



MAPS

MULTIDISCIPLINARY ASSOCIATION
FOR PSYCHEDELIC STUDIES

Bulletin

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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

Rise Within by Trey Brasher

Trey is a drug researcher and graphic artist from Denver, Colorado. He has a degree in pharmacology from Stockton University. Trey worked on research teams at Stockton University and Rutgers University; his academic research and expertise touches medicinal chemistry, psychopharmacology, and drug policy. Trey is Content Director at the psychedelic research non-profit Unlimited Sciences, designs hats and apparel for Grassroots California, does graphic design for Chacruna Institute for Psychedelic Plant Medicines, and does freelance art and design. Beginning this fall, he will be pursuing a Ph.D. at UC Davis working with novel psychedelics.

 @jarma_sutra



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From the Desk of Rick Doblin, Ph.D.

MAPS is making increasing progress as we enter the final phase of our 36-year-long—and ongoing—journey to medicalize the therapeutic use of MDMA-assisted therapy, initially for PTSD and then for other clinical indications.

Yet in the face of so much progress, we continually seek to improve the safety and efficacy of our therapeutic work. While we are thrilled with the positive results, we are sobered to know that this treatment simply does not work for everyone. Some, we have learned, feel that additional sessions, fewer sessions, or more flexibility with the timing of sessions would have been more supportive. For others, the path to improved symptoms may be circuitous or especially difficult after the treatment ends. We have worked to allow some additional integration sessions within the trials, but the restrictions associated with clinical trial protocols limit our ability to work with clinicians to personalize treatment programs. Nonetheless, we can learn as much—if not more—from the experiences of participants who do not experience clinically significant symptom improvement.

We are encouraging all subjects who have been treated in our PTSD studies to participate in our long-term follow-up so that we can gather accurate information about the durability of the treatment effect, if any, and about challenging outcomes for participants, all of whom had severe PTSD prior to enrolling in the study.

As we have received news that the National Center for PTSD now estimates that 12 million Americans are living with PTSD, we are as dedicated as ever to ushering this novel treatment for PTSD through regulatory approvals (and always learning along the way). In the U.S., Canada and Israel, MAPS has already enrolled the 100 people—all with moderate to severe PTSD—required for our second Phase 3 study. An interim analysis was conducted in May and the final data point will be gathered near the end of 2022. If the second Phase 3 study is statistically significant and no new safety problems arise, MAPS will have conducted two successful Phase 3 studies. If so, regulatory approval for prescription use will almost certainly be obtained from FDA, Health Canada, and the Israeli Ministry of Health around the end of 2023. Mike Mullette, the new COO of the MAPS Public Benefit Corporation, formerly Vice President and Managing Director of North America for Moderna, is expertly helping us to prepare for post-approval access by prescription, building a large new team for patient access and commercialization.

In the US Veterans Administration, veterans with PTSD have already been treated at the Loma Linda VA outside of Los Angeles and at the Bronx VA. In March, the Bronx VA hosted a therapist training program for about 60 VA therapists from 18 VA medical centers around the country. The FDA recently indicated that it will approve a

All are invited to join us at a location still to be determined for MAPS' 38th anniversary and the full solar eclipse.

protocol for research into MDMA-assisted group therapy for PTSD at the Portland, Oregon VA. The Principal Investigator (PI) of the Portland OR VA group therapy study, Dr. Chris Stauffer, presented an enthusiastically received webinar on MDMA-assisted therapy for PTSD that was attended by over 975 VA therapists.

In Europe and England, MAPS is in the process of training therapists in seven countries (Netherlands, Czech Republic, Germany, Portugal, Spain, Norway, and England) in preparation for launching a Phase 3 trial within a year. Ten people living with PTSD have already been treated in Phase 2 trials, and another 30 or so will be treated in conjunction with training of therapists in these seven countries. Regulatory approval by EMA is targeted for about a year or two after approval in the US. Research into MDMA-assisted therapy for PTSD is also starting in Australia and has already been conducted in Brazil. MAPS is also working to start humanitarian research to treat people with PTSD in Armenia, Ukraine, Somaliland, South Africa, and elsewhere around the world where PTSD is widespread.

MAPS is moving forward with planning for what we anticipate will be the world's largest psychedelic conference ever held, **PSYCHEDELIC SCIENCE 2023**, from June 17-25, in Denver at the Denver Convention Center. The field of psychedelic research is at the doorway of potential regulatory approval for prescription use. Drug policy reform is moving forward with the decriminalization of plant-based psychedelics in an increasing number of U.S. state and local jurisdictions. State-legal access to therapy with psilocybin is being implemented in Oregon and on the ballot for Colorado in November 2022. Psychedelic Science 2023 will provide space for the leaders and learners across the spectrum of the psychedelic renaissance.

Beyond Psychedelic Science 2023, we're also starting to plan for the celebration of MAPS' 38th anniversary on April 8, 2024, when the universe itself is celebrating with a full solar eclipse visible along a band of the US. Another full solar eclipse won't take place across the US for another 20 years, and not on MAPS' anniversary. All are invited to join us at a location still to be determined for MAPS' 38th anniversary and the full solar eclipse.

Rick Doblin

Rick Doblin, Ph.D.

MAPS Founder and Executive Director



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MAPS Research

MDMA-Assisted Therapy for Post-Traumatic Stress Disorder

MAPS Completes Enrollment, as Planned, for the Confirmatory Phase 3 Trial of MDMA-Assisted Therapy for PTSD

- *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*
- *Completion of enrollment on schedule supports targeted submission of the New Drug Application to the U.S. Food and Drug Administration (FDA) in the first half of 2023*
- *Health Equity initiatives to enroll BIPOC and LGBTQIA+ participants improved representation of populations more likely to develop PTSD following exposure to trauma*

The non-profit Multidisciplinary Association for Psychedelic Studies (MAPS) and MAPS Public Benefit Corporation (MAPS PBC), a wholly-owned subsidiary of MAPS, announced that a blinded administrative interim analysis has confirmed no changes to the planned sample size are necessary to provide sufficient statistical power in evaluating efficacy of MDMA-assisted therapy for post-traumatic stress disorder (PTSD) in the second of two Phase 3 trials (MAPP2). Per the special protocol agreement negotiated with the FDA for the confirmatory trial, MAPP2 was designed to enroll at least 100 participants in order to confirm efficacy and further investigate safety of the treatment.

Phase 3 Trials of MDMA-Assisted Therapy for PTSD: Study Site Opens for Phone Screening in Tel Hashomer, Israel

On February 3, our Phase 3 study site for MDMA-assisted therapy for post-traumatic stress disorder (PTSD) in Tel Hashomer, Israel, officially opened for phone screenings and informed consent visits. Led by Principal Investigator Jana Yakirevitch, M.D., this is an FDA-regulated Phase 3 clinical trial of MDMA-assisted therapy for PTSD.

All Study Sites Open in Phase 3 Cross-Over Extension Study

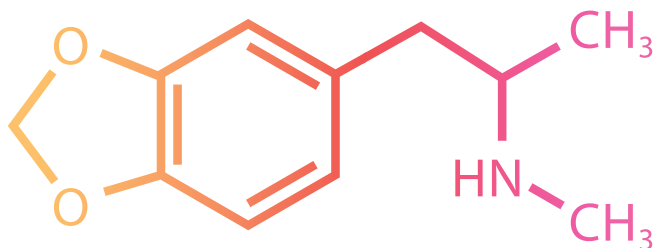
On March 22, 2022, all study sites met the criteria to provide treatment in the cross-over extension study for MAPS-sponsored Phase 3 trials of MDMA-assisted therapy for post-traumatic stress disorder (PTSD).

All subjects who received placebo plus therapy in the double-blind portion of our first Phase 3 study of MDMA-assisted therapy for PTSD are given the opportunity to participate free-of-charge in a similarly designed study to receive MDMA plus therapy.

Long-Term Follow-Up Study of MDMA-Assisted Therapy for PTSD

Enrollment is continuing for our long-term follow up study for our MDMA-assisted therapy parent studies. The long-term follow up study is open to individuals who participated and received MDMA in at least one experimental session in one of the following MAPS-sponsored MDMA-assisted therapy studies: open-label lead-in Phase 2 trials (U.S. and Canada), our two Phase 3 trials, or our Phase 3 cross-over trial.

Participation in this study will help us better understand the long-term effects of our treatment protocols. The long-term follow up study visits will be done remotely if the participant received treatment at a study site within the United States. If a participant had previously declined to participate in this follow-up study, it is not too late to enroll. Volunteers who received treatment in one of the aforementioned studies and wish to participate in this follow-up can reach out to their study coordinator for more information. Volunteers will receive \$250 for participating in this study.



Molecular compound of MDMA

MAPS Places Fully Validated, Multi-Kilogram Synthesis of MDMA in the Public Domain

- *Multidisciplinary Association of Psychedelic Studies (MAPS) and MAPS Public Benefit Corporation (MAPS PBC) have developed the first validated commercial synthetic process for producing multi-kilogram batches of MDMA under current Good Manufacturing Practices (cGMP)*
- *The availability of larger quantities of cGMP-compliant MDMA will facilitate ongoing clinical trials and provide for future therapeutic use following anticipated regulatory approvals*
- *Publication of this process establishes “prior art,” contributing to MAPS’ patient access strategy by making intellectual property public*

MDMA is a promising psychedelic compound, currently placed by the Drug Enforcement Administration (DEA) in Schedule I of the Controlled Substances Act, that has been produced for legal research in small batches by certified laboratories. An increasing interest in clinical study of the 110-year-old compound, combined with anticipated regulatory approvals of MDMA-assisted therapy, necessitate the development of a multi-kilogram current cGMP production process by the leading research sponsor, MAPS, and trial organizer, MAPS PBC. “Fully Validated, Multi-Kilogram cGMP Synthesis of MDMA” recently published in ACS Omega, a journal of the American Chemical Society, is the first paper to describe a fully validated cGMP synthesis of up to 5 kg (≈30,000 patient doses) of MDMA in a four-step process beginning with a non-controlled starting material.

Expanded Access

Expanded Access is a program that allows patients to receive an investigatory treatment not yet approved by the United States Food and Drug Administration (FDA) for treatment outside of a clinical trial. The program is intended for patients with serious or life-threatening conditions who do not have any promising treatment options and are unable to participate in ongoing clinical trials. Only sites within the U.S. and U.S. territories are eligible to participate in the FDA Expanded Access Program.

The rationale for our Expanded Access program is not only to treat more patients with MDMA-assisted therapy, but also to understand logistics of how MDMA-assisted therapy will be administered post-approval by generating real world evidence (RWE).

Learn more:

maps.org/mdma/ptsd/expanded-access/

Expanded Access Study Site in California Begins Screening

The Expanded Access Program study site at Sage Integrative Health in Berkeley, California, began screening participants for MDMA-assisted therapy for PTSD in early March 2022.

Ten Phone Screenings Conducted in Expanded Access Study for MDMA-Assisted Therapy for PTSD

Our multi-site expanded access study site for MDMA-assisted therapy for patients with treatment-resistant PTSD at the Pearl Psychedelic Institute in Waynesville, North Carolina, was activated for phone screening in December 2021 and currently has ten phone screen calls.



Enrollment Continues 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

MAPS Europe is delighted to announce that several sites have joined those in study sites in The Netherlands, the Czech Republic and Norway in enrolling participants in our open-label Phase 2 study of MDMA-assisted therapy for PTSD. Participant recruitment is expected to begin at sites for this study in London and Hamburg in the coming months, along with a new site in Barcelona, Spain. This Phase 2 study, with an optional fMRI sub-study assessing changes in brain activity in subjects with PTSD, is led by Principal Investigator Eric Vermetten, MD.

On March 23, 2022, the first site in the United Kingdom was activated and began screening participants. The team at the Institute of Psychiatry, Psychology and Neuroscience at King's College London – South London and Maudsley NHS Trust (KCL-SLaM) led by Dr. James Rucker and supported by the UK Chief Investigator Prof. Allan Young, saw their first participants in April.

On March 7, 2022, recruitment of participants into the MP18 study began at the Department of Psychiatry and Neurosciences in the Charité – Universitätsmedizin Berlin, in Berlin, Germany, one of the largest university hospitals in Europe. The site is led by Dr. Dimitris Repantis.

The MAPS Europe team is also working to gain regulatory and ethical approval for the long-term follow-up (LTFU) study (MPELONG). The team recently received Conditional Approval from European regulators via the Voluntary Harmonisation Procedure (VHP). This protocol is currently being implemented in The Netherlands and Norway.

MAPS is Granted Innovation Passport in United Kingdom for MDMA as an Adjunct to Therapy for PTSD

We are thrilled to announce that the Innovative Licensing and Access Pathway (ILAP) Innovation Passport has been granted to MDMA as an adjunct to therapy for PTSD in the United Kingdom! This ILAP designation acknowledges that MDMA-assisted therapy may have unique potential as a safe and effective treatment for PTSD. While the Innovation Passport does not reduce the burden of demonstrating that a treatment may be safe and effective, it does provide research organizers with expert advice, patient input, and collaboration throughout the clinical trial design and development process through a product-specific Target Development Profile.

“The ILAP Innovation Passport will ensure MDMA as an adjunct to therapy can be made widely available, as rapidly as possible, for the UK PTSD patients who need it,” says Berra Yazar-Klosinski, Ph.D., Chief Scientific Officer at MAPS Public Benefit Corporation (MAPS PBC). Read our statement about the ILAP at maps.org/news.



MAPS-Sponsored Phase 1 & 2 Trials

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

Rachel Yehuda, Ph.D., Director at the Mental Health Patient Care Center, James J. Peters VA Medical Center, and Professor of Psychiatry and Neuroscience at the Icahn School of Medicine at Mount Sinai Hospital is leading a Phase 2, open-label randomized controlled comparative study on the effectiveness of MDMA-assisted therapy in U.S. Veterans with chronic PTSD. The study is a part of the investigator-initiated research program of the U.S. Department of Veterans Affairs (VA).

On April 15, 2022, the second and third participants were screened for treatment.

On February 3, the first participant received treatment.

An Open-Label Feasibility and Safety Study of MDMA-Assisted Group Therapy for the Treatment of Post-traumatic Stress Disorder in Veterans Receives Full IRB Approval

In January 2022, a Phase 2 study to assess MDMA-assisted group therapy for the treatment of PTSD in veterans received full approval by the Institutional Review Board (IRB). The study is located at the Portland Veterans Affairs (VA) Medical Center in Oregon and led by Principal Investigator Chris Stauffer, M.D. This is an open-label, non-randomized, three cohort study and will include up to 18 participants.

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.

Awakn Life Sciences and MAPS to Explore Partnership for Treatment of Alcohol Use Disorder in Europe

On January 19, 2022, MAPS entered into a Memorandum of Understanding (MOU) with Awakn Life Sciences Corp., a biotechnology company developing and delivering psychedelic therapeutics to treat substance use disorders. Awakn and MAPS will explore the feasibility of a partnership to utilize MDMA-assisted therapy to treat Alcohol Use Disorder (AUD) in Europe.

"MAPS' role in driving and advancing the use of psychedelics in the clinical setting over the last 35 years is second to none," said Anthony Tennyson, CEO of Awakn. Read our announcement about the agreement at maps.org/news.

Food Effect on Bioavailability of MDMA in Healthy Volunteers Study: January 2022 Update

Enrollment in our food effect study on the bioavailability of MDMA in healthy volunteers is expected to begin in Spring 2022. This study will be conducted at a Phase 1 clinical research unit in Knoxville, Tennessee, and will enroll 12 healthy volunteers.

Participants will have two dosing sessions at least two weeks apart and will check into the clinical research unit the night before the dosing session. In one dosing session, participants will consume a high-calorie meal prior to dosing, and in the other session, dosing will happen while the participant is in a fasted state. Participants will remain in the unit for two days after dosing during which time blood will be drawn at specified time points to assess the effect that food has on the bioavailability of MDMA. There is no therapy component to this study.

Results for Phase 1 Randomized Controlled Trial of MDMA and Fear Extinction Retention in Healthy Adults Published in Psychopharmacology

On February 15, 2022, the results of the MAPS-sponsored study by Barbara Rothbaum, Ph.D., and team at Emory University evaluating MDMA on the startle response in healthy adults was published in the medical journal *Psychopharmacology*. This randomized, blinded, placebo-controlled Phase 1 mechanism of action study investigated the effects of MDMA on startle testing learning in healthy volunteers in comparison to a placebo control.

Investigator-Initiated Trials Updates

We are excited to share recent progress with our investigator-initiated trials (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: clinicaltrials.gov

A Phase 2 Open-Label Study to Assess the Feasibility of MDMA-Assisted Psychotherapy for Veterans with Combat-Related, Refractory PTSD

Dr. Shannon Remick, Dr. Allie Kaigle, and a team of researchers at the Veterans Affairs (VA) Loma Linda Healthcare System in Loma Linda, California, are conducting a study to assess the feasibility of MDMA-Assisted therapy for combat-related treatment-resistant PTSD in U.S. military veterans. This investigator-initiated trial was the first to administer MDMA to a vet with PTSD inside the VA system. Two participants have now completed treatment. The study will enroll up to 10 participants.

