In this summer of turmoil and transformation, with the COVID-19 pandemic far from over and global population levels of trauma, stress, and anxiety rising, MAPS’ Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) are still moving forward, though much more slowly than initially anticipated. On March 19, 2020, when the pandemic was spreading alarmingly around the world, MAPS’ Data Monitoring Committee (DMC) reported excellent results of the interim analysis of MAPS’ first of two Phase 3 clinical trials. The interim analysis was conducted when all 100 participants had been enrolled and 60 of these 100 participants had reached their primary outcome measure. These additional 40 participants were in various stages of treatment, including some who hadn’t started treatment yet. The DMC reported that, according to the interim analysis, there is a 90% or greater probability of obtaining statistically significant results after all 100 participants had completed the study.

Shortly after the interim analysis, due to COVID-19 public health measures and shelter-in-place orders, treatments almost entirely stopped in our study, as in most studies regulated by the U.S. Food and Drug Administration (FDA). In response, the FDA reached out to the sponsors of research to offer the opportunity to discuss ending active studies early. After discussions with the FDA, we have come to agreement to end our first Phase 3 clinical trial early after 90, rather than 100, participants have been treated. However, not all of these 90 participants will have reached their primary outcome measure after three experimental sessions since some will have had treatments halted due to COVID-19 before they completed the protocol. At a minimum, all 90 participants will have had a baseline measurement of PTSD symptoms and at least one outcome measure after one or more of the experimental sessions. Statistical significance is somewhat easier to obtain for 100 participants as compared to 90 participants but our interim analysis suggests that we are in excellent shape for statistical significance, even with 90 participants.

By the time you read this edition of the MAPS Bulletin, all 90 participants will have completed treatments and outcome measures. We will be in the process of monitoring all the data, finalizing the data in the database lock process, then analyzing the data. We will know definitively before the end of September if our first of two Phase 3 clinical trials was statistically significant.

We’re starting our second Phase 3 clinical trial on a site-by-site basis as soon as therapists and participants are safely able to be in the same place. While we can conduct virtual preparation and integration sessions, we believe the experimental sessions with MDMA or placebo must be conducted in person. We’ve now started screening new subjects for our second Phase 3 clinical trial at four sites with more sites starting soon, we’re starting our expanded access/compassionate use treatments in...
To Phase 3 and Way Beyond,

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

some of the sites around October 2020, then completing our second Phase 3 clinical trial in the beginning to middle of 2022 (depending on COVID-19 and the pace of enrolling new participants).

MAPS’ MDMA/PTSD research for the European Medicines Agency (EMA) is also moving forward, starting to take place this summer or early fall in the Czech Republic, the Netherlands, and the United Kingdom, with Germany, Portugal, Finland, and Norway to follow. We’ll be treating PTSD participants in the context of initial open-label Phase 2 studies for the purposes of training therapists by having them treat a PTSD participant under supervision of our therapist training team.

MAPS also accomplished our most ambitious fundraising campaign ever, our $30 million Capstone Campaign, in collaboration with the Psychedelic Science Funders Collaborative (PSFC). We raised the first $10 million from our Board of Directors, PSFC, and a few close allies. Then, author Tim Ferriss arranged for a $10 million, 90-day challenge grant ending September 10, 2020. Thank you to those who have donated to bring us to this historic point!

At a time of global crises, new approaches to heal trauma and treat mental illnesses are needed more than ever. Despite COVID-19, MAPS’ donors, staff, therapists, participants, and even regulators are working collaboratively towards completing our research, reviewing our data, and then potentially approving MDMA-assisted psychotherapy for PTSD.

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MAPS: Who We Are

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 establishing 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. That means that the future of psychedelic and marijuana research is in the hands of individual donors. Please consider making a donation today. maps.org/donate
Thank You, Brad

After more than 10 years at MAPS, Brad Burge, our Director of Strategic Communications, is moving on to a new chapter. Brad played a pivotal role in the cultural and scientific mainstreaming of psychedelic-assisted therapy and has been an active voice denouncing the war on drugs. Brad has been an invaluable asset in reaching new audiences with our message of healing and justice.

Brad joined MAPS in 2009 and became a full-time employee in 2011 as the sole member of the communications team. Since Brad’s arrival to MAPS, our small 8-person team has grown into a roughly 100-person international organization on the cusp of making MDMA into a medicine for PTSD.

When he first started, far fewer knew about the work we do, and many were far more skeptical about it than today. Brad created much of the foundational content we rely on today to frame the work we do while dancing a delicate line between FDA regulations, fundraising needs, and advocating for the potential benefits of non-ordinary states of consciousness.

One of Brad’s key contributions was the development of the Psychedelic Science conferences. He played a key role in MAPS’ first Psychedelic Science conference in 2010 and the following expansion of that in 2013. He was then conference director for the world’s largest psychedelic conference to date, bringing more than 3,500 people together in Oakland, California, for Psychedelic Science 2017. Many of our supporters will remember meeting him at these events.

We are so grateful that Brad shared his unique gifts with MAPS for the past decade. We are confident his words, passion, and dedication to the field will continue. We hope to honor his contribution to the cause and make him proud. Thank you, Brad. Onward and upwards!
Research News

Treating PTSD with MDMA-Assisted Psychotherapy

Interim Analysis Shows At Least 90% Chance of Statistically Significant Difference in PTSD Symptoms after MDMA-Assisted Psychotherapy

- An independent Data Monitoring Committee has reviewed data from MAPS’ ongoing Phase 3 clinical trial
- The results are the strongest confirmation that an interim analysis can provide
- MAPS and the Psychedelic Science Funders Collaborative have completed the Capstone Campaign to raise the $30 million needed to complete the research and make MDMA a medicine

On May 12, 2020, the non-profit Multidisciplinary Association for Psychedelic Studies (MAPS) announced the results of an interim analysis of the data from the first of its two Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD). This is the best-case scenario for an interim analysis, and suggests that MAPS’ research program is on track for approval by the U.S. Food and Drug Administration (FDA).

The analysis was conducted by an independent Data Monitoring Committee, which reviewed the results from the first 60 out of 100 participants. The analysis revealed a 90% or greater probability that the trial will detect statistically significant results when all participants have been treated, and that the trial will not require additional participants beyond the first 100. The interim analysis was approved by the FDA as part of MAPS’ Statistical Analysis Plan approved by the FDA.

The results strongly suggest that the FDA made the right decision in granting MAPS both (1) Breakthrough Therapy Designation for MDMA-assisted psychotherapy for PTSD, which accelerates the clinical trial process and acknowledges MDMA-assisted psychotherapy as a potentially significant advance over currently available treatments for PTSD, and (2) expanded access, which will allow some patients early access to MDMA-assisted psychotherapy for PTSD prior to approval.

Not all interim analyses are successful. For example, in February 2020, Tonix Pharmaceuticals’ Tomnya®, the only other drug granted Breakthrough Therapy Designation by the FDA for PTSD, failed its interim analysis.

“The Phase 3 trials are expected to be complete in 2022, meaning that the FDA could approve the treatment as soon as 2023.”

“In the pharmaceutical drug development community, this is what you dream about,” says Rick Doblin, Ph.D., MAPS Founder and Executive Director. “The results of the interim analysis of MAPS’ pivotal first Phase 3 trial are the most powerful evidence yet that MDMA-assisted psychotherapy could help transform the lives of people suffering from PTSD. We have trained approximately 70 new therapists to work on Phase 3, so these results also show that the treatment is scalable, eventually to tens of thousands of therapists worldwide.”

To complete this research and make MDMA a legal medicine, MAPS, in collaboration with the Psychedelic Science Funders Collaborative (PSFC), recently accomplished the $30 million Capstone Campaign.

“Psychedelic medicines show incredible promise for treating a range of mental health conditions, but psychedelic research has been underfunded for decades,” says Joe Green, Co-Founder and President of PSFC. “This first look at data from the first-ever Phase 3 trial of a psychedelic-assisted therapy only makes us more confident that we’re standing on the cusp of a breakthrough. The approval of MDMA-assisted psychotherapy would be a catalytic event that brings psychedelic medicine into the mainstream. That’s why we are excited to partner with MAPS in creating the Capstone Campaign to bring this research across the finish line.”

MAPS is continuing our Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD at 14 sites in the U.S., Canada, and Israel. The Phase 3 trials are expected to be complete in 2022, meaning that the FDA could approve the treatment as soon as 2023. MAPS is also in the process of obtaining regulatory approvals for Phase 2 trials in the UK, Germany, Czech Republic, and the Netherlands.

PTSD affects millions—and soon to be millions more—due to the global trauma of the COVID-19 pandemic. This includes victims of the disease and their families, health care and emergency service professionals, as well as front-line workers who are risking their lives to provide essential services.

As a non-profit organization focused on mental health services, MAPS is committed to protecting the safety of its study staff and clinical trial participants. MAPS is taking active measures to minimize the risk of exposure to the COVID-19 virus and adhere to physical distancing. As a result of this initiative, new enrollment of participants in MAPS-sponsored trials
Summer 2020

is temporarily postponed, with treatments continuing for some participants as evaluated on a case-by-case basis.

“I believe this medication-assisted treatment will be a breakthrough in treating trauma,” Amy Emerson, Chief Executive Officer (CEO) of MAPS Public Benefit Corporation (MAPS PBC). “I would like to thank the investigators leading the studies, study participants for their time and participation, the independent Data Review Committee for their careful analysis, and the amazing research team at MAPS PBC who helped us achieve this milestone in non-profit pharmaceutical development.”

MDMA-Assisted Psychotherapy May Have Lasting Benefits for PTSD, Results Published in Psychopharmacology

On June 10, 2020, MAPS announced the publication of the long-term follow-up results of six Phase 2 clinical trials of MDMA-assisted psychotherapy for the treatment of posttraumatic stress disorder (PTSD) in the peer-reviewed journal Psychopharmacology. The paper is the most comprehensive analysis yet published of the safety and durability of treatment outcomes following MDMA-assisted psychotherapy for PTSD.

