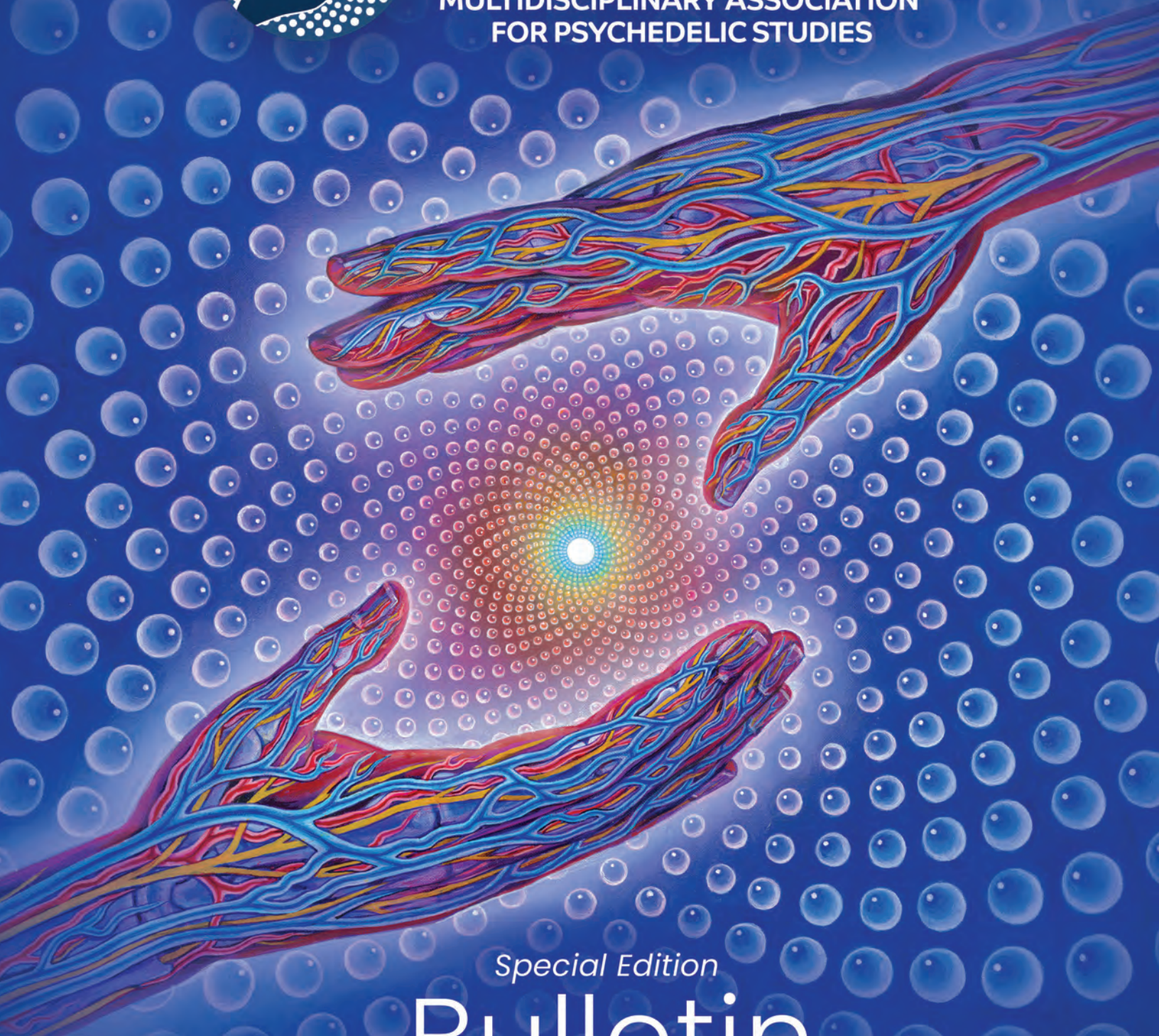




MAPS

MULTIDISCIPLINARY ASSOCIATION
FOR PSYCHEDELIC STUDIES



Special Edition

Bulletin

The Emergent Psychedelic Ecosystem

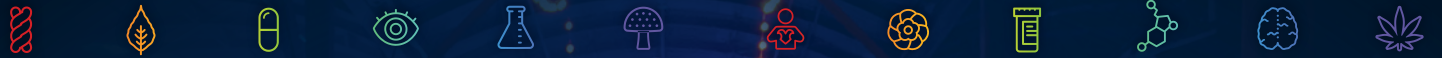
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MAPS

MULTIDISCIPLINARY ASSOCIATION
FOR PSYCHEDELIC STUDIES

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

MAPS furthers its mission by:

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

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

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

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Cover Art

Front: *Psychedelic Healing*

by Alex Grey

Alex Grey is best known for his paintings which “X-ray” multiple dimensions of reality, interweaving physical and biological anatomy with psychic and spiritual energies. Grey’s visual meditation on the nature of life and consciousness, the subject of his art, is contained in three books. His two monographs, *Sacred Mirrors* and *Transfigurations*, follow the history of Grey’s artistic life. The *Mission of Art* reflects on art as a spiritual practice. Grey’s world-renowned career includes exhibitions and keynote addresses from Basel, to Tokyo, to Sao Paulo, and features by the Discovery Channel, Newsweek, and Time Magazine. Grey’s art has been used on albums for the multi-platinum bands Nirvana, Beastie Boys, Tool, and String Cheese Incident.

alexgrey.com • cosm.org

Back: *New Order #1*

by Allyson Grey

An accomplished visionary artist, Allyson Grey’s paintings invent a symbol system representing chaos, order, and secret writing. Co-founder of the Chapel of Sacred Mirrors in New York City, is the wife and partner of internationally renowned artist, Alex Grey, and the mother of film actress Zena Grey. Born in 1952, Allyson received a Master of Fine Arts degree from Tufts University in 1976. She has edited and co-written a dozen publications, and taught art at Tufts University and the Boston Museum School and at Omega Institute for 17 years. A leader of a growing community, Allyson has spoken widely at conferences and symposia. She has received several commissions for long-term and permanent installations of her artwork, which has been exhibited throughout the U.S. with many paintings collected by both corporate and private collections.



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From the Desk of Rick Doblin, Ph.D.

MAPS has recently completed its first Phase 3 study of MDMA-assisted therapy for PTSD for review and potential approval by FDA, Health Canada, and the Israeli Ministry of Health. A scientific paper about the outstanding results was published in *Nature Medicine* and reported on in two *New York Times* articles, one on the front page, and in many other media outlets. MAPS is currently in the early stages of conducting our second Phase 3 study with results from the interim analysis of that study anticipated by May 2022, with completion by August 2022 and potential approval for prescription use before the end of 2023.

MAPS has also started research to train European therapists in preparation for Phase 3 research for review and potential approval by the European Medicines Agency (EMA) around the end of 2024. No other non-profit or for-profit psychedelic company has even started Phase 3 for any psychedelic-assisted therapy for any clinical condition, yet several publicly traded for-profit psychedelic companies have market caps in excess of \$1.35 billion. MAPS has raised about \$110 million in philanthropic donations over the course of its 35-year history. If MAPS' wholly owned pharmaceutical arm, the MAPS Public Benefit Corporation, was publicly traded, it would probably have a market cap in the range of or exceeding these other companies. It's likely that MAPS has created public value 10X or more than total donations to date.

MAPS has earned its reputation as the global leader in psychedelic therapy research, shaping how this work is done and will be done for decades to come. MAPS has garnered a substantial amount of respect and trust in its hybrid non-profit/benefit corporation approach with open sourcing valuable information that has accelerated the growth of this field, including the gold-standard treatment protocol and ethical guidelines for therapists working with psychedelic substances. MAPS is the leading institution within this emergent field and is poised to retain its leadership position by building on decades of work that has been done for the benefit of all.

MAPS has engaged the Boston Consulting Group (BCG) to help us chart a path toward sustainability through income generated from the sale of MDMA by prescription, should we obtain approvals for marketing by FDA and other regulatory agencies around the world. While I studied the FDA drug development process for my dissertation, and we've built the MAPS Public Benefit Corporation into the world's leading team to design, conduct, and monitor psychedelic-assisted therapy research and to negotiate with regulatory agencies around the world, the commercialization of MDMA-assisted therapy for PTSD presents a new set of challenges for which we are just starting to develop the internal expertise.

MAPS is the leading institution within this emergent field and is poised to retain its leadership position by building on decades of work that has been done for the benefit of all.

Our goal is to help
heal thousands, then
tens and hundreds of
thousands, then millions
of PTSD patients.

The contract with BCG has recently concluded. Our work together has been exceptionally instructive in analyzing the tasks needed to market MDMA by prescription. BCG has developed staffing and cost estimates for commercialization in the US. They also analyzed market size, and proposed estimates for US-based income based on review of the capacity of our therapist training program to produce trained therapists, on the numbers of patients that therapists can treat per year, on a range of prices for the MDMA along with cost effectiveness data that will be evaluated by insurance companies in deciding whether to offer insurance coverage for MDMA-assisted therapy for PTSD to the people they insure. BCG reviewed income during the roughly six-year period of data exclusivity that FDA provides for medicines that are off-patent (there is 10 years of data exclusivity in Europe). During the period of data exclusivity, other companies can generate their own data if they want to market MDMA-assisted therapy for PTSD but can't use MAPS' data to market a generic version. BCG also estimated income to MAPS in the US after MDMA becomes generic.

The challenge that MAPS now faces in reaching sustainability through the sale of MDMA by prescription is primarily financial. According to the BCG report, MAPS may be able to reach sustainability sometime in 2024, assuming approval for prescription use is obtained before the end of 2023. MAPS thus will need to raise additional resources to fund commercialization expenses which are usually started two or so years prior to approval, to conduct our European research and continue our other globalization efforts for MDMA-assisted therapy for PTSD, and to support the MAPS Public Benefit Corporation staff until sustainability has been reached. We're in the process of estimating what amount of funds still needs to be raised.

Our goal is to help heal thousands, then tens and hundreds of thousands, then millions of PTSD patients. In that process, we will continue to help catalyze the mainstreaming of psychedelic-assisted therapy with hundreds of for-profit companies now part of the psychedelic corporate ecosystem, for the healing of millions more suffering from a wide range of clinical indications. The medicalization of psychedelics will also build support for drug policy reform efforts to bring about a post-Prohibition world with licensed legalization, to restore the fundamental human right to legally explore our own inner worlds.

MAPS will primarily be seeking to raise funds through philanthropy to reach a point of sustainability. We are also exploring partnerships with several for-profit companies that are interested in clinical indications for MDMA other than PTSD. MAPS has built great value in our existing data about safety of MDMA that is in large part relevant for other uses of MDMA, and we've built expertise in drug development in MAPS PBC.

The next few years will be fascinating as we build a bridge from the founding of MAPS 35 years ago in 1986 to the likelihood of sustainability in 2024. With the continued support of the MAPS community, we can build this bridge together.



Rick Doblin

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

MAPS News

Celebrating 35 Years of MAPS and Introducing Our New Logo

This year marks the 35th anniversary of the Multidisciplinary Association for Psychedelic Studies (MAPS)! On April 8, 1986, MAPS was founded as a non-profit organization by Rick Doblin, Ph.D., to develop medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. While we celebrate our accomplishments, we are also taking this time to set intentions and goals for the decades to come.

Since 1986, MAPS has shown a commitment to change and innovation for the benefit of mass mental health. As we look towards the future, we hope to continue to transform minds and build a global community which collectively values healing for all.

In that spirit, we are excited to introduce our new, reimagined MAPS logo:



We could not have achieved 35 years of groundbreaking work without supporters like you. We invite you to join our growing number of monthly donors, who are an instrumental part of our work and allow us to execute our vision to make psychedelic treatments safe, legal, and accessible.

We hope you'll join us in continuing this journey, both inwardly and outwardly, into the next 35 years of the psychedelic renaissance and mainstream integration.

Research

MAPS' Phase 3 Trial of MDMA-Assisted Therapy for PTSD Achieves Successful Results for Patients with Severe, Chronic PTSD

- *The highly statistically significant results and excellent safety record suggest MDMA-assisted therapy will be an effective treatment for severe, chronic PTSD*
- *67% of participants who received three MDMA-assisted therapy sessions no longer qualified for a PTSD diagnosis and 88% experienced a clinically meaningful reduction in symptoms*
- *The pivotal Phase 3 trial treated 90 patients with severe, chronic PTSD from any cause with an average duration of 14 years and replicated the results of Phase 2 trials*
- *Study participants included patients with PTSD caused by combat-related events; accidents; abuse; and sexual harm; 84% have a history of developmental trauma*
- *MAPS is hopeful that these results will facilitate FDA approval in 2023 for this Breakthrough-designated therapy*

The first Phase 3 trial of MDMA-assisted therapy for post-traumatic stress disorder (PTSD) replicated and expanded on Phase 2 results indicating MDMA-assisted therapy may be an effective and cost-saving treatment for PTSD resulting from any cause. Nature Medicine is expected to publish the peer-reviewed paper detailing the results of the study sponsored by the Multidisciplinary Association of Psychedelic Studies (MAPS) and conducted by MAPS Public Benefit Corporation (MAPS PBC), a wholly-owned subsidiary of MAPS. In this first Phase 3 trial of any psychedelic-assisted therapy, participants who received MDMA-assisted therapy reported a significant reduction in PTSD symptoms compared to those

who received placebo with therapy ($p < 0.0001$), successfully achieving the prespecified primary endpoint for the trial. In fact, 67% of the group who received MDMA, compared to 32% of the group who received placebo, no longer qualified for a PTSD diagnosis after three treatment sessions. In addition, participants treated with MDMA-assisted therapy had statistically significant reductions for the key secondary endpoint of functional impairment relative to placebo with therapy ($p = 0.0116$).

Jennifer Mitchell, Ph.D., lead author of the paper, calls attention to the results for those with the dissociative subtype of PTSD, with depression, or who reported a history of alcohol or substance use. “People with the most difficult-to-treat diagnoses, often considered intractable, respond just as well to this novel treatment as other study participants. In fact, participants diagnosed with the dissociative subtype of PTSD experienced a greater reduction in symptoms than those without the dissociative subtype.”

Mitchell added that MDMA serves as a catalyst to therapy: “MDMA is an experiential therapeutic and therefore necessitates the appropriate set and setting to truly guide change and recovery. While many forms of PTSD therapy involve recalling previous trauma, the unique ability of MDMA to raise compassion and understanding while tamping down fear is likely what enables it to be so effective.”

The randomized, blinded, Phase 3 trial, designed under a Special Protocol Assessment with the FDA, treated 90 patients with severe, chronic PTSD. Participants were randomized to receive three sessions of either MDMA or placebo with identical talk therapy. Forty-six participants received MDMA therapy and forty-four participants received therapy with placebo. The primary efficacy endpoint was based on the change from baseline in an independently assessed clinical interview of PTSD severity after 18 weeks. The assessors also measured average change in functional impairment in work/school, social, and family life. Among the participants in the MDMA-assisted therapy group, 67% no longer qualified for PTSD diagnosis after three MDMA-assisted therapy sessions and 88% of participants experienced a clinically significant reduction in symptoms, while in the placebo group, 32% no longer qualified for PTSD diagnosis at the two-month follow-up and 60% experienced a clinically significant reduction in symptoms.

In the Phase 3 trial, the investigators observed no serious safety or tolerability issues in the MDMA group. MDMA did not increase the risk of suicidal thoughts or behaviors and did not increase cardiovascular risk or abuse potential relative to therapy with placebo. As expected from previous clinical trials, temporary increases in blood pressure and pulse were observed



Jennifer Mitchell, Ph.D., photo © New York Times

during MDMA sessions; adverse events such as muscle tightness, decreased appetite, nausea, sweating, and feeling cold were transient.

PTSD is a profoundly challenging condition with unmet medical need. Bessel van der Kolk, M.D., a leading PTSD researcher and author of the foundational book on PTSD, *The Body Keeps the Score*, served as Principal Investigator for the Boston study site. He explains, “The experience of having been traumatized profoundly alters perceptions; self-experience; and capacity to plan, imagine and anticipate. For 88% of people who receive this treatment, we can expect to see a treatment response. This can lead to fundamental shifts in our subjects’ perspective on self-capacity, affect regulation, and attitude towards those around them. It takes a great deal of courage to address one’s PTSD, particularly when other treatments have failed. These results open the door to a potentially powerful new pathway to healing—once MDMA-assisted therapy has been approved as a treatment for PTSD.”

Listed as a Schedule I drug, MDMA presently is defined as having “no medical benefit” and, therefore, is not currently accessible as a potential treatment for PTSD or other conditions except as administered in clinical trials. “As a result of this study and through the persistent and consistent application of scientific rigor, we have demonstrated that MDMA-assisted therapy is likely to provide relief for people diagnosed with PTSD,” noted MAPS Executive Director Rick Doblin, Ph.D. “Far from having no medical benefit, MDMA, when combined with talk therapy in this protocol, has the potential to catalyze the therapeutic process and generate positive mental health outcomes.”

Michael Mithoefer, M.D., who serves as Senior Medical Director for Medical Affairs, Training, and Supervision, led the team that developed the therapy manual and trained the 70 therapists who provided the treatment in the Phase 3 study. He celebrated their efforts, stating, “The therapists and expert research team who have brought us here are at the vanguard of what may be a revolution in mental health care. The success of this pivotal study is a major step toward regulatory approval, and we hope these results will attract many more researchers and clinicians to join the effort to further explore and deliver MDMA-assisted therapy so we can together address our national—and global —mental health crisis.”

MAPS PBC develops and delivers therapy training programs and is responsible for the development of MDMA as a medicine. MAPS PBC CEO Amy Emerson describes its mandate: “MAPS Public Benefit Corporation is establishing a new paradigm in drug research, development, and commercialization in which we center our efforts wholly on the beneficiaries of our healing modality rather than shareholders. This approach commits us to open science and open books as we research best practices for psychedelic-assisted therapy. Ultimately, any proceeds from our work will be reinvested to generate more research, more training, and more affordable options for treatment.”

A second Phase 3 clinical trial is currently enrolling participants. Prior to the hopeful approval in 2023 of MDMA-assisted therapy for PTSD, the FDA has granted permission for an expanded access program in which 50 patients can receive the treatment prior to FDA approval. MAPS plans to conduct additional studies to explore the potential of the treatment for other mental health conditions and with other treatment protocols such as group therapy and cognitive-behavioral conjoint therapy for couples. Additionally, MAPS is funding a formal commitment to health equity: a holistic plan to create more pathways to access MDMA-assisted therapy for those historically marginalized by the mental health field and society at large.



Bessel van der Kolk,
M.D.

As a result of this study and through the persistent and consistent application of scientific rigor, we have demonstrated that MDMA-assisted therapy is likely to provide relief for people diagnosed with PTSD.



Michael Mithoefer, M.D.



Amy Emerson,
CEO of MAPS PBC

MAPS Wins Appeal and Authorization to Study MDMA in Healthy Volunteer Therapists

- Phase 1 clinical trials of MDMA-assisted therapy for health-care providers will measure development of self-compassion, professional quality of life, and professional burnout among clinicians delivering the treatment to patients
- The study, one of few legal means by which therapists can experience the treatment they provide in MDMA-assisted therapy for PTSD, was placed on clinical hold by the FDA for 20 months.
- FDA's Office of Neuroscience granted the appeal on the grounds of scientific merit, the absence of unreasonable risk to participants, and appropriate investigator qualifications

The U.S. Food and Drug Administration (FDA) Office of Neuroscience granted the Multidisciplinary Association of Psychedelic Studies (MAPS)' appeal of the clinical hold on the Phase 1 study after almost two years of clinical hold. Initially placed on clinical hold by the FDA in 2019, the MT2 study protocol is a Phase 1, open-label, multi-site research study to assess the safety and psychological effects of MDMA-assisted therapy in healthy volunteer therapists undergoing training to treat patients suffering from posttraumatic stress disorder (PTSD) with MDMA-assisted therapy, developed by MAPS Public Benefit Corporation (MAPS PBC), a wholly-owned subsidiary of MAPS. Personal experience is widely considered to be an important element in preparation and training to deliver psychedelic-assisted therapies.

The hold, lifted on May 11, 2021, was placed by the FDA due to concerns about the scientific merit of the study, risk-to-benefit ratio for healthy therapist participants, and the credentials of clinical investigators. If MAPS' appeal was not granted, the hold would have required that the Lead Facilitator in each two-person facilitator team hold an M.D., Ph.D., or equivalent degree and that the physician be on-site instead of on-call during the treatment sessions.

The evidence-based decision from the FDA Office of Neuroscience granting MAPS' appeal notes that this study does not differ in risk or investigator qualifications from MT1, a prior, similarly designed Phase 1 study approved in 2009, and therefore the rationale for a clinical hold is not supported.

Though drug development is often thought of as a linear progression, Phase 1 and Phase 2 investigations can provide valuable data while Phase 3 trials are ongoing. "Even though



Berra Yazar-Klosinski, Ph.D.,
Chief Scientific Officer
of MAPS PBC



Shannon Carlin, M.A., L.M.F.T.
Director and Head of
Training and Supervision
of MAPS PBC

we are in the midst of Phase 3 studies to treat PTSD, Phase 1 studies are an important area of scientific research and inquiry to generate exploratory and safety data to support new indications. We appreciate the Office of Neuroscience seeing the scientific merit of these data," says Berra Yazar-Klosinski, Ph.D., Chief Scientific Officer for MAPS PBC. Other indications such as eating disorders and social anxiety are already in Phase 2 studies, and a number of reports suggest the potential for additional future indications.

While the MT1 and MT2 studies do not provide pivotal safety or efficacy data to support the PTSD treatment indication, they serve to increase understanding of MDMA's clinical effects in a therapeutic setting as well as enhance therapist training, and may therefore prove beneficial in the treatment

of patients. As is typical for therapeutic treatments, these studies serve as a vital part of the MDMA Therapy Training Program by providing therapists with personal knowledge of the treatment; the knowledge gained from firsthand experience is invaluable, difficult to replicate, and illegal outside a clinical trial. Participants in MT1 reported the experience was an invaluable part of their training that improved their ability to provide treatment to PTSD participants in Phase 3 clinical trials. "Allowing therapist trainees to enroll in MT2 will support

the goals of the MDMA Therapy Training Program to provide comprehensive training to future providers. This work builds capacity to deliver quality, accessible care to patients, pending approval of MDMA-assisted therapy as a legal prescription treatment," says MAPS PBC Director and Head of Training and Supervision Shannon Carlin, M.A., L.M.F.T.

"This is MAPS at its best, negotiating with the FDA in an evidence-based manner with existing and new data that we analyzed specifically for our response," explains MAPS Executive Director Rick Doblin, Ph.D. "For three decades, we have sought to educate the FDA in our novel approach rather than simply

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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.

Phase 3 trial participant enrollment is now open for select study sites: mdmaptsd.org.

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.

accept FDA requirements that are unjustified by the evidence. The dedicated work and incisive strategy of our Clinical Development team continues to improve the regulatory landscape for all future patients of psychedelic-assisted medicines.”

