

SAMHSA's Emerging Perspectives on Psychedelics

Dr. Neeraj Gandotra MD
Office of Chief Medical Officer (OCMO)
Office of Assistant Secretary (OAS)



SAMHSA
Substance Abuse and Mental Health
Services Administration

Disclosure Information

No disclosures to report

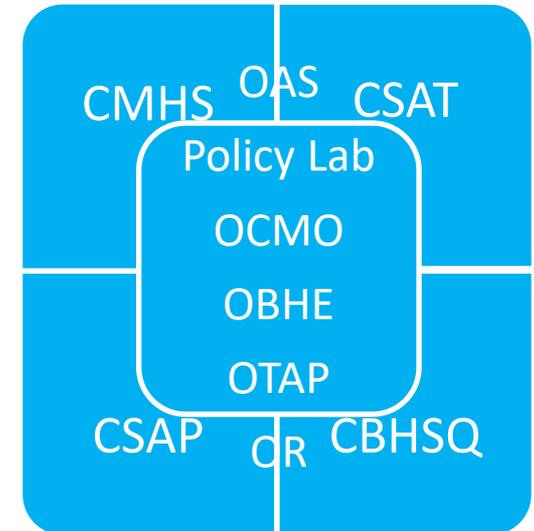
Learning Objectives:

1. Review the National Survey on Drug Use and Health's data collected on psychedelic use and an overview of current development of therapeutic agents.
2. Review selected considerations and perspectives for the implementation of therapeutics as we balance risk and effectiveness.

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services

- The 21st Century Cures Act (Dec 2016) elevated SAMHSA leadership to the Assistant Secretary level
- Funding includes block formula grants, discretionary grants, cooperative agreements and contracts.
- Office of the Assistant Secretary
 - National Mental Health and Substance Use Policy Laboratory
 - Office of the Chief Medical Officer
 - Office of Tribal Affairs Policy
 - Office of Recovery
 - Office of Behavioral Health Equity
 - General organization:
 - CSAT: Center for Substance Abuse Treatment
 - CSAP: Center for Substance Abuse Prevention
 - CMHS: Center for Mental Health Services
 - CBHSQ: Center for Behavioral Health Statistics and Quality



SAMHSA Strategic Plan

Mission

- SAMHSA's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes.

Vision

- SAMHSA envisions that people with, affected by, or at risk for mental health and substance use conditions receive care, achieve well-being, and thrive.



Alaska Air pilot in aborted flight said he used 'magic' mushrooms, documents show

Severe Illness Potentially Associated with Consuming Diamond Shroomz™ Brand Chocolate Bars, Cones, and Gummies



Matthew Perry Died of 'Acute Effects of Ketamine,' Autopsy Says

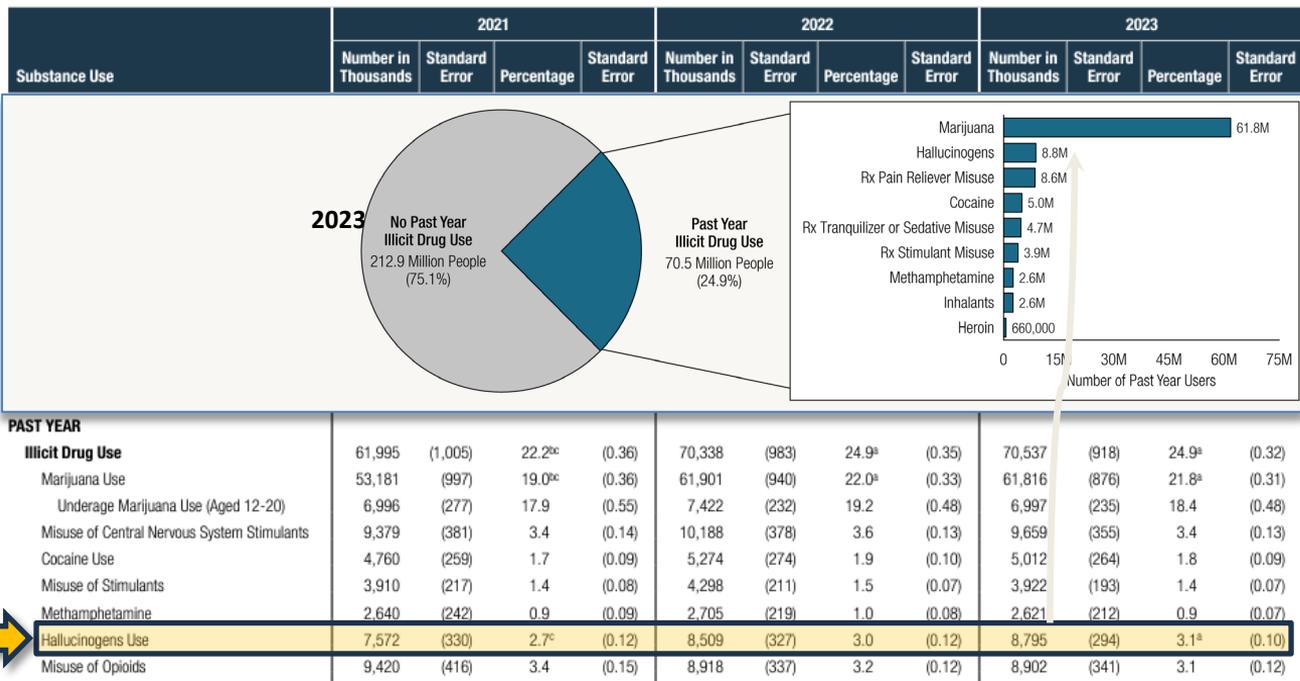
The medical examiner said drowning, coronary artery disease and the effects of an opioid also contributed to the death of the "Friends" actor, who was found in a hot tub in October.