Social Anxiety MDMA-Assisted Therapy Investigation (SAMATI)

Dr. Jason Luoma and a team of researchers at Portland Psychotherapy in Portland, Oregon, are conducting a 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.

The site is seeking volunteers to participate. Learn more by visiting: portlandmdmatherapy.com/participate/



The Influence of MDMA on the Reward Circuits in the Human Brain of Healthy Individuals

Dr. Leanne Williams and a team of researchers at Stanford University in Stanford, California, are conducting an observational study to assess the impact of MDMA on the regulating circuits of the brain in healthy individuals using fMRI. Two participants have received MDMA so far. The team at Stanford University will enroll up to 13 more participants this year. The study will enroll up to 40 participants.

A Phase 2 Open-Label Treatment Development Study of MDMA-Assisted Cognitive Processing Therapy (CPT) for PTSD

Dr. Anne Wagner and a team of researchers at Remedy Institute in Toronto, Ontario, are conducting an open-label treatment development study of MDMA-assisted cognitive processing therapy (CPT) for individuals with PTSD. One participant has completed their first treatment session. The team at Remedy Institute will enroll up to 10 participants.

An Open-Label Feasibility Study to Assess the Safety and Effect of Manualised MDMA-Assisted Psychotherapy for the Treatment of Severe Post-traumatic Stress Disorder among Four Australians

Dr. Stephen Bright and a team of researchers at Edith Cowan University in Joondalup, Western Australia, are conducting a study to assess the safety and effect of manualised MDMA-assisted therapy for the treatment of severe PTSD among four Australians. This study is also being conducted for the training of the therapists by providing supervision as the therapists work with their initial PTSD participants. The team has received the study drug and will begin recruiting participants over the coming months.

A Phase 1 Study on the Effects of MDMA on Prefrontal and Amygdala Activation in Post-traumatic Stress Disorder

Dr. Benjamin Kelmendi and a team of researchers at Yale University in New Haven, Connecticut, are studying the effects of MDMA on prefrontal and amygdala activation in individuals with post-traumatic stress disorder (PTSD), by fMRI. This investigator-initiated trial is recruiting and plans to enroll 20 participants.

Therapy Training

MDMA Therapy Training Program Update: Spring 2022 Update

The 2022 training schedule for the MDMA Therapy Training Program has been posted on the training website (mapspublic-benefit.com/training), including options for a blended (online/in person) training format and an entirely virtual training format.

Applications are being accepted for the MDMA Therapy Training Programs. Previously submitted applications will remain on file and will be reviewed for upcoming training opportunities.

For eligible applicants interested in applying for a MAPS Health Equity Scholarship, please find more information and the link to the application on our scholarship webpage.

Blended Format Cohorts

- May 22-28, Colorado (Online Course started in April)
- June 12-19, New York (Online Course starts in May)
- September 12-18, North Carolina (Online Course starts in August)
- September 25-October 1, Colorado (Online Course starts in August)
- October 9-14, New York (Online Course starts in September)

Virtual Cohorts

- Fall 2022 Virtual Cohort (October - January)

In April 2022, we launched our first 100-hour blended (online/in person) training program and hosted a week-long in-person training retreat in North Carolina (pictured above). We welcomed over 75 trainees from all over the U.S. and a few international locations including Canada and Brazil. The training retreat included learning seminars, case video presentations, ethics and safety education, practice scenarios, and guest speakers. A dozen new employees, including MAPS PBC's new COO, Mike Mullette, participated in this training as part of a recent onboarding process.

In March 2022, the MDMA Therapy Training Program team kicked off the training season with a practice workshop with Naropa University and a week-long virtual training in collaboration with the Center for Psychedelic Psychotherapy and Trauma Research at Mount Sinai and the James J. Peters Department of Veterans Affairs.

Here are a few reflections that our recent trainees have shared about their MDMA Therapy Training experiences:

"Thank you for the opportunity to be part of this training. Gives me hope for the future of mental health care for the Veteran community. Thank you all for putting it together."

"Best training I've ever had, honestly. Including outside of the VA."

"Thank you, Annie and Michael, for weathering so many storms bringing this treatment to the world and for never losing sight of what's important."

"I am grateful I was able to participate in this first in-person retreat after the pandemic and am looking forward to more. Despite my newness to MDMA, I would love to become more involved."

"The training staff was amazing. They were attentive, kind, generous, organized, knowledgeable, responsive, present, and caring. This says a lot about the organization, its leadership, the kind of people it attracts, and how much effort, thought, and care goes into this retreat."

In 2021, the team rolled out and initiated our Health Equity Scholarship program, part of a larger commitment to increasing inclusion and equity in our programs. Over the course of this year, we were able to allocate and award \$900,000 in Health Equity scholarships, amounting to a total of 231 scholarships. We are currently working to continue and expand this initiative for 2022 and beyond.

The training program enrolled 800 trainees in their 2021 online cohorts.

By awarding funds through the MAPS Health Equity Scholarship, the MDMA Therapy Training Program hopes to continue the efforts to create these outcomes in 2022:

- Create a more accessible training program to ensure that the network of MDMA-Assisted Therapy Practitioners is vast and able to support diverse communities suffering from a spectrum of trauma.
- Increase the number of MAPS-Certified MDMA-Assisted Therapy Practitioners who identify as Black, Indigenous, and people of color.
- Train and learn from more therapy practitioners who live and work in historically marginalized communities.
- Foster connection and validate unique experiences of trauma in marginalized communities.

MDMA Therapy Training Program Retreat Takes Place in Black Mountain, North Carolina

We were excited to welcome the special joys of meeting trainees for our first in-person retreat in 2022, which took place from April 3-9 in Black Mountain, North Carolina. We were thrilled and grateful to facilitate a meaningful six days of learning, exploration, discovery, and healing.

The Monte Vista Hotel in charming, historic Black Mountain served as our retreat home. Here trainees watched video-based case studies, listened to informative lectures, and participated in collaborative group work to further develop their therapeutic skills and knowledge. This retreat was taught under the guidance of our MDMA Therapy Training Program Lead Trainers, Annie Mithoefer, B.S.N., and Michael Mithoefer, M.D., who have worked in this field for decades.

Our retreats also serve as opportunities to develop relationships with other aspiring practitioners in the MDMA-assisted therapy community. Trainees can partake in morning yoga, group dinners, and fun outings, which are intended to facilitate deeper connections and networking within the industry.

Training Collaboration with Naropa University

The Naropa University Certificate in Psychedelic-Assisted Therapies is a ten-month contemplatively-based professional training program featuring a hybrid delivery of online and intensive retreat-based learning. This non-degree Certificate will provide post-graduate level training in essential aspects of Psychedelic-Assisted Therapy, trauma-informed care, and spiritual integration. In collaboration with the Multidisciplinary Association for Psychedelic Studies (MAPS), Naropa offers specialized training in the clinical use of MDMA in approved settings. Trainees will also gain foundational competencies in psilocybin therapies and ketamine-assisted therapy. Naropa began as a Buddhist-inspired university and now flourishes as an institution that brings together contemplative pedagogy and a commitment to socially-engaged activism.

Adherence Rating

The Adherence Rater Program completed its sixth Adherence Rater Training. Adherence Raters are mental health professionals who review session videos from the MAPS-sponsored clinical trials to ensure adherence to the treatment manual, and support ongoing therapist oversight. Over the past year, our small-but-mighty team of Adherence Raters has reviewed and rated over a thousand hours of session footage in five different languages for the MAPS-sponsored trials!

Supervision and Consultation

The Supervision Program continues to provide oversight and support to therapists working on the MAPS-sponsored and Investigator-Initiated Trials of MDMA-Assisted Therapy for PTSD. Over the past year, supervisors have conducted 150 supervision meetings with therapists working on the MAPS-sponsored trials.

Planning efforts are underway for our Supervision Program which includes the development of upcoming Supervisor Training events and continued support of MAPS-trained MDMA-assisted therapy practitioners.

Supervision and Consultation are provided to MAPS-sponsored and Investigator-Initiated Trials all over the world. Starting this month, Consultation provided by MAPS-Certified Supervisors is also supporting the use of MDMA-assisted therapy in Switzerland in a clinical setting, where Compassionate Use guidelines allow for the use of psychedelic therapies.

Therapist Training Session Completed in Israel

MAPS Israel hosted a MDMA-assisted therapy training for 75 therapists in Neve Shalom, Israel, in October 2021. During the week-long training, participants were exposed to clinical content focusing on the therapeutic approach of MDMA-assisted therapy for PTSD. The training focused on the core principles and skills of the therapist who will administer MDMA-assisted therapy via case presentations, videos, and experiential exercises based on mindfulness, role-playing games, and discussions in small and large groups. An additional training will launch in September 2022.



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MAPS News



To read the
announcements
in full, please visit
maps.org/news

MAPS and MAPS PBC Publish Patient Bill of Rights for Psychedelic Therapy

- *Patient Bills of Rights are made available to patients in various settings across the mental health and medical fields to communicate clearly with patients about what they can expect from professionals*
- *The Patient Bill of Rights is a plain-language companion to the MAPS Code of Ethics for Psychedelic Psychotherapy*
- *The publication of the MAPS Patient Bill of Rights for Psychedelic Therapy is one of several important tools to inform patients about professional and ethical standards in anticipation of regulatory approval of MDMA-assisted therapy for PTSD*

On February 10, 2022, the Multidisciplinary Association for Psychedelic Studies (MAPS) and its wholly-owned subsidiary responsible for organizing clinical research and training practitioners, MAPS Public Benefit Corporation (MAPS PBC) published the MAPS Patient Bill of Rights for Psychedelic Therapy. Patient Bills of Rights are a standard tool across mental health and medical care which provide patients with the information they need to advocate for their rights and establish expectations for their rights in provision of care, privacy, non-discrimination, decision making, and information about their treatment plan. Read more at maps.org/safety.

MAPS PBC Adopts Charter for Independent Ethics Review Board

- *Independent members will inform continual iteration and improvement of ethical governance of MDMA-assisted therapy research and therapist training program*
- *Independent Ethical Review Board engages outside experts to provide additional layer of review, guiding MAPS and MAPS PBC's commitment to exceptional ethical practice in MDMA-assisted therapy and fostering a culture of safety for all who receive psychedelic-assisted therapies*
- *Outside advisors with established expertise in therapy ethics, alongside an advocate for survivors of abuse in a therapeutic context, will review and recommend improvements on MAPS and MAPS PBC's ongoing development of ethical policies and practices*

The Board of Directors of the Multidisciplinary Association for Psychedelic Studies (MAPS) recommended, and the Board of Directors of its wholly-owned subsidiary MAPS Public Benefit Corporation (MAPS PBC) adopted, a charter to form an Independent Ethics Review Board (IERB). Comprised of independent members, the IERB will include experts in ethics and psychotherapy and, in accordance with best practices, an advocate for survivors with lived experience of abuse or misconduct in a psychotherapeutic context.

Michael Mullette Joins MAPS PBC Senior Leadership as Chief Operating Officer

- *Former Moderna Vice President and Managing Director for North America recruited to prepare MAPS PBC for patient access and commercialization of the first psychedelic-assisted therapy anticipated to be approved by the FDA*
- *Hire represents a major step forward in building world-class pharmaceutical organization capable of meeting significant patient need*

On March 8, 2022, MAPS Public Benefit Corporation (MAPS PBC) announced that Michael Mullette, an experienced drug development and commercialization expert, has joined its senior leadership team as Chief Operating Officer. Mullette most recently served as the Vice President and Managing Director of North America for Moderna, where he oversaw commercialization of the company's COVID-19 vaccine during the height of the pandemic.

Revised Edition of The Secret Chief Revealed: Conversations with Leo Zeff, Pioneer in the Underground Psychedelic Therapy Movement Now Available

One of the most important texts in the history of psychedelic-assisted therapy, *The Secret Chief Revealed*, is again available from your local independent bookstore, the MAPS Store, and perhaps even at your library. *The Secret Chief Revealed* is an in-depth, first-hand account of Leo Zeff, Ph.D., a pioneering psychedelic therapist who conducted MDMA-assisted therapy sessions both prior to and following MDMA's prohibition. Originally published by MAPS in 2004, *The Secret Chief Revealed* is written as a transcription of an interview conducted in the 1980s with Zeff about his research, studies, and practice with psychedelic-assisted therapy.

atai Impact Donates to MAPS to Support Pioneering Work in Psychedelic Medicine

- *Leading non-profit and commercial organizations in psychedelic science united in visions to heal mental health conditions*
- *Donation is from atai Impact, the philanthropic arm of mental health company, atai Life Sciences*
- *Funds will help support the general operations of MAPS, including its Health Equity Program to increase diversity, equity and inclusion in psychedelic healthcare*

On February 18, 2022, atai Impact, the philanthropic program of atai Life Sciences (atai) and the Multidisciplinary Association for Psychedelics Studies (MAPS), announced a \$500,000 donation from atai Impact to MAPS. This donation is an important demonstration of the synergy and collaboration across the leading non-profit and commercial organizations to advance psychedelic medicine and tackle the escalating mental health crisis affecting over one billion people worldwide.

The Zendo Project at Burning Man 2022

The Zendo Project is excited to provide psychedelic peer support services for the 9th year at Burning Man 2022 in Black Rock City, Nevada! Zendo Project volunteer applications have now opened. All volunteers will need to purchase their own Burning Man tickets. Stay tuned to the MAPS Newsletter (maps.org/newsletter) or the Zendo Project Email Newsletter (zendoproject.org) for future details. We are looking forward to reconnecting with the amazing volunteers that make this project thrive!

We encourage you to read and follow maps.org/safety for detailed information regarding **MAPS Code of Ethics for Psychedelic Psychotherapy** and our practices to create a culture of safety in psychedelic therapy.

You may safely and confidentially direct misconduct reports related to MAPS-sponsored studies, MAPS staff, MAPS PBC staff, or collaborators to MAPS' Compliance Team via email or by calling (844) 627-7722.

Cultivating Safety in Psychedelic Therapy

All stakeholders at the Multidisciplinary Association for Psychedelic Studies, MAPS Public Benefit Corporation, and MAPS Europe (collectively, MAPS) are committed to providing quality and comprehensive training and supervision to support therapy providers in delivering safe, ethical care within MAPS-sponsored study protocols.

We recognize that individuals have been harmed by misconduct in therapy, including psychedelic-assisted therapy, and we embrace our obligation to protect participant safety in MAPS-sponsored studies and the safety of others who are associated with our programs.

In service of these commitments, we are continually examining, carefully developing, implementing, and adapting policies and practices to prevent, reasonably detect, and thoroughly respond to allegations of misconduct and safety concerns.

We hope that our work encourages others involved in psychedelic-assisted therapies to adopt similar commitments and participate actively in creating a **culture of safety** for psychedelic therapy. We invite you to review the carefully-considered practices outlined here and adapt them for your communities.

Elements of MAPS' Culture of Safety

MAPS Code of Ethics for Psychedelic Psychotherapy

MAPS' MDMA Therapy Training Program staff, with contributions from psychedelic therapy practitioners and guidance from professional organizations, began creating the **Code of Ethics** in 2018 and published the [original version](#) in 2019. It was [revised in 2021](#).

The Code of Ethics provides the foundation for MAPS' culture of safety, guiding and informing the practice of therapy within MAPS protocols. It is a living document that will continue to grow through the evolution of the field and the ongoing integration of feedback from participants, practitioners, and experts.

For the purpose of protecting the safety and welfare of participants, the MAPS Code of Ethics for Psychedelic Psychotherapy outlines ethical principles governing treatment decisions made by providers delivering psychedelic psychotherapy within a MAPS protocol.

Robust Systems for Reporting and Accountability

MAPS' Compliance Team is comprised of multiple MAPS staff and a member of the Board of Directors who are responsible for recording, reviewing, and determining the veracity of all received reports of misconduct by individuals employed by MAPS, practitioners conducting therapy in MAPS-sponsored clinical trials, or others associated with MAPS. The Compliance Team recommends appropriate discipline to MAPS leadership and the Board of Directors, which may include additional training or supervision, termination of employment or collaborative activities, and, as applicable, filing formal reports with any governing bodies the accused is associated with.

On January 25, 2022, the Board of Directors of MAPS recommended, and the Board of Directors of its wholly-owned subsidiary MAPS PBC adopted, [a charter to form an Independent Ethics Review Board \(IERB\)](#). The IERB will include independent experts in ethics and psychotherapy and, in accordance with best practices, an advocate for survivors with lived experience of abuse or misconduct in a psychotherapeutic context. Potential members are currently being evaluated for recommendation to the Boards.

