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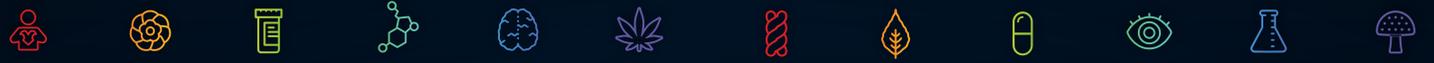
MAPS

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES



BULLETIN

Winter 2021



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MAPS

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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

MAPS furthers its mission by:

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

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

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

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COVER ART: MARNIE RECKER

FRONT: *Medicine Wheel*

30" x 40", acrylic on canvas, 2019

A prayer for Water, Earth, Air, Fire, and Spirit. For Mother Earth and all our relations. May we enter this new decade with a collective intention to move towards harmony, love, compassion and connection. May the suffering of the ages be the catalyst for change. Ushering in a time of Truth. Awakening. Reconciliation, Responsibility and Right Relationship. This medicine wheel depicts Northern and Southern archetypal animals, the elements, sacred plants, constellations, the seasons of the Pacific Northwest and the Celtic Wheel of the Year.

BACK: *Pneuma*

36" x 36", acrylic on canvas, 2020

The first painting I completed in January of 2020. I named the painting Pneuma, the Greek word for spirit and breath. The painting is a prayer, calling in our winged allies, to ride these winds of change with grace and love, surrendering to that which we cannot change and cultivating that which we have so much power to create.

Marnie Recker is a photographer and painter living on the west coast of Vancouver Island, Canada. The open ocean and deep rainforests is a great source of inspiration for her creative life. She moved to Tofino over 20 years ago and has been working as a professional photographer for the past 10 years, creating time capsules of people, weddings and nature.

Her creativity has turned towards painting with the intention of expressing something that her photographs only touch upon. Whereas a photograph can be captured in a fraction of a second, a painting is a long process of learning, layering, and letting go. Her interest in culture, history and social justice had her pursue a B.A. in Anthropology from the University of BC and she recently completed a graduate degree in clinical art therapy. She deeply values how art is medicine for the soul. She believes everyone is an artist and to come back to one's creativity and imagination is the most healing thing we can do.

By observing light and form in nature, I feel a deep connection to the natural world and I wish to share that with others. I usually begin a painting with a vague idea of what I will paint and at a certain point, the painting takes over. Through meditation and deep listening, I feel the spirit of creativity move through me and onto the canvas. I am often surprised at what is revealed.

marnierecker.com

From the Desk of Rick Doblin, Ph.D.

AS WE BEGIN 2021, MAPS is entering a period of incredible opportunity based on accomplishments — decades in the making — realized in 2020.

We completed our first Phase 3 pivotal study of MDMA-assisted therapy for posttraumatic stress disorder (PTSD) with outstanding results, began our second Phase 3 confirmatory study, revamped our therapist training program, and successfully raised \$30 million in pledges over three years in our Capstone Campaign to fund the completion of all the research necessary to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for prescription approval of MDMA-assisted therapy for PTSD.

We obtained FDA permission to conduct MDMA/PTSD research at the Bronx VA in New York with Rachel Yehuda, Ph.D., as Principal Investigator, assisted by Shannon Remick, M.D., and Allie Kaigle, Pharm.D., B.C.P., at the Loma Linda VA in California to obtain permission for their Investigator-Initiated Trial (IIT). The Bronx VA study is only waiting on Drug Enforcement Administration (DEA) registration, which we expect in the coming months, and the Loma Linda VA is only waiting on final approval from the Research Advisory Panel of California. These are the final steps before research can begin and our 30-year effort to catalyze MDMA/PTSD research inside the VA system is realized. We also worked to obtain approval for a pilot treatment development study of MDMA-assisted therapy for people suffering from eating disorders, the first of several to apply our learnings to conditions other than PTSD.

We laid the groundwork in five countries in Europe and England to complete the training of European and British therapists, necessary protocols to initiate Phase 3 research seeking approval from the European Medicines Agency (EMA). We've been in touch with therapists, researchers, and activists around the world interested in our therapist training program and bringing research into MDMA-assisted therapy for PTSD to their countries including Armenia, Bosnia, Chile, Denmark, Rwanda, South Africa, Somaliland, and elsewhere.

