



Americans for Safe Access

The mission of Americans for Safe Access (ASA) is to ensure safe and legal access to cannabis (marijuana) for therapeutic uses & research. Founded in 2002, ASA advocates for a national regulatory framework that invests in the development of standardized cannabis-based products, ensures a safe & consistent supply, fosters the integration of cannabis into patient treatment plans as a frontline medication, encourages insurance coverage, & prohibits employment, housing, parental & healthcare discrimination.

MEDICAL CANNABIS PATIENT.

[me-di-kəl ka-nə-bəs pā-shənt] n. a person living with a medical condition or experiencing symptoms for which cannabis or a cannabinoid-based therapeutic is the only treatment option, a more suitable option, or works as an adjunct treatment including side-effect mitigation to other available care options.



30 MILLION

Americans live

with a

Rare

Disease



129 MILLION

AMERICANS
HAVE AT
LEAST ONE



CHRONIC DISEASE

95%

OF
THE



7,000

KNOWN

RARE DISEASES HAVE

NO

FDA-APPROVED
TREATMENT

1/3

**AMERICANS
LIVE WITH
CHRONIC PAIN**



10%^{OF} AMERICANS

**HAVE INTRACTABLE PAIN
FROM MIGRAINES, CANCER, DEGENERATIVE
DISC DISEASE, CENTRAL PAIN SYNDROME,
OR RHEUMATOID ARTHRITIS**



**1 MILLION
AMERICANS
ARE LIVING WITH
MULTIPLE
SCLEROSIS (MS)**




**UNCONTROLLED
EPILEPSY
EFFECTS
AT LEAST 1 MILLION
PEOPLE IN THE U.S.**



**EVERY YEAR
5K AMERICANS
RECEIVE AN ALS
DIAGNOSIS**

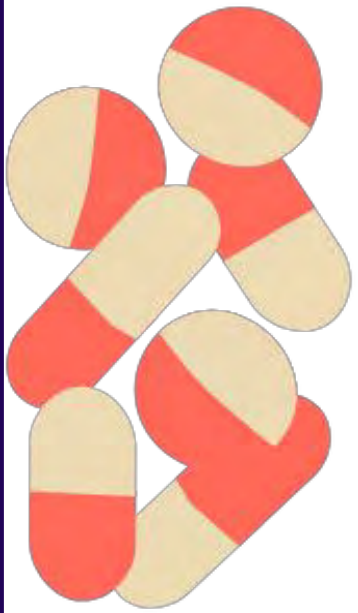


1/3 
**VETERANS
HAVE CONDITIONS
RELATED TO
CHRONIC PAIN**

**CHRONIC
PAIN** 
2x
**RISK OF DEATH
BY SUICIDE**



EVERY DAY 19
**VETERANS & ACTIVE
MILITARY MEMBERS
COMMIT SUICIDE**



**224 AMERICANS DIE EACH DAY
FROM AN OPIOID OVERDOSE**

20% ARE FROM PRESCRIPTIONS.

**1/2 AMERICANS
65 OR OLDER TAKE**



5-20

MEDICATIONS DAILY

9 out of **10**

FDA-Approved

Drugs are

PALLIATIVE.



750



from

**Every Day
Americans, 65+
Are Hospitalized
Due To Serious
Side Effects
from Medications**

**CHRONIC & MENTAL
HEALTH CONDITIONS
ARE RESPONSIBLE FOR**

90% OF
THE
\$41 TRILLION
SPENT ANNUALLY
ON U.S. HEALTHCARE

CHRONIC PAIN COSTS AMERICANS

**\$560-\$635
BILLION**

ANNUALLY

\$35 BILLION

Cost of
OPIOID MISUSE
& Related Healthcare Issues.



The National Academies of
SCIENCES · ENGINEERING · MEDICINE

REPORT

The Health Effects of Cannabis and Cannabinoids

THE CURRENT STATE OF EVIDENCE AND
RECOMMENDATIONS FOR RESEARCH

“

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, and Medicine:
The Health Effects of Cannabis & Cannabinoids, January 2017

The U.S. Department of Health and Human Services has concluded that **cannabis** has “**accepted medical use in treatment in the United States.**”



“
**CANNABIS HAS
CURRENTLY ACCEPTED
MEDICAL USE IN THE U.S.**
”

DEA, DOJ: Notice of proposed rulemaking: Schedules of Controlled Substances: Rescheduling of Marijuana May 21, 2024

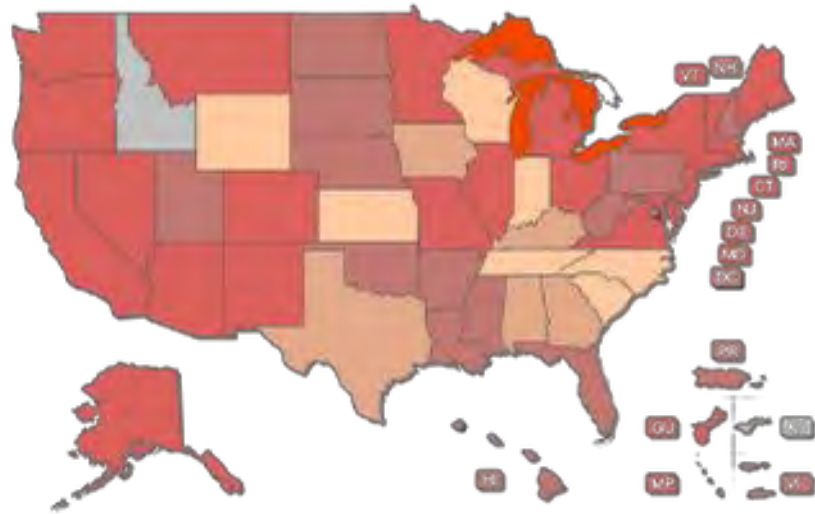


A NATIONAL MEDICAL CANNABIS PROGRAM
A CURE WE CAN'T IGNORE

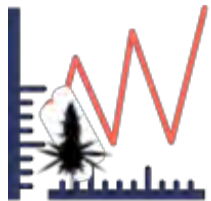


Americans for
Safe Access

STATE PROGRAMS HAVE DEMONSTRATED THE POTENTIAL OF MEDICAL CANNABIS



Improved Patient Outcomes
Lower Healthcare Costs
Benefits to the Workforce
Reduced Opioid Dependency



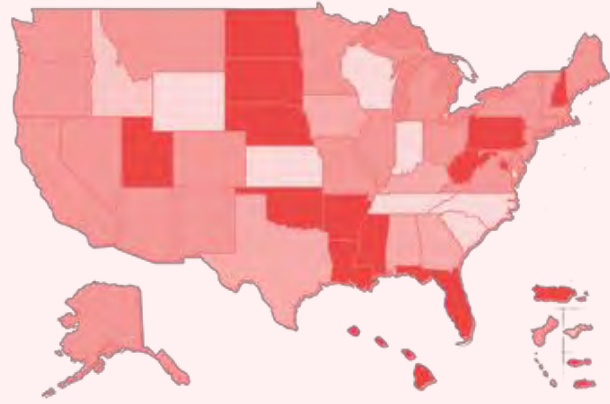
SCIENCE IS CATCHING UP TO THESE FINDINGS



LOWER HEALTHCARE COSTS

A study published in Health Affairs in 2017 found that states with medical cannabis laws saw a reduction of \$165.2 million annually in Medicare Part D prescription drug spending. If implemented nationwide, it could result in billions of dollars in annual savings.

Bradford AC, Bradford WD. Medical Marijuana Laws May Be Associated With A Decline In The Number Of Prescriptions For Medicaid Enrollees. Health Aff (Millwood). 2017 May 1;36(5):945-951. doi: 10.1377/hlthaff.2016.1135. Epub 2017 Apr 19. PMID: 28424215.



REDUCED OPIOID DEPENDENCY

States with medical cannabis laws experienced a 23% reduction in opioid overdose deaths, according to a 2021 study published in *JAMA Network Open* (Wilson et al., 2021). Patients using medical cannabis as part of their treatment report a significant decrease in opioid use, with some studies showing a 64% reduction in opioid consumption (Boehnke et al., 2016).

Wilson, N., Kariisa, M., Seth, P., Smith, H. T., & Davis, N. L. (2021). Drug and opioid-involved overdose deaths – United States, 2017-2019. *JAMA Network Open*, e2110264.

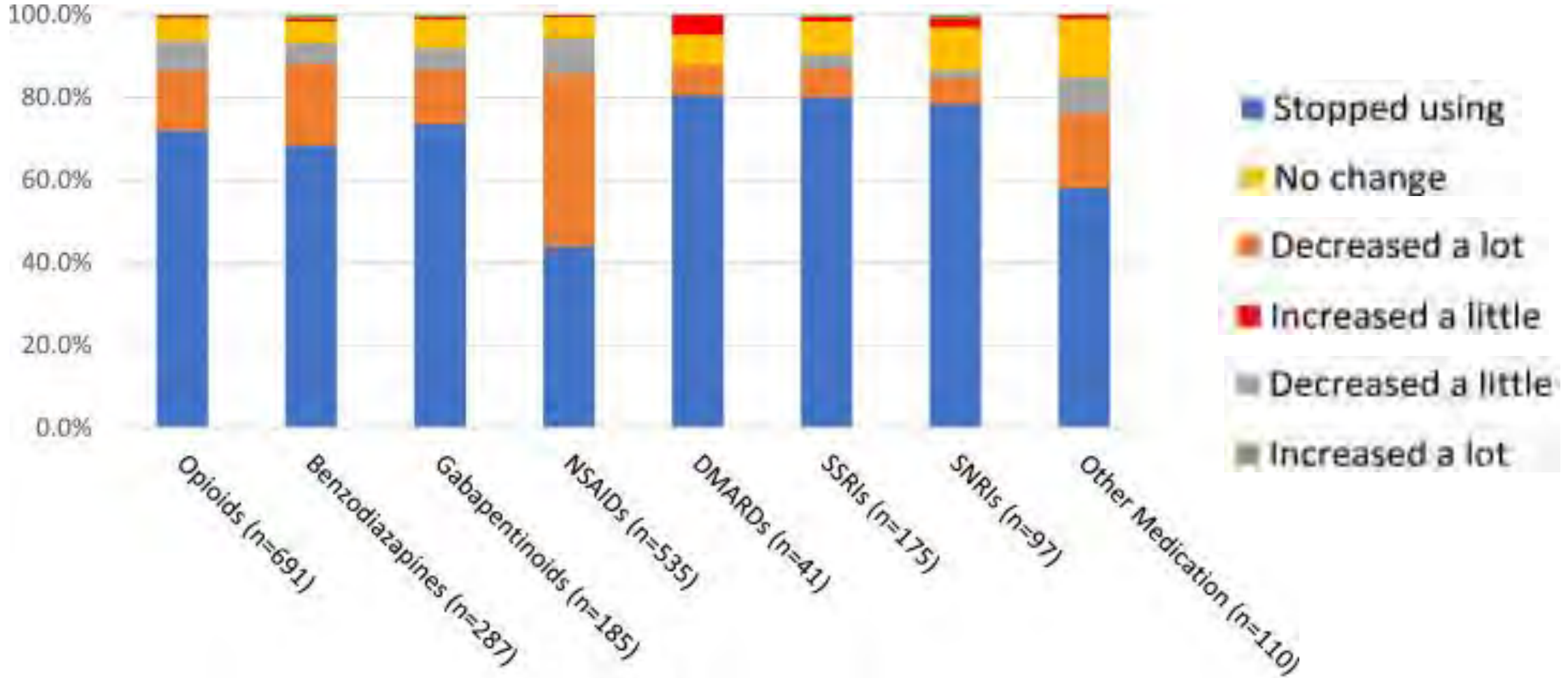
Boehnke, K. F., Litinas, E., & Clauw, D. J. (2016). Medical cannabis use is associated with decreased opiate medication use in a retrospective cross-sectional survey of patients with chronic pain. *Journal of Pain*, 17(6), 739-744.

Medical cannabis treatment was associated with **improvements in pain severity and interference observed at one month and maintained over the 12-month observation period**. Significant improvements were also observed in **physical and mental health domains starting at three months**. Significant **decreases in headaches, fatigue, anxiety, and nausea were observed after initiation of treatment**. In patients who reported opioid medication use at baseline, there were **significant reductions in oral morphine equivalent doses**, while correlates of pain were **significantly improved** by the end of the study observation period. **Conclusions.** Taken together, the findings of this study add to the cumulative **evidence in support of plant-based medical cannabis as a safe and effective treatment option and potential opioid medication substitute or augmentation therapy for the management of symptoms and quality of life in chronic pain patients.**

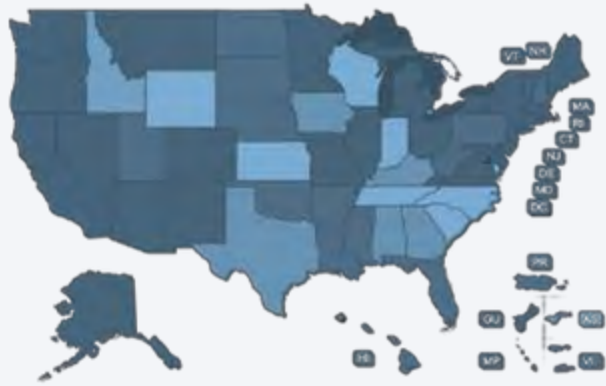
**END PAIN
NOT LIVES**
MAKE CANNABIS AN OPTION
A PROJECT OF AMERICANS FOR SAFE ACCESS

Safakish R, Ko G, Salimpour V, Hendin B, Sohanpal I, Loheswaran G, Yoon SYR. **Medical Cannabis for the Management of Pain and Quality of Life in Chronic Pain Patients: A Prospective Observational Study.** Pain Med. 2020 Nov 1;21(11):3073-3086. doi: 10.1093/pm/pnaa163. PMID: 32556203.

SUBSTITUTION OF CANNABIS FOR PAIN MEDICATION



Pills to Pot: Observational Analyses of Cannabis Substitution Among Medical Cannabis Users With Chronic Pain Kevin F. Boehnke, J. Ryan Scott, Evangelos Litinas, Suzanne Sisley, David A. Williams, Daniel J. Clauw; *The Journal of Pain* Volume 20 Issue 7 Pages 830-841 (July 2019)



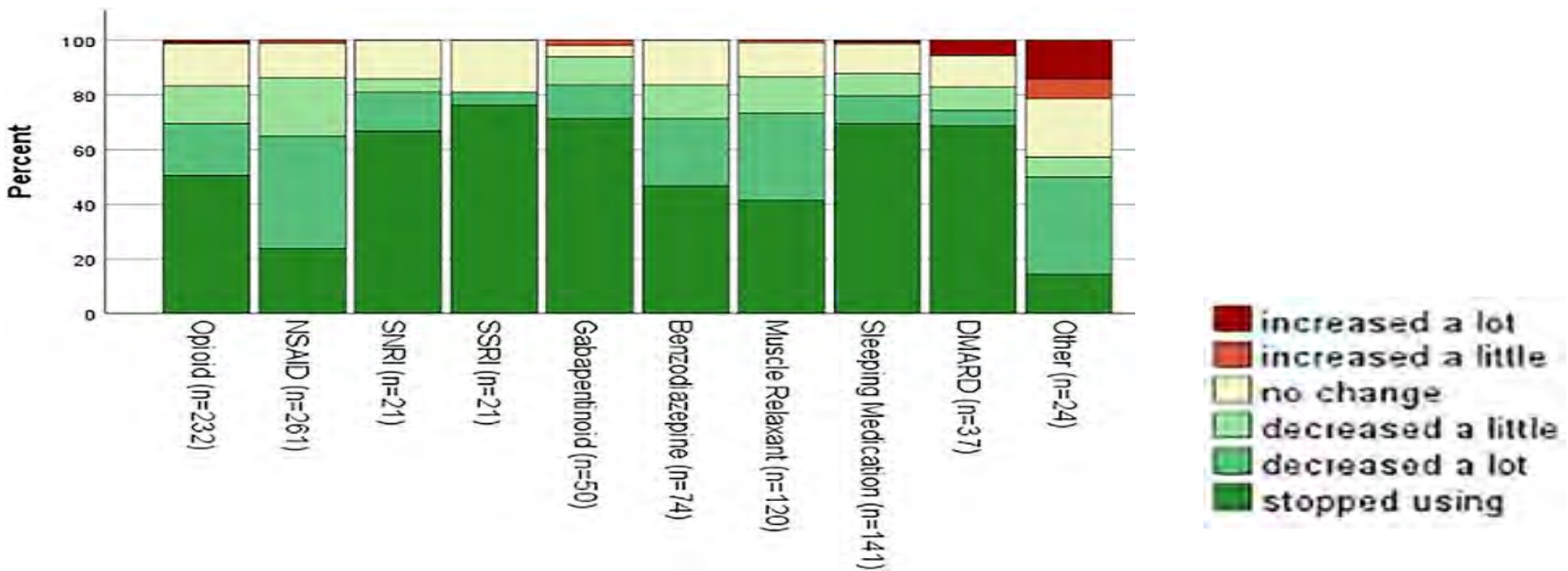

IMPROVED PATIENT OUTCOMES

Patients participating in medical cannabis programs report better symptom management, fewer side effects, and improved mental health. For instance, rheumatic disease patients using medical cannabis report decreased pain, enhanced mobility, and improved sleep (Fitzcharles et al., 2021).

Fitzcharles, M. A., Ste-Marie, P. A., Clauw, D. J., & Shir, Y. (2021). Rheumatologists' attitudes and knowledge about cannabis use in patients with rheumatic diseases. *The Journal of Rheumatology*, 48(5), 745-751



A study in ACR Open Rheumatology found that 62.5% of participants substituted medical cannabis for medications, with 54.7% replacing NSAIDs, 48.6% opioids, 29.6% sleep aids, and 25.2% muscle relaxants. Following substitution, most reported a reduction or cessation in their use of these medications.

