THE MEDICAL CANNABIS & CANNABINOID ACT

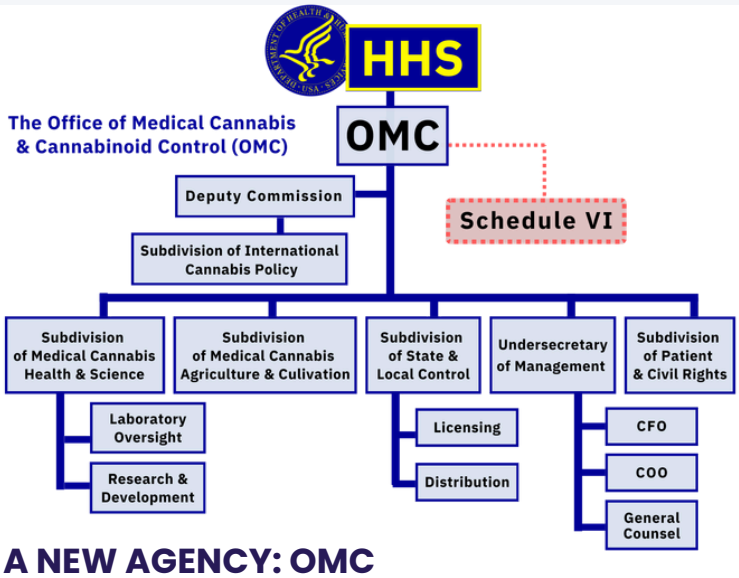
A National Framework for Safe Access & Regulatory Control

Cannabis medicines have become a lifeline for millions of Americans, offering relief when conventional treatments fail or pose risks. The absence of a national medical cannabis program hinders access for many, and unregulated markets pose potential health threats for many more. Integrating cannabis into healthcare systems will enhance the overall quality of healthcare in the United States. **Creating a regulatory pathway that acknowledges cannabis as a medicine will allow healthcare stakeholders to adapt to evolving scientific knowledge and offer patients comprehensive care.**

The Medical Cannabis & Cannabinoid Act (MCCA), was drafted by Americans for Safe Access (ASA) with input from patient organizations, regulators, researchers, and medical professionals. **The MCCA creates a national medical cannabis program through two primary functions: establishing the Office of Medical Cannabis & Cannabinoid Control (OMC) housed under the U.S. Department of Health and Human Services (HHS) and changing the schedule of cannabis to a newly created schedule (Schedule VI).**

"There is conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults, as anti-emetics in the treatment of chemotherapy-induced nausea and vomiting, and for improving patient-reported multiple sclerosis spasticity symptoms."

National Academies of Sciences, Engineering, & Medicine: The Health Effects of Cannabis & Cannabinoids, January 2017



"FDA regulates certain cannabis products under the Federal Food, Drug, and Cosmetic Act, Congress might also consider whether to alter that regulatory regime or create some alternative regulatory framework."

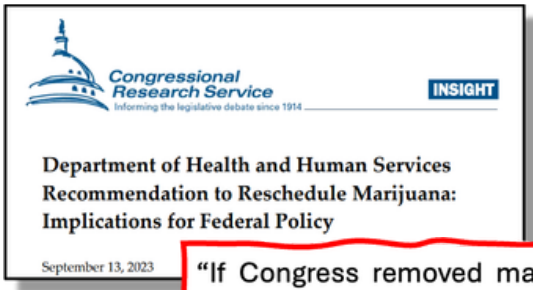
"LEGAL CONSEQUENCES OF RESCHEDULING MARIJUANA"
CRS Report: January 16th, 2024 (updated May 1, 2024)

A NEW AGENCY: OMC

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

A NEW SCHEDULE: Schedule VI

A Schedule VI classification recognizes cannabis as a botanical medicine with a unique profile. Placing cannabis in its own category would allow regulations tailored to its specific properties and uses. Under Schedule VI, the OMC would oversee these regulations, providing a centralized authority dedicated to cannabis.



"HHS RECOMMENDATION TO RESCHEDULE MARIJUANA: IMPLICATIONS FOR FEDERAL POLICY"
September 13, 2023, CRS Report

"If Congress removed marijuana from Schedule I, it might (1) place marijuana on one of the other schedules of controlled substances, (2) create another schedule or separate classification for marijuana under the CSA, or (3) remove marijuana as a controlled substance altogether."

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COMPREHENSIVE MEDICAL CANNABIS & CANNABINOID LEGISLATION IS NECESSARY

Clarify Federal Stance on Medical Cannabis & Cannabinoid Policy

- The Medical Cannabis Amendment to the Commerce-Justice-Science (CJS) Appropriations bill, first passed in 2014, was meant to be a triage measure to stop raids and prosecutions while Congress dealt with federal medical cannabis policies.
- The Hemp Authorization Act of the 2018 Farm Bill removed cannabis with <0.3% THC from the CSA and inferred that the Food and Drug Administration (FDA) would regulate cannabinoid products derived from hemp. Five years later, in January 2023, the FDA told Congress that it needed a new pathway to regulate these products. Congress amended the CSA in 2025 to close the "hemp loophole" by defining industrial hemp, but did not include guidance on the regulation of hemp-derived cannabinoid products.
- The U.S. Department of Health and Human Services (HHS) and the Department of Justice (DOJ) have concluded that cannabis has "accepted medical use in treatment in the United States."

States have Fulfilled their Role as "Laboratories of Democracy"

- Forty states, the District of Columbia, four of five U.S. territories have medical cannabis distribution programs laws and nine states have cannabidiol or low THC laws.
- State policymakers and regulators have not only been tasked with creating the infrastructure and regulations for a supply chain that remains illegal at the federal level, but now they must address new public health concerns from the unregulated hemp-derived cannabinoid market created by the 2018 Farm Bill.
- The state-by-state compassionate use model leaves out those patients living in states reluctant to pass medical cannabis laws, federal employees and contractors, and veterans utilizing VA medical services. In states with medical cannabis laws, this model does not address many medical or logistical needs for patients, only serving a privileged class of Americans.

Science has Changed Understanding & Attitudes on Medical Cannabis

- 93% of Americans are in favor of medical cannabis policies.
- In 2020, the United Nations reclassified cannabis, recognizing its medical benefits, and over 60 countries have legalized the medical use of cannabis at the national level.
- 6 million Americans are using medical cannabis as a stand-alone or as an adjunct treatment to relieve symptoms or side effects experienced from other treatment methods. In many cases, patients and their medical professionals report that cannabis and cannabinoids provide relief when pharmaceutical options have failed.
- In response to the U.S.'s pain and opioid epidemics, over 1/3 of Americans are turning to cannabis and cannabinoids to treat chronic pain and curb opioid use, resulting in fewer opioid deaths in states where medical cannabis is available.

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"None of the evidence from the systematic reviews included in our analysis demonstrated substantial safety concerns that would argue against the use of marijuana in any of the indications where there exists some support for its benefit."

FDA's Center for Drug Evaluation and Research (CDER) "Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act"

For more info, please contact Americans for Safe Access info@safeaccessnow.org