# **SheppardMullin**



# **Cannabis Rescheduling: HHS Findings and Legal Implications**

By: Julia Anderson

On August 29, 2023, the U.S. Department of Health and Human Services (HHS) made a groundbreaking recommendation to the Drug Enforcement Administration (DEA) – that cannabis should be rescheduled from Schedule I to Schedule III under the Controlled Substances Act (CSA). This recommendation was made pursuant to President Biden's request that the Secretary of HHS and the Attorney General initiate a process to review how cannabis is scheduled under federal law. In recent days, the <u>unredacted 252-page analysis</u> supporting the August recommendation was released pursuant to a Freedom of Information Act request. While the DEA is presently reviewing HHS's recommendation and has final authority to schedule a drug under the CSA, it is ultimately bound by HHS's recommendations on scientific and medical matters.

Why does this matter? Cannabis¹ has been a Schedule I substance since the CSA was enacted in 1971. Substances are controlled under the CSA by placement on one of five lists, Schedules I through V. Schedule I controlled substances are subject to the most stringent controls and have no current accepted medical use. As a result, it is illegal under federal law to produce, dispense, or possess cannabis except in the context of federally approved scientific studies. Violations may result in large fines and imprisonment, including mandatory minimum sentences. Comparatively, Schedule III substances are considered to have less abuse potential than Schedule I and II substances, and have a currently accepted medical use in the United States.

In recent years, nearly all the states within the U.S. have revised their laws to permit medical cannabis use. And 24 states, as well as the District of Columbia, have eliminated certain criminal penalties for recreational cannabis use by adults. However, under the U.S. Constitution's Supremacy Clause, federal law takes precedence over conflicting state laws. Thus, states cannot actually legalize cannabis use without congressional or executive action, and all unauthorized activities under Schedule I involving cannabis are federal crimes *anywhere* in the United States.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> The CSA classifies the cannabis plant and its derivatives as "marijuana." The CSA definition of marijuana excludes (1) products that meet the legal definition of hemp and (2) the mature stalks of the cannabis plant; the sterilized seeds of the plant; and fibers, oils, and other products made from the stalks and seeds.

<sup>&</sup>lt;sup>2</sup> Congress has granted the states some leeway in the distribution and use of medical marijuana by passing an appropriations rider preventing the Department of Justice from using taxpayer funds to prevent states from "implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana." Courts have interpreted this as a prohibition on federal prosecution of state-legal activities involving medical cannabis.

## **SheppardMullin**

### **Notable Findings in HHS's Recommendation**

For HHS to recommend that the DEA change cannabis from Schedule I to Schedule III, HHS had to make three specific findings: 1) cannabis has a lower potential for abuse than the drugs or other substances in Schedules I and II; 2) cannabis has a currently accepted medical use in treatment in the U.S.; and 3) abuse of cannabis may lead to moderate or low physical dependence or high psychological dependence. HHS considered eight factors to make those findings, some of which include: cannabis's actual or relative potential for abuse; the state of current scientific knowledge regarding the drug; the scope, duration, and significance of abuse; and what, if any, risk there is to public health. The unredacted analysis provides further insight into HHS's determination to make the forementioned findings.

#### Cannabis has a potential for abuse less than the drugs or other substances in Schedules I and II.

To evaluate cannabis's potential for abuse,<sup>3</sup> HHS compared the harms associated with cannabis abuse to the harms associated with other substances, such as heroin (Schedule I), cocaine (Schedule II), and alcohol.<sup>4</sup> HHS reported that evidence shows some individuals take cannabis in amounts sufficient to create a health hazard to themselves and the safety of other individuals and the community. However, HHS also reported evidence showing the vast majority of cannabis users are using cannabis in a manner that does not lead to dangerous outcomes for themselves or others. From 2015 to 2021, the utilization-adjusted rate of adverse outcomes involving cannabis was consistently lower than the respective utilization-adjusted rates of adverse outcomes involving heroin, cocaine, and other comparators. Further, cannabis was the lowest-ranking group for serious medical outcomes, including death. Overall, the data indicated that cannabis produced fewer negative outcomes than Schedule I, Schedule II drugs, and, in some cases, alcohol.