We filed a lawsuit against the DEA and the U.S. Attorney General (AG) on behalf of Prof. Lyle Craker, UMass Amherst, seeking to compel the DEA to respond to Prof. Craker's application, and over 30 others, for DEA licenses to grow marijuana for FDA-regulated drug development research and other federally legal purposes. We continued our work on research of cannabis for Veterans with PTSD, finalizing the soon-to-be-published scientific paper about our initial pilot study of four kinds of cannabis in 76 Veterans with PTSD and honing a protocol to study marijuana in several hundred Veterans with PTSD for submission to the FDA. The protocol and associated \$10 million budget will be submitted in 2021 to the State of Michigan, which must allocate \$40 million over two years for research into Veterans' mental health and reducing Veteran suicides, with funds coming from taxes from the sale of legal marijuana in Michigan and grants being awarded only to non-profits or academic researchers.

In non-research news at MAPS, we have been investing in programs and activities to better serve the psychedelic community. Our Zendo Project harm reduction program will soon reach beyond festivals and into communities. Our policy and advocacy department has grown to support increased interest in reform. Our website will soon provide easier access to the history and future of the psychedelic renaissance. You'll be invited to engage with MAPS in new ways, learn through new educational opportunities, and show off your MAPS membership with new gear. For many readers, the announcement that we've confirmed our plans for the next installment of the Psychedelic Science conference series and the new Psychedelic City event, scheduled June 18-25, 2023, will be the most exciting news yet.

We've been in touch with therapists, researchers, and activists around the world interested in our therapist training program and bringing research into MDMA-assisted therapy for PTSD to their countries.

One massive new development has been the rise of for-profit psychedelic companies, with several going public. Most notable are Compass Pathways with a market cap of about \$1.65 billion, Mind Medicine with a market cap over \$1 billion, Field Trip Health with a market cap of about \$155 million, and Numinus with a market cap of about \$250 million. None of these companies have started Phase 3 studies, whereas MAPS has successfully completed our first Phase 3 study and our second is underway. MAPS has built tremendous value, but rather than letting that value be privatized, we have ensured it will be returned to the global community through our wholly-owned MAPS Public Benefit Corporation (MAPS PBC). If we obtain regulatory approval, our pharmaceutical arm will market the prescription use of MDMA-assisted therapy for PTSD with all profits being used to advance MAPS' mission.

We face several key challenges for 2021, starting with obtaining publication of the scientific paper about our Phase 3 results in a peer-reviewed journal. We will have several major meetings with FDA to address the credentialing of therapists, whether research sites and potential psychedelic clinics need a doctor on site or on call, whether our protocol to study MDMA and self-compassion will be allowed and limited to participants from the MDMA Therapy Training Program, and the prospect of filing a New Drug Application (NDA) based on the outstanding results of our first Phase 3 study. To globalize research and patient access to MDMA-assisted therapy for PTSD, we will be challenged to raise \$30 million to fund research for approval by the European Medicines Agency (EMA); the research supporting FDA and EMA approval would support approval for patient access to MDMA-assisted therapy in many countries of the world. To reduce costs, improve outcomes, and meet the anticipated demand if MDMA-assisted therapy is approved, we will launch research into MDMA-assisted group therapy and roll out our new therapist training program. Compassionate use programs will serve 50 patients diagnosed with treatment-resistant PTSD in the U.S. through expanded access and 50 patients in Israel through open access.

Continuing our cannabis research, we'll be supporting Prof. Craker to obtain the DEA license he has been seeking for more than 20 years to grow marijuana for FDA drug development research. The current supply from the National Institute on Drug Abuse (NIDA) monopoly is low quality and cannot be sold commercially, limiting its usefulness to academic, not drug development, research. When Prof. Craker obtains his license, MAPS will have a viable source of cannabis for drug development research. That sea-change, alongside obtaining a \$10 million grant for our marijuana/PTSD research in Veterans from the State of Michigan and final approval for publication of the results of our first marijuana/PTSD study, will uncork a decades-long backlog of research into the medical and mental health benefits of cannabis.

Our new strategy department will work with us to balance the opportunities and challenges ahead. It's crucial that we don't get overconfident with all that we have accomplished in 2020: there is still a lot of difficult work ahead, along with inevitable setbacks and unexpected challenges. I'm optimistic that with the continued and expanding support from MAPS' members and our research community, we can continue rising to the challenges.



To Phase 3 and Way Beyond,

Rick Doblin

Rick Doblin, Ph.D.

