CANNABIS SCHEDULING UPDATE

Americans for Safe Access (ASA) has created the following factsheet to clarify the *Cannabis* scheduling process including next steps & potential impacts of a change in scheduling status as well as suggested actions for Congress.

A CALL TO FEDERAL POLICYMAKERS

ASA is encouraged by recent movement on the scheduling of Cannabis. Though the process is ongoing, what is certain is that **federal health agencies have confirmed that cannabis has accepted medical use in the United States**. However, Congress should note that a change in the scheduling of cannabis will *not* resolve national issues facing cannabis policy. In fact, the rescheduling of cannabis will intensify the need for Congressional action including the creation of a regulatory framework for medical cannabis & cannabinoid products.

Cannabis therapeutics are helping millions of Americans, often where all traditional options have failed, or as a safer treatment option. While state-level initiatives have demonstrated the potential of medical cannabis treatments, the lack of federal regulations poses challenges for patients, researchers, & medical practitioners, keeping cannabis treatments from reaching their full potential. *Rescheduling alone will not change this.*

ASA is calling on Congress to create a national cannabis program to ensure uniformity in regulations, restore the rights of medical cannabis patients, create nationwide access for therapeutic use & research, & forge a new, purpose-built pathway for cannabis therapeutics. ASA has developed a legislative framework for a national medical cannabis program that builds on the knowledge from the state level experiment, includes input from patients, regulators, researchers, medical professionals, medical cannabis providers & patient organizations, & incorporates the experience of the 50+ countries with federal medical cannabis programs.

BACKGROUND

In October 2022, President Biden called on Health & Human Services (HHS) & the Department of Justice (DOJ) to conduct a review of the scheduling of Cannabis under the Controlled Substance Act (CSA).

The process of determining the schedule of substance defined under the CSA requires a medical & scientific review outlined by the "Eight Factor Analysis" & "five-element test" for determining whether the drug has a currently accepted medical use for treatment in the United States. The Food & Drug Administration (FDA) conducts the initial analysis for HHS before handing over their findings & recommendations to the Drug Enforcement Administration (DEA) to inform their review & scheduling determination on behalf of the DOJ.

Over the last 50 years, HHS & DOJ have conducted five scheduling reviews of cannabis, initiated by the petition process defined in the CSA. The last review concluded in 2016 with the DEA issuing the report "Denial of Petition to Initiate Proceedings to Reschedule Marijuana" see **safeaccessnow.org/2016_Rescheduling_Denial_Factsheet**

HHS REVIEW

On August 30, 2023, HHS confirmed news reports that their medical & scientific review, which included a recommendation that cannabis be moved to Schedule III, had been sent to the DEA.

The HHS review is not available to the public at this time. Barring a leak, a unlikely successful FOIA filing, or a demonstrative action from Congress, it will not become public until it is added to the Federal Register by the DEA with their review & determination. However, based on HHS' schedule recommendation we can infer the following:

In order for HHS to recommend Schedule III, their scientific review must include evidence supporting:

#1 CANNABIS HAS "ACCEPTED MEDICAL USE IN THE UNITED STATES"

#2 Cannabis has a "moderate to low potential for physical & psychological dependence. Schedule III drugs abuse potential is less than Schedule I & Schedule II drugs but more than Schedule IV".

HHS ASSERTING THAT CANNABIS HAS "ACCEPTED MEDICAL USE IN THE UNITED STATES" IS NOT EQUIVALENT TO FDA APPROVAL OR EVEN A RECOGNITION THAT CANNABIS IS A MEDICINE AS DEFINED BY THE FDA.

WHAT'S NEXT

The DEA is now preforming a review that will include HHS' findings, their internal application of the "8 Factor Analysis", & US obligations to scheduling allowances under international drug treaties. Their determination & rationale will be posted to the federal registry accompanied by a timeframe for public comment.

At that time, stakeholders can request a hearing to present the DEA with additional information in pursuit of a different outcome. If granted, a non-binding hearing will be conducted by an administrative law judge. The last hearing, held in 1985, concluded with DEA rejecting the rescheduling petition in defiance of the judge's findings in 1988.

THERE IS NO STATUTORY TIME REQUIREMENT FOR THE DEA/DOJ RESPONSE.