#### Cannabis Has a Currently Accepted Medical Use in Treatment in the United States

To determine whether cannabis has a currently accepted medical use (CAMU) in the U.S., HHS evaluated a two-part standard: 1) whether "[t]here exists widespread, current experience with medical use of the substance by [healthcare providers] operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine"; and 2) whether "[t]here exists some credible scientific support for at least one of the medical uses for which Part 1 is met."

Under Part 1, HHS confirmed that more than 30,000 healthcare providers across 43 U.S. jurisdictions are authorized to recommend the medical use of cannabis for more than six million registered patients for at least 15 medical conditions. The Part 1 findings, therefore, supported an assessment under Part 2. Under Part 2, HHS reported that, based on the totality of the available data, there exists some credible scientific support for the medical use of cannabis. Specifically, credible scientific support described at least some therapeutic cannabis uses for anorexia related to a medical condition, nausea and vomiting (e.g., chemotherapy-induced), and pain.

Overall, while HHS reported that cannabis has a currently accepted medical use in the U.S., the Food and Drug Administration (FDA) underscored that such a finding does *not* mean that the FDA has approved cannabis as safe and effective for marketing as a drug in interstate commerce under the Federal Food, Drug, and Cosmetic Act.

Page 2 www.sheppardmullin.com

In its report, HHS defined "abuse" to mean the "intentional, non-therapeutic use of a drug to obtain a desired psychological or physiological effect."

<sup>&</sup>lt;sup>4</sup> Alcohol is not a scheduled controlled substance, but was used as a comparison because of its extensive availability and use in the U.S., which is also observed for the nonmedical use of cannabis.

## **SheppardMullin**

#### Abuse of cannabis may lead to moderate or low physical dependence or high psychological dependence.

Lastly, HHS concluded that research indicated that chronic, but not acute, use of cannabis can produce both psychic and physical dependence in humans. However, while cannabis "can produce psychic dependence in some individuals," HHS emphasized that "the likelihood of serious outcomes is low, suggesting that high psychological dependence does not occur in most individuals who use marijuana."

### **Legal Ramifications of New Scheduling**

Changing cannabis from Schedule I to Schedule III may potentially allow cannabis to be lawfully dispensed by prescription<sup>5</sup> and states' medical cannabis programs may now be able to comply with the CSA. However, it would not make state laws legalizing recreational cannabis use in compliance with federal law without other legal changes by Congress or the executive branch. Under the change, medical cannabis users may be eligible for public housing, immigrant and nonimmigrant visas, and the purchase and possession of firearms. They may also face fewer barriers to federal employment and eligibility to serve in the military. Researchers would face less regulatory controls, and the DEA would no longer set production quota limitations for cannabis. Because the prohibition on business deductions in Section 280E of the Internal Revenue Code only applies to Schedule I and II substances of the CSA, changing cannabis from Schedule I to Schedule III would allow cannabis businesses to deduct business expenses on federal tax filing.

Importantly, some criminal penalties for CSA violations depend on the schedule of the substance. Thus, if cannabis were to be reclassified as a Schedule III substance, some criminal penalties for CSA violations would no longer apply or be significantly reduced. However, CSA penalties that specifically apply to cannabis, such as quantity-based mandatory minimum sentences, would not change under a new rescheduling.

Many advocates consider HHS's findings a step in the right direction. Specifically, supporters consider the findings further evidence that cannabis should be removed from the CSA altogether and regulated akin to tobacco and alcohol (referred to as descheduling). Given the momentum of cannabis legalization across U.S. states and breakthroughs in the medical and scientific advantages of cannabis, Congressional or Executive legalization, or – at very least – descheduling of cannabis may be on the horizon.

#### **For More Information, Please Contact:**



Julia Anderson
Associate
415.774.2909
juanderson@sheppardmullin.com

This alert is provided for information purposes only and does not constitute legal advice and is not intended to form an attorney client relationship. Please contact your Sheppard Mullin attorney contact for additional information.

Page 3 www.sheppardmullin.com

<sup>&</sup>lt;sup>5</sup> Although the FDA has approved some drugs derived from cannabis, cannabis is not presently an FDA-approved drug.