



EMERGING THERAPIES


The Legal Landscape for Cannabis and Psychedelics
and Future Implications for MCOs

Presented by Matthew Donze, Jason Mayer, Dasheeda Dawson
June 30, 2025


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Today's Emerging Therapies



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HISTORY



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Cannabis

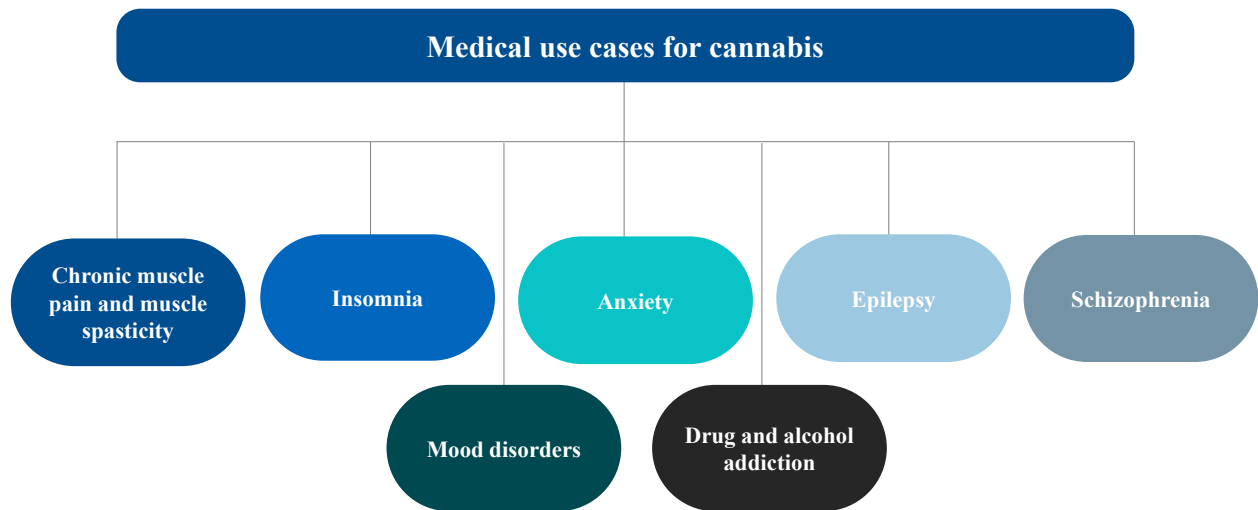


- Cannabis (*cannabis indica*, *cannabis sativa*, *cannabis ruderalis*) is a plant found natively across the world. It has been used medicinally across many cultures to treat pain, fever, and illness
- Cannabis was grown by American settlers for use as both a textile and medicine. It was commonly found in pharmacies up through the 19th century
- In 1937, the U.S. Congress effectively criminalized marijuana with the Marijuana Tax Act. The Act was overturned in 1969, but Congress passed the Controlled Substances Act (“CSA”) in 1970
- The CSA lists cannabis as a Schedule I substance, indicating “no currently accepted medical use and a high potential for abuse.” 21 U.S.C. §812(b)(1)
- Scientifically speaking, the term “cannabis” encompasses both hemp and marijuana

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Current Medical Uses

Despite its Schedule I status, cannabis is currently being recommended to millions of patients nationwide through state legal medical cannabis programs, where it has shown efficacy in treatment of a variety of physical and mental conditions. The top three reasons people shop the adult-use market (regardless of state) are **sleep, pain, and anxiety**.



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Ketamine



- Ketamine (C₁₃H₁₆ClNO) was first synthesized in the 1960s as an anesthetic and analgesic. It was quickly approved by the FDA for use as a field anesthetic for soldiers in the Vietnam War
- During the 1970s and '80s, Ketamine was used recreationally for its psychoactive and dissociative effects
- In 1999, the DEA added Ketamine to Schedule III of the CSA, indicating a "moderate to low potential for physical and psychological dependence." 21 U.S.C. §812(b)(3)

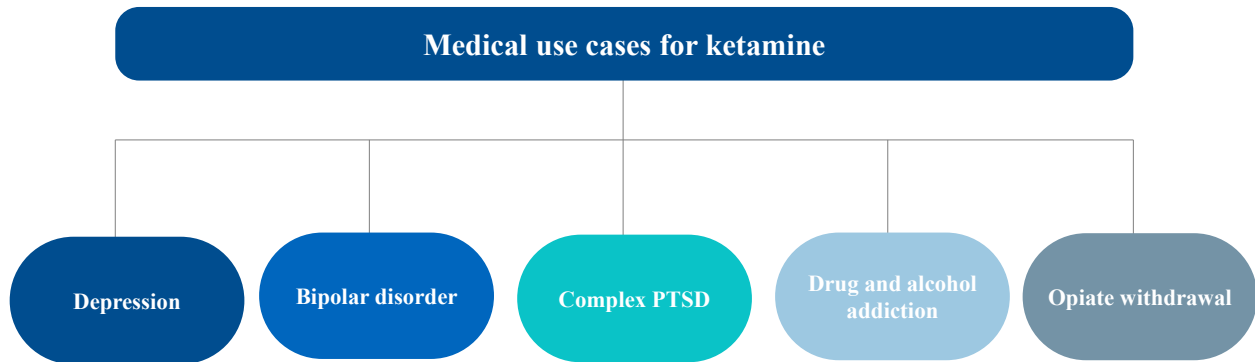
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Current Medical Uses

While Ketamine still has occasional use in its FDA-approved role as an analgesic and anesthetic, particularly for patients with sensitivity to other anesthetic drugs, it is more often prescribed today for “off-label” uses.



