THE MEDICAL CANNABIS & CANNABINOID ACT

A NATIONAL FRAMEWORK FOR SAFE ACCESS & REGULATORY CONTROL

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

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.






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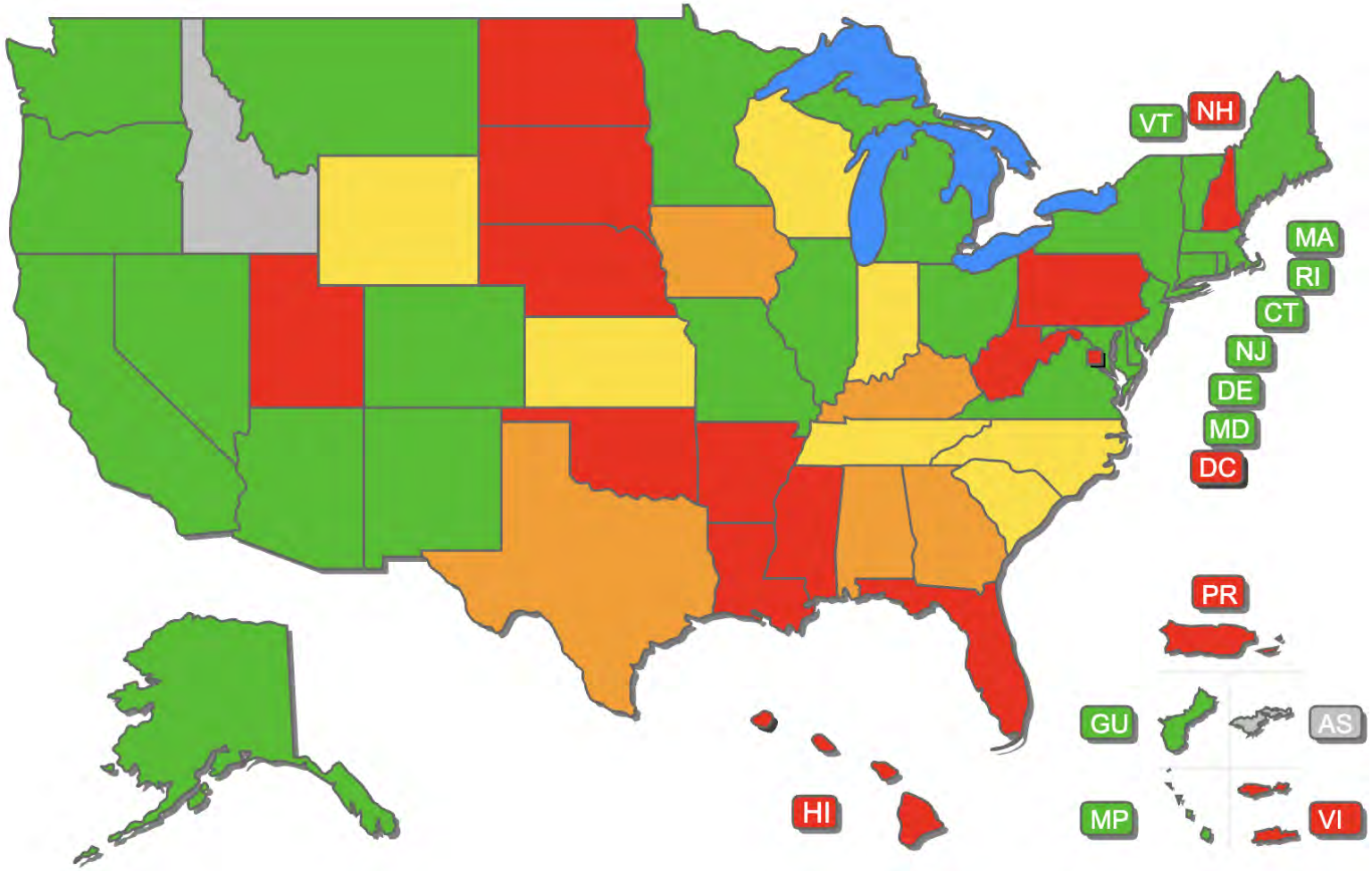
MEDICAL CANNABIS IN AMERICA

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



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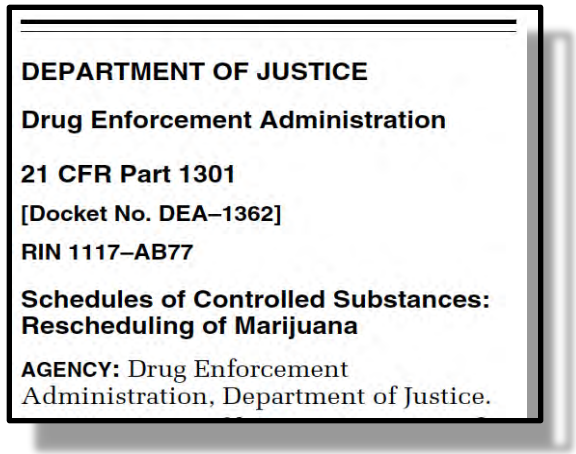
> [T]he Office of the Assistant Secretary for Health found that more than **30,000 HCPs [Healthcare Providers] are authorized to recommend the use of marijuana for more than six million registered patients**, constituting widespread clinical experience associated with various medical conditions recognized 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**

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> 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.

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.**

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.

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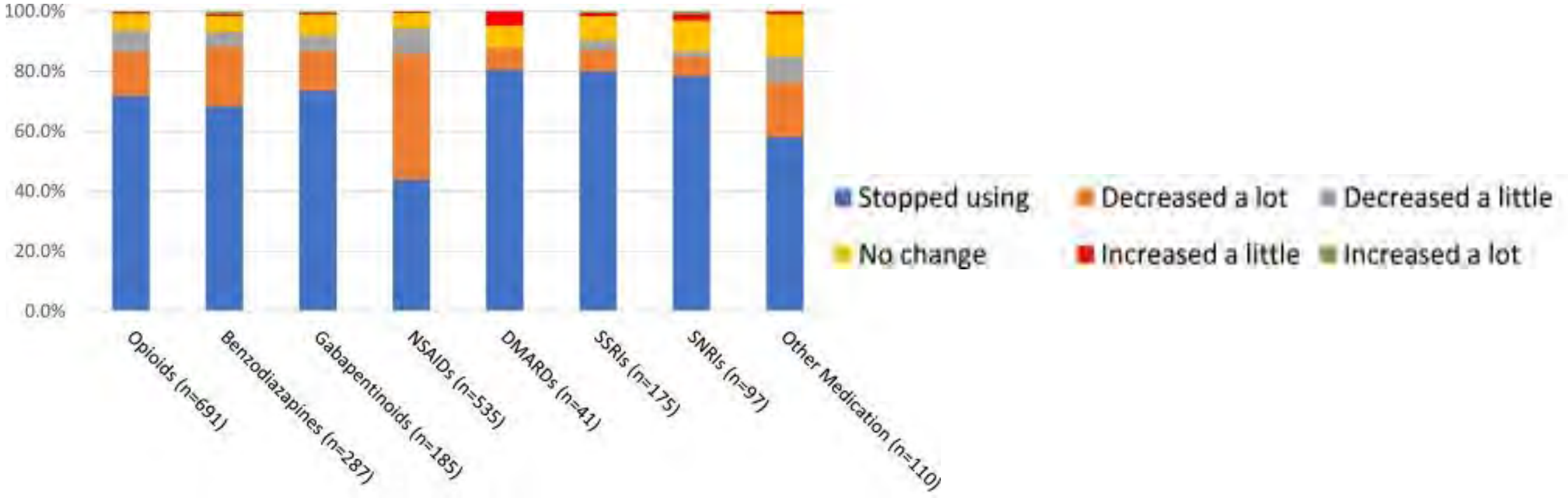
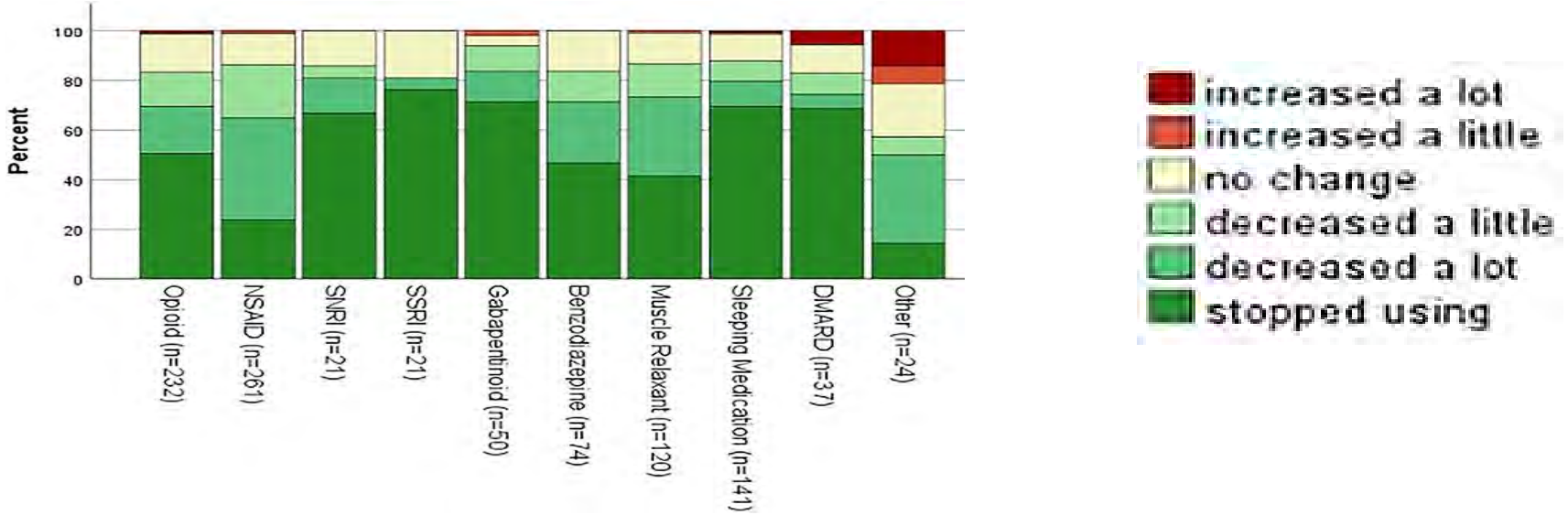
SUBSTITUTION OF CANNABIS FOR PAIN MEDICATION



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)



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.

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.

ASA


MS
National
Multiple Sclerosis
Society


IAVA
IRAQ AND AFGHANISTAN
VETERANS OF AMERICA


BLINDED
VETERANS
ASSOCIATION
SERVING BLINDED VETERANS SINCE WORLD WAR II


AMERICAN ACADEMY OF
NEUROLOGY


AMERICAN
GI
FORUM


AMERICAN
LEGION


EPILEPSY
FOUNDATION


LEUKEMIA &
LYMPHOMA
SOCIETY®


MINORITY VETERANS OF AMERICA


AMERICAN VETERANS
AMVETS

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**.

CONGRESS DETERMINES WHO CAN & CAN'T HAVE ACCESS

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.

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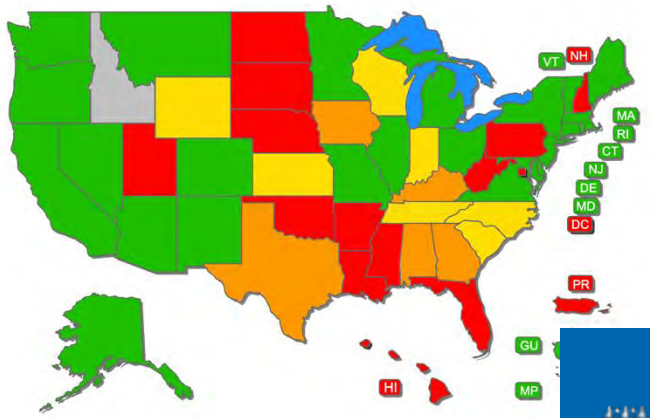
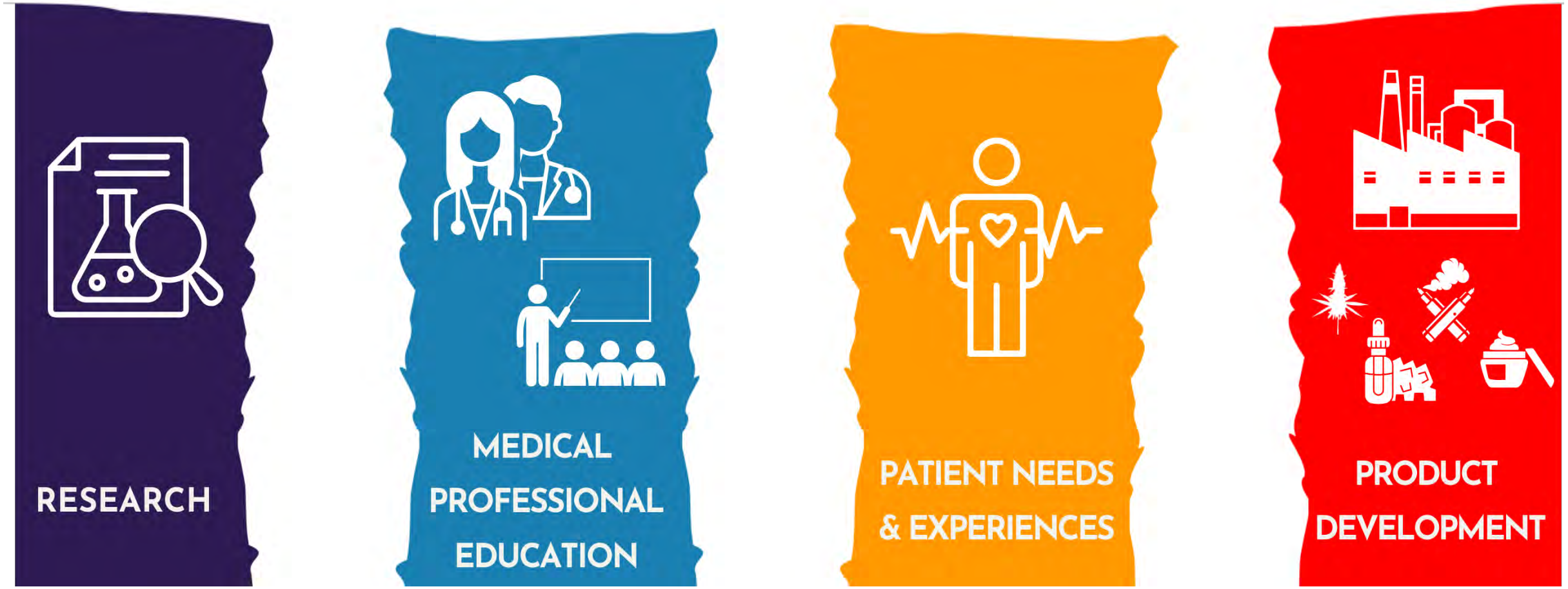
CURRENT STATE OF CANNABIS PRODUCTS AVAILABLE IN U.S. MARKETS



REGULATED STATE MARKETS & UNREGULATED HEMP MARKET

GAPS IN KNOWLEDGE IMPACT PATIENT OUTCOMES



STATES HAVE FULFILLED THEIR ROLE AS "LABORATORIES OF DEMOCRACY"

STATE PROGRAMS ARE NOT MEETING PATIENTS' NEEDS

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

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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.