The results show that for a majority of participants, the benefits of MDMA-assisted psychotherapy for PTSD extended at least 12 months after the treatment sessions. Sponsored by MAPS, the controlled, randomized, double-blind trials found that, two months following their last session, 56% of 100 participants no longer met diagnostic criteria for PTSD. In the newly published analysis, 91 participants were interviewed at least 12 months later. Of these participants, 67% did not qualify for a PTSD diagnosis. One of the studies included data from an average of 3.8 years after treatment.

“Trauma exposure has emerged as one of the most pressing public health issues of our time and is now at the forefront of global consciousness due to the COVID-19 pandemic and rising visibility of systemic oppression,” said Berra Yazar-Klosinski, Ph.D., paper co-author and Deputy Director and Head of Research Development and Regulatory Affairs at MAPS. “Although our Phase 3 trials are not yet completed, these long-term data support the hypothesis that MDMA-assisted psychotherapy may provide significant advantages in treatment outcomes, safety, and durability over available PTSD treatments. This is the breakthrough that the world needs right now.”

The trials were conducted by independent investigators in South Carolina (two trials), Colorado, Canada, Switzerland, and Israel. Trial participants included women and men with chronic, treatment-resistant PTSD from a wide variety of causes.

PTSD symptoms were assessed using the Clinician-Administered PTSD Scale (CAPS-IV) at baseline, one to two months after their last MDMA-assisted psychotherapy session, and at least 12 months after their final session. The course of double-blind treatment included one to three eight-hour MDMA-assisted psychotherapy sessions spaced three to five weeks apart, combined with weekly non-drug psychotherapy sessions. Outcomes were assessed by blinded Independent Raters.

Based on these results, in August 2017, the FDA granted Breakthrough Therapy Designation to MDMA-assisted psychotherapy for PTSD, acknowledging that it “may demonstrate substantial improvement over existing therapies” and agreeing to expedite its development and review. The FDA also considered MAPS’ prior published Phase 2 results when it agreed to MAPS’ expanded access program in January 2020. The research also received major confirmation when it passed its crucial interim analysis in May 2020.

The follow-up study found that long-term adverse events were minimal although the benefits were sustained. The most
common harm reported at the long-term follow-up was worsened mood, reported by less than 4% of study participants. Further assessment of the long-term benefits and risks of MDMA-assisted psychotherapy is needed in future trials that include control groups.

The *Psychopharmacology* article was authored by Lisa Jerome, Ph.D., Allison Feduccia, Ph.D., Julie B. Wang, M.P.H., Ph.D., Scott Hamilton, Ph.D., Berra Yazar-Klosinski, Ph.D., Amy Emerson, B.A., Michael C. Mithoefer, M.D., and Rick Doblin, Ph.D.

“These long-term follow-up findings show that once people with PTSD learn that they can productively process traumatic memories instead of suppressing them, they can continue to heal themselves even after they have stopped receiving MDMA-assisted psychotherapy,” said co-author Rick Doblin, Ph.D., MAPS Founder and Executive Director.

MAPS is also in the process of obtaining regulatory approvals for Phase 2 trials in the Czech Republic, Netherlands, Germany, United Kingdom, Portugal, Norway, and Finland.

PTSD is a chronic mental health condition affecting 3-4% of the global population. PTSD can be caused by sexual assault, violent crime, military or law enforcement service, serious illness, and a wide variety of other causes. A new approach to treating PTSD is urgently needed, especially for those who do not respond to existing treatments.

MDMA-assisted psychotherapy uses MDMA to improve the effectiveness of psychotherapy for PTSD. The treatment involves up to three administrations of MDMA (75-125 mg) in conjunction with psychotherapy in a controlled clinical setting as part of a course of psychotherapy. Once approved, patients will not be able to take the MDMA home—patients won’t be filling their prescriptions at their local pharmacy. Instead, MDMA-assisted psychotherapy treatment will only be available through a doctor and only in supervised therapeutic settings from certified clinicians.

**FDA Agrees to Expanded Access Program for MDMA-Assisted Psychotherapy for PTSD**

On December 20, 2019, the FDA agreed to MAPS’ application for an expanded access program for MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD).

The purpose of the expanded access program is to allow early access to potentially beneficial investigational therapies for people facing a serious or life-threatening condition for whom currently available treatments have not worked, and who are unable to participate in Phase 3 clinical trials.

“We commend FDA for recognizing the great unmet medical need of PTSD by allowing access to MDMA-assisted psychotherapy on a compassionate basis for people with treatment-resistant PTSD,” said MAPS Founder and Executive Director Rick Doblin, Ph.D. “We are delighted to begin generating real-world evidence about this potential new treatment.”

The expanded access protocol will allow 50 patients to receive MDMA-assisted psychotherapy, following the MAPS treatment protocol (maps.org/treatmentmanual). MAPS hopes to expand the number of patients eligible to receive treatment in the expanded access program. MAPS has proposed to the FDA that after the first 35 patients, it will submit patient data for the agency to consider whether to expand the program.

The expanded access protocol differs from MAPS’ ongoing Phase 3 clinical trials in that it is limited to treatment-resistant patients with moderate to severe treatment-resistant PTSD. Other differences are that the FDA is requiring at least one therapist of each therapy pair to have a medical or clinical doctorate degree (M.D., Ph.D., or equivalent), there is no control group, and patients are responsible for the costs of their own treatment.

Up to 10 qualifying treatment sites will be selected to begin the expanded access program, to be announced in the next few months. Over 120 site applications have been received to date. Once the program begins, patients can apply to the individual expanded access sites.

“The resurgence of research into using drugs such as MDMA to catalyze psychotherapy is the most promising and exciting development I’ve seen in my psychiatric career,” said Michael Mithoefer, M.D., Acting Medical Director for MAPS PBC. “Combining the powerful effects of pharmacology with the potential depth of psychotherapy is a compelling model for harnessing advances in neuroscience and psychopharmacology without ignoring the complexity, richness and innate capacity of the human psyche. I’m delighted that the expanded access program will now allow some patients to access to this modality as MAPS’ Phase 3 research continues.”

MAPS’ expanded access protocol must still be approved by the U.S. Drug Enforcement Administration (DEA) and the Institutional Review Board (IRB). Based on the FDA’s review as well as the DEA and IRB’s existing support of MDMA-assisted psychotherapy clinical trials, MAPS does not anticipate delays in those approvals.

This is the second time that a government agency has allowed such a program for MDMA-assisted psychotherapy. On February 3, 2019, the Israeli Ministry of Health announced the approval of compassionate use for MDMA-assisted psychotherapy for PTSD, which will also allow 50 patients to receive the treatment. Patients with PTSD will be eligible to receive treatment at four sites throughout Israel.

In August 2017, the FDA granted Breakthrough Therapy Designation to MDMA-assisted psychotherapy for PTSD.

**Phase 3 Trials of MDMA-Assisted Psychotherapy for PTSD**

While our studies are impacted due to COVID-19, we are continuing to accept applications and begin the screening process for research participants for the MAPS-sponsored Phase 3 clinical trial of MDMA-assisted psychotherapy for PTSD. Participants will help contribute to scientific knowledge and will help us better understand if MDMA-assisted psychotherapy works.
for the treatment of PTSD. MAPS conducts clinical trials under the guidance and regulations of the FDA, in collaboration with all federal regulators, including the DEA.

The Phase 3 clinical trials are assessing the efficacy and safety of MDMA-assisted psychotherapy in adult participants with moderate to severe PTSD. Over a 12-week treatment period, participants will be randomized to receive 12 non-drug preparatory and integration sessions lasting 90 minutes each, along with three day-long sessions about a month apart of either MDMA or placebo in conjunction with psychotherapy. The primary endpoint will be the Clinician-Administered PTSD Scale (CAPS-5), as assessed by a blinded pool of independent raters.

Our FDA-regulated Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) are taking place at 14 locations across the United States, Canada, and Israel. The current Phase 3 trial is being conducted at the following study sites:

- Los Angeles, CA | private practice
- San Francisco, CA | research institution
- San Francisco, CA | private practice
- Boulder, CO | private practice
- Fort Collins, CO | private practice
- New Orleans, LA | private practice
- New York, NY | research institution
- New York, NY | private practice
- Charleston, SC | private practice
- Madison, WI | research institution
- Boston, MA | private practice
- Vancouver, Canada | research institution
- Be’er Ya’akov, Israel | research institution
- Tel HaShomer, Israel | research institution

The trials are the final phase of research required by the FDA before deciding whether to approve MDMA as a legal prescription treatment for PTSD. If approved, MDMA will be required to be used in conjunction with psychotherapy in an outpatient setting.

We are currently seeking research participants for Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD. Participants will help contribute to scientific knowledge and will help us better understand if MDMA-assisted psychotherapy works for the treatment of PTSD. MAPS conducts clinical trials under the guidance and regulations of the FDA in collaboration with all federal regulators, including the DEA. To learn more about our clinical trials or apply to be a study participant, visit this website: mdmaptsd.org

There is now a clear path ahead to make MDMA a legal medicine for millions of people suffering from PTSD. Help heal trauma: maps.org/donate

Israel Embraces Research on MDMA-Assisted Psychotherapy for PTSD

- First two Israeli participants complete treatment in Phase 3 clinical trial of MDMA-assisted psychotherapy for PTSD
- Israel is first national government to approve a compassionate use program for MDMA-assisted psychotherapy
- Israeli Ministry of Health represents the first national government to support therapeutic MDMA research ($500,000 in services)
- MAPS has raised $500,000 through individual donors and the Charles and Lynn Schusterman Family Foundation, and still seeks the final $200,000

On February 26, 2020, MAPS announced that the first two participants have completed treatment in MAPS’ Phase 3 clinical trial of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) in Israel.

