

Policy Suggestions to Support the Safe Uses of Psychedelics

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Disclosures

Industry Relations / Conflicts of Interest (last 3 years):

Advisor – Journey Colab

No FDA-approved uses:

Ayahuasca, LSD, MDMA, mescaline, psilocybin

Open Science

“Statement on Open Science and Open Praxis with Psilocybin...”

<https://files.csp.org/open>

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Policy considerations that support equitable access to responsible, accountable, safe, and ethical uses of psychedelic medicines



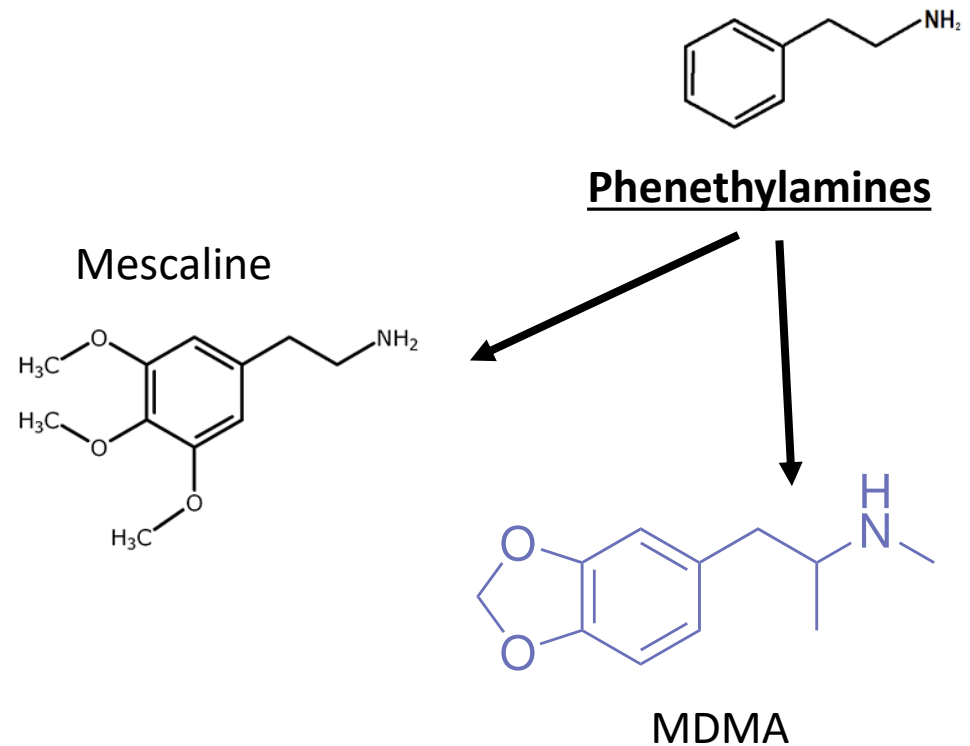
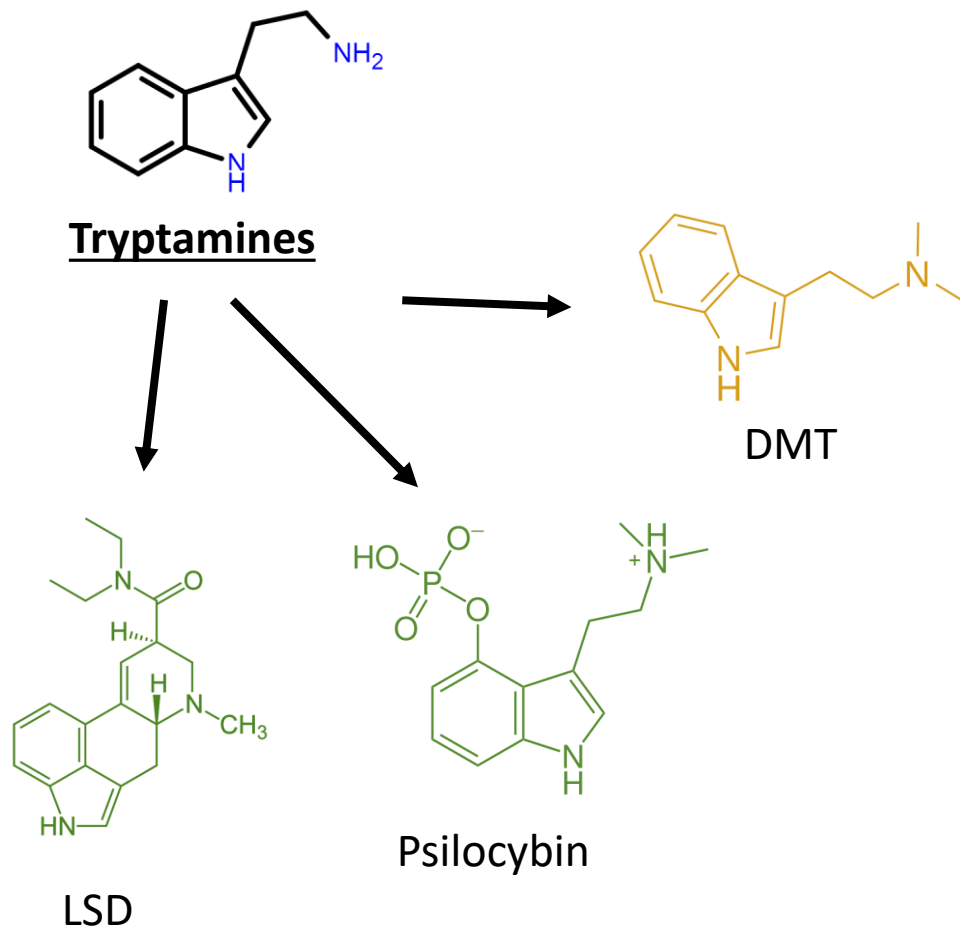
Sean J. Belouin ^{a,b,o,*}, Lynnette A. Averill ^{c,d,e,f,g}, Jack E. Henningfield ^{h,i},
Stephen N. Xenakis ^{j,k,g}, Ingrid Donato ^l, Charles S. Grob ^{m,n}, Ann Berger ^o, Veronica Magar ^p,
Alicia L. Danforth ^q, Brian T. Anderson ^{r,s}