Patients are Unable to Use Cannabis in Hospice or Travel to Attend Life Events. Federal employees and active military are barred from participating in state programs. The Veterans Health Administration (VHA) and Medicare do not cover cannabis treatments, keeping them out of reach for millions.

9,000,000	VETERANS USING VA HEALTH SERVICES
1,870,000	FEDERAL EMPLOYEES
112,846,000	AMERICANS LIVING WITH CHRONIC PAIN

2,100,000	AMERICANS IN SECTION 8 HOUSING (23% ARE DISABLED)
1,720,000	AMERICANS IN HOSPICE
630,000	US POSTAL WORKERS
37,900,000	AMERICANS LIVING IN POVERTY

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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 do not include civil protections.

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

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

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

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FDA U.S. FOOD & DRUG ADMINISTRATION

FDA STATEMENT

FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward

For Immediate Release: January 26, 2023

Statement From: Janet Woodcock, M.D.
Principal Deputy Commissioner - Office of the Commissioner

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	*Trans-delta-9-tetrahydrocannabiphorol*	30.00[43]
Delta-8 THCP	*Trans-delta-8-tetrahydrocannabiphorol*	20.10[44]
Delta-9 THCO	*Delta-9-THC-O-acetate*	3.00[45]
Delta-8 THCO	*Delta-9-THC-O-acetate*	2.01[46]
HHCO Acetate	*Hexahydrocannabinol-O-acetate*	1.50[47]
HHC	*Hexahydrocannabinol*	1.00[48]
THCA	*Tetrahydrocannabinolic acid*	0.877[49,50]
Delta-8 THC	*Delta-8-Tetrahydrocannabinol*	0.67[51]
CBN	*Cannabinol*	0.25[52]

UFCW Local 135

UFCW a VOICE for working America WESTERN STATES COUNCIL

MARCH AND ASH

embarc

ASA

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

FEDERAL MEDICAL CANNABIS & CANNABINOID POLICY NEEDS CONGRESSIONAL ACTION

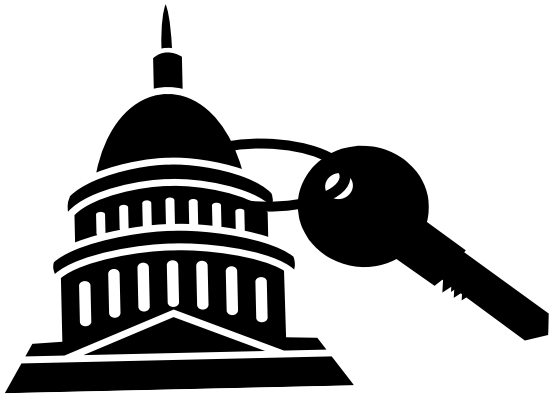
The Medical Cannabis Amendment to the Commerce-Justice-Science (CJS) Appropriations bill, first passed in 2014, was meant to be a triage measure to stop raids and prosecutions while Congress dealt with federal medical cannabis policies.

The Hemp Authorization of the 2018 Farm Bill removed cannabis with <.3% THC from the CSA and failed to define "hemp products." The bill implied that the Food and Drug Administration (FDA) would regulate these products; however, in January 2023, the FDA told Congress they do not have the authority to regulate the products without new authorities.

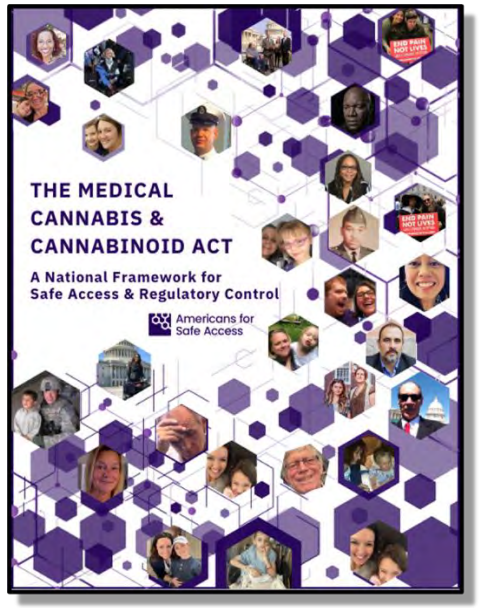
There is confusion for **federal agencies in dealing with cannabis, forcing many to create "workaround" policies for cannabis** without the benefit of medical cannabis policy experts to guide them, and most agencies have found themselves in court trying to navigate the state-federal conflict.

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

ASA'S PROPOSAL



A NATIONAL MEDICAL CANNABIS PROGRAM



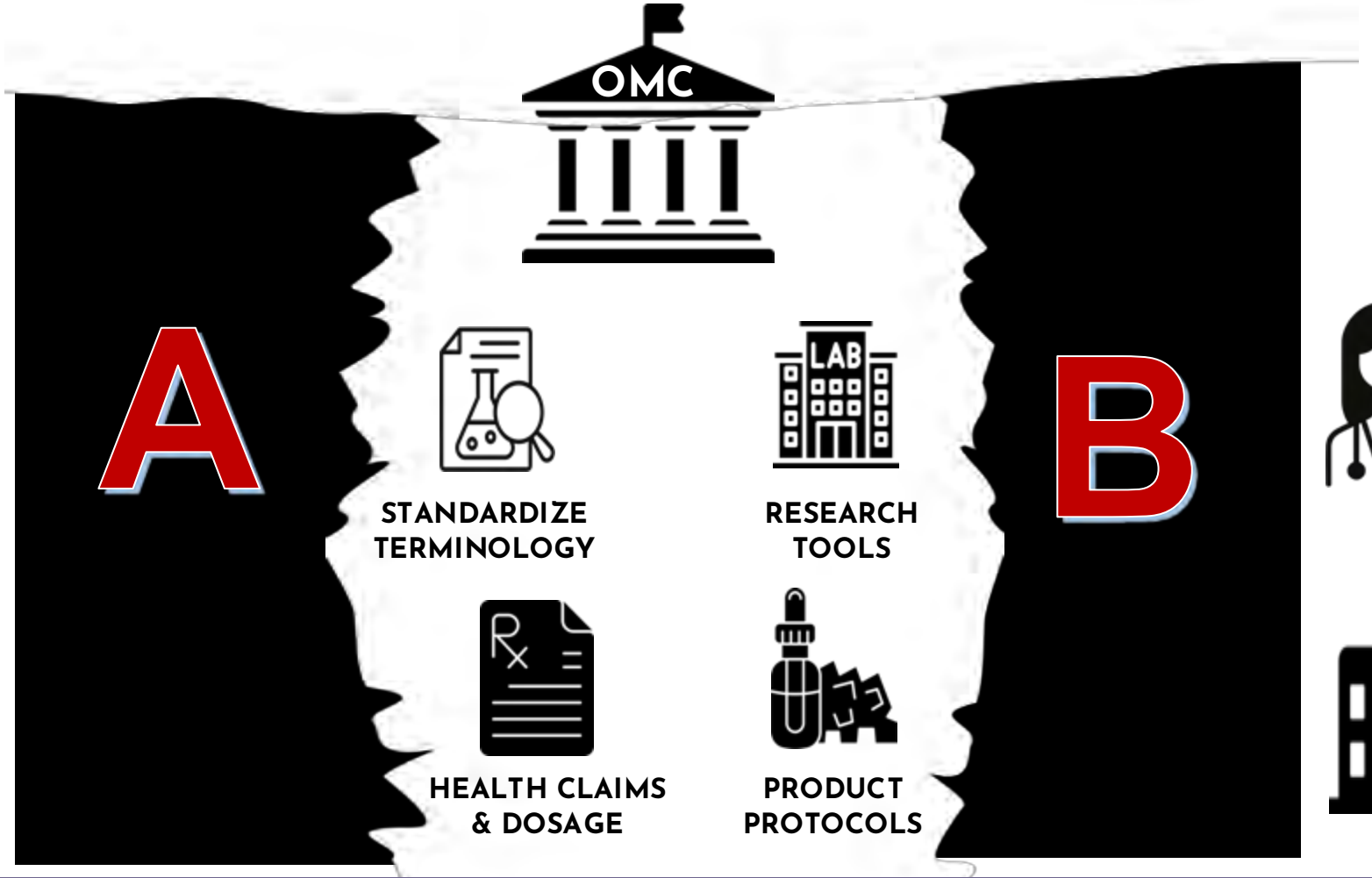
ESTABLISH-

THE OFFICE OF MEDICAL CANNABIS & CANNABINOID CONTROL (OMC)

CREATE-

SCHEDULE VI (UNDER OMC OVERSIGHT)

INTEGRATE CANNABIS INTO U.S. HEALTHCARE SYSTEMS



THE MEDICAL CANNABIS & CANNABINOID ACT

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

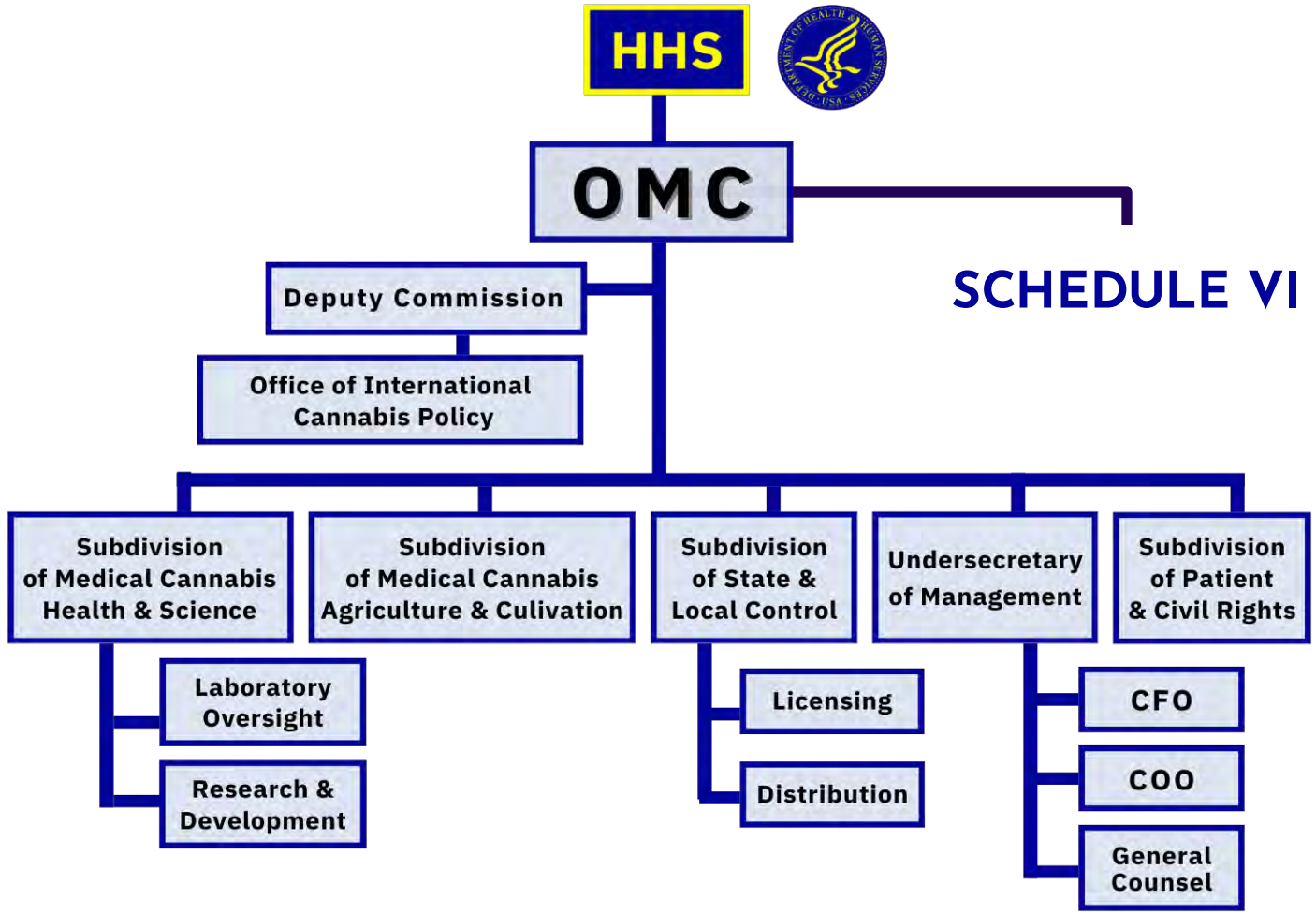
The Office of Medical Cannabis & Cannabinoid Control's mission is to facilitate access to medical cannabis for therapeutic use & research, regulate the production of medical cannabis & cannabinoid products, & oversee the new Schedule VI.

Housed in HHS

Brings US in compliance with UN Drug Treaties

Coordinates cannabis matters across federal agencies & with state regulators

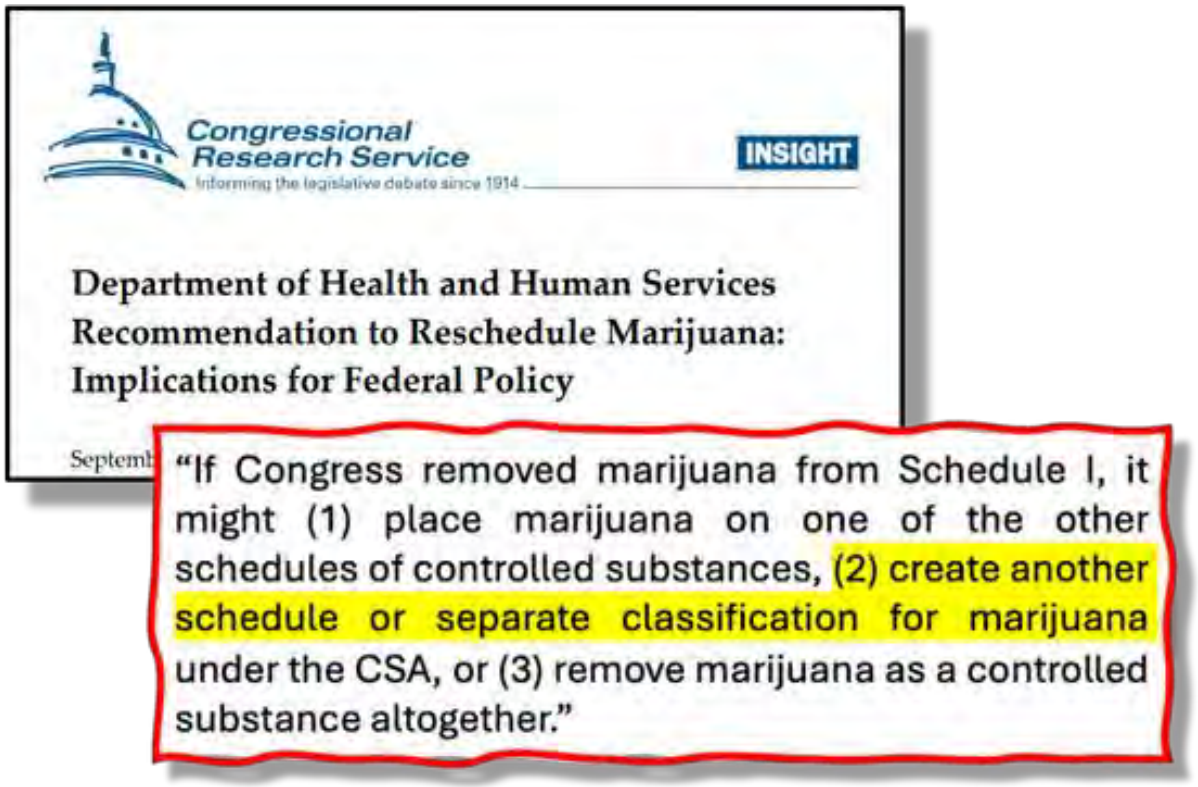
Funded by agency reorganization, licensing & permitting fees, & public-private partnerships



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 manufactures 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.