Extensive and Ongoing Therapist Training

Particular attention has been given to provide training on ethical considerations, particularly the use of nurturing touch and emotional or sexual boundaries. The training module on Integrity thoroughly reviews the elements of the Code of Ethics and provides opportunities for trainees to engage in mock conversations, with each other and trainers, to practice conversations they will have regarding ethical considerations and participant safety.

In the MDMA Therapy Training Program, practitioners learn to discuss the possibility that nurturing touch may be requested or offered during MDMA-assisted therapy sessions. During preparatory sessions, they are required to discuss and establish boundaries with specificity: Does the practitioner have consent to offer a hand to hold? May they offer to place a hand on the participant's shoulder?

During the MDMA-assisted therapy session, practitioners are trained to receive additional and ongoing consent for nurturing touch that has already been discussed, checking in and receiving verbal confirmation that the participant would like to have a hand to hold, for example.

Participant Education

Prior to initiating treatment in a MAPS-sponsored trial, participants and practitioners discuss the risks of the treatment, both medical and psychological. This conversation includes all elements of the [Informed Consent Form](#) (ICF), a required part of any human clinical trial which is reviewed and approved by

an Institutional Review Board overseeing clinical trial ethics. In anticipation of future FDA approval of psychedelic-assisted therapies which may be provided without a required ICF, the [Patient Bill of Rights for Psychedelic Therapy](#) was published early this year as a patient-centered enumeration of the patient rights established in the Code of Ethics.

Each of these documents provides a foundation for an extensive conversation between patients and practitioners during which participants learn about non-ordinary states of consciousness and some of the unique considerations they present, including the possibility of stronger and more complex transference and countertransference.

Clinical Research of Safety and Risks

Since 2004, our [ongoing clinical trials](#) and analysis of non-clinical research of MDMA's effects have provided evidence regarding the safety and risks of MDMA for evaluation by the FDA. From those findings, we are developing psychological and cardiovascular risk mitigation recommendations. Detailed information regarding safety and risks of MDMA is updated annually and available in the [Investigators Brochure and Development Safety Update Report](#).

Continual Improvement

We recognize that policies and practices, no matter how thorough, will not entirely prevent abuses of power. In the interest of continual improvement, we engage in internal practices and stakeholder input solicitation, identifying and addressing opportunities for improvement in our policies, practices, and protocols.

Certification and Professional Associations

MAPS Public Benefit Corporation's Therapy Training Program will offer certification in MDMA-Assisted Therapy for PTSD if the treatment is approved, but our program is one of many certifications that practitioners may opt to maintain. We encourage all people seeking medical or mental health treatment, psychedelic or otherwise, to understand and verify a practitioner's credentials prior to undergoing treatment.

In addition to certification in particular types of training, **independent certification boards** and **professional associations** serve to address a broad range of concerns specific to the expertise needed to competently deliver services. Independent certification boards and professional associations are found in many skilled service industries including financial, construction, legal, human resources, and more. These boards will generally develop and publish service-specific ethical

guidelines, standardized training requirements, and continuing education opportunities.

MAPS is proud to endorse the ongoing development of an independent certification board and a professional association:

- **The Board of Psychedelic Medicine and Therapies** is a non-profit public benefit corporation creating board certification for psychedelic medicine practitioners and educating practitioners, the health care system, and potential consumers about the inherent value of the certification process.
- **The American Psychedelic Practitioners Association** was launched in November 2021 with a mission "to support our community of practitioners, scientists, and lineage keepers of the psychedelic field towards the integration of psychedelic care for advancement of health care and humanity."



Making MDMA a Medicine (I)

Scheduling Process for FDA Drug Approvals

Allison Coker, Ph.D., and
Jack Henningfield, Ph.D.

If the FDA approves the drug for market, this approval and the FDA scheduling recommendation will be passed to the DEA, who has 90 days to respond and issue a scheduling of the drug.

When a new drug is submitted to the Food and Drug Administration (FDA) in a New Drug Application (NDA) for marketing approval, if the drug has central nervous system activity, it will need to be assessed for abuse potential. For novel products with new chemical entities, that assessment typically includes several studies designed to assess the drug's potential for abuse, conducted in both animal models and human participants. The FDA provides detailed guidance¹ describing their generally recommended study designs for these investigations and the types of data to be collected from them. The data from both the animal and human studies are combined in nonclinical and clinical summaries, then included in the application for approval. The sponsor also must include a summary of data from any earlier research that has been published, as well as potentially relevant public health survey data such as real-world use patterns and recreational use of the substance in the product or substances with similar effects. FDA requests the sponsor to make its own recommendation for scheduling based on this analysis. Sponsors may also include a summary abuse potential analysis and recommendation for consideration based on the eight factors laid out in the Drug Enforcement Administration (DEA) Controlled Substances Act (CSA)², because ultimately the new drug will be scheduled based primarily on this Eight-Factor Analysis as required by the CSA. This assessment is largely based on relative comparisons to the abuse and dependence potential of other substances in each schedule. While the sponsor includes its recommendation to the FDA, it is ultimately up to the FDA to assess these abuse potential studies and, with input from the National Institute on Drug Abuse (NIDA), make its scheduling recommendation to the DEA based on the whole of the data. If the FDA approves the drug for market, this approval and the FDA scheduling recommendation will be passed to the DEA, who has 90 days to respond and issue a scheduling of the drug.

MDMA is different from novel drugs that are brought to market, in that it is not a new chemical entity. For novel drug products, typically all of the research on the drug's effects—including efficacy, safety, and abuse potential—are conducted by the study sponsor under controlled conditions based on the specific studies necessary for that product, including abuse potential studies. In the case of MDMA and other well-studied

psychedelic substances (i.e., psilocybin and LSD), they have been independently studied for decades, with many publications in the literature of both clinical and nonclinical studies which were conducted outside of a sponsor-directed drug development program. In addition, there is substantial real-world and epidemiological data collected on naturalistic use of these drug substances including monitoring in major federal health and substance use surveys since the 1970s.

Notably, once MDMA was added to Schedule I in 1985, research into its potential therapeutic effects became more challenging, and a large portion of laboratory research conducted focused on the abuse potential and purported toxicity of MDMA.³ This literature includes much of the data investigating the abuse liability of MDMA, with studies conducted with similar, though not identical, designs to the typical FDA-guided sponsor-conducted abuse liability studies. Based on this extensive pre-existing body of evidence, including many NIDA-supported studies, the FDA waived MAPS' requirement as sponsor to conduct dedicated new studies on the abuse potential of MDMA.

Instead, MAPS will summarize the published preclinical and clinical abuse-related studies that have been conducted with MDMA to guide the abuse potential assessment of MDMA, which will follow and be based on the eight factors of the CSA.

The 8 Factors of the CSA

1. Actual or relative potential for abuse
2. Scientific evidence of pharmacological effect
3. The state of current scientific knowledge regarding the drug or other substances
4. History and current pattern of abuse
5. Scope, duration, and significance of abuse
6. What, if any, risk there is to the public health
7. Psychic or psychological dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled

The eight factors of the CSA that are used to assess abuse potential fall into a couple broad categories. Factor 1 focuses on the actual or relative potential for abuse. This includes preclinical studies which test whether animals find the drug reinforcing, how hard they will work to get more of it, and the degree to which animals will self-administer the drug. Human abuse potential studies similarly assess how much drug-experienced humans "like" a new drug in comparison to a known drug they are experienced with. Factors 2 and 3 assess other lines of scientific evidence relevant to abuse potential, including

information around the chemical structure, receptor targets, pharmacology, and pharmacokinetics. This helps to understand how the drug works in the body, the mechanism of action for the intended effects, and other effects that might be involved. Factors 4, 5, and 6 address the public health impact of the drug. This is focused largely on risks but also typically includes the potential public health benefits of the proposed new drug product. Together, they describe the history and patterns of abuse, including the scope, duration, and significance of abuse and the risks to users and public health. Again, because MDMA is not a new drug, we have a lot of public health and epidemiological data about MDMA use. Though these data are confounded by the fact that unregulated substances sold as "Ecstasy" are represented as MDMA, but may contain other adulterants instead of, or in addition to, MDMA⁴, the public health and epidemiological data are still significant in assessing these factors. The discussion of potential risks to public health will also importantly discuss potential public health benefits of MDMA. Factor 7 looks at the risk amount of potential "psychic" (a.k.a. "psychological" or "behavioral") dependence associated with use of the drug and withdrawal symptoms that may occur when the drug is discontinued. Factor 8 is based on prior scheduling of drugs with similar chemical structure.

Controlled Substances Act Scheduling Assessment

Abuse Potential	No Approved Medical Use	Approved Medical Use
High	I	II
Medium		III
Low		IV
Lowest		V

MDMA was determined in 1985 to have sufficient abuse potential to warrant inclusion in the CSA. Critically, the only schedule a drug may be placed in if it does not have an "approved medical use" is Schedule I, regardless of the actual or relative degree of abuse potential.⁵ There is a common misconception that Schedule I explicitly indicates an exceptionally high abuse potential compared to other substances, but this is

¹ FDA guidance 2017 on abuse potential assessment

² Section 201 (c), [21 U.S.C. § 811 (c)] of the Controlled Substances Act.

³ Belouin and Henningfield, 2018

⁴ Drugsdata.org, 2020 data

⁵ Drugs of Abuse | A DEA Resource Guide: 2020 EDITION [https://www.dea.gov/documents/2020/2020-04/2020-04-13/drugs-abuse]

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Jack Henningfield, Ph.D., is the Vice President, Research, Health Policy, and Abuse Liability at PinneyAssociates, Inc., where he provides scientific and regulatory consulting support for abuse potential assessments and eight factor analyses new CNS-active drugs and nondrug products and regulatory pathways for psychedelics, cannabinoids, and CNS-active dietary supplements. He has been involved in animal and human abuse potential assessment research since the 1970s, and contributed to abuse potential assessments and drug scheduling recommendations at NIDA for 16 years in collaboration with FDA and DEA. Since 1978, he has been a member of The Johns Hopkins University School of Medicine faculty in the Department of Psychiatry and Behavioral Sciences. He has contributed to numerous reports on abuse potential assessment and drug scheduling as a member of various expert committees and in his service at NIDA and with the World Health Organization.

not always the case (e.g. cannabis's inclusion in Schedule I). What often follows from this misconception is that in rescheduling a drug out of Schedule I, that Schedule II is the clear placement. However, the decision of the appropriate Schedule for a newly approved drug should be based on the abuse potential for that drug as evaluated through the assessment described above; there is no presumption of the level abuse liability to be drawn from prior Schedule I inclusion, because its distinguishing factor is the absence of approved medical use. Unlike Schedule I, determination of placement in Schedules II – V is based on a relative comparison of abuse liability to other scheduled drugs and the likelihood of abuse or dependence. In Factor 1, we can compare the degree to which animals will self-administer the considered drug with the animal self-administration studies for other drugs with known schedules, such as cocaine, amphetamine, or opioids. In Factors 4, 5, and 6, we can compare the relative public health risks of MDMA to those of other scheduled drugs. These comparisons inform the appropriate schedule and restrictions that should accompany the newly approved drug, and ultimately its placement in the CSA.

Following the development of the literature-based abuse potential summary, MAPS' application to the FDA will follow a similar process to other drugs that have effects on the central nervous system. The FDA will inform the DEA that the drug has been approved and provides its recommendations for how the drug should be scheduled. By law, CSA Schedule I drugs must be rescheduled or descheduled when approved. The DEA will have 90 days (according to the 2015-2016 Improving Transparency in Medical Therapies Act) to issue an "interim final schedule" that allows the drug to be officially approved and marketed. The schedule assigned for a newly approved drug impacts the distribution, control, and access to the drug. These are significant considerations for MAPS as we continue to work towards pharmaceutical development of MDMA and supporting the accessibility of a potential future treatment modality.



Making MDMA a Medicine (II)

(Re)Scheduling for Schedule I Substances

Ismail Lourido Ali, J.D.

Joy Sun Cooper

Leslie Booher, J.D., M.B.A.



MDMA hasn't always been illegal — it hasn't even been illegal since the passing of the Controlled Substances Act (CSA) of 1971. In fact, the U.S. Drug Enforcement Administration (DEA) only first proposed placing MDMA in Schedule I in July of 1984. In response, MAPS Founder Rick Doblin, Ph.D., organized a group of psychiatrists and psychotherapists to request DEA hearings seeking to maintain MDMA's legal medical use which had rapidly spread over the preceding years. These hearings were granted, but despite positive media attention, DEA's Acting Administrator John Lawn placed MDMA on Schedule I using emergency scheduling powers, based in part on concerns about "potential neurotoxicity and the lack of accepted medical use or established safety for use of MDMA."

In May 1986, after two years of hearings, the DEA's Administrative Law Judge Francis Young recommended against placing MDMA on Schedule I. Notably, his opinion disagreed with the DEA's claim that Food and Drug Administration (FDA) approval of a drug was, "binding on the medical profession with respect to what is, or is not, accepted medical... use" and also acknowledged MDMA's past use in therapy, recommending that MDMA be placed in Schedule III. Despite the weight of the evidence undermining MDMA's placement in Schedule I, and the fact that the DEA had acted outside of its authority when it emergency scheduled MDMA, Lawn overruled Young and classified MDMA as Schedule I in October of 1986.

In 1987, Dr. Lester Grinspoon, a psychiatrist on the faculty of Harvard Medical School, sued the DEA on the grounds that DEA had ignored MDMA's medical use. The federal court agreed, finding DEA Administrator Lawn's ruling "unpersuasive." This decision vacated MDMA's Schedule I status. A month later, Lawn intervened again and reverted MDMA to its Schedule I placement, dismissing the expert testimony of psychiatrists discussing over 200 cases of MDMA-assisted therapy because they were not published in medical journals.

For the last thirty-six years, MDMA has stayed in Schedule I. And today, closer than ever to potential FDA approval, we confront a big question: **If MDMA is approved for medical use, how will it be scheduled?**

Normally, when a drug seeking FDA approval is approved and subsequently recommended for scheduling in Schedules II–V by the Secretary of Health and Human Services (“HHS”), the DEA has ninety days from the later of those two dates to issue what is called an interim final rule, placing the drug on a schedule according to federal scheduling criteria.

Unlike drugs with medical uses recognized by the FDA, drugs in Schedule I are determined by DEA to have “no accepted medical use.” Substances in Schedule I may only be used in government-approved research projects, and are not eligible for prescription, dispensation, and/or administration to any patient other than a qualified research participant. Sometimes, when one of these Schedule I substances is the active ingredient basis for an FDA-evaluated drug product, the DEA will schedule that *drug product* in one of Schedules II–V, or remove it from scheduling altogether. Dronabinol, or synthetic THC, is an example: tetrahydrocannabinols (some of the active ingredients in cannabis) are in Schedule I, but FDA-approved dronabinol drug products are in Schedules II and III. Similarly, Epidiolex is a cannabis-derived cannabidiol drug product that was bifurcated completely out of federal scheduling controls after its approval by FDA.

Each state maintains a system of controlling some substances, similar to the federal CSA. So, in addition to the FDA-approval-triggered federal scheduling, which permits federal marketing and use of a once-Schedule I-controlled drug, each state – if similarly controlling that drug in their Schedule I equivalent – will also need to schedule the approved drug product in a manner that permits medical use in that state (i.e. in a schedule other than Schedule I). Most neatly, and very often, this means each state and Washington, D.C., controls newly-approved drugs, whether bifurcated or not, consistently with the federal scheduling decision—achieving what we call “parity” between the state and federal system.

Today, twenty-seven states have laws or regulations that trigger parity with the federal government upon or at some point after the federal scheduling decision. In other words, when the federal government places a substance or a pharmaceutical drug product into a schedule of the Controlled Substances Act, those states duly conform and place the substance into the same schedule of their state drug control statutes. Because those states automatically schedule controlled substances based on federal scheduling by DEA, that means that when DEA places MAPS’ MDMA drug product in a schedule, the entities responsible for regulating controlled substances in these states will follow suit.

In the remaining twenty-three states that do not automatically maintain parity with federal scheduling decisions, scheduling of controlled substances is determined through a state-level legislative, regulatory, or administrative process. Thus, in order to facilitate timely access to MDMA-assisted therapy in these states following potential FDA approval, MAPS PBC needs to coordinate with the relevant state authorities to ensure the MDMA-containing drug product – though for the reasons above, not uncontrolled MDMA itself – is placed in a schedule other than Schedule I as quickly as possible after federal rescheduling. In states that require legislation to schedule or reschedule a controlled substance, we will work with state legislators, advocates, and other stakeholders to develop and pass legislation that ensures that FDA-approved drug products containing MDMA intended for medical use be excluded from Schedule I and placed in another appropriate schedule. By automatically triggering the appro-

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Ismail is licensed to practice law in the state of California, and is a founding board member of the Psychedelic Bar Association. He also currently serves on the board of the Sage Institute, contributes to Chacruna Institute’s Council for the Protection of Sacred Plants, and participates on the advisory council for the Ayahuasca Defense Fund. He has also previously served as Chair of the Students for Sensible Drug Policy Board of Directors. Ismail is passionate about setting sustainable groundwork for a just, equitable, and generative post-prohibition world.