**OVER 50%
65+ HAVE
ONE OR MORE
RHEUMATIC
CONDITIONS**

Boehnke KF, Scott JR, Martel MO, Smith T, Bergmans RS, Kruger DJ, Williams DA, Fitzcharles MA. Substituting Medical Cannabis for Medications Among Patients with Rheumatic Conditions in the United States and Canada. *ACR Open Rheumatol.* 2024 Dec;6(12):826-835. doi:10.1002/acr2.11717. Epub 2024 Sep 5. PMID: 39236308; PMCID: PMC11638128.



ACCORDING TO FDA'S CENTER FOR DRUG EVALUATION & RESEARCH (CDER):



“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"



Americans for
Safe Access

MEDICAL CANNABIS IN AMERICA



6

MILLION+ PATIENTS



**IN STATE
MEDICAL CANNABIS
PROGRAMS**

22%

OF



VETERANS

**CURRENTLY USE
CANNABIS TO TREAT
MEDICAL CONDITIONS**



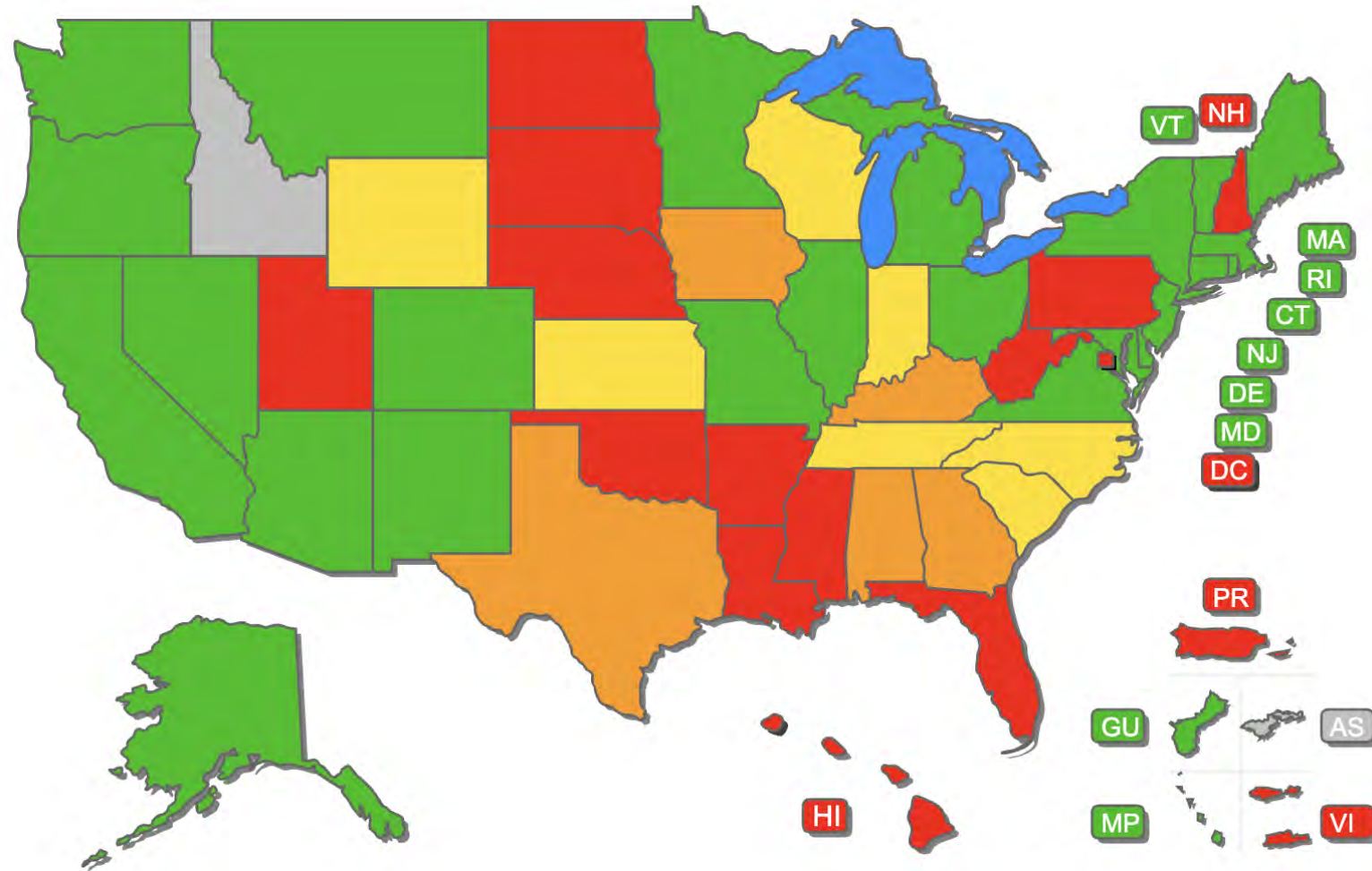
**2/3 MEDICAL
PROFESSIONALS
RECOGNIZE CANNABIS
HAS MEDICAL VALUE**

82% OF VETERANS

**WANT MEDICAL CANNABIS
TO BE A FEDERALLY LEGAL
TREATMENT OPTION**



Since 1996, states 49 states, 4 territories & D.C. have passed medical cannabis laws.



[T]he Office of the Assistant Secretary for Health found that more than **30,000 HCPs [Healthcare Providers]** are authorized to **recommend the use of marijuana for more than six million registered patients**, constituting widespread clinical experience associated with various medical conditions recognized by a substantial number of jurisdictions across the United States. For several jurisdictions, these programs have been in place for several years and include features that actively monitor medical use and product quality characteristics of marijuana dispensed.

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Part 1301
[Docket No. DEA-1362]
RIN 1117-AB77
**Schedules of Controlled Substances:
Rescheduling of Marijuana**
AGENCY: Drug Enforcement
Administration, Department of Justice.

- **DEA, DOJ: Notice of Proposed Rulemaking:
Schedules of Controlled Substances:
Rescheduling of Marijuana May 21, 2024**

“
Over two-thirds (68.9%) of clinicians surveyed believe that cannabis has medicinal uses, and just over a quarter (26.6%) had ever recommended cannabis to a patient.
”

Schauer GL, Njai R, Grant AM. Clinician Beliefs and Practices Related to Cannabis. Cannabis Cannabinoid Res. 2022 Aug;7(4):508-515. doi: 10.1089/can.2020.0165. Epub 2021 Apr 26. PMID: 33998899; PMCID: PMC9418355.

DIVERSE SUPPORT FOR MEDICAL CANNABIS ACCESS



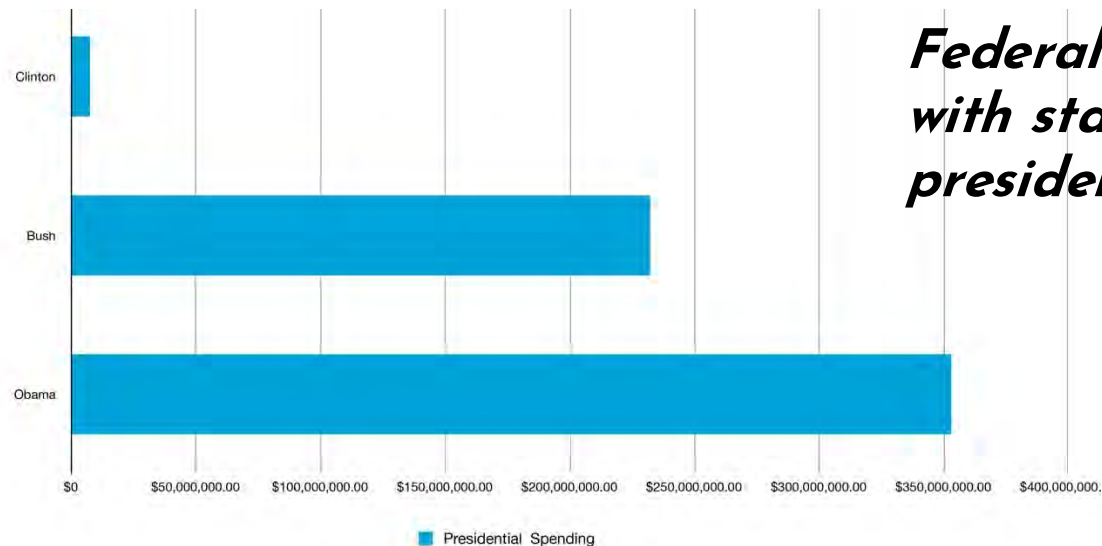
MEDICAL CANNABIS LAWS HAVE LIMITED FEDERAL PROTECTIONS

First passed by Congress in 2014 as the Rohrabacher-Farr Amendment, this amendment to the Commerce, Justice, & Science (CJS) Appropriations Bill created a “ceasefire” of federal interference in state medical cannabis laws.



“None of the funds made available under this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, the Commonwealth of the Northern Mariana Islands, the United States Virgin Islands, Guam, or Puerto Rico, to prevent any of them from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.”

The Medical Cannabis Amendment to the Commerce-Justice-Science (CJS) Appropriations bill was meant to be a triage measure to stop raids and prosecutions while Congress dealt with federal medical cannabis policies. A decade later, medical cannabis programs are still stuck in legal limbo.



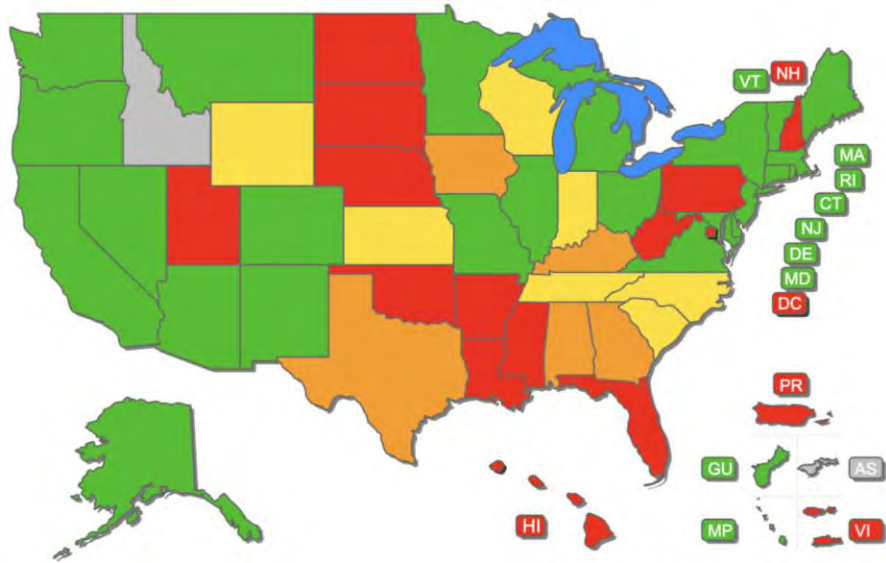
Federal funds spent on interfering with state medical cannabis laws by presidency before CJS Amendment.

STATES HAVE FULFILLED THEIR ROLE AS "LABORATORIES OF DEMOCRACY"



Initially created as "triage" to remove patients from the battlefield of the war on drugs, the state cannabis access experiment has run its course.

State-level medical cannabis programs function separately from healthcare systems, resulting in financial, geographical, and legal obstacles for numerous patients, **ultimately catering primarily to a privileged demographic of Americans.**



POVERTY IN UNITED STATES

43 MILLION PEOPLE LIVE IN POVERTY



15 MILLION PEOPLE LIVE IN DEEP POVERTY
(50% BELOW POVERTY LINE)



49 MILLION PEOPLE LIVE JUST ABOVE POVERTY



“The Epilepsy Foundation believes that an end to seizures should not be determined by one’s zip code.”



MEDICAL CANNABIS PATIENTS HAVE NO FEDERAL RIGHTS

DENIAL OF SERVICES

Federal prohibition prevents medical cannabis patients from accessing services such as subsidized housing, Veterans Affairs benefits, and Medicare.

PURSUIT OF HAPPINESS

Federal cannabis laws restrict the geographical mobility of patients, affecting their ability to travel, relocate for work, or pursue higher education.

HEALTHCARE AUTONOMY

Federal restrictions also extend to healthcare settings, where cannabis use is frequently prohibited in hospitals, hospices, and assisted living facilities.

ADA

Medical cannabis patients are not protected under the Americans with Disabilities Act (ADA) or the Fair Housing Act (FHA).

2ND AMENDMENT RIGHTS

Federal laws restrict the rights of medical cannabis patients to own firearms, conflating responsible medical use with unlawful drug use.





VETERANS & PATIENTS WHO LIVE IN RELUCTANT STATES OR WHO CAN'T AFFORD THE OUT-OF-POCKET EXPENSES ARE EXCLUDED FROM STATE PROGRAMS & THE PROVEN BENEFITS OF CANNABIS MEDICINES.

9 MILLION VETERANS DEPEND ON VHA FOR HEALTHCARE



1.2 MILLION VETERANS LIVE IN POVERTY

VA HEALTH CARE PROVIDERS ARE PROHIBITED FROM RECOMMENDING, MAKING REFERRALS TO, COMPLETING FORMS, OR REGISTERING VETERANS FOR PARTICIPATION IN A STATE-APPROVED MARIJUANA PROGRAM.

AUTHORITY: 38 U.S.C. § 7301(B).





HEALTH

1 in 5 Older Adults Uses Cannabis

AARP-supported research shows many people 50-plus try THC to aid health

MEDICARE DOES NOT COVER THE COST OF CANNABIS SPECIALISTS, STATE PROGRAM ENROLLMENT, OR CANNABIS MEDICINES, KEEPING THEM OUT OF REACH FOR MILLIONS.



**8.2 MILLION
OLDER ADULTS
LIVE IN POVERTY**



**67 MILLION
AMERICANS
DEPEND ON MEDICARE
FOR THEIR HEALTHCARE**

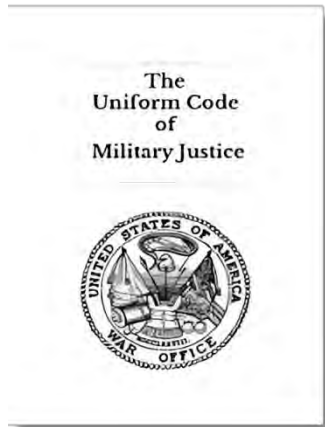


FEDERAL EMPLOYEES & ACTIVE MILITARY ARE BARRED FROM PARTICIPATING IN STATE PROGRAMS.



Federal employees and contractors, regardless of their state of residence, are prohibited from using cannabis and are subject to random drug testing.

Active-duty military members are prohibited from using cannabis & cannabinoid products under Article 112a of the Uniform Code of Military Justice (UCMJ), which forbids:



“the knowing use, possession, or distribution of marijuana and marijuana-derived products, including CBD. This prohibition applies at all times and in all locations. Violations are punishable under Article 92 of the UCMJ.”



MEDICAL CANNABIS PATIENTS' LIFE CHOICES ARE RESTRICTED BY FEDERAL CANNABIS LAWS



FEDERAL CANNABIS LAWS RESTRICT THE GEOGRAPHICAL MOBILITY OF PATIENTS. STATE LAWS IMPACT THEIR ABILITY TO RELOCATE FOR WORK, PURSUE HIGHER EDUCATION, AND TRAVEL TO ATTEND LIFE EVENTS SUCH AS WEDDINGS, FUNERALS, AND GRADUATIONS.

MEDICAL CANNABIS IS PROHIBITED IN HOSPITALS, ASSISTED LIVING FACILITIES, & HOSPICES.

1.72 MILLION
AMERICANS ENROLL IN
HOSPICE EVERY YEAR



2.2 MILLION
AMERICANS LIVE
IN LONG-TERM CARE



PATIENTS ARE PROHIBITED FROM USING MEDICAL CANNABIS IN FEDERALLY SUBSIDIZED HOUSING.

The U.S. Department of Housing and Urban Development (HUD) maintains policies, such as the Quality Housing and Work Responsibility Act of 1998, that prohibit federally subsidized housing tenants from possessing or using cannabis, even if they are doing so in compliance with state and local laws.

10 MILLION AMERICANS LIVE IN FEDERALLY SUBSIDIZED HOUSING

25% ARE DISABLED

STATES GRAPPLING WITH “INTOXICATING” HEMP



EMERGENCY REGULATIONS:
CALIFORNIA [DPH-24-005E](#)

LEGISLATION:
CONNECTICUT ([HB 5150](#))
WYOMING ([SF 32](#))
MINNESOTA ([HB 4757](#))
SOUTH DAKOTA ([HB 1125](#))
WEST VIRGINIA ([SB 679](#))
LOUISIANA ([HB 952](#))
NEW JERSEY ([S 3235](#))

WHITE PAPER

The Great Hemp Hoax:

Much of what's sold as "hemp" today isn't hemp at all — it's a mix of synthetic intoxicants and illicit THC masquerading as a legal, natural product.

| Compound | Scientific Name | Delta-9 THC Equivalency (multiple) |
|--------------|--|------------------------------------|
| Delta-9 THCP | <i>Trans-delta-9-tetrahydrocannabiphorol</i> | 30.00 ⁴³ |
| Delta-8 THCP | <i>Trans-delta-8-tetrahydrocannabiphorol</i> | 20.10 ⁴⁴ |
| Delta-9 THCO | <i>Delta-9-THC-O-acetate</i> | 3.00 ⁴⁵ |
| Delta-8 THCO | <i>Delta-9-THC-O-acetate</i> | 2.01 ⁴⁶ |
| HHCO Acetate | <i>Hexahydrocannabinol-O-acetate</i> | 1.50 ⁴⁷ |
| HHC | <i>Hexahydrocannabinol</i> | 1.00 ⁴⁸ |
| THCA | <i>Tetrahydrocannabinolic acid</i> | 0.877 ^{49,50} |
| Delta-8 THC | <i>Delta-8-Tetrahydrocannabinol</i> | 0.67 ⁵¹ |
| CBN | <i>Cannabinol</i> | 0.25 ⁵² |



17 states pass 21
Hemp-related bills



13 states pass 15
Hemp-related bills



29 states pass 40
Hemp-related bills



STATES ARE MERGING ADULT USE & MEDICAL CANNABIS PROGRAMS TO THE DETRIMENT OF PATIENTS



PROVIDERS MOVE TO SERVE ADULT-USE CONSUMERS.