MAPS PBC completed three requests to remove the clinical hold containing detailed information addressing the scientific benefit of the study, safety data from previous trial participants demonstrating positive risk-to-benefit ratio, and rationales for allowing licensed therapists with masters level, not doctoral level, degrees to serve as Lead Facilitator with a physician on-call. The successful dispute resolution comes after months of ongoing efforts and the engagement of the experienced legal team at Hyman, Phelps & McNamara, P.C. and lead attorney Josephine Torrente, J.D.

The Office of Neuroscience granting the appeal is encouraging for future negotiations with the FDA on requirements. “We choose to dispute MT2, not solely for its specific impact on MT2, but in an attempt to resolve an ongoing issue with the FDA regarding investigator qualifications across studies,” MAPS PBC Regulatory Affairs Manager, Allison Coker, Ph.D., notes. “The Office of Neuroscience’s agreement with our assessment establishes a precedent that can serve as guidance for developing requirements for investigators in future studies. Along with our clinical safety data, we hope this decision may also support our proposals for use guidelines post-approval.”

“While the term ‘dispute’ may seem adversarial, this process can actually strengthen the relationship and trust between us and our review Division and ensures the Division has support on this project from the Office of Neuroscience,” MAPS PBC Chief Executive Officer Amy Emerson explains. “This decision demonstrates how our strategic, data-driven strategy in challenging the FDA rulings can be successful.”



Allison Coker, Ph.D.,
Regulatory Affairs
Manager of MAPS PBC



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

The Institutional Review Board (IRB) has approved MAPS' protocol for a Phase 2, open-label randomized controlled comparative study on the effectiveness of MDMA-assisted therapy in U.S. Veterans with chronic PTSD. Led by esteemed PTSD researcher 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, the study is moving through the investigator-initiated research program of the U.S. Department of Veterans Affairs (VA). On August 25, 2020, the FDA agreed to proceed with the protocol.

The study will enroll 60 veterans and will collect further information on whether there is a difference in two versus three sessions of MDMA-assisted psychotherapy for safety and therapeutic outcome. This study will also act as a training ground for VA clinicians and therapists on the MAPS modality, and will include blood collection samples for later analysis of hormones, molecules, and other biological markers that may be related to having or recovering from PTSD. Dr. Yehuda and her team plan to conduct this trial at the VA pending DEA approval.

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

We are very excited to share updates for the open-label lead-in study of MDMA-assisted therapy for PTSD in Europe, including news about enrollment progress. Data gathered in European trials is required for a planned Marketing Authorization Application to the European Medicines Agency (EMA).

In early May, the first participant completed the second experimental MDMA-assisted therapy session at our first study site in the Netherlands. This participant is expected to complete their final study visit within the next few weeks. The second participant at this study site has completed their first experimental session and is on track to complete the second experimental session at the end of May. Screening has begun for potential patients at our second study site in Maastricht, Netherlands.

Our study site in the Czech Republic currently has its first potential participant in the screening process, and screening additional potential patients is ongoing.

At our study site in Norway, the research team is continuing to screen potential patients. Two participants are currently at various stages in the screening process. If any are eligible to proceed, the first experimental session is expected to take place in mid-June.

Further study sites in Germany, the UK, and Portugal are starting and are expected to begin patient recruitment before the end of summer 2021.

An Open-Label, Multi-Site Phase 2 Study of the Safety and Feasibility of MDMA-Assisted Psychotherapy for Eating Disorders

On May 20, 2020, MAPS received FDA agreement to conduct an open-label, multi-site Phase 2 study for MDMA as an adjunct to psychotherapy for anorexia nervosa restricting subtype (AN-R) and binge-eating disorder (BED), followed by Health Canada's non-objection on October 30, 2020.

This study will explore the safety and feasibility of MDMA-assisted therapy and adjunctive caregiver involvement in the treatment of individuals with AN-R and BED. The addition of a supportive caregiver as a treatment ally with every participant reflects this most recent development in science and practice. Supportive caregivers enrolled in the study will receive non-drug psychotherapy support. The study will enroll 12 participants who meet the Diagnostic Statistical Manual for Mental Disorders Edition 5 (DSM-5) criteria for AN-R, and 6 participants who meet DSM-5 criteria for BED, for a total of 36 participants (12 AN-R, 6 BED, and 18 caregivers).

The study will take place at three study sites. The study site in Vancouver, Canada, will include six BED participants, with Qualified Investigator Christian Schütz, M.D., Ph.D., M.P.H., overseeing the study. The study sites in Toronto, Canada, and Denver, Colorado, will each include six AN-R participants, with Michael Verbora, M.D., overseeing as Qualified Investigator in Toronto, and Co-Clinical Investigators Adele LaFrance, Ph.D., and Mike Rollin, M.D., overseeing the site in Denver.

A Phase 1 Open-Label Study of MDMA Tolerability and Pharmacokinetics in Participants with Moderate Compared to Matched Control Participants with Normal Hepatic Function

MAPS is sponsoring an open-label Phase 1 study of MDMA's effect on hepatic impairment (liver disease). While the study site is prepared, this study has not yet enrolled any participants and enrollment is on hold due to COVID-19.

The primary objective of this study is to evaluate the effect of moderate hepatic impairment on the pharmacokinetics of

oral MDMA and its active metabolite 3,4-methylene-dioxyamphetamine (MDMA). The secondary objective of this study is to evaluate the effect of moderate hepatic impairment on the safety and tolerability of oral MDMA. Led by Principal Investigators Janel Long-Boyle, Pharm.D., Ph.D., and Robert M. Grant, M.D., M.P.H., this study will be conducted at the University of California, San Francisco.

MDMA Therapy Training Program Update: Summer 2021

On Friday, May 14, 2021, the training team officially welcomed the Summer Cohort. This cohort is our largest to date, with a total of 309 trainees currently enrolled. Trainees are joining from across the globe, including those from Canada, Australia, New Zealand, South America, and Europe. Trainees are based in 30 different states in the US. Equally significant are the number of scholarships awarded and the efforts of the training team to expand the reach of the training program. A total of 80 scholarships were allocated to eligible trainees, totaling \$317,500. More than one-third of the cohort are practitioners of color. More than 25 trainers are supporting the Summer Cohort.

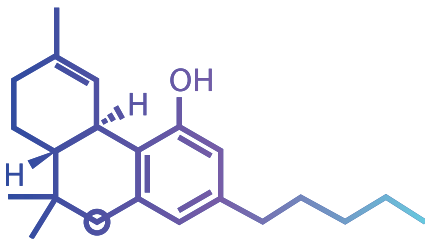
We are accepting applications for our fall 2021 cohort and future training cohorts. Please visit our training website to learn more about the MDMA Therapy Training Program. Qualified applicants are encouraged to submit our training application.

MAPS Health Equity Scholarships are available for the fall 2021 MDMA Therapy Training Cohort! Thanks to the MAPS Health Equity Fund, the MDMA Therapy Training Program is honored to offer a number of full and partial scholarships for tuition costs to eligible practitioners for the fall 2021 training. The MAPS Health Equity Scholarship is part of MAPS and MAPS PBC's larger commitment to increasing inclusion and equity in our programs and advancing the initiatives outlined by the MAPS Health Equity Fund.



To receive updates on 2021 trainings and training program admissions, sign up for the MDMA Therapy Training Program Newsletter:
mapspublicbenefit.com/training

First Controlled Trial of Cannabis for the Treatment of PTSD Raises No Safety Concerns, Further Research is Needed to Determine Efficacy



Molecular compound of cannabis

- *Widespread anecdotal reports of benefit have led to self-treatment of the symptoms of posttraumatic stress disorder (PTSD) with cannabis among Veterans and others; the safety and potential efficacy of such treatments have not previously been studied through randomized clinical trials.*
- *All three active concentrations of smoked cannabis and the placebo cannabis were generally well tolerated.*
- *While the strongest response was to a 9% THC concentration, the study did not find a statistically significant difference in change in PTSD symptom severity between strains with 9% THC, 11% CBD, 8% THC / 8% CBD combination versus placebo.*
- *The cannabis concentrations available for this clinical trial were not reflective of the quality of cannabis available through either legal or informal markets.*

A peer-reviewed paper published on March 17, 2021, in PLOS ONE analyses the results of a randomized cross-over clinical trial of the Short-Term Impact of 3 Smoked Cannabis Preparations Versus Placebo on PTSD Symptoms. The study was funded by a \$2.2 million grant from the Colorado Department of Public Health and Environment (CDPHE) to the Multidisciplinary Association of Psychedelic Studies (MAPS) and was conducted by MAPS Public Benefit Corporation (MAPS PBC), a wholly-owned subsidiary of MAPS. Though no statistically significant difference was shown between the groups, all showed improvement in PTSD symptoms during treatment with the THC group having the largest response.

“This study served as the first randomized placebo-controlled trial comparing the therapeutic potential of varying ratios of THC and CBD for treating symptoms of PTSD” said Dr. Marcel O. Bonn-Miller, Coordinating Principal Investigator and lead author of the study. “These data, coupled with those of a recently completed accompanying study also funded by CDPHE, provide better insight into why individuals with PTSD are turning to predominantly-THC-cannabis as a treatment. We now require larger randomized placebo-controlled trials to determine minimally-effective doses of THC needed to safely treat individuals suffering from PTSD while also mitigating risks of cannabis dependence in this vulnerable population.”

“One of the biggest take-aways from this study is that Veterans with PTSD can use cannabis at self-managed doses, at least in the short term, and not experience a plethora of side effects or a worsening of symptoms,” said Mallory Loflin, Ph.D., co-author of the paper and Volunteer Assistant Professor of Psychiatry at UC San Diego School of Medicine. “That’s what most providers are worried about when their patients with PTSD decide to try cannabis.”

Co-author, Site Principal Investigator, and President of The Scottsdale Research Institute Sue Sisley, M.D., notes that “This study’s safety data and other research in PTSD patients in Colorado using real-world cannabis flower are promising. Despite the absurd restrictions federal prohibitionists have placed on research for more than 50 years, we are squarely focused on launching further Phase 2 trials with imported cannabis of tested, higher potency, fresher flowers that will provide a valid comparison for the millions of Veterans and others with PTSD who are looking for new options.”

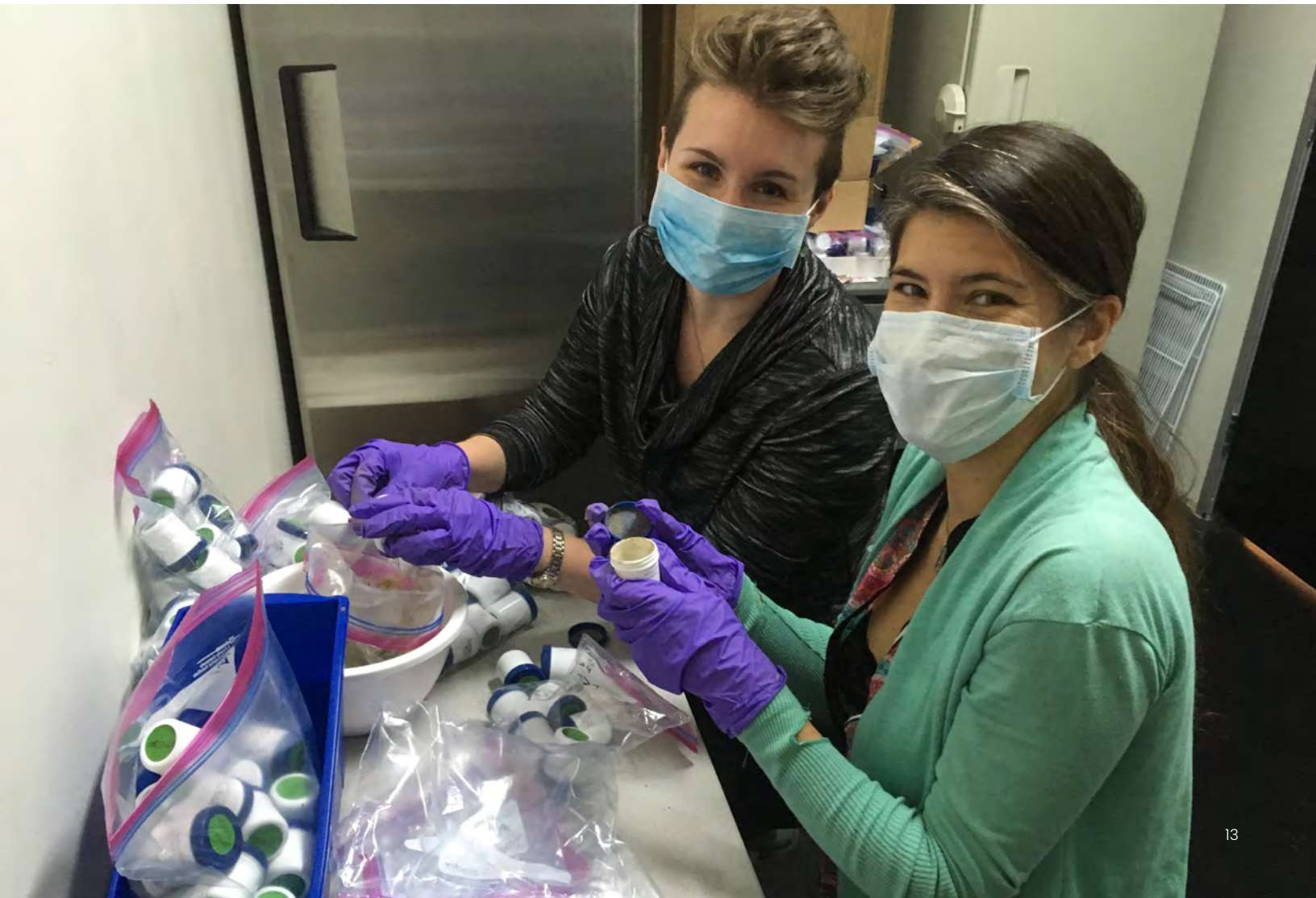
Inspired by preclinical evidence suggesting cannabis may be effective in the treatment of PTSD, this study was the first to evaluate its safety and efficacy in an FDA-regulated placebo controlled double-blind clinical trial in order to measure the effect size. Seventy-six predominantly male Veterans between the ages of 24 and 77 completed the study. In Stage 1, participants were randomized to receive prepared cannabis that was 9% THC, 11% CBD, a mix of 8% THC and 8% CBD, or placebo. All preparations were supplied by the National Institute on Drug Abuse (NIDA) which, despite MAPS' best efforts for the last 20 years, still maintains the only license in the U.S. for production of cannabis preparations for federally regulated clinical trials. PTSD symptom severity decreased among all groups but demonstrated no statistical significance between the placebo group or the groups that received cannabis as measured by the Clinician-Administered PTSD Scale (CAPS-5).

"This study took seven years to obtain approval and three years to conduct at a cost of \$2.2 million. The difference between anecdotal reports and these results may be the quality of the marijuana," said Rick Doblin, Ph.D, Executive Director of MAPS, "which highlights the need for further well-controlled

clinical trials that more closely represent currently available marijuana products. Higher quality cannabis flower suitable for Food and Drug Administration (FDA) approval is currently unavailable domestically due to restrictions on production imposed by the U.S. Department of Justice and Drug Enforcement Administration and must be imported."

It is estimated that 6-10% of the general population and 13-31% of U.S. Veterans experience PTSD. The condition is associated with high rates of comorbid physical conditions, substance use disorder, depression, and suicidality. While currently approved treatments can be effective for some, the majority of military veterans with PTSD who receive one of the best practices psychotherapies for PTSD still qualify for a diagnosis of PTSD by the end of treatment. Self-treatment of PTSD with cannabis has been increasing alongside interest among patients, clinicians, and researchers to determine if cannabis may be an effective and appropriate treatment for PTSD.

NOTE: This study was supported by funding from the Colorado Department of Public Health and Environment (CDPHE). The content and opinions are those of the grantee/authors and do not represent the official views of CDPHE.



Policy and Advocacy

MAPS Celebrates California Senate Passage of Groundbreaking Psychedelic Reform Bill

- *California Senate Bill 519 decriminalizes the personal use and possession of psychedelic substances*
- *SB 519 will establish a task force to recommend regulatory systems California could adopt for safer personal use of psychedelic substances*
- *The historic Senate vote on June 1, 2021, advanced the most expansive psychedelic policy reform to pass through a state chamber*

Fifty years after the War on Drugs was officially declared and psychedelic substance prohibition began in contravention of evidence supporting therapeutic use, the California State Senate has taken the first Legislative step to dismantle psychedelic prohibition with a 21-16 vote on June 1, 2021, in favor of Senate Bill 519 Controlled substances: decriminalization of certain hallucinogenic substances sponsored by California State Senator Scott Wiener (D-San Francisco). The Bill will now move on to the State Assembly, where its members will have the opportunity to join the 91% of Americans who believe the War on Drugs has failed. SB 519 eliminates destructive criminalization policies and creates pathways which could, in the future, address the risks of currently-illegal substances through evidence-based policies such as harm reduction, education, and regulatory measures to combat adulteration.

“SB 519 reflects California’s growing disillusionment with the War on Drugs, a decades-long public health disaster, and increasing desire for a more evidence-based drug policy paradigm. This is an exciting step toward a world where these substances can be used more safely, responsibly, and intentionally,” said Ismail L. Ali, J.D., acting Policy Director for the Multidisciplinary Association of Psychedelic Studies (MAPS). “Ongoing criminalization of drugs and people who use them increases the dangers of drug use and traumatizes communities. As medicalization moves forward through clinical trials, MAPS is committed to ensuring that psychedelic drug policy does not perpetuate a dichotomy in which people using the same substances are celebrated in a medical context but criminalized outside of it.”

Ali and members of the MAPS Policy and Advocacy Department offered expert advice and policy analysis to Senator

Wiener, which included expanding the scope of content covered by the commission proposed by the legislation. Maurice Byrd and Dr. Bob Grant, both of whom were trained in MDMA-assisted therapy for PTSD by MAPS Public Benefit Corporation (MAPS PBC), provided expert testimony to the Senate in support of the framework proposed by SB 519.

“MAPS has laid the groundwork for research showing psychedelics may have great promise in helping people deal with complex trauma, depression, anxiety, and addiction. The War in Drugs has fueled mass incarceration without making us safer or reducing substance use disorder,” said Senator Wiener. “Alongside MAPS and a coalition of dedicated allies, we’ve developed a science- and health-based approach that both reflects the transformational potential of psychedelics and begins to repair the harms of the War on Drugs.”

SB 519 is co-sponsored by combat veteran service organizations Heroic Hearts Project (HHP) and Veterans Exploring Treatment Solutions (VETS). MAPS, HHP, and VETS are part of a broad coalition of allies supporting psychedelic policy reform to increase justice, expand cognitive liberty, or support people living with the mental health conditions that, according to a growing body of evidence, are likely to experience benefits from their therapeutic use. In addition to HHP and VETS, the coalition also included New Approach PAC, Law Enforcement Action Partnership, the Indigenous Peyote Conservation Initiative, Decriminalize Nature, and Sacred Garden Community.

SB 519 decriminalizes, but does not legalize or regulate, the personal possession and use of psilocybin, psilocyn, MDMA, LSD, ketamine, DMT, mescaline (excluding peyote), and ibogaine, all of which are under investigation for their possible beneficial therapeutic use.

The bill also decriminalizes substance analysis tools, and creates a commission to study and recommend regulatory models that may, in the future, be appropriate for these substances. While Oregon voters elected to decriminalize all drugs in 2020, no state Legislature has taken such a bold step to align state psychedelic policy with the potential benefits and risks of these substances which are supported by decades of research and,

in the case of some substances, hundreds or thousands of years of ceremonial use.

MAPS hopes that in the future, such policies will include decriminalizing all drugs as well as more comprehensive reforms including funding for education and harm reduction, access to treatment, and unarmed, appropriately trained crisis response.

Ongoing criminalization of drugs and people who use them increases the dangers of drug use and traumatizes communities.

Public Education

Synergetic Press and MAPS Form Copublishing Partnership

Synergetic Press and the Multidisciplinary Association for Psychedelic Science (MAPS) are pleased to announce they have entered into a copublishing relationship effective May 1, 2021, which will greatly expand the availability of education about psychedelics and psychedelic therapy.

Since MAPS began their mission to open pathways for legal, cultural, and medical contexts for people to benefit from psychedelics in 1986, they have published many pioneers in the psychedelic movement including Stanislav Grof, Albert Hofmann, Myron Stolaroff, Claudio Naranjo, Torsten Passie, Beatriz Cauiby Labate, Phil Wolfson, and Annie Oak. As with MAPS, Synergetic Press has been a leading publisher of cutting-edge books in the field of psychedelics and consciousness. The collaboration rests in the mutually held value to make these authors' knowledge more accessible to a broader world-market. This newly formed alliance, along with Synergetic Press' other copublishing partner, Transform Press, places Synergetic Press as the leading publisher in the field of psychedelics.

"Now that the psychedelic renaissance has overcome political and financial obstacles to research, public education is the most important need," says Rick Doblin, Ph.D., founder and executive director of MAPS. "MAPS is delighted to partner with Synergetic Press to expand the reach of our publications so that people all over the world will be better prepared as psychedelics move into the mainstream."

The first title to be published under the copublishing arrangement is *Psyche Unbound: Essays in Honor of Stanislav Grof*, to be released in October 2021. Edited by Rick Tarnas and Sean Kelly, *Psyche Unbound* honors the life and legacy of Grof, a founder of transpersonal psychology and a pioneering figurehead in the practice of psychedelic therapy. Included are essays from a vast array of notable thinkers including Joseph Campbell, Huston Smith, Fritjof Capra, Frances Vaughan, Thomas Riedlinger, John Buchanan, Jenny Wade, Ralph Metzner, Paul Grof and Arlene Fox, William Keepin, Jorge Ferrer, Gerry Goddard, Ervin Laszlo, Christopher M. Bache, Tom Purton, Gregg Lahood, Jeffrey Kripal, Michael Mithoefer, and Charles Grob.

"I have watched Rick Doblin over the past thirty-five years take on what seemed impossible, that is, to change people's minds about psychedelics and pave a path to decriminalization, regulation, and medical research," shared Deborah Parrish Snyder, Publisher and CEO at Synergetic Press. "Today, he and his team have succeeded at getting very far down that road. The MAPS imprint has curated the leading voices of the industry, funding and publishing pioneering work in the field. We are proud to bring the groundbreaking books from MAPS into our ever-expanding catalog."

With this agreement, the MAPS backlist and new titles will be distributed to the trade through Synergetic Press and their distributor, Publishers Group West, part of Ingram Publisher Services.



MAPS in the Media

The New York Times

A Psychedelic Drug Passes a Big Test for PTSD Treatment

Rachel Nuwer • May 3, 2021

“In an important step toward medical approval, MDMA . . . was shown to bring relief to those suffering from severe post-traumatic stress disorder when paired with talk therapy,” says The New York Times in exclusive coverage. “Two months after treatment, 67 percent of participants in the MDMA group no longer qualified for a diagnosis of PTSD, compared with 32 percent in the placebo group.” The first completed MAPS-sponsored Phase 3 clinical trial of MDMA-assisted therapy for PTSD shows positive peer-reviewed results, marking a historic point in the field of psychedelic science.

