an effort to establish effective control over international and domestic traffic in controlled substances.”).

<sup>106</sup> *See* United Nations, Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, art. 21, [https://www.unodc.org/pdf/convention\\_1961\\_en.pdf](https://www.unodc.org/pdf/convention_1961_en.pdf).

<sup>107</sup> *See* Lawton Memo., at 12–13.

<sup>108</sup> *See* 21 U.S.C. § 826.

<sup>109</sup> Fonzone Memo., at 35.

<sup>110</sup> Fonzone Memo., at 28 (emphasis added).

<sup>111</sup> *See, e.g.*, Fonzone Memo., at 30 (“broad regulatory authority provided by the CSA”).

<sup>112</sup> *See* Letter to Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Asst. Sec. for Health, HHS (Aug. 29, 2023), with Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act, at 1–3, <https://www.hhs.gov/sites/default/files/scheduling-recommendation.pdf>.

<sup>113</sup> *See* Basis for Recommendation, at 2–4. HHS is referring to the Agricultural Improvement Act of 2018 (“the 2018 Farm Bill”), Pub. L. No. 115-334, 132 Stat. 4490 (Dec. 20, 2018) (definitions codified at 7 U.S.C. § 1639o(1)) (Emphasis added).

<sup>114</sup> *See* Ziva D. Cooper and Margaret Haney, “Actions of delta-9-tetrahydrocannabinol in cannabis: Relation to use, abuse, and dependence,” 21 *Int’l Rev. of Psychiatry* 104 (Apr. 2009) (“Delta (9)-tetrahydrocannabinol (THC), identified as the primary active component of cannabis, acts at the cannabinoid CB1 receptor to produce a wide-range of biological and behavioral responses.”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2731700/pdf/nihms-123294.pdf>; UNODC, World Drug Report 2019, Cannabis & Hallucinogens, at 9 (“Cannabis plants contain 70 unique compounds, collectively known as phytocannabinoids, the main psychoactive substance being THC, which provides the psychoactive effects of cannabis.”).

<sup>115</sup> *See, e.g.*, Michigan Cannabis Regulatory Agency, “Delta-8 Information” (visited July 11, 2024) (“Delta-8 occurs naturally in small quantities in cannabis, however, most of the commercially available delta-8 has been synthesized through a conversion process that uses a variety of chemicals to convert hemp-derived CBD into delta-8.”), <https://www.michigan.gov/cra/resources/consumer-connection/delta-8-information>.

<sup>116</sup> *See* Basis for Recommendation, at 3–4.

<sup>117</sup> In contrast to HHS, DEA concurs. In its 2024 NPRM, DEA writes, “This rulemaking would not affect the status of hemp (as defined in 7 U.S.C. § 1639o), because hemp is excluded from the definition of marijuana.” DEA, NPRM, 89 Fed. Reg. 44,596, at 44,620. This is the converse of NSA’s point. Just as rescheduling marijuana will not affect

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hemp’s status (because the 2018 Farm Bill carved hemp out of marijuana’s definition), approvals for hemp-derived or CBD-containing products, like Epidiolex, don’t speak to marijuana’s scheduling.

<sup>118</sup> See, e.g., Eric Berger, KFF Health News, “Hemp-Derived Delta-8 Skirts Marijuana Laws and Raises Health Concerns (Sept. 23, 2022) (summarizing information about delta-8, delta-9, and delta-10 THC, regulations and lack of regulations, and health risks), <https://kffhealthnews.org/news/article/hemp-delta-8-marijuana-laws-health-concerns/>.

<sup>119</sup> See, e.g., Michigan Cannabis Regulatory Agency, “Delta-8 Information” (visited July 11, 2024), <https://www.michigan.gov/cra/resources/consumer-connection/delta-8-information>; Public Health Law Ctr., Mitchell Hamline Sch. of Law, “What’s the Deal with Delta-8 THC?” (June 2022) (“Delta-8 THC, on the other hand, is a compound not naturally occurring in significant amounts in the cannabis plant. Instead, concentrated amounts are manufactured through a chemical extraction process from hemp-derived CBD.”), <https://www.publichealthlawcenter.org/sites/default/files/resources/Delta-8-THC-FAQ.pdf>.

<sup>120</sup> See, e.g., Michigan Cannabis Regulatory Agency, “Delta-8 Information” (visited July 11, 2024), <https://www.michigan.gov/cra/resources/consumer-connection/delta-8-information>; Public Health Law Ctr., Mitchell Hamline Sch. of Law, “What’s the Deal with Delta-8 THC?” at 1 (June 2022) (“Delta-8 THC is estimated to be 50 to 75 percent as psychoactive as Delta-9 THC, and is frequently sold and marketed as an intoxicating product.”), <https://www.publichealthlawcenter.org/sites/default/files/resources/Delta-8-THC-FAQ.pdf>.