Leslie Booher, J.D., M.B.A., (Policy and Advocate Associate) received her bachelor of science (B.S.) in business administration and her master of business administration (MBA) from Southeast Missouri State University, as well as her juris doctor (J.D.) from University of California, Berkeley, School of Law. Before joining MAPS, Leslie gained litigation experience at large and small law firms, from both the plaintiff and defense sides. Leslie is excited because her work at MAPS combines many of her passions: learning and educating others about our shared human physiology and psychology, striving for social contentment through imaginative socio-economic structures, aspiring for criminal justice reform, and calling attention to the unique role that altered states of perception play in conceptualizing, contextualizing, and coping with our own consciousness.

appropriate scheduling of our MDMA drug product upon FDA approval, this kind of legislation would allow for legal commercial sale (for medical and therapeutic use only) in the state as soon as possible after DEA rescheduling.

In states that require action by a regulatory or administrative body, we are working to educate the relevant decision-makers about the scientific evidence behind MDMA-assisted therapy and the need for timely action on their part to appropriately schedule the drug product following potential FDA approval.

We have begun this work in several states where legislative action is required. In Colorado and New York, we worked with state legislators who saw a major unmet need for PTSD treatments for their constituents, and introduced bipartisan legislation to ensure timely rescheduling of medicinal MDMA upon potential FDA approval. In both of those states, the bills were swiftly passed by both legislatures. In California, we are collaborating with a diverse coalition of advocates to advance a bill which would decriminalize the personal use of some psychedelics, create a commission to study the possibility of future regulated use, and also ensure that all drug products derived from Schedule I substances are appropriately scheduled. Our goal is for timely rescheduling to be secured in as many states as possible in 2022, and to pass similar bills in the remaining states that require legislative action in 2023, prior to prospective FDA approval.

To be sure, this issue extends beyond MDMA. Any Schedule I drug that gets developed into an approved drug product will have to look at examples like Epidiolex, Xyrem, and — soon — MAPS' MDMA to make similar changes to avoid confusion and delay for prescribing and use by practitioners at the state level. Whenever possible, MAPS hopes to create legal pathways that benefit the public by supporting the entire field of psychedelic healthcare - not just our products. Different jurisdictions with different political environments require different approaches and — as we can see with the wide variety of state-level reforms moving forward — have different tempos of reform. In some places, we'll have to focus our advocacy narrowly to ensure that at least MDMA will be able to be prescribed as soon as possible. In others, we'll be able to carve out larger permissions that will benefit the entire field.

In addition to creating medical access to psychedelic substances, MAPS was also founded to usher in a post-prohibition environment for the safe and responsible use of psychedelics for spirituality, exploration, and personal growth. Even with medical scheduling, this will not be possible as long as psychedelics remain criminalized. Currently, prosecutors and judges look to the U.S. Sentencing Commission (USSC) to make decisions about what consequences to associate with behavior related to psychedelics and other drugs and related activities. While MAPS PBC works toward ensuring appropriate scheduling of a future MDMA drug product, MAPS has simultaneously worked toward changing sentencing guidelines by reducing the punishment for people using, manufacturing, or distributing presently-illicit MDMA.

In 2017, the USSC almost reviewed the MDMA sentencing guideline — MAPS submitted a [testimony](#) at the time — but the review didn't occur, and the USSC hasn't had a quorum since then. Perhaps soon, science will prevail over politics and the sentencing guidelines will be reviewed — even as the first psychedelic drug product is placed somewhere in the CSA (other than Schedule I).

Joy Sun Cooper (Chief of Patient Access and Head of Commercialization) co-founded and served as Chief Operating Officer of Groups, a venture-backed healthcare services company that is tackling the opioid epidemic in rural America. Groups operates more than 50 outpatient clinics in six states that is pioneering a value-based model for the treatment of opioid use disorder.

Prior to starting Groups, she helped launch GiveDirectly, a global nonprofit that gives cash to the ultra-poor with no strings attached using mobile payments technology and conducts rigorous, experimental evaluation to measure impact. She previously was an engagement manager at McKinsey & Company in the healthcare and agriculture practices and Director of Operations at the Clinton Health Access Initiative (CHAI), where she designed and implemented large-scale HIV treatment programs in Sub-Saharan Africa.

Joy holds an M.B.A. from Stanford University Graduate School of Business and a B.S. in international affairs from Georgetown University School of Foreign Service.



MDMA-Assisted Therapy as a Means to Treat Social Anxiety Disorder

Jason Luoma, Ph.D.

Jason Luoma, Ph.D. is CEO of Portland Psychotherapy Clinic, Research, and Training Center in Portland, OR a unique social enterprise that funds research. His research focuses on shame, self-stigma, connection, and the application of Acceptance and Commitment Therapy (ACT) and psychedelic-assisted therapy as an intervention for treating shame and increasing self-compassion. He is currently conducting a clinical trial of MDMA-assisted psychotherapy for social anxiety disorder that is one of the first trials of psychedelic-assisted therapy in the Pacific Northwest. He's an internationally recognized trainer in ACT, former chair of the ACT training committee, and past president of the Association for Contextual Behavioral Science. He has over 70 publications including two books: *Learning Acceptance and Commitment Therapy* and *Values in Therapy: A Clinician's Guide to Helping Clients Explore Values, Increase Psychological Flexibility, and Live a More Meaningful Life*. His work on shame and compassion can be read at actwithcompassion.com.

Can you remember the first time you had to stand up in front of everyone and give a speech at school? That was an anxiety-provoking event for almost anyone, but for some, that anxiety was crushing. The fear was not just of embarrassment but one of deep humiliation. Some don't just have butterflies in the stomach, but rather, they have shaking hands, quivering voices, sweating, or a flushed face. Some people recount the speech over and over again, reliving each perceived mistake. They might have felt so small that they just wanted to disappear. Now imagine feeling that way *all the time* in every social situation. What would the experience of not being able to escape the fear, constant threat of failure, sense of scrutiny, fear of humiliation, and shame feel like?

For people with generalized social anxiety disorder (SAD), that is what *every day* feels like. Social activities may be curtailed altogether or they might push themselves to keep engaging despite the constant self-doubt, self-consciousness, and self-criticism. Living in a state of perpetual anxiety and fear of not being accepted by others is exhausting. Sometimes the social isolation and shame build and turn into depression. Many people with SAD turn to alcohol to cope with anxiety and develop an addiction.

SAD is very common; about 1 in 14 Americans, about 23 million people, suffer from SAD at any given time. SAD is likely even more common right now as people start to emerge from the isolation of the COVID-19 pandemic. Many people aren't aware that SAD is the fourth most common psychiatric disorder in the USA behind major depression disorder, alcohol use disorders (both of which SAD often contributes), and specific phobias (e.g. fear of heights).

Research shows that many people never seek out treatment for SAD, especially if they identify within a marginalized or oppressed group. Among those who do seek out treatment, only a minority of people ever receive evidence-based treatments and even those treatments may only result in partial recovery. We need better and more accessible treatments for SAD.

Our team at the Portland Psychotherapy Clinic, Research, & Training Center is poised to begin our clinical trial of MDMA-assisted therapy (MDMA-AT) for SAD with the hope it may be able to fill that gap. MDMA-AT has already shown promise in a pilot placebo-controlled clinical trial treating social anxiety in 12 autistic people (Danforth et al., 2018). This initial study found very large effects for MDMA-AT compared to the placebo condition. Other researchers have begun to examine how another psychedelic, the brewed beverage known as Ayahuasca, can help people with social anxiety (dos Santos et al., 2022). Even though the results were promising, the number of people studied is still small, so more research is needed. That is why we are about to begin the first clinical trial investigating the effectiveness of MDMA-AT for SAD in the general population.

Based on our review of the literature, I've listed some ideas below of how we think MDMA might help enhance therapy for people who are suffering from SAD.

It is posited that some of the effects of MDMA is caused by the release of high levels of “social neurohormones” such as oxytocin, prolactin, and vasopressin (Feduccia & Mithoefer, 2018). These hormones are central to the process of social bonding and feelings of safety around other people. For example, mothers express high levels of oxytocin in the critical hours after birth when bonding begins with their infant. Safety is not something individuals with SAD often feel around others. Instead, they often fear that if they reveal their authentic self, they will be humiliated and rejected by others. Through stimulating these social neurohormones, MDMA seems to help people feel safe enough to be able to be themselves and to engage with their therapists in more genuine and authentic ways, which we know is an essential element of effective therapy. This therapeutic process can also help individuals with SAD build new associations where authenticity is associated with safety and acceptance rather than fear and shame (Luoma et al., 2021). Our research seeks to examine whether MDMA-AT can help people with SAD feel safer to be their genuine selves and at ease in social situations.

MDMA may also be effective in that it often creates an emotional experience of peace, acceptance, and empathy. In contrast, people with SAD are typically highly self-critical and believe that others also see them as not being enough or inadequate. Try to imagine for a moment that you are someone who tends to be very hard on yourself, feeling like you are always falling short. You might feel constantly on guard, self-conscious, and unsure of whether others will accept you. You might feel different, inferior, and inadequate – and you might feel shame, so much shame at all the social failure and losses. Imagine this experience has gone on for years without ceasing. See if you can take a moment to really imagine what this would be like. Now imagine there's a day, just one day, where you have a deep and abiding experience of acceptance toward yourself and from others. Imagine that, for hours on end, you feel understood by others; like you belong and are accepted just the way you are. What difference might that make? What possibilities might that open up for you if you were able to tap into a part of yourself that was capable of self-compassion and warmth toward yourself? What might it be like to have felt accepted, *really* accepted, by someone for the first time? Research indicates that MDMA-assisted therapy does this for some people (Frye et al., 2014; Jungaberle et al., 2018; Luoma & Lear, 2021). We're aiming to study how often and how much of a difference this treatment can make in the lives of people with SAD (Luoma & Lear, 2021).

It is essential to note that a safe, ethical, and supportive therapeutic context makes this change possible, not just the medicine by itself. It's also important to note that in our studies, MDMA isn't taken on a daily basis like most antidepressants. In-

stead, it's given a handful of times in the context of careful preparation, support, and integration guided by skilled therapists. In addition, while the description above may sound pleasant, the therapy is also usually hard work. The therapists help create a safe container for the experience and help process the shame that may arise when talking about past experiences of social failure. They provide guidance during difficult periods and help the client integrate insights from the MDMA sessions to work in their lives. But ultimately, it's the client that goes on the journey, who confronts their fears of rejection and inadequacy, and who takes the risk to open up to self-compassion and belonging.

Our research journey is only beginning. Our first step is to complete a waitlist-controlled **randomized clinical trial of 20 volunteers with social anxiety disorder**. This trial began recruitment in April 2022 and will be finished by 2024. From there, we plan to move toward larger trials that will allow more definitive answers. It's only with the courage of our participants, the support of donors, the skill of our therapists, and the careful collaboration of scientists that we can continue to advance this research and help more people who are struggling with social anxiety. If you want to learn more about this research, please go to portlandmdmathrapy.com.

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Expanding Academic Consciousness

More Universities Step into Psychedelic Research

Ali McGhee, Ph.D.

As interest in psychedelic medicine grows across the U.S. and Canada, more academic institutions are venturing into research areas spanning the sciences and the humanities. Since 2018, nine new programs and centers, characterized by innovation, interdisciplinarity, and collaborations with other institutions and organizations, are attracting increasing numbers of hopeful students, faculty, and volunteers for studies. While the majority focus on the science of psychedelics, each center is distinguished by unique research interests. A handful approach psychedelics using other frameworks, including religious studies, theology, and journalism.

A vein of optimism runs through all programs. Psychedelics have ushered in breakthroughs that continue to reshape how we think about mental health, consciousness, and culture, and all of the researchers and scholars interviewed expressed excitement for the future of these plants and compounds. Decriminalization, and even legalization, of several of these substances at the federal level is widely anticipated, with MDMA-assisted therapy for PTSD expected to be evaluated by the FDA in 2023. As scientific journals publish more data showing the promise of psychedelics for mental illness, and as American culture has shifted towards acceptance of these substances, university leadership, once hesitant to broach the subject, have given their blessings to new initiatives to prepare their students and residents to meet increasing demand.

While attitudes continue to shift in support of psychedelics, securing long-term funding and working through the approval process for studies has been a consistent challenge for most programs, which all currently rely on philanthropic gifts and, in the case of centers engaged in scientific research, face regulatory hurdles. Most academic institutions see these challenges as temporary, and have their sights fixed on a future when psychedelic studies departments show up in many more course catalogs.

A Pioneer Gets a Permanent Home

Johns Hopkins University has been involved in psychedelic research since their first psilocybin studies commenced two decades ago. The university now houses the **Center for Psychedelic and Consciousness Research**, founded in October 2019. Dr. Matt Johnson, Acting Director, notes the Center was made possible by the gradual, organic acquisition of faculty and several major philanthropic gifts. It's

Once a taboo topic, psychedelics—and the centers built around them—are being celebrated and recognized by university directors and administrators as critical, both for preparing students for new realities of research and clinical work, and for drawing competitive students, residents, and faculty.

currently one of the most well-funded of the new programs, launching after a grant of nearly \$17 million from a group of private donors including the Steven & Alexandra Cohen Foundation, Tim Ferriss, Matt Mullenweg, Blake Mycoskie, and Craig Nerenberg. Several studies have been supported by the Heffter Research Institute.

Psilocybin remains a focus of current and future studies, including on smoking cessation, chronic pain, opioid use, and chronic Lyme disease. Faculty also completed the first double-blind study of salvinorin A, the active compound in *Salvia divinorum*. An LSD study is in development.

Johns Hopkins University had existing infrastructure to handle drug research prior to launching the Center, including an onsite pharmacy, nursing and medical staff, and other necessary components for administering medical studies. “We’re a part of a research unit that has studied human behavioral pharmacology for half a century,” says Johnson.

According to Johnson, the Center is distinguished from other programs “because of the focus on the experience. When you take people who are 60 years old, including spiritual seekers, and most of them say that their experience with psilocybin is one of the top five most meaningful spiritual experiences of their lives, and a third say it’s the most meaningful – that has so much therapeutic power.”

“That’s part of our contribution,” he adds. “It’s our legacy.”

Science Programs Target New and Established Populations

Psychopharmacology has been a focus of scientific research at **University of California, San Francisco (UCSF)** for 15 years, so they had facilities and the ability to give drugs when Director Joshua Wooley, M.D., talked with venture capitalist and philanthropist George Sarlo about his experiences with psychedelic-assisted therapy for post-traumatic stress disorder (PTSD).

The result was the **Translational Psychedelic Research Program (TrPR)**, which completed its first study, on effects of psilocybin on the demoralization of long term AIDS survivors, in 2020. TrPR was also a site for MAPS’ Phase 3 MDMA-assisted therapy for PTSD trials. TrPR is also collaborating with Filament Health on the first study of a botanically-sourced psilocybin, as well as a study on psilocin, the first of its kind in humans in four decades. Future studies are also planned for ketamine, as well as several novel psychedelics that are under wraps—for now.

TrPR’s focus on higher-risk populations differentiates it from other programs. Three psilocybin trials—on Parkinson’s, bipolar II disorder, and chronic low back pain—are currently active or in final stages of development. Wooley is also working



Roland Griffiths and Matthew Johnson of Johns Hopkins University

on an additional study of psilocybin’s effects on methamphetamine users. “Most other groups have been reluctant to work with patients diagnosed with Parkinson’s and bipolar disorder,” Wooley says. “We feel the field has matured to a place where we need to know the effects of these medicines, and we think the potential benefit outweighs the potential risk, which we do everything we can to mitigate.”

As with the other programs, the interest of prospective researchers and patients currently exceeds capacity. “It totally floored us,” says Assistant Director Ellen Bradley, M.D. “It’s more far-reaching than we expected—we’re physician-researchers who were looking to create a space that would jumpstart collaborations.”

“The enthusiasm from other clinical researchers and basic scientists interested in translational work is awesome,” she continues, “as is the number of patients who are excited to learn more about participating in our studies. But we also hear from clinicians who have many years of expertise in psychedelic work in the community and want to get involved in research, patients

and support groups with lived experience who have ideas for studies, start-ups with novel compounds they want to explore, and impressively motivated high school and college students who want to join the team.”

Massachusetts General’s Center for the Neuroscience of Psychedelics is focusing on “neurochemistry, neuroimaging, and neuroplasticity,” says Program Director Jerry Rosenbaum, M.D., who started the Center after he saw the changes in the brain that psychedelics initiated. Their first two studies, both with psilocybin, have focused on basic science. The team is currently raising funds to do a study of mindful self-compassion in treatment-resistant Gulf War veterans, which they will combine with neuroimaging. Rosenbaum hopes that future studies will research whether mindful-self compassion makes MDMA-assisted therapy sessions more durable. 5-MeO-DMT will also be a subject of future research.