Co-authors and their institutions are not responsible for the content of this presentation.

Disclosures



Psychedelic Medicines



Psychedelic Therapy



(No Rx) Preparation visits (~6-8 hr)



(Rx) Medication visit (~8 hr)



(No Rx) Integration visits (~4-8 hr)

Psychedelic Care



(No Rx) Preparation Session?



(Rx) Psychedelic Session



(No Rx) Integration Session(s)?

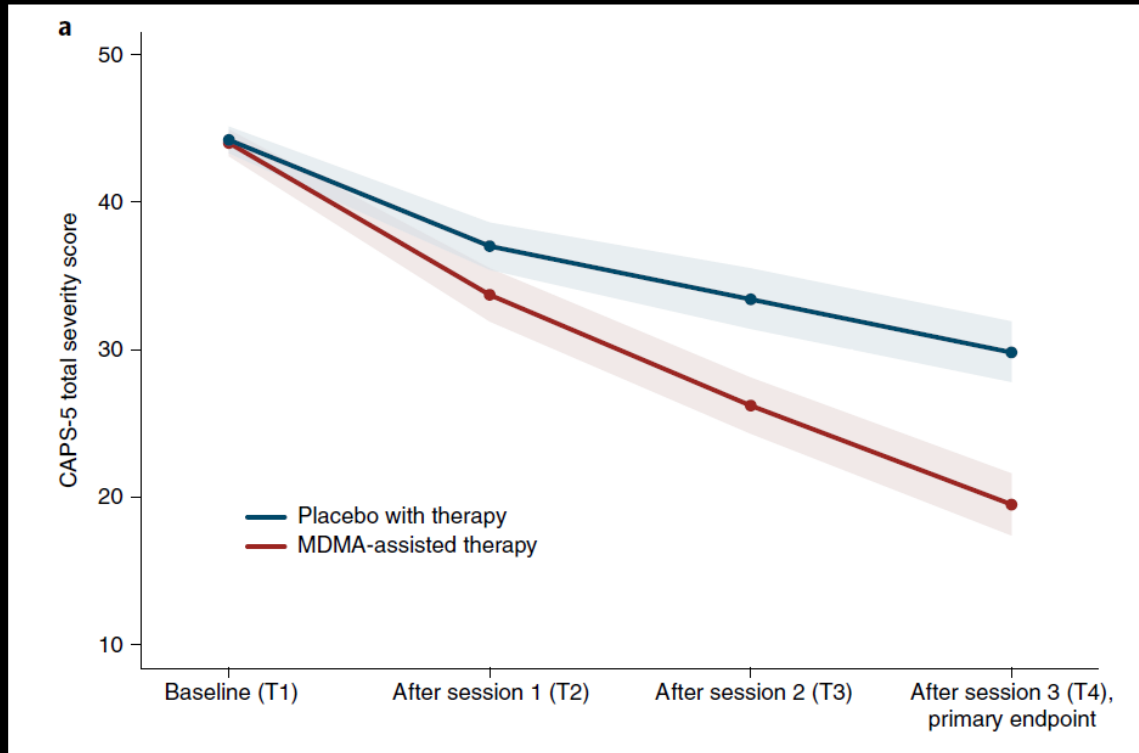
Traditional Knowledge

- Ceremonies, like protocols, are intentional rituals
- Healing, knowledge, and power
- Community-based, relational forms of care
- Unlicensed, faith-based practice is not necessarily unregulated practice