MAPS Founder and Executive Director

Research News

MDMA-Assisted Therapy

MDMA-Assisted Therapy Will Be Cost-Effective in the Treatment of PTSD

A PEER-REVIEWED STUDY PUBLISHED on October 14, 2020, in the research journal *PLOS ONE* demonstrates that MDMA-assisted therapy is remarkably cost-effective when compared to currently available treatments for PTSD. It is estimated that a public healthcare payer or private insurer making MDMA-assisted therapy available to 1,000 patients with PTSD would reduce general and mental health care costs by \$103.2 million over 30 years.

Lead author Elliot Marseille, Dr.P.H., M.P.P., elaborates, “MDMA-assisted therapy is conducted by a licensed psychologist and trained clinician over the course of twelve sessions with three sessions lasting six or more hours. The cost of that time is not inconsiderable, but in just over three years, healthcare providers will break even on the costs of mental health and general medical care. These estimates are promising yet likely too conservative: the study did not measure the value of increased productivity or lower disability payments as patients recover from PTSD and is constrained by the limited availability of data on the long-term trajectory of PTSD. Further research will be needed to determine the full financial, personal, and societal benefits of MDMA-assisted therapy for PTSD.”

Berra Yazar-Klosinski, Ph.D., Deputy Director and Head of Research Development and Regulatory Affairs for MAPS Public Benefit Corporation (MAPS PBC) and co-author, developed the protocols studying MDMA-assisted therapy. She notes, “A growing body of evidence suggests that MDMA-assisted therapy may be more effective than currently available treatments for PTSD, a notoriously difficult-to-treat condition. Previous research has focused on safety and efficacy and indicates statistically significant improvements over psychotherapy with a control, demonstrating reduction in symptoms for 82% of participants. This study should compel healthcare providers to include MDMA-assisted therapy as a covered treatment for PTSD following FDA approval.”

Rick Doblin, Ph.D., Executive Director of MAPS and a study co-author, states, “The profound personal toll of PTSD can include deterioration in physical health, relationships, and ability to participate in social activities along with the anxiety, insomnia, and suicidal ideation that mark the condition. By demonstrating a return of an average of 5.5 quality-adjusted

life-years over 30 years, we have shown that MDMA-assisted therapy has the potential to reduce more than the personal burden of PTSD, contributing to improved health outcomes and reduced healthcare burdens for payers and providers.”

The cost-effectiveness of MDMA-assisted therapy from the U.S. healthcare payers’ perspective was constructed with a decision-analytic Markov model to portray the costs and health benefits of treating patients with chronic, severe, or extreme, treatment-resistant PTSD. Efficacy was based on the pooled results of six randomized controlled trials with the 105 subjects who participated in Phase 2 trials and a four-year follow-up of 19 of those subjects. Other inputs were based on published literature and on assumptions when data were unavailable. Results are modeled over a 30-year analytic horizon and conducted extensive sensitivity analyses. The model calculates expected medical costs, mortality, quality-adjusted life-years, and incremental cost-effectiveness ratio.

MAPS-Sponsored Pilot Study: MDMA-Assisted Therapy for PTSD in Couples May Reduce PTSD Symptoms, Improve Couples’ Happiness

A pilot trial to assess the safety, feasibility, and efficacy of Cognitive-Behavioral Conjoint Therapy (CBCT) for PTSD and MDMA-assisted therapy for PTSD resulted in significant reductions in PTSD symptoms and relational outcomes for couples, according to a peer-reviewed paper published on December 7, 2020, in the *European Journal of Psychotraumatology*. This initial trial, sponsored by the Multidisciplinary Association of Psychedelic Studies (MAPS) and organized by MAPS Public Benefit Corporation (MAPS PBC), included six couples with a range of baseline relationship satisfaction in which one member was diagnosed with PTSD resulting from a range of traumas including childhood physical abuse, childhood sexual abuse, and active military service.

CBCT for PTSD focuses on the relationship between the participant and their partner, encouraging skill development as a couple. CBCT alone has been shown to improve PTSD, enhance relationship functioning, and improve intimate partner well-being. MDMA-assisted therapy for PTSD, currently in Phase 3 trials to gain approval from the U.S. Food and Drug Administration (FDA), has yielded significant improvements for individuals in PTSD symptoms and other outcomes such

It is estimated that a public healthcare payer or private insurer making MDMA-assisted therapy available to 1,000 patients with PTSD would reduce general and mental health care costs by \$103.2 million over 30 years.

as increased openness to experience, post-traumatic growth, and improvement in comorbid conditions. This study represents the first in which MDMA's potential to facilitate the effects of a stand-alone, empirically-supported therapy — other than the protocol developed by MAPS — for PTSD was tested.