<sup>121</sup> U.S. Food and Drug Admin., “5 Things to Know about Delta-8 Tetrahydrocannabinol—Delta-8 THC,” (visited June 6, 2024), <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc>.

<sup>122</sup> See, e.g., Jiries Meehan-Atrash & Irfan Rahman, “Novel Δ8-Tetrahydrocannabinol Vaporizers Contain Unlabeled Adulterants, Unintended Byproducts of Chemical Synthesis, and Heavy Metals,” *Chem. Res. Toxicol.* (Dec. 10, 2021), <https://pubs.acs.org/doi/10.1021/acs.chemrestox.1c00388>; Public Health Law Ctr., Mitchell Hamline Sch. of Law, “What’s the Deal with Delta-8 THC?” at 4 (June 2022) (“Inconsistent labeling practices and impure processing pose additional risks to public health. \* \* \* Moreover, depending on how the product was manufactured, it can contain byproducts or additional quantities of Delta-9 TCH—chemicals that can produce unintended health consequences for consumers.”), <https://www.publichealthlawcenter.org/sites/default/files/resources/Delta-8-THC-FAQ.pdf>.

<sup>123</sup> See, e.g., Britt E. Erickson, “Delta-8-THC craze concerns chemists: Unidentified by-products and lack of regulatory oversight spell trouble for cannabis products synthesized from CBD,” *Chemical & Engineering News* (Aug. 30, 2021), <https://cen.acs.org/biological-chemistry/natural-products/Delta-8-THC-craze-concerns/99/i31>.

<sup>124</sup> See U.S. Food and Drug Admin., “5 Things to Know about Delta-8 Tetrahydrocannabinol—Delta-8 THC,” (visited June 6, 2024), <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc>.

<sup>125</sup> See FDA, “Warning Letters and Test Results for Cannabidiol-Related Products” (visited June 11, 2024), <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>.

<sup>126</sup> See CDC, Health Advisory, “Increases in Availability of Cannabis Products Containing Delta-8 THC and Reported Cases of Adverse Events” (Sept. 14, 2021), [https://emergency.cdc.gov/han/2021/pdf/CDC\\_HAN\\_451.pdf](https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_451.pdf).

<sup>127</sup> See Nat’l Inst. of Health, Press Release, “Delta-8-THC use reported by 11% of 12th graders in 2023,” (Mar. 12, 2024), <https://www.nih.gov/news-events/news-releases/delta-8-thc-use-reported-11-12th-graders-2023>; Public Health Law Ctr., Mitchell Hamline Sch. of Law, “What’s the Deal with Delta-8 THC?” (June 2022) (“The growing popularity of Delta-8 products has raised concerns regarding legal sale and manufacture and health and safety risks, particularly to youth, and spurred a rare health warning by the CDC in September 2021.”), <https://www.publichealthlawcenter.org/sites/default/files/resources/Delta-8-THC-FAQ.pdf>.

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<sup>128</sup> See Michael Tagen and Linda E. Klumpers, Abstract, “Review of delta-8-tetrahydrocannabinol ( $\Delta$ -8-THC): Comparative pharmacology with  $\Delta$ -9-THC,” 179 Br. J. Pharmacology 3915 (Jan. 2023), <https://pubmed.ncbi.nlm.nih.gov/35523678/>.

<sup>129</sup> See HHS, Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act, at 11, <https://www.hhs.gov/sites/default/files/scheduling-recommendation.pdf>.

<sup>130</sup> See Basis, at 2 (“An important difference in the present scientific and medical evaluation relative to the HHS 8FAs for marijuana from 2015 is that Congress amended the definition of ‘marihuana’ in the CSA in 2018.”); *id.* at 3 (“The 2018 Farm Bill additionally had the effect of decontrolling many products containing predominantly cannabidiol (CBD) derived from hemp . . .”).

<sup>131</sup> See Kaitlin Sullivan, “The U.S. has a chance to regulate delta-8 THC. Will it?” NBC News (Sept. 5, 2023) (“The lack of action from the federal gov’t has led a number of states to step in to restrict or even ban the compound.”), <https://www.nbcnews.com/health/health-news/delta-8-thc-regulation-loophole-may-make-hard-know-cannabis-products-rcna102961>; Kaitlin Sullivan, “Delta-8 THC is legal in many states, but some want to ban it” NBC News (June 28, 2021), <https://www.nbcnews.com/health/health-news/delta-8-thc-legal-many-states-some-want-ban-it-n1272270>; Mitch Perry, “Florida Legislature gets rid of ‘delta-8’ hemp products; Puts THC caps on hemp-derived products,” Florida Phoenix (Mar. 6, 2024), <https://floridaphoenix.com/2024/03/06/florida-legislature-gets-rid-of-delta-8-hemp-products-puts-thc-caps-on-hemp-derived-products/>.

<sup>132</sup> See, e.g., Statement of Janet Woodcock, M.D., Principal Deputy Comm’r, FDA, “FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward” (Jan. 26, 2023), <https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol>.