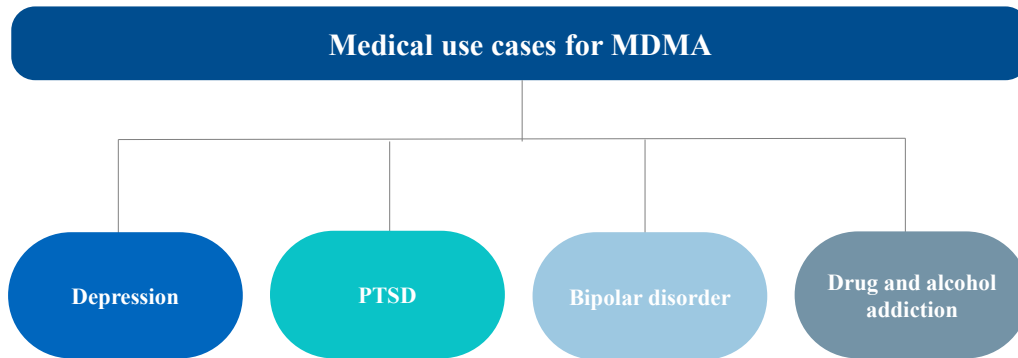
MDMA



- MDMA (methylenedioxymethamphetamine) was initially synthesized by Merck in 1912 as an appetite suppressant, but it was largely ignored for many years
- In the 1970s, MDMA was popularized as a “club drug” for its psychoactive, empathogenic and entactogenic effects
- In 1985, the DEA placed MDMA onto Schedule I of the CSA, indicating “no currently accepted medical use and a high potential for abuse.” *21 U.S.C. §812(b)(1)*

Current Medical Uses

In clinical trials, MDMA has demonstrated efficacy in treating a variety of conditions.



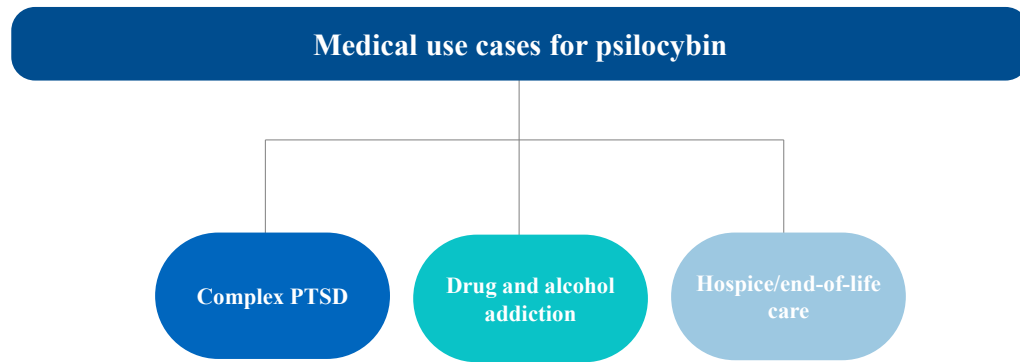
Psilocybin



- Psilocybin (4-phosphoryloxy-N,N-dimethyltryptamine) is a psychoactive substance derived from various species of mushrooms found globally
- It is one of the oldest-known psychoactive substances, used by indigenous cultures around the world throughout pre-history
- When the CSA was passed in 1970, psilocybin mushrooms were included on Schedule I, indicating “no currently accepted medical use and a high potential for abuse.” 21 U.S.C. §812(b)(1)

Current Medical Uses

Though trials have been limited, psilocybin has shown potential efficacy in treating notoriously difficult psychological conditions.



LEGAL LANDSCAPE

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Two Parallel Regulatory Regimes

Federal

- Availability and access for medicinal drugs is determined by the Controlled Substances Act (“CSA”)
- The CSA is divided into five schedules, which rank drugs from the least useful and most harmful – Schedule I – to the most useful and least harmful – Schedule V. 21 U.S.C. § 812(b).
- Drugs on Schedules II through V must be approved by the FDA for specific medical uses before being allowed to enter interstate commerce.

State

- State law is largely pre-empted by the CSA, which governs all drugs that enter interstate commerce.
- State laws are only constitutional to the extent they do not “stand as an obstacle to the accomplishment and execution of the purposes and objectives of the CSA.” *Beek v. City of Wyo.*, 495 Mich. 1 (2014).
- The CSA declines to “occupy the field” and leaves room for states to pass laws regulating drugs within their own borders. *Id.*

Federal: Drug Schedules Under the CSA

SCHEDULE I	SCHEDULE II	SCHEDULE III	SCHEDULE IV	SCHEDULE V
<ul style="list-style-type: none"> • No currently accepted medical use; high potential for abuse • Cannabis, heroin, psilocybin, MDMA, peyote 	<ul style="list-style-type: none"> • Dangerous; high potential for abuse and/or dependence. • Cocaine, Adderall, methamphetamine 	<ul style="list-style-type: none"> • Moderate to low potential for abuse and/or dependence. • Ketamine, anabolic steroids, Tylenol with codeine 	<ul style="list-style-type: none"> • Low potential for abuse and/or dependence. • Xanax, Ambien, Valium 	<ul style="list-style-type: none"> • Lowest potential for abuse, generally for low-grade symptoms and pain. • Robitussin, cough medicine, Motofen

FDA Approval



- Any drug listed on Schedules II – V is eligible for FDA approval
- The FDA does not issue generalized approval for substances. The FDA reviews and approves the specific application of a drug or therapy to treat a particular condition
- In making their determination to approve or deny an application, the FDA relies on clinical trials and peer-reviewed studies to determine the safety and efficacy of a substance
- Only once approved by the FDA for a particular purpose, a drug may be manufactured and distributed in interstate commerce in the United States