Candice M. Monson, Ph.D., is a Professor of Psychology and Clinical Training Director at Ryerson University. Dr. Monson is an expert on traumatic stress and CBCT, having researched CBCT as a treatment for PTSD since 2012 and MDMA-assisted therapy for PTSD since 2015. She described the treatment as promising because, “PTSD in one partner can cause distress in the relationship and barriers to understanding each other. It seems that MDMA-assisted therapy can engender empathy and connection, opening a pathway to remembering why came together in the first place and a desire to understand the other. The literature that inspired this study suggests that MDMA may allow people to talk about painful experiences without experiencing the pain again. The therapist can guide couples to talk about very difficult things that they've either experienced themselves or experienced together — against the other or with the other — with a greater sense of understanding, openness, connection, and empathy.”

Participants received the session content comprising CBCT in a condensed format, including intensive weekends and bi-weekly sessions, over seven weeks. The two MDMA sessions were timed to synergize with the CBCT interventions and both members of the couple were administered 75mg or 100mg of MDMA with an optional supplemental dose. Each member of the couple was scheduled for assessment at pre-treatment, mid-treatment, post-treatment, and three- and six-month follow-ups. In addition, participants completed assessments of self- and partner-reported PTSD symptoms and overall relationship happiness at those assessment points, as well as at each treatment occasion. No unexpected adverse events were observed.

This initial study suggests that MDMA-facilitated CBCT holds promise in facilitating trauma recovery and achieving broader relational outcomes not fully realized with individual evidence-based treatment for PTSD. Though the comparison of effect sizes is tentative due to the small sample size, the effects across all outcomes were largest at six-month follow-up, suggesting that MDMA facilitation may confer ongoing benefits. The authors are currently preparing for a Phase 2 randomized trial led by co-author Anne Wagner, Ph.D., C. Psych., to more rigorously investigate the safety and efficacy of MDMA-facilitated CBCT and to address treatment outcomes across a diversity of participant and partner genders, pre-treatment relationship distress, and type of initial trauma.

Study: MDMA-Assisted Therapy May Reduce Anxiety for Those Diagnosed with Life-Threatening Illness

A peer-reviewed study published on November 24, 2020, in the journal *Scientific Reports* provides sufficient evidence to support further research into the palliative effects of MDMA-assisted therapy for anxiety associated with life-threatening illness. The pilot study, sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS) and using protocols developed by MAPS Public Benefit Corporation (MAPS PBC), demonstrated greater reduction in anxiety among participants who received MDMA relative to participants who received placebo with identical therapy. While the difference between the two groups was not statistically significant, this small pilot study demonstrates the addition of MDMA to the intervention had a large effect size and justifies continued research.

Individuals facing a life-threatening illness may contend with anxiety, depression, anger, and despair that often exacerbate the distress already caused by the illness itself. The trauma of a devastating illness is often deep and difficult to integrate, even for those



who recover. As modern medical care improves life expectancy or recovery rates for serious illnesses, the need to address the psychological trauma of diagnosis and treatment is growing.

Phil Wolfson, M.D., served as Principal Investigator and lead author for the study and authored an accompanying commentary. “Through this intensive psychotherapy, with MDMA experiences as a fundamental part of the process, people who have trauma from life-threatening illnesses were able to significantly improve the impact of their traumatic residues, their fears of relapse and death, and their struggle to make recoveries. The traumatic nature of diagnosis with a life-threatening illness and its aftermath contains a multiplicity of manifestations in cognition, motivation, affect, spirit, meaning, relationships, and view of self. Attention to patients’ suffering, impacted ways of being, and tension with potential recurrence of illness and death should be considered as fundamental to their complete recovery or hospice care as attention to their physical state; this pilot study validates continued research into MDMA-assisted therapy as a meaningful pathway to addressing their suffering.”

Early investigations with psychedelic compounds suggested such psychoactive substances hold promise in addressing distress, pain, and anxiety in people with life-threatening illnesses. Recent studies provide evidence for the use of psychedelic-assisted therapy as an efficacious modality for the treatment of depression, anxiety, and PTSD. MDMA is under investigation as an adjunct to therapy for various anxiety-related conditions; results from six Phase 2 studies led the U.S. Food and Drug Administration (FDA) to issue a breakthrough therapy designation for MDMA-assisted therapy for treatment of PTSD in 2017. Based on these findings, this pilot study was conducted to examine the safety and efficacy of MDMA-assisted therapy to alleviate anxiety and other psychiatric symptoms, including depression and poor sleep quality, related to a life-threatening illness.