✔ First-Ever Congressional Hearing On Psychedelic-Assisted Mental Health Care For Veterans Will Be Held Tuesday

Single dose of LSD provides immediate and lasting relief from anxiety, study says

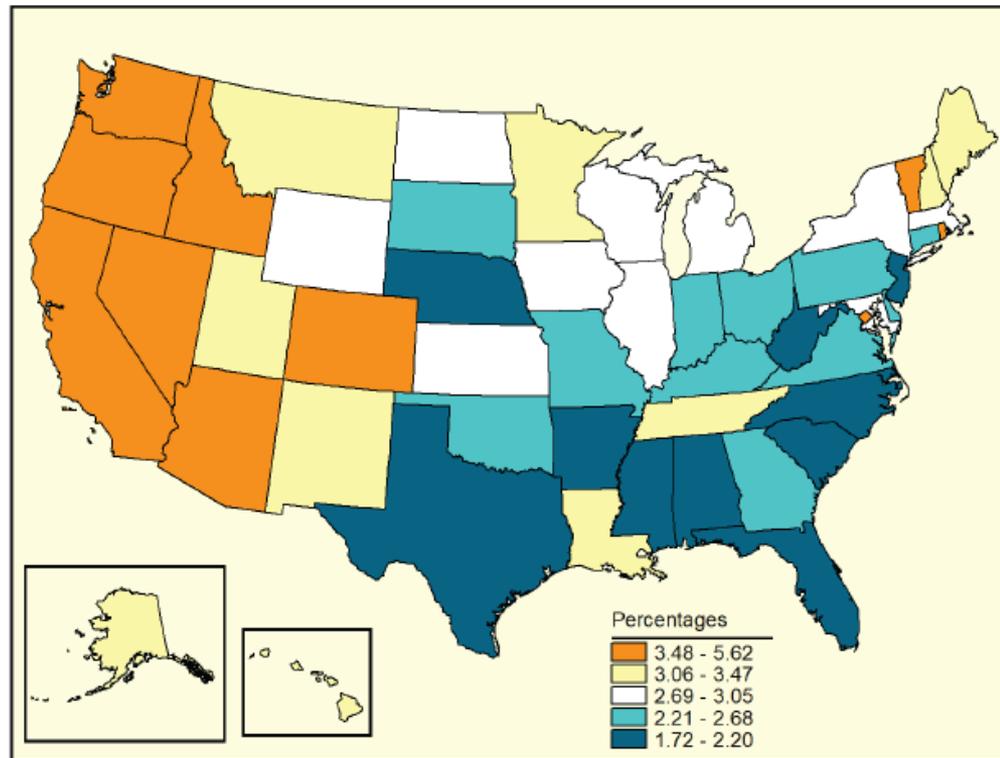
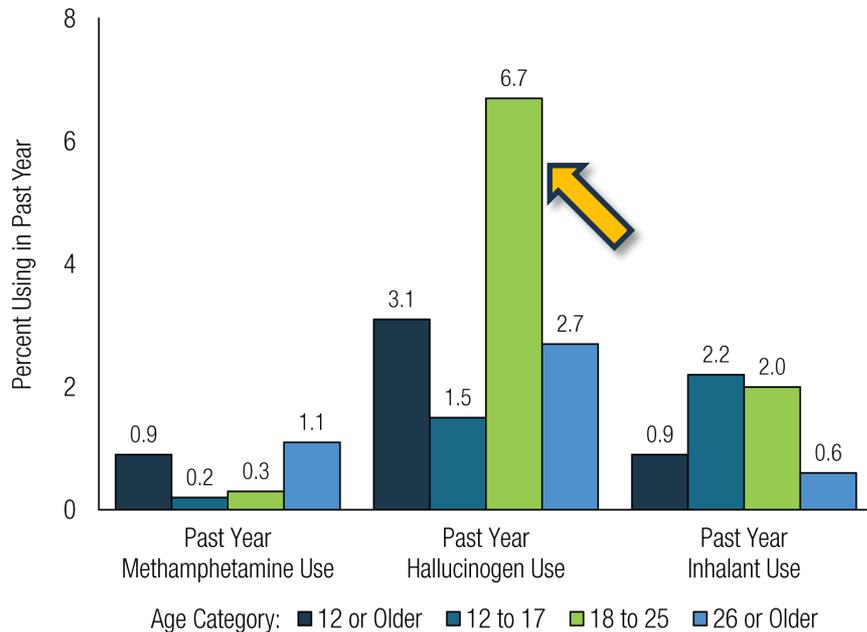
Hallucinogen Use in Past Year Rising among 12+, 2021-2023