Hurdles Facing Schedule I Substances



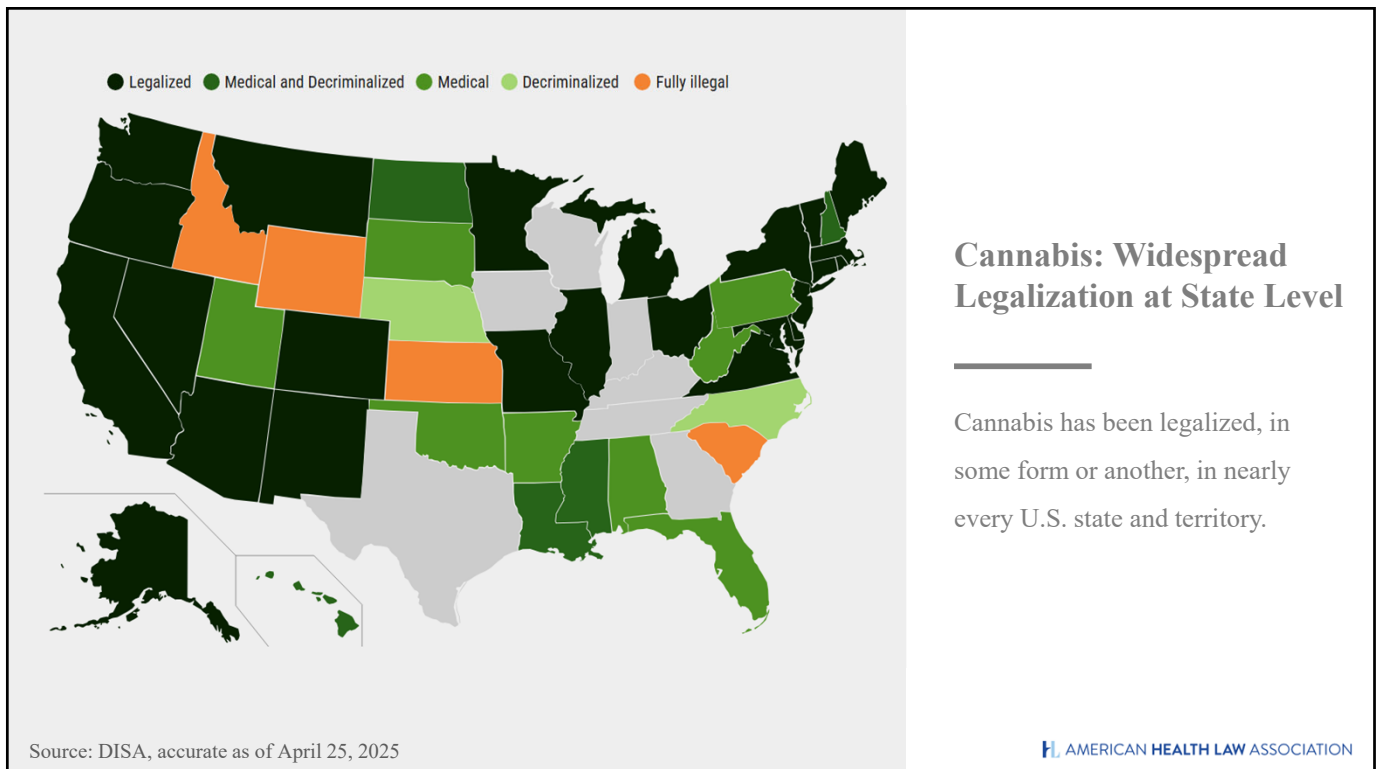
- Research on the medicinal effects of CSA Schedule I substances is particularly difficult to conduct, requiring a long approval process, funding restrictions, and acquisition of the Schedule I substances directly from DEA-approved laboratories
- This process makes it difficult to generate quality medical evidence of the kind that could convince the DEA to change a given drug's Scheduling
- As a result, Schedule I drugs tend to stay on Schedule I indefinitely

CANNABIS

A STATE-LED LEGALIZATION INITIATIVE

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Federal: Cannabis' Gray Legality

Despite being one of the CSA's original Schedule I substances, where it has remained for more than 50 years, cannabis-based medicine has seen widespread adoption by states over the past several decades.



Executive

DOJ memoranda such as the *Cole Memorandum* establish that the DOJ will not prioritize enforcement of the CSA against entities engaged in state-legal cannabis activities, provided certain federal interests are protected (i.e., no interstate commerce, no marketing to children, etc.).

However, the Trump administration's current budget would repeal the Rohrabacher-Farr amendment – and raise concerns for the legal cannabis industry.



Legislative

The Rohrabacher-Farr Amendment, which has been passed as part of budget or spending bills for the last decade, bans the expenditure of federal dollars on drug enforcement against state-legal cannabis activities.



Judicial

Courts have held that the Rohrabacher-Farr Amendment effectively precludes the DEA from using its budget to enforce the CSA against state-legal cannabis activities. See, e.g., *United States v. McIntosh*, 833 F.3d 1163 (9th Cir. 2016).

Federal: FDA Action on Cannabis

To date, the FDA has only approved one medicinal product containing CBD (but no THC): EPIDIOLEX, a drug for treatment of specific seizure disorders (approved 2018).

The FDA has issued warning letters to companies distributing CBD and THC products under circumstances outside the federal government's general posture of non-enforcement. The latest round of letters was sent in 2021.