RollingStone

Phase 3 Trial Shows Promising Results for MDMA-Assisted PTSD Therapy

Jon Blistein • May 4, 2021

“As is widely known, MDMA boosts serotonin, oxytocin, and dopamine to create feelings of euphoria, empathy, trust, and compassion; in a therapeutic context, it also seems capable of re-opening what neuroscientists call the “critical period” — a moment in childhood where the brain is capable of making and storing new memories.”

The New York Times

The Psychedelic Revolution Is Coming. Psychiatry May Never Be the Same.

Andrew Jacobs • May 9, 2021

MAPS is featured in an article on the front page of May 9 edition of The New York Times! Reporter Andrew Jacobs profiles MAPS Founder and Executive Director Rick Doblin, Ph.D., and highlights the success of MAPS' first Phase 3 study of MDMA-assisted therapy for PTSD, the results of which were published in Nature Medicine earlier today. “After decades of demonization and criminalization,” explains Jacobs, “psychedelic drugs are on the cusp of entering mainstream psychiatry, with profound implications for a field that in recent decades has seen few pharmacological advancements for the treatment of mental disorders and addiction.”

RollingStone

How a Psychedelics Call-In Line is Helping People Trip Better

Delilah Friedler • July 7, 2021

Rolling Stone profiles Fireside Project's Psychedelic Peer Support Line, highlighting the experience of a caller who recently utilized the free harm reduction service.



How MDMA-Assisted Therapy Could Treat PTSD in Ways Current Therapy Can't

Nicholas Nissen • May 13, 2021

In an article featuring the perspective of MAPS Founder and Executive Director Rick Doblin, Ph.D., ABC News covers MAPS' efforts to make MDMA-assisted therapy for PTSD a legal prescription medicine, focusing primarily on the successful results of the Phase 3 clinical trial of MDMA-assisted therapy for PTSD, which was sponsored by MAPS and published last week in Nature Medicine. Doblin cautions, however, that although the historic study is now published, “the hardest parts are still ahead.”



The Case for Using MDMA to Help Heal Victims of Trauma

Scott Shannon • May 18, 2021

“In the 30 years since the pharmaceutical revolution began, psychiatry may be the only medical field to lose ground to its diseases,” says Scott Shannon, M.D. “Until MDMA, perhaps.”



A New Study Points to MDMA as a Powerful Treatment for PTSD

Jeffrey Kluger • May 11, 2021

TIME contextualizes the findings of the first Phase 3 clinical trial of MDMA-assisted therapy for PTSD, providing a brief overview of the challenges that face people who experience PTSD, as well as the MAPS-sponsored study's statistically significant results. "I speculate that the demand will be unprecedented," says Jennifer Mitchell, Ph.D., lead author of the study. "There are so many people suffering from PTSD and the current treatment options leave much to be desired."



Psychedelics in Psychiatry: New Data Supporting an Old Idea

Joe Pierre, M.D. • May 3, 2021

"This is an important study because it's the largest study done to date, with results that—similar to previous smaller studies—are encouraging."



MDMA Could Help Trauma Survivors Face Painful Memories

Rachel Schraer • May 13, 2021

BBC News provides their international audience with an in-depth overview of Nature Medicine's publication of peer-reviewed results from the MAPS-sponsored Phase 3 clinical trial of MDMA-assisted therapy for posttraumatic stress disorder (PTSD), including expert perspectives on the data, scientific education about trauma, and details about the pathway toward making MDMA-assisted therapy a legal prescription treatment option for PTSD.

"This trial, run by US charity the Multidisciplinary Association for Psychedelic Studies [MAPS], found 88% of people had a 'meaningful reduction in symptoms' and 67% no longer qualified for a PTSD diagnosis at all after 18 weeks and three sessions of MDMA-assisted therapy," reports Rachel Schraer of BBC News. "[MAPS'] chief scientific officer Dr. Berra Yazar-Klosinski said MDMA could be legalised and available for prescription by 2023 in the US, and this summer she plans to travel to Europe to begin the process of seeking regulatory approval from the EU and the UK."



A Psychedelic Drug Boom in Mental Health Treatment Comes Closer to Reality

Eric Rosenbaum • May 10, 2021

In a new article from CNBC, journalist Eric Rosenbaum explores how the first completed Phase 3 clinical trial investigating the treatment of posttraumatic stress disorder (PTSD) with MDMA-assisted therapy is leading to a "psychedelic drug boom in mental health treatment," referencing the recent peer-reviewed publication of results from the MAPS-sponsored research in Nature Medicine. CNBC highlights how the promising results are supporting potential prescription use of MDMA-assisted therapy becoming approved by the FDA by 2023, noting that future access to psychedelic therapy may help mitigate the increasing prevalence of mental health conditions impacting large portions of the world.

MAPS in the Media, continued

SCIENTIFIC AMERICAN

MDMA Shows New Promise for Trauma, but the Drug Alone Is Not a Cure

Zoe Cormier • May 12, 2021

Scientific American explores how the future of mental healthcare may be impacted by MAPS' first Phase 3 trial of MDMA-assisted therapy for PTSD, the results of which were published one week ago in Nature Medicine. In the article, MAPS Founder and Executive Director Rick Doblin, Ph.D., reflects on the success of the study, stating, "I expected this to work, but the big surprise was how statistically significant it was."

Newsweek

Psychedelic Drug Shows Great Promise As Mental Health Treatment, New Study Finds

Adam Piore • May 10, 2021

"What the MDMA clearly did, is it allowed people to go into dark places where ordinarily they did not want to go," says Bessel van der Kolk, M.D., a Principal Investigator of MAPS' Phase 3 trial of MDMA-assisted therapy for PTSD, in Newsweek. "Sometimes they were quite upset during the sessions. But they always came up with unexpected attitude changes, insights, insights that were more than just intellectual, that often gave them an entirely different orientation towards themselves. Self-forgiveness became a very important part of it also, replacing self-blame for what happened."

BARRON'S

The First Phase 3 Success for Psychedelics Will Pave the Way for an Industry

Bill Alpert • May 11, 2021

Author Bill Alpert of Barron's contrasts MAPS' leading non-profit and public benefit models with the profit-oriented approach of new psychedelic companies. "None of the for-profits are talking about drug policy reform," highlights MAPS Founder and Executive Director Rick Doblin, Ph.D.

GOOD HOUSEKEEPING

Are Psychedelics the Next Big Cure?

Meryl Davids Landau • June 10, 2021

Psychedelic research "studies that have been completed, while preliminary, have been nothing short of amazing," declares Good Housekeeping, as advancements in psychedelic science continue to reach new audiences.



The Joe Rogan Experience: #1661 – Rick Doblin, Ph.D.

Joe Rogan • June 4, 2021

Joe Rogan hosts MAPS Founder and Executive Director Rick Doblin, Ph.D., for his third appearance on the Joe Rogan Experience, one of the top podcasts in the world! Listen to the brand new, long-form podcast episode for a dynamic overview of MAPS' recent accomplishments in the field of psychedelic science and how you can sustain MAPS' mission moving forward.

healthline

Psychedelic Therapy Is Having a Moment – Here's What You Need to Know

Kate Robertson • May 25, 2021

Healthline provides a well-rounded overview about the basics of psychedelic-assisted therapy, including the current research applications and statuses of various psychedelics, stages of the therapeutic process, and potential risks associated with psychedelic use.

The Guardian

The Psychologists Signing Up for Psychedelic Therapy Training: 'Amazing Things Can Happen'

Jenny Valentish • May 29, 2021

The Guardian reports on the psychedelic renaissance in Australia, profiling the experiences of several mental health professionals who are undergoing training in psychedelic-assisted therapy and highlighting the decision of Australia's federal government "to back psychedelic clinical trials with \$15m."



How MDMA Can be Used to Treat Severe Post-Traumatic Stress Disorder

May 18, 2021

"MDMA was a therapy drug before it became a party drug," says MAPS Founder and Executive Director Rick Doblin, Ph.D., in an interview with NBC News Now, "and we're trying to bring it back to being a therapy drug."



Brookline Therapists See PTSD Patients Improve Significantly With Experimental Ecstasy Therapy

Liam Martin • June 29, 2021

MAPS-sponsored therapists join CBS Boston to discuss MAPS' first Phase 3 trial of MDMA-assisted therapy for PTSD, including details about the therapeutic process and study results. Boston-based therapist Jim Hopper, Ph.D., points out the importance of a study participant's "inner healing intelligence" throughout the MDMA-assisted therapy sessions.

BUSINESS INSIDER

Experts Share How a Brewing Fight Could Shape the Future of the \$100 Billion Psychedelics Industry

Yeji Jesse Lee • June 2, 2021

"Rick Doblin, the organization's founder and executive director, said he isn't interested in filing patents related to its work with MDMA. Instead, MAPS is focused on data exclusivity, a protected period of time granted to FDA-approved treatments before rivals can sell similar versions."



Announcing MAPS' Values and Principles

Natalie Lyla Ginsberg, M.S.W.
and Ismail Lourido Ali, J.D.

MAPS' Values were first introduced over a decade ago. The existential inquiry posed to healthcare organizations during the COVID-19 pandemic, and the stark reminder of vast racial inequity in healthcare, gave MAPS a meaningful opportunity to clarify and refine our own commitments to ourselves and to our community. We set out to update and expand our Values, and for the first time, we articulated MAPS' core principles.

We sought to memorialize the values and principles that have guided and grounded MAPS for the past thirty- five years, and simultaneously encourage our collective growth by committing to long-held aspirations. We hope our community will join us in our work to center these principles and values in all that we do.

MAPS' **4** Core Values

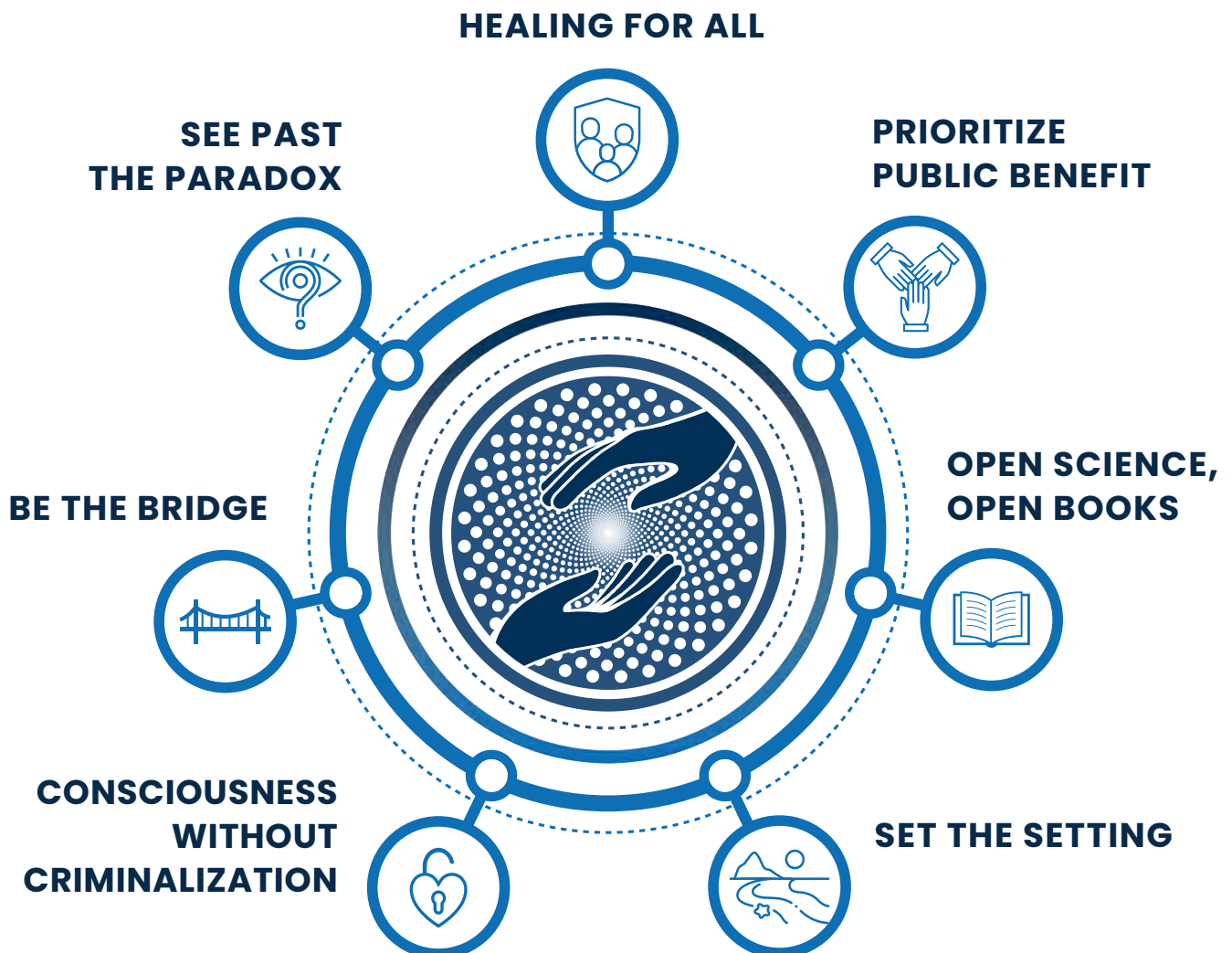
- 1 Integrity** Information is shared transparently. Communications are respectful, honest, and forthright, and our decisions are informed by compassion and research.
- 2 Perseverance** We mindfully persist in the face of challenges, and we build with a balanced, long term vision.
- 3 Curiosity** We are always open to new possibilities: we try new things, take risks, and learn from our mistakes.
- 4 Equity** We work for ethical and equitable access for all.

These values ground and inform MAPS' Seven Principles, integrating our values into our daily work. To develop these principles, we sought input from MAPS and MAPS PBC staff and board members, and reflected on our own understanding of fundamental psychedelic values.

We also drew inspiration from a number of sources. The 10 Principles of Burning Man have inspired many of MAPS staff, board and community to build a loving and sustainable community, and we similarly hope MAPS' 7 Principles can support our broader community in its multitudes of creation, inspiration, and healing. We were deeply influenced by Adrienne Maree Brown's principles of Emergent Strategy and Dr. Bronner's 6 Cosmic Principles. MAPS Founder Rick Doblin has also long drawn on Saul Alinsky's "Rules for Radicals," and many in the MAPS community are guided by the late John Perry Barlow's "Principles of Adult Behavior." We also applaud the North Star pledge, a strong starting point for conscious psychedelic businesses.

Now without further ado...

THE 7 PRINCIPLES OF MAPS



MAPS' 7 Principles

1 Healing for All

We proactively and creatively work to overcome cultural, legal, and economic barriers to equitable psychedelic access.

We work to catalyze mass mental health and spirituality with the belief that saving one life saves a whole world.

2 Prioritize Public Benefit

We prioritize the good of our collective humanity and planet over organizational or individual gain.

We strive to honor the communities, ancestral and modern traditions, and struggles we have learned from by practicing reciprocity and working for the good of future generations.

3 Open Science, Open Books

We commit to sharing what we learn and create, including, our findings, protocols, and finances.

Transparency creates a culture of accountability and contributes to the public domain, facilitating ethical collaboration toward a greater shared purpose.

4 Set the Setting

We approach everything we do like a journey: with clear intention, a resolve to face our shadow, and a commitment to ongoing integration.

Guided by history and inspired by visionary possibilities, we aim to build foundations and tools for symbiotic and inclusive ecosystems.

5 Consciousness without Criminalization

We advocate for the dignity and rights of all people who use drugs, free from fear and stigma.

We firmly reject criminalization of people for growing, making, distributing, or using drugs.

6 Be the Bridge

We build common ground between the medical, the mystical, the marginalized, and the mainstream.

Uniting divergent communities and traversing new territory demands spiritual audacity.

7 See Past the Paradox

We take an incremental approach to radical change.

We employ a diversity of tactics, perspectives, and strategies because we recognize the wisdom that unites seemingly paradoxical approaches.

Everyone carries a piece of the puzzle.

MAPS is committed to working towards upholding and embodying these principles and values in our daily work, and we are grateful for our community and supporters who constantly teach and remind us how to do so with integrity. We look forward to the ways these principles can help us collectively manifest the future we all know is possible.

Investigator-Initiated Trials

From Process to Change

Valerie Ahanonu, B.S.



As MAPS Public Benefit Corporation (MAPS PBC) continues to work toward completing Phase 3 clinical trials and submitting a New Drug Application (NDA) for MDMA-assisted therapy for PTSD to receive prescription approval, the IDEA team have worked to create a beautiful and ever-growing network of investigator-initiated trial (IIT) clinicians whose passion and innovative questioning help to inspire new possibilities within our path to expanding patient access and the conditions that MDMA-assisted therapy may be possible in treating.

By design, investigator-initiated trials (IITs) are unique clinical trials sponsored and implemented by clinicians to investigate a specific product or disease they have interest in furthering within their field. The U.S. Food and Drug Administration (FDA) defines an investigator as “an individual who both initiates and conducts a clinical trial, and under whose immediate direction the investigational drug is administered.” (Klein & Johnson, 2015). The clinician has the responsibility to comply with federal regulations applicable to both the Sponsor and the Investigator.

As both the Sponsor and Investigator, our IIT Clinical Investigators (CIs) take on a daunting feat when they begin the impactful steps towards reaching out to MAPS PBC. By partnering with MAPS PBC for trial oversight support and investigational product (IP), our MDMA-assisted therapy model, an investigator creates opportunities to not only gain experience in FDA regulated research, but to be trained in and introduce psychedelic clinical medicine to their community.

An IIT CI first starts their process with MAPS PBC by submitting a concept proposal. This introduces a specific question within MDMA research or a specific patient population that has not been focused on in psychedelics and has the potential for supporting further proof-of-concept data that might help MAPS PBC find new research pathways to study in the future [1]. IITs also support a more economical approach to conducting research and offer more options for access to patients with some of the most difficult to treat issues.

The IIT team reviews each concept proposal and initiates a discovery call that helps to educate and provide resources to each investigator. MAPS PBC’s IIT team, over the last year, has been working to address the typical barriers that many clinicians face as they begin to develop a passion for exploring their own capacity to treat

outside of standard practices. Our discovery calls serve as an introduction to timelines, regulatory requirements, funding, patient access and the institutional/logistical/community support aspects that are required for clinical research. Each of these components, when not thoroughly planned, can prove to be a challenge when conducting IIT research. To support the safe administration and implementation of psychedelic therapy research, we take great care to truly prepare our investigators for what can be a process that takes up to a year or more, from concept proposal to the first participant's enrollment in an IIT trial.

Once a concept proposal has been supported by the IIT team and approved by the MAPS PBC/MAPS Leadership Team, our IIT team becomes a conduit to navigating and supporting the required aspects the clinician must take on to develop their clinical protocol, implement funding and staffing for the trial, obtain the necessary regulatory approvals and licensure for IP receipt, obtain training for MDMA-assisted therapy administration and trial conduct, set up their clinical site for conducting MDMA research, and meet all FDA sponsor expected trial requirements. IIT research success operates on an investigator's willingness to navigate the many layers of sponsor and investigator requirements, the passion to implement their protocol, and on the IIT team's ability to support the investigator and meet them where they are in their experience and needs.

Many of our investigators find protocol development and funding to be the most difficult aspects of starting an IIT clinical trial. With over 100 concept surveys received to date, it is the goal of our IIT team to help provide the knowledge and process-mapping needed to support the safest and most realistic approach to helping each investigator meet their FDA obligations, while still staying true to the research question within their patient population. As a non-profit benefit corporation, we also understand the challenge of fundraising, so we help to support discovering pathways to funding our IIT study programs when needed. Within the holistic learning approach MAPS PBC takes to IITs, it is each clinician's innovative questioning, fortitude to push through research challenges, and passion for healing that drives the efforts the MAPS PBC's IIT team works to infuse into each of our IIT partnerships.

MAPS and MAPS PBC are driven by their passions for education, social justice, economic welfare and health equity for all, with a continued and growing focus on the disparities

that continue to plague our globe at a systemic level. We have created a purposeful and unique position as a public benefit and education-based company, to not only impact the field of psychedelics, but to create a web of opportunity and knowledge for both patients and clinicians from many cross-sectional communities and backgrounds, to align on the possibilities psychedelic medicine may hold for them. The COVID-19 pandemic served as a beacon to further open many of our eyes on the depth of the ingrained lack of sufficient healthcare access many minority groups face in our country. Many of our IIT CIs have dedicated their lives to treating within these populations, and despite the challenges COVID placed on practitioners this year, have partnered with us to create IIT trials that we believe may not only provide relief to those who participate in the trial, but also have lasting impacts on diversifying patient access and creating health equity in our society.

To highlight the passion and wealth of possibility displayed within our growing community of clinicians, MAPS PBC is honored to share impact statements from three of our IIT Clinical Investigators currently dedicated to implementing an IIT program with us. Their commitment to innovative research questioning and to healing their patients is invaluable to the work that MAPS PBC does. We are grateful for their support on growing the scientific body of data contributing to furthering psychedelic research and the equitable treatment of mental health in the communities they serve.

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Investigators: Willa Hall, Ph.D., Licensed Clinical Psychologist and Casey A. Paleos, MD

Location: Nautilus Sanctuary • New York, NY
nautilusanctuary.org

IIT Title: *An Open Label Study to Treat Post-Traumatic Stress in COVID-19 Health Care Workers Using MDMA-Assisted Therapy*

“Our desire to take on an IIT at Nautilus Sanctuary is motivated by our deep appreciation for the transformative healing power of MDMA-assisted therapy and our passion for expanding access to those whose lives stand to profoundly benefit from its effects, but for whom legitimate forms of this therapy remain unavailable outside of a research context. Beyond the direct impact we anticipate this therapy will have on the suffering

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of our clinical trial participants, we also hope to provide a meaningful volume of practicum experiences and clinical case supervision to recent graduates of the MDMA-assisted therapy training programs, to help populate the ranks of fully qualified MDMA-assisted therapists, who will be in high demand post-FDA approval. We also hope that the data we generate will deepen our understanding of the nature and impact of this work, contribute to its mainstream legitimacy and acceptance, and expand the parameters within which the FDA will permit this work to be conducted post-approval. Finally, our decision to focus on COVID-related post-traumatic stress in health care workers is informed by an intimate understanding of the profound personal cost that is often exacted from caregivers in the act of attending to the suffering of others, particularly under conditions characterized by life-or-death consequences, high degrees of uncertainty and unknown levels of personal danger. These conditions certainly prevailed in the Spring of 2020 as the New York City health care system bravely withstood the brutal brunt of the COVID-19 pandemic's initial, terrifying incursion into the American continent. Above all else, it is motivated by a deeply felt desire to be of service to our fellow comrades in the health care professions, who have given so freely of themselves in the service of our community in this historic hour of its need."