“This study presents a new viable pipeline for the clinical application of MDMA-assisted therapy in the treatment of anxiety symptoms in a population in dire need of palliative care options,” noted Berra Yazar-Klosinski, Ph.D., who serves as Deputy Director and Head of Research Development and Regulatory Affairs for MAPS PBC. “Patients suffering from a life-threatening illness are often only treated for their primary medical diagnosis; their anxiety and existential distress is neglected in our current healthcare system. MAPS has a strong record of supporting treatments addressing this unmet medical need. The results of this pilot study will enable the design of future well-powered studies to change this treatment landscape, and perhaps even the way we approach life and death in our modern lives.”

A total of 18 participants with moderate or severe anxiety symptoms related to diagnosis of a life-threatening illness were enrolled in the study; 17 completed the treatment and follow-up assessments after six and twelve months. Participants had a mean age of 54.9 years; fourteen participants identified as

female; and many had been previously diagnosed with an anxiety disorder (83.3%), major depression (77.8%), PTSD (72.2%), or insomnia (61.1%). Notably, after the experimental sessions, participants who initially received a placebo with therapy received additional therapy sessions with MDMA and results for both groups were combined for the six- and twelve-month follow-up assessments. Study limitations included small sample size, demographic homogeneity, exceptionally strong positive response from one member of the placebo group, and combination of the experimental and control groups following the experimental sessions. Study results support the feasibility of exploring MDMA-assisted therapy as a novel approach for potential long-term treatment of anxiety related to life-threatening illness and will inform development of future clinical trials with larger sample size and among more diverse populations.

MAPS and MAPS Public Benefit Corporation Announce Positive Result from Phase 3 Trial of MDMA-Assisted Therapy for PTSD

In November 2020, MAPS Public Benefit Corporation (MAPS PBC) completed data analysis of the first of two Phase 3 trials of MDMA-assisted therapy for treatment of posttraumatic stress disorder (PTSD). The results confirmed Phase 2 results and prior expectations from an independent interim analysis which determined there was a 90% or greater probability that the trial, when completed, would be of sufficient size to detect statistically significant results. Further, no unexpected or serious safety signals emerged during the course of the trial.

The results indicate MDMA-assisted therapy for PTSD may be an effective treatment for PTSD resulting from various types of trauma, including trauma occurring in childhood and in patients with dissociative subtype of PTSD, pending assessment by the U.S. Food and Drug Administration (FDA). Based on these results, MAPS will begin discussions with the FDA on ways to accelerate the timeframe for approval of this modality.

The Phase 3 trial, the first of its kind in scope and size, treated 90 participants who received 3 day-long MDMA or placebo sessions one month apart and 12 90-minute non-drug therapy sessions over approximately 3.5 months. The severity of PTSD symptoms was measured using the Clinician-Administered PTSD Scale for the DSM-5 (CAPS-5); measurements were taken before and after completion of treatment. Of these 90 participants, approximately half received MDMA-assisted therapy. The other half of participants, the control group, received placebo with identical therapy. A second Phase 3 clinical trial is currently enrolling participants.

Bessel van der Kolk, M.D., a leading PTSD researcher and author of the foundational book on PTSD, *The Body Keeps the Score*, served as Principal Investigator for the Boston site of the study. He noted, “The experience of having been traumatized profoundly alters perceptions; self-experience; and capacity to plan, imagine and anticipate. Since the results of this

study mirror previously published results, we can expect to see fundamental shifts in our subjects' perspective on self-capacity, affect regulation, and attitude towards those around them. It takes a great deal of courage to address one's PTSD, particularly when other treatments have failed. These results open the door to a powerful new pathway to healing once MDMA-assisted therapy has been approved as a treatment for PTSD."

Phase 3 Trials of MDMA-Assisted Therapy for PTSD: Seeking Research Volunteers

We are currently seeking research volunteers for our second Phase 3 clinical trial of MDMA-assisted therapy for PTSD. Volunteers will help contribute to scientific knowledge and will help us better understand if MDMA-assisted therapy works for treatment of PTSD. MAPS conducts clinical trials under the guidance and regulations of the FDA in collaboration with federal regulators, including the Drug Enforcement Administration (DEA). To learn more about our clinical trials or apply to be a study participant, please visit our website: mdmaptsd.org.