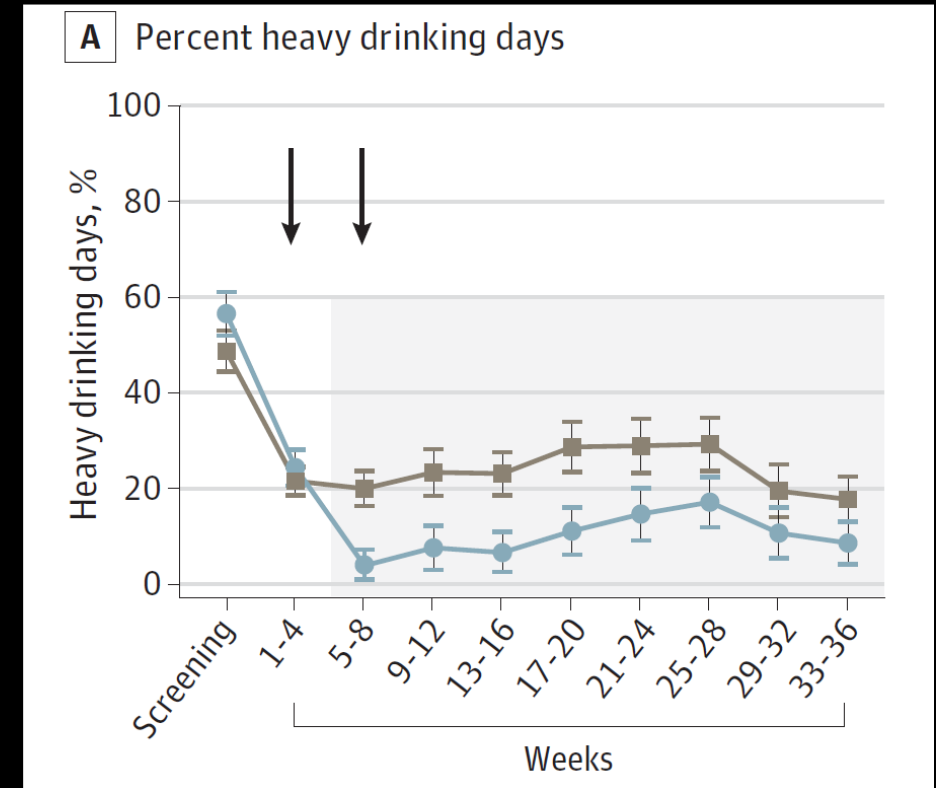
Biomedical Knowledge

MDMA Therapy for Severe PTSD



Effect size $d = 0.91$ (N=91)

Psilocybin Therapy for Alcohol Dependence



Effect size $g = 0.52$ (N=93)

Biomedical Care



- **SWITZERLAND**
 - Compassionate Use
- **CANADA**
 - Special Access Program
- **AUSTRALIA**
 - Authorized Prescriber Scheme

Increasing Concern

VIEWPOINT

Toward Risk-Benefit Assessments in Psychedelic- and MDMA-Assisted Therapies

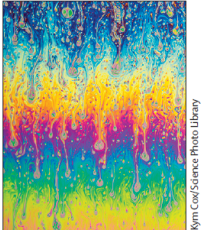
Mazdak M. Bradberry, PhD
Department of Neuroscience,
University of Wisconsin

As a result of demonstrating promise in a range of clinical studies, psychedelic and 3,4-methylenedioxymethamphetamine (MDMA)-based treatments have generated a tsunami of optimistic public interest and

Psychedelic medicine: safety and ethical concerns



in the field of psychedelic renaissance the ability to use these opportunities administration psychedelics were the 1950s and abortentousness atypical psychedelics, such as MDMA, have been found to be relatively well tolerated in early-phase clinical trials.³⁵ However, psychedelics can have lingering effects that include increased suggestibility⁶ and affective instability, as well as altered ego structure, social behaviour, and philosophical worldview.² Stated simply, psychedelics can induce a vulnerable state both during and after treatment sessions. Therefore, to assure the safe and responsible clinical administration