The Phase 3 studies, taking place at two sites in Israel, are part of the international series of Phase 3 clinical trials sponsored...
by MAPS, intended to make MDMA-assisted psychotherapy a legal prescription treatment for PTSD under FDA guidelines. “Preliminary research has shown that MDMA-assisted psychotherapy may be a profound way to help those who suffer greatly from traumatic experiences such as war or sexual assault,” said Dr. Keren Tzarfaty, Clinical Investigator, Training Supervisor, and Director of Israeli Projects and Collaborations with MAPS. “In the face of the perpetual violence in Israel and the surrounding region, this innovative heart-based treatment can transform suffering to wholeness.”

Over 10% of the Israeli population experiences PTSD, and this figure increases significantly in regions frequented by rocket attacks. Military service is compulsory, and most families in Israel have histories of trauma and persecution.

On February 3, 2019, Israel became the first government to approve a compassionate use program for MDMA-assisted psychotherapy for PTSD, which will allow 50 patients to receive the treatment outside of Phase 3 clinical trials. Patients with PTSD will be eligible to receive treatment at sites throughout Israel, including Rambam Medical Center in Haifa and psychiatric hospitals in Be’er Yaakov, Lev Hasharon, Be’er Sheva, and Sheba-Tel Hashomer.

The U.S. FDA followed Israel on December 20, 2019, when the agency agreed to an expanded access program for MDMA-assisted psychotherapy for PTSD, also for 50 patients with PTSD.

“The Israeli Ministry of Health is constantly looking for new tools to get better results in psychological and psychiatric treatment,” says Bella Ben-Gershon, Director of Psychological Trauma for the Israeli Ministry of Health. “After seeing the very promising results of the completed MDMA-assisted psychotherapy research in Israel, we now believe that it is crucial to allow more citizens who suffer from PTSD to have access to this new treatment.”

Israel is also the first national government to financially support MDMA-assisted psychotherapy research. In February of 2019, the Israeli Ministry of Health granted $500,000 in medical and hospital services to MAPS in support of the compassionate use of MDMA-assisted psychotherapy for PTSD in Israel.

The Israeli Ministry of Health inspired the Charles and Lynn Schusterman Family Foundation, a major philanthropic organization that funds projects in the Jewish community and Israel, to contribute a generous grant to MAPS for the Israeli compassionate use program.

“A society is only as strong as how it cares for its most vulnerable communities,” says Stacy Schusterman, Chair of the Charles and Lynn Schusterman Family Foundation. “I am proud that Israel is leading the world in exploring new ways to support and treat people suffering from PTSD and psychiatric illnesses. The compassionate use program in Israel is an opportunity to help high-risk populations, including IDF soldiers who have served their country, whose mental health needs are often overlooked and underserved.”

MAPS estimates the total cost for treating all 50 patients in the Israeli compassionate use program at $1.2 million. With the contributions from the Ministry of Health and the Schusterman Family Foundation, together with additional gifts from Ron Beller, Anat Agmon, Moshe Tov Kreps, and Saggi Malachi, MAPS now has $200,000 left to raise for the Israeli program.

**Startle Testing with MDMA: Thirty-First Participant Receives Experimental Treatment**

On March 25, 2020, the thirty-first participant completed experimental treatment in our ongoing study of the effect of MDMA on startle testing in healthy participants. Led by Principal Investigator Barbara Rothbaum, Ph.D., this study is conducted at Emory University in Atlanta, Georgia. Enrollment to this study is currently on hold due to COVID-19.

**Therapist Training Study: New Protocol Amendment Accepted by the FDA**

On May 12, 2020, a new protocol amendment that increases the number of study participants to a total of 120 was accepted by the FDA. This protocol amendment was submitted to the IRB on April 30, 2020. This study is our ongoing Phase 1 study of the psychological effects of MDMA when used in a therapeutic setting by healthy participants. Enrollment in this multi-site study is on hold due to COVID-19 and is limited by invitation only to therapists in training to work on MAPS-sponsored clinical trials of MDMA-assisted psychotherapy for PTSD. The Boulder, Colorado, study site is led by Principal Investigator Marcela O’talora G., M.A., L.P.C., the Charleston, South Carolina, is led by Principal Investigator Zhenya Gelfand, M.D., and the Santa Fe, New Mexico, study site is led by Principal Investigator George Greer, M.D.

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

MAPS will 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). This study will explore the safety and feasibility of MDMA-assisted psychotherapy 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 3,4-Methylenedioxymethamphetamine (MDMA) Tolerability and Pharmacokinetics in Participants with Moderate Hepatic Impairment 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-dioxymethamphetamine (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

Best wishes from the Training and Supervision Department at MAPS PBC! We hope that you, your loved ones, and communities are taking care of your nervous systems and of each other, as current events continue to unfold around the COVID-19 pandemic and the racial justice movement in the United States.

MAPS PBC Trainers Annie Mithoefer, B.S.N., and Michael Mithoefer, M.D., recently completed the first live online training for the MDMA Therapy Training Program with support from MDMA Therapy Training Program staff. They delivered the online training across two weekends in June to the seventy-student cohort in the California Institute of Integral Studies (CIIS) Certificate in Psychedelic-Assisted Therapies and Research (CPTR) program. The Center for Psychedelic Psychotherapy and Trauma at the Icahn School of Medicine at Mount Sinai and the Bronx VA sponsored an MDMA-assisted psychotherapy training featuring Michael Mithoefer and Annie Mithoefer for twenty-nine VA clinicians. This Bronx VA training was delivered with the support of MAPS PBC training staff and MAPS investigators. MAPS PBC Trainers Marcela Ot’alora G., L.P.C., and Bruce Poulter, M.P.H., will provide an online nine-day training with Naropa University from September 25-27, October 23-25, and October 30 - November 1. During the month of November, Annie Mithoefer and Michael Mithoefer will be delivering the first-ever international online training to a cohort of therapists in Europe preparing to work on the Phase 2 protocol for the open-label lead-in study for the European segment of Phase 3 clinical trials for MDMA-assisted psychotherapy for PTSD.

The Training Team is excited to learn from our online trainings as we progress with training design and program development. The MDMA Therapy Training Program is carrying out an educational design project to further develop the training pedagogy and competency framework to support the growth and continued quality of the program over the coming years. Additionally, the training program continues to support clinical supervision of active MDMA-assisted psychotherapy studies, as many study sessions are continuing with safety practices in place for COVID-19.

Sign up for the Training Program Newsletter to receive updates on upcoming trainings: mapspublicbenefit.com/therapy-training

Clinical Trials, Safety, and COVID-19

The MAPS-sponsored Phase 3 study of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) has been impacted by the COVID-19 global pandemic. With the guidance of FDA, MAPS PBC has decided to conclude the study in August 2020 with 90 participants instead of the originally intended 100 participants following discussions with the FDA. MAPS PBC is developing individual plans for participants who began treatment and had study visits delayed due to COVID-19. By August all participants who have been able to continue study visits during COVID-19 lockdown will have completed the study. We greatly appreciate our study participants, and we are committed to ensuring they have an opportunity to complete treatment within the study protocol as soon as possible.

Participate in Research

MAPS sponsors clinical trials around the world that require human participants. Our studies have strict enrollment criteria based on the goal of the study and the condition the study is investigating.

Enrollment for the first of two Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD has concluded. Our study recruitment website for the second Phase 3 trial of MDMA-assisted psychotherapy for PTSD is accepting applications for select study sites: mdmaptsd.org

We are actively preparing to initiate enrollment for the remaining study sites conducting our second Phase 3 clinical trial of MDMA-assisted psychotherapy for PTSD.

Please visit our Participate in Research page and check it frequently for updates about participant enrollment: maps.org/participate/participate-in-research
MAPS in the Media

THE WALL STREET JOURNAL.
Silicon Valley and Wall Street Elites Pour Money Into Psychedelic Research
Shalini Ramachandran • August 20, 2020
The Wall Street Journal reports on the successful completion of the Capstone Challenge, a fundraising effort to complete Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD. The article highlights multiple $1M+ donations and the support of the Psychedelic Science Funders Collaborative (PSFC) and author Tim Ferriss, illustrating the rapid mainstreaming of psychedelic research and fundraising. “Psychedelic research has been thought of as ‘fringe’ for a long time. But there’s nothing ‘fringe’ about PTSD,” says Bob Parsons, the MAPS donor who founded GoDaddy and PXG. “There are millions of people with PTSD in the U.S. alone, and that includes veterans like me, first responders like those on the front lines of the Covid-19 pandemic, and survivors of sexual assault and domestic abuse. All of them deserve better, significantly more effective treatment options than we give them today.”

LA WEEKLY
DEA Finally Announce Rules to Expand Supply of Research Weed
Jim Devine • April 7, 2020
LA Weekly reports on the Drug Enforcement Administration’s (DEA) announcement to release draft rules for the first round of public comments regarding an expansion of the research-grade marijuana supply in the U.S. beyond the University of Mississippi, which has been the only federally approved cannabis for research for over 50 years. While the DEA’s announcement may mark progress, many researchers are cautiously optimistic; there are “more unnecessary delays since DEA could and should issue licenses now,” says MAPS Founder Rick Doblin.

Forbes
Psychedelic Pioneer Rick Doblin On FDA Trials Of MDMA: Most Important Reality Check Of MAPS’ 34-Year History
David E. Carpenter • May 12, 2020
Forbes reports on the results from MAPS’ interim analysis for the first of two Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD, a monumental milestone in psychedelic research. “The great results from the interim analysis has changed everything in that we are now actively preparing for FDA approval and commercialization based not on hopes and dreams but on actual data from Phase 3,” explains MAPS Founder Rick Doblin, Ph.D.