The Center’s dual focus is on “innovation and the deep scientific understanding of the cascade of events in the brain that gives rise to changes in brain networks,” says Rosenbaum. “We’re looking at the window of opportunity to create change in the brain,” including during periods of neuroplasticity and shifts in brain connectivity. The Center is also developing an educational arm and will eventually offer training for therapists, including training in mindful self-compassion, in collaboration with Cambridge Hospital and California Institute of Integral Studies (CIIS).

University of Texas Austin’s Center for Psychedelic Research and Therapy at Dell Medical School is focused on neuroscience and brain imaging. Dr. Greg Fonzo, Co-Director of the Center, notes that “Our goal is understanding the mechanisms of psychedelics to design novel treatments with a rigorous scientific approach.” The Center will be a site in Compass Pathways’ Phase 3 trial on psilocybin therapy for treatment-resistant depression. Faculty are also interested in how psychedelics might improve neuromodulation techniques, like transcranial magnetic stimulation (TMS) and brain-focused ultrasound (FUS). “A window of plasticity is opened after the administration of psychedelics,” Fonzo says. “We’re currently using psychotherapy in that window, but our hypothesis is that neuromodulation could also be a kind of aftercare.”

The Center is especially interested in enrolling study participants with a history of childhood maltreatment and depression or PTSD diagnoses. It will also partner with the Heroic Hearts Project and The Mission Within, programs for veterans seeking psychedelic treatment options.

A Focus on Training and Education

Dr. Rachel Yehuda founded **Mount Sinai Medical School’s Center for Psychedelic Psychotherapy and Trauma Research** after completing the MAPS MDMA Therapy Training Program in 2019. She brought the protocol back to Mount Sinai to use in her work with veterans. “Once I realized how much was involved in launching a single study, it made a lot of sense in terms of economy of scale to put a center together,” she says. The Center is collaborating with MAPS on a current clinical trial comparing the efficacy of two versus three doses of MDMA for veterans with chronic PTSD.

Currently, the Center’s clinicians use the MAPS protocol, and they are highly focused on treatment-resistant PTSD and trauma. “We could not do without MAPS,” says Yehuda. The Center plans to offer trainings “to address questions for people that really don’t know that much about psychedelics,” she says. “A lot of people seeking formal training now may know about psychedelics, but the trainings we’re going to offer are designed for

people who really know a lot about PTSD—and can apply what they know about PTSD and other forms of therapy to this model.”

The Center, which is funded for five years, will offer its second training program this October free of charge. Research on psilocybin is planned, but Yehuda says that researchers will likely stay focused on MDMA and psilocybin, and will slowly expand study participants to non-veterans while maintaining a “veteran-centric perspective.”

Dr. Michael Mithoefer, MAPS Public Benefit Corporation (MAPS PBC) Senior Medical Director for Medical Affairs, Training and Supervision, has advised on the **Medical University of South Carolina’s new Psychedelic Research Center**. Mithoefer and his wife, Annie Mithoefer, B.S.N., were among the earliest collaborators with MAPS on MDMA trials, beginning in 2000, and helped develop the training protocol MAPS uses for MDMA-assisted psychotherapy.

The Center’s current focus is ketamine-assisted therapy for treatment-resistant major depression and substance abuse disorder, with plans to expand to include training with MDMA and psilocybin. Future studies will recruit for post-traumatic stress disorder (PTSD), major depressive disorder, and alcohol and substance use disorders.

The Center’s Acting Scientific Director, Dr. Jennifer Jones, traces three parts of the Center’s mission: “to deliver high-quality clinical care for treatment-resistant conditions, to develop



Dr. Rachel Yehuda

a diverse research portfolio that furthers understanding in psychedelic science, and to provide a comprehensive training program that expands the pipeline of clinicians trained in psychedelic assisted therapies.”

Jones explains that the Center primarily offers longitudinal training opportunities for resident-level trainees in psychiatry. Medical students will be able to enroll in research-based summer electives through the school’s Diversity in Research Training Program (DART). The program has also supported pre-doctoral trainee projects.

“The intention is to train psychologists and psychiatrists in this field,” says Michael Mithoefer, M.D. “If they choose the psychedelic track they’ll have the chance to be involved in research, and will get training working with psychedelics in the clinical trials they’re going to do.”

The program’s focus on therapy makes it unique amongst psychiatry residencies. “These days in psychiatry, there’s so much more emphasis on pharmacology and less emphasis on therapy than there used to be,” notes Mithoefer. “This combines therapy and pharmacology, and brings therapy back into a central role.”

The Rise of Interdisciplinarity

University of Ottawa’s Psychedelics and Spirituality Studies Initiative, housed in the Department of Psychology, is anchored in multiple disciplines, including psychology, religious studies, and consciousness studies. Dr. Anne Vallely, Director, is a professor of religious studies whose background in anthropology, specifically end-of-life and grief traditions in India, sparked her interest in psychedelics.

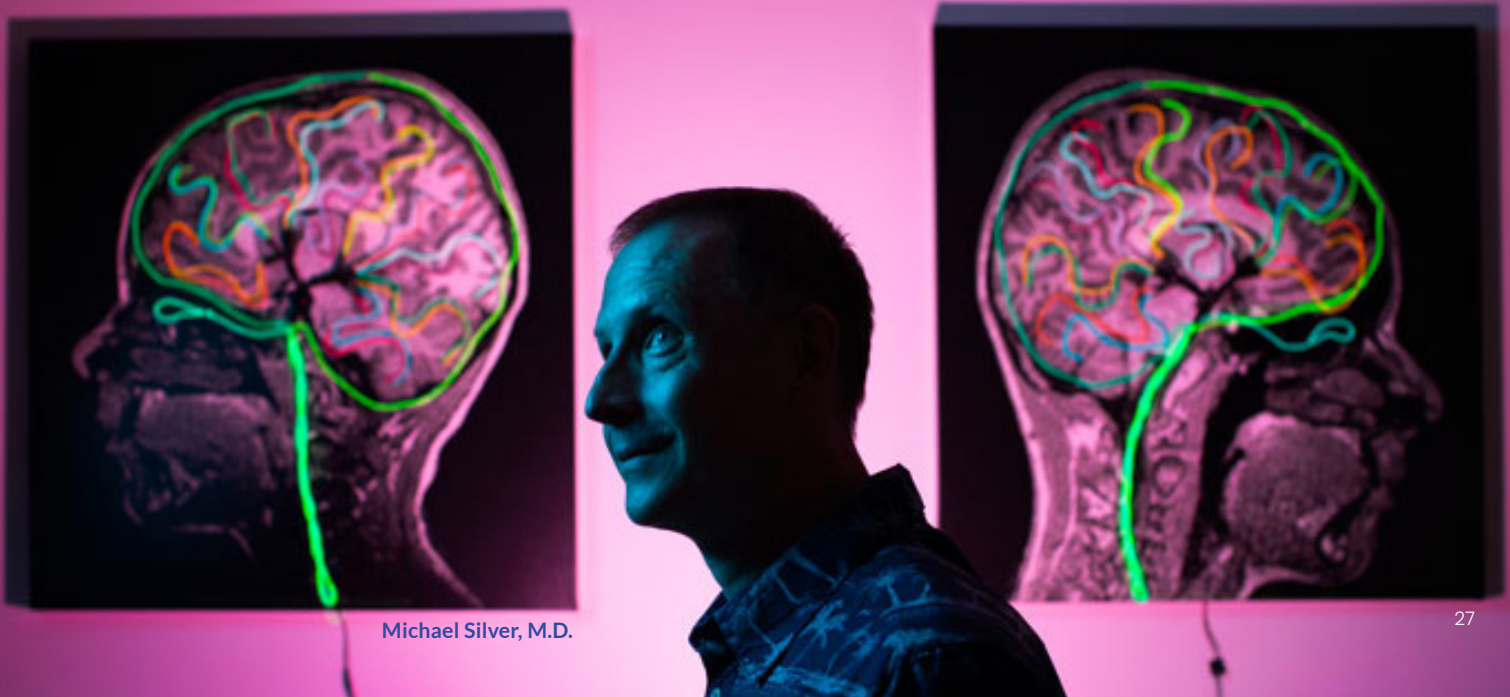
“I became interested in the potential of psychedelics to alleviate existential angst and depression, which are considered

normative in North America, at the end of life” she says. “Maybe this would allow us that sense of mystery and awesomeness around end-of-life. The dying process can be a learning process, with insight possible until the last minute.”

Now in its second year, the interfaculty graduate microprogram offers stackable courses in three streams: clinical, research, and spiritual care. Vallely, along with Dr. Monnica Williams, is developing a Master’s program in Psychedelics and Consciousness Studies that will build on the microprogram. Vallely is hopeful that the program will affiliate with Vancouver Island University, which has a graduate-level certificate program in psychedelic-assisted therapy, as well as St. Paul’s University in Ottawa, which will offer the courses for students in that school’s Counseling and Spirituality Master’s Program. “The way in which we are emphasizing the spiritual component of this makes it unique,” says Vallely of the initiative and planned Master’s. They also plan to work with MAPS so that students can go through the MDMA Therapy Training Program.

“The program is remarkable,” she adds. “It was greenlit all the way by the administration—they see the value and want the University of Ottawa to be the first university in Canada to launch the Master’s, so things have been really positive.” The initiative has received high interest and is actively seeking funding sources.

University of California, Berkeley’s Center for the Study of Psychedelics is also characterized by cross-departmental interdisciplinary. It began with a conversation between Michael Silver, M.D., the current Program Director, and fellow UC Berkeley faculty members Dr. Michael Pollan, Dr. Dacher Keltner, and Dr. Alison Gopnik. Together, they envisioned “a center of psychedelics focused on all aspects of psychedelics—science, journalism, public education, and training guides for psychedelic experiences.”



Michael Silver, M.D.

Ali McGhee has a Ph.D. in English Literature from the University of Rochester. She is the Culture and Team Development Leader for 6AM City, and is a core faculty member at the Enneagram School of Awakening, as well as an International Enneagram Association (IEA) Accredited Professional. Her journalism has been published in outlets including *Lucid News*, *Sallywag*, and *WNC* magazine, and her fiction has been published in *Dark Mountain*, *Slippery Elm Literary Journal*, and *Holler*. She lives in Asheville, N.C.

One current study at the Center examines how the brain processes visual information on low-dose psilocybin. But unlike many other programs, the focus is not on clinical trials. “There are wonderful applications that show the power of these medicines for healing,” says Silver, “but we are consciously not doing that kind of work. We aren’t a medical school and don’t have a hospital on campus.” The Center’s concentration is basic research on how psychedelics act in the brain and mind, and, Silver adds, “deeper, broader questions about psychedelics as tools for perturbing the brain and studying the consequences of that,” including looking at enduring effects and tailoring set and setting to produce the best possible outcomes.

Another distinction is the Center’s prioritization of public education. “There is so much misinformation in the world, and people are looking for trustworthy sources,” Silver says. The just-launched Ferriss-UC Berkeley Psychedelic Journalism Fellowship will award fifteen \$10,000 reporting grants “to journalists reporting on the science, policy, business and culture of this new era of psychedelics.”

The Center has established a training program in partnership with Graduate Theological Union tailored to religious and spiritual care professionals. The first cohort is moving through the program now, and current members will be a part of an ethnographic study. Program organizers will use the results to refine the training.

Silver and his team are also working to center Indigenous voices and perspectives, including increasing Indigenous participation at all levels and building Indigenous wisdom into educational offerings.

“Indigenous people have developed ceremonies and traditions over centuries and have a lot to offer in terms of how to make psychedelic experiences more effective,” Silver says. “We want to work with Indigenous groups in a mutually beneficial way, by helping them retain traditions that have often been under threat, and having them be a part of educational offerings.” He notes that the Center has just finished a strategic plan that keeps this goal “at the heart of everything we do.”

The program has received substantial funding so far, but Silver notes that more will be needed as it grows. “The initial rounds have been very successful,” he says, “and it’s lovely to see the resonance between things we want to do and the interests of prospective donors.”

Looking Ahead

As more universities, medical schools, and training programs step into psychedelic research, they shift the landscape of academia, much as psychedelics shift the landscape of the mind. Once a taboo topic, psychedelics—and the centers built around them—are being celebrated and recognized by university directors and administrators as critical, both for preparing students for new realities of research and clinical work, and for drawing competitive students, residents, and faculty.

Students moving through these centers will also help with scaling efforts to provide care for populations that might be helped by psychedelic-assisted therapy and support. Mithoefer, although speaking specifically about MDMA-assisted psychotherapy, details a challenge for all psychedelic interventions: scaling up training without losing quality.

Mithoefer notes that he has misgivings about scaling too fast, but that the entry of more universities into this work will support a deep, strong foundation. “It’s really important to have good training and good ethical grounding to do this work,” he says. “We have a strong motive to scale for public benefit, but we don’t want to sacrifice quality. People are in university programs for years with lots of supervision, especially in graduate school and residency.”

“In my mind, the collaborations we’ll be able to build are another exciting part of this,” he says. It’s a sentiment shared by all.

Mentorship

A Key Component of the Emerging Psychedelic Career Field



Gina Giorgio

For most young adults, identifying a career path does not come easy. Typically, we are expected to choose a field of study around the age of 18 which is before we have substantial work experience and a good understanding of who we are. This premature career decision is often accompanied by a lot of trial and error (if someone is privileged enough to have the flexibility), becoming stuck in a career that is no longer suitable, or that was never of interest in the first place.

For those aspiring to a career in psychedelics, the path is even harder to chart, since the field is new and psychedelic legalization is still emerging. There is no clear road map for a viable psychedelic career and positions as psychedelic professionals can be limited. It likely comes as no surprise that pursuing a career in the psychedelic field as a young adult is extremely daunting for several reasons:

1. It is difficult to follow the steps of psychedelic professionals when there are few of them and many got their start through underground psychedelic work.
2. Psychedelic substances are overwhelmingly surrounded by stigmas and proclaiming support can be a reputational and professional risk.
3. Psychedelic careers, aside from therapy, are not widely available and it can take years to get your foot in the door.

Despite the difficulties that come with walking an uncharted path, I knew a career in psychedelics would be deeply rewarding, so I promptly applied to Students for Sensible Drug Policy's (SSDP) Psychedelic Career Development Pipeline in the Fall of 2020. SSDP's Psychedelic Pipeline program was created in 2019 and is **the first formal pathway for young people interested in working in the psychedelic field**. The program provides mentorship, scholarships, and training opportunities for those seeking to enter the psychedelic workforce—offering a unique opportunity for one-on-one career guidance with a mentor that has an established psychedelic career.

Upon my acceptance into the Pipeline, I did not have a clear sense of the career path I wanted to pursue, and I didn't personally know anyone who was interested in psychedelic careers. Luckily, having a mentor is one of the main things that has helped me define my goals and the steps I can take to achieve them.

Since the Pipeline is now in its third year, it has not only had a profound impact on me, but it's shaped many other participants's lives and careers as well. As I reflect on how far I have come throughout Cohorts Two and Three, I've gathered some key takeaways that reflect how crucial a psychedelic career mentorship is.

One-on-One Support

I felt very isolated at the beginning of my pursuit of a psychedelic career. I did not have people close to me that were interested in psychedelics and I reside in a city with no psychedelic communities. It was very unnerving to be the only person to pursue a psychedelic job because my friends, family, professors, and coworkers did not understand my goals or know how to support me. Fortunately, joining the Pipeline and meeting regularly with my mentor, MAPS PBC's Corporate Communications Project Manager, Anya Kramer, minimized my feelings of isolation, which granted me a renewed sense of confidence as I carve my own psychedelic career path.

Blake Durst, a mentee from Cohort Two, also commends his mentor, Ryan Beauregard, MAPS' Zendo Project Programs Manager, for being a great source of support and knowledge. Ryan helped Blake integrate some of his challenging experiences following a week of ayahuasca ceremonies in Ecuador, and he provided encouragement and ideas for Blake's dissertation. Blake recently received his counseling license and he will apply for MAPS' MDMA-Assisted Therapy Training Program; he felt "so much more hope and confidence" since Ryan was willing to assist him in the process.

Providing Professional Opportunities

One of the main benefits I have experienced as a mentee is an influx of psychedelic career enrichment opportunities. Anya and I took advantage of the option to create a project together, which ultimately allowed me to volunteer with MAPS' Communications team and assist with organizing their "Mentioned in the Media" document and writing information about psychedelic compounds for MAPS' "Newsroom." The final portion of my project (writing this article!) has given me further experience in psychedelic communications, along with the opportunity to strengthen my writing skills and publicize my work.

