



MAPS

MULTIDISCIPLINARY ASSOCIATION
FOR PSYCHEDELIC STUDIES



Bulletin

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SPECIAL EDITION
Drug Reform and Drug Access Pathways

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MAPS

MULTIDISCIPLINARY ASSOCIATION
FOR PSYCHEDELIC STUDIES

Founded in 1986, the Multidisciplinary Association for Psychedelic Studies (MAPS) is a **501(c)(3) non-profit** research and educational organization that develops medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana.

MAPS furthers its mission by:

- Developing psychedelics and marijuana into prescription medicines.
- Training therapists and working to establish a network of treatment centers.
- Supporting scientific research into spirituality, creativity, and neuroscience.
- Educating the public honestly about the risks and benefits of psychedelics and marijuana.

MAPS envisions a world where psychedelics and marijuana are safely and legally available for beneficial uses, and where research is governed by rigorous scientific evaluation of their risks and benefits.

MAPS relies on the generosity of individual donors to achieve our mission. Now that research into the beneficial potential of psychedelics is again being conducted under federal guidelines, the challenge has become one of funding. No funding is currently available for this research from pharmaceutical companies or major foundations. That means that the future of psychedelic and marijuana research is in the hands of individual donors. Please consider making a donation today.

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Cover Art

FRONT: Color Bird, 2022

BACK: Dehydration, 2021

by Natasha Chomko

Natasha (b. 1995) is a Los Angeles-based digital artist mainly focused on surreal landscape collage art with refined visionary and psychedelic elements. Her style aims to be palatable for both the seasoned psychonaut and average Joe, and everyone in between. Her work combines snippets of landscapes from all over the globe to demonstrate how interconnected we all truly are. As a lifelong collager, Natasha challenges perception of shapes, color, and texture to create entirely new universes out of pre-existing photos. Natasha picked up collage in 2007 after drawing and painting didn't feel quite right, and always stayed close to the medium. After completing university with a BA in Political Science and working on a political campaign, Natasha felt creatively starved and sought out an outlet, once more turning back to collage. Freeing her inner child through art was not only therapeutic, but eventually became an integrated part of Natasha's life. As a self-taught artist, she never intended to become a professional artist, but now strongly believes in the importance of therapeutic and self-taught art.

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From the Desk of Rick Doblin, Ph.D.

The theme of this special edition *MAPS Bulletin*, **Drug Reform and Drug Access Pathways**, encapsulates two foundational and parallel strategies of achieving my long-term goal: mass mental health and global spirituality.

The first strategy is FDA-regulated drug development potentially leading to prescription access to psychedelic-assisted therapies, starting with MDMA-assisted therapy for PTSD, with globalization of research and regulatory approvals supplemented by insurance coverage from private and national health insurance, followed by expansion to medical uses of other psychedelics and cannabis. MAPS works to facilitate the entire psychedelic-assisted therapy ecosystem rather than just prioritizing our own research, leading to our policy of transparency and practice of collaboration rather than competition.

The second strategy is drug policy reform leading to a post-prohibition world of legal access for adults outside of medical and religious contexts accompanied with honest drug education, harm reduction services, treatment on demand for dependence or other challenging experiences, and access to unadulterated substances at low, generic prices. There would be prohibitions against use by minors but with overrides by parents and guardians to return the education and training of their children about psychedelics and cannabis to the family, as opposed to having government agencies dictate that families should educate their children in a failed abstinence-only model that has counter-productive outcomes, as in the case of alcohol.

As the last several decades of the reform of cannabis policies have taught us, medicalization precedes legalization. Regulated research into medical applications generates scientifically validated data about contexts and clinical applications in which benefits may outweigh risks. Due to the media interest in new scientific studies, and public interest in new treatments for problematic, painful, and sometimes fatal mental health conditions, scientific drug development research with psychedelics and cannabis generates a large amount of free, earned media. This earned media provides substantial public education that helps to counteract decades of propaganda from the War on Drugs that exaggerates risks and denies any benefits, in part through the suppression of research to prevent evidence of treatments for specific clinical indications where there is a favorable risk-to-benefit ratio.

As the last several
decades of the
reform of cannabis
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us, medicalization
precedes legalization.

Some for-profit psychedelic companies fear that drug policy reform with legal access at generic prices will be bad for their business model of selling psychedelics and cannabis at pharmaceutical prices, after spending hundreds of millions of dollars on research, patient access, and commercialization. My view is that legal access will actually be helpful for the pharmaceutical model as psychedelics are further destigmatized, the general public becomes more familiar with non-ordinary states of consciousness, and the occupation of psychedelic therapist becomes professionalized. It seems likely that all these developments will result in an increase in the number of people interested in seeking out treatment for clinical conditions at psychedelic treatment centers (with insurance coverage) where therapists are cross-trained in all the available psychedelic treatments and able to design a personalized sequence of experiences for each patient.

It is possible that my view is incorrect, and that legalization will indeed reduce income for the psychedelic and cannabis pharmaceutical business models. If that turns out to be the case, then it is an outcome that needs to be accepted—eliminating the disastrous outcomes of the Drug War, and establishing the fundamental human right to explore one’s own consciousness, must be prioritized over generating pharmaceutical profits.

This issue contains fascinating articles about a range of topics related to Drug Reform and Drug Access Pathways. The special themed editions of the *MAPS Bulletin* are designed to raise and address issues to enhance and inform discussions as we all think through the many implications of the mainstreaming of psychedelics and cannabis into both medicine and broader legal access. Discussions about Drug Reform and Drug Access Pathways are not just hypothetical deliberations about possible outcomes in the distant future. In the coming months, MAPS will gather the final data point in our second Phase 3 study of MDMA-assisted therapy for PTSD, and Colorado will vote on an initiative to create legal access to plant medicines in a manner similar to the Oregon Psilocybin Initiative. We invite everyone to continue these discussions in person at MAPS’ Psychedelic Science 2023 conference at the Denver Convention Center from June 19-23, the world’s largest psychedelic conference ever convened. You can learn more about the conference and register at [psychedelicscience.org](https://www.psychedelicscience.org).



Rick Doblin, Ph.D.
MAPS Founder and Executive Director



MAPS Research

MDMA-Assisted Therapy for PTSD

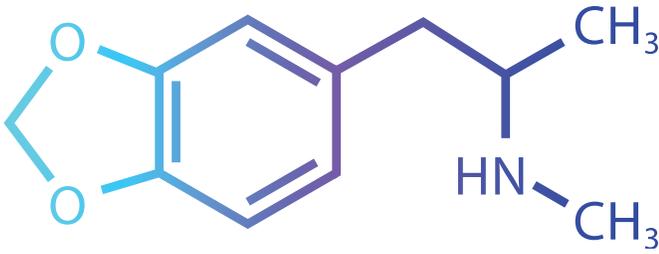
Novel PTSD Treatment Advances Toward Regulatory Evaluation with New Collaboration

- On PTSD Awareness Day, MAPS PBC announced plans to develop the New Drug Application for MDMA-assisted therapy in collaboration with MMS Holdings
- The second Phase 3 trial of the Breakthrough-Designated Therapy for PTSD will be completed in late 2022, with a targeted NDA submission in 2023 supported by MMS Holdings
- MMS Holdings was selected for extensive experience supporting neuroscience-related and first-in-class NDAs

MAPS-Sponsored Phase 1 & 2 Trials

MDMA-Assisted Group Therapy for PTSD Among Veterans Study Will Proceed Following Successful Safety Negotiations

- The FDA lifted the clinical hold from a MAPS-sponsored Phase 2 study of MDMA-assisted group therapy for the treatment of posttraumatic stress disorder among veterans at the VA Portland Health Care System
- This essential proof-of-principle study tests safety and logistics of group therapy, the first step in fully investigating the treatment for efficacy and broader patient access
- The data-driven negotiation strategy included substudies of participants' no-overnight stay conducted in the first Phase 3 trial of MDMA-assisted therapy for PTSD



Molecular compound of MDMA

A Phase 2, Open-Label, Randomized Comparative Effectiveness Study for MDMA-Assisted Therapy in U.S. Military Veterans with Chronic PTSD

As of August 8, 2022, a total of five participants have been enrolled and the Bronx VA site continues to actively screen for new participants.

As of July 19, 2022, one subject completed the trial. Two additional subjects have been treated, and four subjects are enrolled into this study.

Enrollment is continuing for this Phase 2, open-label study on the effectiveness of MDMA-assisted therapy in U.S. Veterans with chronic PTSD. This study is a comparative study that assesses two versus three active MDMA-assisted sessions.

Food Effect on Bioavailability of MDMA in Healthy Volunteers Study (MPKF) Open for Enrollment

On July 28, 2022, the first participant was screened for the Phase 1 food effects study. This study is enrolling healthy volunteers and examines the effect of food on the bioavailability of MDMA. The study is being conducted at the Alliance for Multi-specialty Research, a Phase 1 unit in Knoxville, TN.

First Participant Screened in Open-Label, Phase 2, Multicenter Feasibility Study of Manualized MDMA-Assisted Therapy with an Optional fMRI Sub-Study Assessing Changes in Brain Activity in Subjects with PTSD in Europe

On July 18, 2022, the first UK participant in our open-label Phase 2 study of MDMA-assisted therapy for PTSD was screened by the research team at the Institute of Psychiatry, Psychology and Neuroscience at King's College London – South London and Maudsley NHS Trust (KCL-SLaM). The site principal investigator is Dr. James Rucker.

Investigator-Initiated Trials

We are excited to share recent progress with our investigator-initiated trial (IIT) program! The MAPS Public Benefit Corporation (MAPS PBC) IIT program is designed to create an ever-growing network of qualified clinicians whose passion and innovative questioning help to inspire new possibilities within the path to expanding patient access and the conditions that MDMA-assisted therapy may be possible in treating. To learn more about these studies, visit the official study page: maps.org/iit

Now Recruiting for Investigator-Initiated Trial in Portland, Oregon

Recruitment of participants has begun at our investigator-initiated trial at Portland Psychotherapy in Portland, Oregon. Dr. Jason Luoma and a team of researchers are conducting this study to assess the safety and effectiveness of MDMA-assisted therapy in treating individuals with moderate-to-severe social anxiety disorder (SAD). The team at Portland Psychotherapy plans to treat up to 20 participants. [Visit the recruitment website to apply to participate.](#)

[Enrollment continues](#) for other study sites conducting Investigator-Initiated Trials. The MAPS Public Benefit Corporation (MAPS PBC) [Investigator-Initiated Trial \(IIT\) program](#) is designed to create an ever-growing network of qualified clinicians whose passion and innovative questioning help to inspire new possibilities within the path to expanding patient access and the conditions that MDMA-assisted therapy may be possible in treating.

Participate in Research

MAPS sponsors clinical trials around the world that offer volunteers the opportunity to participate in our research studies. Our studies have strict enrollment criteria based on the goal of the study and the condition the study is investigating.

The second, confirmatory Phase 3 trial of MDMA-assisted therapy for PTSD is now fully enrolled at 13 sites in the United States and Israel.

Please visit our [Participate in Research](#) page and check it frequently for updates about participant enrollment: maps.org/participate-in-research. The safety and efficacy of MDMA-assisted therapy is currently under investigation. This treatment has not yet been approved by the FDA, does not work for everyone, and carries risks even in therapeutic settings. To learn more, please visit mdmaptsd.org.

Therapy Training

MDMA Therapy Training Program Updates

Cohorts for 2022 are now full. The MDMA Therapy Training Program is no longer accepting applications. For updates on future opportunities, please sign up for the training newsletter: mapspublicbenefit.com/training

In August, the training team hosted the first MAPS PBC Trainers retreat in New York. The 4-day retreat was delivered in collaboration with [Reconsider](#). The gathering brought together more than 25 MAPS PBC trainers and assistant trainers to discuss best practices for developing and delivering gold-standard MDMA-assisted therapy training. The training team also supported a week-long in-person training retreat in Boston in collaboration with the California Institute of Integral Studies (CIIS) Certificate in Psychedelic-Assisted Therapies and Research.

In September, the therapy training team delivered two in-person trainings in New York and Colorado. In July 2022, the MDMA Therapy Training team delivered training for Naropa University's inaugural psychedelic-assisted therapies certificate cohort.

In June 2022, the MDMA Therapy Training Team delivered two more trainings, including a week-long in-person training retreat in New York and a week-long training in California in collaboration with the California Institute of Integral Studies (CIIS) Certificate in Psychedelic-Assisted Therapies and Research.

search. The New York training was led by mentor trainers Bruce Poulter, MPH, and Marcela Ot'alora G., MA, LPC. In addition to the synchronous and online course content, the training retreat incorporated art therapy projects, an evening music experiential evening, and Holotropic Breathwork, among other immersive learning components. The retreat was supported by a team of Assistant Trainers including Harvey Schwartz, Ph.D., LCP; Veronika Gold, LMFT; Jennifer Jones, LCSW; Genesee Herzberg, LCP; and Jason Butler, Ph.D., LCP. The CIIS training was led by mentor trainers Michael Mithoefer, M.D., and Annie Mithoefer, BSN, and supported by Assistant Trainers Eric Sieneck, Ph.D., LCP, and Joanna Simundic, LPC, LCSW.



In May 2022, the MDMA Therapy Training Team hosted their second 100-hour blended (online/in person) training program and hosted a week-long in-person training retreat in Colorado (pictured above). In addition to the synchronous and online course content, the training retreat incorporated immersive learning components including art therapy projects, an evening music experiential evening, gong bath performance, and the SoundSelf technology by EntheoDigital, which engages your voice in a biofeedback loop enhanced by vibro-acoustics and light therapy.

Volunteer with MAPS!
 If you would like to be a part of our volunteer team, fill out our form at maps.org/participate/volunteer

MAPS News

MAPS Dedicates Legacy Circle to Ashwana Hailey

Ashawna Hailey was a software pioneer and MAPS board member who cared deeply about making a better world for all. When she passed away in 2011, Ashawna left \$10 million in bequests to drug policy reform organizations, including \$5.5 million to MAPS. The newly named Ashawna Hailey Legacy Circle honors Ashawna's memory and recognizes donors who follow her extraordinary lead and include MAPS in their will. Visit maps.org/legacy to learn more.



Following Landmark Achievement, California Psychedelic Decriminalization Bill Slated for 2023 Reintroduction

- Senate Bill 519 would have decriminalized the personal possession of certain psychedelic substances, legalized life-saving public health interventions, and studied future approaches to increasing use of psychedelics
- Bill sponsor Senator Scott Wiener, who enlisted MAPS to advise on the bill, led the reform closer to passage than any previous state-wide psychedelic decriminalization legislation
- Going forward, MAPS will focus on advocating for psychedelic policy reform to include state funding for public education, harm reduction, and unarmed crisis response services.

MAPS, in Coordination with Allies, Assists U.S. Sentencing Commission in Reaching Quorum

- United States Sentencing Commission, which establishes and advises Congress on federal sentencing guidelines, reaches first quorum in three years and a full slate for first time since 2014
- Delayed appointments inhibited implementation of drug sentencing and other reforms to reduce disparities in the federal prison system, including First Step Act of 2018
- This concluded a year-long bipartisan effort by MAPS to support successful appointments

Statement: Biden Administration Preparing for Potential FDA Approval of MDMA-Assisted Therapy for PTSD

On July 26, a letter from the U.S. Department of Health and Human Services was [made public](#) describing the Food and Drug Administration's "anticipated approval... within approximately 24 months" of psychedelic-assisted therapies.

We applaud the Biden Administration for taking psychedelic-assisted therapies, and their potential to treat life-threatening mental health conditions, seriously. A Federal Task Force on psychedelic-assisted therapies should take a multidisciplinary approach to ensuring that red tape, administrative delays, or insurance coverage questions don't leave Americans suffering as they seek to access approved treatments.

For the first time, research that has been driven by philanthropists could additionally be supported by the same types of Federal grants that have funded other health care revolutions and develop patient access strategies that prioritize public benefit over profit. For decades, we have been making the case for what the Administration is now acknowledging: psychedelic-assisted therapies may become a key in addressing the most urgent mental health challenges of our time and reducing needless suffering.

*Rick Doblin, Ph.D.
Founder and Executive Director, MAPS*

MAPS Launches Psychedelic Fundamentals, an Online Education Curriculum From Leading Psychedelic Organization

- Psychedelic Fundamentals is the initial offering in the new MAPS Digital Learning program introducing learners to the most important aspects of psychedelic history, research, uses, and harm reduction
- The series of short, easy-to-follow modules is the perfect starting point for people trying to learn about psychedelics for the first time, but is also useful for psychedelic veterans looking to refine their knowledge
- "This is the drug training we should have all received as teenagers."

MAPS Appoints Jeff George and Dan Grossman to MAPS PBC Board of Directors

- Experienced healthcare leaders bring decades of experience in global drug commercialization and patient access
- Appointment brings significant pharmaceutical leadership experience to the MAPS PBC board
- MDMA-assisted therapy, a novel treatment for PTSD with FDA breakthrough therapy designation, is on track for NDA submission in 2023 pending results of the confirmatory Phase 3 trial

MAPS Raises Nearly \$1.6 Million in Christie's NFT Auction

- Digital art, inspired by personal experience and the potential of psychedelic healing, was donated by leading digital artists including Beeple, David Choe, and Alex Grey
- Cartography of the Mind represented the single-largest sale of art to benefit MAPS in its 30+ year history of philanthropic art sales
- Select pieces will be exhibited at [Psychedelic Science 2023](#), marking the first time digital art will be exhibited in the extensive Psychedelic Science galleries and exhibits



MAPS' Strategic Priorities for a Post-Prohibition Reality

Kan Yan and Fede Menapace

Introduction

This article sets forth the long-term strategy of MAPS, which was developed by the MAPS Strategy Department in collaboration with the MAPS Board of Directors, staff, and numerous allies. This strategy articulates a long-term, achievable, and aspirational goal and highlights the areas of focus that require a significant investment of time and resources to achieve that goal.

MAPS and its subsidiary [MAPS Public Benefit Corporation \(MAPS PBC\)](#) have complementary missions and strategies. While this article focuses on the broader strategy of MAPS, it is essential to note the current priorities of MAPS PBC as they reflect a major focus of MAPS' strategy:

Within a year, MAPS PBC aims to submit to the FDA a New Drug Application for MDMA-assisted therapy as a treatment for PTSD), which has been the primary focus of the company for the past eight years. As MAPS PBC approaches this monumental milestone, the team is focused on completing the critical work required to make this submission successful and establishing the commercial functions necessary to support MDMA-assisted therapy as an approved treatment for PTSD. Some specific areas of focus include: completing Phase 3 clinical trials, working with regulatory agencies to establish minimum safety standards, and increasing awareness among healthcare providers and payers (insurance companies) about research into MDMA-assisted therapy for PTSD. Concurrently, MAPS PBC is developing a pipeline to conduct research in other mental health conditions and with other compounds.