DOJ is not bound to HHS's Schedule III recommendation for their final determination. However, it is unlikely that the DEA will keep cannabis in Schedule I because:

#1 DOJ IS BOUND TO HHS' DETERMINATION ON THE ACCEPTED MEDICAL USE

#2 DOJ is bound to the definitions of the schedules: "Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use & a high potential for abuse."

#3 The CSA has strong ties to United Nation (UN) drug treaties & the UN has recognized cannabis' medical use by rescheduling cannabis in 2020.

IMPACT OF ANY CHANGE IN CANNABIS SCHEDULING

A scheduling change will likely impact social attitudes about medical cannabis in general, potentially reducing the stigma, & increasing the acceptance of cannabis for medical professionals, employers, & state & federal policy makers.

While state medical cannabis programs will continue to be protected from federal interference by the DEA & DOJ under the protections provided by the "CJS Medical Cannabis Amendment", when cannabis is classified as Schedule II, III or even if de-scheduled, all commercial cannabis activity would fall under the purview of other federal regulations & oversight. Enforcement would be up to the priorities of the Executive Branch.

A change in scheduling, especially under Schedule III, would make conducting research on cannabis more accessible by decreasing costs to meet requirements for the handling, storage & security associated with Schedule I substances. This will expand & improve scientific cannabis research & lead to greater knowledge of its effects, safety, & potential uses.

IMPACT OF CANNABIS RESCHEDULING ON STATUS QUO

Products produced in state medical cannabis programs would NOT move into federally regulated protocols without guidance from Congress & a registration process.

For example, these products would NOT be available by prescription nor would prescriptions be required for patients to participate in state medical cannabis programs. These products could not be used in efficacy-related clinical trials, etc.

Unregulated Schedule II/III substances are federally illegal. The protection of individuals for possessing these substances is through a prescription, & luckily for patients, the federal government rarely enforces simple possession charges. However, cultivating, manufacturing, &/or distributing these substances outside the regulatory process is referred to as trafficking & carries steep penalties.

Penalties for Trafficking Any Amount of Schedule III drugs:

***First Offense**: Up to 10-15 years in prison. Fines up to $500,000 for individuals & $2.5 million for organizations.*

***Second Offense**: Up to 20-30 years in prison. Fines up to $1 million for individuals & $5 million for organizations..*

While the **280E** statute specifically prohibits entities selling Schedule I & II substances from deducting business expenses from their taxes, these restrictions apply to any proceeds generated from illicit activity as defined in other statutes. US tax laws apply to all earnings regardless of the source; however tax deductions are not extended to illegal endeavors.

If cannabis becomes a Schedule III substance, state licensed cannabis businesses would still be operating outside federal law, making it unlikely that they would be allowed tax deductions for business expenses **without additional Congressional action**.

However, businesses with DEA cultivation licenses would be allowed tax deductions because they are regulated under federal law.

CONGRESS' ROLE

ASA is calling on Congress to adopt a comprehensive approach to cannabis regulations that would include the creation of a new schedule for cannabis & cannabinoids (Schedule VI) & the creation of the Office of Medical Cannabis & Cannabinoids Control (OMC) housed in HHS.

ASA has developed a legislative framework for a national medical cannabis program that builds on knowledge from state cannabis programs, includes input from patients, regulators, researchers, medical professionals, medical cannabis providers, & patient organizations, & incorporates the experience of the 50+ countries with federal medical cannabis programs.

Download Full Text of Legislation:
safeaccessnow.org/model_federal_legislation

A NEW AGENCY: OMC

The mission of the OMC is to facilitate access to medical cannabis for therapeutic use & research, regulate the production of medical cannabis & cannabinoid products, facilitate private-public partnerships for product development & research, & oversee the new Schedule VI.

The OMC will require initial federal funding though most operational funds will come from the reorganization of current cannabis oversight funding, licensing & permit fees, & private-public research partnerships.

A NEW SCHEDULE: Schedule VI

Since 1996, states have been authorizing cannabis programs that operate completely outside the purview of the CSA. By amending 21 USC 812(b)(5) of the CSA to create a new scheduling category for cannabis, Schedule VI, Congress will maintain moderate control over medical cannabis & cannabinoids for human consumption, give clear guidance to federal & state agencies, all while allowing the greatest number of patients to access cannabis as a medicine.

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