U.S. FOOD & DRUG ADMINISTRATION

## From development to patient use: opportunities & challenges

# Psychedelic Drugs in Psychiatry: An American Regulatory/FDA Perspective

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# COI Statement

- I have no conflicts of interest to disclose.

# Overview of Talk

- Indicators of growing interest in psychedelics
- Recent FDA activities involving psychedelics

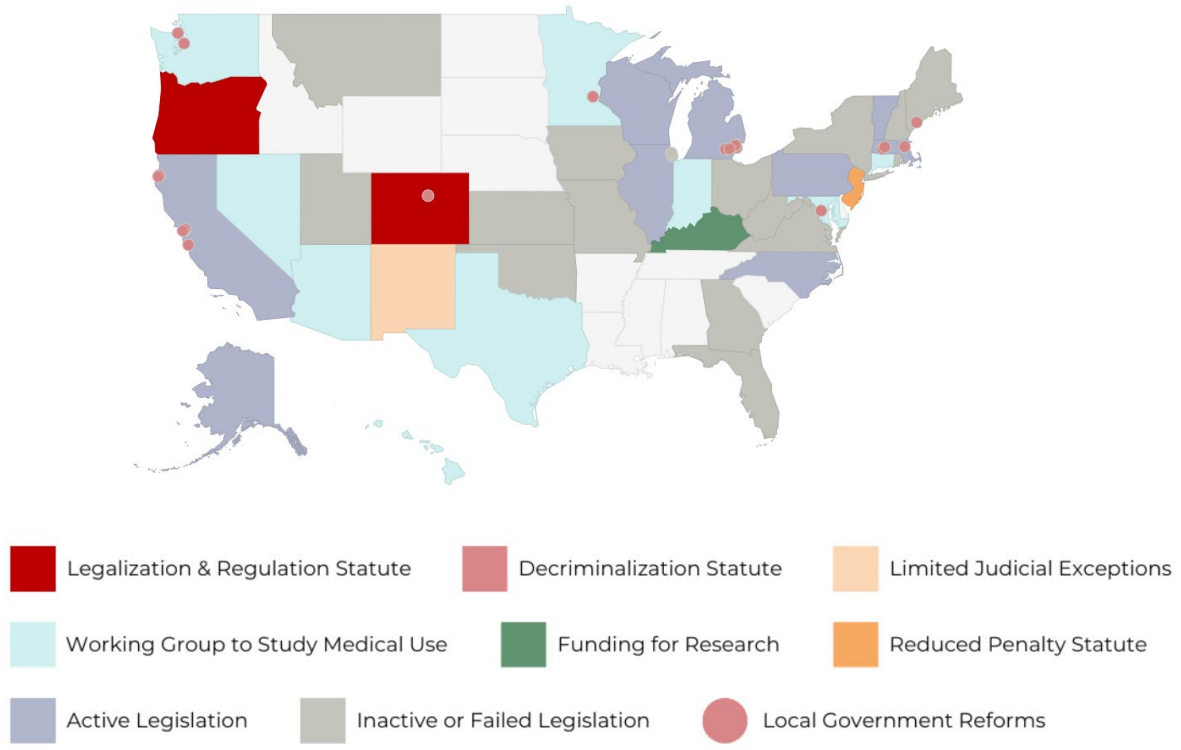
# Indicators of Growing Interest in Psychedelics

# Legislative Action Involving Psychedelics

## Federal[1]

- National Defense Authorization Act for FY 2024
  - Contains provisions requiring Department of Defense to study treatment of certain conditions (e.g., PTSD and TBI) using certain psychedelic substances (e.g., MDMA and psilocybin)
  - Eligible populations include active-duty service members

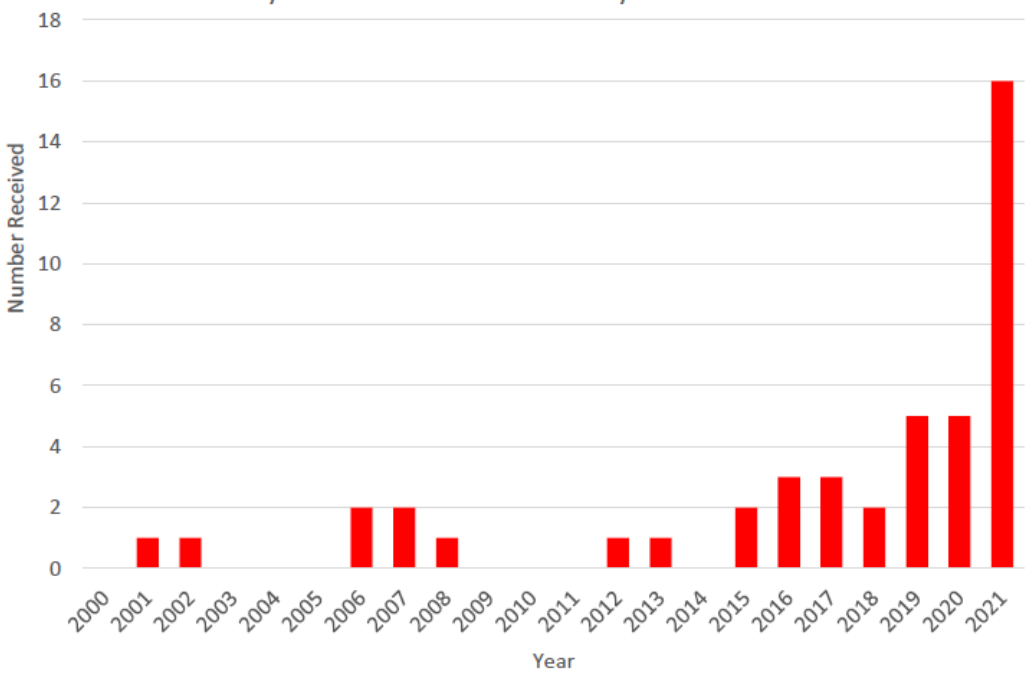
## State and Local[2]