Although our work focuses on psychedelics, we stand firm on our commitment to reform broader drug policy, to end the War on Drugs, and to set the groundwork for a post-prohibition reality.

Big, Hairy, Audacious Goal (BHAG)

Our BHAG is a vision statement that orients the MAPS strategy around a simple and specific objective:

Legal and equitable access to psychedelics for healing and personal growth for a billion people by 2035 in a post-prohibition context

Here is an overview of our vision:

- **Legal and Equitable Access:** We advocate for legal access to psychedelics through multiple channels, including working toward FDA approval; state and federal decriminalization; and legalization for social, spiritual, or sacramental use. MAPS seeks to develop socially and economically suitable solutions to help ensure safe, responsible accessibility.
- **Healing:** A primary focus of our work is enabling the healing use of psychedelics in medical contexts (e.g., sponsoring research that promotes healing regardless of financial potential).
- **Personal Growth:** MAPS also believes that the careful use of psychedelics can be beneficial in non-medical contexts. These compounds have a variety of uses that allow for the flourishing of healthy individuals, groups, and communities.
- **A Billion People:** Our aim is an audacious expansion of access into geographies around the world for anyone who may benefit from the careful uses of psychedelics.
- **Post-Prohibition Context:** Although our work focuses on psychedelics, we stand firm on our commitment to reform broader drug policy, to end the War on Drugs, and to set the groundwork for a post-prohibition reality. We work for a world where no one is incarcerated for drugs — and drugs are legal and regulated according to their potential benefits and risks.

2026 Strategic Priorities

To move toward our BHAG, MAPS sets forth the strategic priorities below to realize by the end of 2026. These priorities will be the focus of new resources as we build up our staff and capabilities over the coming years. These Strategic Priorities will be pursued in alignment with the [MAPS Values and Principles](#),¹ which are core to our mission.

1. Be financially self-sustaining

MAPS seeks to create financially self-sustaining models both for itself as a non-profit entity and for its public benefit subsidiary MAPS PBC. This requires securing financing for MAPS PBC to attain commercial viability as a psychedelic drug development company. It will also require MAPS itself to raise sufficient philanthropic funds to enable success for its other strategic priorities.

Example Initiative: In December 2021 MAPS and Vine Ventures announced a novel financing model called the *Regenerative Financing Vine (RFV)*,² which aims to infuse \$70 million into patient access infrastructure and research for MDMA-assisted therapy for PTSD. This model fully maintains both MAPS' non-profit mission and gov-

ernance as well as MAPS PBC's public benefit drug development and patient access activities.

2. Become a leading activist think tank for psychedelic policy and major funder for drug policy reform

MAPS seeks to significantly influence drug policy reform (not just psychedelic drug policy reform) as an activist think tank in the near term and as a granting organization in the long term. As an activist think tank, MAPS' Policy and Advocacy Department will continue to employ legislative, judicial, and direct action pathways to achieve landmark reforms in decriminalization, regulated adult use, and in the criminal justice system. Once MAPS PBC generates sufficient revenue to send a portion to MAPS, we will provide grants to other drug policy organizations to further our vision of a post-prohibition world.

Example Initiative: MAPS provides expert advice, training, and resources to advocates, legislators, and regulatory and advisory bodies involved in passing and implementing psychedelic policy reform. In these contexts, we advocate for a broadly accessible network of harmonized, complementary systems of access to psychedelics as well as for broader drug policy reform. Highlights include providing key input on *California Senate Bill 519*³ (slated for reintroduction in 2023); the *Natural Medicine Healing Act (NMHA)*⁴ in Colorado (on the ballot in November 2022); and *Connecticut House Bill 5396*⁵ (passed in 2022); and related bills in Florida, Hawaii, New York, and Washington.

¹ Ginsberg, N. L., & Ali, I. L. (2021, November 12). *Announcing MAPS' values and principles - Multidisciplinary Association for Psychedelic Studies*. MAPS. Retrieved August 25, 2022, from <https://maps.org/news/bulletin/announcing-maps-values-and-principles-bulletin-2021/> and <https://www.opb.org/article/2022/06/09/oregon-psilocybin-rules-shape-who-can-provide-and-access-care/>

² Aldworth, B. (2022, February 2). *MAPS and Vine Ventures pioneer novel regenerative funding structure to infuse psychedelic-assisted therapy research and access with timely \$70 million - Multidisciplinary Association for Psychedelic Studies*. MAPS. Retrieved August 25, 2022, from <https://maps.org/2021/12/02/maps-and-vine-ventures-pioneer-novel-regenerative-financing/>

³ *Bill text*. Bill Text – SB-519 Controlled substances: study of decriminalization of certain hallucinogenic substances. (2021). Retrieved August 25, 2022, from https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB519

⁴ *Colorado Secretary of State*. Natural Medicine Health Act of 2022. (n.d.). Retrieved August 25, 2022, from <https://www.sos.state.co.us/pubs/elections/Initiatives/titleBoard/filings/2021-2022/58Final.pdf>

⁵ *Raised Bill No. 5396 - cga.ct.gov*. An Increasing Access to Mental Health Medication. (n.d.). Retrieved August 25, 2022, from <https://www.cga.ct.gov/2022/TOB/H/PDF/2022HB-05396-R00-HB.pdf>

Fede Menapace, M.B.A., M.S.

serves as the Chief Strategy Officer for MAPS. Born and raised in the Trentino region in northern Italy, he began his career as a civil engineer, working on road and railway bridge construction projects in the Italian Alps. He then joined McKinsey & Co. in Milan, Italy, where he worked as a management consultant advising multinational financial institutions. He later moved to the internet technology sector, most recently at Segment in San Francisco, where he built and led the Business Operations and Business Development teams. In his role at MAPS, Fede aims to continue building bridges – this time among people and organizations in the psychedelic medicine field – to further MAPS’ mission to provide broad and safe access to mental health treatments for those who are most in need. Fede also works on internal strategy projects to identify and execute growth opportunities for MAPS and its subsidiaries. Fede received his M.B.A. from the Stanford Graduate School of Business and his M.S. in structural engineering from the University of Michigan, Ann Arbor.

Kan Yan, J.D., M.A.L.D.

served as Strategy and Partnerships Officer at MAPS. Kan has worked as an international humanitarian for the United Nations, a lawyer for the US Federal Courts, and a management consultant for McKinsey & Company where he consulted Fortune 500 clients across numerous industries with a focus on organizational health and leadership development. He has a law degree from Harvard Law School and a masters in law and diplomacy from the Tufts Fletcher School. He currently works as an executive coach and consultant to psychedelic organizations.

3. Catalyze research for the humanitarian use of psychedelics

MAPS seeks to ensure culturally-informed MDMA therapy is available to those who most need it. We are committed to developing multidisciplinary research and access projects for people in global conflict zones and communities experiencing social and political marginalization. We seek to partner with researchers and research institutions around the world to explore psychedelic therapy’s potential role in addressing a broad range of issues, from climate change to political conflict.

Example Initiative: MAPS worked with researchers at Imperial College London and Holy Land Trust Institute to develop and conduct an observational study interviewing Palestinians and Jewish Israelis who participated in ayahuasca ceremonies together. The purpose of the study was to explore the potential impact of psychedelic experiences on conflict transformation and healing intergenerational trauma. The results of the study were published in the 2021 *Frontiers in Pharmacology* papers: “Relational Processes in Ayahuasca Groups of Palestinians and Israelis”⁶ and “On Revelations and Revolutions: Drinking Ayahuasca Among Palestinians under Israeli Occupation.”⁷

4. Mainstream psychedelic and harm reduction education

MAPS seeks to strengthen and amplify its role as the “go to” source for mainstream audiences to learn about psychedelics and harm reduction. We will invest in our reach to become a top hit for common search engine queries related to psychedelic education and harm reduction, ensuring that the public has access to valid, useful information. We intend to educate 700,000 people through our conferences and courses between 2022 and 2026.

Example Initiative: In July 2022, MAPS launched *Psychedelic Fundamentals*,⁸ an online psychedelic education program which provides people with accurate, evidence-based information about psychedelics. The educational curriculum, developed in collaboration with *Interwoven* and delivered over five modules, covers a range of topics including psychedelic history, science, clinical research, therapeutic uses, and harm reduction.

How You Can Help

MAPS has been and continues to be successful due to the support of thousands of individuals like you. If you believe in our mission and its potential, please consider donating⁹ or volunteering your time.¹⁰

⁶ Roseman, L., Ron, Y., Saca, A., Ginsberg, N., Luan, L., Karkabi, N., Doblin, R., and Carhart-Harris, R. (2021, January 1). *Relational processes in ayahuasca groups of Palestinians and Israelis*. *Frontiers*. Retrieved August 25, 2022, from <https://www.frontiersin.org/articles/10.3389/fphar.2021.607529/full>

⁷ Roseman, L., & Karkabi, N. (1AD, January 1). *On revelations and revolutions: Drinking ayahuasca among Palestinians under Israeli occupation*. *Frontiers*. Retrieved August 25, 2022, from <https://www.frontiersin.org/articles/10.3389/fpsyg.2021.718934/full>

⁸ *Psychedelic fundamentals – Multidisciplinary Association for Psychedelic Studies*. MAPS. (2022, July 22). Retrieved August 25, 2022, from https://maps.org/psychedelic-fundamentals/?pk_campaign=2022-07-Psychedelic-Fundamentals-Full-List&pk_kwd=text-psychedelic-fundamentals&mc_cid=7cfee5ec74&mc_eid=UNIQID

⁹ *Support psychedelic science – Multidisciplinary Association for Psychedelic Studies*. MAPS. (2022, April 11). Retrieved August 25, 2022, from <https://maps.org/donate/>

¹⁰ *Vital. Vital Psychedelic Training*. (n.d.). Retrieved August 22, 2022, from <https://www.vitalpsychedelictraining.com/>

Dare We Do Better?

Drug Education for the MAPS Movement



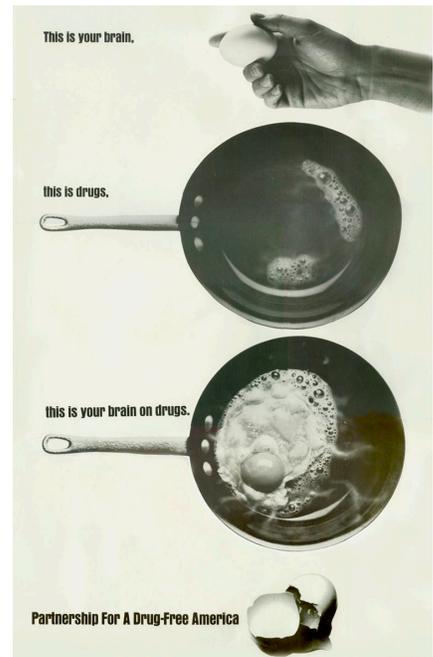
Shirelle Noble

Education is a key pillar of the MAPS mission to create safe and legal contexts for the use of psychedelics and marijuana in society. To date, people in the U.S. and beyond have primarily been exposed to fear-based, abstinence-focused drug education. Dare we do better?

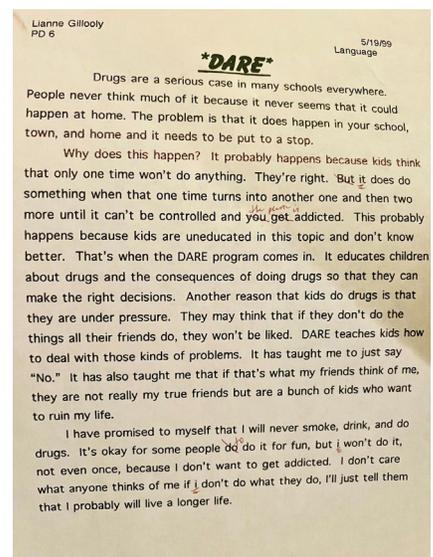
With the launch of MAPS' *Psychedelics Fundamentals*¹ course, we are setting the foundation for modern drug education: balanced, fact-based, trauma-informed, and rooted in harm reduction practices. As psychedelics enter the mainstream, and more people see documentaries like Netflix's *How to Change Your Mind*,² MAPS is doubling down on our commitment to provide best-in-class drug education. Since launching in July 2022, 1,500 students have enrolled in *Psychedelic Fundamentals* and we expect to reach many thousands more.

For too long, people who use drugs have been stigmatized. Government agencies have masked anti-drug propaganda as education. These programs propagated through school curricula and then trickled into dinner-time conversations between families. The powerful image of an egg frying in a hot pan, coupled with the message, "This is your brain on drugs," became iconic for the D.A.R.E. generation. You may have been asked to write a purity pledge in middle school (see picture from Liana Gillooly, MAPS' Strategic Initiatives Officer, for her essay). D.A.R.E.'s propaganda has impacted me too. Before learning about the therapeutic use of psychedelics, I remember telling my friend with great certainty, "They call it acid for a reason... it'll ruin your brain!" What starts as fear-based education trickles into the culture at large, and stifles open conversation—between friends and family—about risks, benefits, and harm-reduction. Without open and honest conversations, research into psychedelics was nearly impossible for decades.

The public narrative of psychedelics and marijuana has shifted, though. From once being associated with the counterculture in the 60s, it is now common to see media that associates psychedelics with wellness, mental health research, and future medical models. While this is an improvement, there is a need to acknowledge that people will explore drug use on their own, for whatever purposes they desire. In *Drug Use for Grown Ups: Chasing Liberty in the Land of Fear*,³ MAPS Board Member Carl Hart, Ph.D., writes: "Clearly, many people consume psychoactive substances 'in the pursuit



"This is your brain on drugs." Partnership for a Drug-Free America. 1986

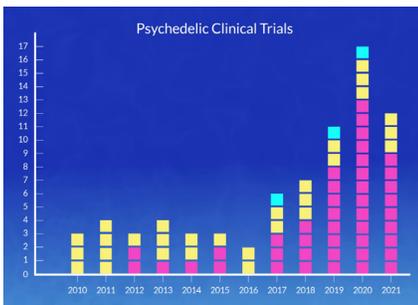
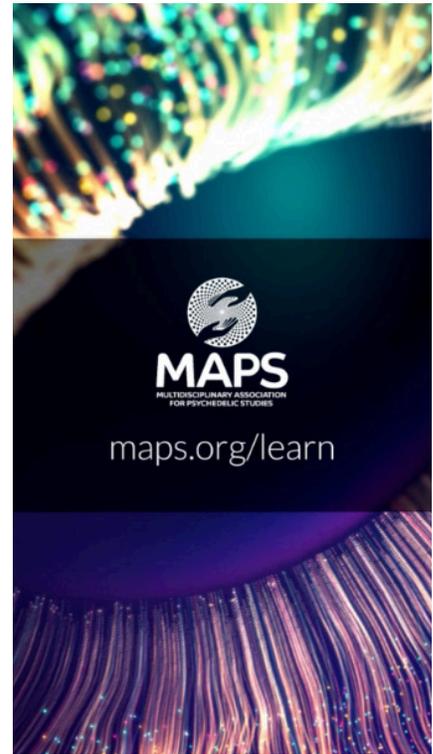
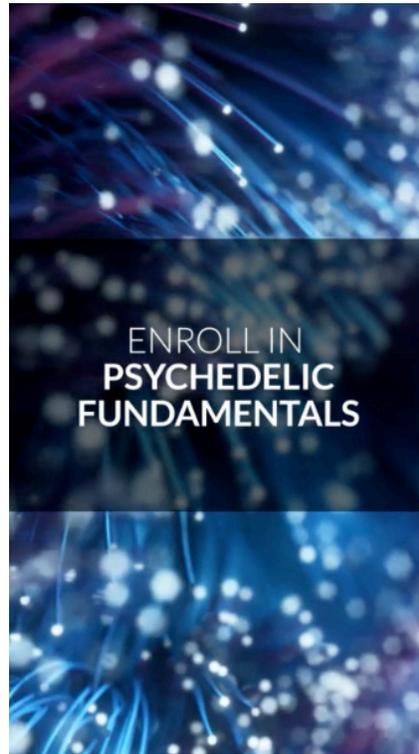


D.A.R.E. Essay by MAPS team member Liana Gillooly. 1999.

¹ "Psychedelic Fundamentals," MAPS. Accessed August 26, 2022. <https://maps.org/psychedelic-fundamentals/>

² *How To Change Your Mind*, Three, "Chapter 3: MDMA," directed by Lucy Walker, presented by Michael Pollan, aired July 12, 2022, on Netflix, <https://www.netflix.com/title/80229847>

³ Carl L. Hart, *Drug Use For Grown-Ups: Chasing Liberty in the Land of Fear*. New York: Penguin Books, 2021.



of happiness,' a right the government was established to secure, to protect. So why then is our current government arresting one million Americans each year for possessing drugs? Why are so many drug users hiding in the closet? This reality does not align with the spirit of the Declaration [of Independence].” When a government criminalizes people who use drugs rather than providing honest and nuanced education about how to minimize the risks—and perhaps even maximize the benefits—of substances, MAPS and our allies must step up to the challenge. As the leader in psychedelic research and medicalization strategies, MAPS aims to introduce a common language and a fact-based, scientific understanding of risks and benefits for potential explorers.

MAPS also aims to provide psychedelic harm reduction education and peer support for safer psychedelic journeys. Since 2012, the [Zendo Project](#),⁴ a program sponsored by MAPS, has provided psychedelic peer support and harm reduction services at festivals and other events. In fact, Psychedelic Fundamentals was born out of the Zendo Project vision “where communities are educated, resourced, and engaged in applying harm reduction principles to support individuals, exploring psychedelic states; recognizing that challenging experiences can be opportunities for self-exploration and healing.” The insights from Zendo Project’s on-the-ground work are interwoven throughout the course.

Psychedelic Fundamentals is the first course in a series of digital education opportunities from MAPS. The two-hour course is video-based and it’s the perfect starting point for those who are considering psychedelic use, seeking information to support a loved one, or interested in how psychedelics work and what benefits and risks they may provide. You can purchase the course at maps.org/learn and complete it in your own timeline.

⁴ Zendo Project. Accessed August 26, 2022. <https://zendoproject.org/>



▶ 0:13 / 2:38



In the course, we introduce:

- Ordinary and non-ordinary states of consciousness
- A brief history of psychedelics, from the earliest known human uses to today's cutting-edge research
- How psychedelic compounds mimic naturally-occurring neurotransmitters, and how they're able to create conditions for positive changes in thought patterns
- The similarities, differences, and therapeutic uses of four common psychedelic substances: psilocybin, MDMA, ketamine, and ayahuasca
- The careful planning that increases the likelihood of a safer psychedelic trip

This launch is only the beginning. Our team is actively planning and raising funds to develop our next set of lessons. The next round of courses will be “deep-dives” into popular topics like integration, peer support, trip planning, science, and professional opportunities in the psychedelic field. Honest and informed public education is necessary for individuals who choose to use psychedelics as well as the psychedelic movement itself. It's our sincere hope that you share this course with friends and family members. Together, we can create opportunities for shared understanding and safer exploration.