Another exciting professional opportunity is that I became the Pipeline's first intern in November 2021. I consider this to be the most valuable aspect of my psychedelic career development thus far due to the scope of impact I can have on the field and on others. The benefits of this internship are that I get to meet and collaborate with numerous psychedelic professionals; I have gotten involved in psychedelic policy reform work;

and I have started psychedelic journalism. These opportunities would not have been possible without the Pipeline and the connections I have made throughout it. Countless other mentees share this same sentiment.

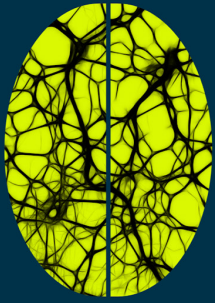
A mentee from Cohort One, Chelsea Pederson, also had the opportunity to publish psychedelic work with the help of her mentor, MAPS' Founder and Executive Director, Dr. Rick Doblin. Chelsea and Rick wrote a historical policy analysis together because they are both passionate about shifting psychedelic drug policies. Chelsea dreamed for years of writing something with Rick—to ultimately be matched with him in a mentorship was "a dream come true." Currently, Chelsea is working with the Texas Drug Users Health Alliance to create a website (using the data she compiled with Rick and others) and to teach harm reductionists how to fight Texas drug policies and advocate for themselves. She is in the process of furthering her psychedelic policy work, and, this Spring, she is writing a document like the one she wrote with Rick to organize the fundraising to make her dream research come to fruition. My and Chelsea's time in the Pipeline both reflect how the chance to collaborate with one person can open countless doors and fulfill lifelong goals.

Education About the Field and Navigating Uncertainty

When I joined the Pipeline, I felt lost about whether I should pursue a path in research, therapy, or communications. I was overwhelmed by the barrier of entry into some of these careers. Luckily, Anya educated me on a wide array of psychedelic companies and organizations, which in turn, expanded my knowledge of training opportunities, research, substances, and psychedelic literature. Subsequently, I was introduced to resources to effectively learn about psychedelic policy, the history of psychedelics, and reliable psychedelic news sources.

Arguably, one of the most valuable concepts I have learned is that not all psychedelic companies are created equally because people can have very different motivations when it comes to their involvement in the field. Supporting psychedelic non-profits, public benefit corporations, and for-profit companies that seek to expand equity of psychedelic-assisted therapy is a great way to ensure that psychedelic-assisted therapy becomes widely accessible. This information has shifted how I approach the field of psychedelic communications and what types of psychedelic policies and organizations I advocate for.

Vanessa Grifford, a mentee in all three Pipeline Cohorts, also stated that "this program has helped [her] understand that not everyone coming into the field of psychedelic medicine may have the same intentions or values and that [she] needs to be



PSYCHEDELIC PIPELINE

By SSDP

cognizant of where [she] chooses to attend school and who [she] decides to work with.” She is a non-traditional returning student and, like me, was unsure how to navigate a field that has not quite come into the mainstream yet. SSDP’s Psychedelic Pipeline has provided her with tremendous mentorship—not just through the field of research, but also through indigenous reciprocity, harm reduction techniques, and re-educating the public about the benefits of psychedelic medicine.

The Current Replacement for Formal Psychedelic Curriculum

I believe mentorship is an integral part of any career field, especially in the psychedelic science sector whose future is filled with ambiguity. Fortunately, psychedelic career mentorship can be the key to bridging the gap in a field that has few definitive paths. With the potential use of psychedelics to achieve mass mental health, it is vital that the next generation of researchers, therapists, clinicians, policymakers, harm reductionists, and educators are properly supported so that their goals can become a shared reality and for psychedelic-assisted therapy to be equitable and accessible.

Current psychedelic professionals have many tools and connections that can be passed down to young, aspiring psychedelic professionals so their paths may not be so rocky. Mentorship is a two-way street: a constant give and take and exchange of information. Many mentors find their roles to be extremely rewarding and come back to the Pipeline year after year. With the lack of academic curriculums dedicated to instructing people about psychedelic substances and therapies, we turn to psychedelic professionals to be our teachers. Like lessons one may learn from one’s own psychedelic journeys, increased connectivity will only catapult progression.

As I continue my second year in the Pipeline, I greatly look forward to how my mentorship with Anya develops and to continue to create meaningful opportunities and connections for others in the Pipeline. I still do not know exactly where my path will take me, but I have learned the value of embracing the opportunities that are presented to me, even if they aren’t a dream fit. Perhaps more importantly, when opportunities are not being presented, I’ve learned the value of creating my own projects, asking for what I want, and collaborating with like-minded people.

SSDP’s Psychedelic Career Development Pipeline is a unique way for SSDP members and alumni all over the world to step into the field of psychedelics. By prioritizing applicants of color and individuals of marginalized communities, the Psychedelic Pipeline is paving the way for much needed diversity and inclusivity in the psychedelic sciences. If you are interested in joining SSDP’s Psychedelic Career Pipeline, I highly encourage you to join your local SSDP chapter or create your own if there isn’t one nearby—and look out for next year’s [application!](#)

With the lack of academic curriculums dedicated to instructing people about psychedelic substances and therapies, we turn to psychedelic professionals to be our teachers.

Like lessons one may learn from one’s own psychedelic journeys, increased connectivity will only catapult progression.

Gina Giorgio currently resides in North Carolina and works for SSDP’s Psychedelic Career Development Pipeline Program, Psychedelic Spotlight, and NisonCo. She is an active member of SSDP’s U.S. Policy Council and is advocating for drug policy reform in North Carolina, New Jersey, and New York. She hopes her work in psychedelic communications, program development, and policy will increase the prevalence and accessibility of psychedelic substances and therapies and reduce drug stigmas and mental health stigmas. She recently started managing Psychedelic Grad’s Talent Collective to increase psychedelic job connections for young people. She will start her Master’s in Communications at Wake Forest University in the Fall of 2022.



Psychedelics Teach Ordinarity

Mary Cosimano, LMSW

This essay is based on my personal experiences and observations both as a psychedelic guide and my life journey, and not that of Johns Hopkins Center for Psychedelic and Consciousness Research (CPCR).

Mary Cosimano, LMSW, has been working with the Johns Hopkins Center for Psychedelic and Consciousness Research since 2000 when they began research with psilocybin. In her role as Director of Guide/Facilitator Services she is responsible for training and supervising Session Facilitators. She has served as Session Facilitator and research coordinator involved with all the psilocybin studies and has conducted over 450 study sessions. In addition to her work with the psilocybin studies, she has worked with the Club Drug Studies including Salvia Divinorum and Dextromethorphan. She taught individual and group meditation to breast cancer patients in a Johns Hopkins research study, and taught at California Institute to Integral Studies (CIIS) for their Psychedelic-Assisted Therapies and Research program. In 2003 she started and has maintained a meditation group for employees in her department. She also has 15 years of experience with direct patient care as a hospice volunteer. In addition to her interest in altered states of consciousness, Mary enjoys time with family, friends, nature, reading, walking, meditating and playing games.

Watch Mary Cosimano's TED Talk on Psilocybin, Love, and the Meaning of Life

Reference

Reflections of an Elder Brother: Awakening from the Dream by Bartholomew

Permission was granted from the participant referenced to share her experience

I was inspired to write this after a particularly powerful weekend of teaching for a psychedelic-assisted therapy certificate program. These classes were more energizing than usual. I was in my element talking about love and psychedelics. I felt incredibly connected with the participants—and it seemed they felt this as well, given their outpouring of gratitude, admiration, and joy. I loved it. It was magical. All of this brought up questions I have been dealing with, contemplating, and trying to make sense of for a long time: I know I am not alone in this quest. Specifically, why do I love these feelings so much? And how do I take this all in? Is it pure passion or is it ego, or both? Could love and psychedelics be part of the answer?

Let me step back and give a little history. My name is Mary Cosimano and I have been working at Johns Hopkins conducting psilocybin research for over two decades since these studies were first initiated. I was recruited to be one of the two guides needed for our first clinical trial with psilocybin. I have now been a guide for approximately 500 psilocybin study sessions. Since that time, the field of psychedelic research has grown immensely. I am not one of the most prominent in this field, and yet having been involved for so long and been witness to so many incredible healing journeys along the way at Johns Hopkins, I am fairly well known in the psychedelic community. I have been referred to as the “heart” of our studies. It is something I strive to be (living from the heart), so I am honored to be seen in this way. This is exactly what my dilemma has been about starting many years ago, but the culmination of my questions rose to the forefront of my mind as I was teaching this particular weekend. I felt overwhelmed with the feedback I was given by this group.

The praise raised new questions within me: How does one take in praise/adoration respectfully while at the same time remaining humble without being self-deprecating? Was it my ego creeping in and saying that I am better than others? And yet when I sat with this question about the ego, it didn't feel right. I wondered if it is egotistical to acknowledge praise.

I continued to sit with the question that weekend. I had a deep desire to get to the root of it—right then! I was tired of dealing with it and knew there was an answer. I just hadn't found it. I kept going inward and asking—asking for the answer.

Slowly, I began to understand something I knew but hadn't put in the following context. That is, the people at that teaching weekend who were projecting the admiration, the love, the joy towards me likely felt that way because I became a mirror into their own hearts and they into mine. They think they love someone else, that the teacher is special. But from my perspective, it is the opposite—it is because they saw and felt that love in themselves. A reflection! I began to point this out to them during that weekend and it seemed that they got it. The result was that this outpouring of love for me was given back to them. Exactly where it belongs.

I knew there was more to understand, so I continued asking and searching for more clarity. I was exhausted. I went to bed. When I woke, I began my day as I had been doing for a while, writing affirmations, breathing, meditating, and reading a passage from a

book that I feel sets me in the direction I want to be for the day. I usually open to a random page. That particular morning I opened the book, *Reflections of an Elder Brother: Awakening from the Dream*, and the sentence I read was, **“Ordinary is the answer.”**

In awe, I read more:

“You are ordinary because love is absolutely ordinary. It is ordinary because it is what you are and what everyone is! It is what everything is! To love is not the exception. It is the easiest thing to do because it is your very nature.

Please think of ordinary as simple, as in uncomplicated, as in ‘like everyone else...’ when you attempt to be something other than yourself you kill the feeling in the moment. If you are trying in any way to act loving, to be right, to feel better, to convince others, whatever it might be, just ‘let go’ and be ordinary in the moment. Ordinary is the answer.”

I see ordinary as the state of love.

As I read further, it became even clearer.

“There is only One. If you feel yourself to be extra-ordinary, you are trying to place yourself above the stream of the ordinary wonder of consciousness... when you get into the realm of the finder, there is nothing but the ordinary, which is love, the One, light, peace. What is extra-ordinary is the ego motion that tries to move itself out of the ordinary and become greater.”

There is no hierarchy in consciousness, love, nor in ordinary.

In the past I have written and talked about my belief that one of the teachings of psychedelics is that love is our true nature, our authentic self. I had not thought about love as ordinary but now I see the connection. Love is ordinary because it is who we are, who everyone is. I believe that love is connection—to ourselves, others, to everything, and that we are all one, all connected. To be ordinary is to be “like everyone else” because we are all one, all connected—that is ordinary consciousness in all its wonder.

Shortly after I wrote this, I went on a walk. At one point I started thinking about the psilocybin experience of one of my study participants. Towards the middle of her experience, as she lay on the sofa, with eyeshades and headphones, her body began stretching upward (towards the ceiling) and she was beaming. She wasn’t talking during this time but later told us what took place. In a session report she wrote:

“... I floated onward into a vast love that I could feel all around. Propelled on this love I rose upward toward a great light. As I approached, the light grew brighter and began to coalesce into form.. It was truly magnificent and awesome. It glowed

more brilliantly than anything imaginable. I continued to propel upward. It was so bright as to be partially blinding. I began to form the thought and then realized that I was approaching the ultimate reality, the source of all the universe. What would this look like? Could I stand it? My anticipation and excitement compounded. At a point as I drew closer to the mountain top I realized with a sense of intense awe and exhilaration that I was about to see the face of the Creator Intelligence Force, the face of “God.” As I moved closer my vision seemed to be blocked somewhat by what appeared to be a section of screen floating before me. I squinted and pressed forward to see. Suddenly an ordinary nickel appeared in sharp detail before my eyes. Astounded I asked, “You’re a nickel?” The voice came back with humor and said, “A nickel is as good as anything!”

I was immediately struck with the coincidence that this experience spoke to that of being ordinary. I interpreted this as the participant expecting the face of God to be extra-ordinary. And God turned out to be a nickel—an ordinary nickel—a simple, uncomplicated nickel.

This is just one example of the many volunteers’ psychedelic experiences that I have witnessed relating to the ordinariness of who we are. Another study participant wrote:

“Thinking about being a doer of good deeds, I don’t need to dedicate my life to it. I don’t need to go to either extreme- good (higher) or bad (fire) evil. I’m neither a saint... nor a sinner. Just an average guy, a regular guy. But I have everything that I need.”

His insight that he need not be “a saint or a sinner” and he had everything he needed speaks to that of being ordinary and affirms to me my belief in the merit of being ordinary.

The desire to be ordinary is the desire to be simple, uncomplicated, “like everyone else.” Love is ordinary and our true nature. It is our authentic self. These are the teachings of psychedelics. I too am ordinary with a heartfelt passion for the healing properties of the psychedelics and the tremendous joy I receive when teaching the classes. The love, joy, and laughter and simply the reflection of ourselves in all of our ordinary love—me to you and you to me—together we are one. I just want to meet you where you are and connect with you.

So, is my love of this work, the boundless rewards I receive and embrace, the healing I see happening all around me, purely ego? I don’t think so. At least not when my ordinary self responds with gratitude, love, joy, and laughter as one. When we respond in this way, we feel at one with each other and together in ordinary love, our true nature.



Considering the Relationship between Abstinence and Harm Reduction

an Interview with Andrew Tatarsky, Ph.D.

Chelsea Rose Pires, LMFT

** this interview has been edited for length and clarity*

Andrew Tatarsky, Ph.D., (Founder and Director of the Center for Optimal Living in NYC) is a psychologist who developed Integrative Harm Reduction Psychotherapy (IHRP) for treating the spectrum of risky and addictive behavior. IHRP brings psychoanalysis, CBT and mindfulness together in a harm reduction frame. The therapy has been described in his book, *Harm Reduction Psychotherapy: A New Treatment for Drug and Alcohol Problems*, and a series of papers. The book has been translated into Polish and Spanish.

He holds a doctorate in clinical psychology from the City University of New York and is a graduate of New York University's Postdoctoral Program in Psychoanalysis and Psychotherapy. He is Founder and Director of the Center for Optimal Living in NYC, a treatment and training center; founding member and Past-President, Division on Addiction of New York State Psychological Association, and Member of the Medical and Clinical Advisory Boards of the New York State Office of Alcoholism and Substance Abuse Services. Dr. Tatarsky trains nationally and internationally.

Dr. Andrew Tatarsky is an internationally recognized leader in the treatment of problematic substance use and a psychobiosocial process model for understanding it. He has developed Integrative Harm Reduction Psychotherapy (IHRP) as an effective treatment for the full spectrum of substance use issues. IHRP has been described in his book, *Harm Reduction Psychotherapy: A New Treatment for Drug and Alcohol Problems*, and a series of papers. He is the founder and director of the **Center for Optimal Living** in New York City, a treatment and professional training center based on this model.

Substance use issues impact millions of Americans; not only individuals struggling with substances, but the friends and family dearest to them. Current models treat addiction as a disease, and abstinence is the primary goal in most treatment programs. As Andrew's work emphasizes, harm reduction may be a more compassionate and successful option for treating those struggling with addiction. In this interview, we explore the relationship between abstinence and harm reduction, and how they might fit together to support healthier outcomes for treatment of problematic substance use.

Chelsea Rose: Do you feel that we can define abstinence as a tool that we can all keep in our harm reduction toolboxes?

Andrew Tatarsky: Harm reduction from the beginning has been a set of ideas as well as specific practices. If we think about the ideas as a set of principles that guides how we develop our healthiest, least harmful, or most beneficial relationships to substances, then it's not about a particular practice. It's about supporting people in discovering or creating practices that support them in achieving their ideal relationship to substances, which really then bridges the entire gamut of outcomes. So that includes abstinence. Abstinence falls under the harm reduction umbrella. I think that what has been in conflict is harm reduction and abstinence-only. Because

abstinence-only is what dominates the addiction treatment field, there's an abstinence only ethos that dominates our culture, which presumes that abstinence is the only acceptable goal, it's the only measure of success.

Are there cases in which you or your patients have found abstinence to be the most effective and healthy option, or an essential step in their healing process?

The way to rework an addictive relationship is to develop the capacity to sit with that urge [to use] and surf it. As Alan Marlatt put it, "to ride the wave of the urge and not give in to it." That capacity to put a pause around the urge is what makes it possible to rework a relationship to the behavior or to the substance. So if a period of abstinence could be a period in which one develops the capacities, the skills to sit with urges and not act on them, that might give somebody a space to reflect on what they want their longer term relationship to the substance to be. And it might also be that people discover what it's like to not be using. And some people decide they really prefer not using a drug and may choose to remain abstinent indefinitely.