Suppositories, sublinguals, high-CBD/low THC, 50/50 CBD/THC, & other cannabinoid profiles disappear.



DISCRIMINATION & STIGMA

Adult-use laws don't include civil protections.



AGE-GATING

Excludes 18-21-year-old & pediatric patients.



LIMITED ACCESS

Cities frequently ban adult-use retail. Quantity restrictions don't accommodate patient needs.

PATIENT GUIDANCE

Patients need access to experts to help guide them toward the right products & dosing guidelines.



GEO-FENCED PROGRAMS PERPETUATE STAKEHOLDER GAPS



RESEARCH



MEDICAL
PROFESSIONAL
EDUCATION



PATIENT NEEDS
& EXPERIENCES



PRODUCT
DEVELOPMENT

RESCHEDULING OF CANNABIS

SCHEDULE II or III will have little to no impact on the current US cannabis market...

but is a **game changer** for patients & advocates working to close the gap between **politics & medicine**; allowing the federal policy focus to evolve from proving “if cannabis has medical value” to “how can patients access cannabis.”

CONGRESS WILL HAVE TO ACT FOR PATIENTS TO BENEFIT FROM THE CHANGE IN CANNABIS CLASSIFICATION.



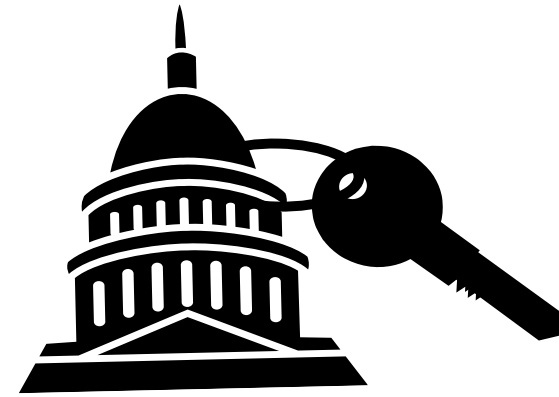


ALL STAKEHOLDERS AGREE, IT IS TIME FOR CONGRESS TO ACT!

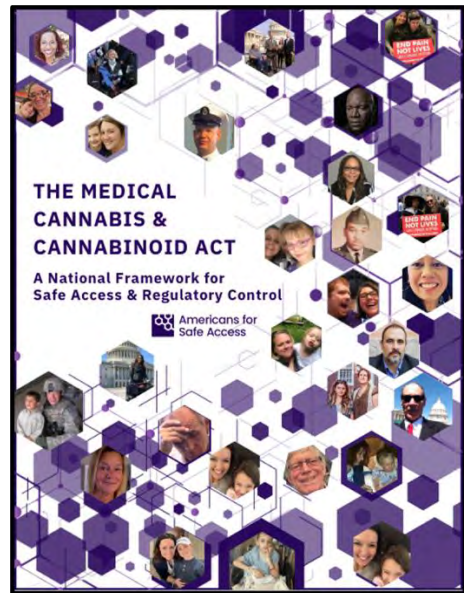




THE SOLUTION:



A NATIONAL MEDICAL CANNABIS PROGRAM



ESTABLISH-

**THE OFFICE OF MEDICAL CANNABIS
& CANNABINOID CONTROL (OMC)**

CREATE-

SCHEDULE VI (UNDER OMC OVERSIGHT)

THE MEDICAL CANNABIS & CANNABINOID ACT



THE MEDICAL CANNABIS & CANNABINOID ACT



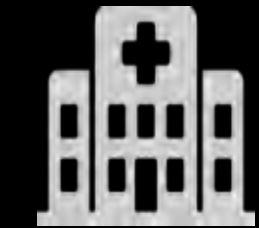
TRANSITION FROM
COMPASSIONATE USE TO
HEALTHCARE INTEGRATION

HEALTH CLAIMS
& DOSAGE

PRODUCT
PROTOCOLS

STANDARDIZE
TERMINOLOGY

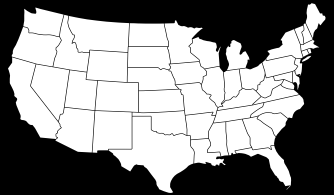
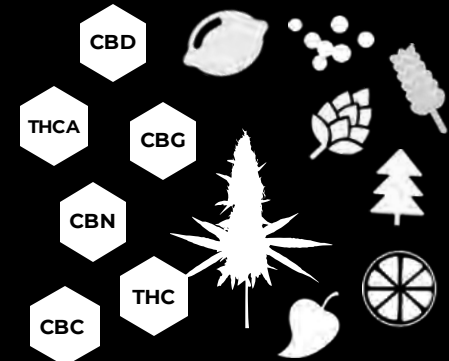
RESEARCH
TOOLS



A



B



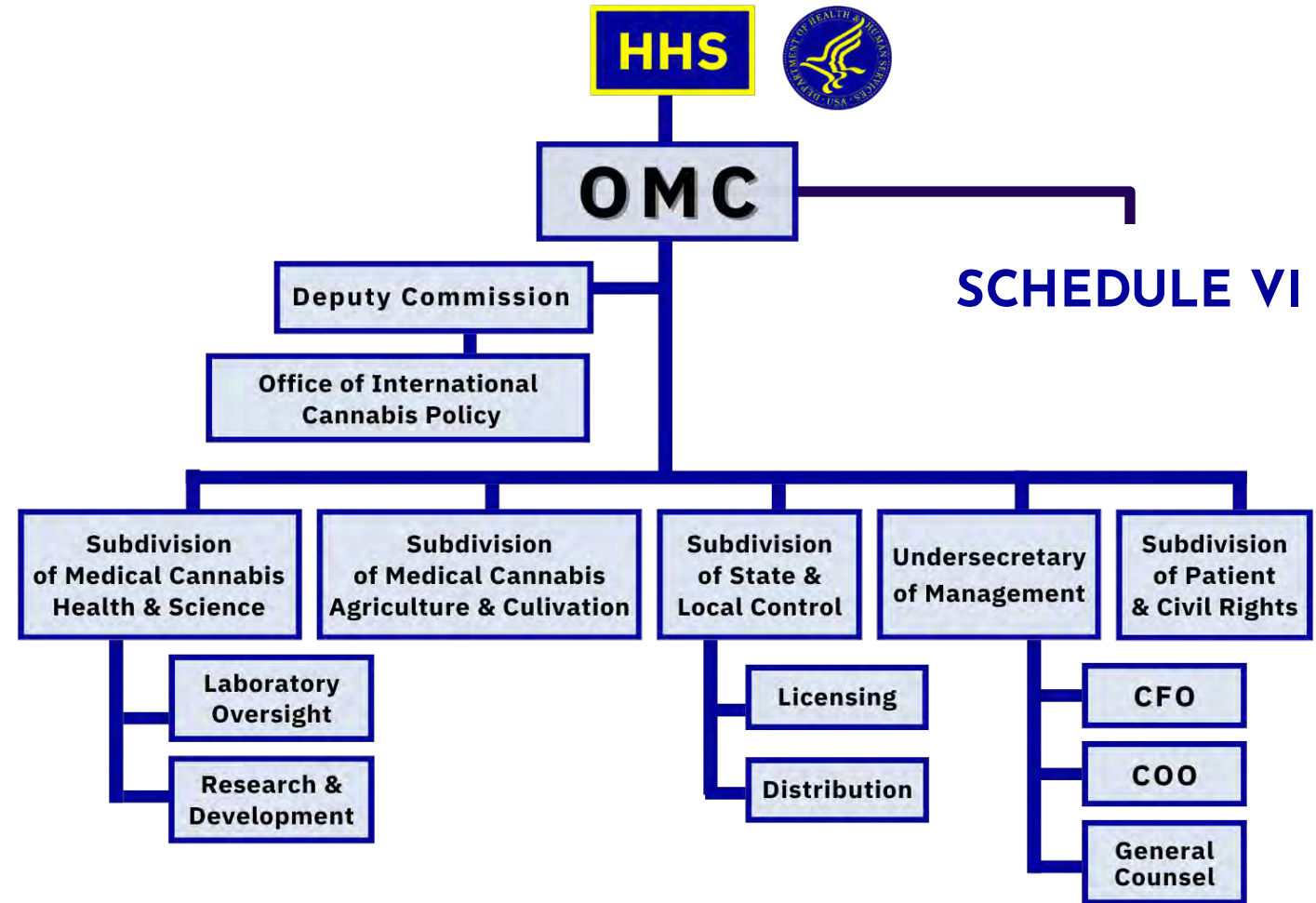
The Office of Medical Cannabis & Cannabinoid Control's mission is to facilitate access to medical cannabis for therapeutic use & research, regulate the production of medical cannabis & cannabinoid products, & oversee the new Schedule VI.

Housed in HHS

Brings US in compliance with UN Drug Treaties

Coordinates cannabis matters across federal agencies & with state regulators

Funded by agency reorganization, licensing & permitting fees, & public-private partnerships



SCHEDULE VI (& SCHEDULE VI-A)



- ❑ Regulated by OMC.
- ❑ Covers ALL cannabinoid products intended for human and animal consumption.
- ❑ Includes oversight for non-intoxicating cannabinoid products (Schedule VI-A).



- ❑ Laboratory, pharmacy, research and transportation permitting and cultivation, manufacturing, and distribution licensing (no restrictions for prior drug convictions for permits or licenses).



- ❑ Schedule VI permits granted to state licensed medical cultivators and manufacturers in Phase 1 for continuity of access.



- ❑ Schedule VI specialty pharmacy licenses for access points/dispensaries.
- ❑ Interstate commerce allowed between VI permitted/licensed businesses.
- ❑ No criminal penalties associated with Schedule VI.



- ❑ Patients would have all protections granted to any other prescription recipient.
- ❑ OMC will create policy to transform state-based “physician recommendations” to specialized prescriptions.



Congressional
Research Service

Informing the legislative debate since 1914

INSIGHT

Department of Health and Human Services Recommendation to Reschedule Marijuana: Implications for Federal Policy

Septemb

“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.”

Department of Health and Human Services
Recommendation to Reschedule Marijuana: Implications
for Federal Policy” -September 13, 2023, CRS Report



Congressional
Research Service

Informing the legislative debate since 1914

Legal Sidebar

Legal Consequences of Rescheduling Marijuana

Upd

“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”.
January 16th, 2024 (updated May 1, 2024), CRS report



ASA

NATIONAL CANNABIS PROGRAM ROLE OUT

FIRST 60 DAYS

- New Schedule Created: Schedule VI
- Office of Cannabis & Cannabinoid Control (OMC) established
- Commissioner & Under Secretary of OMC Appointed
- Direct agencies to update cannabis policies
- Provisional Schedule, VI & specialty pharmacy permits, issued with protocols for interstate distribution



Title I- Office of Medical Cannabis & Cannabinoid Control
Sec. 801: Amend Controlled Substance Act
Sec. 802- Amend Hemp Authorization Act.

Sec. 602- Notification to Agencies
Title VII- Implementation
Sec. 604- Continuity of care
Sec. 603- Reorganization Plan
Sec. 705- Advisory Committee



HOUSING & URBAN DEVELOPMENT- Exempt the medical use of cannabis from drug-free housing policies & tax credits.



VETERAN AFFAIRS-Update policies to allow agency physicians to recommend medical cannabis, amend policies that impact VA benefits, & add cannabis therapeutics to intake forms.



OFFICE OF PERSONAL MANAGEMENT- Update hiring and employment policies concerning past or current cannabis use & create process for agencies to reinstate or appeal past actions.



DEPARTMENT OF JUSTICE- Review & formalize guidelines in 2013 DOJ Cole Memo & expunge all non-violent federal cannabis convictions & adjudications for & any arrests associated with each.



TRANSPORTATION SECURITY ADMINISTRATION-Cannabis does not need to be confiscated



BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES- Remove cannabis warning from Form 4473



INTERNAL REVENUE SERVICE- Permit medical cannabis businesses with Schedule VI permits/licenses to file as legal business & create process for these business to refile tax returns with deductions to lower or eliminate tax debt.



HEALTH & HUMAN SERVICES- Inform hospitals, health clinics, rehabilitation centers, hospice services providers, their medical professionals, or any other patient service provider that participating in medical cannabis programs or allowing clients/patients in their care to lawfully possess and/or consume cannabis products in their care will not jeopardize HHS funding or any accreditations.



DEPARTMENT OF THE TREASURY- Provide guidance for financial institutions on providing banking services, loans, & any other financial services to Schedule VI licensed businesses.



THE STATE DEPARTMENT -Work visa eligibility includes employment with any business with a Schedule VI permit/license.



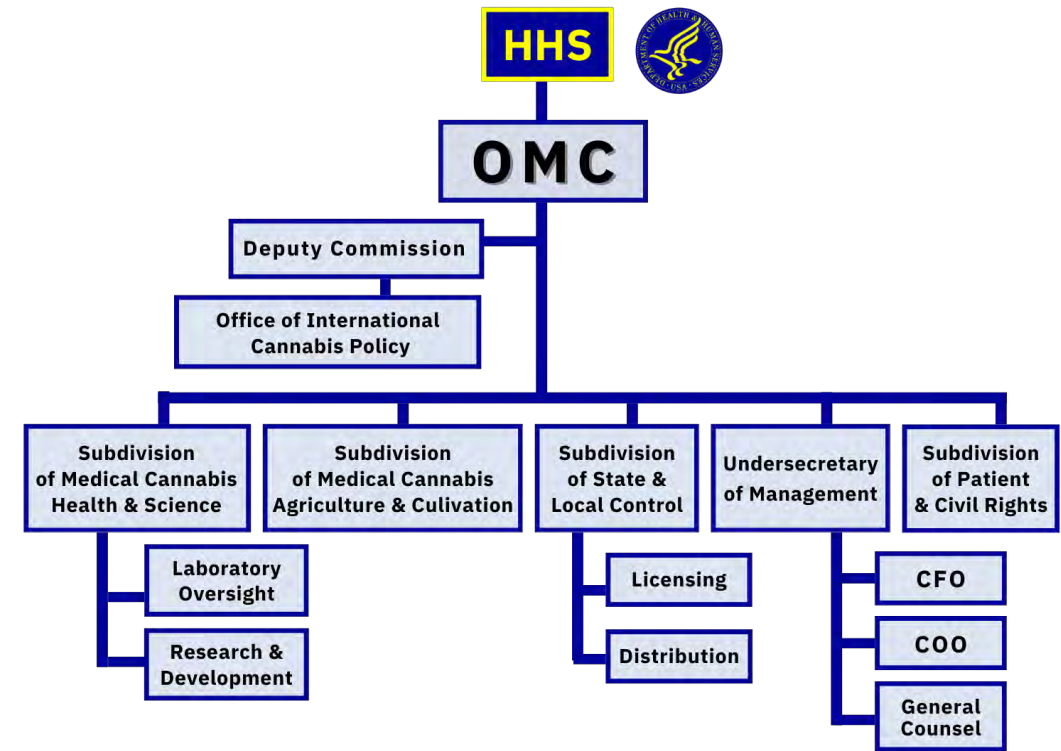
FOOD & DRUG ADMINISTRATION- Issue requirements for products containing cannabinoids to include 1) source of the cannabinoid 2) "The safety of this product has not been evaluated by the FDA" 3) "This product has not been tested for contaminants" or a QR code to Certificate of Analysis & 4) Batch number on labels.

ALL FEDERAL AGENCIES- Cannabis is no longer a factor for federal employees, contractors or officers.

NATIONAL CANNABIS PROGRAM ROLE OUT

FIRST 12 MONTHS

- Agency Staffed
- Schedule VI licensing program launched
- Advisory groups seated
- Initiate research priority map with NIH
- OTC guidelines for cannabinoid products
- Determination of NDA requirements for synthetic cannabinoid & terpene products
- Establish safe additive list for Schedule VI products
- Labeling, research, & testing requirements for Schedule VI products established



**Title I, Title II, Title III, Title IV, Sec. 404,
Sec. 501, & Sec. 504-Staffing Subdivisions**

**Sec. 303- Transfer Of Functions
Sec. 701- Licensing and Permits; General Provisions
Sec. 305- Cannabis Production; State & Tribal Plans
Sec. 306- Effect on Industrial Hemp
Sec. 701- Licensing & Permits; General Provisions
Sec. 702- Specialty Licensing**

NATIONAL CANNABIS PROGRAM ROLE OUT

Sec. 701- Licensing & Permits

Title VI- Transition Subtitle A- Coordination with Agencies

Sec. 306- Effect on Industrial Hemp

Sec. 701- (d) Imports, Exports

Sec. 204- Research & Development Center

Sec. 704- Prescription Protocols






FIRST 24 MONTHS

- Guidance for “prescription system” & importation/exportation of Schedule VI ingredients & products issued
- Guidance to Centers for Medicare & Medicaid Services for Schedule VI product coverage
- OMC establishes private-public partnerships for research with NIH
- Each federal DOJ district completes comprehensive review & expungement of all adjudicated & non-adjudicated cannabis cases
- Initiate process for producing guidance document for health claims for Schedule VI products issued
- Guidance for environmental impact & sustainable agricultural practices



NATIONAL MEDICAL CANNABIS PROGRAM

PHASE I

-  = FINISHED PRODUCTS
-  = RAW INGREDIENTS
-  = PERMITTED BY STATE
-  = SCHEDULE VI PROVISIONAL PERMIT
-  = STATE/TRIBAL LICENSE

 REQUIRE 
(except B2B Transport)



CULTIVATION



PROCESSORS



MANUFACTURERS



TESTING LABS



B2B TRANSPORT



RESEARCHERS

 
HOME CULTIVATION

STATE-ID CARDS
REMAIN VALID





DISPENSARY



HOSPITAL/HOSPICE
ASSISTED LIVING



Schedule VI products with permits can move across US between permitted businesses

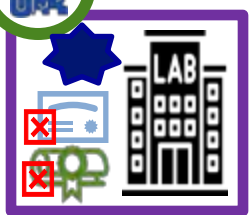
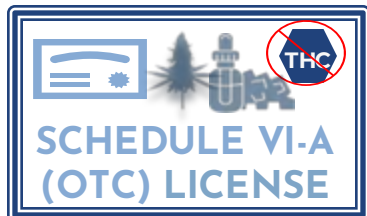


CBD & Hemp derived products will remain available in retail markets as they transition into regulated market.