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Interstate commerce

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Deceptive marketing

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Suggesting medicinal use or therapeutic effects

Federal: Cannabis – HHS Letter on CAMU

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On August 29, 2023, HHS published an open letter calling for the rescheduling of cannabis to Schedule III of the CSA based on its conclusion that cannabis did in fact have currently accepted medical uses:

Based on the totality of the available data, we conclude that there exists some credible scientific support for the medical use of marijuana in at least one of the indications for which there is widespread current experience in the United States, as identified by OASH under Part 1 of the CAMU test. Seven indications were selected for evaluation under Part 2 of the CAMU test based on conclusions from Part 1 of the CAMU test as well as the FDA's analysis of the landscape of medical use of marijuana. The indications evaluated anorexia related to a medical condition, anxiety, epilepsy, inflammatory bowel disease, nausea and vomiting (e.g., chemotherapy-induced), pain, and post-traumatic stress disorder. The analysis and conclusions on the available data are not meant to imply that safety and effectiveness have been established for marijuana that would support FDA approval of a marijuana drug product for a particular indication. However, the available data do provide some level of support for the way marijuana is being used in clinical practice. Thus, based on the widespread HCP experience and the extent of medical use evaluated by OASH under the Part 1 test, and an evaluation of available credible scientific support described herein for at least some therapeutic uses identified in the Part 1 test, we find that that, for purposes of the drug scheduling criteria in 21 U.S.C. 812(b), marijuana has a CAMU in the United States for: anorexia related to a medical condition; nausea and vomiting (e.g., chemotherapy-induced); and pain.

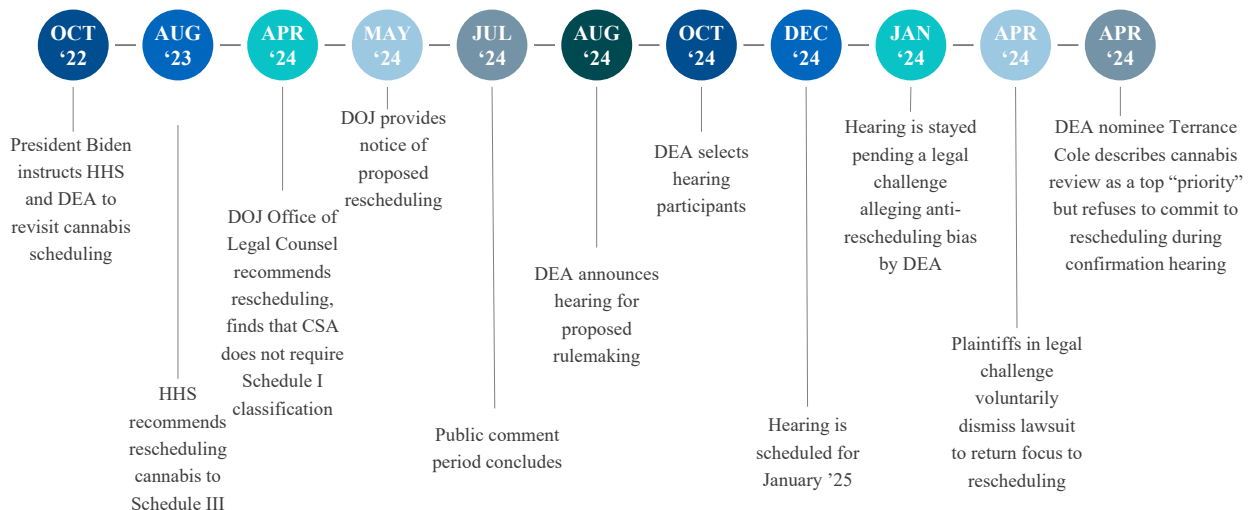
Rescheduling would allow clinical trials on cannabis to go forward at an unprecedented pace, potentially paving the way for FDA approval of new cannabis-derived drugs and treatments. **If approved by FDA, cannabis products will be legally no different from other Schedule III medicines, such as Tylenol with Codeine.**

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Timeline: Rescheduling Review for Cannabis

While rescheduling efforts are currently on hold, cannabis could be reclassified as a Schedule III substance within the next three to twelve months – *if* the DEA adopts a pro-rescheduling stance under the Trump administration.



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Cannabis' Move to Schedule III (On Hold)



- Rescheduling efforts have stalled in 2025, and the Trump administration's nominee for DEA administrator, Terrance Cole, has taken anti-legalization positions in the past. Cole has declined to commit to rescheduling cannabis to Schedule III, though he has described reviewing the issue as a "priority."
- For now, cannabis remains a Schedule I controlled substance. State regulations mandating or otherwise governing the coverage of medical cannabis may be preempted by federal law.

KETAMINE

INNOVATION IN THE PRIVATE SECTOR



Ketamine: “Off-Label” Uses

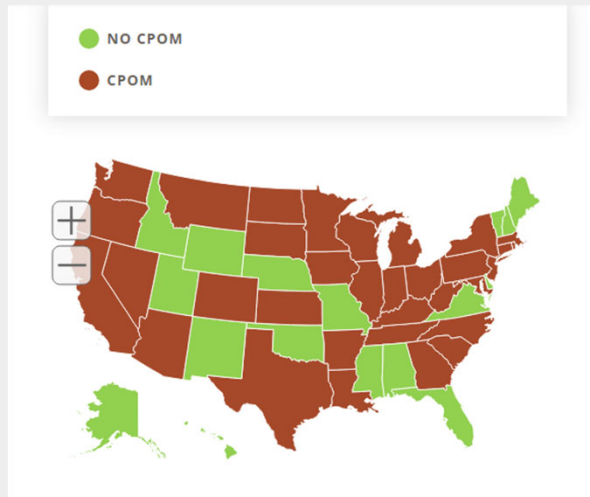


- As a Schedule III substance, Ketamine is currently approved by the FDA for a narrow range of anesthetic and analgesic uses, for which it can be distributed in interstate commerce
- Over the last 25 years, many physicians have started prescribing Ketamine for “off-label” uses, including treatment of depression and PTSD. While these uses have not been approved by the FDA, the prescriptions are still legal so long as the medical provider has a strong justification for it
- Businesses have sprung up in many states which aim to distribute Ketamine for “off-label” treatments.