Investigator: Lawrence (Larry) Leeman, MD, MPH

Location: University of New Mexico Maternal Child Health Program

IIT Title: *MDMA-Assisted Therapy for Postpartum Women with Opioid Use Disorder and Coexisting Post Traumatic Stress Disorder*

"My IIT is MDMA-Assisted Therapy for Postpartum Women with Opioid Use Disorder and Coexisting Post Traumatic Stress Disorder. I am a Family and Addiction Medicine physician caring for pregnant woman with opioid use and their babies in New Mexico. I have seen a recurring pattern of women relapsing during the first postpartum year, as we have treated their opioid dependence but not the underlying trauma and PTSD. The trauma is often personal and attributable to sexual assault and violence, with the added effects of systemic racism for our primarily Latina and Native population. The addiction and underlying trauma may be transgenerational and epigenetic, as they may have affected the pregnant woman's family of origin and can now affect her ability to bond with and nurture her newborn. Our objectives are to study the effect of MDMA-assisted therapy on PTSD in postpartum women, the effect of treating PTSD on the likelihood of postpartum relapse of their opioid use, and to observe the effect of treating PTSD on maternal

infant-bonding and attachment. We will offer the women the opportunity to bring their infants into the medication sessions about five hours after receiving their MDMA. My awareness of the research on MDMA and PTSD, as well as classic psychedelics for addiction, led me to design and propose this IIT. As part of my preparation for working with psychedelic therapies for addiction, I have taken a partial sabbatical from the University of New Mexico to complete the CIIS Certificate program on Psychedelic Assisted Therapies and Research and participate in research at the University of Wisconsin on Psilocybin and Opioid Use Disorder."

Investigator: Darron T. Smith, Ph.D., PA-C, DFAAPA

Location: University of Memphis Department of Sociology

IIT Title: *Safety, Feasibility, and Preliminary Effectiveness of MDMA-Assisted Therapy Compared to Neurofeedback Training for Race-Based Trauma in African Americans*

"In my capacity as an African American healthcare provider, researcher, and educator, I have always been deeply passionate about the plight of stigmatized minority groups in the U.S. and how systemic white racism negatively impacts access to society's most valued resources and opportunities. More importantly, how race-based mistreatment in the form of daily microaggressions persist, despite Constitutional guarantees that all men and women are created equal. My research on racism has led me to conclude that black antipathy wounds the soul and gets beneath the skin shortening the life span of its victims. The sequela brought about by white imposed systemic racism not only affects physical health, but also brain cognition and function. In other words, the cumulative impact of racism can lead to the development of a debilitating form of race-based posttraumatic stress disorder symptomology or racial trauma. Seeing black family members, friends, students, patients and fellow colleagues recount experiences where race-based microaggressions and the stress it engenders was a call to action for me.

I believe the potential impact of this study will be a greater insight into the relationship between how African Americans live with persistent racial stress ranging from hair touching, name-calling, to police involved shootings where the victim was black and unarmed. These experiences keep the body in a state of constant fight or flight robbing people of precious mental resources needed to sustain the rigors of life. My deepest wish is that in our study on racial trauma, we find that there is synergy when MDMA is administered with neurofeedback therapy.

Valerie Ahanonu is the former Clinical Program Operations Manager at the MAPS Public Benefit Corporation (MAPS PBC), and led the Pilot, Investigator-Initiated and Expanded Access trials, and Clinical Operations teams in the successful growth and execution of MAPS PBC non-Phase 3 clinical programs.

Given the evidence of neuroplasticity with many hallucinogens such as MDMA, and similar findings in the neurofeedback scientific literature, the brain learns through experience.

We simply do not have enough information regarding how psychedelic substances work with a diverse population. Most studies conducted on hallucinogens over sample white participants with little or no people of color. In this respect, these same studies are somewhat limited in the clinical information gained without a diverse representative sample population to draw from. This opportunity to study racial trauma came about after years of research into the cause and effect of systemic white racism and the need to address the many health consequences. Also, there are not enough scholars doing this kind of work as it was not taken seriously if race was a central factor. The murder of George Floyd brought about greater public awareness to the reality of institutional racism and the unjust and unequal treatment that Africans Americans have faced at the hands of the police for decades. In that moment, I knew this would be a topic worthy of study. I'm grateful to the MAPS organization for sharing my interests and seeing value in diversity and inclusion."

These clinicians willing to explore and invest in their patients, meeting them where the current scope of treatment may not yet have answers, drive the impact of investigator sponsored research. IIT research helps provide clinicians room to educate themselves, other providers, and their patients, about what is possible and may provide the answer to potential relief for many other patients who have not had access to supportive medical alternatives, especially those affected by the systemic nature of the development of health equity in our country or who may not have economic access to treatment at all.

The complex web of navigating one's own mental health care can be an overwhelming and lonely experience, particularly for minority communities or people who have tried many standard-of-care treatments and have not yet found relief. Finding a healthcare provider who is committed to taking the time to walk through the complex web is something every patient seeking solace hopes for. For many people this means opening themselves up to new ideas and treatment modalities that may seem unconventional, but with the right clinician willing to explore and question new potential treatment methods, it could be the difference between sheltering through acute pain and living life again.

Every person has the potential to be affected by IIT research and can support the vital growth and interest needed to continue expanding access to psychedelic therapies. Each of us can invest in prioritizing our mental health and the health of those around us, particularly those suffering from lack of access. Invest time in understanding your own health rights and needs; write to your local legislation regarding state support of healthcare and research grants within your community; talk to your practitioners and loved ones in an open, exploratory, and educational dialogue; get involved in supporting local research in your area through hospitals, community clinics, and universities; and donate to research that is impactful to your community. An investment in investigator research is an investment in the future health of us all.

We extend our gratitude to the research team managing our IIT program: Rebecca Matthews, Hailey Gilmore, M.P.H., and Michael Mithoefer, M.D.

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MAPS Harm Reduction Department Initiates Psychedelic Response Training for Denver First Responders



Sara Gael, M.A., and Bryan H. Lang

MAPS has been providing psychedelic harm reduction and peer support services at festivals and events since the early 2000s. For over 20 years, MAPS staff and volunteers have engaged in peer support provision at numerous events where psychedelic use was being explored in the setting of what is today known as transformational festivals and events. Over the years, MAPS approach to psychedelic support has been informed through collaboration with other groups and organizations within the fields of psychedelic research and therapy and built upon the knowledge and principles of early psychedelic care pioneers. The Zendo Project, the flagship program of the MAPS harm reduction department was officially launched in 2012 at the Burning Man event. Over the past 9 years, the Zendo Project has provided psychedelic peer support services at dozens of events around the world and assisted over 6,000 individuals experiencing difficult emotional experiences, psychedelic or otherwise.

Education Rooted in Experience

From its inception, public education has been a primary focus of the harm reduction department. The Zendo Project has provided peer support training to over 5,000 individuals. We have facilitated over 40 training workshops to volunteers and the public. Zendo Project staff have given presentations at over two dozen conferences worldwide and have been invited to speak on numerous podcasts, webinars, and online panels.

In collaboration with the MAPS Communications and Events department, the Zendo Project curated two annual webinars and an annual lecture series featuring leading pioneers and experts in the fields of psychedelic harm reduction, research, and



therapy. The public education and outreach of the departments has inspired and seeded the psychedelic field for other organizations and individuals to psychedelic harm reduction and peer support.

The Zendo Project was born out of the festival and events industry. However, the experiences, learning, and the expertise forged in providing psychedelic crisis care was never meant to stay solely within the context of mass gatherings. Music and arts festivals and events can be seen as a type of microcosm. What we learn in these settings is directly transferable to the larger society. As is the case in society, at mass gatherings multiple health and safety departments work together to help ensure the health and safety of the public. At events we have attended, we have worked in close collaboration with other health and safety providers including paramedics, security, law enforcement, and mental health crisis intervention teams.

Uniquely positioned as a leader in the psychedelic field, the MAPS Harm Reduction Department now plans to take what has been learned at events and festivals out into the public sector, integrating psychedelic harm reduction into existing health and safety infrastructure and informing policies and protocols related to psychedelic use..

Decriminalization and Harm Reduction

In May of 2019, the City and County of Denver passed Ordinance 301, becoming the first U.S. city to effectively decriminalize the personal use and possession of psilocybin mushrooms and making personal psilocybin use the lowest law enforcement priority. Mandated by the passage of Ordinance 301, the Denver Psilocybin Mushroom Policy Review Panel (DPMRP) was formed, a first-of-its-kind panel whose primary purpose is to collect data and advise policymakers on the effects decriminalization may have on the community, including but not limited to health, safety, and fiscal impacts.

In February 2020, MAPS Harm Reduction Officer and former MAPS Director of Harm Reduction Sara Gael was appointed as the harm reduction advocate for this effort. The panel is comprised of two members of city council, two proponents of Ordinance 301, one certified addictions counselor, one harm reduction advocate, one representative from the Denver Police Department, one representative of the Denver Sheriff Department, one criminal defense attorney, one representative from the Denver District Attorney's Office and one representative from the Denver City Attorney's Office.

The panel implemented a harm reduction training working group to discuss the possibility of integrating psychedelic harm reduction training into City and County of Denver Health and Safety Departments including the Denver Police and Sheriff Departments, mental health co-responder units, Denver Paramedics, and the Denver Fire Department. On September 11, 2020, the panel voted to involve the Multidisciplinary Association for Psychedelic Studies (MAPS) in their harm reduction training initiative.

Goals of the Multi-Responder Training Initiative

At MAPS, a team of over 20 professionals has been engaged to undertake the curriculum and training development effort. The team has backgrounds in risk management, law, medicine, psychiatry, mental health, neuropsychopharmacology, law enforcement, crisis response, quality improvement, insurance, education, certification, human resources, and information technology.

The curriculum is undergoing development according to the gold standard medical education model used for instructing physicians at academic medical centers.

The overarching goal of this training initiative is for first responders to enhance their knowledge, attitudes, and skills required to quickly recognize and effectively respond to emotional and behavioral crisis incidents involving psilocybin and other psychedelics. Paramount to the success of this program is enhancing responder safety and reducing risk and liability in situations where individuals are experiencing a psychedelic-induced crisis.

This initiative expects to deliver a comprehensive public safety and risk reduction curriculum developed to support the following goals:

1. Provide education to create understanding of psilocybin usage, psychological and physiological response, and potential adverse effects of psilocybin ingestion
2. Demonstrate the need—and legal considerations—for proper education of first responders
3. Create standards and protocols for effective psilocybin-related crisis response planning, training, and deployment
4. Increase the knowledge, capabilities, and preparedness of city first responders to effectively respond to psilocybin-related crises.

Training development encompasses substantial research into the problems, current approaches, and ideal responses, so that gaps are identified and filled by the curriculum. Multiple pilot programs will be conducted and feedback assessed and incorporated into the training design.

The Denver Harm Reduction training initiative has been enthusiastically received by City of Denver leadership. We are looking forward to offering training based on this program to other municipalities and states where psychedelic reform has passed leaders understand that psychedelic harm reduction improves public health and safety.

In Spring of 2021, the Denver Psilocybin Mushroom Policy Review Panel is delivering a Comprehensive Report to the city, which will include the findings and learnings of the panel and recommendations to inform public policy decisions. In addition to continuing to advance the training initiative, the panel is advocating for increased public edu-

cation and awareness around psilocybin mushrooms, including possible benefits, and exploring the potential for psilocybin therapy and research in the city and county of Denver.

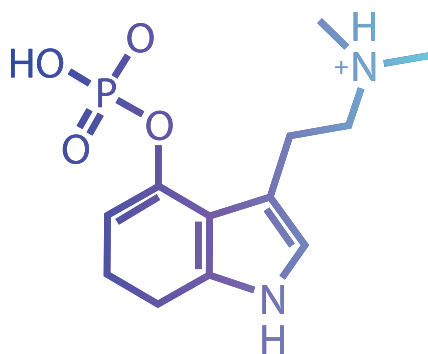
Creating a Model for a Post-Prohibition World

Recent surveys indicate that individuals are using psychedelics now more than ever, and this use spans all age groups. This increase is accompanied by a lack of widespread public informational campaigns highlighting potential risks of adverse experiences. The absence of such information, combined with a growing number of first-time users, would predictably increase the incidence of psilocybin-induced crises which would in turn warrant deployment of first responders. Most educational substance use programs focus on opioids and methamphetamines and do not address the differing effects and impacts of psychedelic substances. As such, specialized training focusing on effective approaches for first responders to psilocybin-induced crises stands to increase public safety and responder safety while minimizing risk of first responder liability.

It will forever be important to provide psychedelic harm reduction services at events and gatherings where psychedelic use may be more concentrated. However, as psychedelics become more integrated into our society and people choose to take psychedelics in other settings—at home and in nature, and in community—it is important that society's first responders are equipped with knowledge and education about psychedelics to help them adequately respond to potential adverse effects.

The majority of individuals who choose to take psychedelics do so outside of clinical or ceremonial settings. As we explore the vast potential benefits of psychedelics as a society, it is also our responsibility to help people adequately understand and mitigate risk. The vast majority of psychedelic experiences have little to no severe physical or psychological adverse effects or impact, but emotionally or psychologically challenging or uncomfortable psychedelic experiences are not uncommon. The very nature of the psychedelic state, with its varied sensations, expressions, and dynamics, can be disorienting, confusing, and at times frightening.

A small percentage of people may respond particularly adversely to psychedelics. Some experiencing psychedelic-induced altered states can become unstable and erratic, which in turn can



Molecular compound of psilocybin, the active ingredient in psychedelic mushrooms

Bryan H. Lang is CEO of Trans World Health Services, Inc., an international healthcare consultancy and IT firm. His has served over 400 commercial, government, military, and not-for-profit organizations on five continents in medical performance improvement, risk management, artificial intelligence, aviation, and neuropsychopharmacology. His first organization became the first publicly-listed population health management company. Processes and systems on which he led development supported care for 93 million Americans as well as all hospitals in NHS England. His interests in PTSD and chronic conditions led to publications on psychotropic crisis care as well as design and development of artificial intelligence-based care management systems.

Sara Gael received her master's degree in Transpersonal Counseling Psychology at Naropa University. She began working with MAPS in 2012, coordinating psychedelic harm reduction services at festivals and events worldwide with the Zendo Project. She served as the Director of Harm Reduction at MAPS from 2017-2020. Sara continues to train individuals and organizations in principles of psychedelic peer support. She is a therapist for the MAPS clinical trials of MDMA-assisted psychotherapy for PTSD in Boulder. She maintains a private practice as a psychotherapist specializing in trauma and psychedelic integration. She has presented at conferences, universities, and events around the world. She serves on the board of directors at DanceSafe and as the harm reduction advocate on the city of Denver psilocybin policy review panel. Sara believes that developing a comprehensive understanding of psychedelic medicines through research and education is essential for the health and well-being of individuals, communities, and the planet.

lead to harmful behaviors. People experiencing psychedelic crises who are subject to inappropriate first response have been shown to experience severe adverse outcomes including trauma.

Honest and informed education is necessary for both individuals who choose to use psychedelics as well as the psychedelic movement itself. Psychedelic research and the exploration of its therapeutic potential during the mid-20th century was disrupted and impacted in no small way by the inability of the psychedelic movement to effectively address and navigate adverse psychedelic experiences. We must do better this time around by providing adequate education, information, and tools to help our society deal with the complex psychological and emotional territory of the psychedelic experience.

Many adverse incidents and crises related to psychedelics can be prevented and avoided by increasing public education and awareness around the importance of set and setting, preparation and integration, and providing tools and knowledge that increase the likelihood of mindful and responsible use. The prohibitionist "just say no" approach to drug education made access to this type of education very challenging. In Denver and in other cities and states where psychedelics are being decriminalized, we have an opportunity for policies and protocols to be shaped by science, research and harm reduction philosophies and practices rather than fear, stigma, and misinformation.

Bridging the Gaps

Developing the first psychedelic career development program for young people



Vilmarie Fraguada Narloch, PsyD.

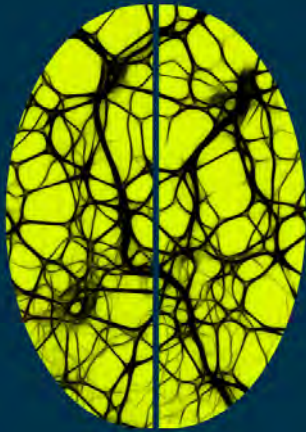
To those who regularly read the *MAPS Bulletin*, it will come as no surprise that psychedelics offer significant promise for our healing professions, for our communities, and, hopefully, for some semblance of collective growth. But what of psychedelics as a viable career path? Those of us in the space carry with us our memories of a disjointed pathway, scary decisions, potentially career-ending risks, beautiful synchronicities, and sheer gut instincts that eventually got us here. Those of us who identify as BIPOC and who are part of marginalized communities most negatively impacted by the War on Drugs carry the additional weight of the reality that we also had to navigate around racial trauma, closed doors, and inaccessible dream opportunities afforded to our more privileged peers. Fortunately, for the next generation of us, the pathway need not be so rocky, complicated, scary, or inaccessible. Thanks to those who have paved the way, the road to a successful and fulfilling psychedelic-related career is becoming more clear each day. As readers will see in this *Bulletin*, the increase of psychedelic-related training programs focused on a variety of professions, progressive drug policy reform, and access to telephone support, and new technologies is directly related to the expanding landscape of psychedelics, opening doors of opportunities that were not previously available.

Students for Sensible Drug Policy has partnered with key stakeholders to develop the Psychedelic Pipeline career development program as a global network to connect SSDP members and alumni who are interested in working with psychedelic medicines to quality training, scholarship funds, and career development opportunities, with a deliberate focus on providing access to people of color.

SSDP's Psychedelic Career Development Pipeline, officially launched in 2019, is the first formal pathway for young people interested in working in the psychedelic field. The pipeline provides resources for members interested in all aspects of the field, to include professional skill sets beyond therapy and research that are necessary for the field to develop and thrive.

Intersectionality and Inclusion

One area of pressing concern in psychedelic science is that of intersectionality. As the field now stands, people of color and those most negatively impacted by the War on Drugs are not adequately represented in training, conferences, and studies (Herzberg



PSYCHEDELIC PIPELINE

By SSDP

et al., 2019; Michaels, Purdon, Collins & Williams, 2018). We are concerned that there won't be enough therapists of color who can work to heal the trauma of racism that people of color face on a daily basis, much of which is interconnected with the War on Drugs. The pipeline provides a strong opportunity to shift this narrative, and SSDP strongly encourages people of color and all individuals of marginalized communities to participate in building a diverse future of equal access and opportunity.

The Psychedelic Pipeline consists of three primary components: Mentorship, Scholarship, and Training.

Mentorship

Psychedelic-assisted therapy and psychedelic research are the two most established career paths related to psychedelic science; however, they are far from the only relevant skill sets. If MDMA and psilocybin become legal for therapeutic purposes as many are forecasting, and if interest in psychedelic-related work continues to grow, professionals from diverse disciplines will be needed to support the expanding infrastructure.

Categories of mentorship outside of research and therapy include policy, communications, harm reduction, technical systems, program development, event planning, and more. This list is not exhaustive, and SSDP encourages anyone who has a skill set—or intends to develop a skill set—they see as beneficial to furthering psychedelic medicine to get involved.

SSDP's Psychedelic Pipeline mentorship program consists of pairing mentees with mentors in the field who have similar interests and experiences, or interests and experience that will aid mentees in their career development. Mentors and mentees are expected to communicate at least once per month, focusing on discussion and guidance on career development.

Communication can occur via Zoom, phone, or any other method deemed best, opening the possibility of remote connection. Each mentorship pairing continues for ten months from the start of the program.

Mentors benefit from the program by getting connected to hard-working, passionate, and intelligent young people who are eager to learn from them. Research shows that mentoring is positively associated with job satisfaction, job performance and career success for mentors (Ghosh & Reio Jr., 2013). A mentee could become someone who collaborates with a mentor on a research project, helps a mentor with their website, or can serve as an intern, research assistant, or employee in the future. SSDP Psychedelic Pipeline mentors help pave the way for the future of this growing field.

"It's an incredible opportunity to help shape the future leaders in the field of psychedelic therapy and research. As the field of psychedelics continues to grow, there will be more opportunities and needs for passionate individuals from a variety of backgrounds and I'm honored to play my part in helping to connect these individuals with their calling through the Psychedelic Pipeline Career Mentorship Program."

– Wes Hale *20, MAPS PBC

Mentees benefit from the program by getting connected to professionals in the field who are doing research, preparing to become psychedelic-assisted therapists, running integration groups, doing advocacy and policy work, and much more. Additionally, becoming a mentee may lead to collaboration on research projects, internships, and future employment.

“Before the mentorship, I felt very isolated in my pursuit of knowledge around psychedelics and becoming a practitioner of psychedelic assisted therapy. Few clinical supervisors or mentors knew much about these topics and/or were not always comfortable speaking with me regarding them. This mentorship has opened a gateway to learning as I have been able to explore psychedelics in a more supported and intentional way.”

– Nick Chmura ‘19, SSDP Cleveland Ambassador

Scholarship

If fully funded, the pipeline will also include a scholarship program that will provide opportunities for SSDP members and alumni to obtain funding that can be used to assist with costs of training, attending conferences, and other related career development expenses our members may face as they complete their training to enter the field. Additionally, the scholarship program would allow SSDP to provide compensation or other resources to mentors and other community partners for their time and labor in supporting our members. This scholarship component of the pipeline will focus primarily on providing access to people of color, people from marginalized communities, and people directly impacted or harmed by the War on Drugs.

Training

The final phase and long-term goal of the pipeline will be to work with existing clinics, research teams, and training programs to develop a formal training consortium consisting of comprehensive hands-on training opportunities which meet training requirements such as clinical hours, practicum, fellowship, or internships for the completion of a degree, license, certification, or academic programs.

The SSDP Psychedelic Pipeline career development program is currently limited to SSDP members and alumni. If you wish to become an SSDP member, ambassador, or to start a local chapter, please complete this form. If you are interested in becoming a mentor, community partner, or otherwise supporting this program, please reach out to Vilmarie Narloch at vilmarie@ssdp.org.

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The development of the SSDP Psychedelic Pipeline would not be possible without the wisdom, patience, passion, dedication, time, and effort of Wesley Hale, Brandy Irby, Sean Lawlor, Oriana Mayorga, the SSDPers and young people who inspire us, and our own mentors and elders who guided us here.

Vilmarie Fraguada Narloch, PsyD.

is a licensed clinical psychologist focusing on integrated treatment of co-occurring mental health and substance use disorders. She is an activist working to end the War on Drugs and advocates for science and reality based drug education and harm reduction approaches for all through her role as Director of Drug Education for Students for Sensible Drug Policy. She approaches her work from a harm reductionist and humanistic lens, focusing on the individual needs of the person, group, or community. She received a certificate in psychedelic therapies and research from the California Institute of Integral Studies in 2018, and is co-founder of Sana Healing Collective, which is a 501c3 non-profit harm reduction-based psychedelic-assisted therapy clinic committed to individualized, client-led approaches promoting the well-being of the whole person and community.



Tending the Sacred

The Emerging Role of Professional Chaplaincy in Psychedelic-Assisted Therapies

Jamie Beachy, MDiv, Ph.D.