NATIONAL MEDICAL CANNABIS PROGRAM

PHASE II

SCHEDULE VI LICENSES & PERMITS



HOSPITAL/HOSPICE ASSISTED LIVING

PHARMACY

DISPENSARY-SPECIALTY PHARMACY



STATE ID CARDS REMAIN IN EFFECT



HOME CULTIVATION

RETAIL OUTLETS



Schedule VI-A
License is not required for retailers, but selling unregulated Schedule VI products carries fines.

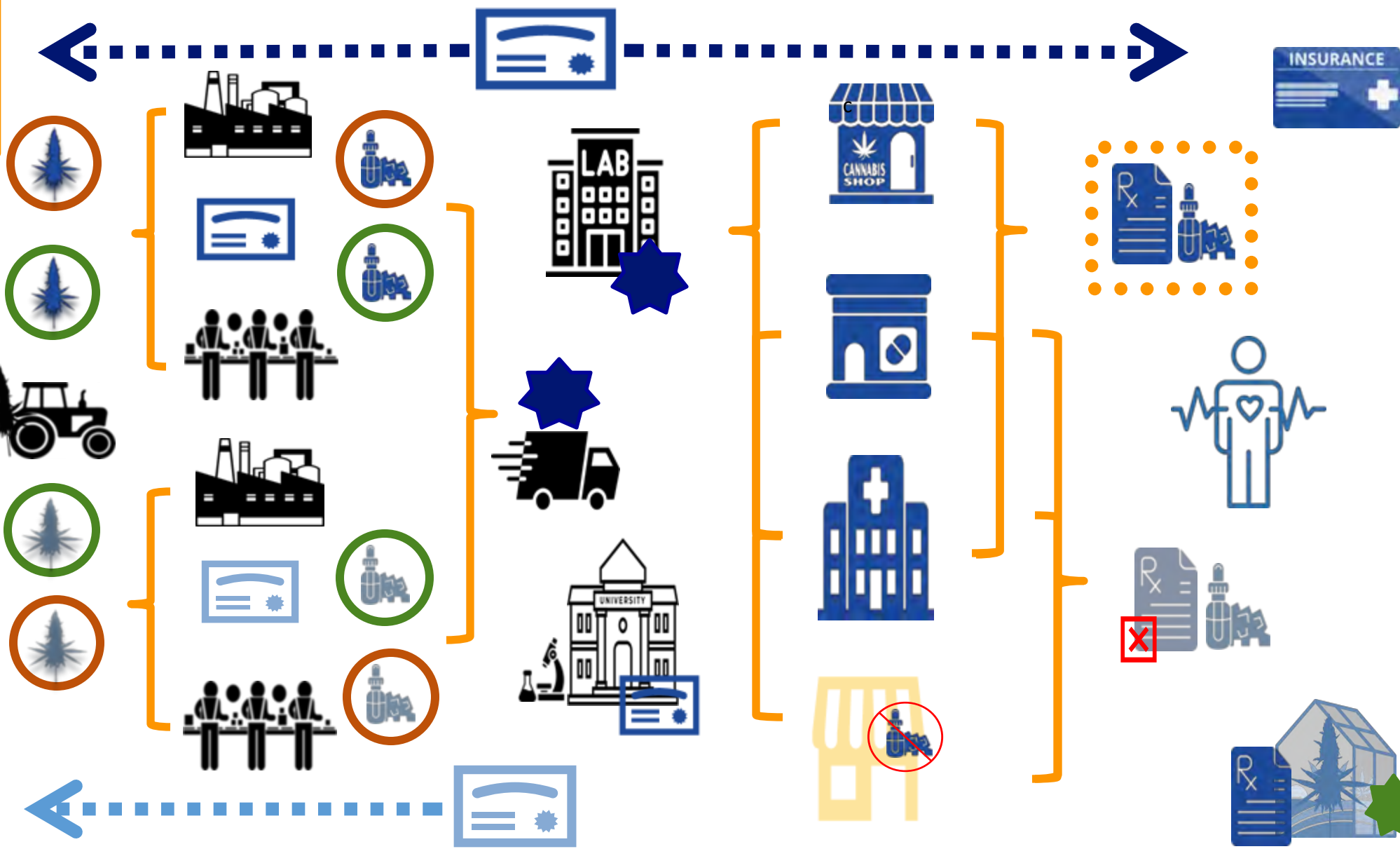
NATIONAL MEDICAL CANNABIS PROGRAM PHASE III

IMPORT/EXPORT

PROOF OF ORIGIN

OMC

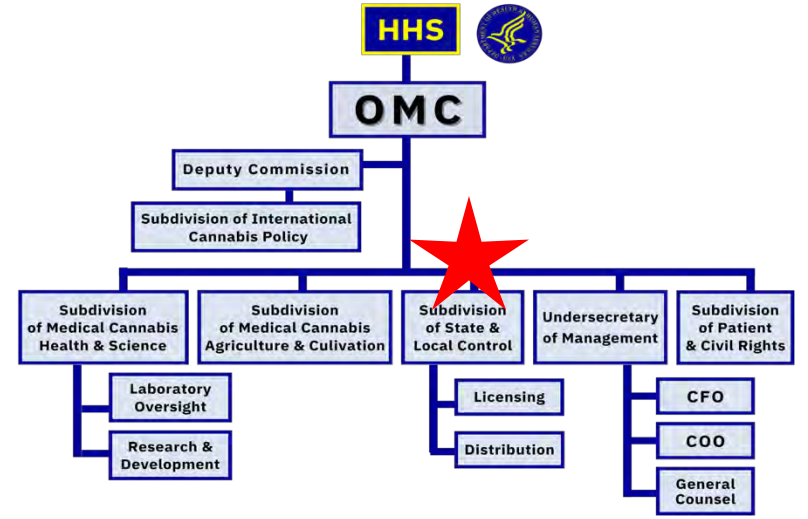
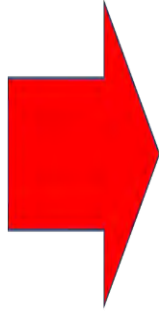
USA



OMC STRUCTURE & AGENCY TRANSITION

SEC. 501- SUBDIVISION OF TRIBAL, STATE, & LOCAL CONTROL

- Sec. 603- Reorganization Plan
- TITLE VII- Implementation
- Sec. 305- Cannabis Production; State & Tribal Plans
- Sec. 705– Advisory Committee

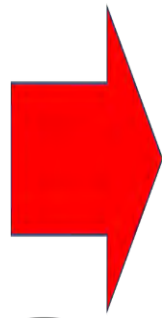


- Work with state regulators on Schedule VI Permits for state licensed medical cannabis businesses
- Create protocols for interstate sales & transportation
- Create vendor/licensee database

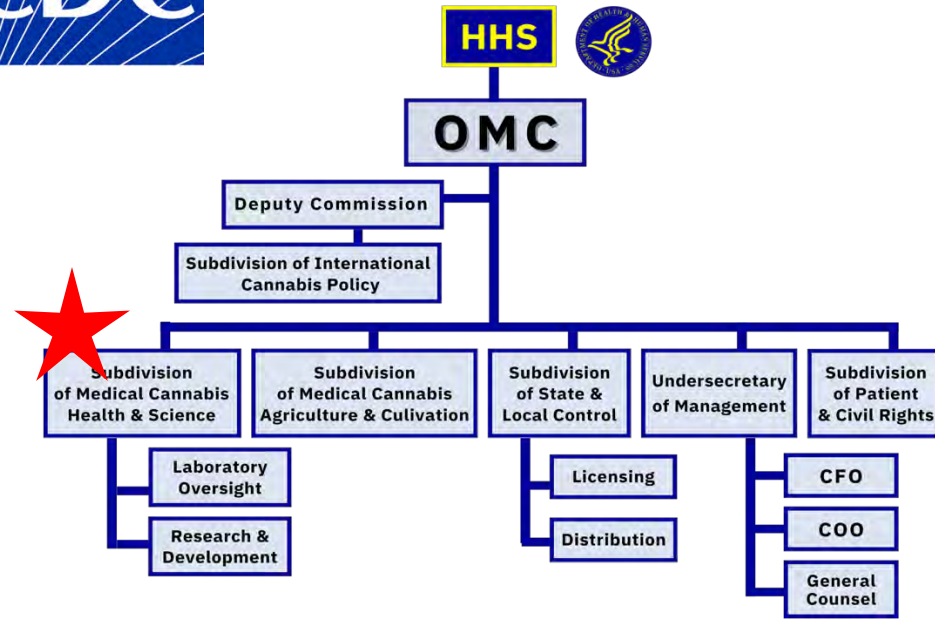
TITLE II- SUBDIVISION OF MEDICAL CANNABIS HEALTH & SCIENCE

OMC STRUCTURE & AGENCY TRANSITION

- Sec. 201-206
- Sec. 603- Reorganization Plan
- Title VII- Implementation
- Sec. 704– Prescription Protocols
- Sec. 205- Research, Testing, & Evaluation
- Sec. 705– Advisory Committee



- Work across agencies to create & fund research priority map
- Spearhead guidelines for standardization of testing & labeling
- Issue permits to laboratories for cannabis (schedule VI)
- Create prescription protocols & educate physicians



OMC STRUCTURE & AGENCY TRANSITION

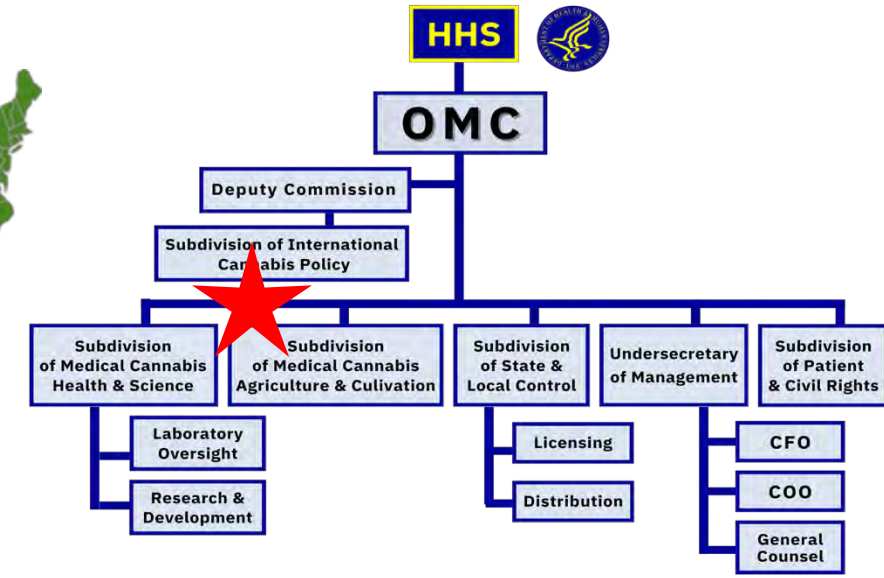
Sec. 301-306

Sec. 603- Reorganization Plan

TITLE VII- Implementation

Sec. 305- Cannabis Production; State & Tribal Plans

TITLE III- SUBDIVISION OF MEDICAL CANNABIS CULTIVATION & AGRICULTURE

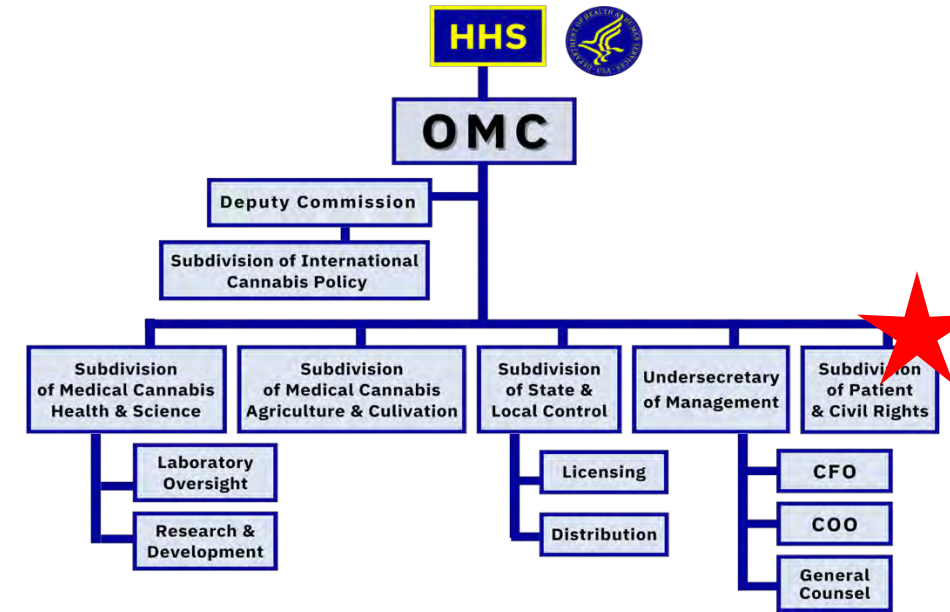


- Work across agencies to create seed registry
- Pesticides guidance for cannabis for human consumption
- Train inspectors
- Create research & marketing orders

OMC STRUCTURE & AGENCY TRANSITION

Sec. 603- Reorganization Plan
Title VII- Implementation

SEC. 404- SUBDIVISION OF PATIENT & CIVIL RIGHTS



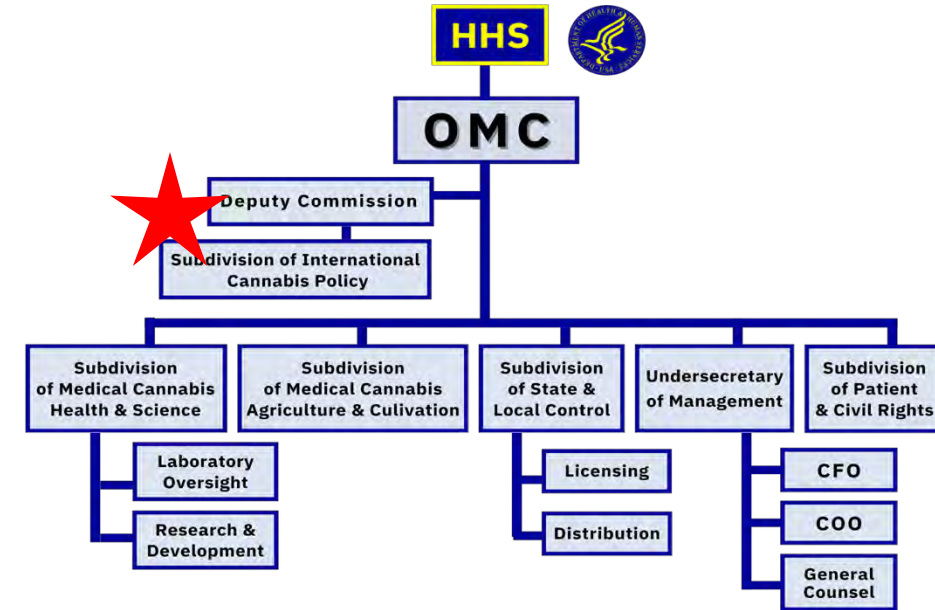
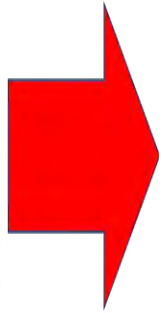
- Review & monitor the implementation to ensure patient rights are protected
- Work across agencies to ensure that patient rights are included in their policies
- Work with CMS to ensure cannabis medications are covered



SEC. 504-OFFICE OF INTERNATIONAL POLICY

OMC STRUCTURE & AGENCY TRANSITION

Sec. 603- Reorganization Plan
 TITLE VII- Implementation
 Sec. 701- (d) Imports, Exports



- OMC designated agency for Cannabis under UN single treaty
- Report to INCB on cannabis
- Establish & oversee cannabis/cannabinoid import/export procedures

WHY SCHEDULE VI?

Cannabis was placed in Schedule I as a political decision in 1970, not based on scientific evidence. Creating Schedule VI will correct this historical wrong, allowing cannabis to be classified based on its actual medicinal value and safety profile.

Cannabis is a complex botanical medicine with multiple active compounds that interact with the body in unique ways. A new Schedule VI will recognize its distinct nature, allowing for appropriate regulation that doesn't force it into an ill-fitting category designed for synthetic and single-compound drugs.

Creating Schedule VI acknowledges that cannabis is not just another drug—it's a botanical medicine with a unique profile. By placing cannabis in its own category, Schedule VI would allow for regulations tailored to its specific properties and uses.