ASA'S APPROACH IS POSSIBLE



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

"Legal Consequences of Rescheduling Marijuana". January 16th, 2024 (updated May 1, 2024), CRS report

NATIONAL CANNABIS PROGRAM ROLE OUT

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

FIRST 60 DAYS

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

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

GUIDANCE FOR FEDERAL AGENCIES

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 polices 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.

GUIDANCE FOR FEDERAL AGENCIES

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 businesses with a Schedule VI permit/license.

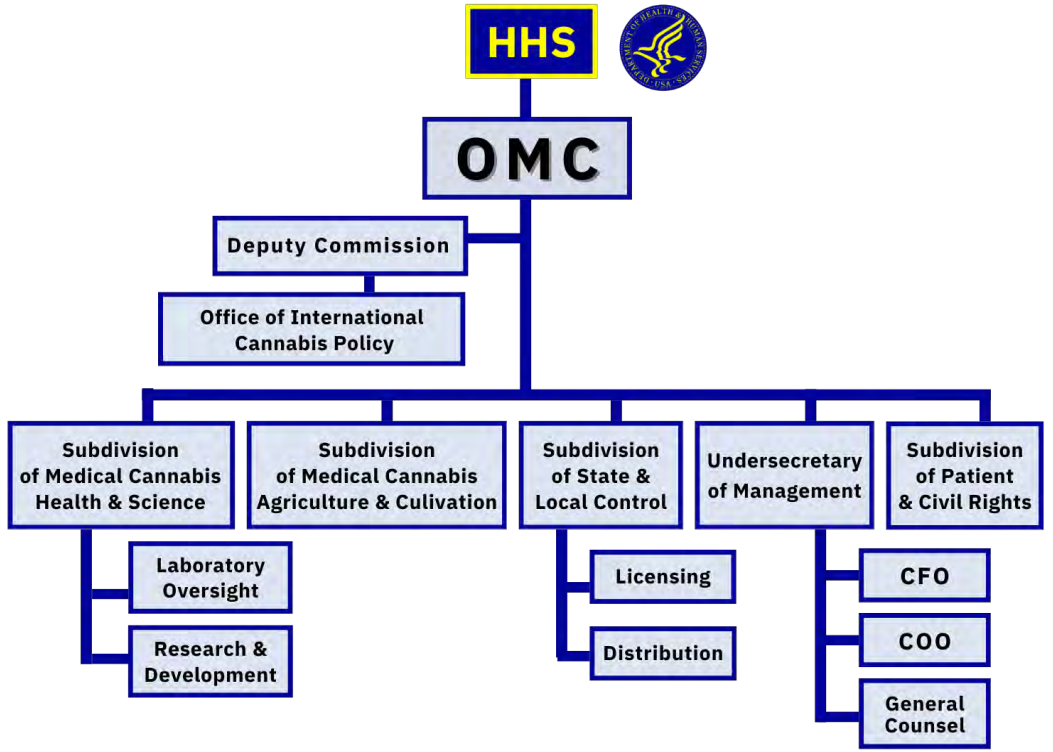
FOOD & DRUG ADMINISTRATION- Issue requirements for products containing cannabinoids to include 1) source of the cannabinoid 2) "The safety of this product has not been evaluated by the FDA" 3) "This product has not been tested for contaminates" or a QR code to Certificate of Analysis & 4) Batch number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

ALL FEDERAL AGENCIES- Cannabis is no longer a factor for federal employees, contactors 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

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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

NIH

USDA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

SBA

ASA

NATIONAL MEDICAL CANNABIS PROGRAM

PHASE I

= FINISHED PRODUCTS

= RAW INGREDIENTS

= PERMITTED BY STATE

= SCHEDULE VI PROVISIONAL PERMIT

= STATE/TRIBAL LICENSE

CULTIVATION

PROCESSORS

MANUFACTURERS

OMC

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

REQUIRE

(except B2B Transport)

TESTING LABS

B2B TRANSPORT

RESEARCHERS

HOME CULTIVATION

STATE-ID CARDS REMAIN VALID

DISPENSARY

HOSPITAL/'HOSPICE ASSISTED LIVING

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

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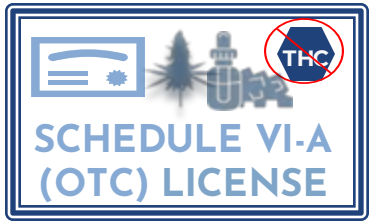
NATIONAL MEDICAL CANNABIS PROGRAM

PHASE II

SCHEDULE VI
LICENSES & PERMITS

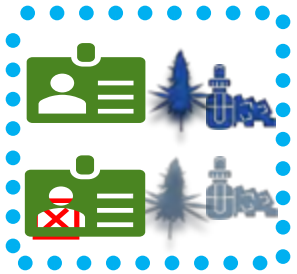


HOSPITAL/HOSPICE ASSISTED LIVING

PHARMACY

DISPENSARY-SPECIALTY PHARMACY

STATE ID CARDS REMAIN IN EFFECT

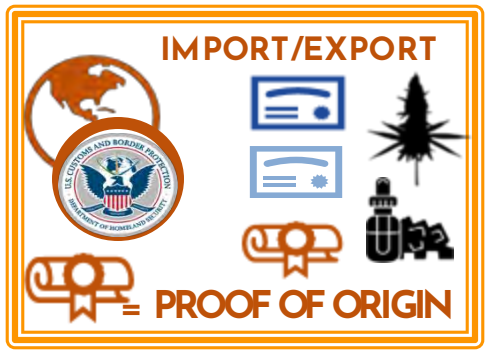


HOME CULTIVATION

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



OMC STRUCTURE & AGENCY TRANSITION

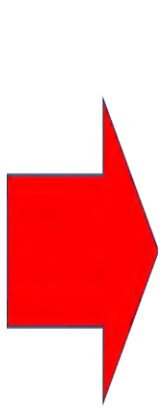
Sec. 603- Reorganization Plan

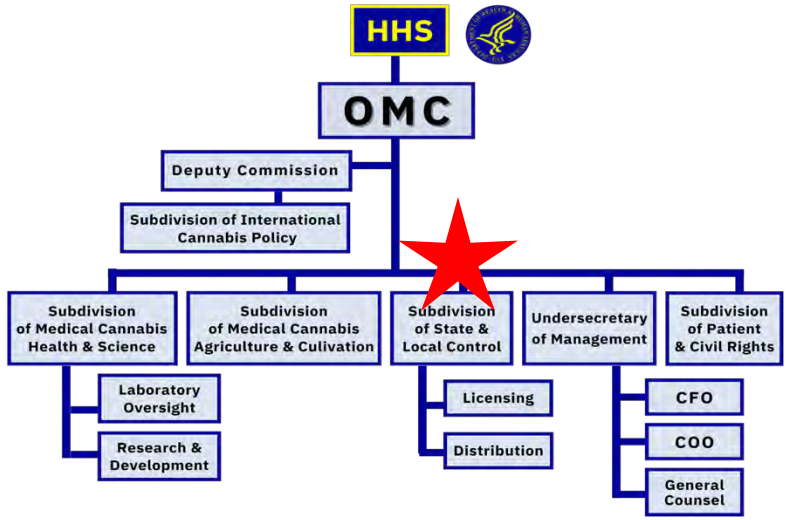
TITLE VII- Implementation

Sec. 305- Cannabis Production; State & Tribal Plans

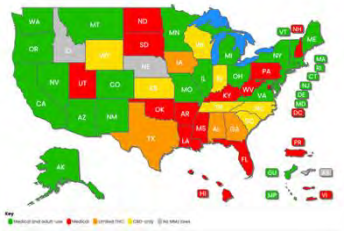
Sec. 705– Advisory Committee

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





- 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

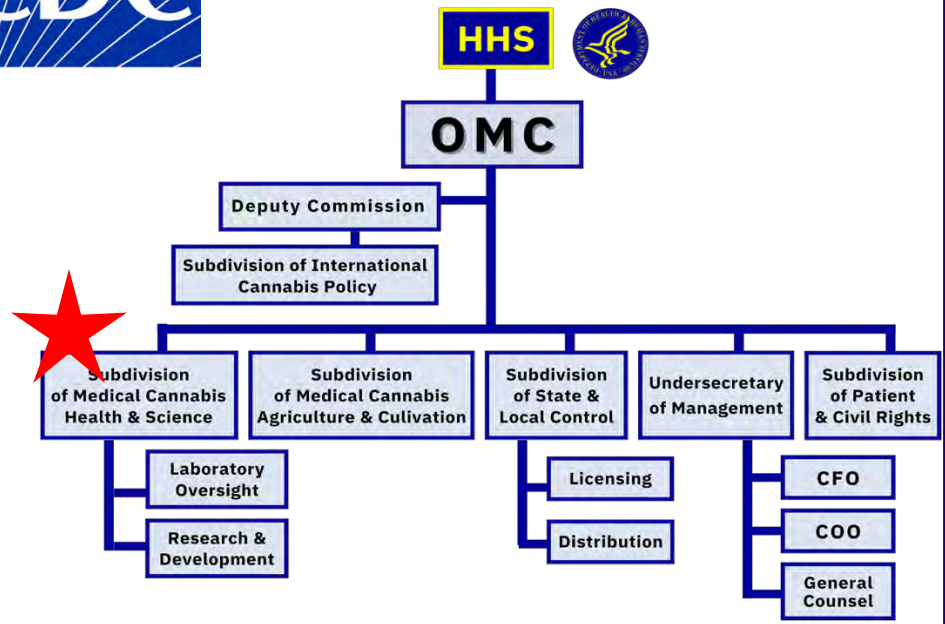
Title VII- Implementation

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

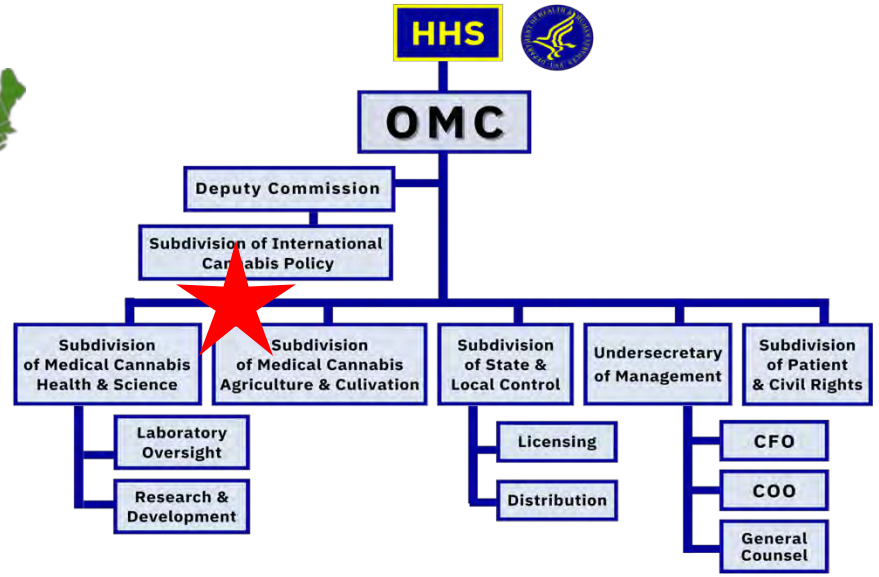
TITLE III- SUBDIVISION OF MEDICAL CANNABIS CULTIVATION & AGRICULTURE

NIDA NATIONAL INSTITUTE ON DRUG ABUSE

OMC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

USDA



U.S. JUSTICE DEPARTMENT DRUG ENFORCEMENT ADMINISTRATION

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

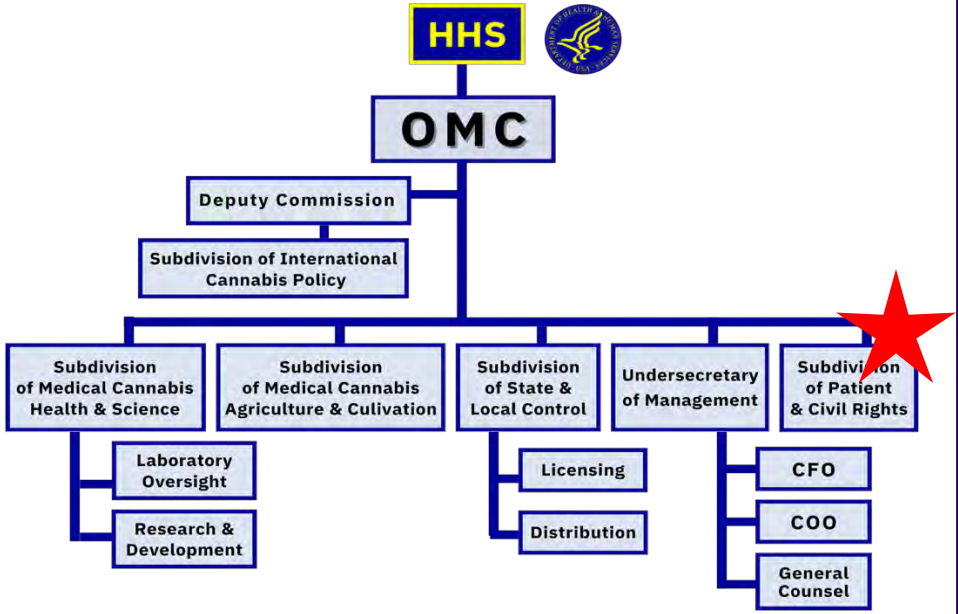
ASA

OMC STRUCTURE & AGENCY TRANSITION

Sec. 603- Reorganization Plan

Title VII- Implementation

SEC. 404- SUBDIVISION OF PATIENT & CIVIL RIGHTS

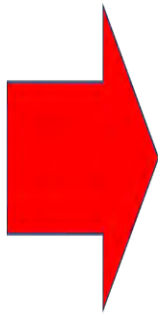


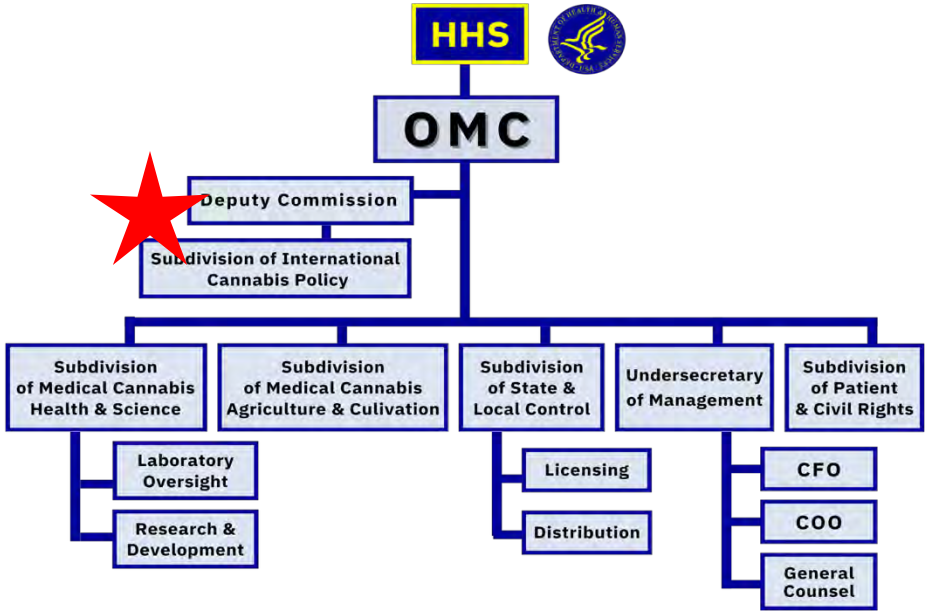
- Review & monitor the implementation to ensure patient rights are protected
- Work across agencies to ensure that patient rights are included in their policies
- Work with CMS to ensure cannabis medications are covered