We are recruiting participants in the following locations:

- Los Angeles, California | Private Practice
- San Francisco, California | Private Practice
- Boulder, Colorado | Private Practice
- Fort Collins, Colorado | Private Practice
- New Orleans, Louisiana | Private Practice
- Charleston, South Carolina | Private Practice
- Boston, Massachusetts | Private Practice
- San Francisco, California | Research Institution
- New York, New York | Private Practice
- New York, New York | Research Institution

Not yet recruiting:

- Madison, Wisconsin | Research Institution
- Vancouver, Canada | Research Institution
- Be'er Ya'akov, Israel | Research Institution
- Tel Aviv, 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 therapy in an outpatient setting.

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

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

The Institutional Review Board (IRB) has approved MAPS' protocol for a Phase 2, open-label randomized controlled

comparative study on the effectiveness of MDMA-assisted therapy in U.S. Veterans with chronic PTSD. Led by esteemed PTSD researcher Rachel Yehuda, Ph.D., Director at the Mental Health Patient Care Center, James J. Peters VA Medical Center, and Professor of Psychiatry and Neuroscience at the Icahn School of Medicine at Mount Sinai Hospital, the study is moving through the investigator-initiated research program of the U.S. Department of Veterans Affairs (VA). On August 25, 2020, the FDA agreed to proceed with the protocol.

The study will be a Phase 2, open-label randomized controlled comparative study on the effectiveness of MDMA-assisted therapy in U.S. Veterans with chronic PTSD. The study will enroll 60 Veterans and will collect further information on whether there is a difference in two versus three sessions of MDMA-assisted therapy for safety and therapeutic outcome. This study will also act as a training ground for VA clinicians and therapists on the MAPS modality, and will include blood collection samples for later analysis of hormones, molecules, and other biological markers that may be related to having or recovering from PTSD.

Dr. Yehuda and her team plan to conduct this trial at the VA pending institutional and DEA approvals.

An Open-Label, Phase 2, Multicenter Feasibility Study of Manualized MDMA-Assisted Therapy with an Optional fMRI Sub-Study Assessing Changes in Brain Activity in Subjects with Posttraumatic Stress Disorder

Taking place in the United Kingdom, Germany, Portugal, Norway, the Czech Republic, and the Netherlands, this open-label Phase 2 study of MDMA-assisted therapy for PTSD will serve as the lead-in to the planned Phase 3 study in Europe providing an opportunity for clinical supervision of therapy teams to complete their training, and to validate assumptions made for statistical power calculations supporting the planned Phase 3 clinical trial. This study will also provide cross-cultural validation data on the updated version of the Primary Outcome measure, the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), which will be used in the Phase 3 study. In addition, the study will gather supportive data on the safety and effectiveness of manualized MDMA-assisted therapy. This study will be the first multi-center study of MDMA-assisted therapy for PTSD in Europe and will explore reproducibility of findings from FDA-regulated Phase 2 and Phase 3 trials to confirm the Phase 3 study design.

The study site in the Czech Republic is currently screening participants, screening at the first of two Netherlands sites will begin imminently, and screening at the Norway site is expected to start before the end of the year. The sites in the United Kingdom and Germany require further permissions before they can begin screening, most likely in early 2021, and the study set-up in Portugal is still in an early stage. Data gathered in European trials would provide support for a planned Marketing Authorization Application for potential approval by



the European Medicines Agency (EMA). For more information, please visit: mapseurope.eu/research

Startle Testing with MDMA: Thirty-Four Veteran Participants Complete Enrollment in Experimental Treatment

On July 30, 2020, MAPS completed enrollment in our study of the effect of experimental treatment with MDMA on startle testing in thirty-four healthy participants. Led by Principal Investigator Barbara Rothbaum, Ph.D., this study was conducted at Emory University in Atlanta, Georgia. Dr. Rothbaum presented a subset of findings at the 36th Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) on November 12, 2020.

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 therapy for PTSD. The Boulder, Colorado, study site is led by Principal Investigator Marcela Ot'olora 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 Therapy for Eating Disorders

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

This study will explore the safety and feasibility of MDMA-assisted therapy and adjunctive caregiver involvement in the treatment of individuals with AN-R and BED. The addition of a supportive caregiver as a treatment ally with every participant reflects this most recent development in science and practice. Supportive caregivers enrolled in the study will receive non-drug therapy 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 multiple study sites. The study site in Vancouver, Canada, will include six BED participants, with Qualified Investigator Christian Schütz, M.D., Ph.D., M.P.H., overseeing the study. The study sites in Toronto, Canada, and Denver, Colorado, will each include six AN-R

participants, with Michael Verbora, M.D., overseeing as Qualified Investigator in Toronto, and Co-Clinical Investigators Adele Lafrance, Ph.D., and Mike Rollin, M.D., overseeing the site in Denver.