Ketamine: FDA Regulation



- Ketamine’s recent “off-label” use as a psychiatric drug has not been approved by the FDA. Individual practitioners develop their own treatment protocols, sometimes with wide variability.
- In 2022, the FDA released a “Compounding Risk Alert” describing safety concerns with off-label ketamine usage based on adverse effect reports it had received from patients
- The FDA was particularly concerned about patients having sedative and dissociative effects at home without monitoring by an onsite health care provider



State: Ketamine and CPOM Laws

One of the main challenges faced by Ketamine distributors are Corporate Practices of Medicine (“CPOM”) laws, which prohibit business entities from practicing medicine or employing physicians for the provision of medical services, and/or prohibit physicians from joining certain business ventures.

CPOM laws vary widely from state to state, making it difficult for providers to establish a universal standard of care. This further adds to the risk in a business model based on providing “off-label” treatment.

PSYCHEDELICS

DIRECT APPEALS TO THE FDA FOR REFORM



Federal: MDMA and Psilocybin



- The 2024 Defense Authorization Act contained for the first time a provision enabling studies to analyze the effects of psilocybin, MDMA, and other psychedelic therapies on combat veterans suffering from PTSD
- More than 30% of veterans experience PTSD at some point in their lives, making it the most common mental disorder among that demographic group
- Current treatment for PTSD costs ~\$25,000 annually per affected veteran. In total, the U.S. spends ~\$230 billion annually on PTSD treatments

Federal: Request for FDA Approval of MDMA



In August of this year, the FDA rejected an application for MDMA-based treatment of PTSD. However, the FDA signaled some support by making suggestions on how a future application could be approved and requested an additional Phase III study demonstrating the efficacy and safety of MDMA treatment

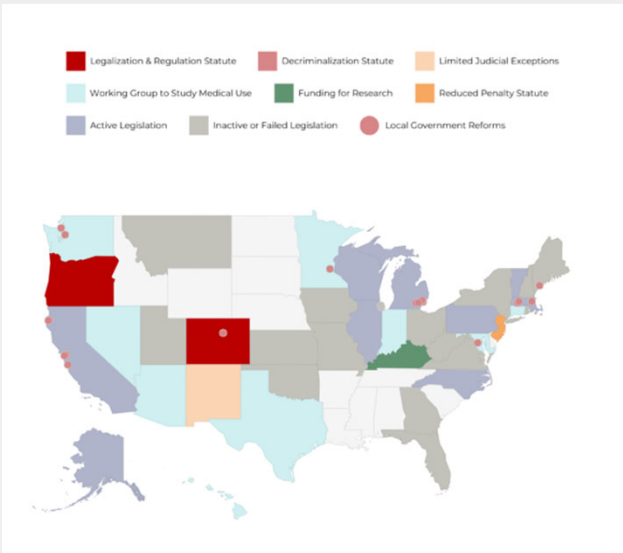


The FDA based its decision in part on the non-binding opinion of an FDA Advisory Committee, which took issue with several aspects of the application, including the lack of rigorous clinical trials. This highlights the difficulty of obtaining approval for treatments based in Schedule I substances, with their high barriers for conducting clinical trials

State: Patchwork Reforms

While reforms slowly wind through federal agencies, some states have taken matters into their own hands, passing piecemeal reforms as part of a broader strategy to normalize psychedelics the same way they successfully did with cannabis.

In May 2019, Denver became the first U.S. city to decriminalize psilocybin. Numerous other cities and states have since followed, in one form or another.



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Three Strategies for Reform

Cannabis: State Leadership

- States have taken the lead in passing legislative reforms
- Benefit of federalist innovation
- Comes at the cost of being patchwork and piecemeal in nature with risk of federal enforcement

Ketamine: Private Action

- Private physicians leading the way through off-label prescriptions
- Largely sidesteps federal regulation
- Potentially creates liability for the private practitioners involved

Psychedelics: Appeals to FDA

- Direct appeals to the FDA for further drug trials and potential approval
- FDA approval of a Schedule I substance would likely cause the DEA to reschedule it
- But this pathway has proven slow and difficult to navigate

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CLINICAL RESEARCH

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Clinical Trials for Ketamine



Depression

EudraCT Number:	2016-004764-18	Sponsor Protocol Number:	01-17	Start Date	: 2017-07-24
Sponsor Name:	St Patrick's Mental Health Services				
Full Title:	Ketamine as an adjunctive therapy for Major Depression - a randomised controlled pilot trial: The KARMA-Dep Trial				
Medical condition:	Depression				
Disease:					
Population Age:	Adults, Elderly			Gender:	Male, Female
Trial protocol:	IE (Completed)				
Trial results:	View results				

Neuropathic Pain

EudraCT Number:	2006-000767-28	Sponsor Protocol Number:	20061	Start Date	: 2006-09-29
Sponsor Name:	Vienna Medical University				
Full Title:	Standardisierte Verlaufsbeobachtung von Patienten mit Intrathekalem S(+)-Ketamin				
Medical condition:	Intrathecal S(+)-ketamine is a potent option in the treatment of chronic severe neuropathic pain in cancer patients refractory to conventional therapeutic strategies (Benrath et al. 2005). However,...				
Disease:					
Population Age:	Adults, Elderly			Gender:	Male, Female
Trial protocol:	AT (Completed)				
Trial results:	View results				

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Clinical Trials for Cannabis

Cancer

EudraCT Number:	2018-004505-34	Sponsor Protocol Number:	201800881	Start Date :	2021-02-17
Sponsor Name:	University Medical Center Groningen				
Full Title:	A phase 2a study on the anti-tumoral effect of cannabis oil (THC 10% / CBD 5%) in patients with advanced untreatable hepatocellular carcinoma				
Medical condition:	The anti-tumoral effect of cannabis oil will be investigated in patients with untreatable HCC				
Disease:					
Population Age:	Adults, Elderly			Gender:	Male, Female
Trial protocol:	NL (Ongoing)				
Trial results:	(No results available)				