SEC. 504-OFFICE OF INTERNATIONAL POLICY

OMC STRUCTURE & AGENCY TRANSITION

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





NIDA
NATIONAL INSTITUTE ON DRUG ABUSE

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

ASA

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.

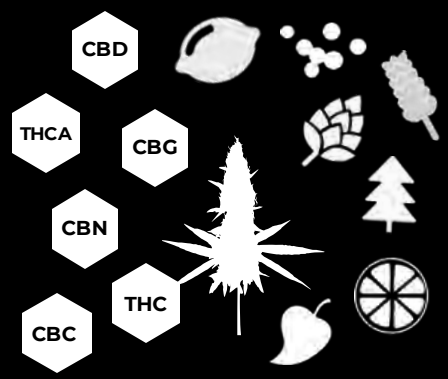
Creating Schedule VI acknowledges that cannabis is not just another drug—it's a botanical medicine with a unique profile. By placing cannabis in its own category, Schedule VI would allow for regulations tailored to its specific properties and uses.

WHY SCHEDULE VI ?

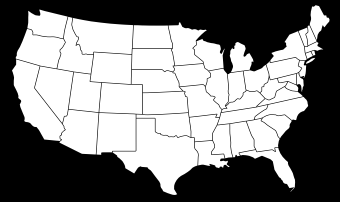
CANNABIS FEDERAL CLASSIFICATION	SCHEDULE I	SCHEDULE III	DE SCHEDULE	SCHEDULE VI
Recognizes Medical Use of Cannabis		✓		✓
Regulates Cannabinoid & "Hemp Product" Market				✓
Harmonizes State & Federal Medical Cannabis Laws				✓
Removes Criminal Penalties for Cannabis Possession			✓	✓
Removes Criminal Penalties 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				✓

ASA

THE MEDICAL CANNABIS & CANNABINOID ACT



TRANSITION FROM COMPASSIONATE USE TO HEALTHCARE INTEGRATION

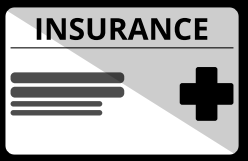


HEALTH CLAIMS & DOSAGE

STANDARDIZE TERMINOLOGY

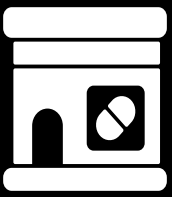
PRODUCT PROTOCOLS

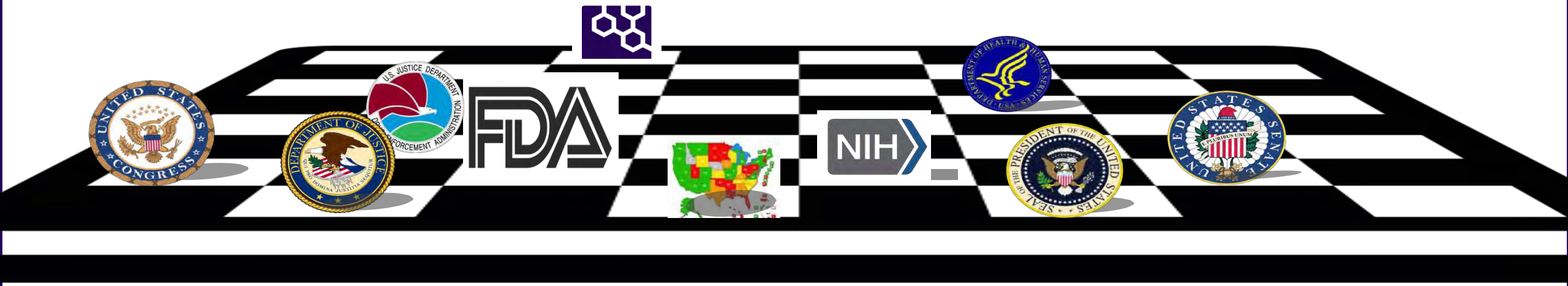
RESEARCH TOOLS



A

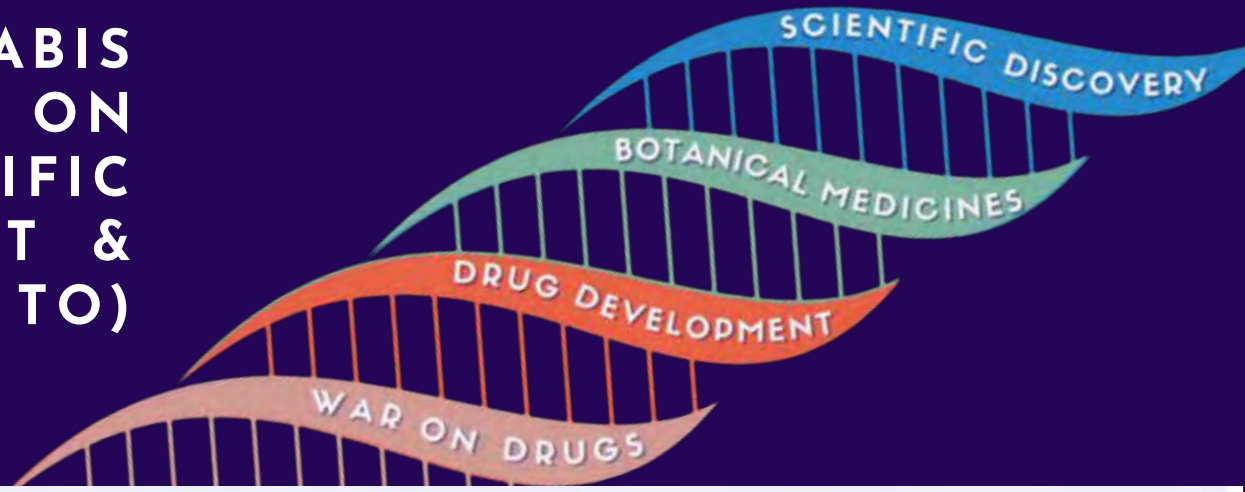
B





20+ YEARS PATIENTS WORK TOWARD A NATIONAL MEDICAL CANNABIS PROGRAM

THE U.S. HISTORY OF CANNABIS MEDICINES INCLUDES THE WAR ON DRUGS, THE EVOLUTION OF SCIENTIFIC DISCOVERY & DRUG DEVELOPMENT & U.S. MOVE AWAY FROM (& BACK TO) HERBAL MEDICINES.



1804 — 1st active ingredient to be isolated from plant- morphine from opium

1850 — Cannabis in U.S. Pharmacopeia

1906 — Pure Food & Drugs Act: created FDA

1906 — Ehrlich's "magic bullet" concept,- 1st single targeted therapy, Salvarsan

1913 — Eli Lily's Cannabis tincture on market

1937 — Marihuana Tax Act passed,

1942 — Cannabis removed US Pharmacopeia

1962 — Kefauver-Harris Drug Amendments- Proof of efficacy to FDA before marketing them

1964 — THC First Identified & Synthesized

1971 — Controlled Substances Act passed-Cannabis classified "No Accepted Medical Use"

1975 — Scientist discover "enkephalin" 1st endorphin: endogenous opioid peptides.

1978 — Federal Government IND Compassionate Use Program Supplies Patients with Cannabis

1992 — Scientists Discover 1st Endocannabinoid

2014 — CJS Amendment

2023

1996-2024 — HHS Finds Cannabis has "accepted medical use"

49 states passed medical cannabis laws/ 39 full access

1916 — 40% of official medicinal preparations in U.S. Pharmacopeia were crude plant extracts (299 preparations)

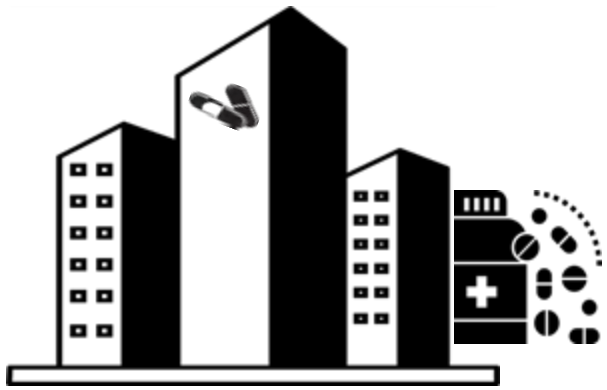
1950 — 19% of official medicinal preparations in U.S. Pharmacopeia were crude plant extracts

1990 — < 1% of official medicinal preparations in U.S. Pharmacopeia were crude plant extracts

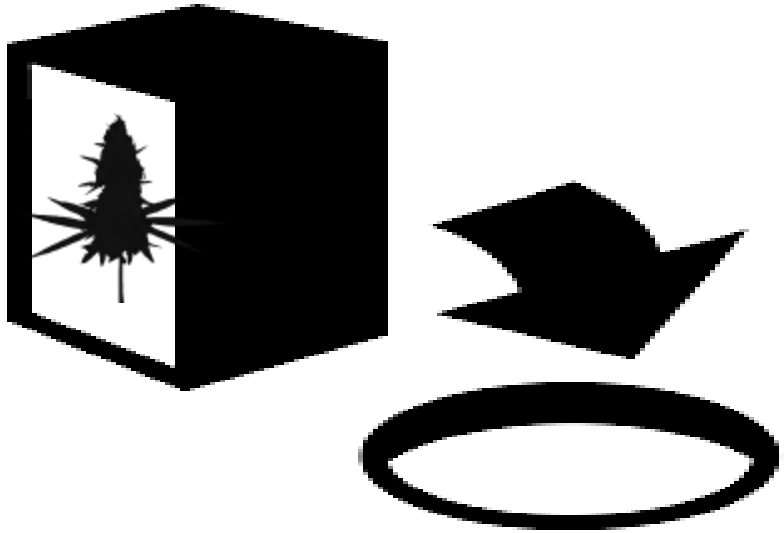
2024 — 3% of official medicinal preparations in U.S. Pharmacopeia were crude plant extracts

ASA

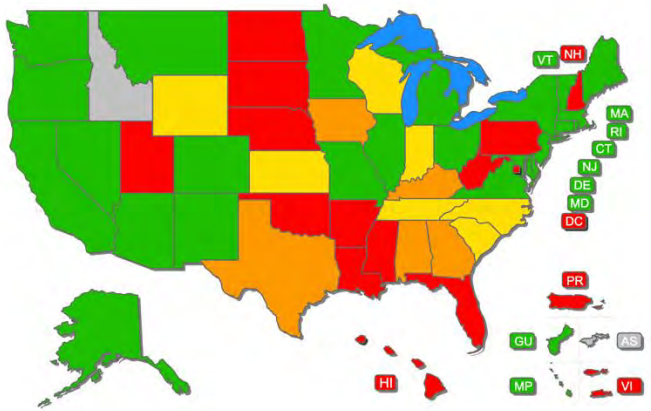
ONLY FDA APPROVED DRUGS ARE "MEDICINE" IN THE US



HEALTHCARE INFRASTRUCTURE

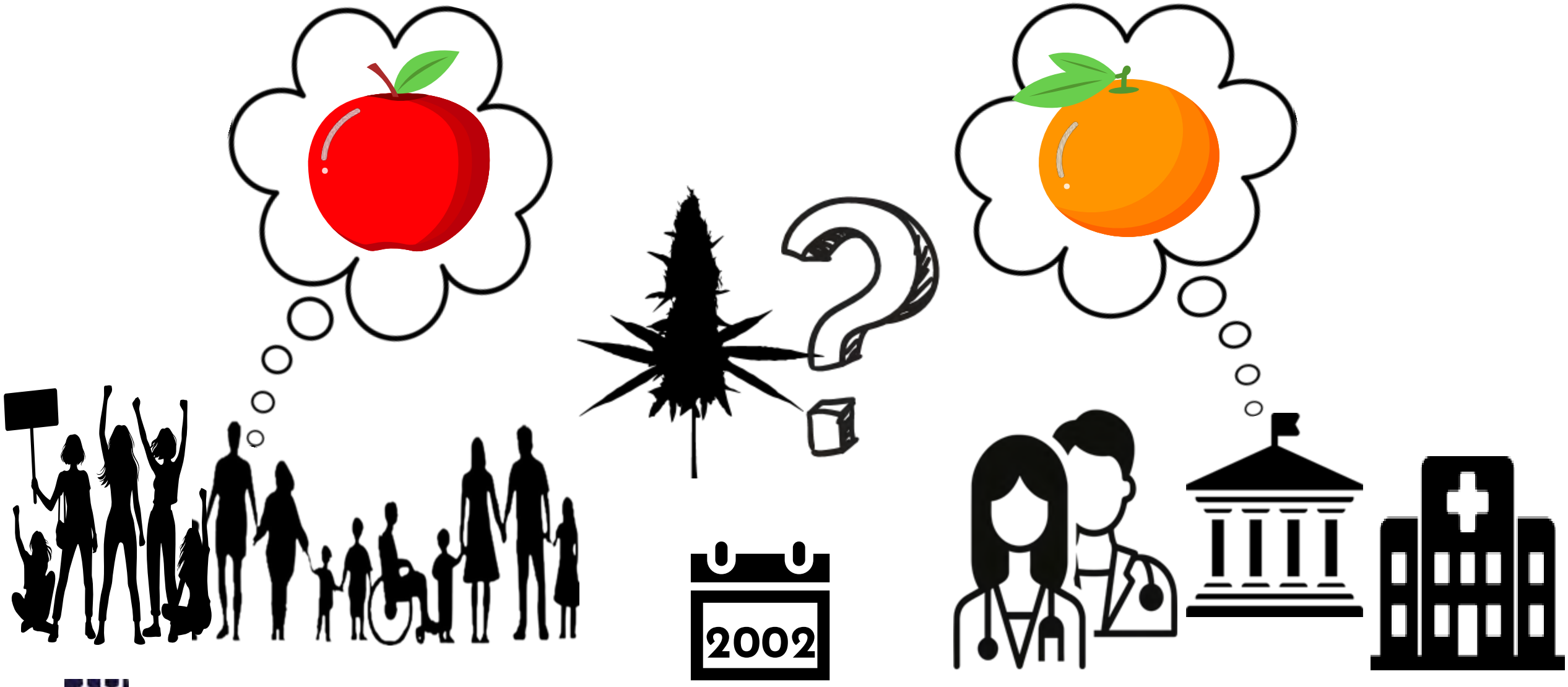


FDA

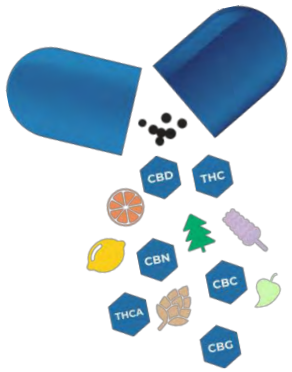


ASA

A RECENT HISTORY OF CANNABIS THERAPEUTICS



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, 5630 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 Ensor 240-402-2733, or (CBER) 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