Table 1. Substance Use: Among People Aged 12 or Older; Numbers in Thousands and Percentages, 2021-2023



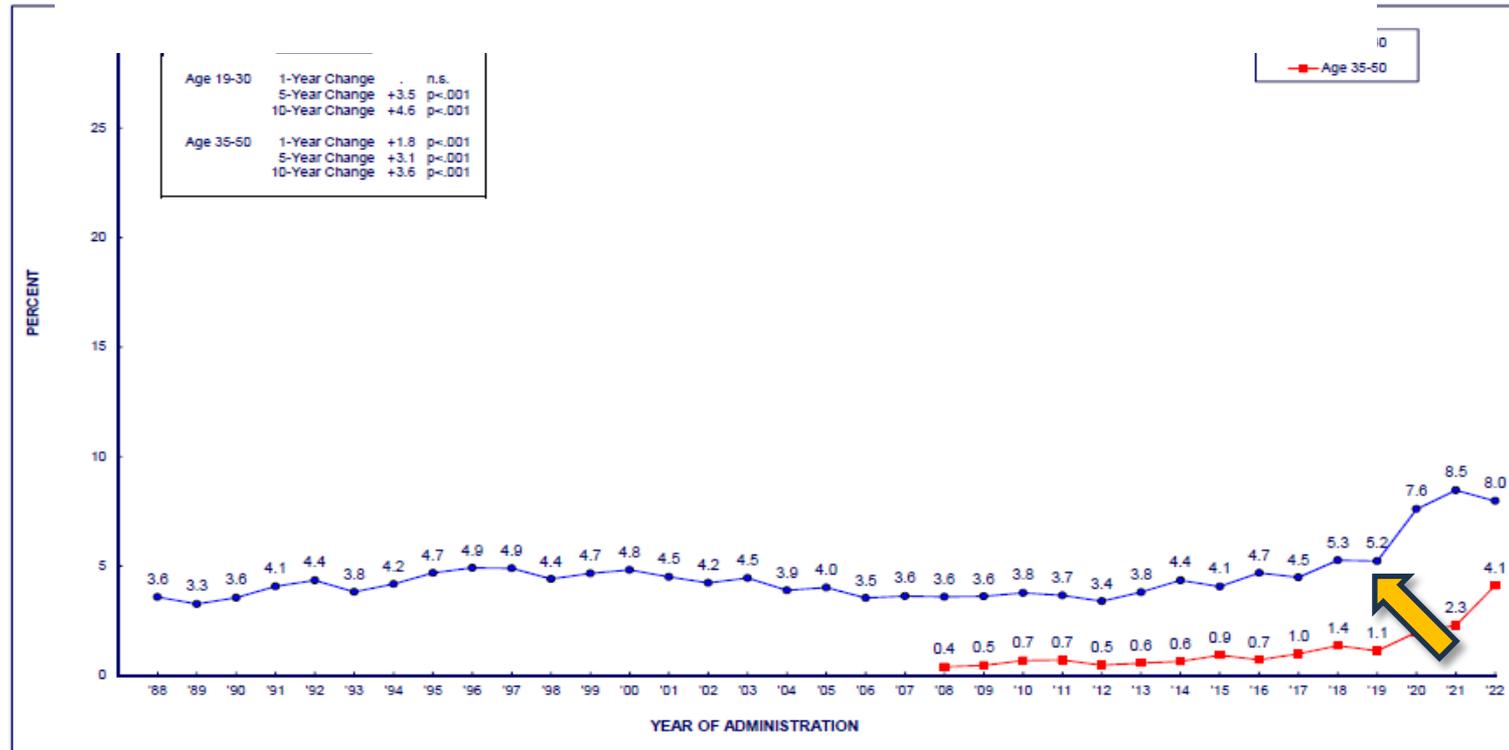
***Statistically significant increase among hallucinogen past year use ($p < .05$) from 2021 to 2023 - past year use of hallucinogens among 8.8 million Americans in 2023**

Past Year Use of Methamphetamine Use, Hallucinogens, and Inhalants by Age Group, 2023