Multiple Sclerosis

EudraCT Number:	2005-005263-29	Sponsor Protocol Number:	25-01	Start Date*:	2006-01-31
Sponsor Name:	Gesellschaft fuer klinische Forschung e.V. (Society for Clinical Research) [-]				
Full Title:	Multiple Sclerosis and Extract of Cannabis (MUSEC): A randomised, double-blind, placebo-controlled phase III trial to determine the efficacy and safety of a standardised oral extract of Cannabis sa...				
Medical condition:	Multiple Sclerosis				
Disease:					
Population Age:	Adults			Gender:	Male, Female
Trial protocol:	GB (Completed)				
Trial results:	(No results available)				

Clinical Trials for Cannabis (Cont'd)

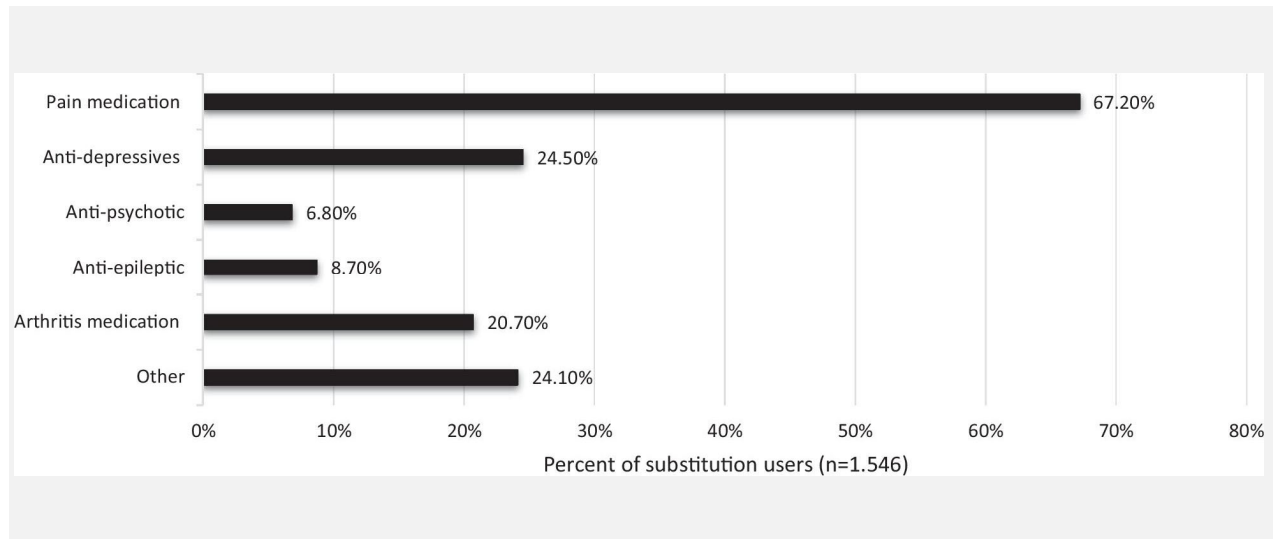
Neuropathic Pain

EudraCT Number:	2017-005198-38	Sponsor Protocol Number:	CANNA1	Start Date:	2018-10-26
Sponsor Name: Odense University Hospital					
Full Title: Tetra-hydro-cannabinol, cannabidiol and their combination for the treatment of peripheral neuropathic pain. A randomised placebo-controlled trial.					
Medical condition: Peripheral neuropathic pain due to polyneuropathy, postherpetic neuralgia, or peripheral nerve injury (surgical or traumatic).					
Disease:	Version	SOC Term	Classification Code	Term	Level
	20.0	100000004852	10077974	Peripheral neuropathic pain	LLT
Population Age: Adults, Elderly				Gender: Male, Female	
Trial protocol: DK (Completed)					
Trial results: View results					

Fibromyalgia

EudraCT Number:	2019-002394-59	Sponsor Protocol Number:	P142	Start Date *	2020-11-30
Sponsor Name: The Parker Institute, Bispebjerg and Frederiksberg Hospital					
Full Title: Medical Cannabis for fibromyalgia - The CANNFIB trial Protocol for a randomized, double-blind, placebo-controlled, parallelgroup, single-center trial					
Medical condition: Fibromyalgia					
Disease:	Version	SOC Term	Classification Code	Term	Level
	20.0	100000004859	10016631	Fibromyalgia syndrome	LLT
Population Age: Adults, Elderly				Gender: Male, Female	
Trial protocol: DK (Completed)					
Trial results: (No results available)					

Cannabis Prescription Replacement



Clinical Trials for MDMA

PTSD

EudraCT Number:	2018-001718-13	Sponsor Protocol Number:	MP18	Start Date* :	2019-10-18
Sponsor Name: MAPS Europe B.V.					
Full Title: An Open-Label, Phase 2, Multicenter Feasibility Study of Manualized MDMA-Assisted Psychotherapy with an fMRI sub-study Assessing Changes in Brain Activity in Subjects with Posttraumatic Stress Dis...					
Medical condition: post-traumatic stress disorder (PTSD)					
Disease:					
Population Age: Adults, Elderly				Gender: Male, Female	
Trial protocol: NL (Completed) CZ (Completed) NO (Completed) DE (Completed) GB (GB - no longer in EU/EEA) ES (Prematurely Ended)					
Trial results: (No results available)					

Depression

EudraCT Number:	2021-000805-26	Sponsor Protocol Number:	PSYKFORSK_MAT-MDD	Start Date :	2021-11-19
Sponsor Name: Østfold Hospital Trust					
Full Title: An Open-Label, Phase 2, Feasibility Study of Manualized MDMA-Assisted Psychotherapy in Subjects with Major Depressive Disorder					
Medical condition: Major Depressive Disorder					
Disease:					
Population Age: Adults, Elderly			Gender: Male, Female		
Trial protocol: NO (Ongoing)					
Trial results: (No results available)					

Clinical Trials for Psilocybin



Depression

EudraCT Number: 2019-003984-24	Sponsor Protocol Number: EPIsoDE_01	Start Date [*] : 2020-11-17
Sponsor Name: Central Institute of Mental Health		
Full Title: A phase II randomized, double-blind, active placebo-controlled parallel group trial to examine the efficacy and safety of psilocybin in treatment-resistant major depression		
Medical condition: Treatment-Resistant Depressive Episode or Treatment-Resistant Recurrent Depressive Disorder of moderate to severe degree without psychotic features		
Disease:		
Population Age: Adults	Gender: Male, Female	
Trial protocol: DE (Ongoing)		
Trial results: (No results available)		

PTSD

The Psychedelic Future of Post-Traumatic Stress Disorder Treatment

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Received 2023 Apr 27; Revised 2023 Sep 11; Accepted 2023 Sep 13.