Special thanks to: Sara Gael Giron, Ryan Beauregard, Chelsea Rose Pires, Bryan Lang, Brian Broom-Pelz, John Poncini, Kynthia Brunette, Bryson Voirin, Keila Torre-Santiago, Rick Doblin, Kris Lotlikar, Betty Aldworth, Wes Hale, Kelsey Laird, Vilmarie Narloch, Patrick Shea, Melissa Salpietra, Stephen Silvius, and all our team members and advisors for their contributions to this project. Thank you to our donors for making this work possible. Your support makes our work possible.

Enroll today at
maps.org/psychedelic-fundamentals

Use the discount code
fundamentals-bulletin-33

Shirelle Noble (she/her) is a systems-thinker who brings 13+ years of strategy, marketing, operations, and product management experience to the emerging commercialization era of psychedelics. Shirelle is the former Director of Digital at MAPS, where she led a 2-year digital transformation project and launched MAPS' first online education course, Psychedelic Fundamentals. Shirelle recently joined the Beckley Academy as the VP of Marketing and Operations, where she will be developing online psychedelic therapist training programs. Prior to MAPS, Shirelle co-founded The North Star Project, a non-profit think tank focused on ethical business in the field of psychedelics. Shirelle began her career as a consultant at Bain & Company and has BBA in Finance and a BA in English from The University of Texas at Austin. Shirelle is a “third culture kid,” raised by Indian/Persian parents in Indonesia, Australia and the USA. She loves to read, travel, hike, dance, DJ, participate in dusty art projects, and pull pranks on people.



MAPS Doubles Ethnoracial Diversity in Trials Again

Re-Designing Systems of Care

McKenna Leighton and Charlotte Harrison

In the Health Equity Plan¹ published in December 2020, MAPS announced its dedication to providing safe and effective care to as many people as possible by designing programs to serve those who are most marginalized by society. One of the first material successes of this plan was the increase in ethnoracial diversity among participants in our Phase 3 clinical studies of MDMA-assisted therapy for the treatment of PTSD. In our second Phase 3 study (MAPP2), people of color constitute a majority of enrolled participants. This success was not the result of wishful thinking, but a dedication to addressing causes of health inequality in order to provide greater care.

Diversity and inclusion are familiar issues in clinical trials, and psychedelic-assisted studies face unique challenges to the enrollment of participants of color (Fortuna 2010, Williams 2019, Herzberg 2019). In MAPS' Phase 2 studies of MDMA-assisted therapy for the treatment of PTSD, only 12.4% of participants were people of color² – 35% less than demographic data published on the PTSD population in the United States³ (Mithoefer 2019, Roberts 2011).

We implemented solutions between Phases 2 and 3 which included establishing an advisory council, requiring therapists and independent raters to complete training on racial justice and preventing microaggressions, providing participant reimbursement at select study sites for study-related costs, and prioritizing interested volunteers who identified as POC. These interventions had a significant (but insufficient) effect in the first Phase 3 trial completed in 2020 (MAPP1), doubling representation of POC from 12% to 27%. But the study demographics were still far from representative of the PTSD patient population in the U.S. (Roberts 2011) and fell short of MAPS' health equity mission.

Over the course of the second Phase 3 trial (MAPP2⁴), the previous seeds of change and a renewed commitment to diversity blossomed. Enrollment of participants of color doubled again, from 27% to 53% – participants of color constituted a majority.

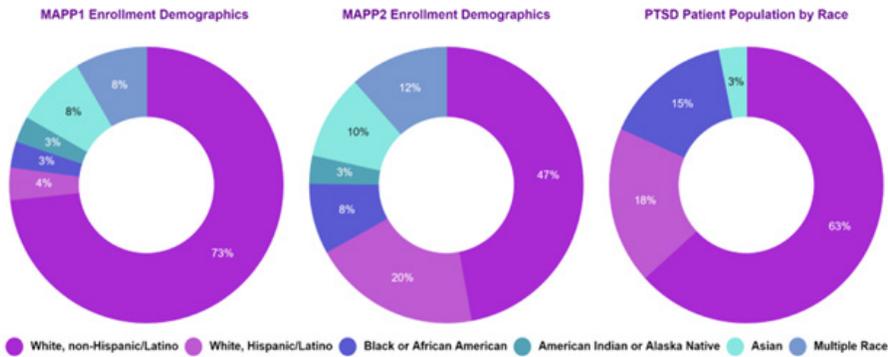
In this article, we will review some of the specific solutions we implemented in the second MAPS-sponsored Phase 3 study (MAPP2) to overcome systemic issues in clinical research and psychedelic science with the hopes that our efforts can illuminate a pathway for improving diversity and inclusion in both of these fields.

¹ Ginsberg, N., Ali, I., and Aggarwal, R. (2020), *Prioritizing Public Benefit Means Healing for All: Announcing MAPS' Health Equity Plan*. MAPS Bulletin. Published online December 2020.

² Per FDA guidance, clinical trial participants are asked to indicate their race according to the following options: White (which includes Middle Eastern and Jewish), African American/Black, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander. Participants are additionally asked to indicate whether they are 'Hispanic/Latino'. Participants are also given the opportunity to self-describe their race and ethnicity. For the purposes of this article, we use the FDA categories as will be required in the New Drug Application and other presentations of our data. In this article, "participants of color" includes all participants who identified with at least one race other than White/Caucasian and/or identified as "Hispanic". The authors acknowledge that these categories do not represent the beauty and complexity of our participants' racial and ethnic identities.

³ MAPS clinical trials consist of trial sites in multiple countries, including the U.S., Canada, and Israel. A majority of evaluable participants were from US sites; for simplicity, our data is compared to US population data.

⁴ MAPP2, the second Phase 3 study of MDMA-assisted therapy for the treatment of PTSD, finished enrolling in April 2022.



United States PTSD patient population data is provided by the nationally representative demographic study Roberts, A.L., et al., Race/ethnic differences in exposure to traumatic events, development of post-traumatic stress disorder, and treatment-seeking for post-traumatic stress disorder in the United States. *Psychol Med*, 2011. 41(1): p. 71-83. MAPP1 demographic data was published in *Nature Medicine*. MAPP2 demographic data represents our preliminary enrollment data. The demographics of our final enrollment, treated, and evaluable participants may differ.

Diversifying Psychedelic Clinical Research

Factors that contribute to racial health disparities are often described as “obstacles” toward health equity. The avoidance of these obstacles compounds years of neglect and underinvestment in the health and well-being of communities of color. In order to provide safe and equitable care to a racially diverse population in our clinical trials, it was critical to stop thinking about health disparity factors through this lens. These obstacles actually reveal political and economic realities that not only explain health disparities but also, and importantly, imply solutions.

Understanding structural causes of health inequity can unveil practices of collective liberation. Collective liberation, a framework that MAPS uses to address racial justice and equity, aims to free all people from systemic oppression and enable us to collaboratively imagine and build a new future. These practices must go beyond addressing the immediate needs of marginalized communities; they must also transform systems of power that currently manufacture inequality.

Clinical research, psychedelic-assisted therapy, and the healthcare industry are all fertile sites for these practices, in part because of the histories of violence which precede and contextualize our work. Racialized peoples have ample reason to mistrust a study involving a Schedule I substance — and sponsored by a novice clinical research organization — due to historic malpractice and harm in clinical research (Williams 2019, Scharff 2015); militarization and incarceration due to the racist War on Drugs (Williams 2019); and daily experiences of pathologization, abuse, and neglect in health care (Braunstein 2008, Jaiswal 2019).

The responsible practice is not to induce or coax the trust of racialized communities; the responsible practice is to be trustworthy. This requires education, attention, transparency, reflection, responsibility, and loyalty. In other words, it requires care. It requires a true commitment to the safety and well-being of participants of color. Without this care, the recruitment of POC makes these communities vulnerable to the same historic practices of exploitation, harm, and control. The stakes are even higher in clinical trials involving psychoactive substances that can induce the feeling of trust and safety (Smith 2022, Williams 2020).

McKenna Leighton is a Clinical Research Associate II at MAPS Public Benefit Corporation (MAPS PBC), where she supports the safe inclusion of marginalized populations in MDMA-assisted therapy programs and manages clinical research sites. She earned her B.S. in Molecular, Cell, and Developmental Biology from the University of California, Santa Cruz in 2019, where she additionally studied political philosophy and critical theory in the History of Consciousness department. She passionately believes a better world is possible, beyond a revolution that loves and creates life.

Charlotte Harrison currently serves as the Director of Clinical Operations at MAPS Public Benefit Corporation (MAPS PBC), overseeing the Phase 3 Pivotal Program for MDMA-Assisted Therapy for PTSD in the US, Canada, and Israel. She has been working at MAPS Public Benefit Corporation (MAPS PBC) for six years and in the field of clinical research for twelve years.

Collective liberation, a framework that MAPS uses to address racial justice and equity, aims to free all people from systemic oppression and enable us to collaboratively imagine and build a new future.

Becoming Trustworthy Critically Informed Interventions

The MAPS Diversity Working Group, formed in October 2020, consisted of internal and external members who could contribute meaningfully to the careful recruitment of participants of color. Some of the external members were or would become therapists on our studies, including Marcela Ot'alora G., M.A., L.P.C., Jennifer Jones, Ph.D., L.C.S.W., and Joseph McCowan, Psy.D.; others were prominent voices of color in the world of psychedelic medicine, including Kwasi Adusei, DNP, PMHNP, and Ritika Aggarwal, M.S., A.M.F.T. In general, the members were experienced and knowledgeable about the intersections of race, capitalism, and medicine and the systemic barriers to clinical mental healthcare. This group met monthly to identify factors preventing the successful inclusion of POC in our studies and determine solutions, some of which are detailed below.

Informed Consent: Building Trust

One of the first accomplishments of the Diversity Working Group was to revise the Informed Consent Form (ICF) provided to all study participants (and made available at clinicaltrials.gov after the trial concludes). POC may be more likely to underreport the severity of traumatic experiences and symptoms for a variety of reasons, including fear of punitive or social consequences and differences in the experience of trauma and safety (Malcoun 2015, Carpenter-Song 2010). We, therefore, felt that it was critical to the careful and successful enrollment of participants of color to improve our transparency regarding the purpose of study procedures, the uses of study data, data confidentiality, and the possibility of unwanted consequences related to study participation. The conversations that informed the revision of the ICF also informed guidance we issued to the clinical staff about establishing trust and rapport with participants of color. We believe this intervention increased our enrollment of POC and improved the quality of care.

The Burden of Expense

While participants did not have to pay to be screened or treated in the clinical trials, they may have incurred a study-related financial burden, including child and elderly care and transportation. Given that POC communities have historically been financially subjugated by state practices like slavery, forced segregation, discriminatory policing and incarceration, these personal expenses can be prohibitive to study participation. Partway through MAPP2, we added a \$100 stipend for screening activities and increased maximum reimbursement from \$350 to \$1,500 for study-related expenses. Site staff were

also empathetic and supportive of specific participant needs. These interventions protected the right of low-income people to participate in clinical research without incurring additional financial stress.

Addressing Schedule I Stigma

Due to the racist War on Drugs, the historic experimentation on Black Americans in clinical and military research, and the visible psychedelic movement in the U.S., we anticipated people of color would be hesitant to participate in our trials. Indeed, our clinicians reported that POC tended to have more concerns about the legality and safety of a clinical trial involving a Schedule I substance. They worried about participation impacting their job security or affecting their relationships. To address this concern, our clinical sites offered to speak with the families and employers of our participants to abate economic and social ramifications, with the participant's permission. This intervention was fundamentally a practice of care that again reduced race- and class-based burdens of participation.

Committing to Care: Racial Equity

Our most important intervention was to improve the diversity of clinical staff, particularly the therapists. This project was integrated with the MAPS MDMA Therapy Training Program, which has greatly increased the inclusion of clinicians of color in the MDMA-assisted therapy training program by [organizing programs](#)⁵ for clinicians of color and [offering scholarships](#)⁶ to reduce the financial burden for clinicians of color. We increased the number of therapists of color from 11% in MAPP1 to 28% in MAPP2 (unpublished data).

This was a significant intervention because clinicians of color are often better able to form therapeutic alliances with patients of color, in part due to shared experiences of marginalization and stigmatization (Smith 2022, Williams 2020), which could support an increase in quality of care. Increasing the diversity of clinical staff also guaranteed that there will be trained therapists of color who may be better situated to treat marginalized populations if the FDA approves this modality. Thus, the diversification of clinical staff served both goals of collective liberation practices: attending to inequalities in need and returning power to the communities from which it was stolen.

⁵ Carlin, S. (2020). MDMA Therapy Training for Communities of Color. MAPS Bulletin. Published online December 2020. <https://maps.org/news/bulletin/mdma-therapy-training-for-communities-of-color/>

⁶ MAPS. (2020). MDMA Therapy Training Program Update: January 2022. MAPS Update. Published online January 2022.



On March 11, 2022, psychedelic therapists Picolya McCall, Psy.D., and Joseph McCowan, Psy.D., made MAPS history by becoming the first Black co-therapy pair to conduct an experimental session within MAPS-sponsored clinical trials of MDMA-assisted therapy for PTSD.

A Final Note

These were just some of the many ways we carefully increased our inclusion of participants of color. Some of these solutions are reproducible and will certainly contribute to the successful recruitment of POC for other studies. But the crux of our success was a sincere commitment to protecting the right of POC to safely participate in clinical research. This required redesigning our processes to challenge the status quo of clinical research and health care practices that reproduce racialized inequality and harm. Diversity is not about metrics; our enrollment numbers were just a tool for measuring our progress toward a much greater goal: healing for all, racial justice, and collective liberation.

References

- Braunstein JB, Sherber NS, Schulman SP, Ding EL, Powe NR. (2008) Race, medical researcher distrust, perceived harm, and willingness to participate in cardiovascular prevention trials. *Medicine*. 2008 Jan;87(1):1-9. DOI: 10.1097/md.0b013e3181625d78. PMID: 18204365.
- Carpenter-Song E, Chu E, Drake RE, Ritsema M, Smith B, Alvenson H. (2010) Ethno-cultural variations in the experience and meaning of mental illness and treatment: implications for access and utilization. *Transcult Psychiatry* (2):224-51. DOI: 10.1177/1363461510368906. PMID: 20603387.
- Fortuna, L.R., Alegria, M. and Gao, S. (2010), Retention in depression treatment among ethnic and racial minority groups in the United States. *Depress. Anxiety*, 27: 485-494. <https://doi.org/10.1002/da.20685>.
- Ginsberg, N., Ali, I., and Aggarwal, R. (2020), Prioritizing Public Benefit Means Healing for All: Announcing MAPS' Health Equity Plan. *MAPS Bulletin*. Published online December 2020.
- Herzberg, G. and Butler, J. (2019) *Blinded by the White: Addressing Power and Privilege in Psychedelic Medicine*. Chacruna. Published online March 2019.
- Jessica Jaiswal & Perry N. Halkitis. (2019) Towards a More Inclusive and Dynamic Understanding of Medical Mistrust Informed by Science. *Behavioral Medicine*, 45:2, 79-85, DOI: 10.1080/08964289.2019.1619511.
- Malcoun, Emily & Williams, Monnica & Nouri, Leyla. (2015) Assessment of Posttraumatic Stress Disorder with African Americans. DOI: 10.1007/978-1-4939-1004-5_11.
- Mithoefer, M.C., Feduccia, A.A., Jerome, L. et al. (2019) MDMA-assisted psychotherapy for treatment of PTSD: study design and rationale for phase 3 trials based on pooled analysis of six phase 2 randomized controlled trials. *Psychopharmacology* 236, 2735-2745. <https://doi.org/10.1007/s00213-019-05249-5>.
- Multidisciplinary Association for Psychedelic Studies (2021, May 3). MAPS' Phase 3 Trial of MDMA-Assisted Therapy for PTSD Achieves Successful Results for Patients with Severe, Chronic PTSD. maps.org/news/media/maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd/.
- Multidisciplinary Association for Psychedelic Studies (2022, May 9). MAPS Completes Enrollment, as Planned, for the Confirmatory Phase 3 Trial of MDMA-Assisted Therapy for PTSD. maps.org/2022/05/09/maps-completes-enrollment-as-planned-for-the-confirmatory-phase-3-trial-of-mdma-assisted-therapy-for-ptsd/.
- Roberts, A.L., et al., (2011) Race/ethnic differences in exposure to traumatic events, development of post-traumatic stress disorder, and treatment-seeking for post-traumatic stress disorder in the United States. *Psychol Med*, 41(1): p. 71-83.
- Scharff DP, Mathews KJ, Jackson P, Hoffsuemmer J, Martin E, Edwards D. (2010) More than Tuskegee: understanding mistrust about research participation. *J Health Care Poor Underserved* (3):879-97. doi: 10.1353/hpu.0.0323. PMID: 20693733; PMCID: PMC4354806.
- Smith, Darron T. (2022) The Need for Anti-Racist Training in Psychedelic Therapy. *MAPS Bulletin* 2022 Vol. 32 No. 1.
- Williams, M., Reed, S., and Aggarwal, R. (2019), Culturally informed research design issues in a study for MDMA-assisted psychotherapy for posttraumatic stress disorder. *Journal of Psychedelic Studies*. DOI: 10.1556/2054.2019.016.
- Williams, M., Reed, S., and George, J. (2020) Culture and psychedelic psychotherapy: Ethnic and racial themes from three Black women therapists. *Journal of Psychedelic Studies*. DOI: 10.1556/2054.2020.00137.



Bringing Psychedelics Under Control

Legal Regulation as a Pathway to
Safety and Wider Access

Scott Bernstein

Introduction

North America is in crisis. Each day, around 260 people die from drug overdose, totaling over 300,000 lives lost over the past three years¹. These deaths are the product of unsafe conditions imposed by a lack of regulation and oversight in the illegal drug market, a fact exacerbated by years of overprescribing of opioids to consumers who now turn to alternate sources. As a result of punitive drug policies that leave non-medical substance use unregulated, there is a thriving illegal drug market where the quality, content and potency of products are largely unknown to consumers, but often are filling in a very present demand for access. With psychedelics, a complex informal system of underground practice and access has been instrumental in advancing the learning and acceptance of psychedelics for growth, spirituality, and wellness, while presenting some infrequent but important challenges around ethics and safety that can emerge because of the unregulated nature of the work.

Within the whole spectrum of substances, overdose deaths are only one facet demonstrating the failure of current policies. Drug law enforcement and supply reduction-focused policies—often referred to as “prohibition”—contribute to the proliferation of organized crime, money laundering, violence, infectious disease, stigma, and other well-documented social and individual harms². It is widely acknowledged that these policies perpetuate legacies of racism and classism that emerged over a century ago³.

