After Schedule I: Federal Psychedelic Rescheduling and the Impact on State Law

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Vincent Joralemon

Vincent Joralemon is the Director of the Life Sciences Law and Policy Center at the Berkeley Center for Law & Technology (BLCT). His scholarship focuses on: psychedelics, psychopharmacology, and other emerging therapeutics; evidence generation and FDA reform; and innovation policy that enables responsible use of data across life sciences research and development.

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Ismail L. Ali

Ismail Lourido Ali, JD serves as Multidisciplinary Association for Psychedelic Studies (MAPS) Co-Executive Director. Ismail has been actively participating in the drug policy reform movement for over a decade, informed by half a lifetime of diverse personal experience with psychedelics and other substances. Previously as the Director of Policy & Advocacy at MAPS, Ismail supported the design, advancement, and implementation of psychedelic policy reform across the country and world. Ismail co-founded and co-chaired the Board of the Psychedelic Bar Association and is licensed to practice law in the state of California.

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Graham Pechenik

Graham Pechenik is a registered patent attorney and the founder of Calyx Law, a firm specializing in intellectual property for cannabis and psychedelics ventures. He serves on the Board of Directors of the Psychedelic Bar Association, is editor-at-large at Psychedelic Alpha, and works with the UC Berkeley Center for the Science of Psychedelics on tracking federal and state developments in psychedelic regulation and policy.

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Shahin Shams

As a Data and Patent Analyst at Porta Sophia, a nonprofit public benefit organization dedicated to protecting psychedelic access and innovation, Shams' work has focused largely on pre- and post-grant patent interventions and state policy advocacy. She holds a Ph.D. in Biomedical Engineering and is currently a 2L at UC Berkeley Law.

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Tamar Todd

Tamar teaches courses on cannabis and psychedelics law and police at Berkeley Law. She is an experienced attorney with expertise in policy advocacy, legislative drafting, statewide political campaign strategy, regulatory implementation, and non-profit management in the areas of drug law reform, marijuana law and policy, public health, and criminal justice.

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Schedule I

Under the Controlled Substances Act (CSA), Schedule I drugs are defined by three criteria:

1. High potential for abuse;
2. Lack of accepted safety for use under medical supervision;
3. **No currently accepted medical use in treatment**

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Scheduling matters: A Schedule I substance:

- Cannot be prescribed for any indication;
- Carries the most severe criminal penalties for possession, selling, or trafficking;
- Imposes considerable limitations on research access; and
- Business expenses for the drug cannot be deducated from federal tax filings

Rescheduling: Part 1 (Formal DEA)

Path	Mechanism
Congressional Action	Congress can pass a new law at any time to reschedule or deschedule any substance
Administrative Review	A review can be initiated by petition from any “interested party”

Rescheduling: Part 1 (Administrative Review)

Agency	Role
HHS (acting via FDA)	Conducts 8-factor analysis of medical use and abuse potential
DOJ (acting via DEA)	Holds “final authority” to issue the rule and manage enforcement

Rescheduling: Part 2 (FDA)

The FDA "Backdoor":

1. Sponsor submits a New Drug Application (NDA).
2. FDA approves the NDA.
3. This approval serves as legal proof of "currently accepted medical use".
4. The DEA is legally forced to move the drug out of Schedule I.

U.S. JUSTICE DEPARTMENT
DRUG ENFORCEMENT ADMINISTRATION

(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has no currently accepted medical use in treatment in the United States.
(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Bifurcated Rescheduling

The DEA typically does not reschedule a raw substance wholesale. It reschedules the specific, FDA-approved drug product.

Precedent: GHB / XYWAV

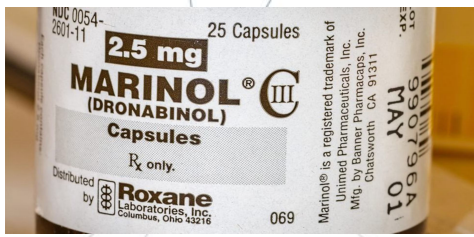
- GHB itself remains a strictly controlled Schedule I substanc
- However, the FDA-approved drug product XYWAV which contains GHB, is placed in the less-restrictive Schedule III, allowing it to be prescribed.

xywav®

(calcium, magnesium, potassium, and sodium oxybates) oral solution Ⅲ

Precedent: Marijuana / Marinol

- Marijuana is a Schedule I controlled substance
- However, the FDA-approved drug product Marinol which contains 100% THC (Marijana's primary psychoactive ingredient) is a Schedule III drug.



State Law Patchwork

YES on 109
Heals Hearts and Minds

State "wellness" models

YES ON 122
NATURAL MEDICINE COLORADO

State Law Patchwork

State Law Type	How it Works
"Coupled" States (*e.g.*, TX, IL)	State laws automatically conform to federal DEA schedules
"Decoupled" States (*e.g.*, CA, NY)	State laws are not linked to federal schedules

"Sleeper" or "trigger" bills in "decoupled" states bypass future legislative vote by stating:

- If the FDA approved a specific psychedelic drug,
- And DEA reschedules it,
- Then that specific drug is automatically rescheduled under state law.

This creates an express lane for FDA-approved medicines in states that would otherwise lag behind.

State Bifurcation

House Committees
Health & Human Services

Senate Committees

A BILL FOR AN ACT

CONCERNING THE LAWFUL USE OF CRYSTALLINE POLYMORPH PSILOCYBIN THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://leg.colorado.gov.)

The bill makes a prescription medicine that contains crystalline polymorph psilocybin legal to prescribe, dispense, distribute, possess, use, and market in Colorado upon its approval by the United States food and drug administration.

Bifurcation

HOUSE BILL 22-1344

BY REPRESENTATIVE(S) Neville and Ortiz, Bernett, Boesenecker, Cutter, Esgar, Exum, Gray, Herod, Hooton, Kennedy, Lindsay, Michaelson Jenet, Sirota, Titone, Valdez A., Woodrow, Young;
also SENATOR(S) Cooke and Ginal, Buckner, Gonzales, Jaquez Lewis, Kolker, Lee, Moreno, Pettersen, Rankin, Rodriguez, Simpson, Smallwood, Story, Fenberg.

CONCERNING THE LAWFUL USE OF A PRESCRIPTION DRUG THAT CONTAINS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Legislative declaration. (1) The general assembly finds and declares that:

(a) The effects of post-traumatic stress disorder (PTSD) in patients, along with common comorbidities such as, but not limited to, disassociation, depression, and childhood trauma, represent a major public health crisis for which the currently available treatments are described by medical experts as modest at best;

Non-Bifurcation

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