Treating PTSD With Psychedelics
Terry Gross • June 22, 2020
“MDMA is just an exquisitely perfect chemical for augmenting the process of psychotherapy,” says Dr. Julie Holland on an episode of NPR’s Fresh Air podcast with host Terry Gross. “MDMA, because it increases oxytocin, there is a quieting of the amygdala — the fear response. Exploring trauma is scary, and often if people become afraid, they close down and they don’t want to talk,” explains Dr. Holland. Listen to the full episode to hear an insightful conversation about the potential for psychedelic therapy, cannabis, and plant medicines to treat the root cause of trauma, promote healing, and facilitate neuroplasticity.

CLINICAL TRIALS ARENA
Long-Term Efficacy Data Shows MDMA Is Effective for Treating PTSD
June 15, 2020
Clinical Trials Arena reports on the long-term follow-up results compiled from six trials of MDMA-assisted psychotherapy for PTSD, which demonstrated continued improvement in most patients for more than one year after the treatment ended. The long-term data shows 67% of participants no longer met diagnostic criteria for PTSD after one year, compared to 56% of participants at the original endpoint of the trials. These results further add to previous data on the potential effectiveness of the treatment and “makes it one of the most promising agents in the pipeline for PTSD,” says Clinical Trials Arena.

Rick Doblin, Ph.D. — The Psychedelic Domino That Tips All Others
Tim Ferriss • June 11, 2020
Listen to the recent episode of The Tim Ferriss Show with MAPS Founder Rick Doblin, Ph.D., for an insightful conversation about psychedelic science, the final steps involved to make MDMA-assisted psychotherapy into a prescription treatment option for PTSD, and MAPS’ goal to raise $10 million in donations through the Capstone Challenge.
Summer 2020

MAPS in the Media

Psilocybin and Psilocybin-Assisted Psychotherapy
Michael Roy • May 1, 2020
American Journal of Psychiatry Audio speaks with Dr. Collin Reiff and Dr. William McDonald about their evidenced-based summary of the literature on clinical psychedelic research for the treatment of mental health conditions. The podcast takes listeners on a journey through the history of psychedelics, the prohibition of psychedelic research in the 1960s, the current shift in mainstream perspective of psychedelics, MAPS-sponsored psychedelic-assisted therapy research, plus conclusions that researchers and mental health professionals may benefit from in their careers.

PTSD Breakthrough: MDMA Shows Promise Healing Mental Trauma in FDA-Approved Clinical Trials
Matt Saintsing • May 5, 2020
Disabled American Veterans (DAV) reports on the promising results from clinical trials of MDMA-assisted psychotherapy for the treatment of PTSD, stating, “the research has been so promising that the U.S. Food and Drug Administration (FDA) has granted the drug ‘breakthrough’ status.” MAPS Public Benefit Corporation (MAPS PBC) Acting Medical Director Michael Mithoefer, M.D., explains, “It can be very painful to process trauma, whether you have MDMA or not.” MDMA in conjunction with psychotherapy “tends to make processing more possible,” says Dr. Mithoefer.

The Power of Psychedelics
Erica Rex • July 12, 2020
“Treatment with psychedelic drugs represents a paradigm shift in the approach to mental health,” explains author Erica Rex in a Scientific American article where she shares her experience as a participant in a clinical trial of psilocybin for cancer-related depression. From this experience, Rex examines the differences between the therapeutic process in traditional psychotherapy versus psychedelic therapy and explores the potential for psychedelic-assisted therapies, including MDMA and psilocybin, to treat a variety of mental health conditions.

Can Psychedelic Therapy Reduce the Mental Health Impacts of the Coronavirus Pandemic?
Morgan Campbell • April 2, 2020
The Sacramento Bee explores the potential psychedelic-assisted psychotherapy may have in treating mental health conditions resulting from the coronavirus pandemic. “To address the inevitable spike of mental illnesses, we must hasten the approval of new evidence-based medications for depression and PTSD. These include the psychedelic compounds MDMA and psilocybin,” says The Sacramento Bee.

Revolutionary Drug Trial Using Ecstasy to Treat PTSD and Mental Illness
David E. Carpenter • May 4, 2020
60 Minutes Australia explores therapeutic potential of MDMA-assisted psychotherapy for PTSD. The episode follows the experience of a former participant in a Phase 3 clinical trial and includes an interview with Erik Sienknecht, Psy.D., a MAPS-sponsored therapist working on Phase 3 trials of MDMA-assisted psychotherapy for PTSD. “It is going to change the face of psychiatry,” says Sienknecht.

A Formerly Secret Memo Explains the DEA’s Long Delay in Approving New Producers of Marijuana for Research
Jacob Sullum • April 30, 2020
Reason reports on a new memo released by the Drug Enforcement Administration (DEA) as part of a settlement agreement with MAPS-sponsored researcher Sue Sisley, M.D., and her company, Scottsdale Research Institute (SRI). Reason says that the memo “explains why the DEA has been so slow in following through on a 2016 commitment,” which would end the government-created monopoly on research cannabis.

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Erica Rex • July 12, 2020
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MDMA Therapy Training for Communities of Color
SHANNON CARLIN, M.A., AMFT

Two powerful events exploring community, culture, race, trauma therapy, and psychedelic medicine took place in Louisville, Kentucky, in August 2019: Psychedelic Medicine & Cultural Trauma Workshop and MDMA Therapy Training for Communities of Color. Sara Reed, M.S., M.F.T., is a marriage family therapist who worked on the MAPS-sponsored Phase 2 clinical trial of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) in 2018, becoming the first Black therapist to provide MDMA-assisted psychotherapy in a clinical trial. Reed is a Kentucky native and welcomed the crowd to her home state.

Due to its history, Louisville is a significant setting for a gathering on cultural trauma. Although Kentucky was a Union state during the U.S. Civil War, many of its white residents still owned slaves. The town of Louisville sits on the southern bank of the Ohio River, where Black slaves risked passage to freedom. The harmful effects of racism compound over time and impact communities of color today. The recent deaths of Breonna Taylor and David McAtee echo a familiar grief in the heart of Louisville. In a 2019 Pew survey on public perceptions about race, 84% of Black respondents and 58% of white respondents believe that “The legacy of slavery affects the position of black people in American society today a great deal/fair amount” (Horowitz et al., 2019). I’m curious what the responses would be today.

Racial, historic, and intergenerational traumas are complex, chronic, and widespread. While these sources of trauma have gained attention in clinical research over the past few decades, their diagnosis and treatment aren’t well defined. It has become clear that in order to appropriately and effectively address identity- and race-based traumas, a culturally responsive approach is needed.

The National Center on Domestic Violence, Trauma, and Mental Health defines being culturally responsive as, “proactively integrating meaningful attention to the cultural identities of participants and staff, and to the ways culture can shape people’s experiences of trauma and healing” (Warshaw et al., 2018).

One of the most direct ways to provide culturally responsive and informed care is to include a diverse workforce. According to the American Psychological Association (APA),
86% of psychologists are white (Lin et al., 2018). Within the therapists currently working on a MAPS trial, 90% are white. As mentioned above, when Reed started working on the MDMA-assisted psychotherapy for PTSD protocol in 2018, she was the first Black therapist to administer MDMA-assisted psychotherapy in a clinical trial. The demographic of clinicians working on MDMA-assisted psychotherapy trials, and psychedelic clinical research in general, falls far short of a racially representative workforce.

Lack of diversity is also reflected in the population of people receiving MDMA-assisted psychotherapy in clinical trials. In six completed Phase 2 clinical trials of MDMA-assisted psychotherapy for PTSD conducted from 2004-2017, 105 participants were enrolled: 88% white, 3% Latinx, 2% Native, 2% Middle Eastern, 6% multiracial. No participants identified as Black or Asian for their primary race, though participant(s) may have identified as one of multiple races. Note that these studies include participants in the United States, Israel, and Canada (Mithoefer et al., 2019). Racial representation in MDMA-assisted psychotherapy trials has somewhat improved in the last few years. In the current FDA-regulated Phase 3 study, 110 U.S.-based participants met initial eligibility: 68% white, 11% Latinx, 4% Black, 8% Asian, 3% Native, 3% multiracial, and 3% did not respond (unpublished raw data). According to 2010 U.S. Census data, 72% of respondents reported their race as white, 13% Black, 5% Asian, 1% Native, 6% some other race, and 3% multiracial. The U.S. Census reports Latino origin separately from race: of the total U.S. population in 2010, 16% of respondents were Latinx, 20% were neither Latinx nor white, and 64% were white alone (Humes et al., 2011). Compared to the demographics of the U.S. general population, Black communities are severely underrepresented in MDMA-assisted psychotherapy studies, with Latinx and Asian groups also not being adequately represented.

One of the barriers to including a racially diverse population is a lack of trust in the medical establishment, especially medical research. The U.S Public Health Service Syphilis Study in Tuskegee and other harmful projects have failed patients of color. A 2002 study conducted by Corbie-Smith, Thomas, and St. George explored race and distrust in research. “Even after controlling for markers of social class, African Americans were less trusting than white Americans. Racial differences in distrust have important implications for investigators as they engage African Americans in research” (Corbie-Smith et al., 2002). “These differences are generally attributed to current and historical evidence of inequitable treatment of Blacks by the health care system, as well as racial differences in patient–provider communication, insurance coverage, and physician characteristics” (Armstrong et al., 2007).

People are less likely to seek treatment if they don’t have trust in health care professionals. A 2011 study by Roberts et al., found that, “When PTSD affects US race/ethnic minorities, it is
usually untreated. Large disparities in treatment indicate a need for investment in accessible and culturally sensitive treatment options. The question about increasing access is inherently tied to rebuilding trust after a history of health care abuse. Research organizations today, especially those with a predominantly white workforce, must take steps to establish trust with communities of color if they wish to serve a racially diverse patient population.

