

**Bay Area MCLE Conference
Tuesday, November 19, 2024
3:00 PM to 4:00 PM**

**Reclassification of Marijuana from Schedule I to Schedule III,
Emphasizing its Use in Medical Treatment**

Outline

Background

- I. October 6, 2022 Statement From President Biden on Marijuana Reform (See *Attached Exhibit A*): Acknowledged the failed “War on Drugs” and that, “[s]ending people to prison for possessing marijuana has upended too many lives and incarcerated people for conduct that many states no longer prohibit.”
 - a. Proposed three steps:
 - i. A pardon of all prior Federal offenses of simple possession of marijuana.
 - ii. Urged all Governors to do the same with regard to state offenses.
 - iii. ***Asked the Secretary of Health and Human Services and the Attorney General to initiate the administrative process to review how marijuana is scheduled under federal law.***
- II. Federal law currently classifies marijuana in Schedule I of the Controlled Substances Act (“CSA”), the classification meant for the most dangerous substances. This is the same schedule as for heroin and LSD, and higher than the classification for fentanyl and methamphetamine.
 - a. The CSA contains five schedules, with Schedule I containing drugs deemed to be the most dangerous and having the highest potential for abuse. Schedule I substances have:
 - i. No currently accepted medical use (even under medical supervision); and
 - ii. A high potential for abuse.
- III. What does “rescheduling” mean, and how does it differ from “descheduling,” or “legalization”?
 - a. Rescheduling means changing the schedule to which a drug has been assigned under the CSA.
 - b. Descheduling or legalization would involve removing marijuana from the CSA altogether, and regulating it (or not) in a manner similar to alcohol or tobacco.

- IV. Why is rescheduling important?
- a. Research on Schedule I substances is extremely difficult, and is hampered by “a tremendous bureaucratic superstructure involving licensing, certification, security, background checks, and other requirements.”¹
 - b. This creates a catch-22 where the Schedule I presumption that marijuana has no currently accepted medical use is difficult to disprove.
 - c. There are also cultural and societal biases against marijuana’s medical value, which obstructs the scientific community from evaluating such value.²

The Rescheduling Process

- I. Rescheduling can happen in two ways:
- a. Congress can amend the CSA (Congress placed drugs into their respective schedules upon enactment of the CSA); or
 - b. Administrative action pursuant to Section 201 of the CSA:
 - i. The Attorney General or another official (i.e. President Biden, as is the case currently), such as the Secretary of Health and Human Services (“HHS”), can initiate review (or an outside group can file a petition requesting review).
 - ii. The Attorney General reviews the petition and submits it to the secretary of HHS – Generally, HHS’s obligations are delegated to the Food and Drug Administration (“FDA”).
 - iii. The review must include “a scientific and medical evaluation, and his [secretary of HHS] recommendations as to whether such a drug or other substance should be so controlled or removed as a controlled substance.” 21 U.S.C. §811.
 - iv. Five factors must be considered:
 - 1. Scientific evidence of its pharmacological effect, if known;
 - 2. The state of current scientific knowledge regarding the substance;
 - 3. What, if any, risk there is to public health;
 - 4. Its psychic or physiological dependence liability; and
 - 5. Whether the substance is an immediate precursor of a substance already controlled.
 - v. As well as: “any scientific or medical considerations” involving “its actual or relative potential for abuse ... its history and current pattern of abuse ... [and] the scope, duration, and significance of abuse.”
 - vi. Once the report is complete, the FDA sends its report to HHS, who in turn sends it to the Attorney General.
 - vii. Simultaneous with the FDA review, the Attorney General delegates review of the petition to the Drug Enforcement Agency (“DEA”).

¹ John Hudak, *Marijuana: A Short History* 126 (2020).

² *Id.*

- viii. Once a report is compiled and reviewed, if a determination re: rescheduling is made, this initiates the so-called rulemaking process, which can be lengthy and complex.

Where Are We Now?

- I. On May 16, 2024, the Justice Department announced that the Attorney General had submitted to the Federal Register a notice of proposed rulemaking initiating a formal rulemaking process to consider moving marijuana from Schedule I to Schedule III of the CSA. The DOJ's report, incorporating the findings of HHS, can be found [here](#).
- II. According to the press release, "The rescheduling of a controlled substance follows a formal rulemaking procedure that requires notice to the public, and an opportunity for comment and an administrative hearing. This proposal starts the process, where the Drug Enforcement Administration will gather and consider information and views submitted by the public, in order to make a determination about the appropriate schedule. During that process, and until a final rule is published, marijuana remains a schedule I controlled substance."
- III. The DEA's public hearing to commence the rulemaking process is scheduled for December 2, 2024.
- IV. TBD how this process will proceed given President Trump's reelection and the shift in both the Senate and House.

What Will Rescheduling NOT Do?