An alternative approach is the legal regulation of drugs, an idea that seems novel at the outset, but is based on well-established tools employed by the regulatory state to minimize risk to consumers in activities ranging from driving to skydiving to alcohol.

¹ *Current Data*. Song For Charlie. (n.d.). Retrieved August 23, 2022, from https://www.song-forcharlie.org/data?gclid=Cj0KCQjwxIOXBhCrARIsAL1QFCYPzQAFXR-oEA5ynPdC-88GAqFZI9c-7LfgwGhviGVRvbDL5IMsWLIcaAlcMEALw_wcB

² Boyd, S., Carter, C. I., & MacPherson, D. (2016). *More Harm Than Good: Drug Policy in Canada*. Black Point, N.S.: Fernwood Publishing.

³ Boyd, S., MacPherson, D., & Vancouver Area Network of Drug Users. (2018). The Harms of Drug Prohibition: Ongoing Resistance in Vancouver's Downtown Eastside. *BC Studies*, 200, 87–96.

As clinical trials for psychedelic substances proliferate, the practicality of envisioning what legal regulation would look like is no longer an exercise of speculating about an uncertain future. Although psychedelic possession, production and distribution remain under the umbrella of prohibition in most places, several jurisdictions globally have to date decriminalized one or more psychedelic substances, including Denver, Colorado; Santa Cruz and Oakland, California; Washington D.C.; Somerville and Cambridge, Massachusetts; Seattle, Washington; Ann Arbor, Michigan; Detroit, Michigan⁴; Oregon; and British Columbia, Canada⁵. In 2020, the state of Oregon passed Measure 109, which started on a path to legally regulated psilocybin for mental health treatment in supervised settings that will be in place around mid-2023⁶, and about 12 states have similar proposals in development that would decriminalize or legally regulate psychedelics. Additionally, both the United States and Canada have mechanisms for legally obtaining some psychedelic substances before completion of ongoing clinical trials for serious illness. Decriminalization is different from legal regulation, however. Broadly speaking, the former removes criminal penalties for certain activities (e.g., possession of substances) while the latter establishes a comprehensive system controlling all aspects of the market – from production to consumption – through a set of regulatory rules or “levers.”

In 2017, I began work on the Regulation Project, a collaboration for fostering discussions about the mechanics, benefits, and risks of legally regulated drugs⁷. This project was intended to move the discussion beyond *whether* drugs should be legalized and towards *how* a government might structure legalization. It is now a collaborative effort among 11 organizations from three countries. The organizations involved advocate for an approach to legal regulation that supports not only public health and human rights goals, but social justice as well.

Regulation of any activity or thing presents opportunities for governments to shape the regulatory environment through various levers, such as rules or requirements that shape the market and consumer experience. With mind-altering substances (i.e., “drugs”) there have been over a hundred such levers identified⁸. For simplicity, we can focus on five drug-specific regulatory choices that directly affect (either mitigate or exacerbate) the risks of taking drugs, and would shape the “front end” or consumer experience of a legally regulated market: (1) who has access to the drug; (2) what must a person do to access the drug; (3) where can a person obtain the drug; (4) what quantity of the drug could someone get; and (5) where can the drug be consumed. For our work with public engagement on legal regulation, these five were modified into a collaborative, role playing game format to further discussion about what people would like to see in a regulated market⁹. For each of these questions, we

presented a spectrum of choices from minimal or no restrictions to tight restrictions and presented how each would affect public health or the human rights of drug consumers. Here is a brief overview of the spectrum of choices within each area.

Who has access to the drug?

The spectrum on this issue includes open access—to anyone of legal age—on the one end and medicalized access—to someone with a diagnosed condition—on the other. Open access helps move the largest segment of people into the legal market and mirrors regulations for alcohol, tobacco, and non-medical cannabis. However, the relative lack of barriers risks increasing demand. For the majority of people who consume drugs for non-medical reasons, a medicalized system remains out of reach, and they could turn to the unregulated market.

What must a person do to access the drug?

On the most lenient end, there may be no requirements other than proof of legal age. Beyond that, a regulated system may require registration in a program; training and licensing in safer use, alternatives, available mental health and dependence resources, and/or risks of use; or other strategies aimed at educating and monitoring substance use. Training programs could train “facilitators” who supervise drug consumption and intervene if necessary. A system of registration and/or licensing raises issues of privacy and security of personal information, creating potential barriers.

⁴ *Psychedelics Legalization & Decriminalization tracker*. Psychedelic Alpha. (n.d.). Retrieved August 23, 2022, from <https://psychedelicalpha.com/data/psychedelic-laws>

⁵ Addictions, M. H. and. (2022, May 31). B.C. receives exemption to decriminalize possession of some illegal drugs for personal use. Retrieved August 23, 2022, from <https://news.gov.bc.ca/releases/2022MMHA0029-000850>

⁶ Feuer, W. (2020, November 6). *Oregon becomes first state to legalize magic mushrooms as more states ease drug laws in ‘psychedelic renaissance’*. CNBC. Retrieved August 23, 2022, from <https://www.cnbc.com/2020/11/04/oregon-becomes-first-state-to-legalize-magic-mushrooms-as-more-states-ease-drug-laws.html>.

⁷ Bernstein, Scott & Amirkhani, Emily & Werb, Dan & MacPherson, Donald. (2020). The regulation project: Tools for engaging the public in the legal regulation of drugs. *International Journal of Drug Policy*. 86. 102949. 10.1016/j.drugpo.2020.102949.

⁸ Emerson, B. & Haden, Mark. (2016). Public Health and the Harm Reduction Approach to Illegal Psychoactive Substances. 10.1016/B978-0-12-803678-5.00510-5.

⁹ *A new vision for drug policy—home*. Regulation Project. (2022, July 28). Retrieved August 23, 2022, from <https://regulationproject.org/>

Scott Bernstein is a Vancouver-based lawyer who served as the Executive Director of MAPS Canada from 2021-2022 and conceived of the Canadian Psychedelic Summit, a three-year project to create a vision for psychedelics in Canada based on equity, fairness, and inclusion. Prior to that, Scott worked as Director of Policy with Canadian Drug Policy Coalition, where he led the organization's work on decriminalization and the legal regulation of drugs, including founding the Regulation Project. Through his own legal practice and with Vancouver-based Pivot Legal Society, Scott litigated cases advancing human rights of people who use drugs, including fighting for access to prescription heroin treatment, and defending Insite, North America's first sanctioned injection site at all levels of court. Previously, Scott was a program officer with the Global Drug Policy Program of Open Society Foundations in New York, where he supported a global collection of organizations advocating for drug policy reform at the United Nations and a nascent drug policy movement in Africa. Scott has an M.Sc. from the University of Wisconsin and a J.D. from the University of British Columbia.

Where can a person obtain the drug?

Substances with minimal risks may be distributed in restaurants or cafés, in corner stores, or on pharmacy shelves. Substances with more documented potential risks might be obtained through pharmacists, supervised consumption sites, or secure 24/7 dispensing machines requiring ID (biometric or otherwise). This would follow registration in a program or with a physician's oversight. Models such as compassion clubs, where consumers cooperatively manage distribution of supply, should also be considered. Psychedelics might be restricted to use within a therapist's office or in a sanctioned ceremonial setting. These choices can balance autonomy of the consumer with the public health need to mandate or encourage contact with health professionals before or during drug consumption.

What quantity of the drug could someone get?

Public health strategies suggest reasonable limits should be placed on how much of a riskier substance can be obtained in order to prevent diversion to unauthorized users and reduce the potential for excessive use¹⁰ (Rolles & McClure, 2009). Since drug consumption (like most products) is governed by supply and demand dynamics, it is reasonable to expect any unmet need will be addressed through the unregulated market. This will lead to increased risk to consumers. However, over a century of prohibitory policies have taught us that the appropriate response is not criminalization of those who utilize the unregulated market, but rather better adjustments of the regulations. Limits—tighter or looser—can help to attract consumers to less risky substances, for example.

Where can the drug be consumed?

On the most lenient end of the spectrum, the answer is anywhere that is allowed by law and local ordinances. Given a choice, people choose to consume drugs in a variety of environments. With alcohol, tobacco and cannabis, there are restrictions prohibiting public consumption which would likely apply to other substances, including psychedelics, in a regulated system.

To increase control and safety of consumption, the regulated system may require a licensed facilitator be present, consumption be witnessed at a pharmacy or distribution centre, or that drugs be consumed at a designated consumption venue. These could include medically-supervised sites or merely a licensed venue (as a bar is for alcohol). As with other controls, increased monitoring correlates with increased barriers that could dissuade consumers from participating in the legal system.

Models under consideration

Most of the proposed models for accessing psychedelics that will be realized in the short-term lean towards a more restricted approach rather than a liberalized one. To date, no jurisdiction has considered a plan that would allow for access to legally produced psychedelics through a model similar to alcohol or tobacco. Following successful clinical trials, patients diagnosed with certain mental health issues will be able

¹⁰ Rolles, S., & McClure, C. (2009). *After the war on drugs: blueprint for regulation*. Bristol: Transform Drug Policy Foundation.

to access MDMA or psilocybin administered by licensed health care providers in traditional therapeutic settings. Dosage will be guided by clinical trial protocols that will be coded into the drug's governmental approval. Therapeutic sessions involving the drugs will most likely be bookended by preparation and integration sessions. Oregon's plan for legal regulation of psilocybin will allow clients to access psilocybin through licensed service centers staffed by licensed and trained facilitators without a diagnosis. Service centers will provide substances to be consumed onsite that are manufactured under strict control. Dosage limits are still under consideration, but there will likely be limits and guidelines to how much psilocybin is allowed, as well as mandated preparation and integration sessions. For access to psychedelics for religious purposes (e.g., ayahuasca) that have been sanctioned through court action, participation in these ceremonies is restricted to members of the religious group. Recently, Washington State had a bill come up for consideration that was not approved and will be resubmitted. It aimed to improve Oregon's Measure 109, and specifically would allow for at-home administration of psilocybin for those not physically able to travel to a facility¹¹, which would expand where psilocybin could be legally consumed under that plan.

Conclusion

With the legal regulation of psychedelics becoming an emerging reality, it's important to consider what our choices could and should be with respect to responsible adult use. The choices that governments make about how psychedelic substances are regulated will shape future access and use of psychedelics for medical and non-medical purposes. Arguably, it is long overdue to move beyond the question of whether we should legalize drugs, towards how we should legalize them. Unless we are able to decide on regulatory safeguards for production, distribution, and consumption of currently illegal drugs, we will continue to face challenges to public health, human rights, and safety that are inherent in an unregulated market. While initial proposals for legal regulation of psychedelics lean more towards the "control" aspect of the spectrum, these policy changes are still quite new. Over time, we can expect some loosening of access and regulation around psychedelics, particularly those with the lowest risk profile.

Sadly, for drug policy issues, perceptions and dialogue about drug use among the greater public continue to be dominated by morality, stigma, and myths about drugs. Turning the tide requires engagement with the public in a non-threatening and purposeful way: introducing people to other perspectives, unpacking the values and beliefs behind opinions, and asking them to compromise on solutions that they can tolerate.

¹¹ Frost, A. (2022, June 16). *Oregon psilocybin rules shape who can provide and access care*. opb. Retrieved August 23, 2022, from <https://www.opb.org/article/2022/06/09/oregon-psilocybin-rules-shape-who-can-provide-and-access-care>

References

- Current Data*. Song For Charlie. (n.d.). Retrieved August 23, 2022, from https://www.songforcharlie.org/data?gclid=Cj0KCQjwx-IOXBhCrARIsAL1QFCYPzQAFXR-oEA5yn-PdC88GAqFZl9c-7LfgwGhviGVRvbD-L5IMsWLlcaAlcMEALw_wcB
- Boyd, S., Carter, C. I., & MacPherson, D. (2016). *More Harm Than Good: Drug Policy in Canada*. Black Point, N.S.: Fernwood Publishing.
- Boyd, S., MacPherson, D., & Vancouver Area Network of Drug Users. (2018). The Harms of Drug Prohibition: Ongoing Resistance in Vancouver's Downtown Eastside. *BC Studies*, 200, 87–96.
- Psychedelics Legalization & Decriminalization tracker*. Psychedelic Alpha. (n.d.). Retrieved August 23, 2022, from <https://psychedelicalpha.com/data/psychedelic-laws>
- Addictions, M. H. and. (2022, May 31). B.C. receives exemption to decriminalize possession of some illegal drugs for personal use. Retrieved August 23, 2022, from
- Feuer, W. (2020, November 6). *Oregon becomes first state to legalize magic mushrooms as more states ease drug laws in 'psychedelic renaissance'*. CNBC. Retrieved August 23, 2022, from <https://www.cnn.com/2020/11/04/oregon-becomes-first-state-to-legalize-magic-mushrooms-as-more-states-ease-drug-laws.html>
- Bernstein, Scott & Amirkhani, Emily & Werb, Dan & MacPherson, Donald. (2020). The regulation project: Tools for engaging the public in the legal regulation of drugs. *International Journal of Drug Policy*, 86. 102949. 10.1016/j.drugpo.2020.102949.
- Emerson, B. & Haden, Mark. (2016). Public Health and the Harm Reduction Approach to Illegal Psychoactive Substances. 10.1016/B978-0-12-803678-5.00510-5.
- A new vision for drug policy—home*. Regulation Project. (2022, July 28). Retrieved August 23, 2022, from <https://regulationproject.org/>
- Rolles, S., & McClure, C. (2009). *After the war on drugs: blueprint for regulation*. Bristol: Transform Drug Policy Foundation.
- Frost, A. (2022, June 16). *Oregon psilocybin rules shape who can provide and access care*. opb. Retrieved August 23, 2022, from <https://www.opb.org/article/2022/06/09/oregon-psilocybin-rules-shape-who-can-provide-and-access-care>



A Framework for Regulating the Promotion of Psychedelics in a Fully Legalized Context

Dana Karout

As many readers of this *Bulletin* will know, psychedelics are increasingly entering mainstream consciousness because of their documented positive effects. As most readers will also know, to date, most public education and communication around psychedelics have been focused on prohibition and abstinence. Given this uptick in interest and the historic state of psychedelics education and communication, there is a need for new policy around psychedelic promotion and education to help users maximize potential benefits and minimize potential risks, especially outside of a therapeutic context. Policy research on psychedelics use and regulation has been limited, given these are controlled substances and research focuses mostly on the medical model.

In the academic year 2022/23, I conducted research on psychedelic policy in partial fulfillment of the requirements for my degree of Master in Public Policy at the Harvard Kennedy School. The research was as a policy analysis exercise with MAPS as my client and the full report is available at the [Harvard Library](#). It addressed the following problem statement: In a fully legalized setting, how should a government entity regulate the promotion of psychedelics by private sector actors to minimize risk and maximize potential benefits for consumers? This project focused on psychedelic promotion for the general public. Its goal was not advocacy for full legalization of psychedelics. Rather, it attempted to look down the road and provide analysis that could inform regulatory policies in the case of a full legalization scenario.

My research methodology involved qualitative findings, based on interviews with psychedelic experts and other drug experts, as well as a review of psychedelic products sold legally in Canada and the Netherlands, cannabis products, ketamine services, dietary supplements, and a proposed FDA framework for over-the-counter



versions of prescription drugs. Noting that these substances are markedly different from psychedelics in their effects and outcomes, the aim of this exercise was to help provide examples on how different products are regulated, and a spectrum of different approaches that could be suitable for psychedelic promotion regulation.

Most individuals interviewed for this project believe that psychedelic advertising and branding should be heavily regulated, unlike current regulations in the United States on the promotion of substances such as alcohol, tobacco, dietary supplements, cannabis, and ketamine. A concern shared by most interviewees is the inherent tension between the same companies profiting from psychedelics and then educating people about their use. One potential pushback recognized by interviewees is that the potential safety of psychedelics may provide space for less strict regulation on promotion, but these interviewees emphasized that public education is a much more effective tool for maximizing benefits and minimizing risks than promotion by private sector actors. While all interviewees recommended substantive regulation on psychedelic promotion, recommendations ranged from a complete ban on branding and advertising to certain controls on what to advertise, who to advertise to, and how to brand.

As there has been interest in how state-level cannabis legalization can inform psychedelic policy, I will highlight some of my specific findings on cannabis in this article. One interviewee for this project highlighted that cannabis companies “are making all sorts of claims based on fuzzy science,” catering to people’s growing interest in wellness and self-help by offering products that they claim can help with increased sleep or libido, decreased anxiety, and more. This interviewee and others provided some best practices for regulating the promotion of psychedelics based on experiences with cannabis, which were:

- A public health-informed process that determines what the most important claims and risks to be shared with potential users are, similar to the process in Canada that ensured potential mental health effects or risks to pregnant women were included on product labels.
- A system where key education and its delivery is coming from a source that is not motivated by profits, such as an independent standard setting organization funded by the industry or a quasi-governmental organization.
- Regulation that is not based on a consumers’ packaged goods precedence. For example, banning the type of lifestyle branding currently employed by cannabis companies in the U.S., which one expert felt was “determinantal to public health and meaningful education.” Experts referenced examples from Canada and the Netherlands, where branding, advertising, and even the use of cannabis symbolism is very limited.

Capturing these opinions and insights from the regulation of other substances, I developed a list of design principles that regulators could consider and then assessed the different examples considered in this project against them:

- **“Just say know”** – A more informed psychedelic “culture” is required so that the public can develop critical thinking skills about promotional material they may see. Given the harm reduction point of view, the potential safety of psychedelics, and the thousands of years of their usage in many cultures, “even-handed” information on both their potential benefits and risks are needed so that potential users can make informed choices.
- **“Designing situated policy”** – As one expert mentioned, providing corrective information requires an understanding of where people are, especially given the wide range of narratives the population holds when it comes to psychedelics. There is much misinformation on psychedelics, including on dosage, potential harmful effects, potential beneficial effects, and more. Both this misinformation and who a regulator is regulating for needs to be understood prior to designing specific policies on promotion.

Dana Karout is an Adaptive Leadership Teaching Fellow at the Harvard Kennedy School (HKS). She graduated with a Master in Public Policy from HKS in May 2022, where she completed her capstone project on psychedelic policy. She has worked with dozens of leaders on complex challenges in government and other sectors. Her work draws on psychology, philosophy, and contemplative modalities to create possibilities for individual and systemic transformation.