A 2015 interview with racial trauma researcher Monnica Williams, Ph.D., ABPP, caught the attention of Natalie Ginsberg, M.S.W., MAPS Director of Policy and Advocacy (Wortham, 2015). A thorough understanding of racial trauma was missing in the work of MAPS. Williams and Ginsberg quickly became familiar with each other’s work, and Williams attended an MDMA Therapy Training Program course in October 2015, with trainers Annie Mithoefer, B.S.N., and Michael Mithoefer, M.D. Williams was motivated by simultaneous concern about the lack of racial diversity as well as hope for MDMA’s potential to treat racial trauma. In a moving podcast, Williams shares what inspires her to pursue MDMA-assisted psychotherapy: to make the best treatment options available for people of color (The Nod, 2019). She initiated a MAPS-sponsored MDMA-assisted psychotherapy for PTSD study site at the University of Connecticut, where Reed worked on the study team. To date, Williams has been the only Black Principal Investigator to work on a MAPS clinical trial site, and possibly any psychedelic clinical trial ever. While MAPS and other research organizations work to increase racial diversity of participant populations, we must include more people of color in research and leadership positions within and around the organization.

In 2018, Williams was approached by Open Society Foundations (OSF) with a $70,000 grant to support the development of MDMA-assisted psychotherapy clinics in communities of color. One of the first steps in establishing an MDMA clinic is for therapists to undergo training. The MDMA Therapy Training Program is a prerequisite to working on a MAPS protocol. Williams and Ginsberg reached out to me to initiate our collaboration on the event. To support further scholarship and staffing, we raised an additional $230,000 from Riverstyx Foundation, Libra Foundation, Dr. Bronner’s, and the Psychedelic Science Funders Collaborative (PSFC). Seeds were planted for an MDMA Therapy Training for Communities of Color and a workshop on Psychedelic Medicine & Cultural Trauma.

The Psychedelic Medicine & Cultural Trauma Workshop took place from August 10-11, 2019, with a dozen presentations, performances, and speakers’ panels, and an evening storytelling event at a local restaurant. Over 100 attendees from across the U.S. gathered on the 16th floor of a historic hotel in downtown Louisville, Kentucky. The hotel, with framed portraits of white men riding horses lining the hallways, felt like a strange setting for a gathering of many cultures, yet the community came together regardless. The room was full of therapists, doctors, students, community organizers, patient advocates, professors, researchers, a couple of lawyers, a few journalists, and filmmakers.

Inspiring presentations explored community, culture, race, psychedelic medicine, traditional healing practices, harm reduction, policy, education, research, intergenerational trauma, music, spirituality, and the body’s wisdom. To support community space, Camille Barton of the Collective Liberation Project (thecollectiveliberationproject.com), and Ismail Lourido Ali, J.D., MAPS Policy and Advocacy Counsel, offered an interactive session on mindfulness and connection. Throughout the week, Barton offered presentations and activities for movement and mindfulness. Williams presented a talk titled Marginalized Voices, Racial Trauma, and the Psychedelic Healing Movement. Belinda Eriacho, M.P.H., of Dine’ and Zuni lineage, spoke about intergenerational trauma and its legacy for Native Americans. Reed performed a passionate dance, a somatic expression of racial trauma and healing with MDMA-assisted psychotherapy. Carl Hart, Ph.D., gave a characteristically gripping speech on the real-world impact of the drug war on people of color, and the right to life, liberty, and the pursuit of happiness. Kwasi Adusei, D.N.P., PMHNP-BC, spoke about risk reduction and peer support in psychedelic spaces.

On Sunday morning, Jamilah R. George, M.Div., delivered a passionate message, Let Justice Roll Down: Relinquishing Psychedelic Healing for People of Color, a nod to Dr. Martin Luther King Jr. George described the meaning of the word relinquish: allowing resources and healing to flow into and through communities of color. Bringing the event together towards the end of the workshop, Joe Tafur, M.D., delivered a presentation titled Psychedelic Medicine: Illuminating the Integration of Biology, Emotion, and Spirituality. A dozen presenters in all contributed to an energetic and meaningful gathering. Several panel discussions and breakout sessions rounded out the workshop before the workshop came to a close on Sunday afternoon. As people who came just for the weekend started to depart, the events transitioned to the MDMA Therapy Training Program course.

Fifty-five therapists, doctors, counselors, and nurses attended the MDMA Therapy Training for Communities of Color: clinicians working in and with communities of color. The group was made up of 13 Black, 7 Asian, 8 Latinx, 4 mixed Latinx/Native, 3 Native, 1 Pacific Islander, 1 Pakistani, 1 Arab, 1 Egyptian, 1 Lebanese, 13 Multiracial, and 2 white trainees. It
was hopeful seeing almost all people of color in the room of a psychedelic training: hope for strengthening the community of psychedelic providers and hope that psychedelic therapy would become more accessible to people of color.

The MDMA Therapy Training Program is a five-part training, including a week-long retreat, led by two MAPS trainers. The program recently grew from two to seven trainers, though the only person of color on the team is Marcela Ot’aílora G., L.P.C. She is also the only Principal Investigator and Supervisor of color working on the current MDMA-assisted psychotherapy studies. The program’s lack of diversity is a challenging reality. Since inclusion of a diverse pool of therapists wasn’t prioritized from the beginning of the program, it will take time for more clinicians of color to gain the experience necessary to become supervisors and trainers.

There was concern about having a white trainer at an event focused on communities of color. After much discussion with Williams and others, I was selected to support Ot’aílora G. as an MDMA therapy trainer. As a white woman helping to put on a training retreat for therapists of color, I took this job seriously. Putting on an event about psychedelic medicine and cultural trauma is a major undertaking: racial identity, power, and privilege were going to be central themes. Establishing trust between the trainers, program staff, and the cohort would be essential in creating a container for learning and dialogue. Williams, Reed, Ot’aílora G., and I served as the core staff for the event. Two Black women, a Colombian woman, and a white woman stood in the face of racial trauma to create a gathering for cultural healing.

Over the six days of training, Ot’aílora G., Reed, Williams, and I delivered case presentations and content centered on trauma therapy and the clinical applications of MDMA. Presentations included lectures, discussions, slides, videos of therapy sessions, demonstrations, and activities. Williams shared insights and strategies during her presentation, Culturally Informed Outreach for MDMA-Assisted Therapy for PTSD. Several people who worked with Williams on the MDMA-assisted psychotherapy for PTSD study at the University of Connecticut shared their research and experiences, including Reed, George, and Terence Ching, M.S.

In a talk titled, MDMA-Assisted Psychotherapy for Participants of Color with PTSD: Does It Work?, Ching presented an analysis of data that seems to indicate that people of color who received MDMA-assisted psychotherapy in the study had equally positive improvements as white participants, though there may be differences in how quickly the change occurred. The sample size was small, so more data is being collected to support a detailed analysis. Ching also shared reflections from his recent publication: “Intersectional insights from an MDMA-assisted psychotherapy training trial: An open letter to racial/ethnic and sexual/gender minorities.”

Jamilah George, M.Div., and I collaborated to share information about the culturally informed use of music in MDMA-assisted psychotherapy, which concluded with a half-hour activity for trainees to experience the music first-hand. Ot’aílora G. and I shared several case presentations including video recordings of therapy sessions that took place at various sites, some of our own clinical work, as well as that of therapists who Ot’aílora G. supervises. Reed shared her case with the cohort, playing a powerful video of an MDMA-assisted psychotherapy session. The study participant, a man of color, was processing the pain he had endured in his life.

Video case presentations, which are recordings of actual MDMA-assisted psychotherapy sessions, are a core element of the training program. Video helps to convey the core principles of the modality and demonstrate their application, such as how to conduct preparatory, integration, and MDMA-assisted psychotherapy sessions. Several cases are shared through the training retreat to demonstrate different therapists and participants and the various ways MDMA-assisted psychotherapy treatment can look. Many therapists have little or no experience with MDMA and find the video recordings to be an invaluable learning tool.

Before enrolling in the study, participants are informed about video recordings and the use of their video. Videos in MDMA trials are used for clinical supervision, assessing therapist adherence, monitoring safety, and research. Additionally, videos may be used for educational purposes in the MDMA Therapy Training Program run by MAPS Public Benefit Corporation (MAPS PBC). Research staff at the study sites review the Informed Consent Form with each person before they choose whether to give their consent.

Occasionally, a former study participant will reach out to the trainers to inquire about attending the MDMA Therapy Training. Over the years, a handful of former study participants have attended the training, either to speak about their experience receiving MDMA-assisted psychotherapy in the study, or to attend the training as a mental health professional, and sometimes both. In a surprising chain of events, a former study participant, who is also a clinician, attended the August 2019 training, unbeknownst to the training staff and trainers. While the study participant had notified the therapists at the site where they received treatment, the training program wasn’t informed that a former study participant would be in attendance at the event. Out of dozens of study participants, this person’s video was selected to be shown at the August event: a seven-minute clip of a preparatory session.

The participant was shocked to see their therapy session playing in the training room and distressed to be in this challenging situation. The trainers and the cohort were dismayed to learn of this. Already in a tender place of trust building, the group felt this shock as a rupture in the developing relationship between a cohort of clinicians of color and a predominantly white psychedelic research organization. After many discussions, and group processing, the former study participant, the cohort, and the trainers rebuilt cohesion to the point that training could continue. Deeper repair of the rupture and rebuilding of trust would take time. The cohort adopted new mottos: “Move at
Moving forward required re-establishing the container, this time co-created by the community of the cohort.