Caroline Peacock, Director of Spiritual Health at Emory's Winship Cancer Institute and Ali John Zarrabi, Palliative Care Physician Scientist are engaged in a ground-breaking psilocybin treatment study and the training of spiritual health guides.

As more and more people turn to guided therapeutic encounters with psychedelics for healing and connection, chaplains are stepping in to tend the gap between these therapies and participants' spiritual and religious belonging. Professionally trained chaplains mediate a felt sense of compassion and wellbeing that is connected to sources of meaning that are more sustaining than medical and psychological models alone can provide.

Professional chaplains, also referred to as spiritual health practitioners and spiritual care providers, serve in hospitals, hospices, prisons, universities, and military settings. To become a board-certified professional chaplain in a North American context requires three years of graduate theological education and a full-time year of closely-supervised clinical training. To supervise chaplaincy, one must complete an additional 3 to 5 years of education and mentorship. Along with academic and clinical preparation, chaplains are endorsed by our religious or spiritual traditions, placing professional practice within communities of accountability and belonging. Professional chaplaincy training emphasizes theological depth, empathic and non-judgmental presence in the face of emotional, spiritual, and existential distress, and the capacity to offer skilled interventions that prioritize the care-seeker's spiritual values and guidance as the central ethos of care.

Professional chaplaincy is now expanding beyond the walls of traditional societal institutions. Eco-chaplaincy training programs prioritize tending to the ecological crisis and the human relationship to the natural world, while movement chaplaincy emphasizes accompanying protesters and building resilience in social justice movements. As psychedelic use becomes more mainstream and clinical research progresses, chaplains are beginning to contribute to psychedelic therapies as guides and spiritual caregivers as well.

While some seekers who turn to psychedelic use and psychedelic-assisted therapies are embedded members of traditional communities where plant medicines have long held an important role within the life of the community, many others looking to psychedelics for help or expansion lack a spiritual or religious context to make sense of powerful non-ordinary experiences. Once the therapeutic session is over or the psy-

chedelic retreat comes to a close, psychonauts and participants from non-indigenous contexts may struggle with integration as they return home to their families and communities with religious or spiritual insights that may not be well received or understood. In such instances, chaplains can offer a safe space to explore religious and spiritual experiences and insights in light of previously held beliefs and the culture of family, community, and society.

Consider the following composite case, constructed from the experiences of chaplains in psychedelic therapy settings:

Daniel, a 35-year-old combat veteran, sought MDMA-assisted therapy for PTSD. Daniel's religious community refrains from all mind-altering substances including alcohol. After a powerful experience of self-forgiveness in his MDMA-assisted therapy session, Daniel expressed dis-ease and shame about the joy and connection he felt in the session. One of Daniel's guides - a chaplain - wondered if perhaps Daniel was feeling at odds with the beliefs of his community of faith. Daniel shared that he believed God uses many different and unexpected pathways for healing and that God "wants me to feel joy" even if his community and extended family would not understand. In an integration session, Daniel explored ways to share his experience without revealing details about the therapeutic process that might alienate him from his religious community.

Jeannie, a 75-year-old woman with advanced colon cancer scheduled a psilocybin-guided therapy session to work with her fear of death. A long-time member of a Buddhist community, Jeannie regularly attended the sangha as well as her husband's synagogue during high holy days. In preparing for Jeannie's psilocybin-assisted therapy session, Jeannie's guides - a chaplain and a palliative care nurse - met with Jeannie to explore her values, beliefs, and hopes for the experience. Jeannie is a life-long classical musician and choral singer. After assessing her spiritual needs and resources, Jeannie's chaplain co-created a playlist of classical music and Buddhist mantras and worked with Jeannie to create a ritual to open and close the session that included elements from her daily Buddhist practice. After her medicine session, Jeannie reported feeling less afraid of dying and more connected to her sources of support including family members who had passed on before her. Jeannie shared that the playlist was a profound aspect of her psilocybin journey. Her hospice team had the playlist playing in the background as Jeannie died peacefully at home surrounded by her family.

In addition to deepening the preparation and integration processes, capable professional chaplains offer the following gifts and commitments to the field of psychedelic-assisted therapies:

Empathic Self-Awareness and Presence

In knowing our own inner landscape well, chaplains cultivate a welcoming presence that leaves room for others to be fully themselves. With awareness of the spiritual, religious, and cultural biases and resources we bring into each encounter, professional chaplains guard against unconsciously imposing our own spiritual or religious beliefs and interpretations onto another's experience. Whether it is our connection with a transcendent deity, a religious community of belonging, a cosmic creative source, or a sense of our place in an intelligent interconnected web of being -- when chaplains bring the gift of empathic presence into care encounters, we are mediating something greater than ourselves while inviting the spiritual and religious beliefs and values of the patient or client to guide the healing process. Whatever the source of connection, chaplains know to orient to that which is broader than any one person's gifts, skills, expertise, and limitations while taking care not to impose our beliefs and convictions onto others.

Compassion-Based Resilience

Chaplains are skilled in guiding meditation, loving-kindness, centering prayer, religious rituals, earth-based practices, and other contemplative approaches that support resilience and wellbeing. Chaplains are committed to our own spiritual health and offer spiritual care interventions that support the wellbeing of our care-seekers and colleagues. A spiritually-integrated approach to care allows us to navigate crises without becoming despairing or burned out over time.

Ritual Care

Chaplains co-create rituals to invite healing, healthy mourning, celebration, and the integration of significant life transitions. Rituals emerge from the collaboration between the chaplain's expertise and training and the care-seeker's world of spiritual and/or religious meaning, offered after careful assessment, and always with consent.

Spiritual Assessment and Integration

Models for spiritual and religious assessment and intervention guide the practice of chaplaincy. Inviting reflection on healthy and unhealthy religious coping, spiritual resources for navigating crisis and distress, and the role of community belonging enhances medical and psychotherapeutic approaches to care.



Rick Doblin and Jamie Beachy at the Shambhala Mountain Center in Colorado during the 2019 MAPS MDMA-assisted therapy training



(from left to right) Wael Garas, Study Physician/Study Therapist; Jamie Beachy, Study Therapist; Marcela Ot'abora, Principle Investigator/Clinical Supervisor; and Bruce Poulter, Study Therapist/Clinical Supervisor; at the MAPS MDMA-assisted therapy Phase 3 study site in Boulder, Colorado.

Jamie Beachy, MDiv, PhD, is Assistant Faculty and Director of the Center for Contemplative Chaplaincy at Naropa University in Boulder, Colorado. Jamie is a certified spiritual care educator (ACPE) and has served as a chaplain and ethics consultant in diverse contexts including hospice, palliative care, and trauma care settings. In addition to her faculty responsibilities with Naropa's Master of Divinity program, Jamie is a co-therapist for the MAPS-sponsored Phase 3 MDMA-assisted therapy study in Boulder.

Ethical Accountability

Professional chaplaincy prioritizes ethical practice and accountability through peer review and ongoing professional formation. The right use of power, the importance of spiritual health and wellbeing, and the ethical practice of interreligious and intercultural care are integrated into chaplaincy education and training.

Experience with Non-Ordinary States of Consciousness:

Chaplains bring experience with non-ordinary states of consciousness gained from deep spiritual practice, death awareness, and encounters with grief and loss.

As a discipline, professional chaplaincy is not without its limitations. Chaplains may lack experience with psychedelics and plant medicines and creating opportunities for guided experiences will strengthen the field's capacity to contribute to psychedelic-assisted therapies. Additionally, many chaplains belong to religious communities with strong taboos and prohibitions against the use of mind-altering substances and such taboos will need to be addressed. Finally, the majority of chaplains are endorsed by institutional religious communities, and chaplaincy as a specialized profession within indigenous communities is rare. Inviting dialogues that include input from indigenous spiritual leaders and practitioners with expertise in plant medicines will strengthen the field of professional spiritual care and allow for more sophisticated ethical discourse regarding cultural appropriation and the impact of psychedelic use on indigenous communities.

As psychedelics move further into mainstream settings, professional chaplains can serve as interpreters who build bridges between those turning to psychedelics and their religious and spiritual communities. The important role of chaplains in influencing outcomes for psychedelic therapies is yet to be clearly demonstrated but the values and commitments of the field suggest that chaplains will have an important role to contribute to the interdisciplinary unfolding of these therapies.

Navigating Uncharted Waters

An Emergent Professional Psychedelic Therapist Training Program

Elizabeth Nielson, Ph.D., and
Ingmar Gorman, Ph.D.



Many readers of the MAPS *Bulletin* will resonate with the notion that psychedelic experiences can be some of the most significant events of an individual's life. With recent developments in research, deprioritization efforts in multiple jurisdictions, and increased attention to the potential benefits of psychedelics, there is a greater and greater need for health care providers to be educated about psychedelics to adequately serve people who've had such significant experiences. To answer this need, multiple entities such as professional associations, independent study programs, conferences, and a variety of continuing education programs have emerged. Yet mere availability of information cannot overcome the stigma around psychedelics and their unfortunate absence in the existing Western psychotherapeutic paradigm—an absence keenly felt by those for whom psychedelic experiences are indeed a central facet of the human experience. Fluence (fluencetraining.com) seeks to address this gap in both knowledge and practice. By developing a means to explore and integrate the nuances and insights associated with psychedelic experiences into daily life, we work to move healthcare beyond symptom reduction and toward empowering individuals in their capacity for flourishing—a process in which psychedelic-assisted psychotherapy and psychedelic integration therapy will play increasingly important roles.

Presently, the psychedelic therapy training landscape encompasses a broad spectrum of programs that:

1. Train psychedelic therapists specifically for working on clinical trials
2. Train therapists to work with psychedelics outside of research settings, with still-unclear legal pathways to practice
3. Train clinicians to work with ketamine, incorporating psychedelic therapy orientations and legal avenues to practice ketamine-assisted psychotherapy
4. Provide transtheoretical training in psychedelic harm reduction and integration which can be easily incorporated into a therapist's or clinician's existing practice.

Fluence is the only training organization with a psychedelic integration therapy training program where therapists can learn a peer-reviewed model for the conduct of psychedelic integration in private practice, outside of clinical trials or the administration of a psychedelic (Gorman & Nielson et al., 2021). Our Continuing Education (CE) and Continuing Medical Education (CME)-accredited programs can be taken individually or as part of more comprehensive certificate programs which serve physicians, psychologists, pharmacists, nurses, social workers, coaches, and wellness practitioners. Our offerings range from introductory workshops on the burgeoning psychedelic-assisted psychotherapy field and practice of psychedelic integration therapy, to in-depth reading groups and experiential practice retreats. Additionally, we offer ketamine training programs for providers interested in working with local ketamine clinics and/or expanding their existing private practice to include legal ketamine-assisted psychotherapy. We provide custom online classrooms, course materials, and discussion boards as part of program participation; live-online small-group classes with leading researchers in the field; and a place of connection and collaboration for our course graduates via ongoing community and networking.

Fluence also provides services to and builds relationships with a wide range of entities currently seeking to expand access to psychedelics as medicines, including drug sponsors, clinics, and independent researchers. Our active work as psychedelic therapists and trainers in research studies provides us with a valuable perspective on the quality and adoptability of current psychedelic-assisted psychotherapy protocols. Our team helps Fluence trainees apply these perspectives in their own research and practice, which in turn can contribute to the development of new psychedelic-assisted psychotherapy approaches. Most recently, we've partnered with Beckley Psytech to develop a 5-MeO-DMT therapy model suitable for the research setting. Fluence cultivates a reflexive approach, whereby firsthand experience as therapists and trainers continuously informs the development of more effective ways of working therapeutically with non-ordinary states of consciousness in research settings, and ultimately beyond research. As legal avenues to practice psychedelic-assisted therapies emerge from the drug development pipeline, we stand ready to translate this knowledge into accessible training programs for clinicians in the community.

The links between our training program and MAPS' MDMA Therapy Training program are long-standing. One

of the first places we (Fluence's co-founders) connected and worked together was as participants in MAPS' "Part D" training at Stony Point, New York, in 2017. When we started offering our own workshops on psychedelic harm reduction and integration in 2018, the MAPS training program significantly influenced our approach—particularly with respect to incorporating multiple methods of learning such as: in-person training, roleplays, autodidactic approaches, mentorship, experiential practices, artistic expression, and learning from community. MAPS' MDMA Therapy Training Program is groundbreaking in both its breadth and depth, and we have incorporated its emphasis on learning (adopting new ideas) and unlearning (releasing old ideas) into our training as we attempt to facilitate a shift in perspective among our trainees with regard to their role as therapists and the role of psychedelics in their patients' treatment. Both programs thus shift the concept of therapist from being someone who "provides" information, treatment, and health, to someone who creates the space and opportunity for patients to generate their own insights and become active agents in their own healing. In doing so, the two approaches and training programs honor the patient's healing intuition and the intuition of the therapist.

Moving away from a biomedical, overly materialist, symptom-reduction model can be a challenge for therapists and for their patients. We seek to address this challenge by emphasizing the therapeutic relationship's central role throughout our training program. In our view and experience, therapists can actively create the conditions for their patients' insight to arise by cultivating an open, curious, non-judgmental stance to the patient's experience, and engaging with uncertainty rather than imposing a predetermined road-map for their patient's course of treatment. Fluence teaches the necessary skill of sitting with patients when they have not yet developed the words to describe their experience, as the territory of the unformulated is rich in therapeutic possibility and especially relevant in the context of psychedelic-assisted psychotherapy. Fluence teaches MAPS' ethical guidelines (2021) as part of our training, and our broader mission (fluencetraining.com/mission-statement) and values reflect our commitment to diversity and inclusion in the burgeoning psychedelic-assisted psychotherapy space. At Fluence, we recognize the foundational connections between stigma, drug policy, and drug-related harms which disproportionately affect marginalized communities and communities of color. We are dedicated to addressing this through our diversity fund (flu-

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encetraining.com/diversity-fund) and, more broadly, through consistently teaching topics such as ethics and the role of systemic inequities in healthcare. Ultimately, our goal is to provide an open, honest, and welcoming learning atmosphere in which providers can become knowledgeable about the true risks and potential benefits of psychedelics; engage in authentic, patient-centered, research-informed discussions; and offer access to the highest quality of care available.

Our vision for the future is both expansive and well-defined. First, we recognize the need for and desire to uphold consistent accreditation and credentialing standards for programs and practitioners in the psychedelic therapy landscape—especially within the context of the United States’ changing drug policies. Second, we envision a wide consortium of trainers and training programs whereby a variety of qualified leaders are involved in the establishment of said standards. Third, we see Fluence as involved in producing new peer-reviewed literature on the development and delivery of training programs for psychedelic therapy which may inform and help refine training standards. Fourth, we will continue to expand our resources to train and foster a diverse group of professionals in this field, and to grow our training offerings to cover various kinds of psychedelic-assisted psychotherapy approaches for clinical practice in accordance with regulations in a post-approval world. In this vein, we will endeavor to provide accessible and high-quality evidence-based training to clinicians at the scale needed to facilitate wider dissemination and equitable access to psychedelic therapies.

Fluence will continue to inform the blossoming of a new psychotherapeutic paradigm which effectively incorporates psychedelic experiences into the path of individual and collective healing. As an organization grounded in a bio-psycho-social-spiritual approach to human suffering and flourishing, we recognize the inherent complexity of the psychedelic experience, the human experience, and indeed the psychedelic nature of the human experience. Fluence is helping practitioners discover how psychedelic experiences may liberate and empower people to access new ways of being and how psychedelics can be marshalled to help grow more holistic, care-oriented, and sustainable relationships with ourselves, with each other, and with the wider world.

fluencetraining.com

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Dr. Elizabeth Nielson is a co-founder of Fluence and a psychologist with a focus on developing psychedelic medicines as empirically supported treatments for PTSD, substance use problems, and mood disorders. Dr. Nielson is a Site Co-Principal Investigator and therapist for an FDA approved Phase 3 clinical trial of MDMA-assisted Psychotherapy for Post-Traumatic Stress Disorder, and has served as a therapist on FDA approved clinical trials of psilocybin-assisted treatment of alcohol use disorder, psilocybin-assisted treatment of treatment resistant depression, and earlier phase 2 and 3 trials of MDMA-assisted psychotherapy. Through Fluence, she provides continuing education and training programs for therapists who wish to engage in integration of psychedelic experiences in clinical settings. Her research includes qualitative and mixed-methods projects designed to further understand the phenomenology and mechanisms of change in psychedelic-assisted therapy, including the experiences of trial participants and of the therapists themselves. Having completed an NIH postdoctoral fellowship at NYU, she has published and presented on topics of psychedelic therapist training, therapists’ personal experience with psychedelics, and including psychedelic integration in group and individual psychotherapy.

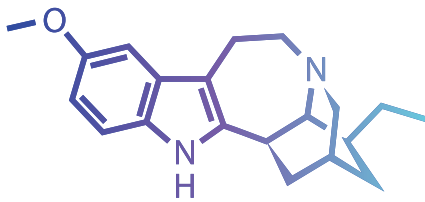
Dr. Ingmar Gorman is a co-founder of Fluence, a psychedelic education company training mental health providers in psychedelic treatments. As a psychologist, he shares his expertise in empirically supported psychedelic treatments with his clients and trainees alike. Dr. Gorman received his clinical training in New York City at the New School for Social Research, Mount Sinai Beth Israel Hospital, Columbia University, and Bellevue Hospital. He completed his NIH postdoctoral fellowship at New York University. He simultaneously served as site co-principal investigator on an FDA approved Phase 3 clinical trial of MDMA-assisted Psychotherapy for Post-Traumatic Stress Disorder and is currently a study therapist on the same study, as well as another FDA approved clinical trial of psilocybin for treatment resistant depression. Dr. Gorman has published on the topics of classic psychedelics, ketamine, MDMA, and Psychedelic Harm Reduction and Integration.



The Case of Brazil

After Ayahuasca, Ibogaine Opens Up Opportunity for First-Class Research in the Global South

Marcelo Leite, Ph.D.



Molecular compound of ibogaine

Ask researchers active in psychedelic science which three top countries publishing papers with the greatest annual citation rates in the biomedical field, and chances are, they will give you at least two right answers: the United States and the United Kingdom (UK), of course. Some would possibly rank Switzerland or Netherlands third, and they would be in the wrong; Brazil comes before them.

To be precise, both Brazil and Switzerland scored five articles each in the list, totaling 50 items compiled by David Wyndham Lawrence, Bhanu Sharma, Roland R. Griffiths, and Robin Carhart-Harris (Lawrence et al, 2021). However, a study carried out in Natal, in the state of Rio Grande do Norte (Northeastern Brazil), amassed 76 citations in just two years after its publication in 2019 (Palhano-Fontes et al., 2019), an average of 38 per year that put it in sixth place (the first Swiss paper appears in the twentieth position).

It might come as unexpected that an investigation originating in one of the poorest regions of the big South American nation would rank that high. Those in the know are not surprised, though, because we are talking of the first randomized placebo-controlled trial of a psychedelic substance (ayahuasca, in this case) to confirm a rapid antidepressant effect in treatment-resistant depression. The most cited article in the list (50.2 per year) also involved a psychedelic substance (psilocybin) against treatment-resistant depression, but it was just an open-label feasibility study, devoid of placebo control (Carhart-Harris et al., 2016).

The outstanding psychedelic research done in Brazil was completely unknown to me until 2017, when I almost by chance ended up attending and reporting on the Psychedelic Science conference held in Oakland. My 35-year career in science journalism until then had concentrated in issues such as genomics, climate change and Amazon deforestation, with a few incursions in neuroscience but no attention to entheogens. After seeing an announcement about the event in California, I browsed the online program and was startled to find there two Brazilian researchers that I knew and respected, Sidarta Ribeiro and Stevens Rehen. I got in touch with them, and they reassured me that the conference merited coverage by *Folha de S.Paulo*, the leading Brazilian newspaper I have worked for since 1986. They also recommended that I contact anthropologist Beatriz Labate, who was organizing the Plant Medicines track of the conference and helped me get a press badge to cover it.

Once in Oakland it became clear to me that the biomedical research in psychedelics was burgeoning, and that Brazil had a prominent place in the so-called renaissance. I started writing about the subject for the Brazilian audience, which soon developed into a book project – under the title “Psychonauts: Trips with Brazilian Psychedelic Science”, the book will be launched May 10th in Portuguese by Editora Fósforo. Noticing that there was much more to report about psychedelics than could reach the pages of the actual paper, *Folha* agreed to publish a blog, “Virada Psicodélica” (meaning “psychedelic turnaround”) where I have been posting on average twice a week since October 2020. The newspaper is quite open-minded and progressive on the issue and has defended drug reform in editorials for at least three decades now.

There is a long tradition of research with psychoactive drugs in Brazil, beginning with marijuana and ayahuasca. The brew is legal in the country, based in its ceremonial use by ayahuasca religions such as Santo Daime, União do Vegetal, and Barquinha. The group that conducted the clinical trial is led by Dráulio de Araújo in the Federal University of Rio Grande do Norte (UFRN, in Portuguese) and has its roots in the Ribeirão Preto campus of the University of São Paulo (USP), a hub for ayahuasca research. It was there, at Jaime Hallak’s lab, that Araújo had organized a pioneering brain imaging study of subjects under the influence of ayahuasca published online in 2011 (de Araujo et al., 2012).

Araújo, a neuroscientist with background in physics, works in close collaboration with biologists Sidarta Ribeiro at the UFRN’s Brain Institute and Stevens Rehen at the Federal University of Rio de Janeiro (UFRJ) and IDOR (a private research institute), as well as with psychiatrist Luís Fernando Tófoli at the State University of Campinas (UNICAMP) in São Paulo State. In 2019, the quartet circulated with 13 other colleagues a study showing LSD’s potential as a cognitive enhancer, based on behavioral experiments with rodents and proteomics screening of human brain organoids (Cini et al., (2019). Anti-inflammatory and neuroplasticity effects of ayahuasca components (DMT, harmine, harmaline) and 5-MeO-DMT also belong in the group’s research portfolio.

In comparison with ayahuasca research, ibogaine’s potential for treating addiction is somewhat incipient in Brazilian labs and university hospitals, but this is expected to change in a matter of weeks or months. Under the leadership of André Brooking Negrão, the Institute of Psychiatry at USP is ready to start recruiting patients for a randomized placebo-controlled study of the Taber-

nanthe iboga shrub’s alkaloid with 80 cocaine and crack addicts in São Paulo to test safety and efficacy (phase IIb clinical trial).

Ibogaine is a powerful psychedelic that launches subjects in a dreamlike state that can last for many hours and is said to facilitate the detoxification process of addicts, both by lessening withdrawal symptoms and giving access to the trauma roots underpinning the condition. Its anti-addiction qualities have been known since 1962, when heroin addict Howard Lotsof noticed the disappearance of such symptoms after a 30-hour trip under the influence of ibogaine (Brown et al, 2016). Lotsof himself became involved with research on the alkaloid with Kenneth Alper (Alper et al., 1999), and treatment with the controlled compound started to spread in countries where legislation and law enforcement tolerate its use.