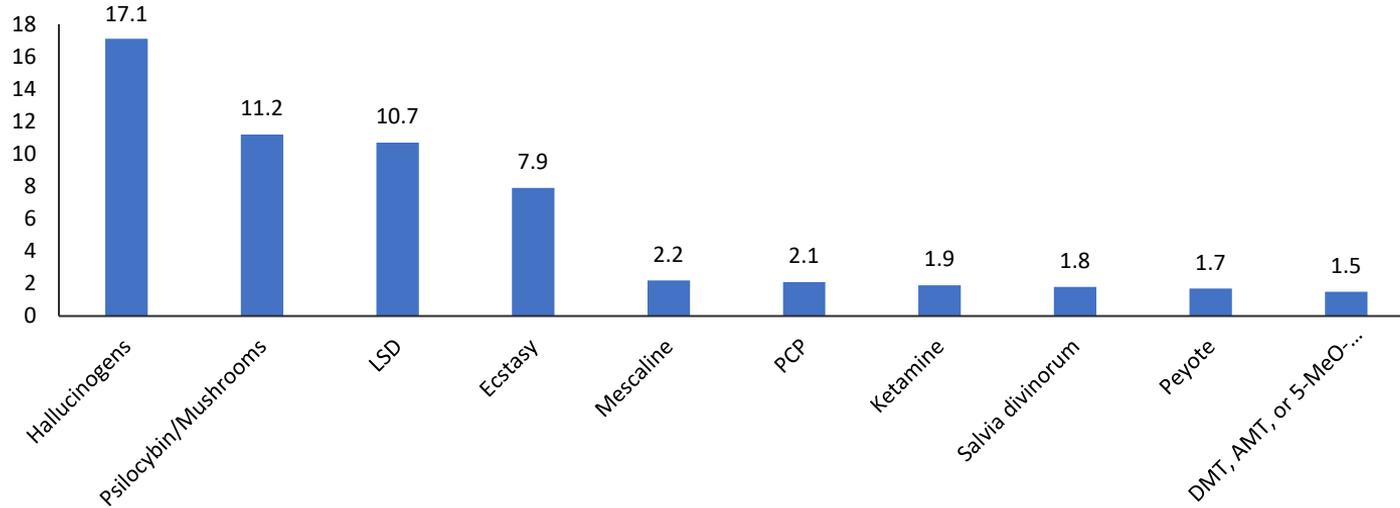
Highest past year hallucinogen past year use among 18-25 years age group (green)

HALLUCINOGENS
Trends in 12-Month Prevalence



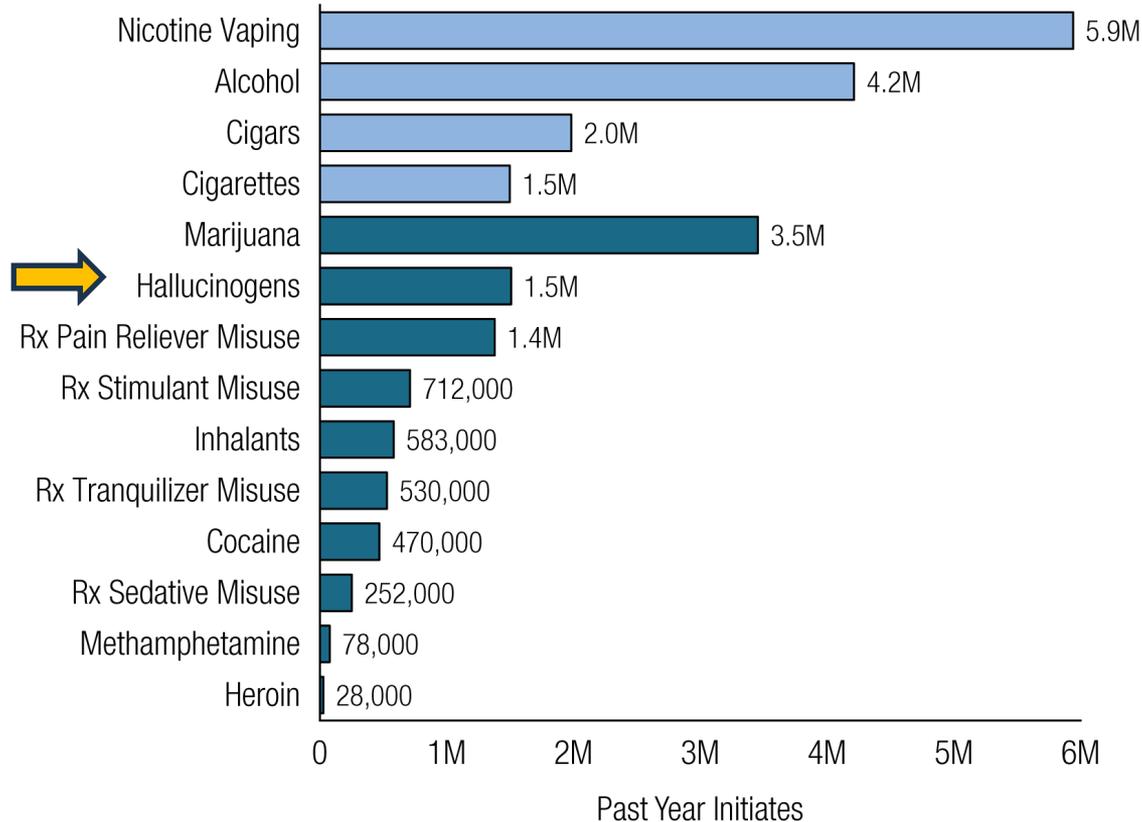
From NIDA's Monitoring the Future Panel Study, we see recent increasing rates of past year hallucinogen use among those 19-30 years (blue) and 35-50 years (red)