To prevent this situation from happening again, MAPS PBC has been updating its process for obtaining consent from study participants who choose to include their therapy video recordings in the MDMA Therapy Training Program. The new process will go further to protect participant autonomy and to clarify the participant’s power of choice. The change includes the creation of a separate, stand-alone consent form where a study participant can choose, after the course of treatment, whether they release their videos to be included in the MDMA Therapy Training Program. Additionally, the form provides more detailed instruction for study participants who later wish to withdraw consent for the use of their video in training. Currently, participants are informed to contact the Institutional Review Board (IRB) for questions about consent and other ethical considerations. The process being developed by MAPS PBC would go further to clarify the participant’s choice of using video in training.

The wisdom and strength of the community shone through. Trainees built an altar of natural elements in the center of the room. In the process of slowing down and honoring this gathering of tribes and traditions, there is one plant medicine that deserved special reverence: sassafras. Eriacho shared the background of longstanding Native traditions working with sassafras, including medicinal and spiritual uses. Trainee and Advisory Council member Marca Cassity, R.N., L.M.F.T., of the Osage people, gifted the cohort with the medicinal bark of a local sassafras tree. Several others came forward to lend support, guidance, and encouragement. Music, dance, an outdoor gathering at the Ohio River, and many opportunities to connect wove their way through the final days of training.

Several trainees visited the local Muhammad Ali Center (alicenter.org), connecting with the reality of oppression and Ali’s dedication to civil rights. They brought back bracelets for everyone in the cohort, with one of the Ali Center’s six qualities written on each. Confidence, conviction, dedication, giving, respect, and spirituality emerged as community came together.

The training proceeded through all six days, and Ot’alora G. and I delivered the remaining case presentations. Training content centered around learning the therapeutic approach of MDMA-assisted psychotherapy and discussing ways the modality could be offered in a culturally informed manner in communities of color. On the last night of the training retreat, Reed hosted a Community Celebration, an open-mic style event. Trainees shared jokes, beat boxing, dance, song, and stories. This gathering called forth cultural trauma and healing, psychedelic medicine, and the cycles of oppression, revolution, and liberation. Amidst the pain and complexity of racial trauma, a group of dedicated people brought forth a training for healing and cultural compassion, challenging as it was.

Evolving as a culturally responsive organization is an in-depth process of assessing power and expanding culture, which permeates through all aspects of program development. A sense of urgency, tokenism, patterns of oppression, abuse of power,
and fragility threaten projects. These pervasive patterns take intentional effort to overcome. People working with psychedelic modalities are called to engage in self-assessment and seek honest feedback. To support equity, we must examine the distribution and use of power; support each other in stepping into our power; use our power with and for each other; and be accountable for the times we have abused power. A commitment to act in integrity, cultivate true healing, build relationships with trust, serve community, and examine ourselves and the systems in which we work are what nourish inclusive and impactful projects.

Over the past two years, initial efforts towards diversity and inclusion have developed roots at MAPS and MAPS PBC. Vicky Dulai joined the MAPS Board of Directors as the first person of color on the board. Staff members established a working group focused on diversity and inclusion, called Psychedelic Allies for Intersectional Navigation and Transformation (PAINT). The Catalyst Project delivered a training on antiracism for collective liberation to staff. MAPS PBC examined participant demographics more closely and continues to track progress on addressing racial disparity. Funds were allocated to offset financial hardship facing study participants, such as lost wages or childcare expenses. MDMA therapists were surveyed about their experience in culturally relevant care and provided training in cultural competency. Barton facilitated a conversation on access and inclusion at the MDMA Therapy Training in the Netherlands, setting a precedent to incorporate this discussion in all trainings. At the May 2019 training, Gata Mika, Ph.D., facilitated a workshop on privilege, power, and oppression. In 2019, MAPS PBC gathered an Advisory Council to consult on diversity, equity, and inclusion and the preparations for the Communities of Color training. Council members included: Barton, Cassity, Angella Okawa, L.M.F.T., Reed, and Jae Sevelius, Ph.D. Several researchers and clinicians, including MAPS PBC Chief Executive Officer Amy Emerson, created the statement “Towards an Ethos of Equity and Inclusion in the Psychedelic Movement” to support a public commitment to inclusion (Herzberg et al., 2019). These initiatives are an important start, though they are not enough alone. These initial efforts shed light on areas for predominantly white psychedelic research organizations to grow in their understanding of cultural trauma and commitment to cultural healing.

At the heart of MDMA-assisted psychotherapy is safety, support, compassion, integrity, and trust. Psychedelic organizations can embody these qualities through self-reflection, ethical evaluation, seeking honest feedback, advocating for and with marginalized communities, prioritizing access and inclusion, committing to collective liberation, broadening networks of consultants and advisors, developing authentic transparency, and taking care of people in and around the organization. Efforts rooted in community are more grounded and informed. Building trust takes time, and an investment in meaningful relationships.

Starting at the beginning of the COVID–19 pandemic, the MDMA Therapy Training Communities of Color cohort initiated a self-organized online gathering, which met once a week starting in March, and is still going strong. On Sunday, August 9, 2020, many members of the cohort and training staff came together to acknowledge and celebrate the one year anniversary of the MDMA Therapy Training Program for Communities of Color that took place in 2019. Thirty-five participants, and many others who couldn’t make it but joined in spirit, came together for the anniversary gathering, a two-hour online call for sharing, celebrating, and connecting. The themes of integration, meaning, purpose, healing, and community wove through as each person shared reflections on and experiences with the group, the training a year ago, racial inclusion and equity in psychedelic therapy, the pandemic, Black Lives Matter, and the current political climate. Many attendees expressed their gratitude for the lasting relationships they developed at the training. Several people shared that the experience of community and the journey of the training had deepened their relationship with their own cultural roots and identity, and nourished a sense of belonging that became a vital resource during the world events that would transpire in the year ahead.

“As a compassionate society, we must find or make ways to reach all segments of our society with promising new treatments, so that everyone has an optimal chance of recovery and an excellent quality of life.”
—Monnica T. Williams, Ph.D., ABPP, and Chris Leins, M.A. (2016)

“MAPS has been a leader in conducting research into MDMA-assisted therapy and to our knowledge has been the first to make a deliberate effort to include people of color in the work. Still more work is needed and hopefully this trajectory of inclusion will continue as other groups begin the work of ensuring that psychedelic research meets the needs of everyone.”
—Monnica T. Williams, Ph.D., ABPP, Sara Reed, M.S., M.F.T., and Ritika Aggarwal, B.A. (2020)

“I have seen how MDMA-assisted psychotherapy has alleviated great suffering and improved the quality of the lives of so many people through MAPS MDMA studies. MAPS is committed to ensuring that this powerful treatment is available to all communities. My commitment is to listen, ask questions, have tough conversations to ensure this treatment is readily available to all, including historically marginalized communities within our society. Working together, our acts towards inclusion become a powerful force towards collective healing.”
—Marcela Ot’alora G., L.P.C., Principal Investigator for Phase 3 and Healthy Volunteer MDMA Studies in Boulder, Colorado

“Training more therapists of color brings us closer to health equity. Health equity ensures that this powerful healing modality will be accessible to people impacted by systemic rac-
is and state-sponsored violence.”

—Ritika Aggarwal, B.A., MAPS PBC Executive Support and Operations Coordinator, and UnCommon Law Therapist Intern

“The best way to make your dreams come true is to wake up.”

“He who is not courageous enough to take risks will accomplish nothing in life.”

—Muhammad Ali

The MDMA Therapy Training Program would like to thank the MDMA Therapy Training for Communities of Color trainees, staff, presenters, elders, supporters, and communities who are creating pathways of healing and thriving for people of color.

References


Shannon Carlin, M.A., AMFT, is the Director and Head of Training and Supervision at the MAPS Public Benefit Corporation (MAPS PBC), a wholly owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS), a 501(c)(3) non-profit. As the Director of Training and Supervision, Shannon oversees the development and implementation of the programs that provide training and supervision to prepare mental health and medical professionals to deliver MDMA-assisted psychotherapy in approved clinical settings. Shannon started working with MAPS in 2011 before joining MAPS PBC in 2016.

In her dedication to supporting people through growth and healing, Shannon has served as a co-therapist on MAPS-sponsored Phase 2 trials researching MDMA-assisted psychotherapy for anxiety associated with life-threatening illness and MDMA-assisted psychotherapy for severe PTSD. Shannon’s direct clinical work continues to inform the implementation of the programs she oversees. Shannon received her master’s degree in Integral Counseling Psychology from the California Institute of Integral Studies (CIIS) and a bachelor’s degree in Cultural Anthropology from the University of California, Santa Cruz.
The current cultural moment has exposed for many what people of color knew was always there. The thin veil covering our society’s deep wounds has been removed. What we are seeing is not pretty. It never was.

While psychedelics can often help us see the interconnectedness of our world, it is not hard to see the current duality, and that we have much work toward becoming more connected. Psychedelic research, communities, and spaces remain mostly white, privileged spaces. Communities of color remain on the sidelines. If left alone, this gap will remain and likely widen. To address disparities in access and provide healing support to individuals and communities that need it most, intentional strategies must be developed toward engaging communities of color with psychedelic medicines and treatments.

People of color and indigenous peoples carry the collective trauma from centuries of slavery, colonialism, and oppression inflicted on our ancestors. More recently, here in the United States, violent methods of subordination and segregation have been applied to Blacks and people of color, taking various forms, ranging from lynching to police brutality. Explicit and implicit discrimination, as well as overt and covert acts of racism, are daily occurrences for many. Right now, much attention is being paid to these injustices and racial trauma. But marginalized people have always dealt with this reality, while many others have continued on without much thought to the lived pain all around them. This needs to change.

In many ways, the combination of the COVID-19 pandemic and the death of George Floyd have been a collective retraumatization for Blacks, people of color, and indigenous peoples around the world. The pandemic brought economic disenfranchisement and revealed disparities in health care that people of color know all too well. The knee of a police officer on the neck of George Floyd reminded us that we are still living in a racist and oppressive police state. The officers standing by while not getting involved brought us face to face with the reality that most of society remains complicit in the perpetuation of that system.