- **“Cultivating respect”** – Psychedelics have a history of thousands of years of use in spiritual practices among Indigenous cultures. They also have a history of being condemned in the West for decades. Now that psychedelics are beginning to reenter the legal framework (e.g. psilocybin and Oregon), cultivating respect among potential users and regulators can help design more thoughtful policy.
- **“Breaking the allure”** – Psychedelics are used therapeutically and socially, however, they are not panaceas or silver bullets and contain potential risks in any setting. Policy can focus on “breaking the allure” through designing regulations that restrict private sector actors from glorifying these substances, while also ensuring regulation does not villainize them.
- **“Emphasizing set and setting”** – Any individual experience is a result of drug, set, and setting. Thus, any claims made on product packaging or in product advertising taken from clinical trials results can be misleading. Regulators can ensure that potential users understand the variability of experiences based on external and internal factors as well as methods of ensuring more effective set and setting (e.g., having a trusted companion or professionally trained guide around for the experience).
- **“Protecting those who have a lot to gain and lose”** – Regulators must consider the variability of each individual experience in evaluating claims or in considering whether to permit certain advertising techniques (e.g., targeted advertising, patient testimonials).
- **“Incentivizing science”** – Similarly to cannabis, there will be a risk with psychedelics that the science is behind the marketing claims. However, in contrast to cannabis, psychedelic science is already rich with data from clinical trials. This may provide a challenge in the context of full legalization, as a clinical trial is a controlled environment with a specific set and setting. More research will be needed on the use of these substances outside of these controlled environments, which regulators can work to incentivize.

I then provided recommendations on what an “ideal” advertising regulatory framework would look like, and discussed how the general risks of private sector advertising of psychedelics in a fully legalized context could be mitigated by regulators – mainly through comprehensive public education and public investment into psychedelic research. In the conclusion of my report, I considered that policymakers may choose other less “ideal” regulatory frameworks, such as a model based on cannabis promotion in some places within the U.S. I then provided ideas on how the risks of these models may be mitigated. A key message I hope to convey from this framing is that there are political, economic, and cultural forces that will shape psychedelics policy, sometimes in contrast to expert consensus. If regulators are to make these choices, I believe they must understand why they are making them, take their risks seriously, and develop mitigation strategies.

Coordinated Federal and State Psychedelic Policy

So Outrageous It Just Might Work?

Brett Waters

Co-Founder and Executive Director of Reason for Hope



Deaths of despair in our nation rose sharply over the last decade, despite significant increases in spending on mental health care. Given the continuously worsening trajectory and the failure of the mental health industry to keep pace with the advances made in nearly every other area of medicine over the last 50 years, we have reached a unique moment of urgency for bold but thoughtful measures to change the status quo.

Suddenly, psychedelic medicines no longer seem so crazy, do they? In fact, the coveted FDA breakthrough therapy designation has been given to both MDMA- and psilocybin-assisted therapies. This designation is meant to expedite the development of drugs intended to treat a serious condition where preliminary clinical evidence demonstrates substantial improvement over available therapy on a clinically significant endpoint.

In our mission to prevent deaths of despair, Reason for Hope has worked on a variety of policy initiatives over the last year, seeking to increase access to these potentially life-saving treatments for those most in need, while also streamlining the comprehensive regulatory infrastructure necessary to ensure MDMA- and psilocybin-assisted therapies are provided as safely and affordably as possible in the long run. Nonetheless, given the widely acknowledged bottleneck of qualified, trained providers based on expected demand, we believe a phased roll out—balancing urgent access and safety—is warranted. However, the success of this strategy depends heavily on proactive measures from the federal government in advance of potential FDA approval of MDMA- and psilocybin-assisted therapies.

Given the continuously worsening trajectory and the failure of the mental health industry to keep pace with the advances made in nearly every other area of medicine over the last 50 years, we have reached a unique moment of urgency for bold but thoughtful measures to change the status quo.



Around a year ago, Reason for Hope began educating members of the Biden Administration on the need to establish an interagency federal task force. Considering the critical role that agencies such as the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) will play from both a cost and access perspective in how this field develops, we need a dedicated federal entity working with a broad mix of stakeholders — rather than just pharmaceutical companies — to inform the various agencies’ decision-making. This form of “participatory democracy” would enhance public trust in the process.

Reason for Hope devoted significant time on a volunteer basis working to advance this proposal over the last year, including preparing briefings for both the White House Domestic Policy Council and leadership within the U.S. Department of Health and Human Services (HHS), before seeking support for this initiative from a bipartisan group of federal and state legislators.¹ The broad concept of the task force—at least as we proposed it—is to work with stakeholders to develop standards for training, credentialing, and state licensure for a broad-spectrum workforce of interdisciplinary clinical and non-clinical practitioners, and to build out necessary educational materials and peer support networks for communities throughout the country. Additionally, the task force should establish nationwide safety and ethical violation reporting systems that can hold session facilitators accountable both inside and outside the medical model. Guidelines developed through this collaborative process should then be published in the federal register, so states could adopt or adjust the guidelines to meet their individual needs.

Critically, throughout this process, the task force must ensure that relevant agencies such as the FDA and DEA are apprised of the guardrails being put in place, as to prevent potentially harmful overregulation that inhibits equitable access to these novel treatments once available. For example, potential FDA approval of MDMA- and psilocybin-assisted therapies would be tied to a Risk Evaluation and Mitigation Strategy (REMS) that determines the parameters of safe use. The REMS may involve considerations of who can provide treatment (i.e. requiring the presence of a medical doctor), where it can be provided, and how it can be provided (i.e. the number of required sessions, conducting group therapy, etc.). These are traditionally matters of state authority—regulating the practice of medicine and therapy—which have not historically been decided by the FDA. Further, state infrastructure that extends beyond the traditional medical model would create the conditions for the DEA to reschedule all psilocybin, allowing states to experiment with purely intra-state regulatory systems (such as in Oregon) without violating federal law.²

Finally, the task force should develop independent economic analyses to determine healthcare and broader social cost savings that will inform insurers on reimbursement, including working with the Centers for Medicare and Medicaid Services to ensure adequate coverage. Unfortunately, however, prohibition has left us scarce

¹ Recently, the letters of support sent to The Honorable Xavier Becerra, Secretary of HHS, both from Congress and from state legislators and Reason for Hope (along with a small group of other stakeholders), were made public. As was the response to our letters from Assistant Secretary of Mental Health and Substance Use, Dr. Miriam-Delphin Rittmon (on Secretary Becerra’s behalf), which generally agreed with our underlying policy arguments and noted the Biden Administration was exploring the establishment of the proposed task force.

² Separately, the task force should work with the DEA to issue updated guidelines on Religious Freedom and Restoration Act exemptions from the Controlled Substances Act.

data with which to conduct such analyses or determine optimal protocols that balance safety, efficacy, and access.

Reason for Hope's state policy initiatives seek to address this knowledge gap by establishing coordinated state-funded pilot programs throughout the country, utilizing the FDA's existing expanded access program. According to the FDA's 2018 Expanded Access Program Report, the agency has a 99% expanded access approval rate across all application types. Yet, clinicians hesitate to take advantage of this program due to the time, cost, and administrative burden of securing FDA and Institutional Review Board approvals. For MDMA and psilocybin, Schedule I licensing requirements and administrative hurdles further impede this option.

While far from a perfect option to navigate some of these expanded access bureaucratic obstacles, Reason for Hope is working to establish state pilot programs that will allow approved treatment sites to split administrative costs, fund the treatment of a select number of qualified patients (including Veterans), and collect and analyze real-world data.³ Coordination between these types of state pilot programs and the federal task force would create a thoughtful and intentional common-sense mechanism to advance the field, as opposed to having dozens of states across the country conducting their own work groups, task forces, or literature reviews exploring the efficacy and regulation of these therapies, without any additional data to inform best practices. The real-world evidence developed through these pilot programs can be utilized by the federal task force—both before and after FDA approval—to flexibly update guidelines as we learn new information.

We recognize, however, that these initiatives will take time to develop. As a team primarily connected by the loss of loved ones to suicide or deaths of despair (for me, my grandfather to suicide when I was young, and my mom to suicide in 2018), we are acutely aware that some people do not have the luxury of time to wait. Thus, Reason for Hope and the recently formed Veteran Mental Health Leadership Coalition (VMHLC) [provided a letter in support](#) of the Right to Try Clarification Act (RTTCA) for Senators Cory Booker and Rand Paul.⁴ The RTTCA has the potential to open immediate access to MDMA- and psilocybin-assisted therapies for those at serious risk of suicide who have exhausted all other treatment options.

Access to these treatments under the Right to Try Act is particularly significant to our VMHLC members, who have already funded over 1,000 Veterans to receive psychedelic-assisted therapy in other countries after exhausting all available treatment options. With thousands of additional Veterans on the waiting lists for these organizations, and a conservatively estimated 17-22 Veterans dying by suicide every day, the status quo cannot be justified. Individuals struggling with mental health conditions who have exhausted all treatment options deserve the opportunity to access breakthrough therapies that can be safely provided, with informed consent, here at home.

Brett Waters, Esq. is an antitrust attorney at Winston & Strawn, LLP in New York City and the Co-Founder and Executive Director of Reason for Hope, a non-profit organization working to prevent deaths of despair by helping to develop and advocate for the policy and legal reforms needed to facilitate safe and affordable access to psychedelic medicine and assisted therapies.

Reason for Hope is named in memory of Brett's mom, Sherrie Hope Waters, who he lost to suicide in 2018. Brett's grandfather, a fighter pilot in WWII, also died by suicide when Brett was young. These losses are the driving force behind his work, which to date, has been solely on a volunteer/pro bono basis. Prior to founding Reason for Hope, Brett served as the Policy and Advocacy Chair for the American Foundation for Suicide Prevention, NYC Chapter.

³ Earlier this year, we worked with Connecticut legislators to successfully pass a law creating the first such program, which passed as part of the state's budget bill. Additionally, the bill includes provisions to streamline the post-FDA approval regulatory process for MDMA and psilocybin through automatic rescheduling and language to automatically consider adoption of the federal guidelines that we anticipate will be developed by the task force and published by HHS.

⁴ <https://www.booker.senate.gov/imo/media/doc/vmhlc.pdf>



Oregon's Journey

The Implementation of Ballot Measure 109, The Oregon Psilocybin Services Act

Angie Allbee

Implementing a regulatory framework that centers on client safety and access requires us to shift from a drug policy framework rooted in the War on Drugs to a health policy approach that holds promise for healing and wellness.

Oregon Psilocybin Services (OPS) is housed within the Oregon Health Authority Public Health Division's Center for Health Protection and is working to implement Ballot Measure 109 (M109), the Oregon Psilocybin Services Act. M109 was passed in November 2020 by Oregon voters and is now codified in Oregon Revised Statutes (ORS 475A). M109 created a two-year development period from January 1, 2021, to December 31, 2022, in which OPS has been working to set up systems and processes for the licensing and regulation of psilocybin products and provision of psilocybin services. OPS will adopt all rules for the section by December 31, 2022, and will begin accepting applications for licenses on January 2, 2023.

Under M109, a client 21 years of age or older may access psilocybin services. While no prescription or referral from a medical or clinical provider is necessary, a client will be required to complete a preparation session with a licensed facilitator before participating in an administration session. The client will only access psilocybin at a licensed service center during an administration session in the presence of a trained, licensed facilitator. An optional integration session will be made available to each client after an administration session.

Oregon is the first state in the United States to implement and regulate legal psilocybin services. Implementing a regulatory framework that centers on client safety and access requires us to shift from a drug policy framework rooted in the War on Drugs to a health policy approach that holds promise for healing and wellness. To accomplish this, OPS is working to provide meaningful ways for community members to provide feedback on framework development, with an emphasis on engaging with historically underrepresented communities. This includes communicating in clear and timely ways, so community members can engage in the process and access information that meets their communication preferences. For public listening sessions and public hearings on rules, OPS provides Spanish and American Sign Language (ASL) interpretation as well as Communication Access Realtime Translation (CART) captioning.

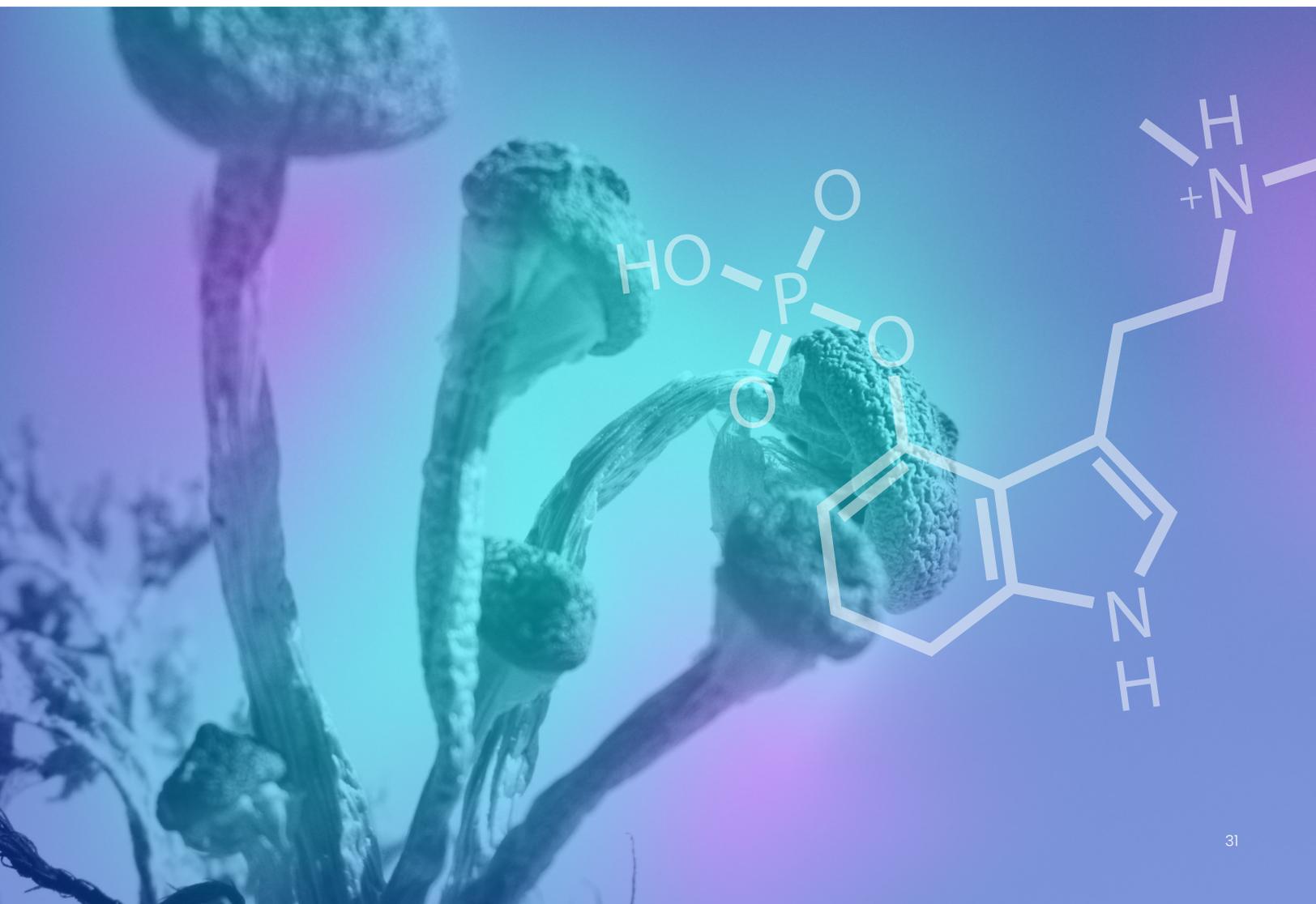
OPS has been working to introduce the M109 framework to community leaders, government partners, organizations, and members of the public who may not yet be aware that psilocybin services will soon be a new option in Oregon, while also working closely with partners that have experience and knowledge with psilocybin. We are faced with the challenge of building trust with communities that have not been well-served by government systems, as well as a focus on working within the statutory container of M109 that sets the boundaries for what we can or cannot do. From public listening sessions to community circles, we are listening and learning from the insights that community partners share. As we work to decrease barriers to access and create pathways into this new body of work, we understand that continuous evaluation and adjustment will be necessary.

While affordability is important to ensure equitable access to services, OPS does not have the authority to regulate the costs of psilocybin products or services under M109. In addition, OPS is a fee-based section, which means the license fees must cover the costs of administering the work. OPS is committed to equitable licensure fees and will continuously review costs and trends over time to ensure sustainability of the section. OPS anticipates many more robust discussions

with partners and the public, as well as subsequent recommendations from the Oregon Psilocybin Advisory Board to find ways to ensure access to psilocybin services within the statutory container of M109.

Successful implementation also relies on support for licensees. While no additional funds are available for those seeking to be licensed under M109, OPS will provide an educational and technical assistance approach with our regulated community. To help support these small businesses in Oregon, OPS is partnering with the Oregon Secretary of State's Office of Small Business Assistance to identify business support for future licensees. In addition, training will be provided to licensees after rules are adopted to support a successful launch of M109.

M109 creates additional opportunities for the workforce in Oregon, specifically for licensed facilitators from diverse backgrounds that may support the health of their communities through culturally responsive and equity-centered psilocybin services. Culturally responsive and equity-centered services may reduce harm to clients that have experienced trauma from societal structures that have exhibited control through power and privilege, implicit bias, and institutional racism.



Angie Allbee joined the Oregon Health Authority Public Health Division as Oregon Psilocybin Services Section Manager after working to shape legislative policy for nearly a decade. After serving as Senior Policy Advisor for Oregon Health Authority Government Relations, she served in policy roles with the Oregon Department of Human Services, Oregon Criminal Justice Commission, Oregon House Majority Office, and Oregon Legislative Assembly. Prior to policy work in Oregon, Angela spent nearly a decade in the non-profit sector serving older adults, individuals experiencing disabilities, refugees, asylees, veterans, and survivors of domestic and sexual violence. She recently served on the Board of Advisors for the Voxapod Menstrual Equity Project and worked with community members in rural St. Thomas, Jamaica to secure infrastructure for water through the Access to Safe Drinking Water Project. Angie received her Executive Master of Public Administration degree from the Hatfield School of Government at Portland State University.

Over the past year, the OPS team has been working on many facets of implementation—establishing budget authority through the Oregon legislative process; hiring and training team members; developing the Training Program, Licensing, and Compliance (TLC) system for applicant tracking and case management; customizing a psilocybin spore-to-sale product tracking system; establishing safety, equity, and justice centered background checks within the agency’s Background Check Unit (BCU); developing section and program-specific policy and procedures; collaborating with state and local partners; creating opportunities for community partner and public engagement; and working with the Oregon Psilocybin Advisory Board on recommendations for draft rules. While there is much preparation for the January 2, 2023, date, there is also long-term planning work taking place. The team is working to align with agency and division priorities, and build section evaluation processes to measure this alignment. Currently, a team of six people, OPS will soon be welcoming new team members as it builds out the licensing and compliance teams. We are excited to build relationships and cultivate understanding as we move forward in the implementation process.