A Phase 1 Open-Label Study of MDMA Tolerability and Pharmacokinetics in Participants with Moderate 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-dioxyamphetamine (MDMA). The secondary objective of this study is to evaluate the effect of moderate hepatic impairment on the safety and tolerability of oral MDMA. Led by Principal Investigators Janel Long-Boyle, Pharm.D., Ph.D., and Robert M. Grant, M.D., M.P.H., this study will be conducted at the University of California, San Francisco.

MDMA Therapy Training Program Update: January 2021

The MDMA Therapy Training Program is currently supporting the final segment of training for therapists preparing for the open-label lead-in study for the European segment of Phase 3, researching MDMA-assisted therapy as a treatment for PTSD. A cohort of new supervisors, experienced MDMA-assisted therapy researchers who have met additional training and certification requirements to provide supervision, will be supporting therapists on this protocol.

The training program will deliver trainings entirely online this year. We are excited about the possibility of expanding access to training with the shift to online education. Our program staff and various subject matter experts are continuing to engage in a training curriculum design initiative to support the growth and continued quality of the program. To better support training thousands of future therapists, we are developing training protocols for new supervisors and trainers, who are also contributing their expertise to the curriculum design initiative.

We look forward to re-opening enrollment for the MDMA Therapy Training Program in the coming months. To receive updates on 2021 trainings and training program admissions, sign up for the MDMA Therapy Training Program Newsletter: mapspublicbenefit.com/training.

Participate in Research

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

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

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

The safety and efficacy of MDMA-assisted therapy is currently under investigation. This treatment has not yet been approved by the FDA, does not work for everyone, and carries risks even in therapeutic settings. To learn more, please visit mdmaptsd.org

MAPS in the Media



'This Is Life' Explores Psychedelic Healing

Lisa Ling • December 20, 2020

The CNN original series This is Life with Lisa Ling explores the potential healing effects of psychedelics in an investigative report during the series finale. In this new episode, journalist Lisa Ling interviews MAPS Founder Rick Doblin, Ph.D., and other notable figures in the field of psychedelic therapy.

Herald-Tribune

Can Psychedelics Save the Planet? New College Alum Rick Doblin's Mission is to Find Out

Billy Cox • January 11, 2021

The Sarasota Herald-Tribune features a front-page profile of MAPS Founder and Executive Director Rick Doblin, Ph.D., which outlines Doblin's path that led to his founding of MAPS, as well as research updates from the front lines of the psychedelic renaissance. "No one is pushing establishment thinking harder than Rick Doblin and MAPS," reports Billy Cox of the Sarasota Herald-Tribune.



Another Scientist Sues DEA To Cultivate Marijuana For Research Purposes

Kyle Jaeger • December 3, 2020

Marijuana Moment reports on the new lawsuit filed by Dr. Lyle Craker, with support from MAPS, which compels the U.S. Drug Enforcement Administration (DEA) to issue licenses for Dr. Craker and more than 30 other applicants to manufacture research-grade marijuana, a process that has been delayed for over 4 years despite administrative guidance. "DEA announced in 2016 that it would begin the process of approving additional marijuana cultivators. Currently, there's just one, at the University of Mississippi, that has held a monopoly on federally authorized cannabis cultivation," explains Kyle Jaeger of Marijuana Moment. "Researchers and lawmakers have argued that the quality of the plant grown at that facility is inadequate. Indeed, a study found that its cannabis is more chemically similar to hemp than marijuana sold in state-legal commercial markets."



MDMA-Assisted Couples Therapy Investigated in Landmark Pilot Trial

Rich Haridy • December 8, 2020

New Atlas investigates new research results from a MAPS-sponsored pilot study of MDMA-assisted Cognitive-Behavioral Conjoint Therapy (CBCT) for posttraumatic stress disorder (PTSD) in couples consisting of one partner diagnosed with PTSD. "The therapist can guide couples to talk about very difficult things that they've either experienced themselves or experienced together—against the other or with the other— with a greater sense of understanding, openness, connection, and empathy," explains MAPS-sponsored researcher Candice Monson, Ph.D.