In Australia, New Zealand, and South Africa, for instance, ibogaine can be prescribed to treat drug dependence. A similar situation prevails in Brazil, where it is neither prohibited nor controlled, but can be imported as a non-registered medicine for personal use. After meeting Lotsof over lunch at the University of Miami in 1994, Brazilian physician Bruno Rasmussen Chaves began to treat addicts with ibogaine in 1997, and by 2020, he had already ministered the alkaloid to more than 1500 patients. Other clinics in the country have treated hundreds of addicts, some of them following the burdensome bureaucratic process, others simply under the radar of public health authorities.

Rasmussen’s clinical experience resulted in a few scientific papers, such as the retrospective study published in 2014 showing 61% of abstinence over five months after 75 alcohol, cannabis, cocaine, and crack users were given ibogaine (Schenberg, 2014). But a full, controlled, double-blind study with placebo group on ibogaine has never been performed, as is required for any drug or treatment to get approval and become standard procedure.

Negrão, a psychiatrist who worked for five years as a researcher at the NIH in Bethesda and now heads the alcohol and drug clinic at USP’s Hospital das Clínicas, where 20 addict patients seek help on any given day, five of which chronic users of crack or cocaine. “The daily praxis of a doctor attending to crack and cocaine users is very unhappy,” he says, out of frustration with high relapse rates and the lack of effective treatments.

After being turned down by quite a few research facilities, Rasmussen landed at Negrão’s door and finally found someone willing to put his claims about ibogaine’s efficacy to test. Negrão secured approvals for a clinical trial with 80 subjects (40 females and 40 males) that will be hospitalized for 10 days each to make

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Marcelo Leite, Ph.D., former Nieman Fellow at Harvard University (1998) and Knight-Wallace Fellow at the University of Michigan (2012), is a science and environment columnist with *Folha de S.Paulo*, leading Brazilian daily newspaper. From 1994 to 1996 he worked as an Ombudsman (Reader's Advocate) for the same newspaper, where he also led the Science, Opinion and International sections. Since October 2020 he writes the blog *Virada Psicodélica* (Psychedelic Turnaround) for *Folha*.

sure that they remain abstinent. The research protocol involves nine psychotherapeutic sessions: four of preparation, one experimental (ibogaine), and four of integration. The drug itself will be donated by the firm Phytostan, provider of ibogaine in Brazil, at about \$1,000 per dose, and the research team has already a batch for eight patients in stock.

This is not the only Brazilian clinical trial involving ibogaine, though. The group led by Hallak is also about to start a randomized, double-blind placebo-controlled clinical trial to investigate tolerability and efficacy of the alkaloid in the treatment of alcoholism. The principal investigator is USP's Rafael Guimarães dos Santos, who plans to recruit 12 subjects among literate adults diagnosed with alcohol use disorder and a history of at least two previous failed treatments, with drug use and/or psychotherapy. The study was ready to begin last January, but the Covid-19 pandemic has hit the city of Ribeirão Preto really hard, and recruiting has been postponed until the coronavirus scourge gets under control in the region.

According to Negrão, nobody risked a clinical trial with ibogaine to treat addiction because of the drug's bad reputation. It has, indeed, been associated with fatal cardiac problems, but the risk is deemed manageable with close monitoring in a clinical setting; such as has been the case in Rasmussen's practice and will be provided at USP's hospital. There is still some prejudice in academic circles against psychedelic science, but it has been slowly eroded by the flurry of impeccable research being published in the field.

Everything is in place to start the pioneering study that will no doubt boost Brazilian psychedelic research's reputation even higher; if it were not for the COVID-19 second and deadliest wave of infections in 2021 that left no beds available for the clinical trial. Negrão is not easily discouraged, though, and plans to resume the trial as soon as the coronavirus scourge is tamed. Ibogaine against addiction is just the beginning, he promises: "I decided to do this [psychedelic research] for the rest of my life."

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The Psychedelic Revolution Will Be App-ified



How emerging tech tools are working to expand access to psychedelic therapy and make tripping more transformative

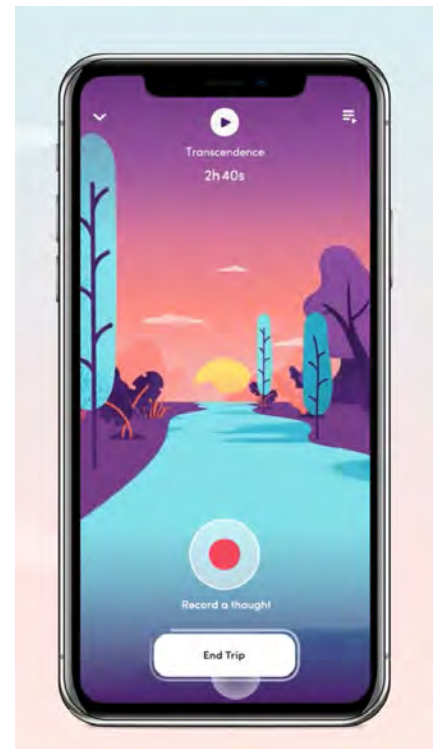
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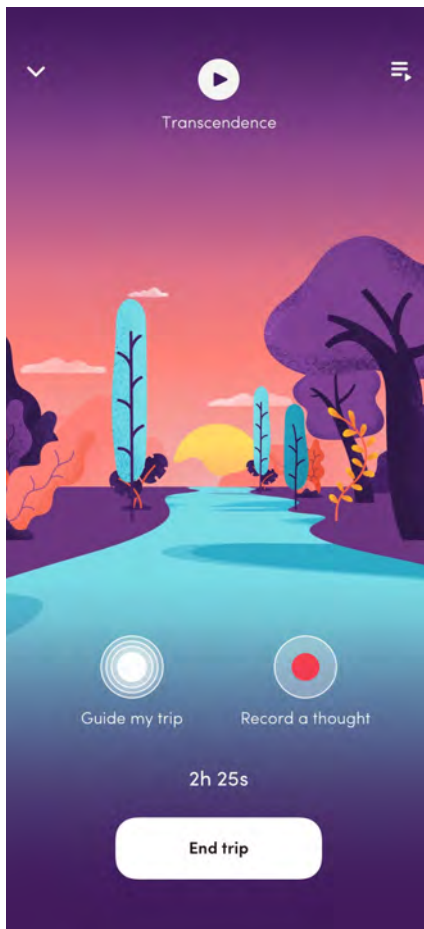
After more than half a century of open flirtation with psychedelics, the tech industry is taking the relationship to the next level with an influx of apps and digital tools designed to expand access to psychedelic medicine, facilitate transformative psychedelic experiences, and equip people to have safer, more informed trips.

These products mark the latest chapter in a modern tech history that has been infused with psychedelics since the beginning. In his best-selling book, *How to Change Your Mind*, author Michael Pollan traces the intersection of these two worlds back to the 1950s, when computer engineers at the electronics firm Ampex first took LSD to help them visualize the complex patterns used in early microchips (Pollan, 2018). Decades later, tech titans like Steve Jobs famously experimented with psychedelics, leading the Apple co-founder to call it “one of the two or three most important things” he did in his life (Mackenzie, 2011). And more recently, the media has fixated on psychedelic use in Silicon Valley, where techies have been microdosing (Dean, 2017) and tripping (Swisher, 2018) to boost creativity, increase productivity, and achieve mental breakthroughs.

Over the course of this history, tech has clearly taken a lot from psychedelics, and received a lot in return. But the tech industry hasn’t always been as eager to give back, or to share. Now, in the midst of a psychedelic renaissance that has put these substances on a path toward mainstream acceptance—and multi-billion-dollar corporate valuations—tech companies have come flocking like moths to a psychedelic flame (PRNewswire, 2020). Many of the early players in the psychedelic tech sector claim these products are an effort to give back, by helping to advance the field of psychedelics. But if they’re going to do that—and do it responsibly—their execution will make all the difference.

Many of the initial entrants into this space have been developed with clinical applications in mind. Companies like Field Trip Health, Osmind, Mindbloom, Mindleap, and Wavepaths all offer services around psychedelic-assisted therapy, but they vary in terms of style and approach.





Nick Wing is a journalist who has covered a wide variety of issues ranging from drugs and drug policy, to race and criminal justice, to gun violence and other public health crises. He believes that the best journalism challenges the status quo, and uplifts the voices and issues that so often get ignored by legacy media. Nick previously worked as a reporter at the Huffington Post, and is currently an editor at The Appeal, a nonprofit newsroom dedicated to covering injustice and the U.S. criminal legal system. He received a bachelor's degree from Colorado College in 2009.

Field Trip Health and Mindbloom are directly involved in administering psychedelic medicine and therapy — only with ketamine for now, the lone FDA-approved psychedelic drug, which studies have shown to be effective in treating depression and anxiety. As the landscape changes though, protocols and procedures could likely be adapted to fit new substances and therapies.

On the boutique end, Field Trip Health offers ketamine-assisted therapy sessions in “spa-like” clinics, paired with a digital platform to help patients to get the most out of their psychedelic experiences. Field Trip’s online tool provides information and exercises to aid with intention setting ahead of clinical sessions. Afterward, clients can use the platform to follow up with their clinician, track outcomes, and complete exercises to help integrate their experiences. The baseline package, which includes two psychedelic sessions and four follow-up sessions comes in at \$2,400, and can be completed in one to two weeks.

For a less lux approach, Mindbloom is harnessing the power of telemedicine to offer at-home ketamine-assisted psychotherapy. The company’s licensed clinicians and trained guides prescribe ketamine to qualifying patients, oversee medical care, and facilitate one-on-one remote sessions, as well as group integration sessions. Mindbloom also has a digital tool with interactive educational content for use before and after psychedelic experiences. And if patients need to get in touch with clinicians during treatment, they can reach out on the app (Mindbloom, 2021).

Other companies never actually touch psychedelics. Osmind has created software and digital infrastructure for clinicians who are already doing psychedelic-assisted therapy. The platform allows providers to track outcomes and collect detailed feedback from patients, which will make it easier for clinicians to integrate emerging psychedelic therapies into the healthcare system, says Osmind co-founder and CEO Lucia Huang.

The Mindleap app takes a more familiar tech industry approach to the psychedelic space, serving as a peer-to-peer platform to connect clients with licensed specialists who conduct therapy sessions over video calls — kind of like Uber, but for psychedelic integration. This format also allows Mindleap to keep psychedelics at an arm’s length. While the company’s website advises that conversations between therapists and clients are “secure and private,” it clarifies that Mindleap “does not endorse, encourage, or support the attainment or use of illicit substances”

Wavepaths offers an entirely different sort of service for therapists, providing them with customizable musical soundtracks for sessions. Creator Mendel Kaelen, Ph.D., has partnered with instrumental and electronic music artists like Jon Hopkins to compile a library of original tracks that can be arranged and adjusted in real-time throughout a session. The goal, says Kaelen, is to help clinicians create a “completely flexible musical environment, adaptive to the constantly evolving therapeutic needs.”

The creators of these products all shared excitement about how technology could improve issues of access and equity to psychedelic medicine. Mindbloom, for example, has been able to use telemedicine to lower the price of ketamine-assisted psychotherapy to \$250 per session, says Mindbloom founder and CEO Dylan Beynon. He adds that Mindbloom can also reach people who might not live near a ketamine clinic, or who might feel more comfortable at home than in a clinical setting.

But there are also trade-offs to consider amid a shift to digital and remote methods of delivering care. Therapeutic touch, for example, can’t be replicated through a computer screen. And with the provider and patient in separate places, the container for healing becomes more difficult to standardize and control, notes Sara Reed, a li-

censed clinician and CEO of Mind's iHealth Solutions, a digital health company. "Not everyone has access to a quiet, private space for an online dosing session and this can impact how comfortable someone feels in exploring their inner wounds," says Reed. "What really gets lost is the human connection."

For people who may not be interested in psychedelics for approved therapeutic use, other products are aligned toward personal use in more recreational settings. Field Trip Health has released a separate app called Trip, which it brands as a digital toolkit to promote more informed, transformative psychedelic experiences. The app asks users to set an intention before they trip, then provides music and guided support throughout the experience, along with a button to record voice notes. Afterward, Trip reminds users to journal and follow up with other integration exercises.

Mydelica, a forthcoming app being developed by Dr. Robin Carhart-Harris and other researchers at Imperial College London, seeks to teach users about tripping — and to learn from their experiences. The app will provide educational resources for every stage of a psychedelic experience, along with an online health tracking tool that can chart the mental health effects of a psychedelic experience. Using detailed surveys across a variety of psychometrics, users will be able to see how a trip affects their mood and mental wellbeing, says Carhart-Harris.

The content on both Trip and Mydelica is based on vetted protocols created by psychedelic experts, the creators say, but they're quick to note that their products aren't intended to be a replacement for psychedelic-assisted therapy supervised by a clinician or guide. Still, there's no point pretending people aren't using these substances on their own, says Ronan Levy, executive chairman at Field Trip Health, citing recent moves to decriminalize psilocybin and other natural psychedelics in cities like Oakland, Santa Cruz, Cambridge, Massachusetts, and Washington, D.C. By providing curated and validated information, they believe they can reduce harm, and in the process help people have more meaningful psychedelic experiences, says Levy.

"The biggest risk probably right now is someone experimenting with psychedelics, doing something stupid, and engendering the same kind of backlash that we saw in the 60s," says Levy, before paraphrasing a quote from psychedelic pioneer Stan Grof, M.D., Ph.D. "The most important thing we can do right now in terms of the psychedelic renaissance is not fuck it up."

So far, the initial products in the psychedelic tech space seem to be taking some care not to mess it up for everyone else. The largest companies on the clinical side note that they conform to best practices that are grounded in psychedelic science and research, and developed in conjunction with experts.

But that alone may be setting the bar too low. Sara Reed

of Minds iHealth Solutions says she's concerned about the blindspots that will inevitably emerge when combining tech and psychedelics, two fields that have historically lacked diversity and struggled to incorporate the experiences of people from different backgrounds.

"There's going to be a fundamental difference in the tone and the objectives of a company that's run by, just to be frank, serial entrepreneurs or predominantly white men, versus a company that's founded by a clinician who is also a black woman," says Reed. "Though the missions and visions might sound the same, the execution of them can look a lot different."

On the recreational side, the most popular and polished offerings also seem to be starting off in the right direction, with an eye toward harm reduction and a commitment to credentialed information. Of course, an eye test is not a substitute for more rigorous studies to determine whether these apps are actually helping people, or harming them, or doing nothing at all, says David B. Yaden, a research fellow at the Johns Hopkins Research Fellow at the Johns Hopkins Center for Psychedelic and Consciousness.

And even if there are no obvious red flags yet, in a highly decentralized, unregulated tech world filled with potentially unscrupulous players who may be motivated more by profit than a genuine interest in advancing the field of psychedelics, there are no guarantees that this will remain the case.

"What kinds of companies will enter this space?" asks Yaden, "And will there be highly problematic iterations of these apps in the future?"

Right now, the answers to those questions are anybody's guess.

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Fireside Project

Providing Real-Time Support When
Time Doesn't Seem Real

Joshua White and Hanifa Nayo Washington

A landmark event in the history of the psychedelic movement occurred on April 14, 2021. Starting on that day, any person in the midst of a psychedelic experience or integrating a past psychedelic experience now has a number they can call or text to receive free, confidential peer support. The number is 6-2FIRESIDE. That's (623) 473-7433.

On the other end of the line are kind, understanding, well-trained volunteers who are devoted to providing compassionate peer support. To listening deeply and from the heart. To connecting. To helping callers minimize the risks and fulfill the potential of their psychedelic experiences.

Just let the implications of that sink in for a moment: so long as a person has their phone with them, they'll never have to be alone with a psychedelic experience. Ever again.

Say a person consumes a psychedelic substance while home alone. They reach down and feel their phone in their pocket. Even if they don't actually dial 6-2FIRESIDE, they feel reassured just knowing that a peer support volunteer—someone who gets it—is waiting to support them. Or, say someone had an intense mushroom journey last week. Since then, reality doesn't seem to fit quite right, like clothes left in the dryer for too long. Then they remember 6-2FIRESIDE. They call the number, and hear, "Fireside Project. This is Hanifa. How can I help?"

The Psychedelic Peer Support Line is an offering from a nonprofit we founded called Fireside Project. As our tagline says, we provide "real-time support, for when time doesn't seem real."

We see the support line as a mycelial web of connection and community, beginning first in the United States and eventually germinating across the globe and realizing our vision of a world where every person feels safe, supported, and seen during and after their psychedelic experiences.

Our first six weeks of operation highlight the need for this vital risk-reduction tool. We've had 308 conversations total, which have been evenly split between phone calls and text messages. Our volunteers de-escalated 82 people from psychological distress. In response to our post-call survey, 29 people told us they would have called 911 or gone to the emergency room but for Fireside Project. 88 percent of people expressed that they felt heard, understood, and supported during the conversation, and would recommend Fireside Project to others.

Beyond just the numbers, testimonials paint a vivid picture of the beauty and necessity of this life-saving service. One person expressed: "Sometimes just one rock to cling to can keep you out of the tide before it sweeps you away." Another caller shared this story: "I reached out to Fireside to help me process what had been a very intense and confusing psychedelic experience the week before. The person speaking to me reassured me that what I had experienced was normal and provided a lot of perspective and anecdotal experience sharing to help me grapple with my own experiences in a relatable way. I felt so much better after our call and I appreciated all of the empathy exhibited by the Fireside Project. I came out with a much greater appreciation of my own experience and psychedelics."

We chose the name Fireside Project in part because it evokes feelings of openness and connection, of coming in from the cold to join a community around the fire. But also, at a deeper level, a return to the fireside is a reconnection to a primordial ritual. As long as humans have been humans, we've gathered beside the fire to connect and share stories. To dance and sing. To build community and be in ceremony. To heal together.

Fireside Project's arrival has coincided with a wave of psychedelic decriminalization. We launched on October 28, 2020, only five days before a watershed moment for the psychedelic movement. At the November 3 election, Oregon decriminalized small amounts of all drugs and required the state to develop a regulatory infrastructure for psilocybin-assisted group therapy. On the same day, Washington, D.C. decriminalized all plant-based psychedelics. The following week, California State Senator Scott Wiener announced that he would be introducing a bill to decriminalize psychedelics in California, SB519. We see the Psychedelic Peer Support Line as a risk reduction tool that will play a foundational role in a post-prohibition landscape.

One of the things we've noticed in our conversations about Fireside Project is that people often refer to us as a "hotline" or a "crisis line." But those terms don't quite fit. Yes, we help people having psychedelic crises. But what we offer is much broader. We support people on their journeys of integration. We support people who need real-time support tripsitting others. And we support tripsitters who themselves need to decompress. All of that said, we're not a substitute for pre-trip preparation; it is imperative that people educate themselves about the best risk-reduction practices before they begin their trip.

We hope volunteering on the support line will be one of the most enriching volunteer opportunities ever to exist in the psychedelic movement. Our volunteers work at least one four-hour shift per week and commit to one year of service. That's over 200 hours per year per volunteer. During our pilot year, we'll offer approximately 11,000 hours of psychedelic peer support! Each volunteer has completed a training program curated by our Co-Founder and Support Line Director, Adam Rubin. The training included experiential components as well as presentations on topics such as the art of holding space, understanding psychedelics, creating a culture of belonging, and integration.



Joshua White is Fireside Project's Founder and Executive Director. With experience serving as a crisis counselor on a helpline and a psychedelic peer support volunteer at the Zendo Project, Joshua has seen firsthand the role that compassionate peer support can play in community mental health. Before devoting his life to the psychedelic movement, Joshua spent 11 years as a Deputy City Attorney at the San Francisco City Attorney's Office, focusing on suing businesses exploiting vulnerable communities. In that capacity, he co-taught a nationally renowned clinic at the Yale Law School, where he helped students generate and litigate public interest impact litigation lawsuits.

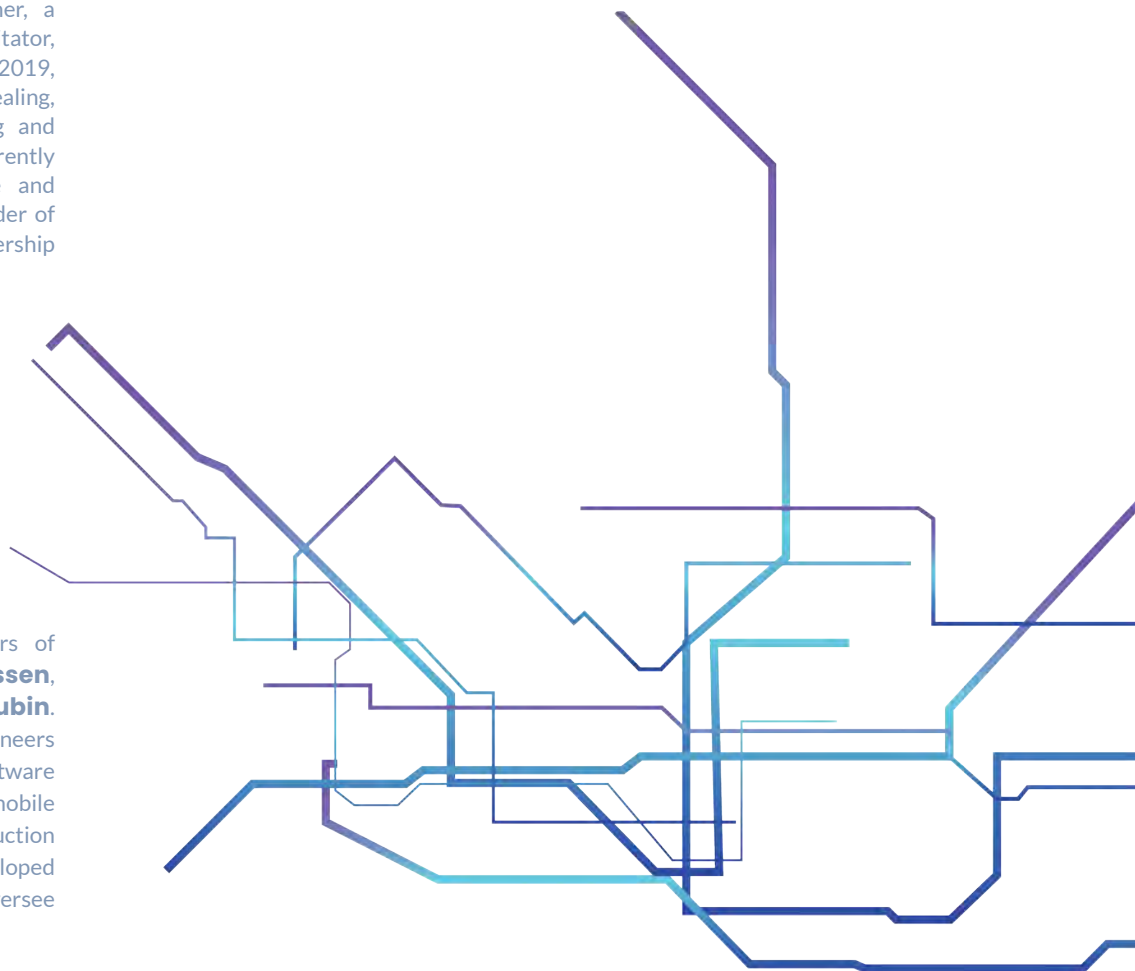
Hanifa Nayo Washington is Fireside Project's Cultivator of Beloved Community and is a contributor to several other emerging psychedelic enterprises including the Equity in Psychedelic Therapy Initiative. Hanifa Nayo is an award winning cultural producer and sacred activist. For 20 years she has radicalized her gifts and talents as tools for liberation, healing, and community building. A Detroit native, Hanifa Nayo is a certified Usui/Holy Fire Reiki Master Practitioner, a masterful heart-centered group facilitator, and prolific creative designer. In 2019, Hanifa Nayo launched One Village Healing, a BIPOC-led and centered healing and wellness initiative. She also currently works with Co-Creating Effective and Inclusive Organizations and is a leader of the New Haven Community Leadership Program.