**WHY
SCHEDULE
VI
?**

| CANNABIS FEDERAL CLASSIFICATION | SCHEDULE I | SCHEDULE III | DE SCHEDULE | SCHEDULE VI |
|--|-------------------|---------------------|--------------------|--------------------|
| Recognizes Medical Use of Cannabis | | ✓ | | ✓ |
| Regulates Cannabinoid & "Hemp Product" Market | | | | ✓ |
| Harmonizes State & Federal Medical Cannabis Laws | | | | ✓ |
| Removes Criminal Penalties for Cannabis Possession | | | ✓ | ✓ |
| Removes Criminal Penalties for Cannabis Cultivation & Distribution | | | ✓ | ✓ |
| Increases & Improves Patient Access | | | | ✓ |
| Ensures Employment Protections | | | | ✓ |
| Ensures Housing Protections | | | | ✓ |
| Ensures Healthcare Rights | | | | ✓ |
| Improves Access to Cannabis for Research | | ✓ | ✓ | ✓ |
| Improves Quality of Cannabis Research | | | | ✓ |
| Levels the Playing field for Research, Development, & Innovation | | | | ✓ |
| Ensures Product Safety Across the Supply Chain | | | | ✓ |
| Expands U.S. Definition of Medicine | | | | ✓ |

ENDORSORING ORGANIZATIONS:

Americans for Safe Access

VETERANS INITIATIVE 22

U.S. PAIN FOUNDATION

SAFE ACCESS Tennessee

NATIONAL Clinical Director CONSORTIUM

A NEW PATH
Parents for Addiction Treatment & Healing

Bay Area
ASA CHAPTER OF THE YEAR 2021

THE HOPE GROWS FOUNDATION

ASA
SAN DIEGO

CNOC
CANNABIS NURSES OF COLOR

Coalition for Medical Marijuana New Jersey

ISCPH
International Society of Cannabis Pharmacists

TX
Texans For Safe Access

LEAF 411™

PARTNER ORGANIZATIONS:

REALM OF CARING

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

INCBA
International Cannabis Bar Association

ACR
ASIAN CANNABIS ROUNDTABLE

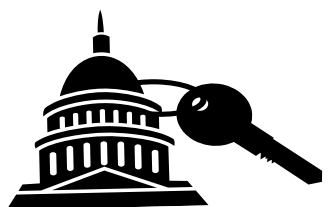
MCBA
MINORITY CANNABIS BUSINESS ASSOCIATION

MASSACHUSETTS PATIENT ADVOCACY ALLIANCE

SC
Compassionate CARE ALLIANCE

SOCIETY OF CANNABIS CLINICIANS

ACNA
American Cannabis Nurses Association

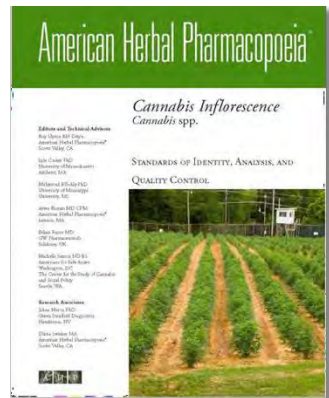


20+ YEARS PATIENTS WORK TOWARD

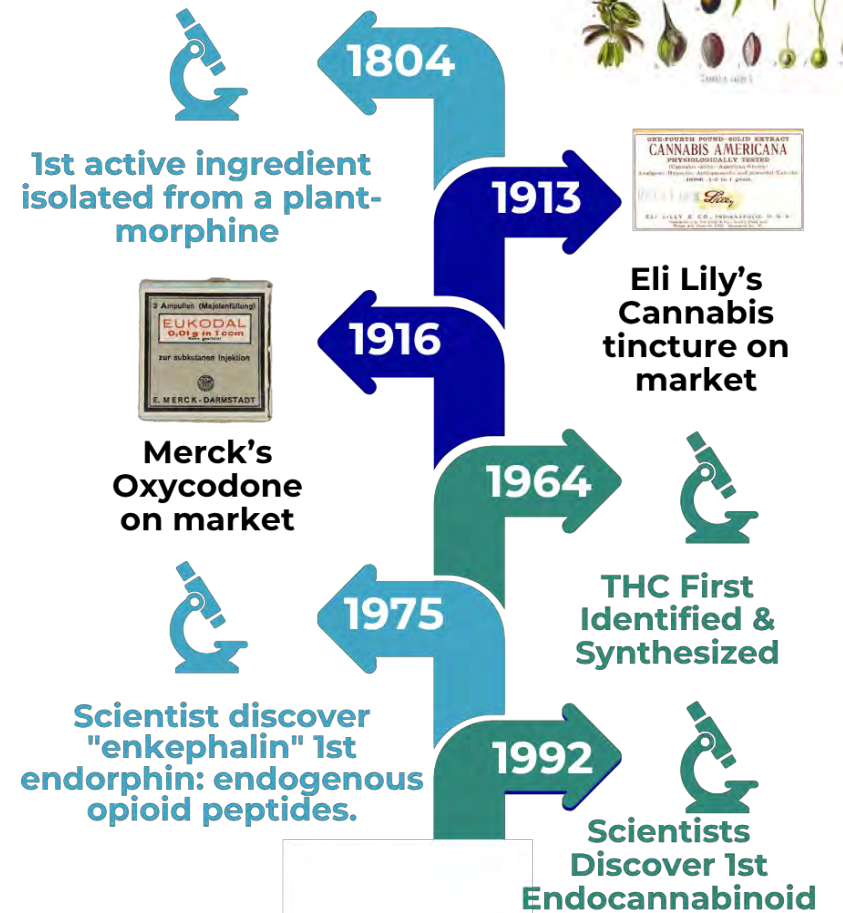
A NATIONAL MEDICAL CANNABIS PROGRAM

THE HISTORY OF CANNABIS MEDICINES IN THE UNITED STATES

Cannabis Cannabis was removed from the U.S. Pharmacopoeia in 1942 along with over 200 other natural compounds like St. John's wort and Echinacea. Medicinal herbal products, such as St. John's Wort and Echinacea, were not included in the U.S. Pharmacopoeia until 2004.



In 2013, the American Herbal Pharmacopoeia published the first cannabis monograph, "Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control," to provide scientifically valid methods for cannabis and its preparations.



THE HISTORY OF STATE-BASED MEDICAL CANNABIS EXPERIMENT

Controlled Substances Act passed-Cannabis classified "No Accepted Medical Use"

The IND Compassionate Use Program Supplies Patients with Cannabis

California Passes Prop 215- "The Compassionate Use Act"



1970

1975

1978

1992

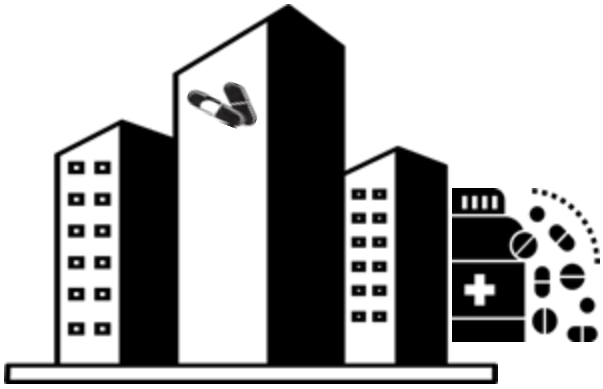
1996

D.C. Court Upholds Robert Randal's "Medical Necessity" Defense

Pres. Bush closed IND Compassionate Use Program

State Medical Cannabis Experiment Begins!

ONLY FDA APPROVED DRUGS ARE "MEDICINE" IN THE US



HEALTHCARE INFRASTRUCTURE



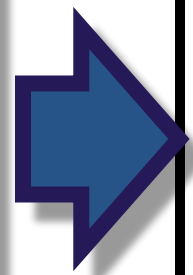
NO FDA PATHWAY FOR COMPLEX BOTANICAL MEDICINES



Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

January 2023
Pharmaceutical Quality/Chemistry, Manufacturing, and Controls (CMC)



Drug Master Files
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

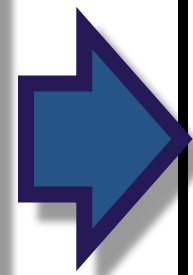
Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5670 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Rick Enser 240-402-2733, or (CDER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2019
Pharmaceutical Quality/CMC

Revision 1



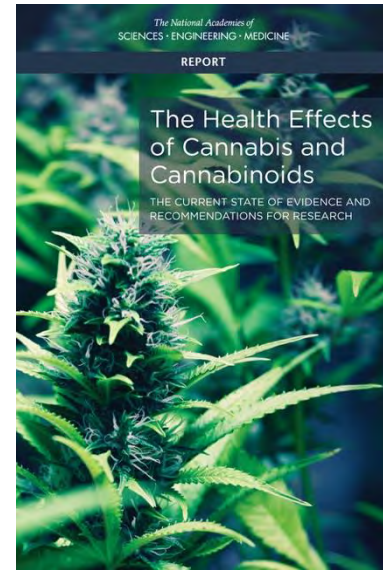
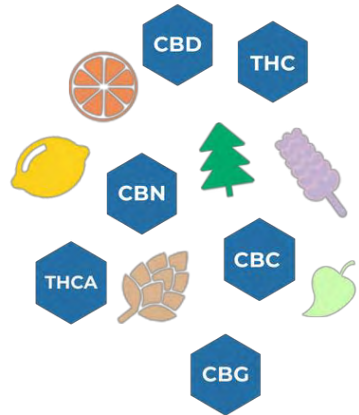
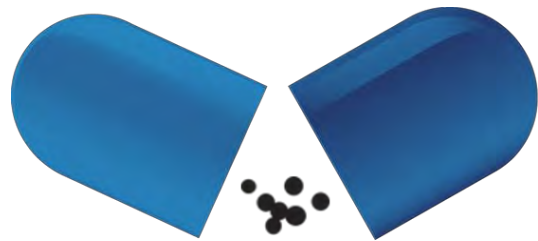
Botanical Drug Development
Guidance for Industry

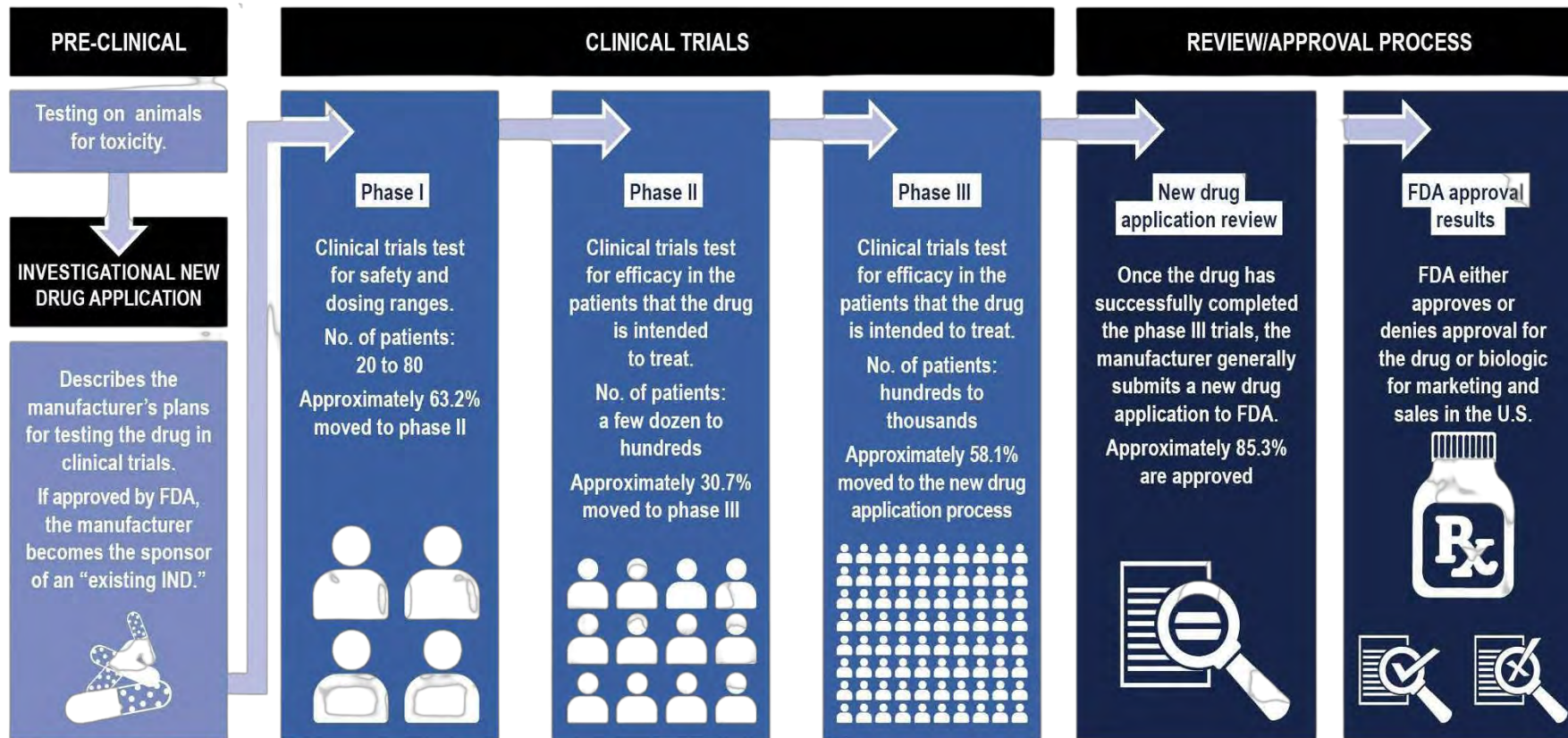
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

“The Agency recognizes the technical challenges in determining standard pharmacokinetic measurements of systemic exposure because a botanical drug product often consists of more than one chemical constituent and the active constituents may not be identified” page 14.

“The Agency recognizes that demonstrating each botanical raw material’s contribution to safety and efficacy in a product with multiple botanical raw materials may not always be feasible” page 22.

TRADITIONAL FUNDING SOURCES FOR THERAPEUTIC DISCOVERY





\$2.6 BILLION



Source: GAO analysis of FDA data and a 2016 collaborative study by Biotechnology Innovation Organization, Biomedtracker, and Amplion.^a | GAO-17-564

8-10 YEARS

EPIDIOLEX-purified form of CBD

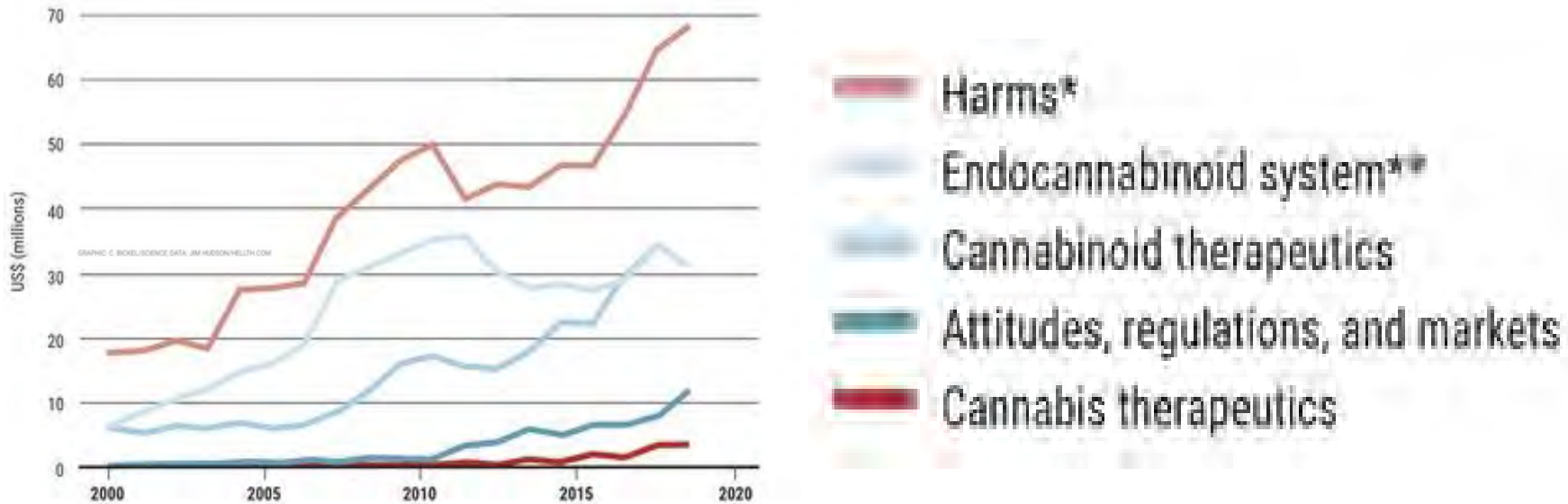
MARINOL & SYNDROS- dronabinol, synthetic THC

CESAMET-nabilone, synthetic structure similar to THC



A recent study found that 356 out of 358 drugs approved by the FDA from 2010 to 2019, NIH spent \$1.44 billion per approval on basic or applied research for products with novel targets (spending from the NIH was not less than industry spending).

Between 2000 and 2018, NIH spent a similar amount on cannabis research, \$1.47B, but instead of investing in research to unlock the therapeutic benefits, a majority of \$1.25B were spent on investigating the harms of cannabis consumption.



Source: Cannabis research database shows how U.S. funding focuses on harms of the drug. ScienceInsider Aug 2020

Galkina Cleary E, Jackson MJ, Zhou EW, Ledley FD. Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019. *JAMA Health Forum*. 2023;4(4):e230511. doi:10.1001/jamahealthforum.2023.0511

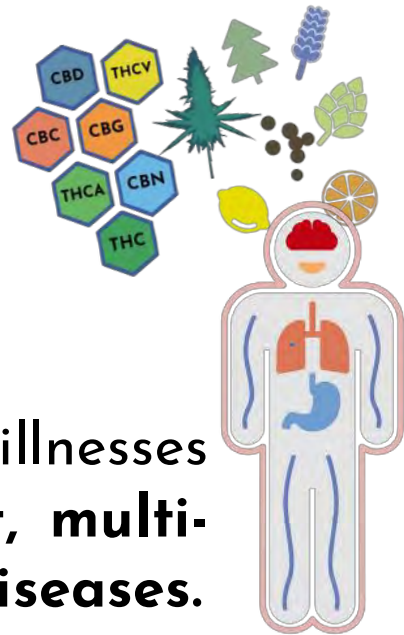
FDA APPROVED CANNABINOID DRUGS

WHY CANNABINOID-BASED PHARMACEUTICALS ARE LESS EFFECTIVE THAN WHOLE-PLANT MEDICINES

- **Marinol (dronabinol) (1985):** nausea from cancer chemotherapy; anorexia associated with AIDS -Schedule III
- **Cesamet (nabilone) (1985 (2006)):** nausea from cancer chemotherapy -Schedule II
- **Syndros (dronabinol) (2016):** nausea from cancer chemotherapy; anorexia associated with AIDS -Schedule II
- **Epidiolex (CBD) (2018):** for childhood seizures & Tuberous Sclerosis Complex - No longer controlled



This preference is attributed to the "entourage effect," wherein over 140 phytocannabinoids, terpenes, & flavonoids in cannabis work synergistically to provide comprehensive relief. Full-spectrum cannabis can simultaneously modulate multiple physiological targets and help to provide symptomatic relief to a diverse set of patients.