From the harm reduction point of view, which we might think of as very much about meeting people where they are or working with affirming and honoring and respecting that whatever the positive change plan is, it really needs to be geared toward who that unique person is, what they really feel motivated and up for.

When people are using problematically, it seems that they often don't realize the harm their use is causing to themselves or others. How can a harm reduction approach help people to see some of these pieces that they have been unable to see?

A central part of our work with Integrative Harm Reduction Psychotherapy is mindfulness. Mindfulness supports a deep exploration into that urge, to unwrap the multiple meanings of that urge. But also, mindfulness supports becoming a keener observer of connections between thoughts, feelings, choices, behavior and consequences. The harm reduction framework creates a safe space to support people in making those connections. And as people get better at noticing and learning about how it helps and when it helps and how it hurts and when it creates problems, that can naturally lead to healthier choices or strategizing about how you might change your relationship to the substance so that it would work better and minimize or eliminate the negative consequences.

I think that this framework can really support people in developing their healthiest optimal relationships to substances of all kinds. For all purposes, whether it's recreational self-medicating or psychedelic substances that people are using for healing and growth.

Because health insurance companies or the judicial system refer people to abstinence based programs only, do you have any thoughts on the accessibility of treatments that are centered around harm reduction?

[There is a] sea change that's happening right now. The Office of National Drug Control Policy, SAMHSA and CDC have gotten on board supporting Harm reduction in a big way.

And, at the Center for Optimal Living, we are working on developing a whole new treatment service that will be insurance based, and many major insurance companies will be paying for harm reduction therapy for folks on their plans.

We have to dismantle the criminal justice approach and support more effective, comprehensive care for people

who struggle with drugs on every level. We have to change the way that insurance companies pay for treatment to support harm reduction. We have to keep people out of prison and offer them help. And we have to retool the entire addiction treatment system, retrain it. So we have a lot of work to be done.

What are some things our communities can do to begin to support a more human-centered harm reduction approach to chaotic drug use issues?

People can educate their families and friends; and if they're clinicians, they can raise questions in their medical practices and with their colleagues. People can educate their local politicians and criminal justice folks by bringing up questions from a compassionate, pragmatic standpoint. There are so many bizarre practices that need to be questioned, like: Why do treatment programs kick people out for using drugs when they're in treatment for using drugs? I encourage people to raise these questions and be a leader in harm reduction, trailblazing to a better future; helping to create a better world.

Chelsea Rose Pires, M.A., LMFT (Zendo Project and Clinical Support Officer) graduated from the University of California, Los Angeles Honors College with a B.A. in psychology in 2007, and received her master's degree in Integral Counseling Psychology from the California Institute of Integral Studies in 2012. She has a passion for harm reduction as a therapeutic and practical approach to drug use and abuse prevention. Chelsea also works with DanceSafe, a public health organization, as manager for the reagent testing kit program. Additionally, she supervises the Crisis Response Team in Nevada County, supporting clients who come into the emergency room in psychiatric crisis. She lives in the Sierra foothills of California with her husband Alexandre, who is also involved in harm reduction work, their three children, and their chickens, fish, and kitties.



The Need for Anti-Racist Training in Psychedelic Therapy

Darron T. Smith, Ph.D.

Darron T. Smith, Ph.D., PA-C, DFAAPA is a US Army veteran and board-certified physician associate with a wealth of experience in primary care, behavioral health, and integrative medicine. He completed his medical training at the University of Utah in 1996 and later completed his Ph.D. at the University of Utah in 2010. Dr. Smith is presently a faculty member at the University of Memphis in the Department of Sociology, working with undergraduate and graduate students. He combines the roles of clinician, scholar, researcher, thought leader, and educator to find evidence-based solutions for people with mental illness. His unique background lends him a deep understanding of social and environmental factors that underscore mental illness.

Dr. Smith's overall areas of research focus on how systemic race-based discrimination affects healthcare outcomes, especially for communities of color. His latest research and practice intersect the study of applied neuroscience (neurofeedback therapy) and psychedelic research (MDMA, Ketamine, Psilocybin) with victims of childhood trauma. Dr. Smith is a distinguished fellow and member of the American Academy of Physician Assistants (AAPA) and the International Society for Neuroregulation and Research (ISNR). He is also a board member with the American Psychedelic Practitioners Association (APPA) and a member of the Racial Equity and Access Committee for Chacruna Institute for Psychedelic and Plant Medicines.

It's difficult to properly appreciate how persistent and extensive systemic white supremacy¹ is and the harm it brings to black,² indigenous, and people of color (BIPOC) unless you live in a melaninated body. The daily grind of race-based mistreatment sustained by stigmatized minority groups is a major stressor. Those with racial privilege readily dismiss these microaggressions (i.e., slights, jeers, unwanted touching, victim-blaming, invalidating reactions, minimization) as trivial or innocuous. And yet, when social actors who have never encountered anti-black racism downplay the suffering produced by white supremacy, it contributes to the trauma exposure cycle that black people endure. Additional stress is compounded with each racialized aggression, and the more traumatic the event, the greater the insult to the brain, mind, and body.

Black Americans experience both macro and microaggressions directly related to their blackness that leaves deep psychological and physiological **scars**.³ And these marks form race-based traumas that have generational effects, as they are passed down to future progeny by altering how our genes respond to our environment through a process called epigenetics. If we have learned anything in America's 400-year history of brutalization and oppression of BIPOC it is that change is painfully slow and people in positions of power and privilege are reluctant to give that up. Though we must continue to strive for diversity, equity, and inclusion (DEI), BIPOC cannot rely on widespread societal change to heal centuries-old wounds. The desire to ease the burden of social injustice of black and brown folk has driven my professional work, which

¹ Systemic white racism should be understood as an organized system of white domination predicated on the ranking of human beings based on physical characteristics (i.e., bone, hair, skin, eye shape), which devalues, demeans, and disempowers the black body. This oppressive system of white supremacy was historically put in place to differentially allocate resources and opportunities for white Americans and their descendants at the expense of those deemed inferior.

² The term "black" here refers to a "racial group" as defined by the United States Census Bureau. A racial group is typically linked to, but not identical to, ethnic group identification, and it is not always linked to genetic relatedness (biology). In fact, it has long been known in the social sciences that race is a social construct, which means we humans ascribe meaning (i.e., sexuality, criminality, athleticism, intelligence, competence), as defined by white Europeans, to identifiable skin tones. And through this, we create categorization and differentiated thinking and subsequent mistreatment of minoritized peoples. Ethnicity, on the other hand, refers to a social group from a common location and/or with a shared language, customs, food and culture. Individuals racialized as black (e.g., black American, African American, or black) are included in this article's definition of black..

³ Stress causes changes at a cellular and biochemical level, leaving blacks more vulnerable to mental health disorders, substance use disorders, and poor physical health, particularly with diseases of slow accumulation (i.e., cardiovascular disease, diabetes, cancer).

is built around interdisciplinary teaching and research on difficult topics of racial inequality that affect health—both mental and physical. My clinical interest in mental illness such as PTSD⁴ is bolstered by my career as a former army and current civilian physician associate in primary care and child & adolescent psychiatry. Just as psychedelic-assisted therapy is demonstrating efficacy and safety in multiple clinical trials underway in the treatment of PTSD, I see great promise in its use for those besieged by race-based trauma.

For BIPOC healing, a joint effort at DEI in the psychedelic metaverse requires the support of white individuals. But this support necessitates that whites in positions of authority examine parts of themselves. It has notoriously been hard for some white stakeholders to let go of their unfounded fears and perceptions of difference because they have not challenged the racial biases programmed from society and the white racial framework inherited from their forebearers. Many white people in positions of power have a hard time listening to and making adjustments for people of color. It is difficult for some white people to hear the pain that white supremacy has inflicted on others. If they do acknowledge that pain, they are forced to reconcile their own biases and possibly give up their unjust and unearned privilege and power.

These experiences beg the question, are all white people racist? Most white Americans bristle at the thought of being accused of racism. As Robin DiAngelo discusses in her well-known book, *White Fragility*,⁵ the white ego is so fragile that it is more distressing for a white person to be labeled “racist” than it is to recognize the distress that their actions (even unknowingly and unintentionally) have caused others. For many Americans, racist acts are synonymous with extremism (e.g., cross burning, acts of violence). Racism, by definition for countless numbers of white people, is a verb embodied at the interpersonal level of society where white supremacy manifests in interactions that happen between people. By this understanding, a white person cannot be “racist” if they harbor no ill-will or exact individual acts of meanness against a person of another race. And by these same ideals, black people can likewise be racist. But social scientists maintain that this analysis leaves out a key element of racism—power.

Most white Americans grossly underestimate the degree to which racial group affiliation shapes and colors life experiences for BIPOC communities in every domain, particularly within institutions where white supremacy is evidence in policies, methods, and culture. It is not a coincidence or irony that blacks commonly struggle in all sectors from education and employment to housing and health. Whether it is creating laws that overtly pun-

ish minorities, denying a home loan, hiring, and firing employees, or simply calling the police on the black person, all white people have the power to take action that can significantly impact the lives of black and brown people while simultaneously having little effect on themselves as the white actor. Thus, they belong to a group that collectively benefits from the repeated relegation of people of color. Because white individuals have been socialized to view the world through the lens of rugged individualism, they are resistant to the notion that the problems that plague black people are more widespread than mere isolated racist incidents. The well-intentioned white liberal who does recognize the realities of systemic racism, still often refuses to examine their place within a group that holds such privilege. Ultimately, as the gatekeepers to opportunities and human capital, many whites often stand in the way of progress thus maintaining the status quo.

From financial resources to clinical research and development, white individuals have controlled the psychedelic space in every aspect. Black people have been routinely and systematically left out. Simply including black bodies but not their mind in the psychedelic space equates to mere window dressing. For example, when white staff members shut down direct interactions that contain feedback from staff of color, not only is equity constrained, but this is also a form of microaggression. BIPOC come with racial traumas informed by hundreds of years of dehumanization and racial oppression that need specific care to unpack. Without this race-based awareness and training, people of color will inevitably be re-traumatized through inadequate attempts to treat them. Training must include qualified individuals of color in positions of responsibility from the top down without silencing their opinions or undermining and harming their efforts.

MAPS and other well-intentioned psychedelics organizations are poised to be trailblazers in the rapidly evolving psychedelic industrial complex despite, and perhaps because of, their previous shortcomings. But this can only be accomplished with BIPOC voices as co-contributors. Mistakes are inevitable when only white people are involved in the decision-making process. In order to achieve equity, there must be a shared vision and intergroup dialogue. Organizations that utilize racially coded language such as accountability, diversity, and inclusion without a clear concept or meaning create a space where their words might come across as empty rhetoric in attempts at political correctness. Change cannot be accomplished rhetorically. Openness and inclusivity mean nothing without decisive action and without people of color in positions of influence. MAPS has shown commitment to anti-racism by analyzing their own mistakes and redressing their approach to anti-oppressive practices in psychedelic-assisted therapy. As the psychedelic field blossoms in the near future, MAPS can forge a pathway of unmistakable unity and commitment to ensuring that homage is paid to traditional healing practices found in indigenous communities.

⁴ Smith, D. T., Faber, S. C., Buchanan, N. T., Foster, D., & Green, L. (2022). *The Need for Psychedelic-Assisted Therapy in the Black Community and the Burdens of Its Provision*. *Frontiers in Psychiatry*, 2532.

⁵ DiAngelo, R. (2018). *White fragility: Why it's so hard for white people to talk about racism*. Beacon Press.



Collective Liberation Depends on You

A Call to Decolonize Your Life

Charlotte James

Co-Creator of *The Ancestor Project*



The Ancestor Project is a Black-led psychedelic collective focused on providing accessible education, ceremony, and integration rooted in ancestral wisdom. We provide training to clinicians and facilitators on how to decolonize their personal and professional wellness practice as a means of harm-reduction for modern journeyers.

Charlotte James has been a harm reductionist and psychedelic explorer for over 10 years, but her path through this work has certainly not been linear. After leaving harm reduction years ago because of rapid burn out, she is returning to this work with a new energy - thanks to the power of healing with Sacred Earth Medicines. Charlotte is fascinated by communication, has a love of language, and is captivated by the power of human connection. She has been in fearless pursuit of her passions since she can remember, always gifting herself new experiences and opportunities to expand her mind. Charlotte works to create a world in which everyone is able to live in fearless pursuit of their radical transformation. She uses her skills as a digital strategist, coach, and space holder to build and engage a community focused on pursuing equitable liberation.

At this point, you have most likely heard the terms collective liberation and decolonization work thrown around in the burgeoning psychedelic space. Usually, these terms are accompanied by academic observations and theories, yet less commonly, are they accompanied by actual steps one can take to catalyze this process on a personal and then collective level. You may even be questioning how one begins this seemingly massive undertaking of decolonizing themselves, and more importantly, why does it even matter?

First, it is helpful to set a basic framework of the process of colonization and how it unfolds at a systemic and social level. I think it is important to note here that this is a process we can observe globally; before exporting violent and widespread conquest to the global South, groups found in present-day Europe were busy plundering and colonizing each other. Think, the Greeks and Romans, the Crusades, or the Anglo-Saxon conversion of Pagan Nordic tribes, who were seen as more savage because of their animist practices. This era was just the practice round.

When we analyze this repeating pattern in history, it is clear that there are four primary stages of colonization as it relates to psychedelics, Sacred practices, and practitioners:

1. Demonization

The first step of colonizing Indigenous medicine practices and animist traditions was to demonize the practitioners, beliefs, and rituals associated with the practice. This was most often done in the name of conversion to “save the souls of the savages.” There were often severe or even fatal punishments for disobeying the colonizer’s law.

2. Suppression

Through consistent violent oppression, practitioners of these traditions and entire communities were forced to practice in secret, or not at all. Over time, it became easier to assimilate to the ways of the colonizer as a means of survival. Through this process, profound sacred knowledge of entheogens, and overall understanding of communal care, have been lost or forgotten across the world.

3. Appropriation

Over the passing of time, we have watched as many of these previously demonized traditions have become a part of the mainstream wellness industry. We have watched this process play out with tea, tobacco, chocolate, Cannabis, and now, Psilocybin, Ayahuasca, Iboga, and so many other Sacred Earth Medicine allies and practices.

4. Capitalization

Lineages that previously contributed to the demonization and suppression of these traditions are now benefiting financially from their resurgence. These Sacred Earth Medicines are subject to the same cycles of abuse that have been carried out for centuries. The question is: Why does any of this matter to you and your relationship with yourself, with the medicine, and with the collective?

We all have been forced to internalize and participate in perpetuating the process of colonization. We carry this out every day through socialization. This complex and persistent practice of socialization transforms us into agents of our own and our shared oppression. Through media, peers, family, religion, school, and other institutions, we are taught time and time again that who we are, and who others are, is not acceptable. We are pushed to cast judgment on ourselves and others for anything that falls outside of a White-heteronormative viewpoint. We hold shame for our mental health struggles in a world of suffering, and feel guilty for the exploration of “alternative” modes of healing. We are constantly policing the world within us and around us, guided by what is deemed to be “socially acceptable,” yet what is seen as acceptable is informed by the colonized perspective.

Now that we have some shared language and baseline understanding of how we are all subject to these patterns, the question remains: **What steps can we each take to support our decolonization and move boldly towards collective liberation?**

Understand intersectional theory

Individuals are often disadvantaged by multiple sources of oppression: their race, class, gender identity, sexual orientation, religion, immigration status, ableism, and other identity markers (Kimberlé Crenshaw)

Connect with your ancestry

One of the greatest ways to resist colonization is by reconnecting with your ancestral traditions. We all come from Indigenous and animist traditions - find yours and begin incorporating those rituals into your spiritual practice.

Participate in social justice movements

Support the fight to dissolve these systems of oppression for individual and collective liberation. Do not assume how to help, always ask how you can be of service to the movement.

Take time for self-reflection

It is key to reflect on your identities and your role in maintaining or eradicating systems of oppression. This process may be challenging and uncomfortable but will ultimately support your personal and our collective liberation.

Take continued action

Once you have a deeper understanding of your role within these systems of oppression, it is time to make commitments to dismantle the structures that ultimately oppress us all. Being an agent of change is a daily, embodied practice. Be patient with yourself as you begin to dismantle the internalized and external conditioning that perpetuates suffering.

Which step can you commit to working through first?

I'd like to leave you with the concept of 'Ubuntu'. Ubuntu is a word from Nguni and Bantu languages in Southern Africa that reminds us that: I am who I am because of who we all are. There can be no collective liberation without a deep dedication to liberating yourself.



Oneness, Liberation, and Revolutionary Revelations

Observational Research
on Ayahuasca Rituals of
Israelis and Palestinians

Leor Roseman, Ph.D.