COVERAGE CONSIDERATIONS



Constitutional Bars to Coverage



Even where states have passed legislation “legalizing” cannabis or other controlled substances within their own borders, these substances remain federally illegal. This is true regardless of the federal posture on enforcement.



It is federally illegal for entities to “aid and abet” the commission of federal crimes by directly or indirectly financing the purchase of federally illegal substances.



While federal non-enforcement of drug laws is the reality on the ground, some courts have held that private actors cannot be forced to violate the CSA by aiding and abetting the commission of nominal federal crimes. See, e.g., *Mann v. Gullickson*, 2016 U.S. Dist. LEXIS 152125 (N.D. Cal. 2016); but see Appeal of *Panaggio*, 260 A.3d 825 (N.H. 2021).

Medical Necessity

All plans require items and services to be “medically necessary” to receive coverage.

Schedule I

- Substances on Schedule I of the CSA, such as cannabis, MDMA, and psilocybin, are not medically necessary because under the CSA, they are considered to have “no accepted medical use.”

Schedule III

- Ketamine – and cannabis should it be moved to Schedule III – may be considered medically necessary if used as part of an FDA-approved treatment. When used as part of “off-label” treatments, however, their medical necessity is less clear.

FDA Approval

Plans generally only cover drugs and treatments that are FDA-approved.

Schedule I

- Cannabis, MDMA, and psilocybin have not been approved by FDA for any purpose.
- The recent drug application for MDMA suggests that the FDA has power to approve applications for even Schedule I substances.

Schedule III

- Ketamine has been approved by the FDA for use as an anesthetic and analgesic. Its other “off-label” uses have not been FDA approved. Some plans may require pre-authorization of off-label treatments.
- Even if cannabis is moved to Schedule III, there is potentially a long road ahead before FDA approval of particular cannabis treatments.

Drug Formularies

- Many plans contain lists of drugs and treatments specifically covered by the plan.
- If approved by FDA, cannabis would go through plans’ standard formulary development processes; may be excluded if it does not offer superior efficacy or safety compared to alternative therapies.
- Drugs not on the plan’s drug formulary require prior authorization. Thus, even if cannabis and other emerging therapies are excluded from drug formularies, participants could still seek coverage via prior authorization.

Access



- Health plans and pharmacy benefit managers generally implement network pharmacy requirements to obtain prescription drugs.
- Access and availability would be impacted by pharmacies' decision on whether to stock cannabis and/or dispensaries join traditional pharmacy networks.
- If approved by FDA, IRS guidance regarding qualified medical expenses would need to be updated to support use of Health Savings Account (HSA) funds to purchase cannabis.

Exclusions



- Some plans contain exclusions which expressly forbid coverage for medical cannabis, or more generally deny coverage for experimental and investigative therapies without prior authorization
- Exclusions are a clear and reliable method of informing members that the plan will not cover a specified drug or therapy, and plans face little risk excluding Schedule I drugs.
- However, an exclusion could run afoul of mental health parity laws in a world where cannabis was moved to Schedule III and approved by the FDA for medicinal use, since cannabis is commonly used in treatment of mental health conditions.

APPLICATION

ULTRA HEALTH V. BLUE CROSS AND BLUE SHIELD OF NEW MEXICO



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Basis of Litigation

Plaintiffs in *Ultra Health et al. v. Blue Cross and Blue Shield of New Mexico* argued that the defending payors are obligated to cover medical cannabis treatments under New Mexico state law. They contended...



Cannabis is medically necessary under state law and must be covered as a behavioral health service



Cannabis is prescribed by a licensed provider in accordance with state law for medically appropriate indications



The federal government does not enforce federal law against those lawfully participating in state-legal cannabis activities



State law has found no preemption in the worker's compensation context



The federal government – including HHS and FDA – has signaled that cannabis has currently accepted medical uses and is on the verge of re-scheduling it

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Arguments Against Coverage

Defendants in *Ultra Health et al. v. Blue Cross and Blue Shield of New Mexico* (e.g., several large payors) argued against coverage based on...



Federal preemption: cannabis is still illegal and does not have FDA approval, which is necessary for a valid prescription under federal law.



State law permits cannabis use but does not compel coverage and does not change federal illegality.



Plan terms do not cover cannabis because:

- cannabis is not medically necessary as a Schedule I substance with “no currently accepted medical use”;
- cannabis is not FDA approved;
- cannabis is not on the plans’ drug formularies; and
- plaintiffs did not submit a claim seeking benefits for cannabis.

The Result



In May 2025, a federal judge dismissed *Ultra Health et al. v. Blue Cross and Blue Shield of New Mexico* with prejudice, ruling that state law does not mandate such coverage and that federal law, which classifies cannabis as a Schedule I drug, would preempt any state requirement.

The Implications

While MCOs may choose to offer coverage for cannabis in states that permit medical use, states cannot compel coverage (nor can plan members seek to enforce coverage requirements in court) unless cannabis is rescheduled and FDA-approved.



By providing coverage for medical cannabis, Defendants would be aiding and abetting illegal drug procurement. The likelihood of whether Defendants would be prosecuted for that crime is irrelevant. The criminalization of cannabis at the federal level remains intact, and therefore would conflict with a state law mandating coverage of medical cannabis.”