There is much work to be done in the way of healing this trauma, and MDMA-assisted psychotherapy is a potentially powerful, yet unexplored, treatment for the long-term racially based trauma that has arisen from the broken American system of policing, health care, justice, and employment. The time for healing is now, and concrete action toward the exploration of this avenue of care must continue.
Bridging the Gaps In Our Work

In the modern psychedelic renaissance, burgeoning psychedelic wellness spaces and communities have inadvertently benefited from a lack of diversity. These spaces might have struggled to develop and grow if more people of color had been a part of their ranks. Research might have failed to launch. Burning Man could not have been started by Black and Brown faces burning effigies on a beach, and an eventual move to the Nevada desert would have been completely out of the question.

But psychedelics have deep cultural roots, from ayahuasca to ibogaine, in native cultures worldwide, and have seen racism and colonization push out tradition and ceremony for research and science.

Most current psychedelic spaces, systems of support, and models of therapy have not been influenced by, or included individuals of color in their research or treatment teams. In a review by Monnica Williams, Ph.D., ABPP, it was found that going back to 1993, more than 80 percent of participants in psychedelic therapy trials have been white (Janikian, 2019). These realities beg for diversification. More inclusion is beginning to happen, and continuing to bring more diverse participants, perspectives, and backgrounds into the fold.

I stood on the sidelines of this movement for years. Much of my inaction was related to not seeing myself represented in research, at conferences, and at festivals. I couldn’t envision myself doing the work. I felt like an imposter. I was avoiding the potential for the psychological injury that I had experienced in attempts to integrate myself into other professional, predominantly white spaces.

Last year, things changed. I was invited to a MAPS-hosted MDMA Therapy Training and Cultural Trauma Workshop (maps.org/mdma-poc-training) for therapists of color desiring to work in the current MDMA-assisted psychotherapy studies, and beyond. Current researchers, therapists, and advocates in the fields of psychedelic medicine, drug policy, and cultural trauma shared the work that is being done and perspectives on moving forward in advancing access to psychedelic medicines for people of color and indigenous peoples.

The experience was humbling, emotional, unforgettable, and career-shifting. This beautifully diverse and dynamic...
gathering provided space for therapists of color to lean into conversations about intergenerational trauma, racial trauma, indigenous practices, and share cross-cultural wisdom and techniques toward healing our communities with psychedelics and MDMA-assisted psychotherapy.

Voices were present in psychedelic spaces that have long been absent. Therapists of color were empowered in ways they often are not. I found myself among many who share a passion for making psychedelic medicines more accessible to our communities. I began to see myself doing this work.

The path toward our collective liberation from systemic racism depends on the continued development of these spaces and the inclusion of these diverse voices. These multicultural trainings will be essential in empowering the next diverse wave of therapists, including therapists of color in the research and treatment teams, informing our collective approaches, and in the development of greater cultural humility.

Creating Settings of Safety and Support

Individuals begin to heal in settings of safety and support. We often do not have, and struggle to build, safe and supportive environments in our own communities and neighborhoods. MDMA-assisted psychotherapy will help heal people of color impacted by racial trauma by providing these spaces. This model of therapy curates environments in which individuals are heard, supported, assisted in deep processing, and guided toward healing from within.

MAPS’ current clinical trials underway have shown that MDMA-assisted psychotherapy can be extremely efficacious in treating individuals diagnosed with posttraumatic stress disorder (PTSD). In a recently publicized interim analysis from MAPS, this therapy has proven significantly more effective than other treatments currently available (“Press Release: Interim Analysis,” 2020). This same treatment can be administered to people of color with race-based stress and racial trauma. In fact, the symptoms associated with racial trauma are often very similar to the symptom presentation in individuals diagnosed with PTSD. Dismantling the norms of what we define as “trauma,” and bringing down barriers to access, will truly establish this treatment as a breakthrough therapy (“Press Release: FDA Grants Breakthrough Therapy Designation,” 2020).

The war on drugs has left an indelible impression on Blacks and people of color. Psychedelics have become highly stigmatized, and many remain misinformed and afraid. Culturally sensitive education and outreach to communities of color will go a long way toward reversing that trend and contributing to feelings of trust and safety for participants.

The intergenerational trauma from decades of mistreatment in health settings has developed a fear and distrust of therapy and mental health for many people of color. MDMA may help reduce fear, increase positive emotions, and develop trust with therapists. The combination of MDMA and a supportive setting may help an individual safely encounter their traumas so they can move through obstacles or impasses to healing. The therapy will support people of color in a connection to and activation of their internal healing mechanisms, and catalyze a fuller and deeper engagement with their cultural healing practices and methods.

Institutional racism and systemic oppression interfere with the ability of people of color to express their true selves. This stymieing of authentic being often maintains a masked, false self. This repression of true expression creates a culture of low self-esteem. Oppression becomes stored in the body. This therapy will help participants of color express their deeper true selves, connect with their core beings, and liberate their bodies through somatic processing and expression.

There is safety in knowing we are seen, and knowing we are heard. People of color coming into the studies must see themselves represented in the research and therapy teams. Research will remain incomplete if the participants remain disproportionately white, and strategies, sensivities, and techniques toward healing a diverse population will remain undeveloped.

Collective racial trauma will begin to heal when complex structural, societal, and environmental causes are addressed.

The Road Ahead, and The Need for Future Research

There is an urgent need to increase our education around these issues, and to lean into research and science for discovery. The current reality is that we know very little about underserved populations, their relationships to psychedelics, and their willingness to participate in novel therapies. This is because these populations have been under-resourced and under-researched. Targeted funding is needed to address these gaps. Funding research into racial trauma and intergenerational trauma by therapists and researchers of color will help fill that void.

Experts in the field of racial trauma and intergenerational trauma must continue to be consulted and invited to develop workshops, training, and ongoing education to expand therapists’ understanding and awareness of the complex challenges experienced by people of color, and provide expertise on best practices and approaches to healing.

Deeper qualitative research and community engagement can support outreach efforts and the development of culturally sensitive education for targeted inclusion of people of color in research studies, and ultimately for treatment when these medicines become more widely available.
Building bridges to spiritual centers will connect to the beacons of safety and trust in these communities. These spaces will also provide safe launching and landing for some participants.

Financial assistance and sliding scales will help support many who live on the margins in accessing MDMA-assisted psychotherapy due to the duration of the studies and the costs of lost time for those who work full time, are unemployed, or living paycheck to paycheck. If we cannot reduce economic barriers to access, we are maintaining the same systems we are striving to dismantle.

Collective racial trauma will begin to heal when complex structural, societal, and environmental causes are addressed. MDMA-assisted psychotherapy is a powerful treatment that is available now, and has proven to heal at the individual level. These treatments may support the collective healing, recovery, and transformation of people of color and indigenous peoples. When we heal, our ancestors heal, and so do all the generations to come.

Throughout its history, MAPS has dedicated its work to taking on structural inequality and drug criminalization as they move toward destigmatizing and increasing access to psychedelics. At the core of their mission is justice and access. In alignment with that mission is a stance against systemic racism and a commitment to racial justice.

The time is now for therapists and researchers of color to deepen our connections, come together more intentionally, support one another, and get actively involved in the outreach, education, research, and treatment of individuals in our communities. The broad cultural lens and expertise we bring to this work is needed to support the great work that has been done by many before us. We must join this powerful movement and help carry the torch toward those who remain in the dark about these medicines.

References


Joseph McCowan, Psy.D., is a licensed clinical psychologist and psychotherapist, currently working with MAPS in Los Angeles as a co-therapist in the Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD. He is an alumni of MAPS’ MDMA Therapy Training for Communities of Color, held in August 2019. Joseph is deeply passionate about furthering education and awareness of the healing benefits of psychedelics for communities of color and in working to improve mental health outcomes for historically underserved communities. Additionally, Joseph works as a therapist, educator, and clinical supervisor with the non-profit St. Joseph Center in Venice, California, which provides mental health and housing resources to homeless individuals and families across Los Angeles County. There, he provides individual and group supervision, along with ongoing training and education in trauma-informed care, harm reduction, and cultural humility. Joseph received his undergraduate degree in psychology from the University of California, Santa Barbara, and his doctorate in clinical psychology from the Chicago School of Professional Psychology. He can be reached at djmccowan@gmail.com.
Beyond the Festival: How Zendo Project’s Four Principles Can Provide Guidance in a Time of Change

CHELSEA ROSE, M.A., AMFT, MAPS HARM REDUCTION OPERATIONS MANAGER

The Zendo Project typically spends weeks at festivals during this time of year, providing safe space for festival attendees, and is now doing its work from behind the scenes (and screens!). The Zendo Project is currently offering peer support groups in collaboration with DanceSafe’s Party in Place Initiative, where Zendo Project staff and volunteers facilitate peer support groups for those who work in the events industry and whose livelihood have been impacted by COVID-19. Additionally, the Zendo Project provided virtual peer support for the online Bicycle Night event on April 19, where sitters were available to support event attendees through online video conference rooms. These offerings have allowed us to engage our community and discover the unique ways that support can be provided in our changing world.

We have also been asking ourselves how can the Zendo Project’s four principles support change and healing in a time of crisis. As we connect with how our principles extend beyond the psychedelic experience, the following are a few reflections we’ve considered.

Let’s begin with a look at our principle “Difficult is Not the Same as Bad,” which encourages us to discover how difficult situations are opportunities for growth and change. To be honest, some things are just plain bad. Racism and a global pandemic go beyond just a difficult situation. The impacts are endless and, in some cases, unimaginable. However, if we are going to make changes in our global community, we have to start with ourselves by asking, “What am I learning during this time that will make me a better person – an advocate for a better world?”