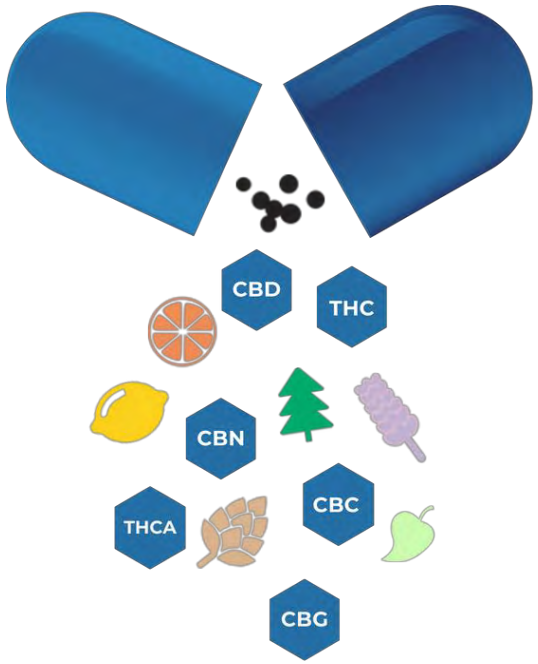
Guidance for Industry

"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.

ASA

TRADITIONAL FUNDING SOURCES FOR THERAPEUTIC DISCOVERY



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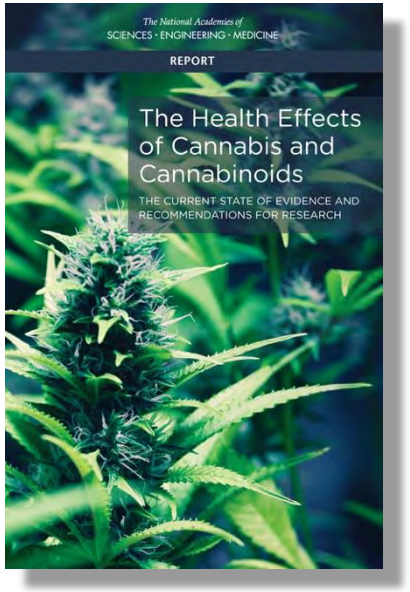
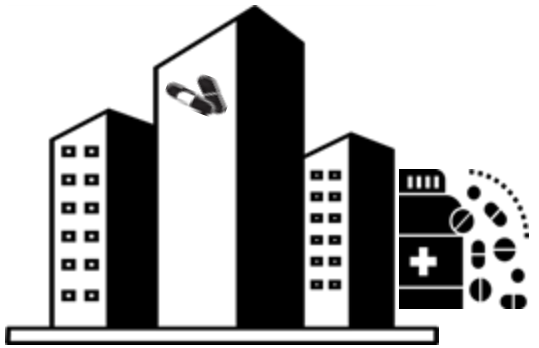


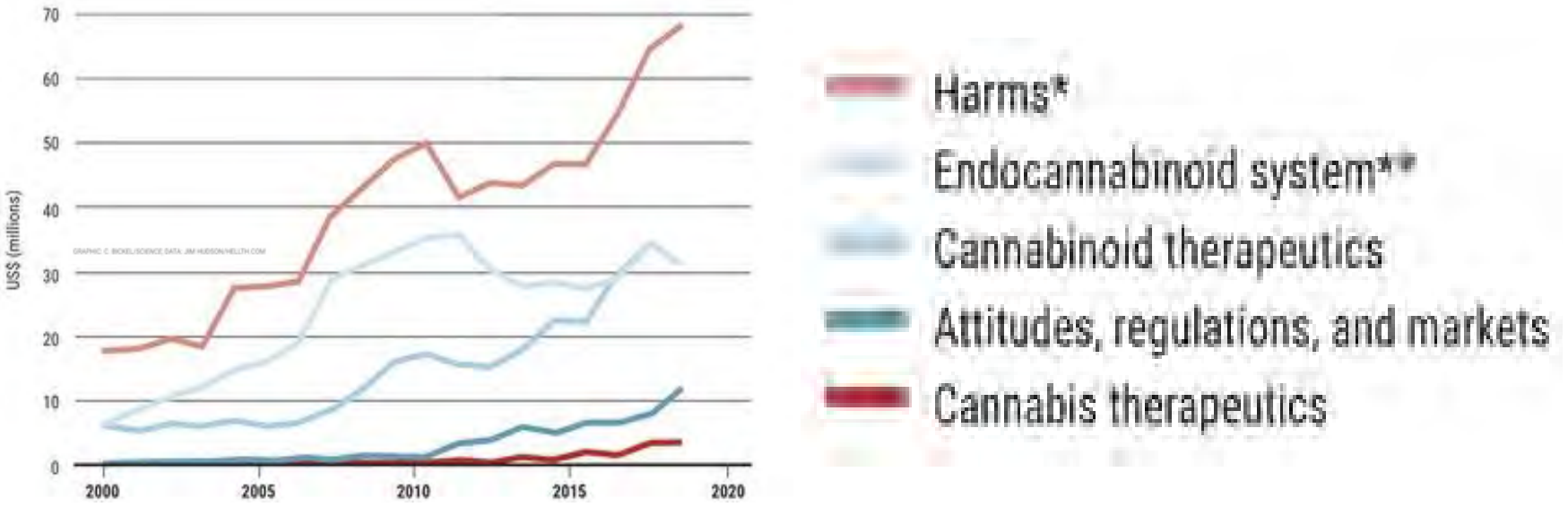


NIH

ASA

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).

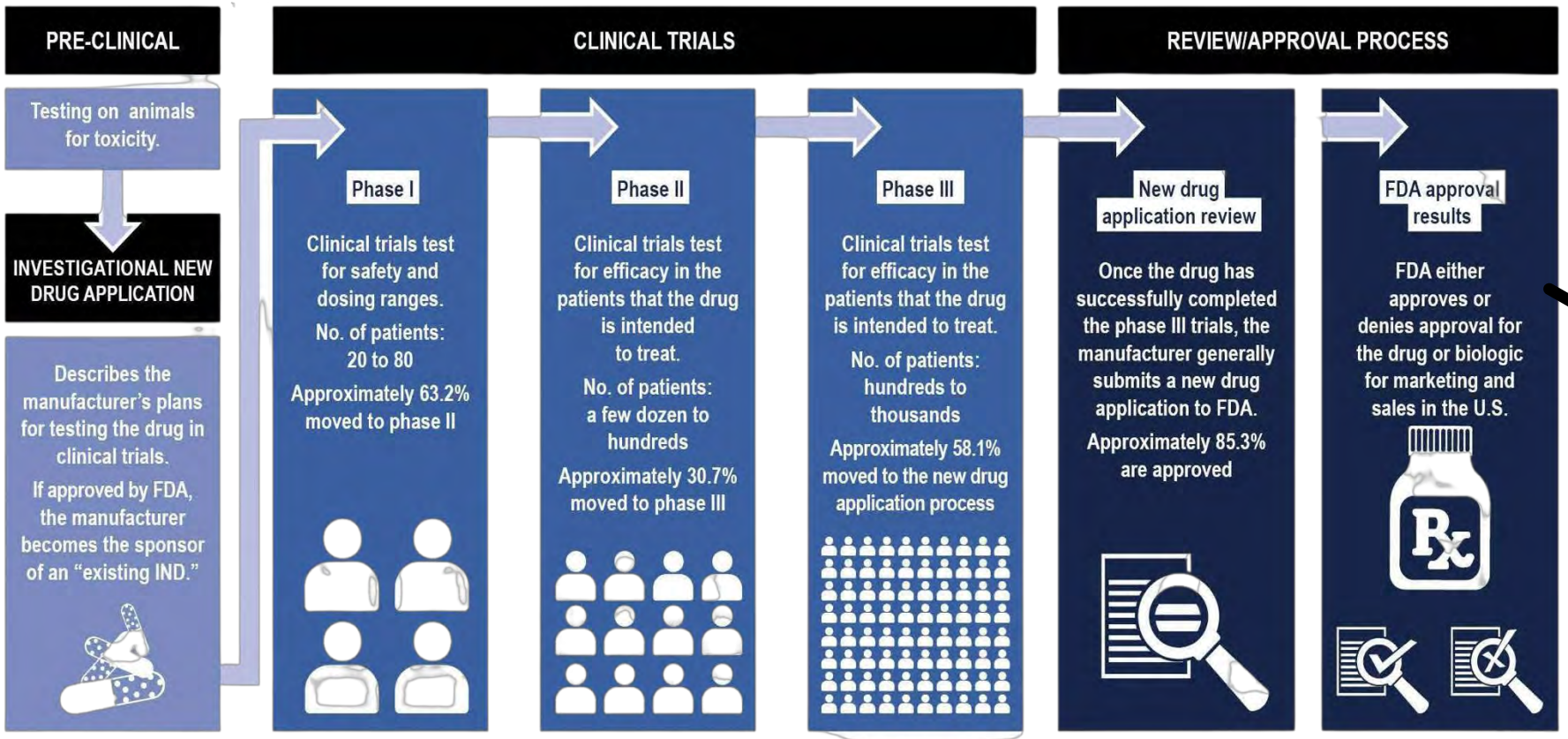
Between 2000 and 2018, NIH spent a similar amount on cannabis research, $1.47B, but instead of investing in research to unlock the therapeutic benefits, a majority of $1.25B were spent on investigating the harms of cannabis consumption.



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

ASA



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

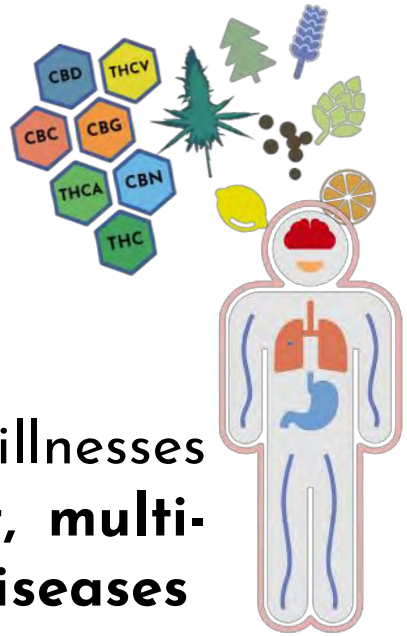
ASA

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

FDA APPROVED CANNABINOID DRUGS

- **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.

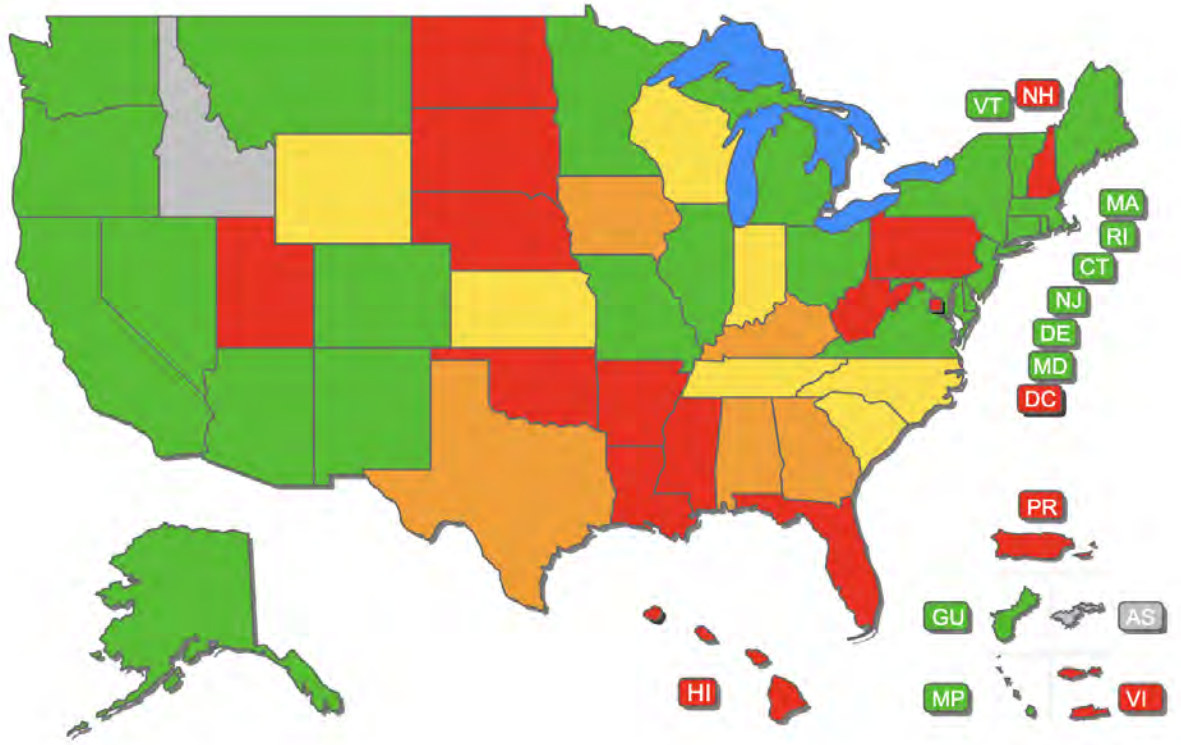


Disorders such as chronic pain, neurodegenerative conditions, and psychiatric illnesses frequently involve multiple overlapping pathways in the body. **Multi-target, multi-component approaches are essential for the treatment of these complex diseases**

