

Washington University
Psychedelic Assisted Therapy Speakers Series
Legal and Regulatory Landscape
of Psychedelics in the United States



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Sean's Legal Experience

- **Nearly 30 years working on drug policy reform**
- **A decade as a criminal defense lawyer defending people on drug crimes**
- **Co-Author, Amendment 64, legalizing adult use cannabis in Colorado**
- **Co-Author, Colorado's Natural Medicine Health Act/Prop 122, decriminalizing and creating regulated pathway for 4 psychedelics**
- **Executive officer, Denver Mayor's Psilocybin Policy Review Panel**
- **Advising doctors and therapists on the legal boundaries of psychedelic assisted therapy, including ketamine and state legal psychedelics**
- **Licensure defense for professionals accused of wrongdoing with psychedelic assisted therapy, including responding to DEA audits and enforcement actions**
- **Assisting companies to be licensed in the Colorado psilocybin program**
- **Attorney for two ayahuasca churches who gained federal recognition from DEA**
- **Advisory Board, Psychedelic Parenthood Community, Brazilian led education project**
- **Outside General Counsel to MAPS' Psychedelic Science Events, LLC**
- **General Counsel to Zendo Project, Inc., a psychedelic harm reduction organization**

Legal Disclaimer

Please note that no information provided here today constitutes direct legal advice; all information is for general educational and informational purposes only.

No participant in this workshop should act on the basis of this information. It is best to seek qualified legal counsel specific to any situation and jurisdiction with respect to information shared during this workshop.

Sean McAllister is not speaking on behalf of any of his clients during this Workshop.

No illegal conduct is encouraged by this presentation.

Overview of Presentation

- 1. Brief History of Psychedelics**
- 2. Federal Controlled Substances Act**
- 3. FDA drug approval process and status**
- 4. State regulated psychedelic therapy systems**
- 5. Unregulated Areas: decrim and religious use**
- 6. Disciplinary issues for therapists**
- 7. Future of psychedelics**

Brief history psychedelics



Brief history psychedelics, cont.



Federal Controlled Substances Act

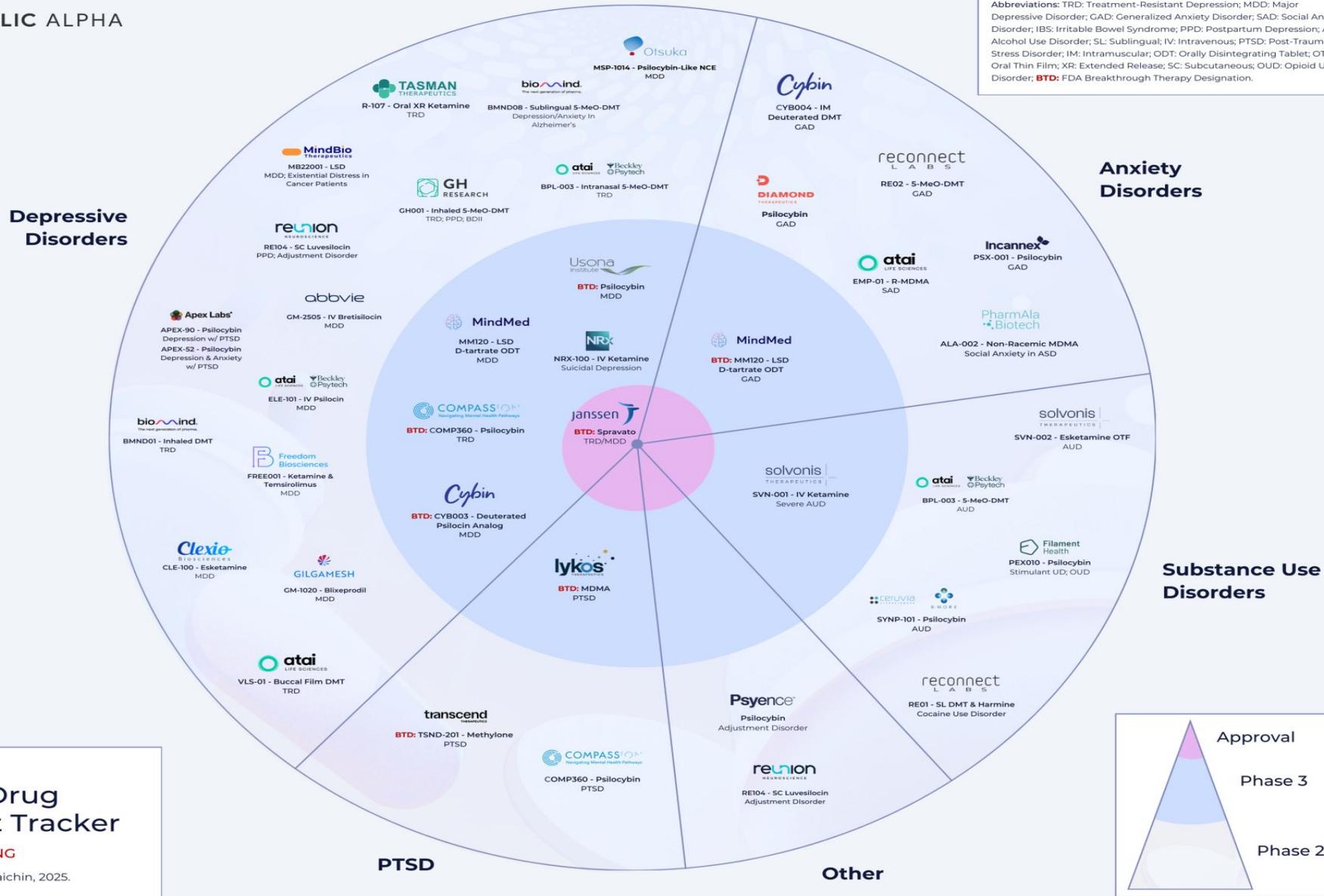
The Controlled Substances Act (CSA) is the federal U.S. drug law that regulates, and generally prohibits, the manufacture, importation, possession, use, and distribution of all classic psychedelic substances: LSD, MDMA, psilocybin, mescaline, iboga, DMT, 2CB, etc.