Please join us in this journey by visiting the [OPS website](#).¹ We encourage you to sign up for the [OPS Distribution List](#)² and access important information, such as the Oregon Psilocybin Advisory Board [Scientific Literature Review](#),³ [Revisión rápida de evidencia y recomendaciones del Consejo Consultor sobre la Psilocibina de Oregon](#),⁴ the [OPS Community Interest Survey](#),⁵ [OPS Public Listening Sessions](#),⁶ [Administrative Rules](#),⁷ and more. Stay tuned for more information!

On a personal note, it is such an honor to be part of this movement. Prior to policy work in Oregon, I spent nearly a decade in the non-profit sector working with older adults, individuals experiencing disabilities, refugees, asylees, Veterans, and survivors of domestic violence and sexual assault. Those years taught me that healing is an essential part of experiencing a healthy, joyful life that every person should have access to. As manager of OPS, I have the opportunity of working with an incredible team of dedicated professionals as we open the door to a new option for healing and wellness in Oregon. My hope is that psilocybin services will lead to meaningful improvements in the health of our communities.

¹ *Oregon Psilocybin Services*. Oregon Health Authority : Oregon Psilocybin Services : Prevention and Wellness : State of Oregon. (n.d.). Retrieved from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Oregon-Psilocybin-Services.aspx>

² The Oregon Health Authority and Department of Human Services. Retrieved from https://public.govdelivery.com/accounts/ORDHS/subscriber/new?topic_id=ORDHS_932

³ *Oregon psilocybin – scientific literature review*. Oregon Health Authority : Oregon Psilocybin—Scientific Literature Review : Prevention and Wellness : State of Oregon. (n.d.). Retrieved from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Scientific-Literature-Review.aspx>

⁴ *Revisión rápida de evidencia y recomendaciones del Consejo Consultor sobre la Psilocibina de Oregon*. <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Revisi%C3%B3n%20r%C3%A1pida%20de%20evidencia%20y%20recomendaciones%20del%20Consejo%20Consultor%20sobre%20la%20Psilocibina%20de%20Oregon%2C%207.30.21.pdf>

⁵ *Oregon Psilocybin Services Section Community Interest Survey Findings: 2022 Report*. <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/OPS-Community-Interest-Survey-Findings-2022-Report-FINAL.pdf>

⁶ *Oregon psilocybin – public listening sessions*. <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Public-Listening-Sessions.aspx>

⁷ *Oregon Psilocybin – Administrative Rules*. <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Administrative-Rules.aspx>



Psilocybin Facilitator Training Programs in Oregon

An Inside Look at Oregon's Burgeoning Psychedelic Marketplace

Jon Dennis

Conflict of Interest Disclosure

Jon Dennis is the executive director and a co-owner of the Vital Oregon facilitator training program, and this article is about Oregon facilitator training programs.

In January, Oregon will begin accepting licensing applications for a new class of psychedelic professional, called a “psilocybin services facilitator.” The facilitator will play perhaps the most crucial role in the administration of Oregon’s new psilocybin program: ensuring client safety. To do this, facilitators will be tasked with screening clients for contraindications, preparing clients for the psilocybin experience, advising on and approving of the amount of psilocybin to be consumed, providing supervision and support during the psilocybin session, and offering integration services after the psilocybin experience to help participants catalyze positive life changes. They will also provide referrals to professionals in other disciplines when clients may benefit from other professional help. With all these responsibilities, Oregon is relying heavily on facilitators to ensure that its psilocybin program is run safely and responsibly.

Oregon’s psilocybin program, known as [Measure 109 \(M109\)](#),¹ is not a medical or mental health program. On the contrary, adults 21 years of age will be permitted to take psilocybin for [virtually any reason](#).² The facilitators who will run the program

¹ *State of Oregon: Oregon secretary of State – Home. Measure 109 Language. (2019). Retrieved August 22, 2022, from <https://sos.oregon.gov/admin/Documents/irr/2020/034text.pdf>*

² Marks, M. (2021, December 17). *Warning: Oregon legalized supported adult use of psilocybin, not psychedelic therapy.* Chacruna. Retrieved August 30, 2022, from <https://chacruna.net/oregon-legalized-psilocybin-supported-adult-use/>

will normally not be medical or mental health professionals. In fact, there are only two educational requirements in order to become a facilitator in the Oregon system: holding a high school diploma or GED and graduating from a state-approved facilitator training program. This means Oregon is also relying heavily on facilitator training programs to implement the M109 program safely and responsibly.

Last May, the [Oregon Health Authority \(OHA\)](#)³ adopted its final rules for the initial facilitator training requirements. In brief, the facilitators must successfully complete a program that is no less than 160 hours. 40 of those hours must be an in-person practicum in which students have the opportunity to “facilitate and observe the facilitation of non-ordinary states of consciousness.” The remaining 120 hours may be offered entirely online and must cover a range of topics, including safety, ethics, pharmacology, core facilitation skills, and cultural equity in relation to psilocybin. Programs must maintain a level of training for students such that graduates “could reasonably expect to possess the knowledge and skills required to practice as a facilitator.” At the end of the program, the director or a lead instructor must endorse each graduating student as “qualified to provide psilocybin services.”

Because M109 allows people to take psilocybin for virtually any reason, there is considerable speculation about what “psilocybin services” in Oregon will actually look like. They might look medical, therapeutic, recreational, religious, or anything in-between. They might look like nature retreats or wellness spas or ceremonial gatherings. They might even look like microdosing-friendly office spaces. Oregon hasn’t published most of the M109 regulations yet, but it appears to some observers that the types of psilocybin services that will be available in Oregon might accurately reflect the wide and varied motivations that people have for taking psilocybin. These conditions are predictive of a niche psilocybin marketplace in which psilocybin facilitation and facilitator training programs assume many different forms.

Last June, the Oregon Health Authority began accepting applications from training programs who wish to become approved by the state. As of July 21, 2022, OHA has approved 8 different training programs, and at least 4 other programs are known to be working through the application process. These programs reflect some of the diversity within the rapidly-expanding psychedelic culture. They also reflect varying philosophies and approaches to psychedelic experience.

Some Oregon training programs require their students to have advanced medical or therapeutic degrees. Others are proud to have previously-underground practitioners on their teaching staff. Tuition for most schools is around \$8,000-\$9,000 with outliers in both directions. At least 2 are nonprofits. Many programs celebrate diversity and seek inclusion of marginalized populations. Several discuss the intersection of Indigenous wisdom with modern clinical research. Generally, schools tend to focus on healing, wellness, personal growth, and safety. Nearly every program’s website discusses the spiritual dimensions of working with psilocybin.

[Earth Medicine Center](#)⁴ has a shamanic character. It partners with an Indigenous plant medicine community in Colombia and teaches from “an ecological perspective.” [The Alma Institute](#)⁵ is a nonprofit that is fiscally-sponsored by MAPS. Its mission is “to strengthen and diversify the network” of facilitators “by offering prioritized enrollment and certification opportunities to members of marginalized and low-income communities.” Another nonprofit, the [Synaptic Care Institute](#),⁶ is also dedicated to diversity in the psychedelic ecosystem and roots its program “in holism, wisdom, and science.” The mission of [InnerTrek](#),⁷ the program started by the co-chief petitioner of M109 Tom Eckert, is “to spark healing and wholeness through Oregon’s newly legal psilocybin therapy and wellness framework.” [Fluence](#)⁸ focuses on training licensed mental health practitioners and offers a Postgraduate Certificate in Psilocybin-assisted Therapy. [Subtle Winds](#)⁹ uses “an integrative humanistic approach” and highlights its team’s decades of hand-on harm-reduction work at music festivals and other events. [SoundMind](#)¹⁰ combines medicinal approaches to psilocybin with ceremonial and traditional approaches, and requires teachers to be centered in anti-racism and anti-oppression.

⁴ [Earth Medicine Center – Psilocybin Education](#). (n.d.). Retrieved August 22, 2022, from <https://www.earthmedicinecenter.com/>

⁵ [Psychedelic facilitator training in alignment with Oregon Measure 109: The Psilocybin Services Act](#). ALMA INSTITUTE. (n.d.). Retrieved August 22, 2022, from <https://www.almatraining.org/>

⁶ [Home](#). Synaptic. (n.d.). Retrieved August 22, 2022, from <https://www.synaptic.care/>

⁷ [Innertrek facilitator training](#). InnerTrek Facilitator Training. (n.d.). Retrieved August 22, 2022, from <https://www.innertrek.org/>

⁸ [Psilocybin-assisted therapy](#). Fluence. (2022, July 27). Retrieved August 22, 2022, from <https://www.fluencetraining.com/>

⁹ [Home—subtle winds](#). Home—Subtle Winds. (n.d.). Retrieved August 30, 2022, from <https://www.subtlewinds.com/>

¹⁰ [Soundmind Institute](#). SoundMind Institute. (n.d.). Retrieved August 22, 2022, from <https://soundmind.center/>

³ [Oregon Psilocybin Services](#). Oregon Health Authority : Oregon Psilocybin Services : Prevention and Wellness : State of Oregon. (2022). Retrieved August 22, 2022, from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Oregon-Psilocybin-Services.aspx>



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Jon is the chief architect of the proposed regulatory framework for protecting community and religious use of psilocybin under Oregon's psilocybin program. He has presented to multiple subcommittees of the Oregon Psilocybin Advisory Board in support of religious and spiritual freedoms and a community access model for psychedelic services. Previously, Jon worked as a civil litigator and managed a nonprofit law office giving free legal assistance to people living in poverty. Jon has a BA in Religious Studies and practices law in Ontario, Oregon.

Vital Oregon,¹¹ the training program from the Psychedelics Today team (and, full disclosure, the program I'm involved with) aims to provide exceptional and affordable training for a niche marketplace in a way that advances psychedelic community and culture. Even **UC Berkeley**¹² has announced that it's going to have an Oregon training program that will emphasize "psilocybin facilitation and its applications for spiritual and psychotherapeutic care." Michael Pollan serves on its leadership team.

Facilitator training programs are regulated both by the Oregon Health Authority and by the **Oregon Higher Education Coordinating Commission**.¹³ Some of the smaller, nonprofit, and more mission-driven training programs have expressed concern that the weight of the regulatory burdens—and in particular the regulatory compliance ordinarily required of private career schools—may cause their programs to no longer be financially feasible. This should be cause for alarm because the prevalence of smaller training programs contributes to the cultural diversity and cultural equity of this fledgling system, which is already facing considerable diversity and equity challenges.

The Oregon Health Authority and its **Psilocybin Advisory Board**¹⁴ worked for 16 months to identify and establish standard minimum training criteria that they expect will create safety and equity in the world's first regulated adult-use psychedelic services program. How that training looks once reflected through the diverging currents of a consumer-driven psychedelic marketplace might provide some clues to where this "renaissance" is headed.

¹¹ Vital. Vital Psychedelic Training Oregon. (n.d.). Retrieved August 22, 2022, from <https://www.vitalpsychedelicttraining.com/oregon>

¹² Anwar, Y. (2020, September 16). *UC Berkeley launches New Center for Psychedelic Science and Education*. Berkeley News. Retrieved August 18, 2022, from <https://news.berkeley.edu/2020/09/14/uc-berkeley-launches-new-center-for-psychedelic-science-and-education/>

¹³ Higher Education Coordinating Commission. State of Oregon: Higher Education Coordinating Commission—Home. (n.d.). Retrieved August 22, 2022, from <https://www.oregon.gov/highered/Pages/index.aspx>

¹⁴ Oregon Psilocybin Advisory Board. Oregon Health Authority : Oregon Psilocybin Advisory Board : Prevention and Wellness : State of Oregon. (2021). Retrieved August 24, 2022, from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Advisory-Board-Meetings.aspx#>:



Considering Complexities with Measure 109 Implementation

Jonathan Perez-Reyzin and
Ismail Lourido Ali, J.D.

In **MAPS' Winter 2021 Bulletin** article, “Beyond Oregon: A New Drug Policy Horizon in the U.S.,”¹ we discussed hopes for Oregon’s regulatory implementation of Measure 109,² the Oregon Psilocybin Services Act. In that article, we sorted our recommendations and reservations into three categories:

1. **“Resist stigma by divesting from coercion, pathologization, and criminalization”**
2. **“Lower barriers to entry while maintaining quality of care”**
3. **“Protect consumers while regulating responsibly”**

Nearly nine months later, we are approaching the end of the deliberations over the [Oregon Health Authority’s final rules](#)³ for psilocybin services — the regulations will be officially set by December 30, 2022. At this pivotal moment, it is worth reflecting on how the process has played out, and on which of our hopes and concerns from last year have come to pass. Notably, many of the most central unresolved challenges with which the Oregon Psilocybin Advisory Board (OPAB), the Oregon Health Authority (OHA), and the general public have been struggling with implicate each of the categories we originally outlined. In this article, we discuss two such challenges: the regulation of microdosing and the potential creation of an entheogenic or community-based practitioner framework, with an eye towards supporting the effective implementation of Measure 109 with safety, accessibility, and equity in mind.

¹ Ali, I. L., J.D., Booher, L., J.D., & Ginsberg, N. L. (2021, March 9). Beyond Oregon: A New Drug Policy Horizon in the U.S. *MAPS Bulletin – Winter 2021*, 31(1).

² Measure 109 was a ballot measure passed by Oregon voters in 2020 which directs the Oregon Health Authority to license and regulate the manufacturing, transportation, delivery, sale, and purchase of psilocybin products and the provision of psilocybin services.

³ The final rules promulgated by the Oregon Health Authority can be found on the Oregon Secretary of State’s website—specifically Chapter 333, Division 333.

Regulation of Microdosing

The topic of whether and how to allow psilocybin [microdosing](#)⁴ has been hotly debated, both during OPAB meetings and during the recent OHA [public listening sessions](#).⁵ Measure 109 itself does not prohibit—or even mention—microdosing, and the only potential OPAB [proposal](#)⁶ explicitly using the term, the Equity Subcommittee’s proposal that “OHA stratify allowed psilocybin products into two categories: a) Hallucinogenic psilocybin products (hallucinogenic doses) b) Sub-hallucinogenic psilocybin products (micro doses)” narrowly failed to make it into OPAB’s final recommendations. But even without such an explicit categorization, microdosing will be permitted in practice if OHA declines to set a minimum dose, as the primary drafter of Measure 109 [noted](#)⁷ in April. Regarding dosage generally, OPAB [recommended](#)⁸ that a standard serving of psilocybin be 25 milligrams, with a typical administration session employing one serving. However, neither a maximum nor a minimum dose was set—indeed, the recommendation allows that “a product package may be subdivided into amounts that are less than one serving.” If OHA were to follow this recommendation, dosage regulations would not be a barrier to microdosing. However, two areas of forthcoming OHA rules will certainly affect the feasibility of microdosing under Measure 109: preparation session requirements and administration session duration regulations. OPAB made recommendations with respect to each.

OPAB made a [recommendation](#)⁸ regarding duration that there be neither a minimum nor a maximum required time for an administration session. Notably, the text of the approved recommendation includes language implicating microdosing, even if it does not name the practice explicitly: “Framing the required duration of administration sessions in this manner leaves room for the administration of subperceptual doses of psilocybin products...” For such subperceptual (or perhaps

more accurately, subhallucinogenic) doses, a short administration session could allow clients to take a microdose, and after a short period of monitoring, go on to resume their day. OPAB also addressed preparation session requirements in the context of potential group services, [recommending](#)⁸ that group preparation sessions be permitted and allowing preparation sessions to be conducted remotely. If OPAB’s recommendations are incorporated into OHA’s final rules, microdosing could be permitted, although certain rules that OPAB has not made recommendations about—including the possibility of requiring only one preparatory session for multiple administration sessions—will affect microdosing’s cost and practicality.

At July’s OHA [public listening sessions](#)⁵ at which OHA listened to questions and recommendations but made no comments on them, microdosing was perhaps the most discussed topic. All three sessions—but especially the final one, on products—included multiple members of the public speaking up in favor of OHA permitting microdosing and making it easily accessible. None spoke out against microdosing. Comments highlighted the perceived benefits of microdosing for mood and mental health, and implored OHA not to ban a practice that is permitted by the language of Measure 109.

OHA has not explicitly signaled its view of microdosing, but could nevertheless come out against the majority public opinion, especially if it shares the concern of [some scientists](#)⁹ that microdosing could pose a potential heart health risk and placebo-controlled trials have not demonstrated clear benefits. However, this heart health risk has not been observed in people who engage in microdosing and so is at this point theoretical. Furthermore, very recent evidence from [a large controlled](#)¹⁰ study suggests that microdosing may indeed improve mood and mental health. Perhaps more importantly, those curious about or committed to the benefits of microdosing will likely continue to microdose regardless of OHA’s decision. From a harm reduction standpoint, it is important to make microdosing safer for those folks—creating a legal, affordable, and well-regulated framework for microdosing would do precisely that.

⁴ NYT article

⁵ *Oregon psilocybin – public listening sessions*. Oregon Health Authority : Oregon Psilocybin – Public Listening Sessions : Prevention and Wellness : State of Oregon. (n.d.). Retrieved from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Public-Listening-Sessions.aspx>

⁶ <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/OPAB%20AGENDA%20FINAL,%206.22.22.pdf>

⁷ Staff, T. P.-F. C. (2022, April 19). *Microdosing under the Oregon Psilocybin Services Act: A definite maybe*. Bill of Health. Retrieved from <https://blog.petrieflom.law.harvard.edu/2022/04/19/microdosing-under-the-oregon-psilocybin-services-act-a-definite-maybe/>

⁸ *Approved OPAB recommendations – Oregon*. Retrieved from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Approved-OPAB-Recommendations.pdf>

⁹ Staff, T. P.-F. C. (2022, April 13). *Safety first: Potential heart health risks of microdosing*. Retrieved from <https://blog.petrieflom.law.harvard.edu/2022/04/13/safety-first-potential-heart-health-risks-of-microdosing/>

¹⁰Rootman, J.M., Kiraga, M., Kryskow, P. et al. Psilocybin microdosers demonstrate greater observed improvements in mood and mental health at one month relative to non-microdosing controls. *Sci Rep* 12, 11091 (2022). <https://doi.org/10.1038/s41598-022-14512-3>

Entheogenic or Community-Based Practitioners Framework

If psilocybin microdosing is the most publicly discussed concern with Measure 109's implementation, the creation of an entheogenic or community-based practitioners framework is undoubtedly a close second. From the start of OHA's process, observers have been concerned with equity and accessibility, particularly because—despite the important work of OPAB's [Equity Subcommittee](#)¹¹—Indigenous practitioners have not been [adequately represented](#)¹² on OPAB or at OHA. Many thus welcomed a proposal for an [entheogenic practitioners framework](#),¹³ drafted by Jon Dennis (who is not a member of OPAB) and subsequently recommended for adoption by both the Licensing and Equity Subcommittees. As lawyer Jon Dennis has [explained](#),¹⁴ the entheogenic framework aims to increase access to the legal framework and protections of Measure 109 for religious and spiritual organizations—including Indigenous groups—who may otherwise be unable to afford or comply with the requirements of facilitator and manufacturer licenses. It would also decrease the cost of psilocybin services for those clients receiving services with an entheogenic practitioner. For example, an entheogenic practitioners framework would create a pathway for communities to employ “peer-support assistance” to replace the role of some paid facilitators, and to manufacture psilocybin in a cheaper and less restricted way.