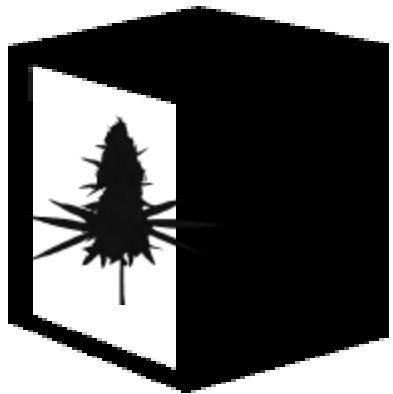


Disorders such as chronic pain, neurodegenerative conditions, and psychiatric illnesses frequently involve multiple overlapping pathways in the body. **Multi-target, multi-component approaches are essential for the treatment of these complex diseases.**

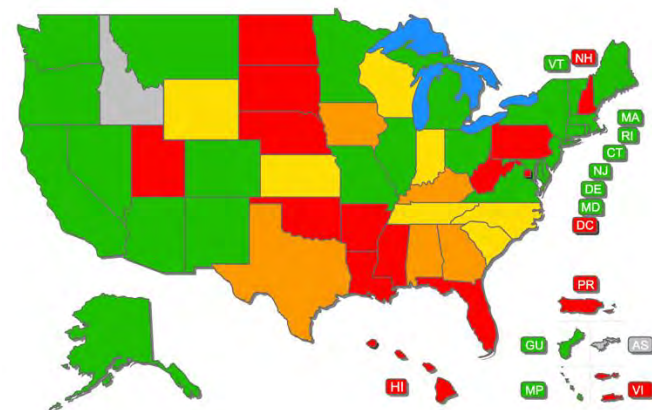
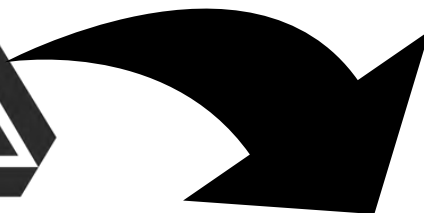
THE WORLDWIDE TREND OF USING BOTANICAL DRUGS & STRATEGIES FOR DEVELOPING GLOBAL DRUGS

“Botanical drugs are, by nature, plant-derived materials and their complexes. This makes them unfit for conventional “single-target/single-drug” development processes and thus have been largely disregarded in the field of medicine. However, it is widely understood in synthetic medicine that **the single-drug “magic bullet” strategy is not adequate for treating chronic illnesses (e.g. cancers, immune disorders, mental illnesses, cardiovascular diseases, lifestyle diseases)** due to their complex pathogenetic mechanisms and that a “multi-target/multi-component” approach involving control over a number of target sites is more effective.”

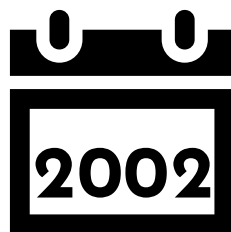
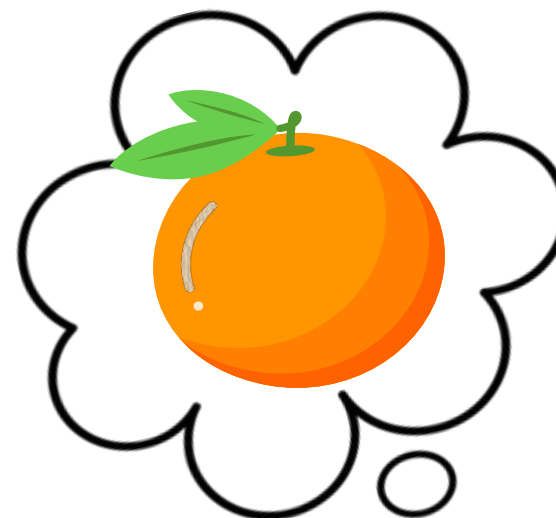
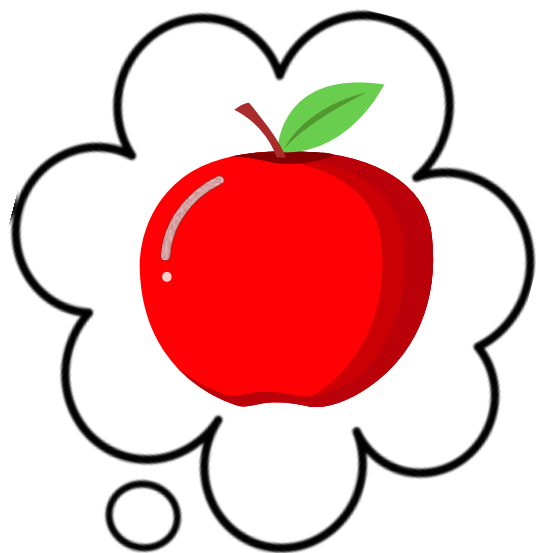
Ahn K. The worldwide trend of using botanical drugs and strategies for developing global drugs. BMB Rep. 2017 Mar;50(3):111-116. doi: 10.5483/bmbrep.2017.50.3.221. PMID: 27998396; PMCID: PMC5422022.



FDA

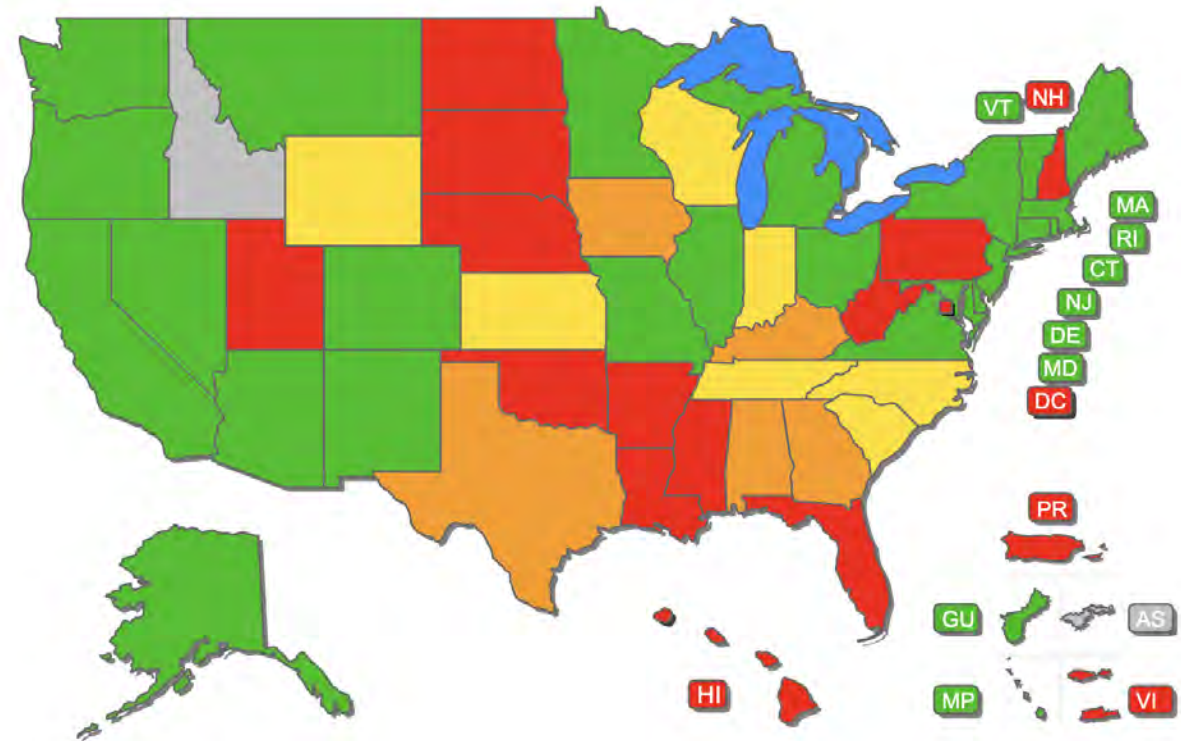


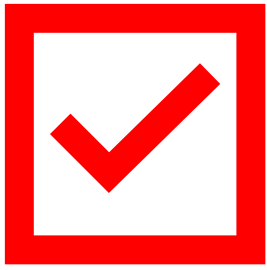
A RECENT HISTORY OF CANNABIS THERAPEUTICS





STATE-BASED COMPASSIONATE USE PROGRAMS ESTABLISH ACCEPTED MEDICAL USE





PRODUCT SAFETY PROTOCOLS CANNABIS & CANNABIS-DERIVED PRODUCTS



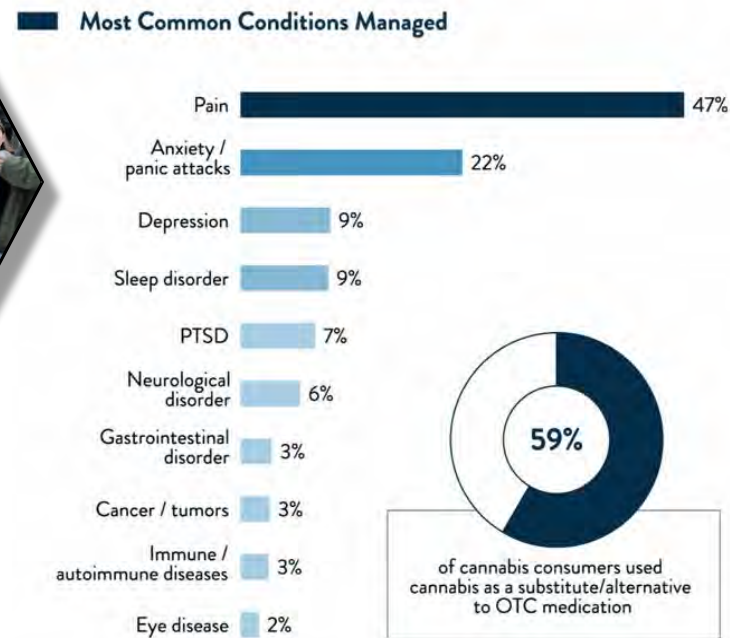


CANNABIS AS A SOLUTION- OPIOID EPIDEMIC

In 2016, CT, DC, FL, IL, NJ, and NY did NOT include pain as a qualifying condition (23 states total).



| Opioid Response ___/40 | |
|--|--|
| Is cannabis available for treatment? -/15 | |
| <ul style="list-style-type: none"> Does the state allow for chronic pain as a qualifying condition without restriction? Does the state allow cannabis to be issued instead of opioid prescriptions? Does the state allow for opioid use disorder? | |
| Doctor education on the interactions between cannabis and opioids -/7 | |
| <ul style="list-style-type: none"> Is doctor education on opioids available through the state department of health or state medical society? Is opioid-cannabis education part of the curriculum? | |
| Can pain patients use cannabis? -/3 | |
| <ul style="list-style-type: none"> Has the state acknowledged the 2016 CDC guidelines on not testing for THC? Has the state issued specific guidance about testing for THC and other cannabinoids in pain patients? | |
| Can pain patients access medical cannabis? -/5 | |
| <ul style="list-style-type: none"> Is there same-day access with a doctor's recommendation? Can patients use their medical cannabis in home health facilities, hospices, and treatment centers? | |
| Can the patient afford medical cannabis? -/5 | |
| <ul style="list-style-type: none"> Veteran discount? Low income discount? Is medicine affordable based on patient feedback? | |
| Research -/5 | |
| <ul style="list-style-type: none"> Are there sufficient research & development tax breaks for medical cannabis facilities? Does the state promote research? | |



END OF STATE DISCRIMINATION OF CANNABIS & PAIN- Pain qualifying

conditions in all States, & CDC urged pain clinics to stop drug testing for cannabis



THE BIDEN ADMINISTRATION'S REVIEW OF CANNABIS SCHEDULING



**INITIATED
OCTOBER 2022**

NOTICE OF PROPOSED RULEMAKING: SCHEDULES OF CONTROLLED SUBSTANCES: RESCHEDULING OF MARIJUANA

May 21, 2024



Office of Public Affairs
U.S. Department of Justice

PRESS RELEASE

Justice Department Submits Proposed Regulation to Reschedule Marijuana

Proposed Rule Seeks to Move Marijuana from Schedule I to Schedule III, Emphasizing its Currently Accepted Medical Use in Treatment in the United States

“The Department of Justice (“DOJ”) proposes to transfer marijuana from schedule I of the Controlled Substances Act (“CSA”) to schedule III of the CSA, consistent with the view of the Department of Health and Human Services (“HHS”) that marijuana has a currently accepted medical use”



ASA

**“CURRENTLY ACCEPTED MEDICAL USE
FOR TREATMENT IN THE UNITED STATES”
OF CANNABIS IS **NOT** POLITICAL**



Americans for
Safe Access

July 16, 2024

The Honorable Robert C. Lighthizer
Assistant Attorney General
U.S. Department of Justice
250 Pennsylvania Avenue NW
Washington, DC 20530

Re: Comments on Proposed Rule: Submission of Controlled Substances: Rescheduling of Marijuana, 21 CFR 1306.99 (R 4459)

Attorney General Counsel

"We intend to propose our comments with the Drug Enforcement Administration's (DEA) Proposed Rule: 'Submission of Controlled Substances: Rescheduling of Marijuana.'"

The Proposed Rule would establish marijuana from Schedule I of the Controlled Substances Act (CSA) to schedule II of the CSA. The rule fails to provide adequate scientific data to support moving marijuana to schedule II and should not have been issued or published.

The background section of the Proposed Rule begins by noting that 24 states and the District of Columbia have legalized the use of medical marijuana. This should be inclusive in the analysis conducted by the Department of Health and Human Services (HHS) and the Department of Justice (DOJ). Nothing in the CSA requires or suggests the FBI should consider a drug's popularity or legal status at the state level when determining a drug's schedule. It is clear that HHS and DOJ have the correct scientific data and worked backwards, when the rule does not provide sufficient science to move marijuana to schedule II.

It is clear that the DEA was not properly involved in the drafting of the Proposed Rule. DEA Administrator Wilson did not sign the rule and it does not state that DEA follows additional information is needed regarding the appropriate schedule for marijuana. The Proposed Rule references DEA's findings from 2016, which it copied verbatim to support its conclusion that schedule I is more than 20 years old by its findings from 2016, all the more reason why this rule should not have been published without input from the DEA Administrator.

The CSA sets the maximum of controlled substances that correspond with the maximum level placed on Schedule I drugs. Schedule I drugs have a high potential for abuse, no currently accepted medical use, and a lack of accepted safety under current supervision. Schedule II drugs have a potential for abuse that is less than schedule I and II, a currently accepted medical use, and a

THANK YOU

ON JULY 10, 2024, 25 GOP SENATORS & MEMBERS OF CONGRESS WROTE A SCATHING LETTER TO AG GARLAND IN PROTEST OF SCHEDULE III PROPOSED RULE FOR CANNABIS.

It is clear that this Proposed Rule was not properly researched, circumvented DEA, and is merely responding to the popularity of marijuana and not the actual science.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-1362]

RIN 1117-AB77

**Schedules of Controlled Substances:
Rescheduling of Marijuana**

AGENCY: Drug Enforcement
Administration, Department of Justice.

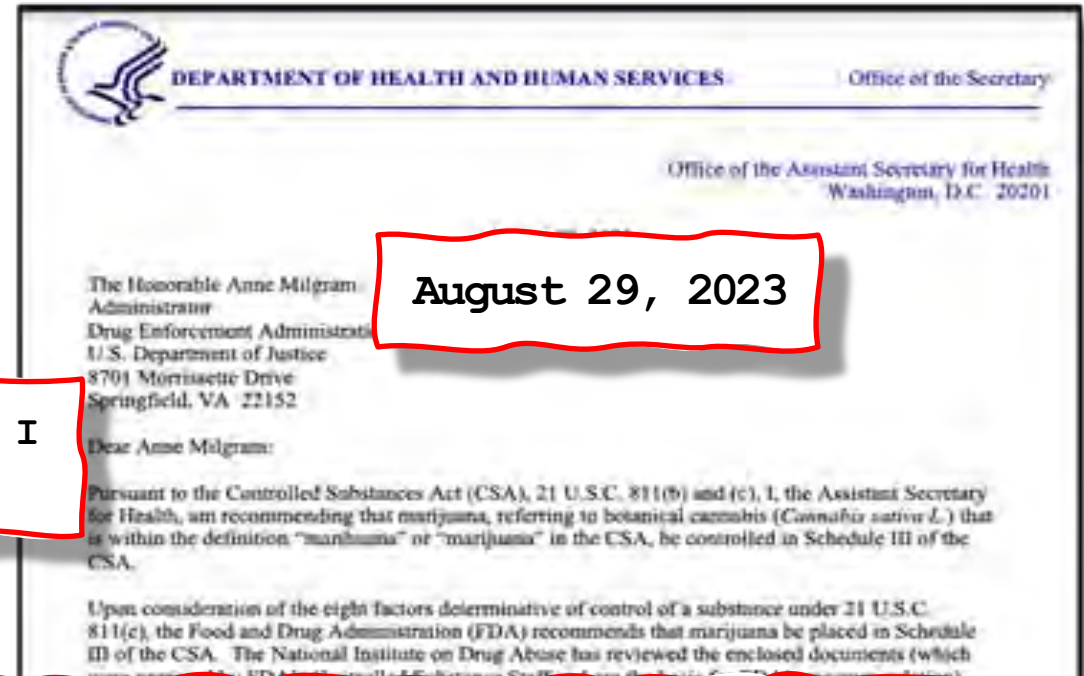
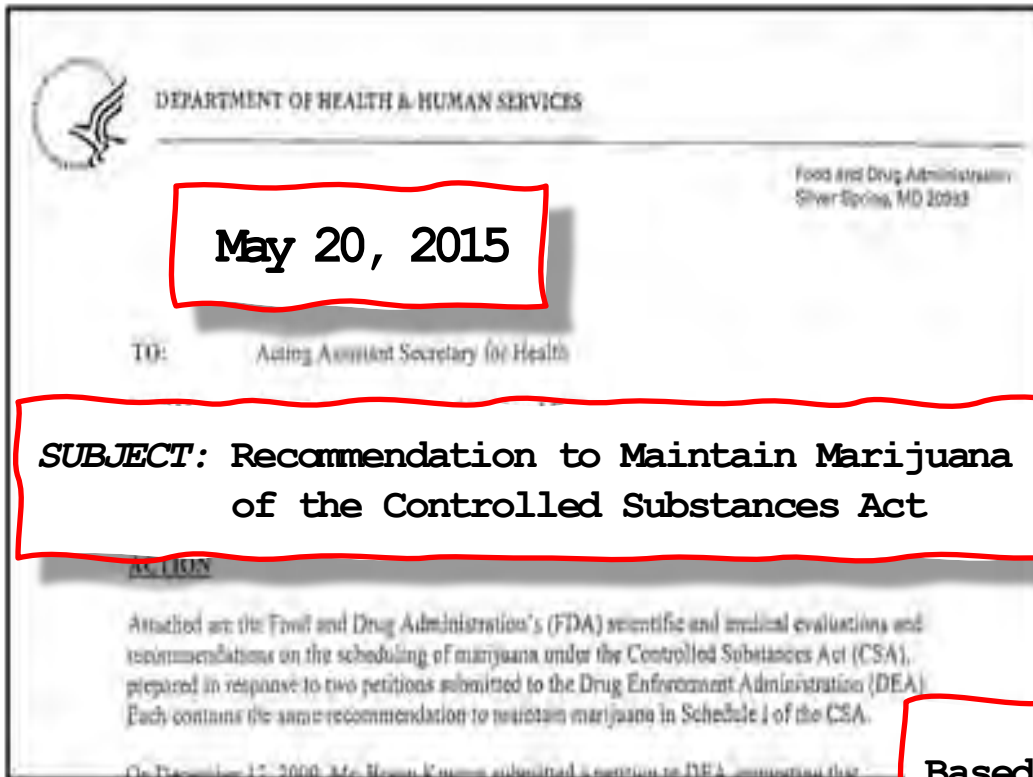
ACTION: Notice of hearing on proposed
rulemaking.