[1] https://www.congress.gov/bill/118th-congress/house-bill/2670/text, [2] https://psychedelicalpha.com/data/psychedelic-laws

# New Investigational New Drug (IND) Applications for Psychiatry-Related Indications, 2000 - 2021





Unpublished internal analysis; includes research and commercial INDs
Psychedelics included: ayahuasca, DMT, LSD, MDMA, psilocybin

# Publicly Reported* Breakthrough Designations

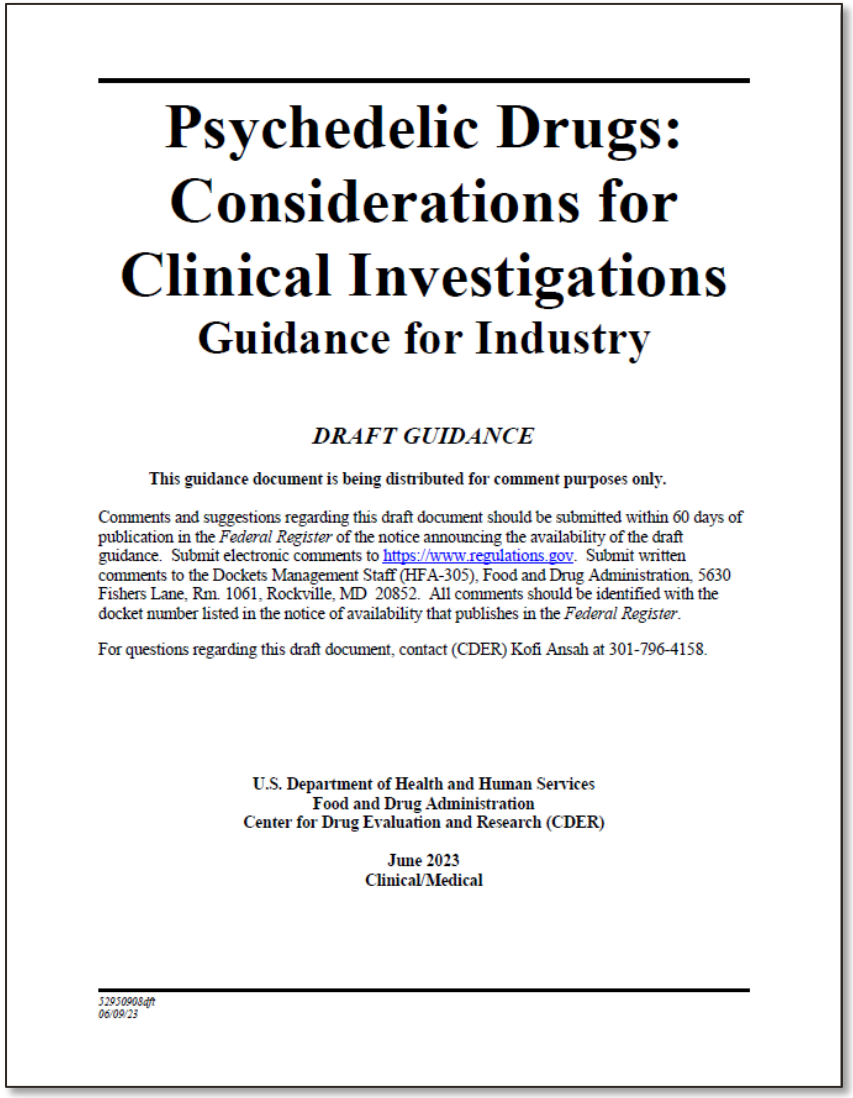
| Month | Drug | Sponsor | Indication |
|---|---|---|---|
| *August 2017* | *MDMA* | *MAPS (now Lykos)* | *Post-traumatic stress disorder* |
| October 2018 | Psilocybin | Compass Pathways | Treatment-resistant depression |
| November 2019 | Psilocybin | Usona Institute | Major depressive disorder |
| March 2024 | LSD | Mind Medicine | Generalized anxiety disorder |
| March 2024 | Psilocybin | Cybin | Major depressive disorder |




*** FDA does not disclose individual Breakthrough Designations; however, each instance has been publicly reported by the sponsor.**

# Recent FDA Activities Involving Psychedelics

# Guidance Overview: Clinical Framework



Psychedelic Drugs: Considerations for Clinical Investigations
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) Kofi Ansah at 301-796-4158.

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# Guidance Overview: Discussion Sections

- Chemistry, manufacturing, and controls
- Nonclinical
- Clinical pharmacology
- Abuse potential assessment
- Clinical

# Guidance Overview: Clinical Considerations

- Factors that might complicate efficacy assessments
  - Adequate and well-controlled trials
  - Making valid comparisons
- Reducing potential biases
- Monitoring requirements
- Additional challenges for real-world use

# Public Workshop: Overview


Materials available at https://reaganudall.org/news-and-events/events/advancing-psychedelic-clinical-study-design

# Public Workshop: Limits of FDA's Regulatory Authority

## What We Regulate

- Human drugs
  - Product labeling
  - Monitoring in clinical trials
  - Risk evaluation and mitigation strategies for safety

## What We Don't Regulate

- Psychotherapy
- Practice of medicine
- Monitoring in post-market setting