Long-term follow-up studies revealed no

Pressing regulatory challenges for psychedelic medicine

Policy must support generation of evidence on safety and effectiveness

By Amy L. McGuire¹, Holly Fernandez Lynch², Lewis A. Grossman³, I. Glenn Cohen⁴

intersect given the challenges of studying illicit use. Meanwhile, pressure from inve



For The Psychedelic Community [Follow](#)

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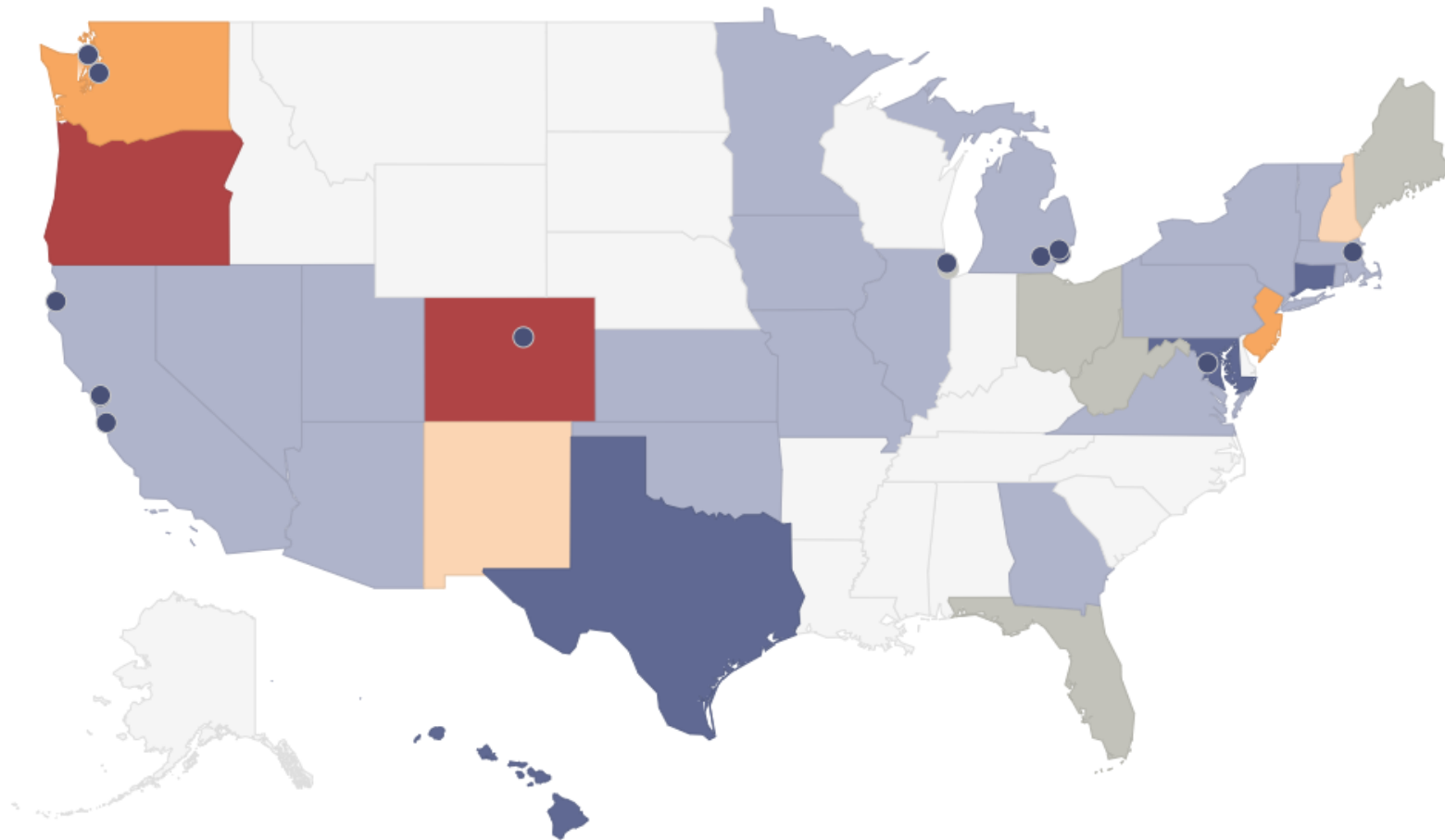