The other founding staff members of Fireside Project are **Nicolai Lassen**, **Kenneth Jønck**, and **Adam Rubin**. Kenneth and Nicolai are software engineers who will design Fireside Project's software console, website, and forthcoming mobile app. Adam is a psychedelic harm reduction activist and crisis counselor who developed Fireside Project's training and will oversee the Psychedelic Peer Support Line.

In addition to minimizing cost barriers to psychedelic and integrative support, we intend to harness the potential of the support line to help create a more diverse psychedelic movement. Starting in 2022, our Fireside Equity Fund will provide scholarships to volunteers from communities that have been underrepresented in the psychedelic movement so they can pursue or deepen their careers in psychedelic healing.

The Psychedelic Peer Support Line currently accepts calls from within the United States only, and is open for limited hours (Thursday through Sunday from 3:00 p.m. to 3:00 a.m. PST and Monday from 3:00 p.m. to 7:00 p.m. PST). But we have plans to expand to Canada in the next few months, followed by other countries. Our long-term goal is to be open 24/7 and available in every country in the world in multiple languages.

Like so many new nonprofit organizations, our central challenge is fundraising. Just as local public radio stations are listener-supported, we too are supported by our community. Our hope is to keep the support line free for everyone. Forever. With the support of our community, we have no doubt we can make that dream a reality.



Psychedelic Societies Empowering Healing Community



Danielle Negrin

Henrita just arrived home from a week-long ayahuasca retreat and she is perplexed by her experiences. What happened there was something she didn't really expect, and she doesn't know how to make sense of it. She now views the world in a completely different way, and feels disconnected from her work, old friends and family. She feels isolated and alone. With these emerging realizations, she decides to find other people she can relate with that can help her gain understanding.

In my role as Executive Director of San Francisco Psychedelic Society, I frequently welcome people like Henrita to our healing community. As research expands, interest in psychedelics is increasing rapidly, so the need for guidance is more in demand than ever. Unregulated information and societal stigma have largely left people to educate themselves, often relying on shaky anecdotal accounts to determine how to navigate their journeys. We believe that every psychedelic seeker will have better outcomes if they learn to prepare for and integrate their experiences within a supportive community.

This can be a lifeline for newcomers and individuals who have just come back from retreat centers, clinical studies, underground ceremonies, clinics, or even experiences with friends. For those who don't know where to start, this support system can make all the difference by introducing them to this unfamiliar landscape.

Psychedelic Societies are here to provide globally available harm reduction services to help grow a contemporary psychedelic culture from the ground up. With over 50 psychedelic societies around the world, thousands of individuals are being guided to improve the quality and outcome of these experiences.

What Do Psychedelic Societies Offer?

Psychedelic Societies are a network of evolutionary healing communities that are empowering modern culture through accessible education, integration and connection. We do this through a series of consistent courses, classes, groups and weekly supportive meetings. This provides opportunities for people to learn about best practices as they transform their lives and develop new ways of thinking. We have seen that our gatherings have a significant positive impact on the mental health of otherwise isolated psychedelic explorers.



We help with the powerful shifts in drug policy reform through our local advocacy work with decriminalization. We welcome people from all walks of life, gender identification, age, race, religious beliefs, cultural backgrounds and experience. Our members consist of every type of person: students, activists, therapists, artists, professionals, parents, technology experts, scientists, lawyers, doctors and travelers. We meet consistently to have a dialogue about some of the most miraculous compounds on the planet.

Our classes feature thought leaders in the space who teach students how to understand psychedelic substances, use them respectfully, grow their own medicine and mitigate risks. Our intention is for our community to become confident and resourced with information, both to minimize harm and increase potential benefits. As this knowledge becomes more widely available, it decreases the stigma and the likelihood of difficult experiences that often come from not having access to the proper information.

We host gatherings known as integration circles to help individuals discover how to embody the extraordinary states of consciousness into their ordinary lives. Many find these groups transformative, where participants can share and learn together. We believe that we have a responsibility to help some of the most marginalized and vulnerable populations. Supporting people overcoming adversity is our shared mission.

Our circles are a safe space to talk about trauma, systemic racial oppression, mental health issues, addiction and even psychiatric drug withdrawal. Countless new friendships have formed and many lives have been saved in the presence of our skilled facilitators. These stories continue to highlight the profound therapeutic powers of integration when practiced in community. Our goal is to normalize the practice of integration, so that it becomes an integral part of our culture.

A New Model For Addiction

There is a new wave of people who are using psychedelics respectfully to interrupt their addictions, which leads to a better life, habits and relationships. The current widely accepted model for addiction treatment is abstinence-only. While this approach does work for some, for others this belief system prevents people from healing themselves with these tools. We encourage people to target their abstinence by having the agency to decide which substances and behaviors are harmful to their lives, and which are transformative and helpful.

We aim to shift the current treatment model for addiction away from the disease model, to one that is more holistic, loving and harm-reducing. Our core belief is that people are more

powerful than their addictions, and through our psychedelic recovery offerings we give them the strategies and tools to overcome them.

The spiritual experiences associated with psychedelics are commonly what break people out of their addictions and once their addiction has been overcome, individuals often develop a practice using psychedelics to further themselves spiritually. Psychedelic medicines can serve as evidence-based tools that afford suffering individuals new ways of thinking and talking about personal change. Psychedelic Societies intend to foster a culture where people are healing the root of the problem which led them to self-soothe in the first place.

Greater Context In Society and Our Future

As we stand on the shoulders of psychedelic medical research, we are birthing a new era of citizen scientists who aim to shift public perception of these sacred medicines by sharing their experiences. Our goal is to facilitate exciting new research about these compounds with data gathered from our communities.

Together our offerings represent an example of how psychedelic culture can be holistically and safely integrated into modern society. We facilitate this by providing a central nexus for information and resources that is focused on ethical practices, inclusivity and bridging the gap between ancient ancestral medicine with psychedelic science. In the future we envision, Indigenous traditions and land are honored, emerging and marginalized voices have a platform to share their teachings, and discussions around using psychedelics for mental health are destigmatized. With legitimate support, integration and connection, we can shape the concept of psychedelic community both locally and globally.

With this structure in place, people like Henrita will know where to go and what to do.

Psychedelic Societies are expanding, growing and empowering individuals to evolve together without outside funding. We need help to make that growth happen. Currently we are building conscious communities, sustaining our work through membership models. As we remind each other that we have the capacity to heal and transform our own lives, we inspire new hope for future generations.



Danielle Negrin and Seth Warner, directors of SFPS, pictured here with Dennis McKenna

Danielle Negrin is Executive Director of the San Francisco Psychedelic Society, founder of Psychedelic Recovery, on the founding team of Decriminalize Nature Oakland and on the advisory board for Project New Day. She specializes in building conscious community, providing education into the use and science of psychedelics, addiction recovery services and integration. Danielle is dedicated to exploring mental health, trauma recovery, personal development and overcoming substance abuse through integrative techniques with psychoactive substances. The intention of her work is to help people and communities through sacred intentional practice, to ultimately make this a better world for us all to live in.

[psychedelicsocietysf.org](https://www.psychedelicsocietysf.org)



Seth Warner
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The Legal Landscape of the Psychedelic Ecosystem

Ismail Lourido Ali, J.D. and Hadas Alterman, J.D.

I. The Approach: Psychedelics and the Law

At the beginning of the modern War on Drugs, conversations about psychedelic substances were banished to the underground. As researchers, practitioners, and advocates have worked toward bringing these powerful substances out into the light, they have had to increasingly reckon with the arcane infrastructure of the legal system. Yet as legal barriers to psychedelics are lowered, questions of accessibility, ethics, and accountability loom large. Decriminalizing, legalizing, or medicalizing may create access in certain cases, but they won't necessarily do so in a way that is equitable and devoid of externalities.

As the legal status of psychedelics changes, so too must the practice of law. To adapt to the new paradigms that are made available by psychedelic substances, and the framework we are building to safely and responsibly access them, lawyers working in the psychedelic ecosystem should consider how the practice of law itself enhances - or hinders - the world we are hoping to create.

While it is true that at the local, state, and federal level, law and policy is being changed to give people the opportunity to use psychedelic substances, there is a meaningful gap between having the right to do something, and being able to reasonably access that right.

For example, the landmark Supreme Court case *Roe v. Wade* established a constitutional right to abortion, and in theory a person can choose whether or not to exercise this right. However, the rhetoric of choice obscures the reality that many people face economic and institutional barriers that deny them, particularly if they are economically disadvantaged and/or people of color, the ability to freely make choices in the same way a consumer of any other good or service does.

Similarly, psychedelic legalization is at risk of replicating comparable dynamics, whereby the right to choose is curtailed by economic and institutional barriers to accessing that right, as well as by stigma and fear.

This is a meaningful distinction because when people throw around words like "access," it is important to unpack what they mean: do they mean geographical availability, financial accessibility, or cultural competency? Is it all of the above? Additionally, the inquiry around access is also a question of the actual settings that will permit the

use of psychedelics. For example, a law that establishes affordable psychedelic-assisted therapy, but does not allow for use outside of the medical paradigm, effectively prohibits access to psychedelics for people who do not have medically cognizable mental health conditions, but wish to use psychedelics for other purposes, like spiritual growth.

Lawyers, whose role is ostensibly to serve the needs of people, companies, and communities seeking to protect and utilize their rights, have a significant role to play - and a new generation of legal professionals are stepping up to think about the complexities of it all.

II. The Landscape: The Legal Status of Psychedelics Today

There are a number of sources of information about the legal status of psychedelics, which is changing rapidly in some places (and not at all in others). At this time, the two most active conversations occurring at the federal level are based in the paradigms of religious use and of medicalization.

The U.S. Constitution guarantees the right to religious freedom in no uncertain terms, yet accessing that right with respect to use of psychedelics is a different and complex story. The Religious Freedom Restoration Act (RFRA), the subsequent cases of the last fifteen years (especially *Gonzales v. O centro Espirita Beneficente Uniao do Vegetal* in the US Supreme Court, and *Church of the Holy Light of the Queen vs. Mukasey* in the Ninth Circuit), and DEA's current policies have created a paradigm in which spiritual practitioners seeking clarity about their congregations don't have a clear path toward such protection.

Today, movement is happening on a number of fronts. There are several emerging religious and spiritual communities that have roots in shamanism and animistic Indigenous practices, but are practiced in the U.S. There are multiple ongoing cases, from litigation against the Drug Enforcement Agency due to its speed of response (hint - it's a slow-moving agency) and efforts to assert religious rights against Customs and Border Patrol.

At the same time, the process to medicalize psychedelics through the FDA continues. For more information about where MAPS is with its clinical trials, read the update in this *Bulletin*. A number of new, mostly for-profit companies have emerged, meaning that there is more money in the space than ever before. In the last few months, the topic of how to navigate com-

plex questions of intellectual property and patents has come up; this *Bulletin* has a deeper dive into that topic too. Many - including MAPS - often cite the possibility of insurance coverage as a reason to continue ensuring that psychedelics are available through medical systems.

Inspired by Oregon, advocates and legislators from Hawaii to Florida, and a number of states in between, are moving forward to shift psychedelic policy. In the last *Bulletin*, the MAPS Policy team wrote about updates to state-level policy in Oregon, observing that while there are requirements to meet in order to become a facilitator, they are not onerous, and will not facilitate a system in which only western medical professionals are able to administer psilocybin. Many have drawn attention to the harms inherent in approaches that would hoard power for professionals who fit into a narrow medical narrative that revolves around profit maximization and elitism. This practice, for which there is historical precedent, robs communities of the traditional practices that are their birthright, and dispossesses healers of their livelihood and life's work.

For example, African-American midwifery practices survived the horrors of slavery, but were nearly eviscerated by the propaganda of an organized group of professionals who didn't want these women cutting into their profit margins. Southern African-American communities had a lineage of respected community midwives, frequently the core health care providers of

their familial and social networks. With the wave of medical professionalization in the mid-19th century, physicians began to challenge these women, viewing them rival practitioners. The American Medical Association advocated solving "The Midwife Problem" with legal measures designed to dismantle midwifery practice, disproportionately impacting African-American and foreign-born midwives.

This should serve as a cautionary tale to the psychedelic industry. Like birth, the use of psychedelics can be done safely when supported by the right

care. We all want competent facilitators, appropriate screening, preparation and integration for participants, and safe, quality supply. However, we cannot allow the private sector to convince us or the government that we are not capable of making our own decisions when it comes to our health and our consciousness. This risk is particularly critical to mitigate when the private sector actors are solely animated by their fiduciary duty to shareholders. Lawyers in the psychedelic space are grappling with how to balance critical legal concerns around risk man-

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agement and liability with the importance of honoring people's desire to access psychedelics in a way that feels meaningful, authentic, and generative at the individual and collective levels.

Today in California, advocates are working to decriminalize multiple psychedelic substances, focusing their efforts on SB519, a bill that would fully decriminalize possession and use, create safe harbor for people non-commercially sharing substances with their friends and community, and expunge the records of people with criminal histories related to psychedelic substances. It also creates a commission that will explore paradigms for future regulated use, from therapeutic to spiritual and beyond. Decriminalizing drugs could slowly but surely change attitudes and the understanding of substances generally, reducing stigma, is a major barrier to effective care and accurate education.

Much has been said about the municipal path to de-prioritize enforcement of psychedelics at the municipal level, as seen by SPORE in Colorado, or Decriminalize Nature in Oakland and Santa Cruz, or Initiative 81 in Washington DC, but these efforts do not legally protect those at highest risk, including and especially formerly incarcerated people, undocumented people, parents, and others. These efforts have nonetheless opened up space for community to form, and that room for discussion is priceless.

Understanding how to safely navigate this multi-layered legal environment is complicated, to say the least!

III. The Ecosystem: The Possibility of New Patterns

Once legal, the contours of the environment that delivers psychedelics and their associated services is upstream of who can and will access them. Given the early stage of this new paradigm, lawyers have a tremendous opportunity to shape it. The law, like psychedelics, is a tool that can be used responsibly or coercively, to help or to harm. Lawyers can enforce and protect the calcified way resources are allocated, or we can create paths to re-route them.

Bringing underground practice into the light brings more complexity, which can increase barriers to entry and thus reduce opportunity for less politically sophisticated or under-funded actors to participate in a system. Yet this visibility also creates opportunities for accountability - something that is sorely needed but usually impossible without any sort of oversight. Part of the value of bringing regulation to any system is a chance to provide people who have been harmed with a formalized pathway to justice and healing.

The prospect of being allowed to seek legal recourse as a means of accountability reminds us that the law relies in part of the coercive power of the state to effectuate its goals. Any move toward regulation must be done with an awareness that the current systems that attempt to create accountability do

so through violence and incarceration. So in the same way that organizations trying to create access through medical means ought to also push to make healthcare more accessible, lawyers that create and maintain systems that use such methods to effectuate behavior ought to also fight to make the criminal legal system more just. This can be done by being in solidarity with, and materially and politically supporting, movements to reallocate state funding away from law enforcement and toward wrap-around social services, restorative justice, and community reinvestment for business, culture, and the arts.

The criminal legal system is not the only one that lawyers need to consider. As the field has entered the mainstream, money has started to flow, impacting the incentives of people participating. This money is overwhelmingly coming from philanthropy and venture capital, but lawyers have an opportunity to help balance creation of value with the incentives of the current economic structure. The question is how to move those resources within the system in a way that brings the maximum benefit to as many beneficiaries as possible.

Some of these decisions happen at the root of organizations, in the decisions made about corporate structure and governance. Others happen at the level of strategy about business and growth. Exploring cooperative ownership, financial structures that share prosperity, solidarity economics, re-establishing commons, and the purpose economy theory, could all allow businesses to unlearn the scarcity complex and reimagine relational networks that allow value to be exchanged in more horizontal ways. Perhaps in the longer term we can truly transform existing structures that prioritize shareholders at the expense of all else, and instead create cultural grooves that lead us to novel structures which account for the interests of all stakeholders.

As governments and businesses start to come to terms with the invisible costs of the status quo of scaling and of accountability, so too must lawyers consider and be present to the externalities of their own rationales. Thankfully, people within the legal practice are indeed stepping up to engage with these complicated questions. The authors of this article, though writing in their personal capacities, are both on the founding Board of Directors for the brand-new Psychedelic Bar Association, which intends to create opportunities for attorneys in the space to connect, learn, and grow, with the specific intention of navigating these complicated questions.

The changing social mores regarding drug use and toward economic systems offer opportunities to break out of the paradigms we have all been conditioned to consider normal. Visionary thinkers, like Dr. Carl Hart, offer a different perspective toward drug use and liberty, while Bennet Zelner offers a blueprint for how legal systems can encourage, rather than undermine, community-based containers.

IV. Conclusion

It is imperative that all sectors of this emerging industry have appropriate safeguards. As a result of negligence or outright malevolence, serious harms can occur without the presence of guardrails. However, we must implement strategies and procedures for harm reduction in a way that is dignified, inclusive, and does not reify the same norms and systems from which so many of us are trying to heal.

A lack of attention towards access will necessarily create a bottleneck effect, where the distribution of psychedelics are only available to the wealthy (who, by the way, are already not being prosecuted for their use). Between the reality of cultural elitism and the ongoing stigma from the war on drugs, people without financial means are still not being reached by the current infrastructure, no matter how visionary it might feel. We have to work together to fix this structural problem.

It would be much easier to throw in the towel now that the tides are turning in the fight for expanded rights. It may be tempting to sit back and let multinational corporations and entrenched government power dictate the parameters of our soon to be quasi-legal relationship with drugs. By contrast, truly equitable access requires questioning our default economic and legal structures, and then rewiring that circuitry to build something more sustainable, beautiful and fair.

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Can We Have a Psychedelic Patent System?

Graham Pechenik, J.D. and Chris Byrnes, J.D.

As the psychedelics space continues its faster-than-light expansion, controversies have exploded over the types of patents being filed and the roles they may play (e.g., Gerber et al., 2021; Leite, 2021; Love, 2021). Are patents fundamentally at odds with a psychedelic ethos, or can they find a healthy role in the ecosystem?

As Rick Doblin explains, “psychedelics are tools; they’re not good or bad in and of themselves. It’s how they are used. It’s the relationship you have with them” (Doblin, 2020). The same can be said of patents. Patents can be tools of profit maximization, resource extraction, and bitter competition. Or they can be tools of outcome optimization, resource allocation, and careful cooperation. While generally wielded as the former, we have the opportunity to reimagine our relationship with them—and choose to use them as tools to facilitate and support ethical ways of doing business. Our choice will shape how the psychedelics ecosystem develops, with potentially profound economic, social, and cultural implications.

Patents are “the creation of society—at odds with the inherent free nature of disclosed ideas,” but provided to “inventions and discoveries which further[] human knowledge” and “justif[y] the special inducement of a limited private monopoly” (Graham v. John Deere, 1966). Property rights like patents were used as early as 500 BCE, where in the ancient Greek city of Sybaris creators of “any peculiar and excellent” culinary dish or “any new refinement in luxury” were entitled to all the profit for a year, “in order that others might be induced to labour at excelling in such pursuits” (Atheneaus of Naucratis, 1854).

The same objective undergirds patents today. To “promote the progress of science and the useful arts” (U.S. Const. Art. I, § 8), the first U.S. patent laws were enacted in 1790, shortly after George Washington used his first State of the Union address to urge for protection of “new and useful inventions” to give “effectual encouragement” to “the exertions of skill and genius in producing them” (Washington, 1790).

But how does the government determine which “inventions and discoveries” are worthy of a patent? How does one—as Thomas Jefferson, the first U.S. patent examiner, struggled to do himself—“draw[] a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not” (Jefferson, 1813)?

What should be entitled to a patent, and what should not, has always caused trouble. In 1883, calling an inappropriately granted patent “unjust in principle and injurious in its consequences,” the Supreme Court explained:

“[I]ndiscriminate creation of exclusive privileges tends rather to obstruct than to stimulate invention. It creates a class of speculative schemers who make it their business to watch the advancing wave of improvement, and gather its foam in the form of patented monopolies, which enable them to lay a heavy tax upon the industry of the country, without contributing anything to the real advancement of the arts” (*Atlantic Works v. Brady*, 1883).

The current controversy over patenting psychedelics is therefore nothing new. “Attempts to patent therapeutic methods invented by others” may be “capitalism gone rogue” (Doblin, 2021), but they’re from the same rogues’ gallery we’ve had since the start—what are euphemistically called “low quality” patents, overbroad and claiming ownership of what is properly in the public domain. The dangers are proven. Conferring market power without public benefit, such patents chill healthy competition and can increase prices and reduce access, lead to rent-seeking infringement disputes, and deter further research and development.

One root of this problem, too, is perennial. “Patent examiners are burdened with many applications and are encouraged to move quickly on each one of them. And as they do their work, they are isolated from an important source of highly relevant information... That information we call ‘prior art’” (Boucher, 2007). Prior art is all of the information that should be used to decide whether an invention is novel and non-obvious—but which is often overlooked. There are ways to educate examiners about prior art (e.g., Hausfeld & Nickles, 2021), and submit it into a pending patent file (e.g., 35 U.S.C. § 122), as well as to challenge a patent that nonetheless issues (e.g., *Kohn v. Compass Pathways*, 2020). Yet these processes are uncertain to succeed. Even if they are successful—producing only “high quality” and appropriately narrow patents on truly novel inventions—will controversies over psychedelic patents disappear?

History suggests otherwise. Some of the most groundbreaking inventions offer case studies in how patents—of whatever quality—can be employed to stifle innovation and suffocate the same creative spirit that earned them.

For instance, James Watt, a key inventor of the steam engine, famously used his 1769 patent to fight all attempts

at competition, suppressing advancement in the field for 31 years—as his engine improved little, and its use remained limited to pumping water out of mines (Boldrin et al., 2008).

Elias Howe Jr., inventor of the lockstitch sewing machine, was so fixated on litigation that his “main occupation” has been called “suing the infringers of his patent for royalties”—so that rivals were “burning up their resources, fighting each other rather than developing the machine itself” in the 1850s “Sewing Machine Patent Wars” (Mossoff, 2013).

The Wright Brothers, similarly, turned their 1906 patent on a “flying machine” into eight years of litigation against competitors (Trainor, 2015). Distracted by expensive litigation, innovation languished, and the industry developed outside their patent’s range in Europe. By World War I, U.S. aviation lagged

so far behind that American pilots initially flew European planes (Nocera, 2014).