The U.S. Department of Justice Drug Enforcement Agency (DEA) is responsible for applying the CSA.

Only exemptions under federal law are: FDA clinical trials, Right to Try law, researchers and manufacturers who hold Schedule I license, and religious exemptions under RFRA

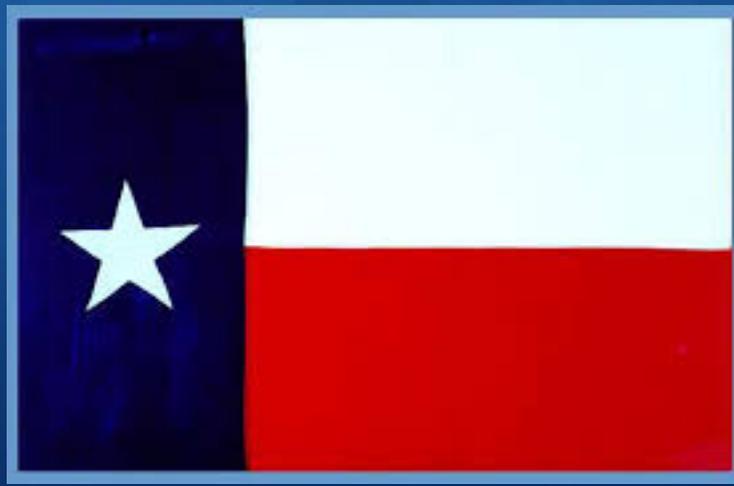
FDA Status/Clinical Trials

Abbreviations: TRD: Treatment-Resistant Depression; MDD: Major Depressive Disorder; GAD: Generalized Anxiety Disorder; SAD: Social Anxiety Disorder; IBS: Irritable Bowel Syndrome; PPD: Postpartum Depression; AUD: Alcohol Use Disorder; SL: Sublingual; IV: Intravenous; PTSD: Post-Traumatic Stress Disorder; IM: Intramuscular; ODT: Orally Disintegrating Tablet; OTF: Oral Thin Film; XR: Extended Release; SC: Subcutaneous; OUD: Opioid Use Disorder; **BTD:** FDA Breakthrough Therapy Designation.



Q3'25
Psychedelic Drug Development Tracker
 BY INDICATION GROUPING
 © Psychedelic Alpha, Michael Haichin, 2025.

State Regulated Programs



State Regulated Programs, cont.

- New Mexico - Under the “Medical Psilocybin Act”—the following qualifying conditions are listed as eligible for psilocybin treatment: “(1) major treatment-resistant depression; (2) post-traumatic stress disorder; (3) substance use disorders; (4) end-of-life care.” The law also allows the New Mexico Department of Health to promulgate regulations that would add qualifying conditions to that list. The law also establishes a research fund to allow New Mexico state universities to research additional medical benefits of psilocybin. Finally, the law establishes an “equity fund” which allows for qualified patients who meet certain income requirements to receive psilocybin treatment. The law requires the program to be implemented by December 31, 2027.
- State approved research allowed in UT (psilocybin) and TX (iboga)
- Study bills in MN and MD

Unregulated areas where research might be possible



Local decriminalization laws

The following cities have some type of decriminalized environment for psychedelics:

Denver, CO

Somerville, MA

Detroit, MI

Oakland, CA

Cambridge, MA

Hazel Park, MI

Santa Cruz, CA

Northampton, MA

Ferndale, MI

Arcata, CA

Easthampton, MA

Ann Arbor, MI

San Francisco, CA

Washtenaw County, MI

Port Townsend, WA

Washington, D.C.

Grand Rapids, MI

Seattle, WA

License Disciplinary Issues

Preparation and integration work is generally legal, touching the medicine is risky outside of regulation

Conant v Walter: doctors have 1st Am rights to discuss any topic

Review your standards of care and scope of practice

Discipline is rare for psychedelic work, but there was a loss of license around MDMA therapy

Some states uncomfortable with ketamine therapy, see AL

What is your training and expertise, how did you keep the patient safe

Liability concerns: LIB case, several threats of lawsuits

The Future of Psychedelics

- 1. FDA approved MDMA, psilocybin and other molecules in the next 5 years**
- 2. Rescheduling of FDA approved psychedelics out of Schedule I**
- 3. Pharma development of neuro-plasticity drugs based on psychedelics but minus the trip**
- 4. Expansion of state regulated programs to CA, WA, MD, NJ, NV and other states in coming years.**
- 5. Increasing numbers of federally recognized psychedelic churches in the coming years, likely dozens recognized**
- 6. Continued disconnect between federal/state law divide on the legality of these substances**
- 7. Lots of HEALING and EXPLORATION!**

Questions?

**For additional input,
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