Save



Addressing Abuse and Repair: An Open Letter to the Psychedelic Community

- Legalization & Regulation Statute
- Decriminalization Statute
- Reduced Penalty Statute
- Limited Judicial Exceptions
- Working Group to Study Medical Use
- Active Legislation
- Inactive or Failed Legislation
- Local Government Reforms



Misconceptions in Public Discourse

“It’s legal”

“Science proved that psychedelics are safe”

“Science showed that psychedelics treat depression, anxiety and PTSD”

Public Education

- Public education needs to include professional education
- ‘Expert’ knowledge may not be ‘Professional’ knowledge
- ‘Bio-psycho-social-spiritual healing’ may happen, but not all Adult Use is necessarily Psychedelic Therapy
- Need for impartial assessment of medical evidence, emphasizing limitations

Assessing Safety and Risk

NSDUH (SAMHSA), 2020: 2.6% of people in the USA >12 years old (7.1 million) used “hallucinogens” in the past year

National Poison Data System, 2000-2016, “Psilocybin mushrooms”:

Cases	Major Effects, n(%)	Deaths, n(%)
5883	126 (2.1%)	3 (0.05%)

Global Drug Survey, 2017, (n=9233) past year psilocybin mushroom users: 0.2% sought emergency medical treatment

Common & Concerning Psychedelic Risks

- Headache, Insomnia, Fatigue
- Drug-drug Interactions
- Nausea and Vomiting
- Hypertensive Urgency/Emergency
- QTc Prolongation
- Client Vulnerability
- Dysphoria & Stress Reactions
- Persisting Perceptual Distortion
- Psychosis, Mania, Agitation
- False Memories and Personality Change



FEATURED

A Theological Reckoning with 'Bad Trips'

We need a more sophisticated assessment
of these experiences.

Check for updates

Article

Towards psychedelic apprenticeship: Developing a gentle touch for the mediation and validation of psychedelic- induced insights and revelations

Christopher Timmermann¹ , Rosalind Watts¹
and David Dupuis² 

transcultural
psychiatry 

Transcultural Psychiatry

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Attend to Facilitator Training & Peer-review

- Widely-accepted, consensus-based, and peer-endorsed practice guidelines do not yet exist
 - e.g., the market for combination services/products
- Which discipline(s) could truly oversee all of psychedelic care?
 - Medicine, counseling, faith-based (spiritual direction), peer-support...
- Is 5 years of Apprenticeship enough?

Gather Data, Learn as You Go

- Patient Registries and Prescription Drug Monitoring Programs?
- Balancing demands for Privacy, Accountability, Equity, and Accessibility
 - Incentive: ‘Protecting People, Programs and *the Plants*’
- Counts of adverse events without prevalence of use (or sales) is insufficient
- Middle road: Training lay Facilitators in Quality Improvement
- Hope for the Future: Community Engaged Research

Community Uses of Psychedelics & Safety (CUPS)



Co-PI Jennifer Mitchell

FDA BAA for Advanced Research & Development of
Regulatory Science

*Oregon
Partners*

FDA (2021) Focus Areas of Regulatory Science

- Public Health Preparedness & Response
 - Substance Use Disorders
- Empowering Patients & Consumers
 - Patient & Consumer Preferences and Perspectives



CUPS1

Dr. Maha Mian

Safety and harms in US psychedelic churches:
A community-based participatory research study

Ethnographic observations and interviews about harms and safety practices in long-standing US psychedelic churches



CUPS2

Dr. Nicky Mehtani

Examining motivations, benefits, and harms of ayahuasca-augmented 12 Step Recovery for the treatment of substance use disorders: An exploratory mixed-methods study

Surveys and interviews conducted in collaboration with a community partner with lived experience



CUPS3

Dr. Juan Carlos Montoy

Association of implementation of drug regulatory changes in Oregon with psilocybin-related adverse outcomes

Methods assessment for capturing psilocybin-related SAEs in medical settings via national databases and EHRs



CUPS4

Dr. Paulo Barbosa

Persisting, acute and subacute effects of ayahuasca: A Cross-cultural neuropsychiatric evaluation

A 3-language online cross-sectional survey of ayahuasca users' psychological status and use patterns



Conclusions



Psilocybe Cubensis Fruiting Body
Photo by Erowid. © 2014 Erowid.org

- Psychedelics present unusual Opportunities for providing Care, which also carry unusual Risks
- Public Education (informed by the Community and Evidence) is needed
- Facilitator Quality is key to Safety
- Research with and for the Community will be essential

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Therapeutic Goods Administration (AU)

Thank You

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