N.M. Top Organics v. Blue Cross & Blue Shield of N.M., No. 22-cv-546 MV/LF, 2025 U.S. Dist. LEXIS 77599 (D.N.M. Apr. 23, 2025).

EXISTING & EMERGING LEGISLATION

BILLS PROMOTING CANNABIS ACCESS



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Medical Marijuana and Cannabidiol Research Expansion Act (H.R. 8454)

The first standalone federal cannabis reform bill to pass both chambers was signed into law by President Biden on December 2, 2022. The bill was introduced by bipartisan sponsors, including Rep. Earl Blumenauer (D-OR) and Sens. Feinstein (D-CA), Grassley (R-IA), and Schatz (D-HI).



Key Provisions

- Streamlines research registration and eliminates duplicate reviews (i.e., DEA registration accepted if already approved by FDA, NIH, etc.)
- Expands cultivation and supply by allowing multiple licensed growers beyond the University of Mississippi's federal monopoly; requires annual assessment to ensure an adequate and uninterrupted supply of cannabis for research
- Enables DEA to license manufacturers and distributors to produce FDA-approved marijuana-derived medications
- Clarifies that doctors may legally discuss the harms and benefits of cannabis and CBD with patients without fear of federal liability
- Directs HHS (with NIH) to study cannabis therapeutic potential, impacts on adolescent brain development, driving impairment, and barriers to research; the DEA must annually report shortages or disruptions in cannabis supply to Congress



Significance

- Removes research bottlenecks; imposes strict deadlines and consolidation for agency reviews
- Supports drug discovery by easing pathways for clinical trials and the development of cannabinoid-based treatments
- Promotes better clinical education by providing health professionals the legal cover to discuss cannabis, improving patient care and informed decision-making



Next Steps

- Federal agencies must issue guidance and rules to operationalize the law. (*Note: we have been waiting on this step since January 2023*)
- Institutions require DEA Schedule I researcher licenses and must comply with new security standards
- With commercial cannabis research still federally restricted, this law helps align federal policy with state-level medical legalization

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Cannabis Coverage: Public Insurance

A NJ program expands state employees' access to medical cannabis via a state insurance benefit; a NY bill aims to declare medical marijuana a "prescription drug" across public insurance.

New Jersey Launches "Bennabis Health" as Plan Add-On *Active*

As of 2025, government employees in Trenton and other select NJ communities can access medical cannabis benefits via the **Bennabis Health** add-on in their government health plan.

- New Jersey the first state to offer medical cannabis benefits to government employees
- Bennabis Health partners with insurers to offer medical cannabis discounts, reducing costs for New Jersey government employees
- Employees can access cannabis-relevant telehealth services through the benefit

New York's Failed Legislation Attempts for Public Insurance (S 6549) *In Committee*

A bill amending existing law to clarify that medical marijuana is classified as a "prescription drug" and a "covered drug" for the purposes of insurance coverage under New York State's medical assistance, elder care, workers' compensation, and health insurance programs.

- Continues the work of S2568 by explicitly declaring medical cannabis as a "prescription drug" across public insurance
- Ensures Medicaid reimburses certified dispensaries, and broadens coverage under social service and eldercare programs
- Aims to expand insurance coverage and integrate dispensaries into healthcare networks

Cannabis Coverage: Proposed Legislation

Two proposed bills would mandate insurance coverage for medical cannabis.

New Jersey Cannabis Insurance Coverage Legislation (A 4371) *In Committee*

A bill mandating that workers' compensation, personal injury protection (PIP), and health insurance plans in New Jersey must include coverage for the medical use of cannabis for qualifying patients.

- Workers' compensation, PIP, and health insurance plans must cover costs associated with the medical use of cannabis for qualifying patients.
- Coverage is not required in the case of federal enforcement of the Controlled Substances Act.
- If direct payment to a dispensary is not feasible, insurers must reimburse patients upon proof of payment.

New Mexico Medical Cannabis Insurance Coverage Bill (H.B. 0527) *In Committee**

A bill requiring insurance coverage for medical cannabis for qualified patients with debilitating conditions in New Mexico. It would apply to group health coverage, public assistance, individual and group health insurance, health maintenance organizations, and nonprofit health care plans.

- The bill lists qualifying debilitating medical conditions.
- Coverage must be consistent with that for other prescribed medications, including cost-sharing requirements.
- Insurers must provide either direct payment to cannabis retailers or reimbursement to patients.

**If enacted, likely pre-empted under Ultra Health*

Pending Legislation: Addressing Federal Preemption of State Regulations

In April 2025, a bipartisan group of U.S. representatives reintroduced two bills – the STATES 2.0 Act and the PREPARE Act – to address the conflict between federal cannabis prohibition and state legalization, and to prepare for eventual federal legalization.



STATES 2.0 Act (H.R. 2934) *In Committee*

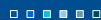
This bill would allow states and tribes to set their own cannabis policies without federal interference, regulate cannabis products, and enable state-legal businesses to access banking, while maintaining federal support for states that prohibit cannabis.



PREPARE Act (H.R. 2935) *In Committee*

This bill would establish a commission to develop federal cannabis regulations modeled after alcohol laws, address the social harms of prohibition, and support research and training for medical professionals.

NEXT STEPS WITH EMERGING THERAPIES



Next Steps



- In the short term, plans currently have strong arguments for opposing coverage for emerging therapies
- In the long term, these emerging therapies may be mutually beneficial for patients and payors by treating complex and difficult psychological conditions such as PTSD, depression, and neuropathic pain, for which current treatment options are inadequate
- Rates of prescription replacement for cannabis provide a glimpse of the potential economic upsides as well. Replacing expensive pharmaceuticals with simple, plant-derived substances may be a win-win for all parties involved