Percentage of Specific Hallucinogen Use in Lifetime among 12+, 2023

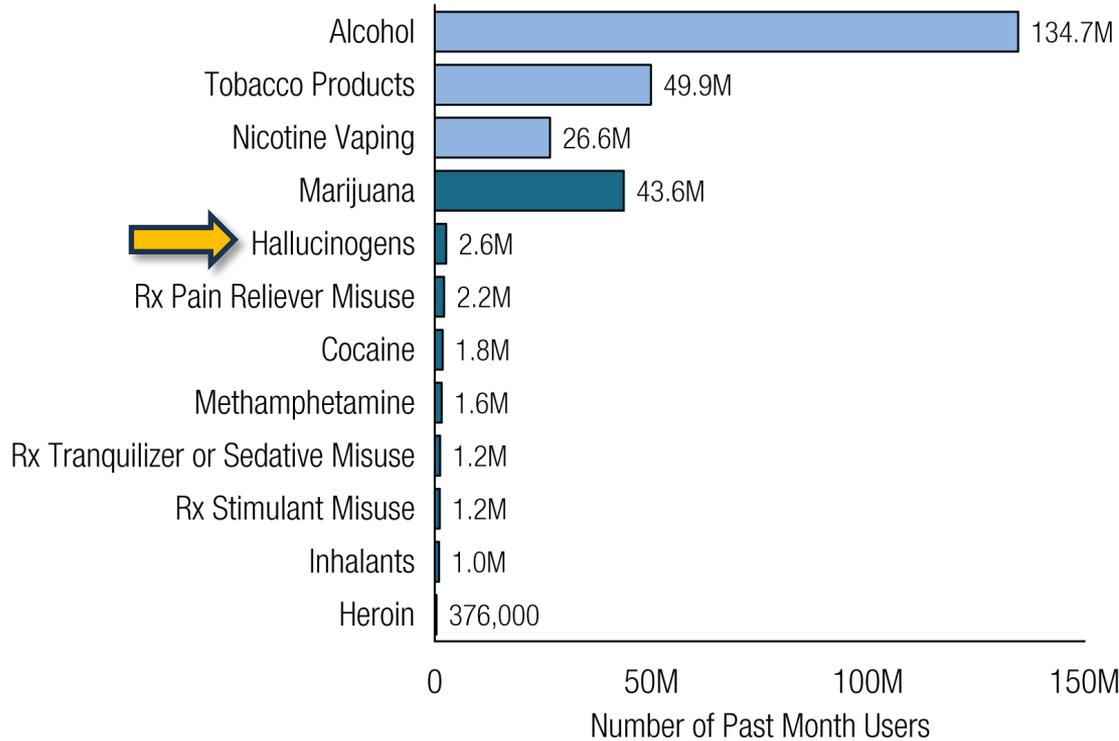


Psilocybin/Mushrooms is the most used hallucinogen, followed by LSD and then Ecstasy (MDMA).