Despite subcommittee support for the entheogenic framework, OHA appeared unsure about its legal or administrative ability to implement it. In a [letter](#)¹⁵ accompanying its first set of rules, which were released in May, it wrote: “Many members of the public expressed support for an ‘Entheogenic Framework’ for licensing.... Because the framework proposes exceptions to rules that have not yet been drafted, and because the Oregon Psilocybin Advisory Board has yet to consider the proposal, OPS [Oregon Psilocybin Services] did not address these comments in the current rulemaking. OPS is committed to understanding the impact of statute and rules on entheogenic practices through collaboration and partnerships with communities.” Eventually, OPAB did take up the proposal, but not before OHA consulted the Oregon Department of Justice as to the feasibility of creating an entheogenic framework. The Department of Justice

¹¹ *Oregon psilocybin – equity subcommittee*. Oregon Health Authority : Oregon Psilocybin—Equity Subcommittee : Prevention and Wellness : State of Oregon. (n.d.). Retrieved from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Equity-Subcommittee-Meetings.aspx>

¹² Marks, M. [@masonmarksmd]. (2022, May 26). *Psychotherapist Rebeca Rocha's letter to the Oregon #Psilocybin Advisory Board explains how Measure 109 rule making excluded Indigenous & other marginalized voices. Instead of acknowledging it or reading it into the record as requested, the Board ignored it. Please read & share.* [Tweet]. Twitter. <https://twitter.com/MasonMarksMD/status/1529849974527123456>

¹³ Dennis, J. *Privileges and Duties of Entheogenic Practitioners*. Retrieved from [https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Privileges%20and%20Duties%20of%20Entheogenic%20Practitioners\(DRAFT%20v.9%20-%20REDLINE\).pdf](https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Privileges%20and%20Duties%20of%20Entheogenic%20Practitioners(DRAFT%20v.9%20-%20REDLINE).pdf)

¹⁴ Psychedelics Today. (2022, April 7). *Religious practice under Oregon Measure 109*. Retrieved from <https://psychedelicstoday.com/2022/02/03/religious-practice-under-oregon-measure-109/>

¹⁵ Retrieved from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Letter-to-Public-5.20.2022.pdf>

publicly released its [memorandum](#),¹⁶ which concluded that OHA cannot adopt rules that would apply different standards to entheogenic (i.e., spiritual) practitioners, since doing so would “likely violate the establishment clause protections of the Oregon and United States constitution.”

Based in part on those grounds, OPAB subsequently [rejected](#)¹⁷ the entheogenic framework. A proposal to consider a “community-based” framework that would have potentially avoided the establishment clause issues by prioritizing community non-profit organizations instead of spiritual groups also narrowly [failed](#)¹⁸ before the full board. Ultimately, OPAB made no recommendations at all regarding such alternative frameworks, despite the early enthusiasm of some of its subcommittees. At July’s OHA [public listening sessions](#),⁵ issues of access and equity for Indigenous practitioners and lower income clients came up repeatedly, and many implored OHA to create a framework — even if not the original entheogenic framework — that would solve some of the issues that Jon Dennis’s original proposal was designed to solve. But without any OPAB-recommended framework to draw from, it is unclear what OHA may seek to do to promote the barrier-reducing and equity-enhancing goals many of us are so keen to see promoted. We hope that OPAB will return to consider these approaches when more data has been collected about the de facto application and practical impact of the final rules.

Conclusion

Much work has been done since the start of the Measure 109 implementation process, and much work still remains. MAPS commends OPAB and OHA for their efforts and consistent hard work creating an entirely novel model for psilocybin services. At the same time, some of our concerns about access, consumer protection, and criminalization remain — as the two controversies explored here show. We hope that OHA charts a path forward that will reduce barriers to access, and, as we said in our first [article](#),¹ “prioritize safety and support for those most impacted by prohibition and insufficient access to mental health care.” Overly complicating or fully disallowing microdosing, or insufficiently considering marginalized, Indigenous, or community-based providers would be an unfortunate divergence from this path.

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¹⁶ Retrieved from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Legal-Memorandum.pdf>

¹⁷ Lekhtman, A. (2022, June 6). *Oregon Board rejects plan to boost psilocybin access, but fight goes on*. Filter. Retrieved from <https://filtermag.org/oregon-psilocybin-religious-access-fight/>

¹⁸ Retrieved from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/OPAB%20Meeting%20Minutes%205-25-22%20Approved.pdf>





This Won't Last Forever

Reframing Perspectives on Drug Sellers

Mitchell Gomez

Even for those who live within the world of unregulated drug markets, it is likely that drug sellers aren't what you likely think they are. For those who don't live in that world, it's a near certainty that they aren't what you think they are. Our collective perceptions about drugs and drug markets have been distorted by decades of taxpayer-funded drug war propaganda and sensationalist Hollywood misinformation. Dating back to the earliest days of drug war propaganda, higher-level drug sellers have been portrayed as purely profit-driven, immoral, or downright evil. Lower-level sellers are often portrayed as having been "tricked" or "trapped" by these higher level sellers through their own "addiction" to these substances.

For many currently illicit substances, the raw base materials are cultivated in very rural locations by subsistence farmers in some of the planet's most destitute areas. Since the price of these raw materials is a tiny fraction of the ultimate retail value, sophisticated and professional production and transportation networks almost always arise to meet the needs of refining these raw materials into the desired drugs, and to transport those drugs to more wealthy areas. However, it would be impossible for these large, multinational organizations to perform the day-to-day minutia of retail sales. For drugs which are produced domestically (or in industrialized, wealthy nations), these networks often don't exist in the way that they do for traditional so-called "drugs of abuse."

At all levels, drug sellers are largely rational economic actors who have looked at the risks and benefits of distributing substances and made a reasoned or principled choice to engage in the behavior that they do.¹ Although some academic researchers claim that only a small fraction of users ever engage in social distribution because of the nature of prohibition and the fear of criminal prosecution, this is unlikely to be true,² especially since countries with lower risk of prosecution and higher trust of aca-

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¹ Dickinson T. Non-violent threats and promises among closed-market drug dealers. *Int J Drug Policy*. 2017 Apr;42:7-14. doi: 10.1016/j.drugpo.2016.12.005. Epub 2017 Jan 16. PMID: 28104571.

² Golub A, Johnson BD. Substance use progression and hard drug abuse in inner-city New York. In: Kandel Denise B., editor. *Stages and Pathways of Involvement in Drug Use: Examining the Gateway Hypothesis*. New York: Cambridge University Press; 2002.

demic studies have shown that social supply is the norm.³ At the retail level for the vast majority of substances, the bulk of so-called “drug sellers” are actually engaged in social supply, simply connecting their friends who don’t have access to substances they are trying to find.⁴

Since so many of these small distributors are not relying on drug sales for an income, they are, by definition, not “professional” sellers. Because of this, their knowledge of the substances they are distributing may be limited, and their understanding of the risks of prohibition created misrepresentation and adulteration may be insubstantial as well, although surely both of these factors vary widely. However, this “amateur” distribution model does mean that the principles of individual harm reduction and drug checking are incredibly important, even as the research on the role of people who distribute substances as harm reductionists continues to grow.⁵ The simple reality is, when drugs are sold in unregulated markets, there is no way for anyone to know what kind of misrepresentations or adulterants may be present in any given substance short of personally testing, and this makes it difficult for consumers to make informed decisions about the true risk profile of that substance.

Perhaps most importantly, this nuanced understanding of how substances are distributed means that both the traditional prohibition-driven models and the “decriminalize” movements are treating “drug sales” as something they are not, and both must be adjusted to create legal, safe supply for those seeking to obtain any given drug.

Under prohibition, all sales are treated in similar ways, and the legal penalties can be incredibly severe. In many jurisdictions, a state is not even required to prove that *any* money changed hands for a charge of distribution, which means many people simply sharing substances with their friends for a financial loss can be charged with distribution if they are caught doing so. With mandatory minimum sentencing “guidelines,” judges are often banned from even considering mitigating factors in regards to how long a defendant is sentenced, so that even if the judge and jury fully know that a person was engaged in gifting, and not in sales, they must still charge, convict, and sentence them as if they were. For the fiscal year of 2021, federal drug charges represented a total of 31.3% of all federal charges, the largest single category of charges. Ignoring the next most common federal charges (which are for immigration violations), drug charges represent more federal charges than fraud, theft,

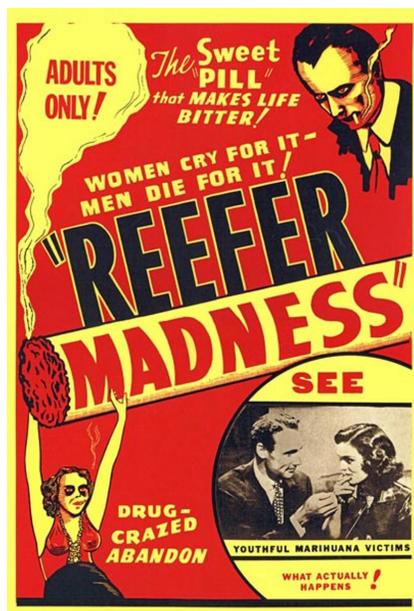
embezzlement, robbery, money laundering, sexual abuse, child pornography, and firearms charges combined.⁶ Clearly, too many people are being charged with “sales,” and the law needs to change to reflect the reality of social sharing, gifting, and small-scale distribution.

Even under many of the “decriminalization” initiatives, the sales of substances are not being addressed (and a big thanks to those in the movement who ARE including social sharing in these ballot measures). This oversight must be addressed by all of those in the decriminalization movement, and any move

to reduce criminal penalties for drug use must speak honestly about the reality of how substances are sold.

Because so many of the harms attributed to drugs are actually caused by prohibition, the best way of addressing those harms is not through simply tinkering around the edges of the drug war, but by dismantling prohibition itself as a system. Combined with the overcharging of social sellers with “drug distribution,” we have created an unsustainable mass arrest and incarceration machine which is targeting too many with severe charges resulting in long periods of incarceration based on misunderstandings in the realities of distribution. When drugs are legal, they can be

regulated for safety, and making sure this distribution model is not for profit would be trivial. Drugs that have been tested and approved can then be sold without fear of misrepresentation or adulteration, people experiencing chaotic use can seek help without fear of incarceration, and social distribution and gifting can be reintegrated into our society in the same way that sharing a bottle of home brew is today.



³ Ross Coomber, Leah Moyle & Nigel South (2016) The normalisation of drug supply: The social supply of drugs as the “other side” of the history of normalisation, *Drugs: Education, Prevention and Policy*, 23:3, 255-263

⁴ Crawford, David. 2020. “Ambivalent Economics of Middle-Class Drug Dealers.” *Anthropology News* website, March 5, 2020. DOI: 10.1111/AN.1369

⁵ Bardwell G, Boyd J, Arredondo J, McNeil R, Kerr T. Trusting the source: The potential role of drug dealers in reducing drug-related harms via drug checking. *Drug Alcohol Depend.* 2019 May 1;198:1-6. doi: 10.1016/j.drugalcdep.2019.01.035. Epub 2019 Mar 6. PMID: 30856370; PMCID: PMC6467706.

⁶ Davis, Neal. “Drug Trafficking Tops Federal Crime Sentencing.” *Neal Davis Blog*, 29 Mar. 2022, <https://www.nealdavislaw.com/blog/drug-crimes/drug-trafficking-federal-sentencing>.



Legal Coca

Colombia's Drug Policy Insurrection

David Restrepo

After suffering through decades of the Andean region's most repressive, expensive, and fruitless drug war, designed and funded by the USA, Colombia is finally revolting against its historical drug policy subservience and choosing to lead the global debate on the legal regulation of drugs. On July 20, 2022, Colombian Independence Day, members of the newly elected, progressive Congressional majority announced they will legalize not just adult-use cannabis, psilocybin mushrooms, and opium poppy, but also tackle perhaps the most important drug policy issue of our times: the legal regulation of coca and its derivatives. During his August 7 inauguration speech, Colombian President Gustavo Petro reiterated his commitment to legal regulation—the first time a sitting president has ever broken this lingering drug policy taboo.

Why Coca Matters

Despite its near absence from global drug policy reform debates focused on cannabis and psychedelics, coca is just as important an issue, if not more—and not just in Colombia. Cocaine, first isolated from coca by Europeans in the 19th century, is second only to cannabis in terms of global illicit drug revenues, and provides even more profits to organized crime. Without punitive drug policy, it would be hard to conceive the scale of cocaine-fueled violence and corruption that afflicts the entire planet but particularly victimizes Latin Americans.

And yet, the threat that coca and cocaine reform is trying to avert is more existential and global in nature than the multi-decade crime wave caused by prohibition. Preserving tropical rainforests, not least the Amazon, is key to avoiding runaway climate change—and the war on coca is one of the main obstacles impeding that goal.

Before detailing the link between coca and climate, it should be noted that, on its own, coca is a remarkable, native South American plant with an 8,000-year history that defines the identity of millions of Indigenous people. It represents bio-cultural

patrimony with enormous untapped potential in nutrition and medicine.¹ For coca cultures and those of us trying to consensually appropriate—or remember—a more comprehensive understanding of coca, this humble-seeming plant is the heart of a distinctive Indigenous worldview: one where the educated use of plants fosters a nature-centric structure to society and supports the pursuit of a balanced life.

This would seem a tall order for coca, with its almost imperceptible effects. Coca chewing is a far cry from psychedelic journeys, cannabis highs, alcohol intoxication, or the rush of isolated cocaine. And yet, despite its subtlety, coca plays a decisive role in our lives. Functionally, coca is a highly nutritious and effective stimulant whose impact is most felt when prolonged effort and concentration are required, such as in strenuous exercise or focused work. But beyond pharmacological function, coca is a powerful community-building tool. By boosting attention and stamina, coca enables *talking circles* with family, friends, colleagues, and neighbors that improve the quality of conversation, and allow us to better understand our relationships with each other and the natural world. At a time in history where social media is undermining communication, coca talking circles help us establish horizontal, empathetic dialogue that fosters a better-informed, shared vision of reality. As a result, coca provides us the energy to implement talking circle agreements in everyday life.

How the War on Coca Drives Climate Change

Unfortunately, until now, none of this perspective on coca has made it into drug policy. Instead, the U.S.-mandated focus on eradication and substitution has stigmatized coca, pushing crops ever deeper into pristine jungle. There, coca prohibition acts as a first domino in a process that is converting carbon-sinking forest into eroded pasture and ash. Glyphosate spraying and cocaine lab interdiction, hallmarks of U.S. drug policy, do little more than chase coca around in a spiral of deforestation, damaged food crops and polluted soils and water. The little illicit cocaine profit that isn't stashed away in tax havens and first-world bank accounts mostly stays in the hands of absentee landlords, their mercenaries armed with U.S. weapons and their allies in government and law enforcement. Since U.S.-concocted anti-money laundering rules hamper investment in the formal economy, drug money winds up diversifying

the portfolio of the illicit drug business via armed land grabs, merchandise contraband, human trafficking, weapons dealing, logging, cattle ranching, and mining.

Drug financing thus fuels extractive capitalism in the ever-expanding pan-Amazonian agricultural frontier. The result is a hostile environment against Indigenous communities whose livelihoods and culture historically utilized psychoactive plants—not least coca itself—to implement sustainable rainforest management. They are now contending with poisoned rivers, rising birth defects and cancer, as well as violent encroachment of their land. Behind the Amazon's thickening ring of fire is not just soy, meat, and mining. Prohibition weaponizes cocaine profits into a replenishable source of seed capital shoving the Amazon towards desertification—and the world towards uncontrolled climate change.

Colombia's Pathway of Indigenous-Led Coca Reform

Unless we radically alter the rules of the economic game at play with coca. In this sense, Colombia's developments are exciting not just because of the switch from prohibition to legal regulation, but because the new government is promising to center "peripheral" communities that have been historically absent from these debates. The new legislature has announced it will design new markets based on principles like the primacy of human rights over international drug control treaties, fully decriminalizing cultivation and drug consumption. Draft legislation shows that regulations will be shaped via the consultation and participation of communities victimized by the drug war, while recognizing that plants like coca are sacred to Indigenous people. This signals that Indigenous and local authorities will have a protagonist role in the work ahead – building on the frameworks of the pioneering 2020 coca and cocaine regulation bill archived by [the previous government](#).²

Colombia's current moment starkly contrasts the Global North's approach: a chimera of top-down over-regulation that sustains illicit economies while excluding communities most hurt by prohibition, with a sprinkling of affirmative actions that are a welcome but insufficient patch-up of systemic disadvantage.

It is no surprise that Colombian Indigenous leaders have resisted coca legalization until now. The medicalization route, used to subvert cannabis and psychedelic prohibition from within, comes at the cost of replicating the very exclusion that

¹ Restrepo, D. A., Saenz, E., & Jara-Muñoz, O. A. (2019, October 21). *Erythroxylum in Focus: An interdisciplinary review of an overlooked genus*. MDPI. Retrieved August 29, 2022, from <https://www.mdpi.com/1420-3049/24/20/3788>

² David, D. (2022, April 25). Documento Temático: Daring to regulate coca and cocaine: Lessons from Colombia's Drug War Trenches. CESED. Retrieved August 29, 2022, from <https://cesed.uniandes.edu.co/daring-to-regulate-coca-and-cocaine-lessons-from-colombias-drug-war-trenches/>

David Restrepo is an economic, cultural, and environmental innovator from Cali, focused on developing community regeneration initiatives in Colombia's Southwest. After 10 years as a strategy consultant in London, he moved back in 2016 to join transformational projects such as creating a legal, inclusive market for coca leaf. He is a researcher at the Center for the Study of Security and Drugs (CESED) at the University of the Andes, where he leads the coca and cannabis research-action agenda. In 2020, he and life-partner Ezra founded ThisTopia Studios to produce stories exemplifying Latin America's contribution to global paradigm shifts. This includes *Torah Tropical* (in production, 2022 winner of Jewish Story Partners grant) and *The Coca Codex* (in development), which documents the coca legalization movement.

prohibition has buttressed. Instead of airplanes laden with glyphosate, the weapons of neocolonial drug regulation are unaffordable clinical trials, unmanageable licensing procedures, and carbon-intensive monocultures: a further imposition of “Western” ideas of medicine, economy and society that offer no relief to coca communities who are still ducking bullets.