ASA

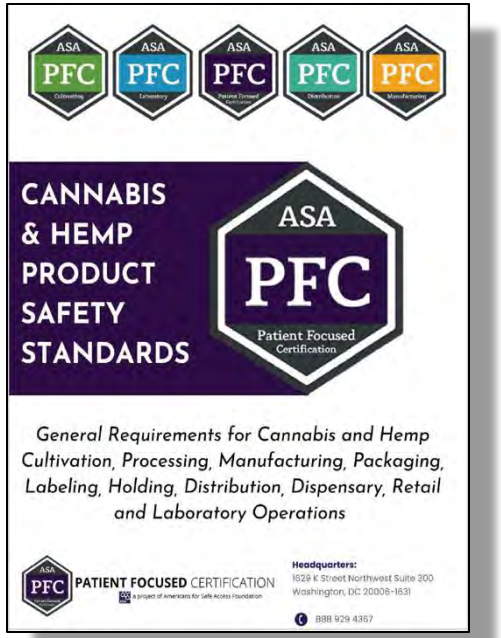
STATE-BASED COMPASSIONATE USE PROGRAMS

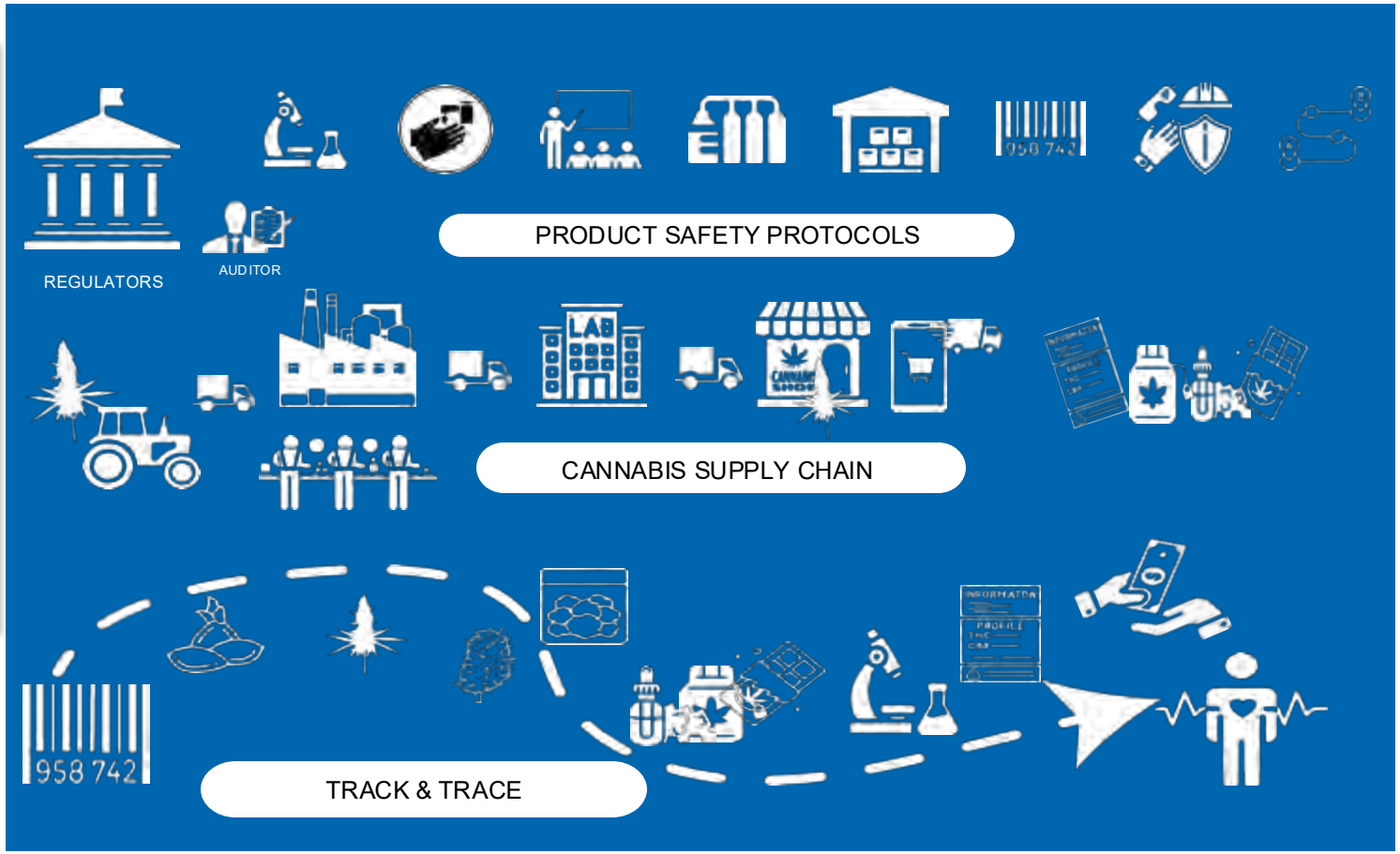
ESTABLISH ACCEPTED MEDICAL USE



ASA

PRODUCT SAFETY PROTOCOLS CANNABIS & CANNABIS-DERIVED PRODUCTS





AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

ASA

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
- 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?

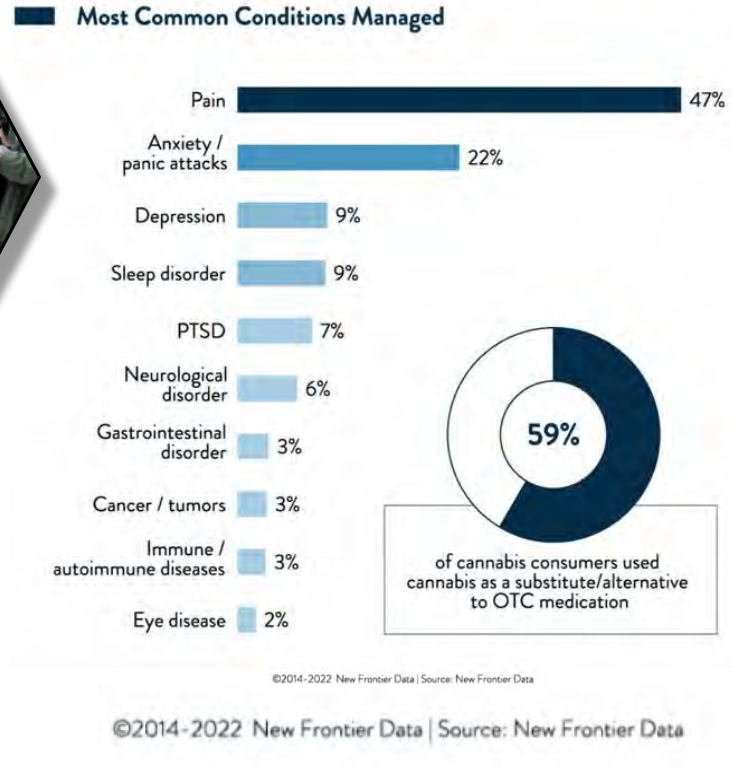
Doctor education on the interactions between cannabis and opioids -/7
- Is doctor education on opioids available through the state department of health or state medical society?
- Is opioid-cannabis education part of the curriculum?

Can pain patients use cannabis? -/3
- Has the state acknowledged the 2016 CDC guidelines on not testing for THC? /2
- Has the state issued specific guidance about testing for THC and other cannabinoids in pain patients? /1

Can pain patients access medical cannabis? -/5
- Is there same-day access with a doctor's recommendation? /2.5
- Can patients use their medical cannabis in home health facilities, hospices, and treatment centers? /2.5

Can the patient afford medical cannabis? -/5
- Veteran discount? /1
- Low income discount? /1
- Is medicine affordable based on patient feedback? /3

Research -/5
- Are there sufficient research & development tax breaks for medical cannabis facilities? /2.5
- Does the state promote research? /2.5



©2014-2022 New Frontier Data | Source: New Frontier Data

END PAIN NOT LIVES
MAKE CANNABIS AN OPTION
A PROJECT OF AMERICANS FOR SAFE ACCESS
ENDPAINNOTLIVES.ORG

END OF STATE DISCRIMINATION OF CANNABIS & PAIN- Pain qualifying conditions in all States & CDC urged pain clinics to stop drug testing for cannabis

ASA

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

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.

ASA

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.

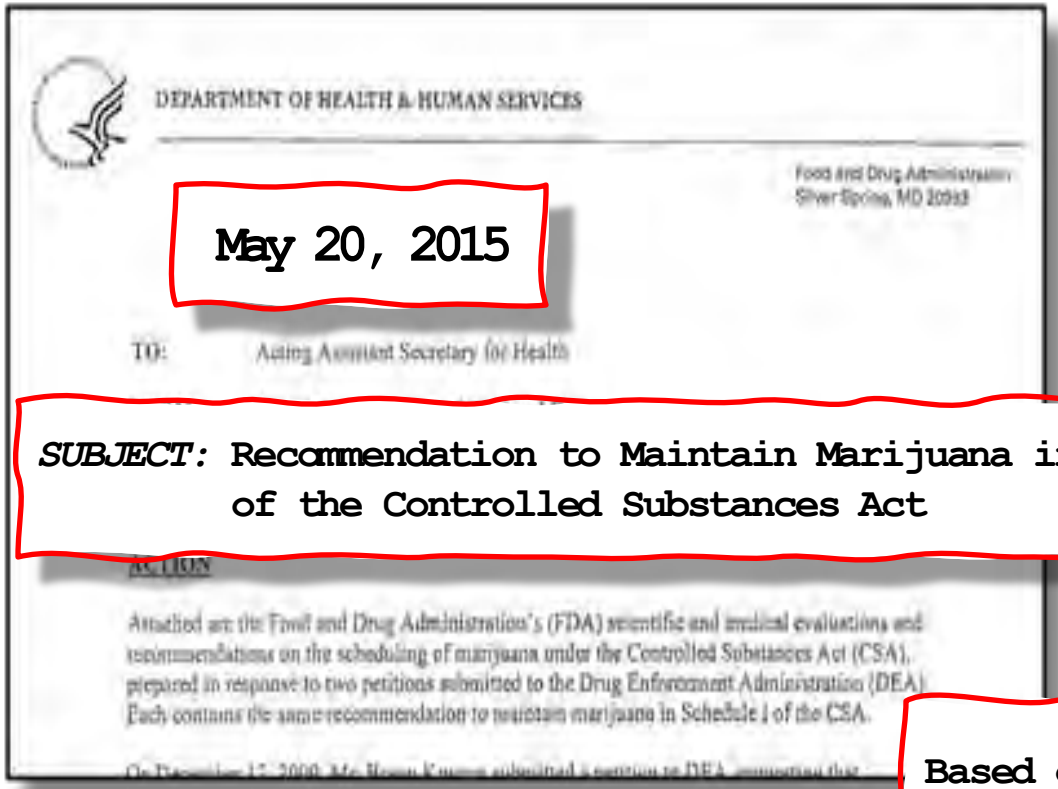
ACTION: Notice of hearing on proposed rulemaking.

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."

ASA

WHAT HAPPENED BETWEEN 2015 & 2023?



DEPARTMENT OF HEALTH & HUMAN SERVICES

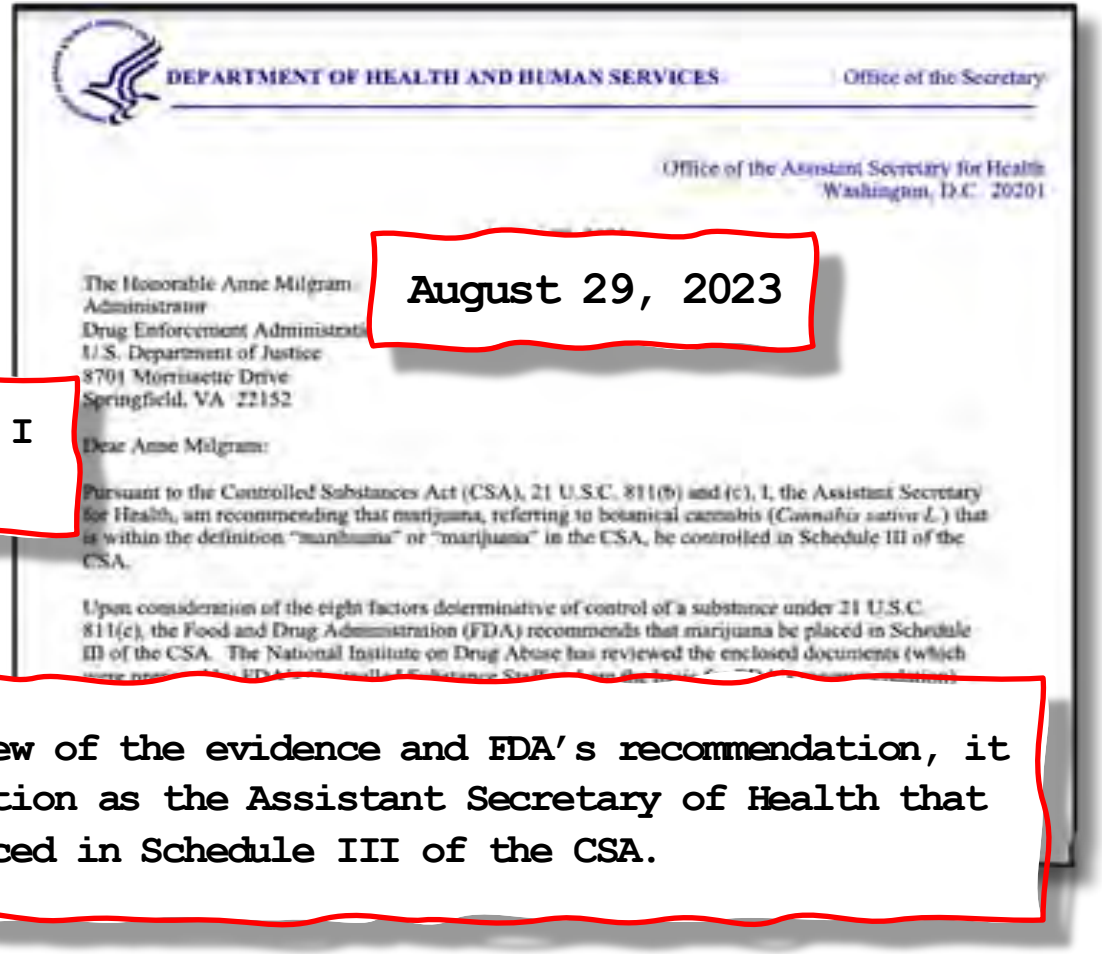
Food and Drug Administration
Silver Spring, MD 20993

May 20, 2015

TO: Acting Assistant Secretary for Health

SUBJECT: Recommendation to Maintain Marijuana in Schedule I of the Controlled Substances Act

Attached are the Food and Drug Administration's (FDA) scientific and medical evaluations and recommendations on the scheduling of marijuana under the Controlled Substances Act (CSA), prepared in response to two petitions submitted to the Drug Enforcement Administration (DEA). Each contains the same recommendation to maintain marijuana in Schedule I of the CSA.