Past Year Initiation among 12+, 2023

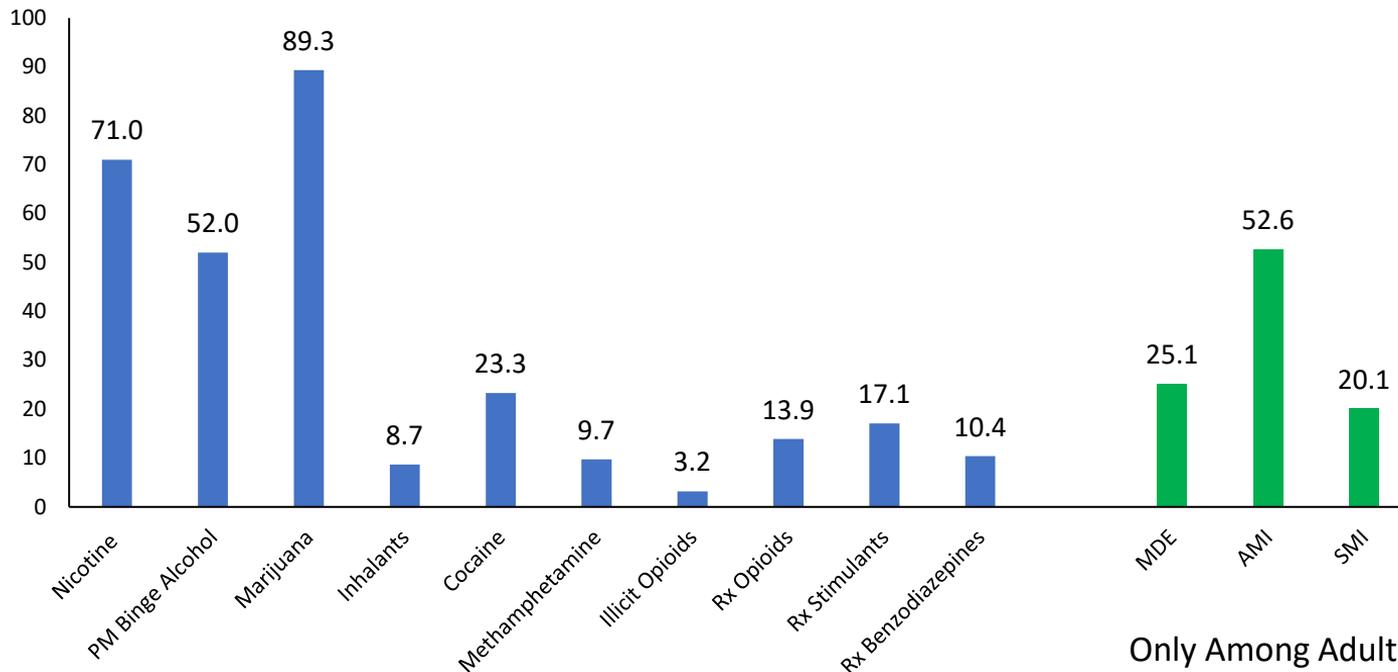


Past Month Use



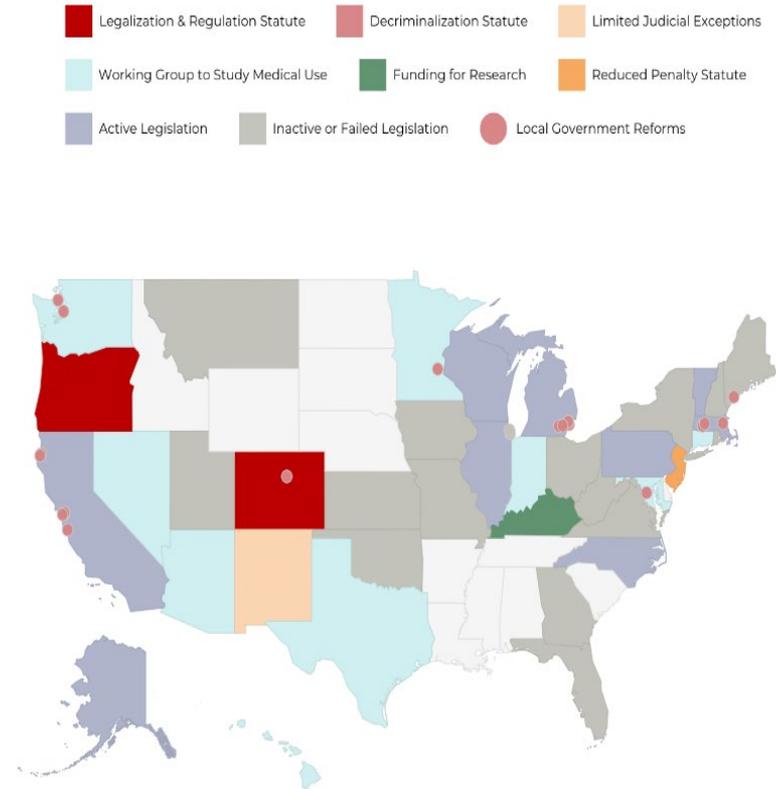
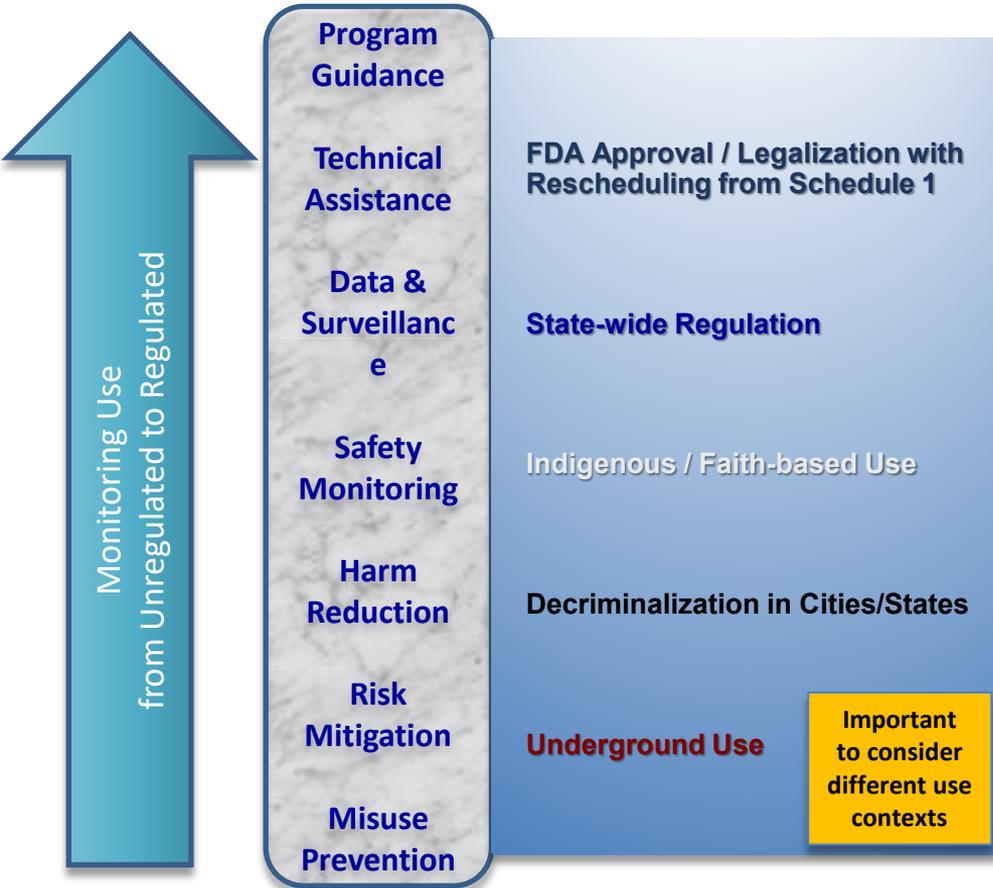
In 2023, 2.6 million Americans 12 years or older reported using a hallucinogen in the last month