By facing and exploring the unimaginable situations that are unfolding on our planet and in our society, we open ourselves to an opportunity. Where better to use the tools borne of our personal healing journeys and psychedelic explorations than to use them now to align more deeply with our values and apply them toward efforts to change our society at large?

The principle “Talking Through, Not Down” is also about the opportunity for self-understanding that arises when we turn toward an experience, including the sensations and feelings, so that we can discover new parts of ourselves. During the past few months, the world has changed rapidly. We don’t know the trajectory of this planetary crisis, and being in that unknown space can be uncomfortable, especially as it impacts our day-to-day lives. And yet, it is from this place of unknown and rapid change that we might be able to see something we couldn’t otherwise see. How can we grok what is happening to bring more compassion to our world? As we integrate these changes, like we would with a psychedelic experience, how are we turning our insight into action?

While being ambassadors for a healthier world, we must guide change appropriately, such as in raising children or advocating for causes like Black Lives Matter. While guiding change...
often means speaking up, at other times we may just need to stop, and listen. This is what the principle “Sitting, not Guiding” is all about. Taking a moment to slow down and listen, with our hearts, to the troubles that touch our lives allows us space to discover insight about what is unfolding. This may mean sitting still enough to hear our own inner guidance, or actively listening to the struggles of a loved one. From this place of listening, we empower compassion and intuitive understanding to develop.

Safety is a foundational human need, and having or offering a safe space to explore these questions and experiences allows us to see what’s happening in a way that provides valuable feedback and personal development. That is why a “Safe Space” is our foundational principle. Holding a safe space means positive regard, compassion, healthy boundaries, and space for differences. It means respecting all people, from all walks of life, even if we walk in very different shoes, in unique ways, and in opposite directions. In the article, “Sacred Reciprocity: Supporting the Roots of the Psychedelic Movement,” Celina De Leon, Ph.D. (C), writes, “We may consider honoring the very principles that psychedelics so often teach us; namely, the significance of our interconnection and the importance of reciprocity.”

So we might encourage you to connect for a moment with what you’ve been learning throughout this time and how those insights might be able to bring about transformation. We don’t know where this world crisis will lead us, so as we surrender to the journey, we can consider our intentions and hopes for the future, and keep an eye out for the seeds of insight that will guide our action toward creating a healthier world for all.

As the Zendo Project takes actions to bring about safe and compassionate care in new ways, we recognize that psychedelic harm reduction and peer support in a time of world crisis means a lot more than providing services at festivals. The principles and practices of psychedelic peer support can help us take what psychedelics have taught us, and bring that out into the world as a means of change and healing for our planet. Psychedelic peer support principles that hold values like compassion, presence, and acceptance can help inform a healthier planetary consciousness, justice for our fellow human beings, and plenty of safe spaces to explore the healing that will bring us closer to these goals.

Reference

The killings of George Floyd, Breonna Taylor, Ahmaud Arbery, Tony McDade, and others, along with the story of Amy Cooper’s attempt to frame Christian Cooper, have shined a light on systemic racism. These events reflect an ongoing, centuries-long pattern of violence involving police brutality, murder, false accusations, and criminalization of Black people. MAPS and MAPS PBC stand in solidarity with people collectively raising their voices to assert that Black lives matter.

Racism is a public health crisis. Not only does it cause ongoing racial trauma, but it is a driving force in other health disparities and severely restricts access to competent and affordable health care, including therapy. Psychedelic-assisted therapy may have the potential to help heal trauma—but individual therapy does not treat institutionalized racism. The emerging field of psychedelic healthcare must commit to creating equitable access to care, and support efforts to end the criminalization of all people who use drugs. Healing is intertwined with justice.

The war on drugs was developed to criminalize people of color and anti-war activists, and has accelerated the militarization of police over the last 50 years. This escalation continues today, as police use military surveillance, equipment, and weapons in attempts to control protestors. It is jarring to witness the stark contrast between the resources available for policing during demonstrations and the resources available for healthcare workers during COVID-19. This disparity highlights how the status quo perpetuates trauma and undermines health equity. We must end the war on drugs.

To heal as a community, we need to transform society by understanding our fears and challenging oppressive ideologies, policies, and systems. We know that ending the war on drugs is just one important step, and psychedelic-assisted therapy alone will not end racism. MAPS and MAPS PBC are working every day to integrate a deeper anti-racist practice into our work. We have made slow, deliberate progress, and acknowledge that we have a long way to go. We commit to doing the work for collective liberation.

Statement of Solidarity:
MAPS Stands Against Systemic Racism and for Justice and Healing
During this time of extreme crisis, the Zendo Project stands in solidarity with those protesting against racism, white supremacy, structural violence, and police brutality. To our Black, Indigenous, and People of Color (BIPOC) communities—we stand with you. Black lives matter.

Systemic racism and the resulting trauma embedded in individuals, communities, and institutions has deep transgenerational roots. The eradication of racist systems requires activism and reform. It also requires personal and interpersonal healing. As we do the outer work, we must do the inner work, and work to integrate the two. We must simultaneously excavate and understand how we as individuals and as communities are perpetuating and benefiting from racist structures.

When done safely and responsibly, psychedelic experiences can help people become aware of the web of interconnection that exists between all human beings, as well as the entrenched and learned systems of violence that exist within that web. However, it is not enough just to become aware of this interconnection. Our actions must integrate our awareness of collective suffering—to be whole as a community we must integrate our shadows.

For those of us who are not BIPOC, this means using our voice and our privilege to stand with, and speak up in solidarity with, BIPOC communities. We must work to heal our own intergenerational trauma so as not to continue to perpetuate systems of oppression.

We can learn to observe our own reactions. Commit to turning toward what is happening and not away. Feeling our discomfort. Feeling our defensiveness. These are symptoms of deeply embedded racism. If we feel frozen, numb, or overwhelmed, and don’t know what to do or how to help, this is a sign to dig deeper into ourselves. It is okay to be afraid, angry, sad, ashamed, or uncertain what to do. But we will not allow our work to stop there.

We invite you to join us in this commitment to anti-racism and collective liberation. Let your internal reactions lead you to your place of grief. Follow the threads of emotion, not just intellectually but in your body. Seek support from therapists and healers who have done their own personal anti-racist work. Work to connect with and heal your own ancestors and lineage. Do not rely on the emotional labor of your friends of color for your healing and education regarding racism. There are many existing resources available for this purpose.

Activism and anti-racist work requires digging into the tangled roots of racism as they live in us, feeling the pain and suffering that is there, and in doing so making space for love, compassion, understanding, and humility. From there, you will know where you are needed and what gifts you can lend to this movement.

The Zendo Project commits to doing the ongoing work of collective liberation, and humbly acknowledges we have much work to do. We are committed to continuing to deepen our individual and organizational anti-racist practices and consciousness.

The Zendo Project is a program of the non-profit Multidisciplinary Association for Psychedelic Studies (MAPS). View MAPS' Statement of Solidarity on page 25 and on the MAPS website: maps.org/statement-of-solidarity
Available now!
maps.org/psychonaut

$24.95 each / $45.95 set
Also available on Kindle: maps.org/kindle

“Stan Grof is a giant amongst us and we are fortunate to stand on his shoulders. Future generations will forever acknowledge him for helping us wake up from our collective hypnosis that we call everyday reality. I stayed up all night to read Stan Grof’s magnificent magnum opus.”
—Deepak Chopra, M.D., author & public speaker

_The Way of the Psychonaut_ is one of the most important books ever written about the human psyche and the spiritual quest. The new understandings were made possible thanks to Albert Hofmann’s discovery of LSD—the microscope and telescope of the human psyche—as well as other psychedelic substances. This comprehensive work is a tour de force through the worlds of psychology and psychotherapy, Holotropic Breathwork, maps of the psyche, birth, sex, and death, psychospiritual rebirth, the roots of trauma, spiritual emergency and transpersonal experiences, karma and reincarnation, higher creativity, great art, and archetypes.

Written in his late eighties, at the height of his magnificent career, _The Way of the Psychonaut_ is possibly Stanislav Grof’s greatest contribution. The commanding breadth and depth of his knowledge is astounding, the tone of his writing easy and accessible, and his narratives brightened with amusing anecdotes, intriguing personal accounts, and brilliant case studies. Grof reviews the history of depth psychotherapy, the important revisions that are needed to make it more effective, and why the inner quest is such an essential pursuit.

As one of the fathers of psychedelic-assisted psychotherapy, its most experienced practitioner, and deeply deserving of a Nobel Prize in medicine, in these two volumes Grof has successfully unveiled a new and sweeping paradigm in self-exploration and healing. The vast and practical knowledge in this book is sure to be an invaluable and treasured resource for all serious seekers.

Stanislav Grof, M.D., Ph.D., is a psychiatrist with over 60 years of experience researching non-ordinary states of consciousness. Dr. Grof is one of the founders and chief theoreticians of transpersonal psychology, and founding president of the International Transpersonal Association. He was chief of psychiatric research at the Maryland Psychiatric Research Center, assistant professor of psychiatry at Johns Hopkins University, and Scholar-in-Residence at Esalen Institute where he developed, with his late wife Christina, Holotropic Breathwork, an innovative form of experiential psychotherapy that is now being used worldwide. Currently he is professor of psychology at the California Institute of Integral Studies in San Francisco, California.
GIVE THE GIFT OF HEALING TRAUMA.

“MDMA is really the support...that allows the participant to go fully into the trauma and their emotions.”
—Marcela Ot’alora G., M.A., L.P.C.

Marcela is a MAPS-sponsored researcher who recently completed a Phase 2 trial of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) in Boulder, Colorado. Now, Marcela is leading a Phase 3 trial and hopes to make it a legal treatment by 2023.

You can help make psychedelic medicine a reality for millions of people suffering from PTSD.

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