DEPARTMENT OF HEALTH AND HUMAN SERVICES — Office of the Secretary

Office of the Assistant Secretary for Health
Washington, D.C. 20201

August 29, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Anne Milgram:

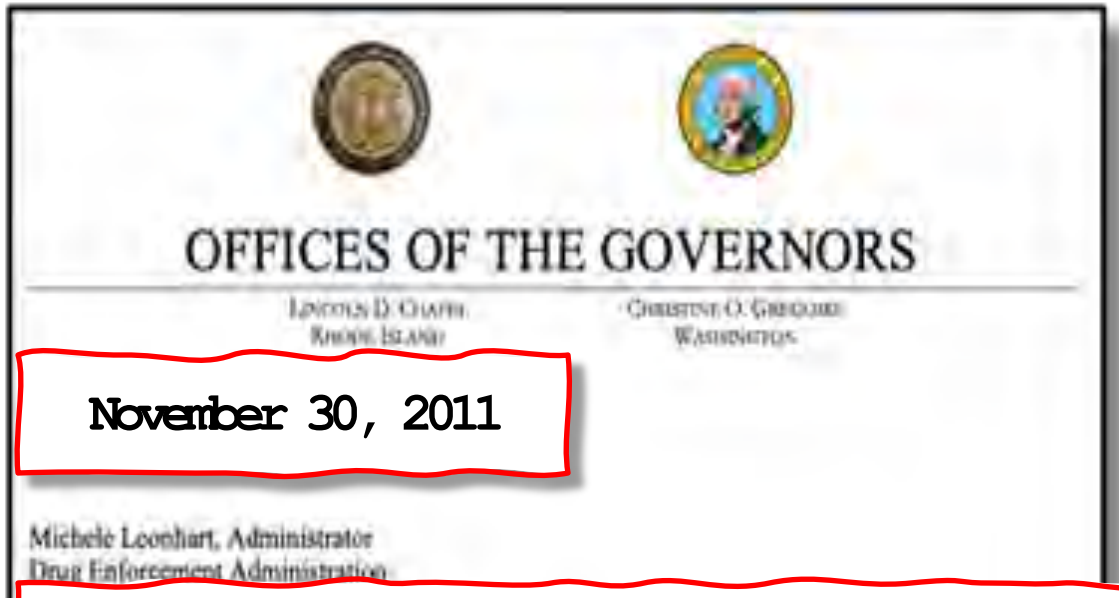
Pursuant to the Controlled Substances Act (CSA), 21 U.S.C. 811(b) and (c), I, the Assistant Secretary for Health, am recommending that marijuana, referring to botanical cannabis (*Cannabis sativa L.*) that is within the definition "marihuana" or "marijuana" in the CSA, be controlled in Schedule III of the CSA.

Upon consideration of the eight factors determinative of control of a substance under 21 U.S.C. 811(c), the Food and Drug Administration (FDA) recommends that marijuana be placed in Schedule III of the CSA. The National Institute on Drug Abuse has reviewed the enclosed documents (which

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.

ASA

HHS 2015 FINDINGS BASED ON DATA PRESENTED IN A 2011 PETITION

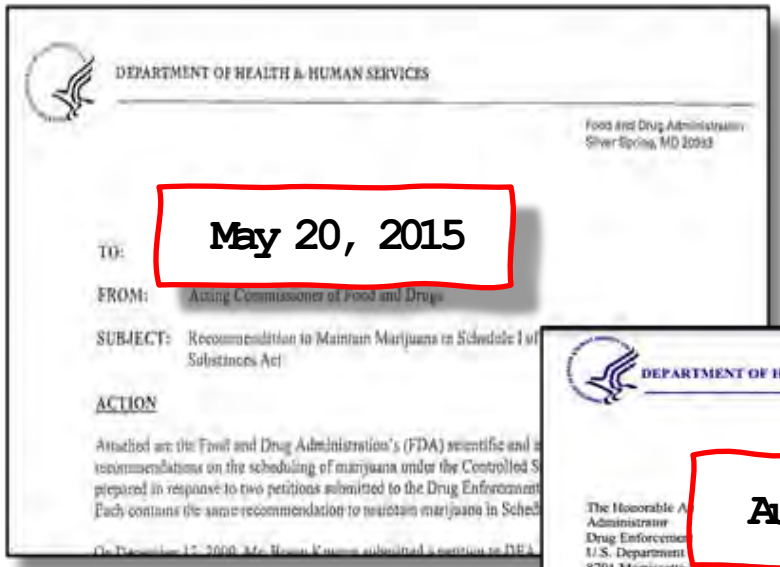


OFFICES OF THE GOVERNORS

November 30, 2011

Michele Leonhart, Administrator
Drug Enforcement Administration

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

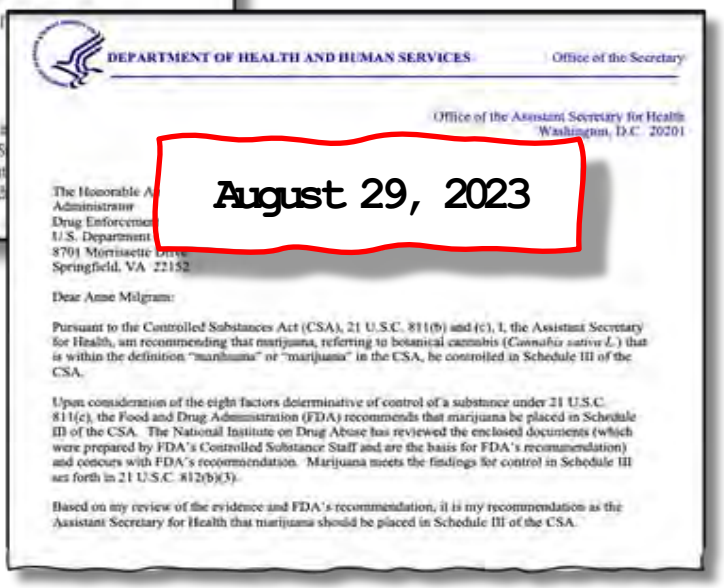
May 20, 2015

TO:

FROM: Acting Commissioner of Food and Drugs

SUBJECT: Recommendation to Maintain Marijuana in Schedule I of Substances Act

ACTION



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Upon consideration of the eight factors determinative of control of a substance under 21 U.S.C. 811(c), the Food and Drug Administration (FDA) recommends that marijuana be placed in Schedule III of the CSA. The National Institute on Drug Abuse has reviewed the enclosed documents (which were prepared by FDA's Controlled Substance Staff and are the basis for FDA's recommendation) and concurs with FDA's recommendation. Marijuana meets the findings for control in Schedule III set forth in 21 U.S.C. 812(b)(3).

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

ASA

12 YEARS OF KEY SCIENTIFIC & MEDICAL DISCOVERIES IMPACT RESCHEDULING FINDINGS

> In 2015, HHS recommended a finding that marijuana had no CAMU due in part to a lack of adequate safety studies or evidence that qualified experts accepted marijuana for use in treating a specific, recognized disorder. 81 FR 53688 at 53707. As a result of its most recent evaluation, which incorporates post-2016 data into its analysis, HHS recommends a finding that marijuana has a Currently Accepted Medical Use CAMU in Treatment in the United States.

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

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."

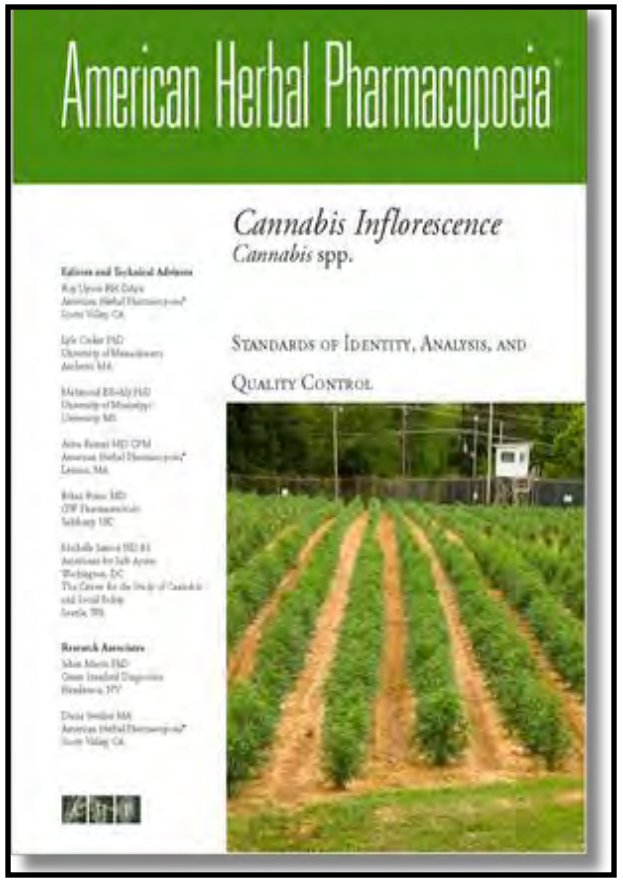
DEA, DOJ: Notice of Proposed Rulemaking: Schedules of Controlled Substances: Rescheduling of Marijuana May 21, 2024

FIRST PRODUCT SAFETY PROTOCOLS FOR CANNABIS SUPPLY CHAIN

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.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION



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

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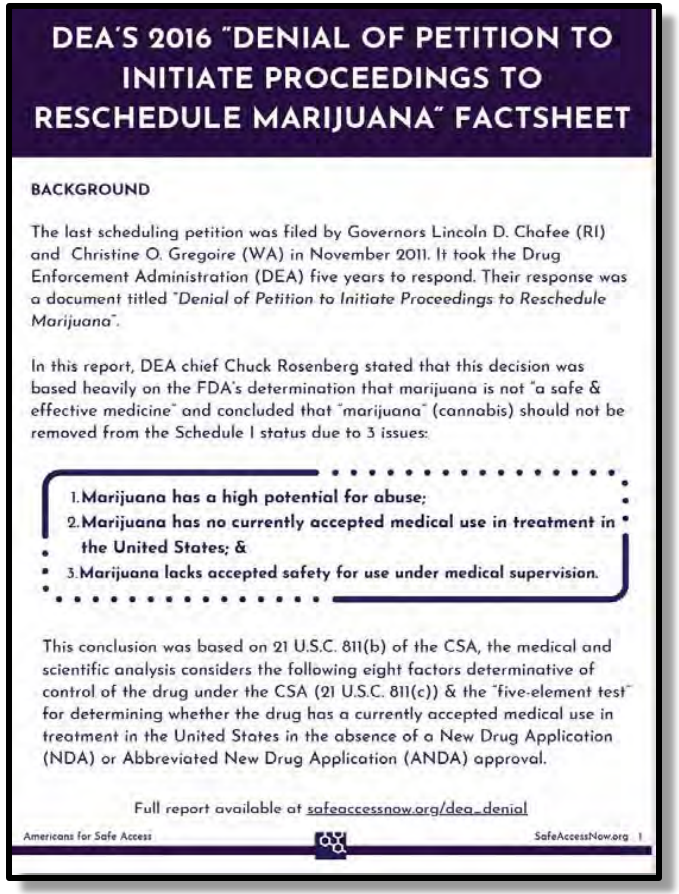
In 2015, HHS indicated that "medical practitioners who are not experts in evaluating drugs cannot be considered qualified experts."

(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."



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

HHS's 2015 "Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act"

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

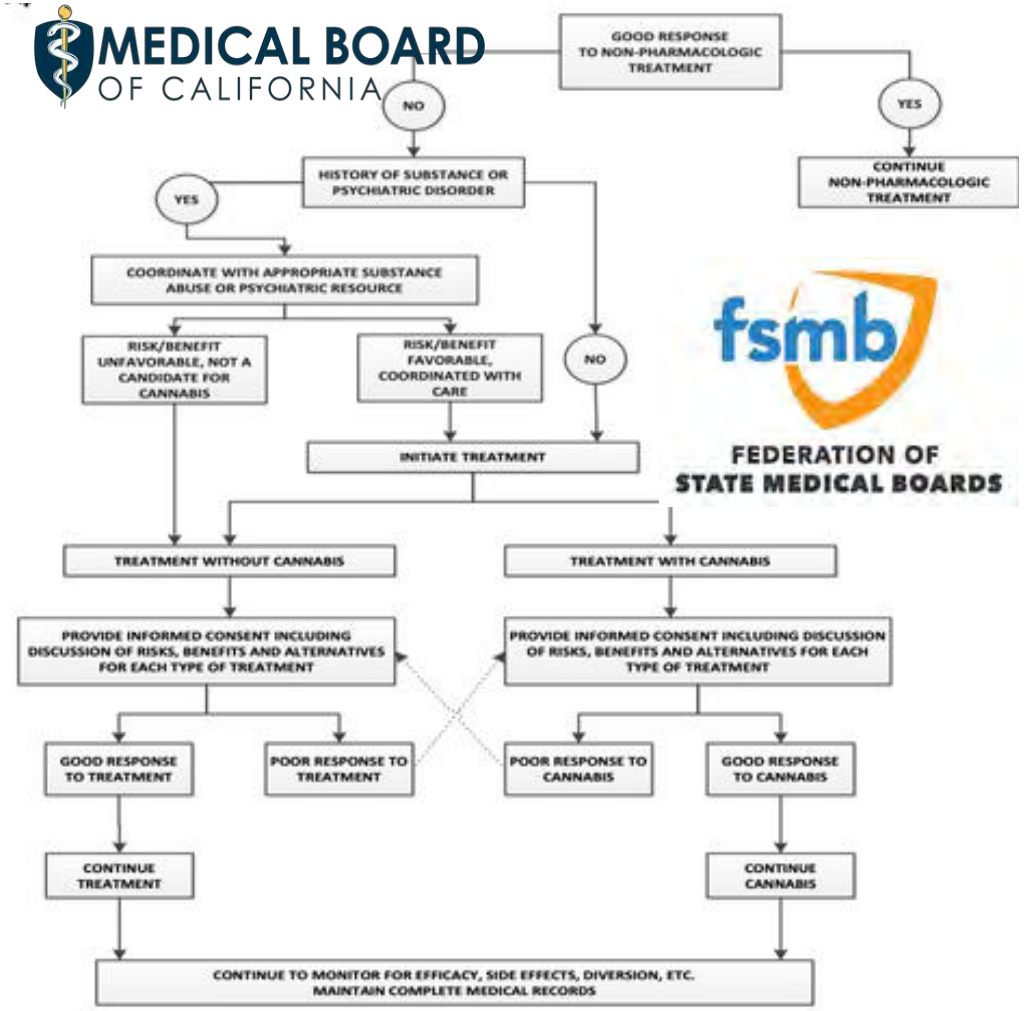
Connecticut Department of Consumer Protection/Board of Physicians
Delaware Department of Health & Social Services
Hawaii Department of Health
Illinois Department of Public Health
State of Michigan Department of Licensing & Regulatory Affairs
Minnesota Department of Health
New Jersey Department of Health
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"



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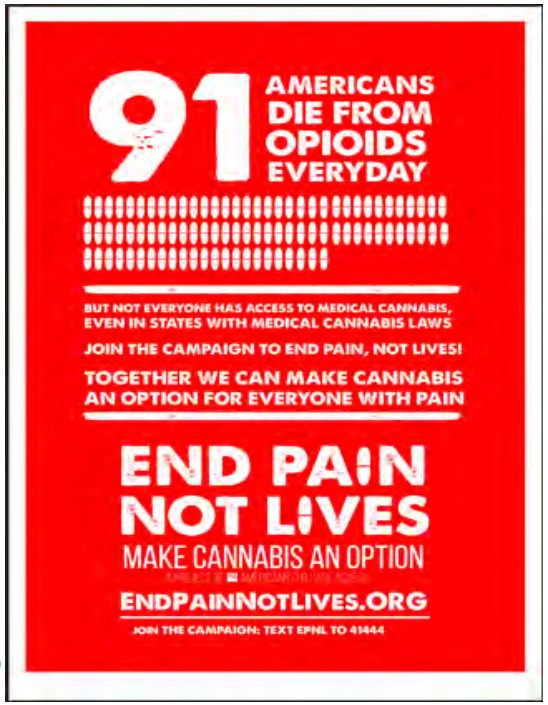
2016- CDC RECOGNIZES CANNABIS' ROLE IN TREATING PAIN & MITIGATING OPIOID DEATHS

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

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

> 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 tetrahyrdocannabinol (THC).