Co-occurrence of Other Substance Use or Mental Health Challenges in Past Year among those 12+ Reporting Past Year Hallucinogen Use



Only Among Adults

Context of Use



US Native American Equities

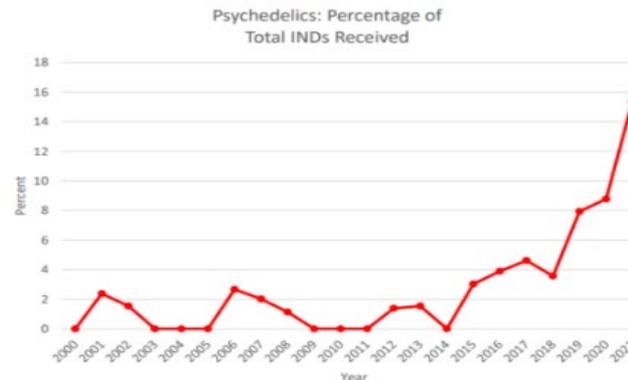
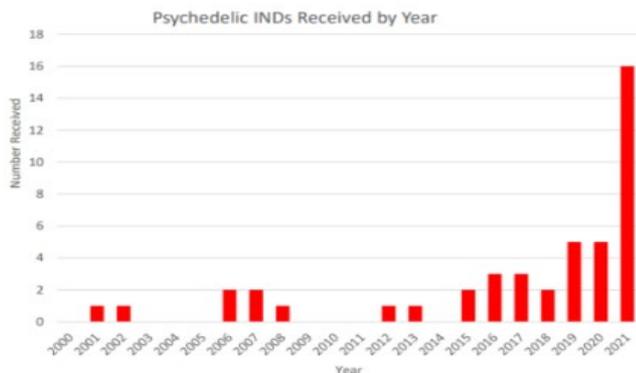
- The use of psychedelic substances has a long tradition in Religious Freedom Restoration Act (RFRA) protected indigenous and faith-based communities, who use them as sacraments in sacred religious healing ceremonies such as through the Native American Church
- The **Religious Freedom Restoration Act of 1993** is a federal law that "ensures that interests in religious freedom are protected."
- The 1994 amendment to the American Indian Religious Freedom Act of 1978 provided that "the use, possession, or transportation of **peyote** by an Indian for bona fide traditional ceremonial purposes in connection with the practice of a traditional Indian religion is lawful and shall not be prohibited by the United States or by any State."
- The impact of the rapidly evolving drug development and policy landscape on risks and access among tribal communities is currently unknown