- I. Misconceptions regarding rescheduling fall along two ends of a spectrum:
 - a. The belief that moving marijuana from Schedule I to Schedule III will make marijuana pharmaceuticals legal, leading to the shut-down of state legal systems (like our regulatory system here in California), and requiring removal of marijuana products from the market until FDA approval is granted.
 - b. The belief that moving marijuana from Schedule I to Schedule III will "legalize" marijuana and eliminate many, if not all, of the problems faced by existing cannabis businesses.
- II. Fortunately and unfortunately, neither of these beliefs is accurate:
 - a. Rescheduling will not shut down existing state-legal cannabis businesses:
 - i. The legal authority keeping marijuana businesses open has nothing to do with rescheduling.³ The authority under which cannabis businesses continue to operate, despite prohibition under the CSA, is a series of memoranda issued by the U.S. Department of Justice

³ John Hudak and Grace Wallack, *Clearing up misconceptions about marijuana rescheduling: What it means for existing state systems*, Brookings (May 27, 2016).

(which have, as of 2018, been rescinded), coupled with a track record of the federal government taking a “hands off” approach to enforcement against businesses operating in compliance with state law.

- ii. If marijuana is rescheduled, enforcement authority will still be vested in individual U.S. Attorneys.
 - iii. The FDA will never approve smoked, whole flower marijuana as a drug, even after rescheduling. FDA-approved marijuana drugs will likely look like pills and liquids, made by isolating individual cannabinoids or compounds of cannabinoids.⁴
 - iv. The concern is that because the FDA won’t allow whole flower marijuana, the existing system of cannabis businesses will be closed. However, the FDA is not the entity that allows those businesses to remain open in the first place.
 - v. A change in federal enforcement is unlikely where movement from Schedule I to Schedule III means a signal from the federal government that marijuana is not as dangerous or useless as previously maintained. It would be surprising for the federal government to deem marijuana less dangerous, and then step up enforcement of federal law by shutting down state-licensed businesses.
 - vi. Marijuana businesses stay open in large part because of presidential prerogative. While Trump’s first administration rescinded federal guidance related to enforcement, in practice, enforcement did not change under his last administration. It is unlikely to change under his next administration, given the number of states that have since legalized medical and/or recreational marijuana.
 - vii. Public opinion is clear, and it matters.
- b. Rescheduling will not “legalize” state-licensed cannabis businesses.
- i. While rescheduling will not shut down state-legal cannabis markets, it also will not legalize them.
 - ii. So, what *does* rescheduling do? Not much, but there are some key benefits:
 - 1. Perhaps most importantly for cannabis businesses, moving marijuana to Schedule III will mean that Internal Revenue Code Section 280E will no longer apply:
 - a. “No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of *schedule I and II* of the Controlled Substances Act) which is prohibited by

⁴ *Id.*

Federal law or the law of any State in which such trade or business is conducted.”

- b. This will be a significant boon for businesses that have struggled under the weight of exorbitant tax liabilities and the inability to deduct many businesses expenses.
 - 2. Research restrictions and their associated bureaucratic hurdles will be somewhat relaxed, paving the way for additional research into the medical potential of marijuana.
- c. Beyond the inapplicability of IRC 280E and the lowered barriers to research, rescheduling will not have much of an impact on state-licensed cannabis businesses.
 - i. State-licensed businesses will still be operating in violation of federal law, meaning:
 - 1. Banking challenges;
 - 2. Insurance challenges;
 - 3. Lack of access to trademark protection and uncertainty regarding patents;
 - 4. Lack of access to bankruptcy;
 - 5. Increased regulatory compliance burden;
 - 6. Ever-present threat of federal enforcement.
- d. Products in state-legal markets are very different than FDA-approved pharmaceutical products.
 - i. Rescheduling will create a complicated (and messy) dual system of regulation, where some marijuana products will be available as drugs prescribed by doctors and approved by the FDA, and some products will be available for medical and/or recreational use from state-licensed cannabis retail stores.

EXHIBIT A



OCTOBER 06, 2022

Statement from President Biden on Marijuana Reform

BRIEFING ROOM • STATEMENTS AND RELEASES

As I often said during my campaign for President, no one should be in jail just for using or possessing marijuana. Sending people to prison for possessing marijuana has costed too many lives and incarcerated people for conduct that many states no longer prohibit. Criminal records for marijuana possession have also imposed needless barriers to employment, housing, and educational opportunities. And while white and Black and brown people use marijuana at similar rates, Black and brown people have been arrested, prosecuted, and convicted at disproportionate rates.

Today, I am announcing three steps that I am taking to end this failed approach.

First, I am announcing a pardon of all prior Federal offenses of simple possession of marijuana. I have directed the Attorney General to develop an administrative process for the issuance of certificates of pardon to eligible individuals. There are thousands of people who have prior Federal convictions for marijuana possession, who may be denied employment, housing, or educational opportunities as a result. My action will help relieve the collateral consequences arising from these convictions.

Second, I am urging all Governors to do the same with regard to state offenses. Just as no one should be in a Federal prison solely due to the possession of marijuana, no one should be in a local jail or state prison for that reason, either.

Third, I am asking the Secretary of Health and Human Services and the Attorney General to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law. Federal law currently classifies marijuana in Schedule I of the Controlled Substances Act, the classification meant for the most dangerous substances. This is the same schedule as for heroin and LSD, and even higher than the classification of fentanyl and methamphetamine - the drugs that are driving our overdose epidemic.

Finally, even as federal and state regulation of marijuana changes, important limitations on trafficking, marketing, and under-age sales should stay in place.

Too many lives have been costed because of our failed approach to marijuana. It's time that we right these wrongs.