Time and again, scorched-earth battles consumed entire emerging industries. Alexander Graham Bell’s company filed 587 patent suits against telephone competitors; more than 600 patent suits were filed over the incandescent light bulb; and two early radio pioneers had in 1896 over 300 patent suits pending just between them (Scott, 2001). Three decades later, litigation over broadcasting patents still occupied the whole industry to distraction, slowing innovation to a crawl in the 1920s “Radio Patent Snarl” (Ladwig, 2018).

Despite this historical repetition, examples continue to the present day. Most recently, in the “Smartphone Patent War” of the 2010s, Steve Jobs promised he would spend his “last dying breath” and “every penny of Apple’s \$40 billion in the bank” pursuing patent infringement claims against Android (BBC News, 2011). Soon after, Apple and Google were spending more on their patent war than they were on R&D (Duhigg & Lohr, 2012).

Are these all failures of the patent system? Or are they simply the unfolding of its inexorable logic? If Steve Jobs spent his last breath and penny destroying Android, isn’t he just doing what the patent system supports? As Christian Angermeyer asserted about the psychedelics space:

“If a monopoly/duopoly emerged, it suggests that all the other would-be competitors had failed with their own creative and entrepreneurial endeavours. Then it would be a sign of quality and constitutional reward. In that case, you should not blame them, but blame the rest, who then clearly would have not done a good job” (Angermeyer, 2021).

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Thus, when Wilbur Wright says in 1907, at the start of the Wright Brothers' protracted patent war: "I want the business built up so as to get the greatest amount of money with as little work. Sell few machines at a big profit" (Hise, 2003)—isn't he just seeking the fruit of his "constitutional reward"? And to claim it, why would one do anything but sue one's would-be competitors?

History again offers us a lesson: while competitors drain their coffers on court battles, innovation—and the entire community that should be served by it—suffers. And while industry titans may have the means to fight it out, smaller players often leave the field entirely (Duhigg & Lohr, 2012 ("We were on the brink of changing the world before we got stuck in this legal muck")). Indeed, for each of these examples, it was only after the wars ended that creative economies emerged and science progressed.

After Watt's steam engine patent expired, a period of collaborative innovation bloomed, and engineers shifted to a "professional ethos favoring sharing and publication" of technical information, resulting in more powerful and fuel-efficient engines, and leading to steam trains, steam boats, and the world's first "road locomotive" (Boldrin, 2008; Alpkunt, 2020).

In 1856, a truce was called in the Sewing Machine Wars, and competitors created the world's first "patent pool" (Mossoff, 2009). Only then did "the concept of the sewing machine move forward," as "dozens of new manufacturers entered the industry," creating a "crowdsourced sewing machine" that was distributed widely (Palmer, 2015).

After the start of World War I, the government forced the creation of a patent pool to prevent the Wright Brothers from continuing to block the building of new airplanes (Dykman, 1964; Surowiecki, 2008 ("Had Congress not stepped in, we might still be flying around in blimps")).

And in 1924, an organization brought the interests of competitors together to end the "Radio Patent Snarl," leading to the standardization of radio parts and transmission rules (and paving the way for development of modern technology standards such as DVD, MPEG, USB, Wi-Fi, and 5G) (Ladwig, 2018).

At times, patent holders have also acted alone for public benefit. One of the most successful patent licensing programs of all time was on recombinant DNA technology owned by Stanford and the University of California. Over 25 years, the program brought in \$255 million from 468 companies, and caused at least 2,442 products to be developed. But despite the economic success, profit was never the primary motive; rather, the program was designed to encourage broad adoption of the technology for public benefit. A focus on purely financial considerations might have led to higher royalty rates and increased total revenues, but could have delayed the rise of a biotechnology industry by decades (Feldman et al., 2007).

What should we expect in the psychedelics space? With sentiments on record like "[m]any psychedelic companies out

there will never be able to bring a product to market" because of patents, and if any "violate existing patents, my portfolio companies would have to protect their rights" (quoted in Love, 2021), should we expect psychedelic patent wars and snarls? And if an aggressive monopoly or duopoly does emerge, where should we direct the blame?

The patent system is "the creation of society"—an ongoing product of lobbying, law-making, litigation, and the values that underlie them. It is designed for, and is a reflection of, the society it is in (or at least, those with political power). But while a winner-take-all and competition-at-all-costs patent system might represent the values of our society-at-large, does it embody a psychedelic ethos? If it does not, can we learn from history and rethink how we use patents?

Beforehand, let's pause to answer a question that may be on many minds, which is why use patents at all? Why not, in the spirit of open science, simply put everything in the public domain? While worthy of its own article, in outline the answer is twofold: First, patents can be versatilely used: cooperatively and defensively as well as offensively, creating new ways for entities to work together, ensure adherence to ethical norms, and fend off predatory actors. Second, patenting certain inventions may be the best way to clarify the prior art and prevent others from claiming it as their own. Whether patent laws are actually necessary to incentivize innovation is up for dispute. But the fact is, we have them—and many will continue to use them—so merely "opting out" does not solve all our problems, and it becomes necessary to find a middle way (Belcher & Casey, 2016; Sampat, 2018). That said, the ethical use of patents can work alongside and help protect those following open science principles, which can still serve as the ideal—and with the cry of "Cooperation over Competition!" as crucial as ever (Jesse, 2018).

If we are to reimagine our relationship with patents, one way is through an intellectual property (IP) commons, broadly defined as a set of IP-related resources shared for the benefit of a community (Lessig, 2001). An IP commons sits between complete enclosure (separate individual rights to exclude) and public domain (everything freely accessible to all), and allows members to decide what resources to contribute and share, and under what rules and limits. While the ultimate structure of a psychedelic IP commons must evolve based on input from all stakeholders—and should take inspiration and guidance from the many existing blueprints for an ethical psychedelics ecosystem (e.g., Jesse, 2018; Gillooly & Conour, 2020; Zelner, 2020; Baggott, 2020; Howell, 2020; Journey Colab, 2020; Zurrer, 2021; Knox, 2021; McGaughey, 2021; Tremblay, 2021)—it is possible to sketch out some dimensions. (And in many ways, the ultimate "commons" is subsidiary in importance to "commoning," the community process and practice of establishing and managing it.) The contours of an IP commons are flexible, with opportunities for:

Protection: At its most basic level, a commons can decrease the costs of doing business for each member (including when balanced against the costs of its administration). For example, a commons can act as a defensive coalition, where members share costs to identify and challenge problematic patent applications and collectively bargain for discounted patent risk management solutions (e.g., infringement insurance). Members can adopt a non-aggression pact, or agree to refrain from abusive litigation tactics. A commons can also network member patents defensively, enabling them to be used as mutually-beneficial shields against outside aggressors, or encumbering them to prevent use by patent trolls.

Cooperation: A commons can generate frameworks to cross-license rights, such as patent pools and other forms of IP assembly, reducing transaction costs and fostering technology diffusion and follow-on innovation. Standard public licenses and digital contracting can further streamline collaboration. Pooled patents can be efficiently licensed to non-members, and can be securitized or used as collateral (e.g., to offer micro-loans). Although patents are generally filed by larger entities, a commons can uncover and attribute value to IP created by all involved stakeholders, and provide pathways for individuals to better manage and protect their own (e.g., therapy practices, research data, patient data, user data).

Support: A commons can create legally binding mechanisms to support ethical imperatives, for instance pledging patents to improve access to medicines (e.g., WHO C-TAP, 2020). Ethical principles can be incorporated directly into licenses and other technology transfer agreements through morals clauses. These can condition the right to use IP on commitments to take certain actions (e.g., promote diversity, equity, and inclusion; meet conservation and sustainability goals) and honor certain practices (e.g., provide meaningful reciprocity; ensure consent from and benefit sharing with indigenous stewards). This enables enforceable transmission of ethical norms to everyone using member IP.

As the psychedelics ecosystem continues to emerge, there is a unique and powerful opportunity to shape the role that patents play. By using them as tools within an IP commons, patents can be positive for the psychedelics ecosystem and work in harmony with a psychedelic ethos. Can we place cooperation over competition, and reimagine—and psychedelicize—the patent system itself? Much of what ails us as individuals results from our isolation, as well as the loss of connection to and support from our community—and one path to healing starts by rebuilding and strengthening these relationships. The same can be said for psychedelic patent holders too.

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What's Going On with Patents and Psychedelics?



Frank Gerratana, J.D.

In the last few months, the topic of patents and psychedelic medicine has turned up several times in the news and social media. Let's look at why, what it means for the future of psychedelics in medicine, and what can be done about patent applications that appear to cover existing, known psychedelic treatments.

What's a patent?

First, some background. A patent is a type of intellectual property (IP) right that protects an inventor's newly created technologies – including devices, methods, and processes. Patents are different from other types of intellectual property that you may have heard of, like copyrights or trademarks or trade secrets.

A key feature is that a patent is a “negative right” – it does not entitle the owner to make, use, or sell the invention, but rather confers the right to exclude others from making, using, or selling the invention.

How do you get a patent?

Patent rights do not arise in new inventions automatically. To obtain a patent in the US, an inventor must submit a patent application describing the invention in detail to the United States Patent and Trademark Office (USPTO). The USPTO will then begin the process of patent examination, in which a bureaucrat is assigned to study the “claims” of the patent (i.e., the specific elements the inventor is claiming to have invented) and determine whether the invention meets the legal requirements for patentability. It is typically several years after filing before a patent application is picked up by a patent examiner.

One of the important requirements an invention must meet to obtain patent protection is novelty, which requires that the invention be distinct from all other inventions that came before it. In other words, you can't get patent protection on technology that is already known to the world. The body of relevant existing knowledge is known in patent lingo as "prior art." When a patent examiner searches for prior art that could invalidate a patent claim, they primarily look for other patents or patent applications describing similar subject matter. However, prior art can also include printed publications, products on sale or in public use, and any other information otherwise available to the public.

If a patent examiner finds prior art that they believe describes the technology in one or more of the applicant's claims, the application will be rejected. To overcome the rejection, the applicant usually has to come back to the patent examiner with a detailed argument or an amendment to the claims that sufficiently narrows their scope to avoid claiming the identified prior art – a back-and-forth process that can go on for years. In fact, about 20-25% of the time, applicants simply give up and never receive their patents. The rest, who still want their patent rights to be granted, often must narrow the scope of their claims.

So, if you see a patent application that seems too broad in scope, it is likely the original application which includes the broadest claims the applicant thought were reasonable. (And while patent applicants are prohibited from acting with dishonesty or deceit, they can sometimes get pretty creative with what they think is reasonable!) The result of this back-and-forth between the applicant and the examiner is that a published patent application rarely reflects the final scope of a resulting issued patent.

What is MAPS doing?

It's not the first time the topic of patents and psychedelics has come up – Rick Doblin wrote about it in the *Bulletin* in 1992.

From the start, MAPS has opted for a strategy that does not entail filing for patent protection. Instead, MAPS is adding the body of prior art in the psychedelics space by continuously publishing research findings and other information about what is already known about psychedelic medicine. This accomplishes two goals.

First, it increases the body of knowledge about psychedelics available to the public and provides patent examiners with reliable information on the state of the art. One problem in patent examination for psychedelics is that psychedelic research is difficult for examiners to find, since a substantial amount of research has operated underground or is otherwise not available in traditional published form.

Second, publishing the results of research prevents others from obtaining patents on any product or practice described in them. Generally, the more prior art that is available in any given field – and the easier it is for patent examiners to find – the more likely it is that a patent application in that field will be narrowed (or abandoned entirely). In contrast, without comprehensive information about the state of the art, examiners might issue overly broad patents that cover existing products and practices.

MAPS also relies on alternatives to patent protection when appropriate. One alternative to patent protection is what the FDA calls "data exclusivity," in which a drug treatment developer can prevent others from relying on data the developer generated when a competitor seeks approval for use of the same drug. This gives the developer a limited period of opportunity to get a head start in the market by claiming exclusive ownership in exchange for their innovation.

What's next?

As more companies appear in the psychedelic space, expect to see more patent applications. Investors and executives typically expect startups to show that they have intellectual property on their balance sheets, and companies are usually incentivized to file patent applications as early as possible. Some patent applications with broad claims on psychedelic treatments have already appeared in the news. We'll be watching closely.

Frank Gerratana is an attorney in Boston specializing in the high tech industry. He advises MAPS on a pro bono basis with respect to patents and intellectual property. He received his juris doctor (J.D.) from American University, Washington College of Law, and his bachelor of science (B.S.) in electrical and computer engineering along with a master of science (M.S.) in computer science from Worcester Polytechnic Institute. Outside of work, Frank participated in the successful effort to advocate for decriminalization of psychedelics at the municipal level in Cambridge, MA. He has also served on the board of directors of Firefly Arts Collective, the New England regional Burning Man affiliate.

Ask MAPS Anything

Grace Cepe



Since its inception in 1997, AskMAPS (maps.org/askmaps) has answered thousands of inquiries about psychedelics, therapy, and research each year. MAPS' Communications Associate Grace Cepe connects with the psychedelic community and provides educational resources through AskMAPS.

Hello-

As I understand it, placebos are typically used as part of single and double-blind studies. Given the nature of the MDMA experience, can you help me understand how anyone participating wouldn't immediately know whether they had taken a placebo versus MDMA?

More to the point — what purpose is being served by this? I do not understand a medical community that would ask people suffering so terribly to go through what they will immediately know is a sham process.

Placebos are necessary tools for single and double-blind studies, no question. But here, they feel like a needlessly cruel requirement imposed by those who have never experienced the pain of mental illness themselves.

My son is slowly dying from the impacts of PTSD. I believe MDMA and/or other psychedelic treatments are his best, last hope. He has tried everything else. What he needs is an awakening beyond all the talk. An experience that offers a new "knowing" that will allow him to begin to move beyond his trauma, his grief and his overwhelming shame and loss, in a way that no other therapy ever has or could. Like I said, he's dying. Even so, I would never subject him to the risk of being selected (HOPE!) only to discover he is the guinea pig on placebo. "Give us your time, son. Your pain. Your dark thoughts. In return, we'll give you nothing you haven't been through before. You exist for the benefit of our experiment. You'll be made to suffer for the good of those who get 'the real thing'."

I would love nothing more than for you to tell me why I am wrong. I would be thrilled to see the evidence that says this is something other than inhumane.

I don't expect a response. I know I am writing to an organization. And I am grateful for what MAPS is trying to accomplish, but the process?

I want my son to be free from this torture.

So I wish you success. But please, don't hurt someone else's sons in the process.

Grace Cepe serves as the Communications Associate for MAPS. She has a B.A. in psychology from the University of California, Santa Cruz (UCSC). At UCSC, Grace was a research assistant for the social psychology department's Sexual and Gender Diversity Laboratory, instructor's assistant for the Introduction to Psychology course, and residential counselor intern for at-risk youth. Before joining MAPS as Communications Associate, Grace volunteered with MAPS and the San Francisco Psychedelic Society and has been an activist with Decriminalize Santa Cruz. Since attending MAPS' Psychedelic Science Conference in 2017, Grace's interests in psychedelics evolved from a primary focus on the clinical applications of psychedelics and into Indigenous ways of life and ceremonial uses, human rights, social justice, and increasing inclusivity and diversity in the field of psychedelics. Outside of her psychedelic work, Grace loves getting involved with her community, spending time in nature, hip-hop and salsa dancing, and getting lost in a good book.

The AskMAPS article is for informational purposes only. MAPS cannot provide legal, medical, or mental health advice, nor do we advise on the use of any prohibited substance outside of the approved clinical study setting. Always seek the advice of your physician, mental-health professional, or other qualified health provider with any questions you may have regarding a medical condition. These emails have been edited for length and to protect the senders' anonymity. Visit maps.org/askmaps for frequently asked questions about psychedelic healing, therapy, or research.

You're correct: placebos are used in blinded studies, and in this case the study was double-blinded (neither the therapists of participants were told what they received) and independent raters measured the PTSD symptoms to increase objectivity. We were grateful and relieved to see that, even among the participants who received placebo, many experienced clinically significant improvements after the therapy. We pay careful and close attention to all participants' mental health during the trials.

I'll try to get to each of your questions.

The placebo itself is selected to mimic some of the physical effects of MDMA. While the nature of the experience is quite unmistakable under many circumstances, it is the case that there were participants and therapists who didn't know which group they were in until after the study was unblinded.

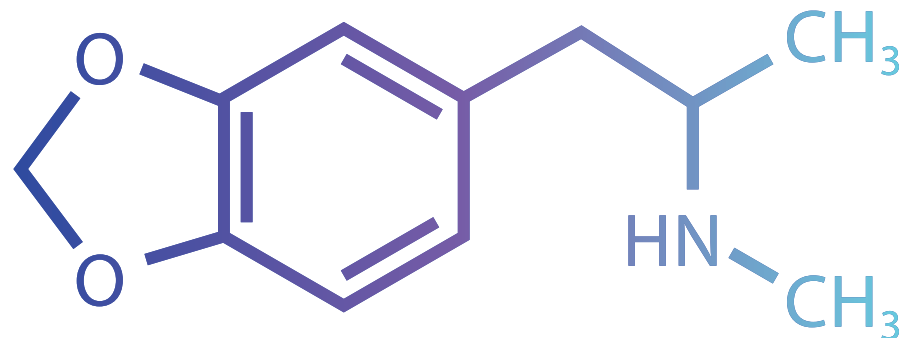
The study was designed to measure outcomes specific to the FDA's requirements, and in this case the biggest question (or primary outcome) was: is MDMA-assisted therapy more efficacious than therapy alone? For that, the FDA required that we split participants into a control group and a placebo group. While we design many elements of the study, we also are required to meet the FDA standards for drug development trials. Please understand that we are not the ones that set up these standards, we are simply abiding by what regulatory and medical authorities request.

Thankfully, we did receive breakthrough therapy status, which means we were able to work directly with the FDA to design a study that would meet the scientific standard. We also applied for and were granted permission to run an expanded access trial with 50 participants prior to approval. I know 50 seems like a tiny number when the need is so great — but that's 50 people who will be able to receive treatment without the study blind (they'll all receive MDMA). Perhaps he lives within the FDA-mandated distance from an expanded access site? Those will be announced soon.

I wish so much that I had more satisfying answers for you than "this is the system we're working in, and these are the choices we have to make." I don't. We have to do the best scientifically rigorous work we can. And we know that millions and millions have suffered since MDMA was made illegal in 1985 despite its obvious potential even then. We're right there with you: not a single person should have to suffer an extra day because of it. We do this work for your son -- and our own families and communities. It will never be fast enough for us, either.

To healing for all,

Grace



Molecular compound of MDMA

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Founder and Executive Director



Kris Lotlikar
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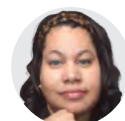
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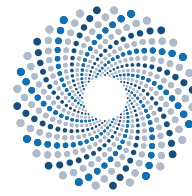


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MAPS
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FOR PSYCHEDELIC STUDIES

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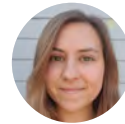
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Ryan Hudgins
Director of Financial
Planning and Analysis



Judy Calkins
Financial Controller



Michael Ruggles
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Administrator



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Jane Zahniser
Program Analyst



Desra Diehl
Staff Accountant

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



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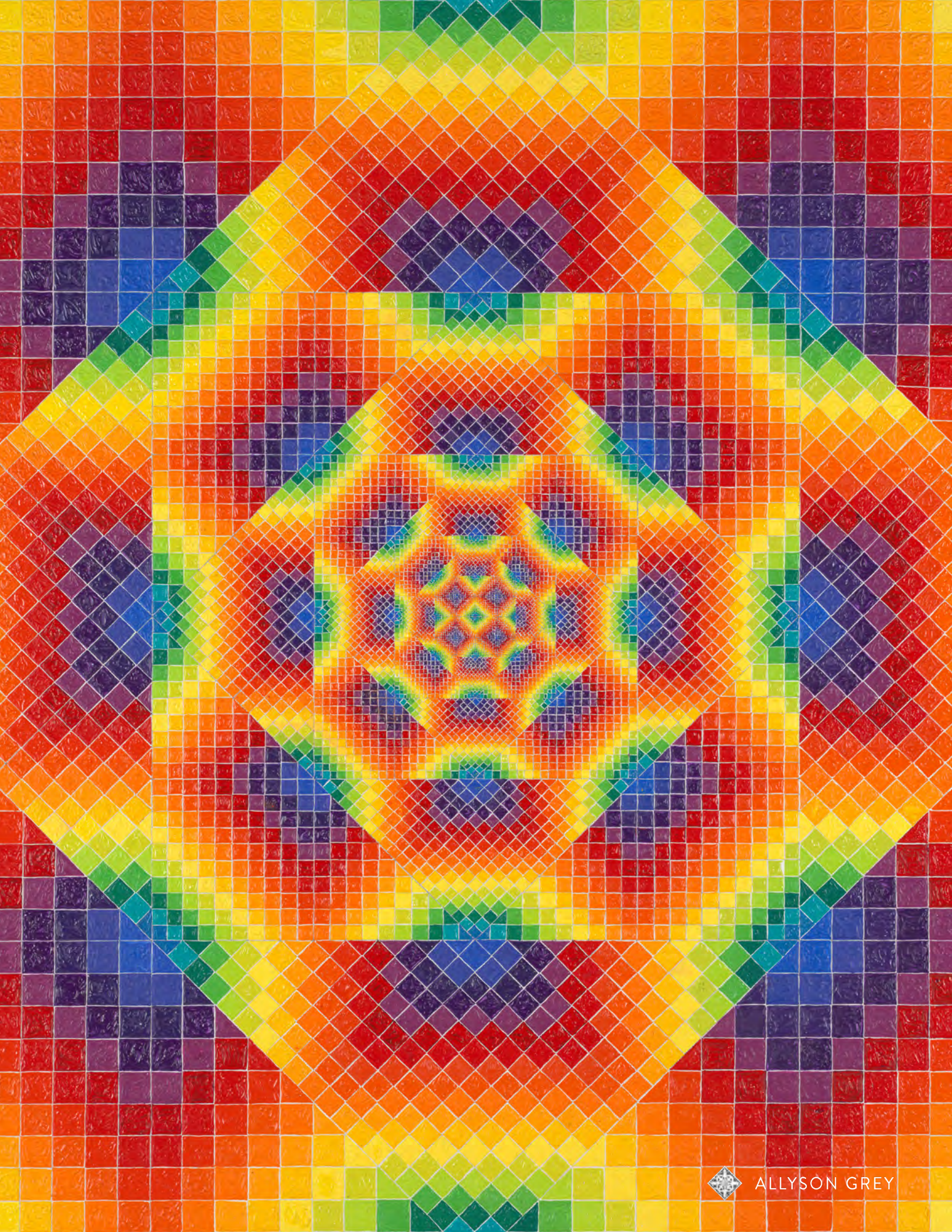
- **Supporting psychedelic science and education** through policy change and advocacy
- **Training practitioners** to deliver MDMA-assisted therapy through professional education in ethics, safety, and therapeutic methods
- **Empowering communities** through our international psychedelic peer support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

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