Increasing Number of Investigational New Drug Applications

Current FDA Landscape



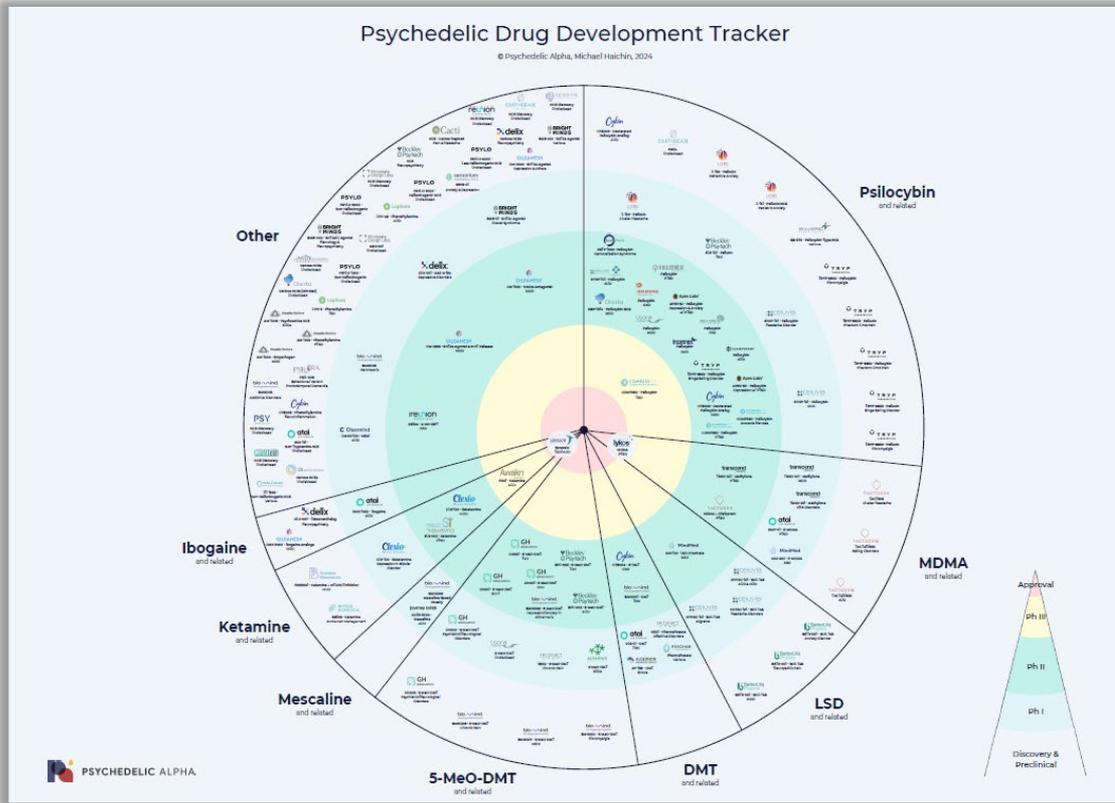
New IND Applications to DP: 2000 to 2021



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

Dr. Tiffany R. Farchione, Director of FDA's Psychiatry Division within the Neuroscience Office, shared unpublished internal analysis on the number of psychedelic Investigational New Drug (IND) applications received since 2000 at a virtual public meeting "Advancing Psychedelic Clinical Study Design", 1/31/24

Psychedelic Drug Development



FDA Breakthrough Therapy Designations

- MDMA – Post-Traumatic Stress Disorder 2017
- Psilocybin – Treatment Resistant Depression 2018
- Psilocybin – Major Depressive Disorder 2019
- LSD – General Anxiety Disorder 2024
- Psilocybin – Major Depressive Disorder 2024

Draft FDA Guidance on Clinical Trials for Psychedelic Drugs

Draft FDA Guidance on Clinical Trials with Psychedelic Drugs

- Growing interest in therapeutic potential of psychedelic drugs in recent years
- Subject to same regulations and evidentiary standards as other drug development programs
- Some unique challenges in conducting such trials, including:
 - Role of psychotherapy in psychedelic drug development
 - Blinding
 - Characterization of dose-response relationship and durability of treatment effect
- Assessment of abuse potential



SAMHSA'S Next Steps

- Partnership (Town Hall 8/14-15, Brown Bags)
- Data Collection- now and future investment
- Policy Guidance Development for:
 1. Therapeutic Implementation
 2. Risk and Prevention Strategies
 3. Messaging to the public, specific communities, workforce, and consumers
 4. Resource allocation for Training and Technical Assistance

Thank You

SAMHSA's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes.

Grant Opportunities

www.samhsa.gov/grants
www.grants.gov/web/grants

988 Suicide and Crisis Lifeline Toolkit

www.samhsa.gov/find-help/988/partner-toolkit