SUMMARY: This is notice that the Drug
Enforcement Administration will hold a
hearing with respect to the proposed
rescheduling of marijuana into schedule
III of the Controlled Substances Act. The
proposed rescheduling of marijuana was
initially proposed in a Notice of
Proposed Rulemaking published in the
Federal Register on May 21, 2024.

“In addition to the data provided in the HHS Basis for Recommendation and the data considered by HHS and DEA in their 2015 eight-factor analyses, DEA anticipates that additional information arising from this rulemaking will further inform the findings that must be made to reschedule marijuana.”

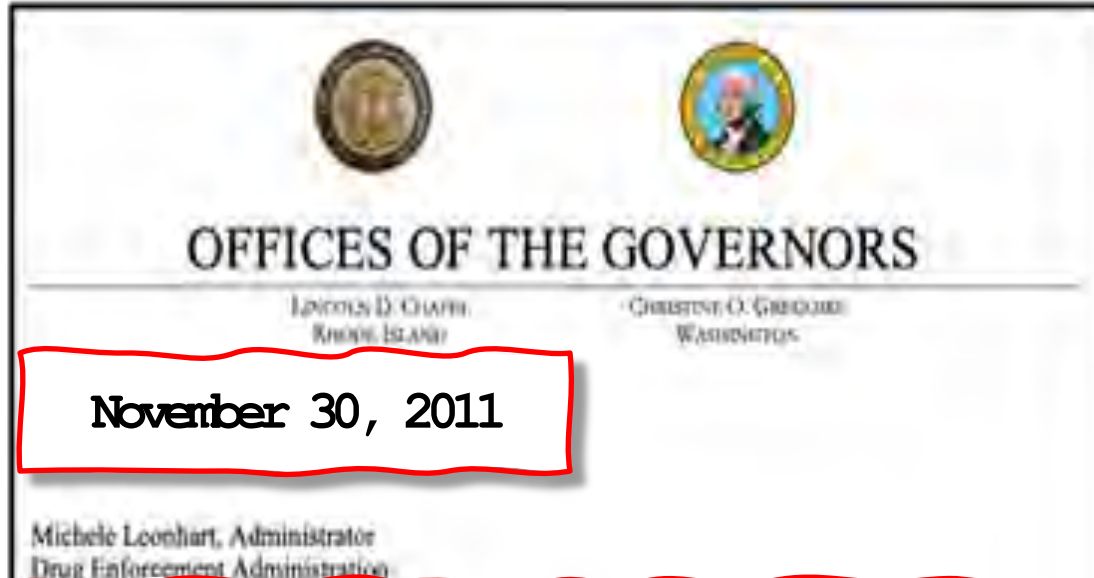


WHAT HAPPENED BETWEEN 2015 & 2023?



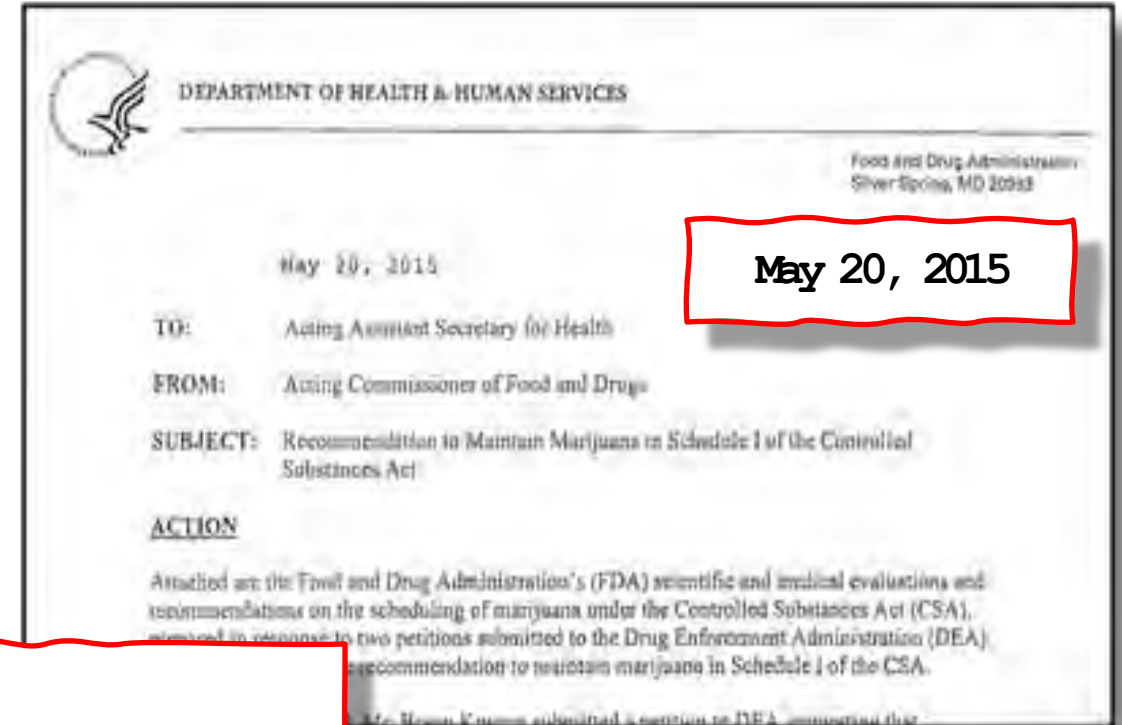
Based on my review of the evidence and FDA's recommendation, it is my recommendation as the Assistant Secretary of Health that Marijuana be placed in Schedule III of the CSA.

HHS 2015 FINDINGS BASED ON DATA PRESENTED IN A 2011 PETITION



November 30, 2011

Subject: Rulemaking petition to reclassify cannabis for medical use from Schedule I controlled substance to a Schedule II



May 20, 2015

**12 YEARS OF KEY SCIENTIFIC &
MEDICAL DISCOVERIES IMPACT
RESCHEDULING FINDINGS**

2011 MEDICAL CANNABIS ACCESS

16 states with medical cannabis laws
13 programs operating
5 operating distribution programs



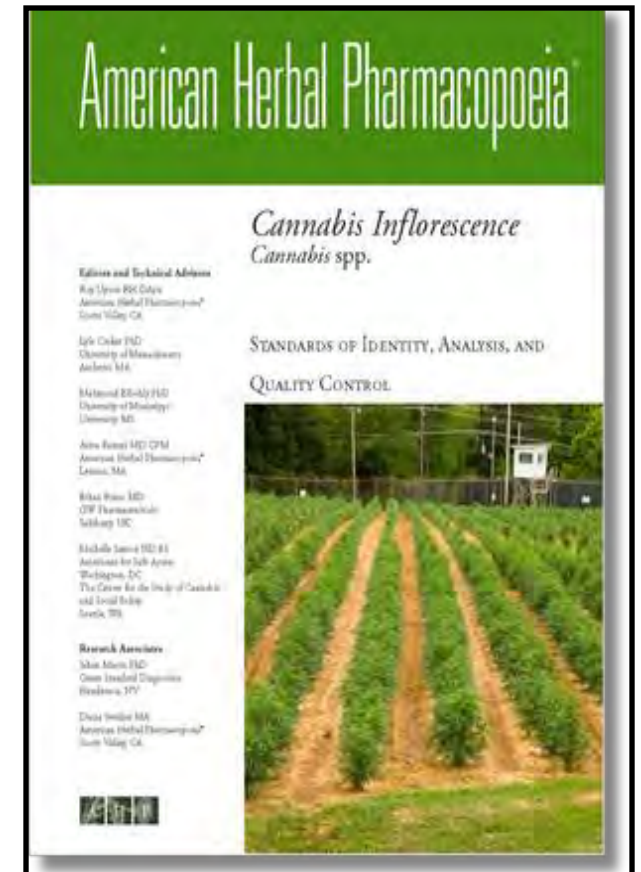
286,243 registered medical cannabis patients (excluding WA, CA, HI, no data available, DC, DE, NJ, not online yet) and an estimated 600,000 non-registered patients.

“ [T]he Office of the Assistant Secretary for Health found that more than **30,000 HCPs [Healthcare Providers]** are authorized to recommend the use of marijuana for **more than six million registered patients**, constituting widespread **clinical experience associated with various medical conditions** recognized by a **substantial number of jurisdictions across the United States**. For several jurisdictions, these programs have been in place for several years, and include features that **actively monitor medical use and product quality characteristics of marijuana dispensed**. HHS Basis for Rec. at 24. ”



DEA, DOJ: Notice of Proposed Rulemaking: Schedules of Controlled Substances: Rescheduling of Marijuana May 21, 2024

PRODUCT SAFETY PROTOCOLS FOR CANNABIS SUPPLY CHAIN ESTABLISHED



2012 the American Herbal Products Association (AHPA), the principal U.S. trade association and voice of the herbal products industry, created supply-chain-wide product safety protocols for commercial cultivation, manufacturing, distribution, and laboratory testing of medical cannabis products for human consumption.

2013 the American Herbal Pharmacopoeia (AHP) issued the Cannabis Inflorescence Monograph, a comprehensive description of the plant's botany, constituent components, analysis, and quality control. This monograph, authored by the world's leading experts on the plant, provides scientifically valid methods of testing the identity, purity, potency, and quality of cannabis products.

In 2015, HHS indicated that “medical practitioners who are not experts in evaluating drugs cannot be considered qualified experts.”

(HHS, 2015; 57 FR 10499,10505).

HHS also highlighted that state-level “medical marijuana laws do not provide evidence of such a consensus among qualified experts.”

HHS’s 2015 “Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act”

DEA’S 2016 “DENIAL OF PETITION TO INITIATE PROCEEDINGS TO RESCHEDULE MARIJUANA” FACTSHEET

BACKGROUND


The last scheduling petition was filed by Governors Lincoln D. Chafee (RI) and Christine O. Gregoire (WA) in November 2011. It took the Drug Enforcement Administration (DEA) five years to respond. Their response was a document titled *Denial of Petition to Initiate Proceedings to Reschedule Marijuana*.

In this report, DEA chief Chuck Rosenberg stated that this decision was based heavily on the FDA’s determination that marijuana is not “a safe & effective medicine” and concluded that “marijuana” (cannabis) should not be removed from the Schedule I status due to 3 issues:

1. Marijuana has a high potential for abuse;
2. Marijuana has no currently accepted medical use in treatment in the United States; &
3. Marijuana lacks accepted safety for use under medical supervision.

This conclusion was based on 21 U.S.C. 811(b) of the CSA, the medical and scientific analysis considers the following eight factors determinative of control of the drug under the CSA (21 U.S.C. 811(c)) & the “five-element test” for determining whether the drug has a currently accepted medical use in treatment in the United States in the absence of a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) approval.

Full report available at safeaccessnow.org/dea_denial

Americans for Safe Access  SafeAccessNow.org 1

2015- STATES ADD QUALIFYING CONDITIONS TO MEDICAL CANNABIS PROGRAMS THROUGH FORMAL REVIEW PROCESS

Twenty-one state medical cannabis programs included a process to add qualifying medical conditions through a designated expert committee appointed by the State's Department of Health. The first state to add a qualifying condition through this process happened in 2015, after completing the HHS review of the petition.

65 QUALIFYING CONDITIONS ADDED TO MEDICAL CANNABIS PROGRAMS THROUGH EXPERT REVIEWS

- | | | |
|-------------------------------------|--|--|
| ADHD | Fibromyalgia | Pancreatitis: Acute & Chronic |
| Age-Related Macular Degeneration | Huntington Disease | Parkinson's |
| ALS | Hydrocephalus | Polycystic Kidney Disease (PKD) |
| Alzheimer's Disease | Interstitial Cystitis | Post Laminectomy Syndrome with Chronic |
| Amyotrophic Lateral Sclerosis | Intractable Headache Syndrome | Radiculopathy |
| Anorexia Nervosa | Irritable Bowel Syndrome (IBS) | Post-Herpetic Neuralgia, Peripheral Neuropathy & |
| Anxiety Disorder | Mal Syndrome | Allodynia from Shingles |
| Arthritis | Migraines | Post-Traumatic Stress Disorder (PTSD) |
| Autism | Muscular Dystrophy | Progressive Degenerative Disc Disease of The Spine |
| Cachexia Or Wasting Syndrome | Neuro-Bechet's Autoimmune Disease | Sickle Cell |
| Cancer, Including Remission Therapy | Neurodegenerative Diseases | Spastic Movement Disorders |
| Cerebral Palsy | Nystagmus | Spasticity |
| Chronic Hepatitis C | Obsessive Compulsive Disorder (OCD) | Spinal Cord Injury |
| Chronic Vocal | Obstructive Sleep Apnea | Substance Use Disorder |
| Motor Tic Disorder Colitis | Opioid Use Disorder | Superior Canal Dehiscence Syndrome |
| Complex Regional Pain Syndrome | Osteoarthritis | Terminal Illness |
| Degenerative Neurological Disorder | Pain; Chronic, Of Visceral Origin | Tourette Syndrome |
| Depression | Pain: Any Condition Opioids Prescribed | Trigeminal Neuralgia |
| Dyskinetic | Pain: Chronic. Chronic Related to | Ulcerative Colitis |
| Dystonia | Musculoskeletal Disorder. Neuropathic, & | Vulvar Lichen Sclerosis |
| Ehler's Danlos Syndrome | Severe Debilitating & Intractable | Vulvodynia & Vulvar Burning |



AGENCIES THAT LED PROCESS FOR EXPERT REVIEWS OF ADDING QUALIFY CONDITIONS :



Connecticut Department of Consumer Protection/Board of Physicians
Delaware Department of Health & Social Services
Hawaii Department of Health
Illinois Department of Public Health
State of Michigan Department of Licensing & Regulatory Affairs
Minnesota Department of Health
New Jersey Department of Health
New Mexico Department of Health/Medical Advisory Board
New York Commissioner of Health
State Medical Board of Ohio
Pennsylvania Department of Health
Rhode Island Department of Health



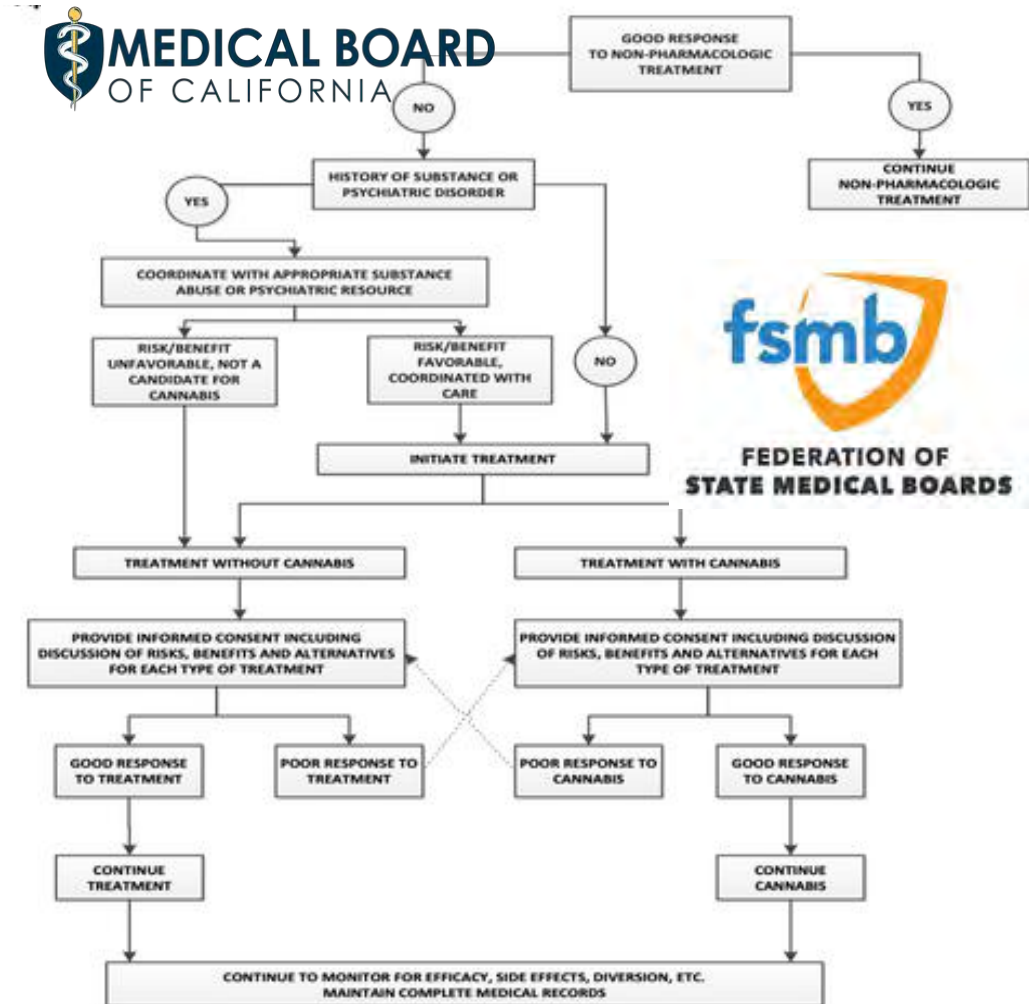
The DOJ Office of Legal Counsel highlighted these programs in support of HHS's finding of "Currently Accepted Medical Use":