Centre for Psychedelic Research,
Imperial College London

Leor Roseman is a postdoc at the Centre for Psychedelic Research, Imperial College London, where he also received his PhD and MRes; under the supervision of Dr Robin Carhart-Harris and Prof David Nutt. His research interests are diverse and cover neuroscientific, phenomenological, therapeutic, and psychosocial aspects of psychedelic use. Currently, Leor is investigating relational processes and group dynamics in psychedelic rituals. His main line of research is examining the potential of psychedelics for peacebuilding (peacebuilding defined here not just as achieving a state of harmony, but of structural equality and political liberation as well). While his research is currently focused on the Palestinian-Israeli conflict, he and his collaborators are hoping to develop an approach which is applicable in other contexts as well.

Sentiments for societal change through psychedelic use have existed in Western psychedelic cultures since Albert Hofmann, Ph.D., became the first person to experience the psychedelic effects of LSD in 1943 and the ripples that followed, promising societal change through a shift in consciousness (Saldanha, 2007). Similar sentiments for societal change can be found in some Indigenous and mestizo practices and ayahuasca churches. I'll start by admitting that while nuanced, I still share those sentiments as well. This is my conflict of interest; these are the sentiments I'm up for testing through the praxis of my research and action, and they motivated my observational research on ayahuasca rituals of Israelis and Palestinians. What I will argue here is that the potential for societal change doesn't only derive from oneness, acceptance, and harmony. In fact, my fellow researchers observed that idealization of oneness and harmony can often suppress marginal voices and prevents systemic change. However, revolutionary and often painful revelations have the potential to inspire people to act and resist the status quo.

Through the ethnographic and phenomenological inquiry into Israeli-Palestinian ayahuasca groups, we observed in few participants revelations that reveal the deep injustice done to Palestinians that suffer and activate people with liberative hope. The revelations were rare as they were in opposition to the dominant focus on apolitical oneness. Such oneness was at times in service of the Israeli status quo, but while the rituals we observed attempted to be apolitical, politics inevitably found its way in through revelatory moments.

Much of what follows is based on observational data gathered in 2018 on a month-long road trip in Israel and Palestine. Data collection and research development was a collaboration with Natalie Lyla Ginsberg, M.S.W., a Jewish American social

worker and the Global Impact Officer of MAPS; and Antwan Saca, a Palestinian peace activist and group facilitator. I am the lead researcher, an Israeli living in London and a psychedelic neuroscientist. The data is based on thirty-one interviews of Israelis and Palestinians who drank ayahuasca together, and some complementary ethnographic research and participatory observations in rituals. I've also used the [microphenomenological](#) interview technique to zoom in on specific experiences. We did not organize the rituals – we simply observed and studied them. We intended to learn from the underground practices about the potential of psychedelics for peace and liberation.

The analysis and theoretical understanding summarized here were guided by Dr. Nadeem Karkabi (Roseman and Karkabi, 2021), a Palestinian anthropologist from the University of Haifa, and an expert in Palestinian counter cultures (Karkabi, 2020). Our [paper](#) was published in the *Consciousness Research* section of *Frontiers In Psychology*, under the [Psychedelic Sociality](#) research topic. The theoretical framework used was the Politicized Philosophy of Alain Badiou, mainly described in his “Being and Event” (1988).

Israelis organized most of the observed rituals, and Palestinians were a minority in them, not just by numbers. Most of the facilitation team, including helpers and musicians, were Israelis. Jewish and Israeli music and ritualistic elements were incorporated into the rituals. The language spoken in this context was mainly Hebrew, (which is also spoken by some Palestinians participants in the ceremony). More Israelis were more acquainted with new age and neoshamanic practices – this was evident by clothes and fashion, new-age language, and having more experience in Western spiritual practices.

Most of the observed rituals were part of an ongoing practice and not one-off retreats, hence communities were formed through these rituals. People joined them for personal reasons, such as psychospiritual growth, but there was also an underlying collective intention related to group harmony and oneness. Three relational phenomenological themes were identified and described in detail in the first paper from this project. These themes were 1) connection based on shared humanity; 2) recognition and intercultural/interfaith connection based on differences; and 3) painful and traumatic visions related to the conflict and its history (Roseman et al., 2021).

During the rituals, powerful moments of “human-to-human” connection occurred, and the tensions of the everyday

hierarchical structure were relieved in inspiring moments of oneness, universal love, and identity dissolution. Furthermore, under the ethos of oneness, cultural and religious pluralism was also accepted. For example, a Palestinian woman offered a pluralist take on oneness and suggested that “[in] the merging of all the wavelengths there is the one which encompasses all colours.” It is argued that the expression of diversity “expands the container” and brings more wholeness to the ritual.

Others, outside this study, also suggest this pluralistic take on oneness, and it is argued that oneness doesn't have to contradict identity politics and queerness (Costello and Cassity, 2021). In other words, unity is not the same as uniformity. This idea has an experiential quality observed in our phenomenological analysis. Different aspects of the Arab culture and the Muslim religion were expressed in the ceremonies through songs and prayers. For many Jewish participants, these moments of intercultural and interfaith connection and recognition were mind-expanding, awe-inspiring, and charged people with hope. It was argued that ayahuasca helped people soften their identity and bring people closer to the other culture and religion in case the other culture was expressed in the ritual.

Now, here is the catch. Contexts that idealize universalism and oneness can suppress marginal voices (Roseman and Karkabi, 2021). The particular can appear universal, but only by those who dominate. Furthermore, contexts that idealize oneness and harmony can prevent change. Other peace researchers have already noted that the “irony in harmony” is that having it as a goal in small groups can lead to pseudo-equality, which prevents attempts of changing larger structural inequality. Oneness has its limits.

The observed ceremonies were mostly organized and guided by Israelis, and the dominance of Israeli culture is natural to this context. Under the ethos of oneness, there was room for pluralism, as long as it was apolitical and non-conflictual. While it is easy to unify Jews and Arabs as offspring of the same ancestral patriarch who worship the same God, it is much harder to unify Israelis and Palestinians by their attachment to the same land. Muslim and Arab identities can exist in the Israeli state, but the Palestinian identity and history is denied as it undermines the dominant Israeli narrative. This denial is most potent for those Palestinians who live as citizens in Israel; they are usually referred to as Israeli-Arabs by Jewish Israelis and are pressured to assimilate into Israeli society. As non-Jews, however, they are not fully part of the Israeli nationality and hence could not be

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come equal citizens in Israel, as long as Israel remains defined as the nation-state of the Jewish people. The denial of Palestinian history is epitomized by the lack of recognition of the Nakba — the Palestinian collective trauma and the displacement of much of the Palestinian population from their homes in '48. We observed that the ideology of oneness and harmony often supports the denationalization of Palestinians and prevents the emergence of conflictual resistance that challenges the hegemony in the Israeli ritual. The spiritual bypassing of politics. Palestinians are subjugated and occupied by Israelis, and any mention of such oppressor-oppressed duality can burst the oneness.

Yet, there is another catch. As I already mentioned, psychedelics are not only about unity, and sometimes ruptures can occur. What is most suppressed is usually what seeks its way out to puncture our limited knowledge, and this is the Palestinian collective trauma in this case.

Some participants recounted visions of war, conflict, the Nakba, collective and intergenerational trauma, the pain of the land, and the pain of “the Other.” Sometimes such visions ignited people with emancipatory missions. Three such cases are described in much detail in our paper (Roseman and Karkabi, 2021). In all three cases, people experienced powerful revelations of collective trauma and injustice inflicted on Palestinians which then motivated them to intervene in the group ritual. The subject felt separated from the rest of the group and had a painful vision; this vision ignited an intervention — each time in the form of a song — to deliver an emancipatory message to the rest of the group (You can imagine the archetypal prophet here). While the message was particular to the Palestinian trauma, it was experienced as universal. This is not the new-age universalism of “all-is-one,” but the liberative universalism at the core of many revolutionary movements. After the revelatory event, the subject kept their loyalty to the event while seeking to transform reality around them and transform the social dynamics within the ayahuasca ritual. Yet, the status quo pushes back, and the subject is divided by their loyalty to the event and their belonging to the social structure and culture of the status quo.

Take this for example. Ruqaiya (names changed for participant safety) participated with her “tribe” in a Yom Kippur ayahuasca ritual. Yom Kippur — the day of fasting and reparation — is considered the holiest day for Jewish people, so this was an important ritual loaded with religious and political meaning. On that day, Ruqaiya was the only Palestinian person in the ceremony, and the rest were Jewish. During the ceremony, she saw a vision of her daughter being lost into a black hole. Her daughter was relatively assimilated to Israeli culture and considered joining the Israeli army with her Israeli friends. Ruqaiya felt like she is “losing her,” and in the vision, she attempts to pull her daughter from the void. Then, suddenly, an intense prophetic revelation is triggered. Ruqaiya sees intergenerational cycles of

war that began long ago and will continue for much more. She sees mothers who sacrifice their children to the land. She sees the blood dripping into the land. She then feels the pain of the land in her own body and “releases a frequency of anger.” She feels like a messenger and sings the first paragraph of the Quran with powerful confidence. She attempts to reveal the injustice to her Israeli friends, to make them see that Yom Kippur is not only about fasting but also about reparation. The sins are political — denying the freedom of other people. Not everyone resonates with her message, but some do, and some even transform their ways. One Israeli person prevented his daughter from joining the army, based on his experience of Ruqaiya's song and message. Later on, he accompanied Ruqaiya musically when she started facilitating ceremonies. Some in these groups deny the political implication of such revelations. The revelation and anger are commonly psychologized and framed as a cathartic moment that is solely required for her personal healing and “shadow work.” Such framing can see these moments as self-liberation from a political past, but this ignores that the action that follows the revelation is also about changing injustice in society. It is about resistance.

In loyalty to her vision, Ruqaiya attempts to transform reality around her. Not an easy task. She seeks like-minded people to support increasing ayahuasca access to more Palestinians without relying on Israeli facilitation, and in politicizing the practice. For example, in a ceremony conducted a few years later with like-minded spiritual activists, Ruqaiya had a moment of inspiration in which she spoke in biblical Hebrew, accusing the Israelites, who were liberated by Moses, of becoming Pharaohs in modern day. From oppressed to oppressors. While she does this, she still belongs to new-age culture but now trying to expand it to be more politically aware of inequality and injustice and not to be blinded by non-dual axioms. She claims her message is universal and not only related to the Palestinian people. Her guiding star is the emancipation of humanity. Though her revelatory event ruptured the ritual with anger, she followed it with a message of love to humanity and the human spirit. For her, the initial anger and agony are directed towards peace, justice, liberation and love. It is their lack that ignited anger.

Psychedelic-induced traumatic visions are not only personal cathartic healing of our past but also warnings for the future, and so they activate us. Michael Taussig observed this in the amazon and how visions of colonial atrocities done in Putumayo were related to the revolutionary spirit of indigenous people (Taussig, 1991). Walter Benjamin — while escaping the Nazis — noted the universal revolutionary forces which follow collective trauma (Benjamin, 1942). Allen Ginsberg, guided by Leary in a mushroom ritual, had agonizing visions which transformed into a momentary messianic frenzy, running naked attempting to call world leaders and turn them on. This vision

ignited in him a revolutionary spirit, and in his integration he made a pact with Leary to leave institutional exclusivity and bring mystical states to the people (Conners, 2010).

Yet, it is not only visions of trauma that are revolutionary in potentia, but many insights are. Prophetic revelations can ignite movements (Taves, 2016; Wallace 1956). The phenomenological structure of the revelatory moment is also revolutionary — seeing something in a new way is also a calling to change the old way, and **the urge for action is embedded in the insight**. Such revolutionary revelations are associated with confidence and charisma. There is something attractive about them. Eureka is followed by mad excitement. It is not the passive amoral acceptance associated with the mystical union, and it is not even the cathartic letting-go of stored trauma. The revelatory moment is of a subject in relation to their environment — therefore, the need for action is inherent to the event. **Ruqaiya's revelation charged her with confidence and responsibility to act.**

It is important to note, that such revelatory and action-motivating events are not always political. They can also happen to the scientist who is filled with the joy of new enlightenment, the artist with the pleasure of new perceptual intensity, or the lover enchanted with new existential intensity. These are revolutionary moments, and psychedelics can sometimes generate them. So I claim.

Within the field, many deny psychedelics' revolutionary spirit and attempt to detach psychedelics from their counter cultural heritage. Even some from the counter culture itself downplay their own heritage while they rightly develop cynicism of the revolutionary language appropriated by the shroombooming "industry". But it is not just about the ideology and language I'm speaking about but the phenomenological dynamics of psychedelic-induced ruptures.

Yes, there are obvious caveats indeed. Not every psychedelic insight is truth to act upon. Is it just an illusionary reaffirmation of existing knowledge, or is it new? Education is crucial for distinction. It is also crucial so we don't become completely "liberated" from our rationality — losing the sense of what is true or false. This is part of what psychedelics can do — for good, bad and ambiguous — and we need to learn how to work with this in a healthy way for individuals and society. For example, therapeutic frameworks such as liberation psychology can help in integrating such revelatory moments into actions. In such frameworks, the therapist and patient seek to recognize internalized oppression and liberate from it by also becoming agents of sociopolitical change (Brennan, 2020).

Many scholars from different backgrounds consider the mystical union and oneness as elitist. It can have a conservative function that maintains the status quo. This function is healthy as long as society is relatively fair to all its population. What will

happen when psychedelics move into marginal and oppressed communities — will they experience union, or will their experiences be related to liberation from injustice? Will therapists know how to work with this explosive energy and create a conducive container for change? Or will they be excluded? Only time will tell, but until then raising our awareness of the psychedelic process, in combination with political education, can nurture the praxis of insight and action, and may indeed help us change society.

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Ask MAPS Anything

Krislyn LaCroix

Since its inception in 1997, AskMAPS has answered thousands of inquiries about psychedelics, therapy, and research each year. Krislyn LaCroix, MAPS' Social Work Intern, is here to connect with the psychedelic community and provide educational resources.

My best friend is in dire need of receiving this treatment but I'm afraid the cost won't be accessible to her. What is MAPS doing to ensure that low income patients may receive this treatment if needed and wanted?

Great question! Equitable access to MDMA-assisted therapy is core to MAPS' principle of Healing for All. If MDMA-assisted therapy for PTSD receives FDA approval, we hope for "broad market access," so we've been working on the many factors that will be required to drive access, particularly equitable access.

1. **A growing pool of 30,000 trained practitioners** who are themselves diverse and can deliver culturally competent care across that is diverse and competent in race, culture, geography, and life experiences (mapspublicbenefit.com/training).
2. **Generous patient assistance programs** to ease financial burdens for treatment are already being planned for implementation if the treatment is approved. Today, the Expanded Access Patient Assistance Program

(EAPAP) provides monetary support for patients who face financial barriers (maps.org/expanded-access).

3. **Flexible post-approval regulatory controls** that are appropriate and evidence-based will prioritize safety without needlessly restricting broad, equitable access.
4. **Broad payer coverage** from insurance companies and single-payer systems like VA will reduce financial burden for insured patients.
5. **Effective patient advocacy** with evolving plans as we get closer to bringing this treatment to market.

I understand your best friend is looking for an effective treatment, however, I also have to note that the safety and efficacy of MDMA-assisted therapy for PTSD is currently under investigation. The treatment is not yet approved by the FDA, does not work for everyone, and carries risks even in therapeutic settings. Thanks for your question, and I wish both of you the best of luck!

I was wondering if there are trainings or certification programming to become a guide for psychedelic therapies? Does MAPS recognize any psychedelic therapy training programs as being more well rounded than the others?

Our own **MAPS MDMA Therapy Training Program** has been developed and refined by MDMA-assisted therapy practitioners in clinical studies for nearly

two decades and is open to licensed therapists, residents and interns seeking licensure, and those with 1,000 hours of behavioral health experience.

Our therapy training program is also collaborating with other training or academic institutions to provide therapy training: **California Institute for Integral Studies (CIIS)**, **Fluence Training**, **Integrative Psychiatry Institute**, **Psychedelic.Support**, **Naropa University**, and **Sound Mind** offer certifications, and many have been developed by long-time MAPS practitioners. They are great starting points for expanding your knowledge about the future of psychedelic science.

Krislyn LaCroix is a recent graduate, earning her Masters of Science in Social Work from Columbia University School of Social Work, with a specialization in Social Enterprise Administration while completing her field education as a MAPS Social Work Intern. She graduated from the University of California, San Diego in 2018 with a Bachelors of Science in Cognitive Science, with a specialization in Language and Culture, and a minor degree in Spanish Literature. Krislyn has a background working with at-risk youth in the greater Phoenix area to help improve social and emotional intelligence. Through interning with MAPS, she has developed a passion for substance-use harm reduction and champions for quality drug-use awareness across communities. In her free time, Krislyn loves crocheting, hiking with her dog, and playing tennis.

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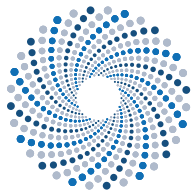
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Pharma-covigilance



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