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


FEDERAL REGISTER

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


BEFORE THE UNITED STATES DEPARTMENT OF JUSTICE
INFORMATION QUALITY GUIDELINES STAFF

REQUEST FOR CORRECTION OF INFORMATION DISSEMINATED BY DEA REGARDING MARIJUANA (CANNABIS)

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

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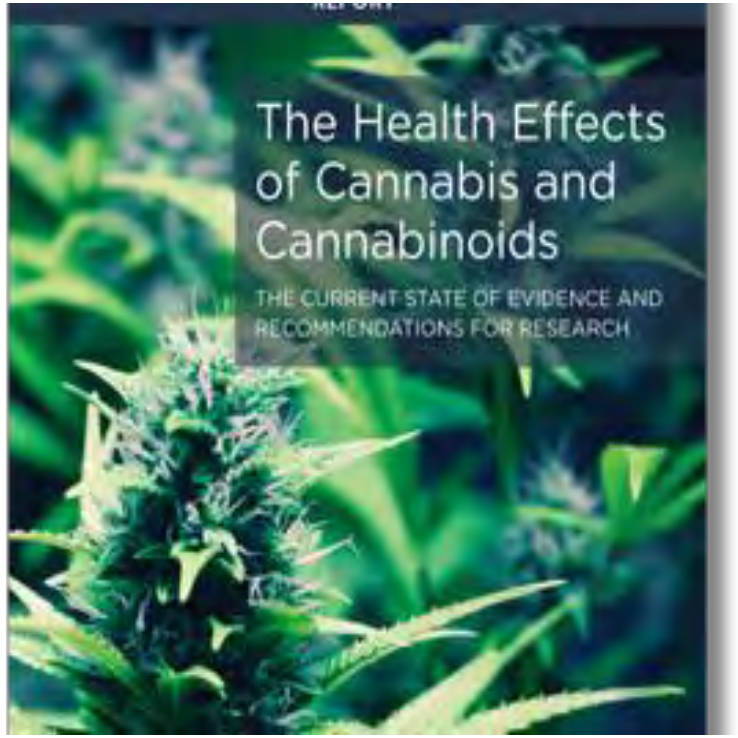
National Institute on Drug Abuse

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 (MTF, 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:

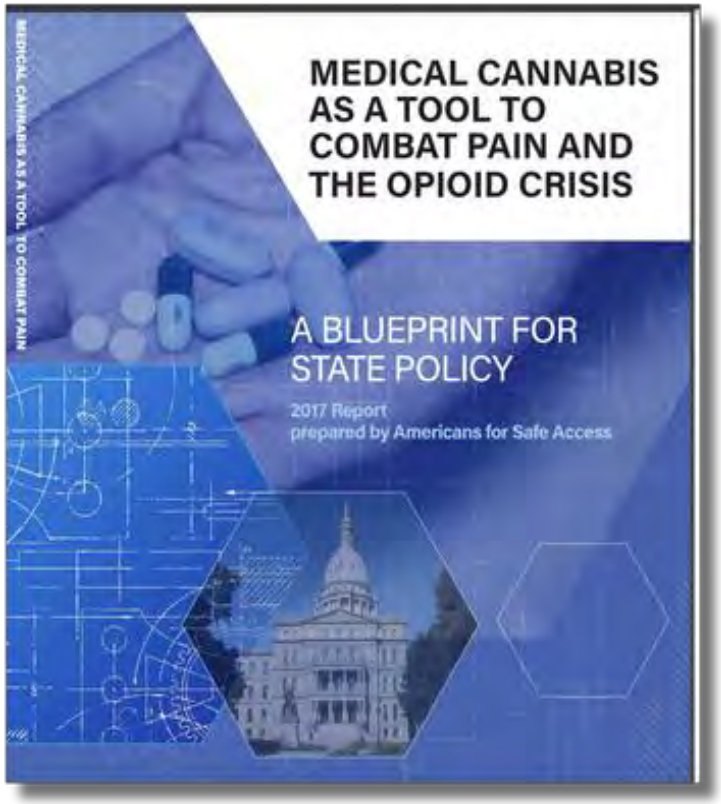


"There is conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults, as anti-emetics in the treatment of chemotherapy-induced nausea and vomiting, and for improving patient-reported multiple sclerosis spasticity symptoms."

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.

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2019

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

CMCR

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

Thomas Jefferson University
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

Consortium for Medical Marijuana Clinical Outcomes Research

UCI Center for the Study of Cannabis

CCR CENTER FOR CANNABIS RESEARCH

NIH National Center for Complementary and Integrative Health

Berkeley Cannabis Research Center

Institute of Cannabis Research
COLORADO STATE UNIVERSITY PUEBLO
Advancing Cannabis Science

RSMJ
RESEARCH SOCIETY ON MARIJUANA

JOHNS HOPKINS Cannabis Science Laboratory

UCDAVIS OFFICE OF RESEARCH

UC RIVERSIDE Center for Cannabinoid Research

UCLA Center for Cannabis and Cannabinoids

STEM
Systematically Testing the Evidence on Marijuana

YC-SCAN2 YALE CENTER FOR THE SCIENCE OF CANNABIS AND CANNABINOIDS

CENTER FOR Cannabis Policy, Research, and Outreach
WASHINGTON STATE UNIVERSITY

Oregon State University | COLLEGE OF AGRICULTURAL SCIENCES | GLOBAL HEMP INNOVATION CENTER

SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF MINNESOTA

HEALTH
UNIVERSITY OF UTAH

DREXEL UNIVERSITY Medical Cannabis Research Center
Dornsife School of Public Health
Drexel College of Medicine

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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

2022: 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.

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2023

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

2023 HHS FINDS CANNABIS HAS "CURRENTLY ACCEPTED MEDICAL USE"

CRACKS IN U.S. 50 YEAR PROHIBITION OF CANNABIS

“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

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.

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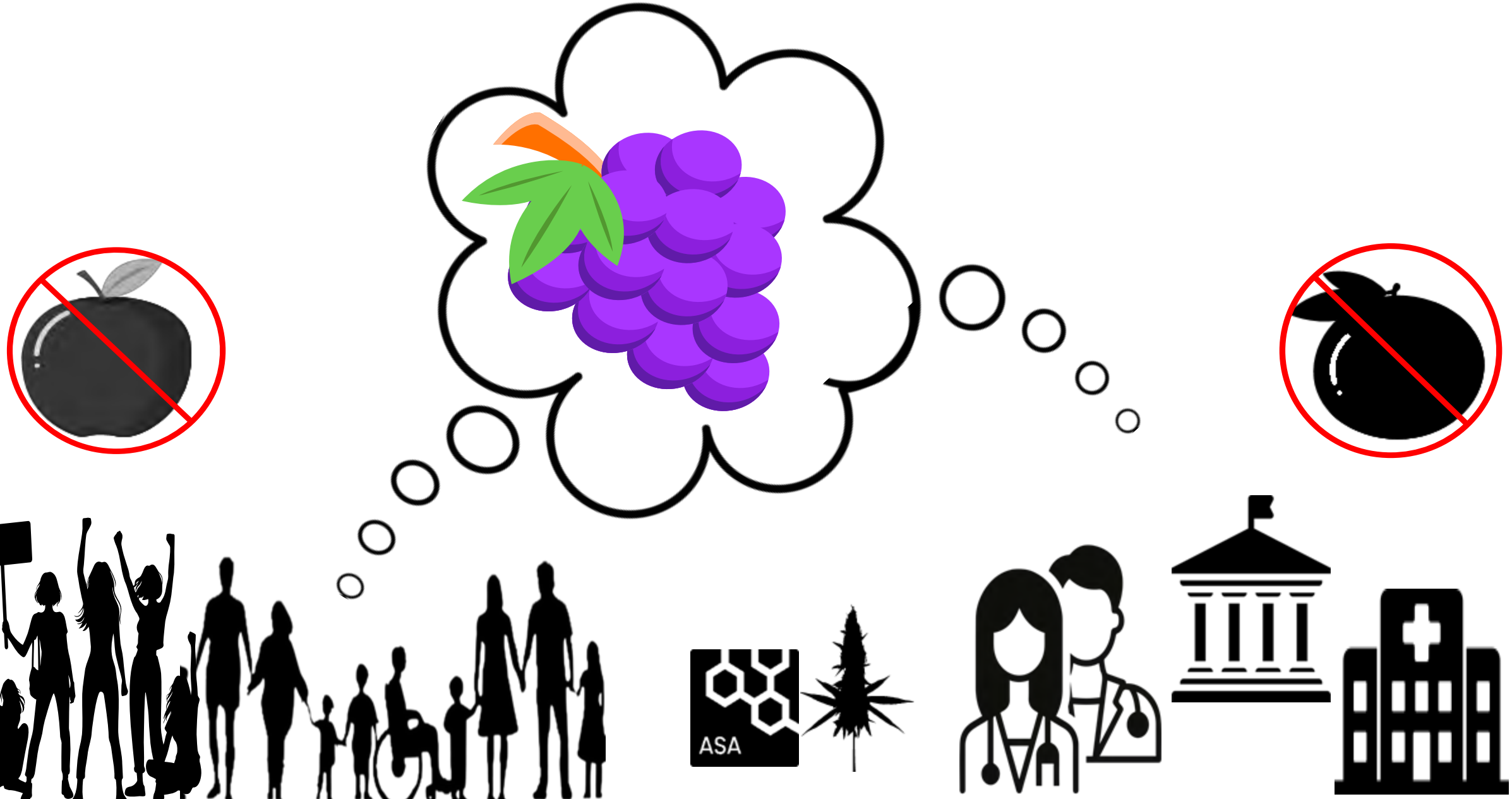
CHRONIC & MENTAL HEALTH CONDITIONS ARE RESPONSIBLE FOR 90% OF THE $4.1 TRILLION SPENT ANNUALLY ON U.S. HEALTHCARE

$35 BILLION ANNUALLY ON OPIOID MISUSE & RELATED HEALTHCARE COSTS

30 MILLION AMERICANS HAVE A RARE DISEASE. 95% OF THE 7,000 KNOWN RARE DISEASES HAVE NO FDA-APPROVED TREATMENT.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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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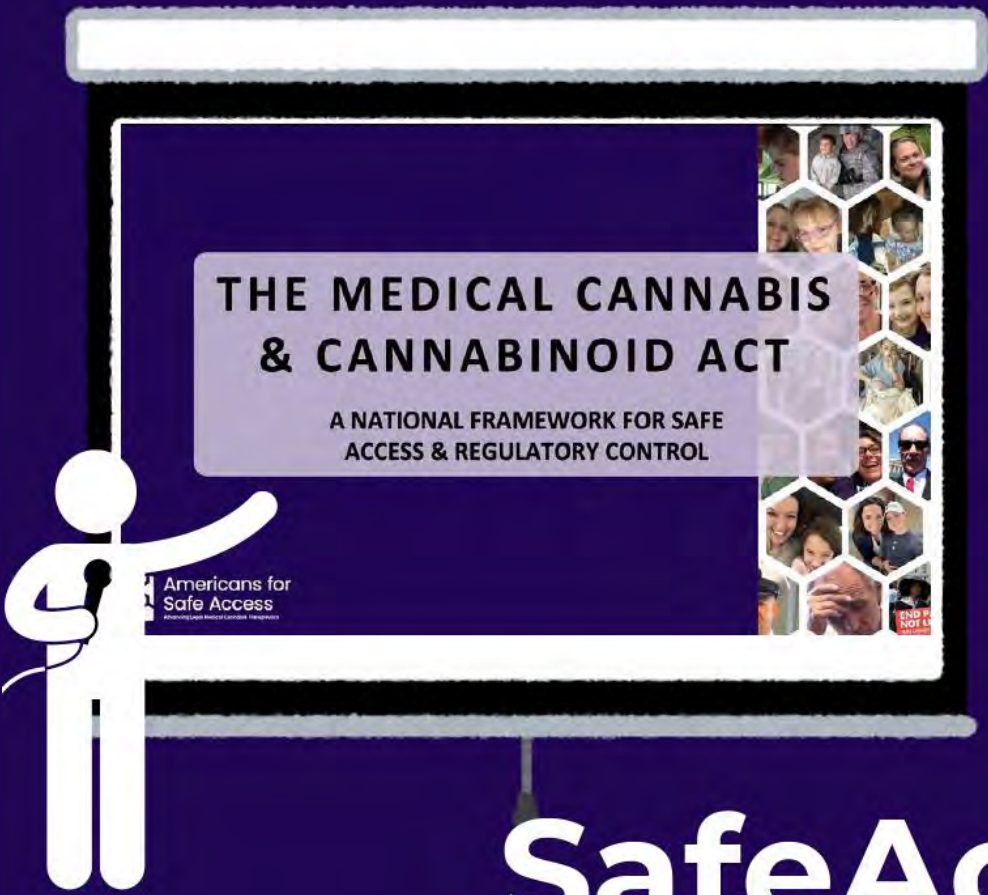

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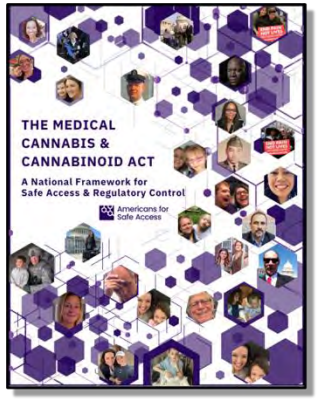

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Americans for Safe Access

Advancing Legal Medical Cannabis Therapeutics

THANK YOU!