“Several states have also established processes through which experts can recommend additions to, or removals from, the list of conditions that marijuana may be used to treat—indeed, HHS has informed us that 17 jurisdictions have added conditions that may be treated with marijuana using such processes; see HHS Part 1 Analysis Memo at 4. **In short, it is simply not the case that state practice concerning medical marijuana is completely divorced from scientific and medical assessment.**”

- DOJ Office of Legal Counsel (OLC)

2016- MEDICAL BOARDS PROVIDE GUIDANCE TO MEDICAL PROFESSIONALS ON WHEN TO RECOMMEND CANNABIS

The Federation of State Medical Boards (FSMB) adopted “Model Guidelines for the Recommendation of Marijuana in Patient Care” and several state medical boards issued guidelines for physicians to incorporate cannabis into their patients’ treatment regime, for example: “Medical Board of California’s Guidelines for the Recommendation of Cannabis for Medical Purposes”

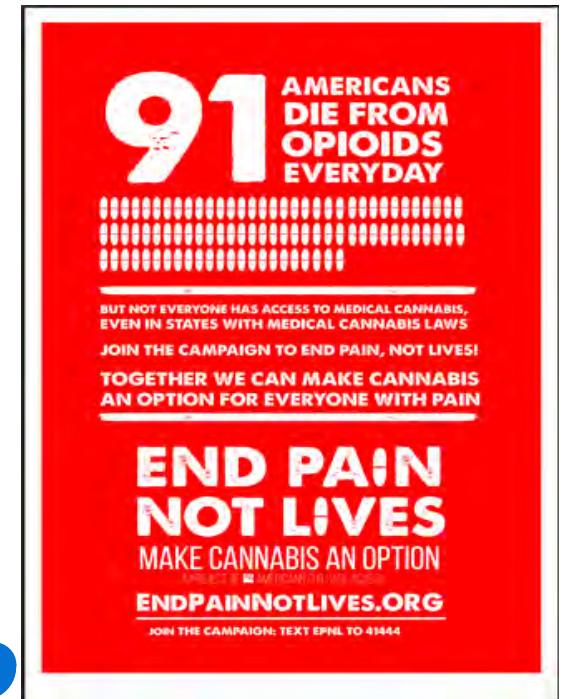


2016- CDC RECOGNIZES CANNABIS' ROLE IN TREATING PAIN & MITIGATING OPIOID DEATHS

The CDC published guidelines for opioid prescribers to stop testing for Cannabis.



“ Clinicians should not test for substances for which results would not affect patient management or for which implications for patient management are unclear. For example, experts noted that there might be uncertainty about the clinical implications of a positive urine drug test for tetrahydrocannabinol (THC). ”



2017 DEA REMOVES "GATEWAY THEORY" REFERENCES FROM WEBSITE/PUBLICATION AFTER DATA QUALITY ACT (DQA) CHALLENGE



DEA's 2016 "Denial of Petition to Initiate Proceedings to Reschedule Marijuana" contradicts "The Dangers & Consequences of Marijuana Abuse" & "Drugs of Abuse"



No scientific basis for (1) the gateway drug hypothesis (2) irreversible cognitive decline in adults; and cannabis causing (3) psychosis or (4) lung cancer




END OF GATEWAY THEORY



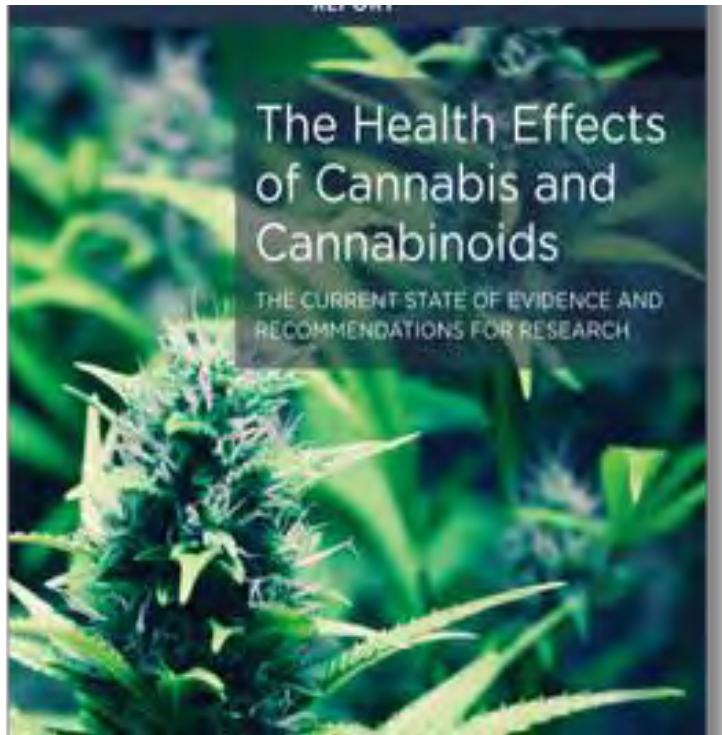
National Institute on Drug Abuse

Is cannabis a “gateway” drug?

Cannabis products are among the first substances along with alcohol and tobacco that a person will likely encounter in their life ([MTE, 2023](#) ) and people who use substances commonly use these before trying others. Still, most people who use or have used cannabis do not go on to use other substances later in life.⁷¹

NIDA WEBSITE 2025

2017 The National Academies of Sciences, Engineering, and Medicine published The Health Effects of Cannabis and Cannabinoids that found:

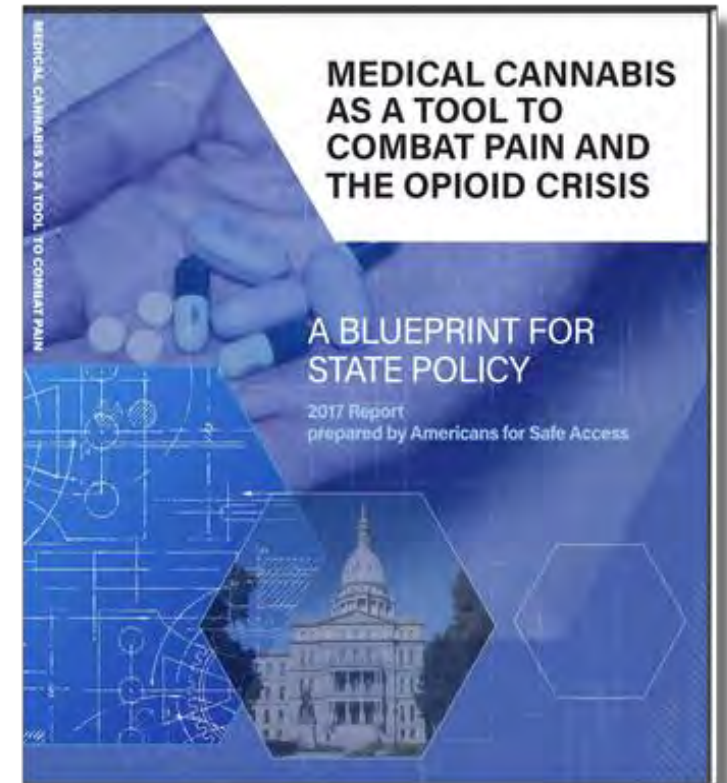


"There is conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults, as anti-emetics in the treatment of chemotherapy-induced nausea and vomiting, and for improving patient-reported multiple sclerosis spasticity symptoms."

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

2017- OPIOID EPIDEMIC DECLARED PUBLIC HEALTH CRISIS, 2018 STATES IMPROVE MEDICAL CANNABIS LAWS TO COMBAT IMPACT

The United States declares the opioid crisis a “public health emergency” after reaching an average of **“91 deaths a day.”** *Connecticut, Washington DC, Florida, Illinois, New Jersey, and New York* add pain as a qualifying condition to their medical cannabis program following the ASA report “Medical Cannabis as a Tool to Combat Pain and Opioid Crisis: A Blueprint for State Policy.”



2019 UNIVERSITIES & COLLEGES CANNABIS SPECIALTY DEGREES

Thousands of Americans have associate, bachelor's, and master's degrees in cannabis studies, including Cannabis Biology and Chemistry, Cannabis Studies, Pharmaceutical Sciences, Agriculture and Horticulture, Cultivation, Policy, Medical Plant Sciences, Business, Commerce, and Administration from over 40 Universities and colleges.



INTERNATIONAL HEALTH AGENCY RECOGNIZES MEDICAL USE OF CANNABIS

2019 The World Health Organization recommends that the United Nations Committee on Narcotic Drugs reschedule cannabis based on “a multi-year review process conducted by the Expert Committee on Drug Dependence (ECDD), an independent scientific advisory body to the WHO. Based on scientific assessment, potential health risk and therapeutic benefit”



DRUG TREATIES MODIFIED TO RECOGNIZE CANNABIS THERAPEUTICS

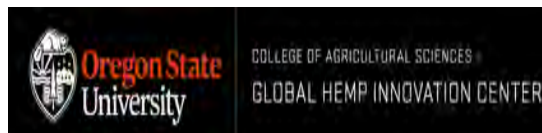
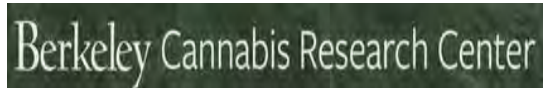


2020- The UN Commission on Narcotic Drugs (CND), the drug policy-making body of the UN reclassified cannabis and cannabis resin under an international drug treaties.

2019 States began contributing to research, creating the first significant source of funding for research outside NIDA.



In 2011, CMCR at UC San Diego was one of the only cannabis research centers in the U.S.



THE MEDICAL MARIJUANA & CANNABIDIOL RESEARCH ACT BECOMES LAW

2022 *-BI-PARTISAN EFFORT LEAD BY TRADITIONAL PRO-PROHIBITION MEMBERS*



“We know that cannabidiol-derived medications can be effective for conditions like epilepsy. This bill will help refine current medical CBD practices and develop important new applications. After years of negotiation, I’m delighted that we’re finally enacting this bill that will result in critical research that could help millions.”-**Senator Feinstein**



“Since 2015, I’ve pushed to expand medical research into marijuana derivatives such as cannabidiol to better understand their benefits and potential harms.” -**Senator Grassley**

“Congress passed this legislation with robust bipartisan, bicameral support because increasing research into the impacts of cannabis requires timely action”-**Andy Harris (R)**



2022- DOSING GUIDELINES FOR CANNABIS & CANNABINOID MEDICINES



The Minnesota Department of Health issues “Dosing and Chemical Composition Report: A Review of Medical Cannabis Studies Relating to Chemical Compositions and Dosages for Qualifying Medical Conditions.”

mn.gov/ocm/dmc/health-care-practitioners/guidance-materials/medical-cannabis-studies.jsp

2023 OVER 60 COUNTRIES HAVE FEDERAL MEDICAL CANNABIS ACCESS PROGRAMS

In 2011, only two countries had laws allowing for medical use of cannabis, Canada and the Netherlands. In 2023, that number rose to over 60 countries with explicit laws and dozens more debating legislation. Patients in the European Union (EU), can petition their government to receive medical cannabis from EU countries that have medical cannabis programs.



Countries with Medical Cannabis Access:

Albania, Argentina, Australia, Barbados, Brazil, Cayman Islands, Canada, Channel Islands, Chile, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, Estonia, Faeroe Islands, Finland, Georgia, Germany, Gibraltar, Greece, Iceland, Isle of Man, Ireland, Israel, Italy, Jamaica, Lebanon, Lesotho, Luxembourg, Malawi, Malta, Mexico, Morocco, the Netherlands, New Zealand, North Macedonia, Norway, Panama, Paraguay, Peru, Poland, Portugal, Romania, Rwanda, Saint Kitts and Nevis, Saint Lucia, San Marino, Saint Vincent and the Grenadines, San Marino, South Africa, Spain, Sri Lanka, Switzerland, Thailand, Ukraine, the United Kingdom, Uruguay, Vanuatu, Zambia, and Zimbabwe.

2023

FEDERAL MEDICAL CANNABIS PROGRAMS OK UNDER DRUG TREATIES: INCB ISSUES GUIDELINES FOR COMPLIANCE

Report of the International Narcotics Control Board (INCB) for 2022:

“Following the recommendation of WHO, the Commission on Narcotic Drugs decided in December 2020 to remove cannabis and cannabis resin from Schedule IV of the 1961 Convention...As far as the specific control measures for cannabis are observed, these medical cannabis programmes are in compliance with the conventions.”



21 USC 811



(d)INTERNATIONAL TREATIES, CONVENTIONS, AND PROTOCOLS REQUIRING CONTROL; PROCEDURES RESPECTING CHANGES IN DRUG SCHEDULES OF CONVENTION ON PSYCHOTROPIC SUBSTANCES(1)If [control](#) is required by [United States](#) obligations under international treaties, conventions, or protocols in effect on October 27, 1970, 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 812\(b\) of this title](#) and without regard to the procedures prescribed by subsections (a) and (b) of this section.



2023

**American Nurses Association (ANA)
Officially Recognizes Cannabis Nursing
as a Specialty Nursing Practice**



**2023 HHS FINDS CANNABIS HAS
“CURRENTLY ACCEPTED MEDICAL USE”**



THE FUTURE OF MEDICAL CANNABIS IS UP TO CONGRESS



Endorse MCCA & Safe Access 4 All

Please select an option below.

× Clear choice

We Endorse the Medical Cannabis & Cannabinoid Act!

My organization would like to find out more about endorsing the Medical Cannabis & Cannabinoid Act.

Yes! We are interested in scheduling a MCCA webinar with ASA for our membership.

Yes! We would like a speaker to attend one of our meetings.

Yes! We need materials to distribute to our members.

Please choose from the following

✓ Select all × Clear choices

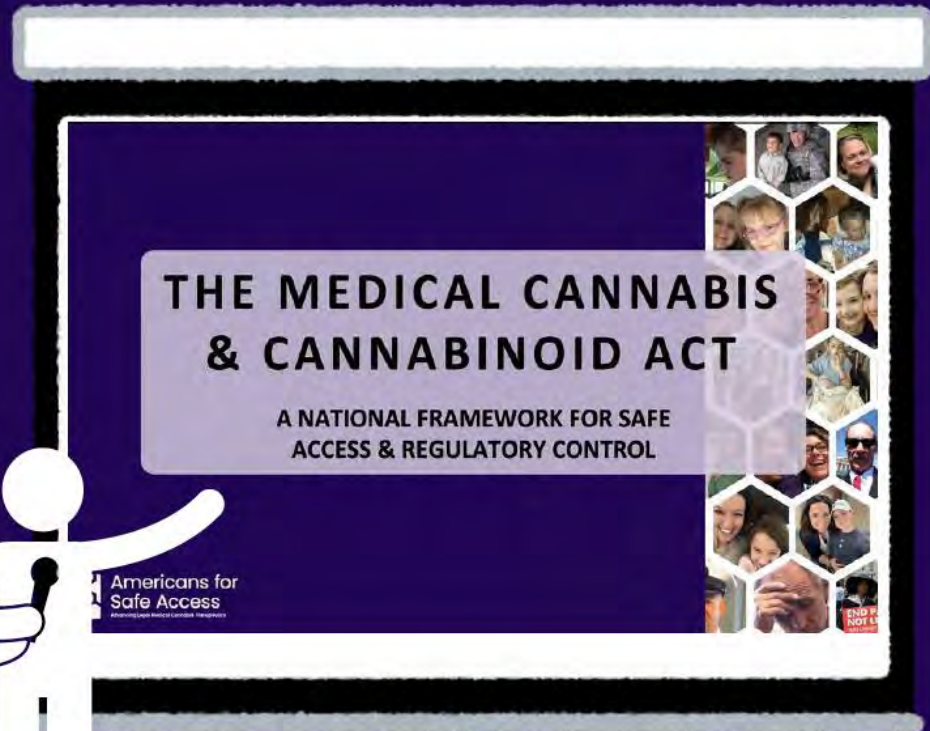
We would like to to schedule a meeting with an ASA representative to learn more.

We would like to attend a webinar about the MCCA.

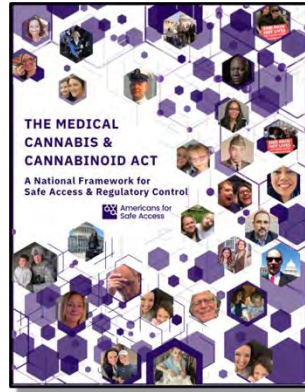
SafeAccessNow.org/Endorse_MCCA_Safe_Access_4_All



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SafeAccess4All.org



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SafeAccess4All.org

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-  [@americansforsafeaccess](https://www.tiktok.com/@americansforsafeaccess)
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Americans for Safe Access

Advancing Legal Medical Cannabis Therapeutics

THANK YOU!