A coca-focused approach, overlooked by the “Northern” cannabis and psychedelic movements, tells us that drug policy needs to do more than add yet another item to over-saturated consumer and pharmaceutical markets. Drug policy reform should be a step towards healing a world sickened by excess and disconnection, where a key focus is to remember—as well as innovate—the beneficial, community-building use of teacher plants and drugs.

In Colombia, we are hopefully accelerating our pace along this path – both at a macro and micro level. In my work, this has meant uniting drug war survivor communities – particularly the queer and artist groups I belong to – with academia and Indigenous leaders around coca talking circles. These have helped build research projects, social start-ups, and cultural interventions that challenge drug policy preconceptions. We are particularly excited about the intercultural research-action process we’re co-creating with Indigenous Authorities—one where Indigenous governance is respected; Indigenous elders and “western” researchers are recognized as equal contributors in building coca knowledge; and coca innovations remain collective property that strengthens Indigenous economies, fulfilling equitable, benefit-sharing agreements.

How we work together – using the ethos and practice of coca talking circles – is as important as what we do. That said, our objectives are another source of excitement. In a world where the racist 1961 UN Single Convention treats coca as a pest that should have been driven to extinction by 1986, we are conducting research to validate the plant’s safety profile and its many benefits identified in traditional knowledge. Our research will help bolster emerging product markets seeking to maximize the benefits of coca and promote the adoption of its profound values. In parallel, we are also exploring the kinds of supply systems needed to reduce the public health damage of isolated cocaine. Legal cocaine supply should avoid corporate capture and profit-based incentives while making harm reduction a design imperative.

However, the growing prevalence of substance use disorders like stimulant addiction are primarily a function of social fragmentation. This is why the ultimate aim of Colombia’s coca movement is transforming coca into a motor for regenerative economies from supply to consumption. The role of coca is to help communities organize and deliberate on how to shift food systems towards carbon-sinking approaches that stabilize the agricultural frontier while promoting equity and bio-cultural diversity.

The favorable political landscape in Colombia is making us optimistic about the future of our efforts. However, there are U.S. Senators already threatening Colombia for daring to innovate away from failed drug policy orthodoxy. We hope allies in the Global North understand the urgency of our work, and choose not to interfere but respectfully listen and contribute to this necessary resistance.



Indigenous Medicine Conservation

Foundational During the Psychedelic Movement

Miriam Volat



In the Spring of 2020, a handful of us working in Peyote conservation wrote a piece for the *MAPS Bulletin* exploring the relationship between Peyote conservation work and the budding psychedelic movement. It was titled “[Sacred Peyote Conservation: Respecting Indigenous Traditions](#).”¹ In the two years since, the potentially healing psychedelic renaissance has continued to evolve, weaving together many big dreams, and big concerns.

The pace of the psychedelic field continues to accelerate. There are a plethora of emerging strategies, new ventures, trainings, clinics, policy efforts, popular media explorations, and conferences. And, as in any big shift in social mores, there is awareness of new concerns—and a responsibility to address unintended consequences while attending to the complexity for community members across cultures, for the benefit of all.

In these times of “Peak Everything”—human economies are shifting from expansion to contraction as we pass our ability to increase extraction of oil/carbon, water, soil nutrients, etc.; polarized politics; the sixth greatest extinction (the Holocene or Anthropocene extinction—ongoing dramatic loss of species on planet earth. Unlike previous extinction eras, this is in great part due to unsustainable human use of land, air, energy, and water); climate disruption; disconnection and violence. It is no wonder we have a mental health epidemic and we must look for nexus and intersectional solutions. What if the psychedelic renaissance can offer support in healing from personal trauma leading to more healthy, whole individuals while also supporting public and community health at systemic levels? What if the way we increase access and integrate these modalities into society—medical, legal, commercial, social norms, knowledge, etc.—can be done in such a way that honors the principles of *Do No Harm* and maintenance of *Respectful Relationships*?

Miriam Volat, M.S. serves as Co-Director with Cody Swift of the RiverStyx Foundation, Interim Executive Director of the Indigenous Peyote Conservation Initiative, Co-Director of the Indigenous Medicine Conservation Fund, and she is on the Board of Directors of MAPS Public Benefit Corporation (MAPS PBC). The RiverStyx team undertakes deeply engaged relational philanthropy supporting social justice; ethical and innovative integration of the psychedelic movement into broader society; addressing mental, spiritual, and ecological crises through biocultural responsibility; and respectful allyship with Indigenous traditional knowledge holders. Miriam works personally and professionally to promote health in all systems. Her background is as a complex systems-facilitator, soil scientist, educator, and community organizer. Her work aims to increase broad-based community and ecological resilience through supporting high leverage initiatives at the intersection of biological, socio-cultural, and psycho-spiritual diversity.

¹ Ali, I. L., J.D., Booher, L., J.D., & Ginsberg, N. L. (2021, March 9). Beyond Oregon: A New Drug Policy Horizon in the U.S. *MAPS Bulletin* – Winter 2021, 31(1).

For the psychedelic field to be truly successful, and for us to be deeply proud of what we are creating and how we are bringing healing to individuals and communities, we have to consider the impact of this movement on traditional knowledge-holding communities, ancestral medicines, and their ecosystems. As we address the negative impacts of the drug wars, usher in our ability to address the mental health crisis at scale, and dramatically increase our collective healing, we have the opportunity to avoid more damage to cultures, communities and territories that have been injured by mainstreaming and colonial ways of doing business in the past.

Peyote and Indigenous Peyote Conservation

Since the aforementioned article, the Peyote conservation effort in the U.S. has continued with significant progress made. Early this year, the [Indigenous Peyote Conservation Initiative \(IPCI\)](https://www.ipci.life/)² initiated a nursery approved by the Drug Enforcement Administration (DEA) in the native Peyote habitat. The nursery is managed by Native American Church ceremonial leaders and it was designed to bring abundance back to the over-harvested and declining native Peyote habitat of the U.S. Despite Native Americans's ceremonial use of Peyote being legally protected, there is no precedent for having access to the infrastructure and land needed to ensure regenerated growth cycles and re-balanced populations through cultivation and culturally managed repopulation of threatened habitat. The half-acre nursery is just one part of ensuring that spiritual and ecological harvesting can include not only harvests done with offerings and proper methods, allowing for re-growth, but also that seeds and seedlings go back into over-harvested and newly harvested areas. This is a historic step for Native communities to be able to directly repopulate the Southern Texas region at the scale of hundreds of thousands (current estimated goal exceeds 2 million per year) of plants. It is also a step toward better understanding the dynamics of this ecological restoration supported by both scientific and traditional cultural knowledge.

In another historic accomplishment this year, the DEA also approved a large-scale repatriation of Peyote through legal import. The medicine was rescued from a greenhouse in Canada and brought home to provide seed stock for the replanting of over-harvested areas of the South Texas habitat. Local landowners and ranchers in the Texas Peyote territory are partnering in this regeneration. Conservation leases initiated over the last years will create access to thousands of acres of native habitat for ecological and spiritual harvest. Though much more work

and land access is needed, these are critical steps towards the region coming back into harmony for an abundant and sustainable future. Repatriation efforts and habitat restoration activities take a biocultural approach and are supported by a collaboration between scientists and traditional knowledge keepers.

Also initiated this year, the Comanche Native American Church has begun construction on its own nursery for propagation and cultivation and sustainable land access to ensure future medicine for each of its members and ceremonial needs in Oklahoma and beyond. Native American Church groups are working on federal resources for land preservation and ceremonial protections, and there is now financial and technical support available for cultivation and/or greenhouse efforts for any Native American Church Chapter that wishes to grow medicine for its own members or for repopulation. In combination, these efforts represent some of the most significant leverage points towards the sustainability of Peyote in the U.S.: the repopulation of wild habitat, conservation harvesting, medicine sovereignty, direct access and cultural strengthening and reconnection, and regional cultivation – efforts which are held and directed by Native leadership.

Partnership as White Allies

Lessons Learned

These are not small accomplishments, and achieving them has required a very careful approach. From this work with Peyote Community Activists, philanthropists continue to learn about the complex dynamics of the role of non-Native allies in partnership with Indigenous leadership. Decision making authority over the use of resources, speakers, messaging, and strategy belongs to Indigenous leadership. We pay delicate attention to pacing—an iterative, slower engagement which gives time for representative processes and honoring different kinds of communication styles; and careful attention given to make sure mainstream thinking and technical support is collaborative with culture. For example, the design of the culturally appropriate Peyote nursery on the IPCI spiritual homesite took three years to design while incorporating various cultural mores and scientific knowledge about cultivation. This led to a beautiful germination chamber built into the soil by hand, made of clay from the native habitat with passive temperature control.

Working from principles of *Do No Harm* and *Right Relationship*, guided by traditional knowledge and elders, sets a stage for honoring relational approaches to carrying out projects. This approach ensures that those who are arguably most impacted from the challenges that come from globalization, and in particular those ecological and cultural pressures that arise from the psychedelic renaissance itself, do not get overlooked or disrespected.

² [Indigenous Peyote Conservation Initiative. August 26, 2022. https://www.ipci.life/](https://www.ipci.life/)

Beyond Peyote

Keystone Medicines, Biocultures and Indigenous Medicine Conservation

After the past seven years of supporting Indigenous-led Peyote biocultural conservation, in 2020, [Riverstyx Foundation](https://www.riverstyxfoundation.org/)³ and [Dr. Bronners](https://www.drbronner.com/),⁴ became seed funders for the [Indigenous Medicine Conservation Fund \(IMC Fund\)](https://www.imc.fund/).⁵ The IMC Fund is an Indigenous-led philanthropic vehicle working to ensure the resilience of traditional medicine holders in the face of cultural pressures, environmental extractivism, human rights violations, and climate change. The IMC Fund directly supports biocultural conservation of five keystone (fundamental) psychedelic medicines: Peyote, Iboga, Ayahuasca, Toads, and Mushrooms. These medicines all have generations upon generations of historical traditional use as part of living biocultures—inseparably intertwined people, territories, and medicines—and the unbroken lineages of spiritual-medical practices. While these traditions may have evolved with time, they are still very much rooted in ancestral ways and worldviews. Unlike modern therapeutic psychedelic treatments where modalities and methods of treatment need to be created, these spiritual-medical systems have an intact, long-lasting living guidance for how medicine work is woven into personal and community health.

Along with amplifying the traditional voices crucial for protecting the health of their cultures, for humanity and the planet, the decision-making body of the IMC Fund—made up of representatives from each of the biocultures—supports requests from Indigenous communities for financial and capacity-building assistance to the folks on the ground who know best what work needs to be done for their medicines and their people. This includes purchases of land; construction of community spaces; radio and art programs; medicine growing and knowledge sharing; ceremonial activities and governance, also supporting partnerships with Universities to conduct ecological assessments, as in the case of the Toad.

³ [Riverstyx Foundation](https://www.riverstyxfoundation.org/). August 26, 2022. <https://www.riverstyxfoundation.org/>

⁴ [Dr. Bronner's](https://www.drbronner.com/). August 26, 2022. <https://www.drbronner.com/>

⁵ [Indigenous Medicine Conservation Fund](https://www.imc.fund/). August 26, 2022. <https://www.imc.fund/>

The Psychedelic Movement and Traditional Indigenous Cultures

Right Relationship, Conscious Action

For the benefit of all, in the last few years, more and more efforts to work toward a positive relationship between the psychedelic movement and Indigenous medicine communities are emerging: Conferences such as [Horizons](https://www.horizonspbc.com/)⁶ are elevating Indigenous voices, [Chacruna Institute's](https://www.chacruna.net/)⁷ [Indigenous Reciprocity Initiative](https://www.chacruna.net/),⁸ [Woven Science's El Puente](https://www.wovenscience.com/),⁹ and other philanthropic efforts inside organizations are becoming more common.

We need a paradigm of listening and trust-building between Indigenous communities, funders, and community organizers. Operating principles of Do No Harm, Right Relationship, and Indigenous Leadership need to be the collective vision set for the psychedelic space to reduce the harm from increasing global pressure. We need to put structures in place that strengthen traditional medicine practices and the people and cultures that steward them. Mechanisms for benefit-sharing by the psychedelic industry and the awareness of the impact of our actions on Indigenous communities should be built into the fabric of the psychedelic movement going forward, and we should continue to educate one another about these principles and their importance. We invite all people to adopt these frameworks as a base for their engagement in all aspects of the psychedelic renaissance: in healing and work in policy, programmatic design, finances and economy and business design. What are the consequences if we don't?

Projecting 50 years into the future, we want to be able to look back and say that the psychedelic movement, in its quest for societal healing, did not harm these still-vibrant traditional biocultures, but actually led to an increased potential for future healing for everyone involved. Through this awareness we may also have an opportunity for healing in the relationship between the mainstream, dominant culture and those cultures with generational colonial trauma. The psychedelic movement should strive for healing far beyond the individual— in fact, this kind of systemic healing is a necessary condition for true individual healing and health. By supporting Indigenous decision making, guidance, and sovereignty, and not further exploiting aspects of traditional cultures, we are actually taking a step toward this systemic-level healing.

⁶ [Horizons PBC](https://www.horizonspbc.com/). August 26, 2022. <https://www.horizonspbc.com/>

⁷ [Chacruna Institute of Psychedelic Plant Medicines](https://www.chacruna.net/). August 26, 2022. <https://www.chacruna.net/>

⁸ [Charuna's Indigenous Reciprocity Initiative](https://www.chacruna-iri.org/). August 26, 2022. <https://www.chacruna-iri.org/>

⁹ "El Puente," [Woven Science](https://www.wovenscience.com/). August 26, 2022. [https://www.wovenscience.com/elpuente](https://www.wovenscience.com/)

In Memoriam

Ann Shulgin, Forerunner of Today's Psychedelic Re-Emergence, Dies at 91



Ann Shulgin, one of the foremost thinkers and authors to have guided the current resurgence of interest in psychedelics, died at home on July 9, 2022, in the company of people who loved her, at the age of 91.

Ann was the widow and co-conspirator of the legendary chemist Alexander “Sasha” Shulgin, Ph.D., and was the matriarch of a decades-old community of therapists, scientists, scholars, and explorers of the realms opened by psychedelic substances. It was Ann who best understood people and the complexities of the psyche, whereas Sasha was a genius in chemistry and psychopharmacology. When they met in 1978, Sasha had already created 2C-B, as well as many other psychedelic molecules. He had also rediscovered MDMA and had described its chemistry and psychoactive properties. He and Ann took note of the unique therapeutic potential of MDMA, thus beginning its launch into today’s prominence.

Ann pioneered the exploration of the therapeutic uses of MDMA and 2C-B, and of several related compounds, during a time when they were not illegal. As a lay therapist, she developed methods of working with these materials, incorporating concepts from Jungian psychoanalysis. She was skilled in doing shadow work with clients and was generous in mentoring other therapists in this process. Ann gave an influential presentation on shadow work at the 2019 Women’s Visionary Congress.

Together, Ann and Sasha conceived and authored two landmark books—PiHKAL: A Chemical Love Story (1991) and TiHKAL: The Continuation (1997)—telling stories of their relationship and their community, interwoven with recipes for Sasha’s molecular creations and descriptions of their properties contributed by collaborators. Established publishers considered PiHKAL too controversial to take on, so the Shulgins started their own imprint, Transform Press, to make the work public. It may be difficult to appreciate that, not long ago, psychedelics were not only demonized by governments and the media, but that enforcement of the prohibition of them was often truly draconian. PiHKAL raised their work to the attention of law enforcement. Sasha’s backyard laboratory was investigated, leading to a great deal of disruption and distress, ultimately to heavy fines, and thankfully nothing worse. Their second book, TiHKAL, opens with a recounting of this experience.

Ann was born Laura Ann Gotlieb in New Zealand on March 22, 1931. Her mother was a New Zealander and her father a

U.S. Consul. As a result of her father’s profession, Ann had an international upbringing. She settled in San Francisco in her twenties, where she studied art, married an art student, and had a son, Christopher McRee. In 1960, Ann married Jungian psychoanalyst John Weir Perry, with whom she had three children: Alice Garofalo, Wendy Tucker, and Brian Perry. Ann and John separated in 1969.

Ann is survived by her children, eight grandchildren, five great-grandchildren, and by the countless community members for whom she has been a maternal figure, master teacher, and an ethical compass.

Ann married Sasha in the garden of the Shulgin Farm in Lafayette, California, on July 4, 1981, and their wedding anniversary became, along with Easter Sunday, an occasion for yearly gatherings of the community of scientists, scholars, and practitioners working with psychedelics, against cultural currents, to meet and to talk. Wednesday Night Dinners (later changed to Friday Night Dinners) began as periodic gatherings for family and extended family, expanding over the years to potluck gatherings for the larger community. The Shulgins served as upstanding parental figures, especially for people whose own families did not understand or support their interest in psychedelics. Ann and Sasha were remarkably inclined to maintain open and friendly relations with a diverse collection of community groups, even when there was competition or factionalization among them. Only in the case of one deeply reprehensible behavior, that of spying and reporting on someone for the government, did Ann close the door on the famed Shulgin hospitality.

Ann modeled how to live as a good citizen in the psychedelic community. Kind, generous, present in connection, an exemplary therapist, and a wise mentor, her big heart shown through in the sparkle in her eyes. She loved her family above all, her husband, her children, and her grandchildren. And she loved those around her. In return, she was surrounded by a circle of love and care to the hours of her last breath and beyond.

The Shulgin family suggests that anyone wishing to honor Ann’s life and contributions do so with a gift to the Women’s Visionary Council (WVC). Since 2008, with Ann’s support, the WVC has successfully highlighted the vital roles of women in psychedelics, has honored the field’s women pioneers, and has encouraged more women to enter the field.

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JEDI



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Founder and Executive Director



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Charleen Justice
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Whitney Wilhelmy
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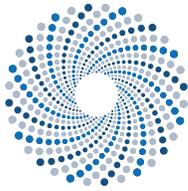
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MAPS Public Benefit Corporation (MAPS PBC) catalyzes healing and well-being through psychedelic drug development, therapist training programs, and sales of prescription psychedelics prioritizing public benefit above profit. Founded in 2014, MAPS PBC is a wholly owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS), a 501(c)(3) non-profit organization.



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MAPS
MULTIDISCIPLINARY ASSOCIATION
FOR PSYCHEDELIC STUDIES

Research • Education • Advocacy • Access

In addition to our worldwide research programs, our top-priority programs include:

- **Supporting psychedelic science and education** through policy change and advocacy
- **Training practitioners** to deliver MDMA-assisted therapy through professional education in ethics, safety, and therapeutic methods
- **Empowering communities** through our international psychedelic peer support and harm reduction program, the Zendo Project

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