Navy Seal Foundation Backs Study of Ecstasy Component for PTSD Treatment

Chad Garland • November 16, 2020

Stars and Stripes reports on the \$50,000 grant gifted to MAPS from the Navy SEAL Foundation in support of completing MAPS-sponsored Phase 3 trials of MDMA-assisted therapy for PTSD, the final stage in the FDA approval process to make MDMA a legal treatment option for PTSD. The grant is the largest in the foundation's history, confirming a need for more treatment options for PTSD and highlighting the potential of a novel solution. "This pioneering work has shown great promise," says Robin King, Navy SEAL Foundation CEO, regarding clinical results from completed Phase 2 trials of MDMA-assisted therapy for PTSD. "We're leaning in to help [Naval Special Warfare] and other veterans overcome the debilitating effects of PTSD," explains King.



Psychedelics in Sports

Bryant Gumbel • December 2, 2020

The HBO series Real Sports with Bryant Gumbel features MAPS Founder Rick Doblin, Ph.D., and psychedelic researcher Robin Carhart-Harris, Ph.D., in a discussion about the history and potential benefits of using psychedelics to treat athletes who have experienced head injuries.

Reimagining Zendo Project

Integrating Psychedelic Harm Reduction into the Community

KATRINA MICHELLE, PH.D, LCSW



OVER THE COURSE OF THE past year since COVID-19 first began to enter into our collective awareness, we as a society have watched our ability to gather in community diminish and our mental health challenges become exacerbated by isolation and uncertainty. Surveys conducted by the Centers for Disease Control and Prevention indicate substantial increases in anxiety and depressive disorders, as well as increased substance use and suicidal thoughts related to the pandemic. Meanwhile, scientific, peer-reviewed studies continue to demonstrate that the careful use of psychedelics can offer significant relief from symptoms of depression, addiction, anxiety, and post-traumatic stress disorder (PTSD). For all the division that we witnessed in last year's election, when it came to subtly furthering the integration of psychedelics into our society, the public seemed to come together at the polls.

Oregon became the first state to decriminalize psychedelic plants and fungi, while also creating a legalization framework for psilocybin mushroom-assisted therapy. Washington, D.C., and Ann Arbor, Michigan, also added their names to the list of U.S. cities like Denver, Oakland, and Santa Cruz, which were the first to succeed with psychedelic decriminalization measures. As the recent elections reflect, following decades of derision, psychedelics are redeeming themselves in public opinion, and perhaps even gaining favor. So, with large-scale public gatherings halted, MAPS is responding to ripening opportunities to meet the need to educate new and diverse sectors of the public, beyond the festival.

Historically, MAPS' psychedelic harm reduction efforts have centered around providing direct, frontline support, education, and training at events through the Zendo Project. Having trained over 6,000 volunteers on how to provide peer support to those encountering challenging psychedelic and emotional experiences, MAPS recognizes the foundational principles of psychedelic peer support that have guided and supported our community over the years to be essential, transferable skills that are necessary to navigate a changing world.

The stressors of this past year brought many of our collective wounds out of the shadows and into our consciousness. Our world being rampaged suddenly and unexpectedly by a coronavirus that exponentially outpaced modern medicine's ability to understand and control it at once showed us how vulnerable and how interconnected we are. In a matter of weeks, our world was forced to come out of our habits of distraction and frivolity to confront the reality of sickness, uncertainty, and mass death. As an unprepared public and an under-resourced medical force, we found ourselves launched into a space of existential anxiety confronted with our human fragility and mortality.

We know from psychotherapy that it is only once the materials harbored in the unconscious are brought to the surface that we are ultimately able to address them and heal them. However, devoid of the proper structures of support, we can get stuck cycling in the trauma instead of moving through it.

Much of the potential benefits of psychedelics are connected to their ability to shift our consciousness away from the mundane, toward illuminating the sublime. On their journeys, however, psychedelic choosers often discover that crossing the threshold of the neatly constructed conscious mind can lead into murky places of repressed traumas and confronting archetypal experiential scenes. Within festival environments, the Zendo structure has served as the physical place where people can come as they are to be received and supported as they traverse through such landscapes in service of their ultimate healing. Without the support of such dedicated spaces, people experiencing challenging journeys may endure unnecessary burdens, ones that can be exacerbated by their communities' lack of education about how to best help.

We are building a post-prohibition world. What happens there will be determined by the infrastructure we put into place now. To properly usher in a new paradigm of healing for all on a global scale we are going to need educated communities at all points of engagement. This includes the curious seekers, who must understand what they are committing to psychologically, as well as the potential chemical and physical risks. It also includes the communities that, knowingly or not, are creating the containers that, perhaps unbeknownst to them, are contributing to the experiences of psychedelic journeyers.

Zendo Project has collected a wealth of information from being in direct service for a decade. In furthering our desire to co-create communities of compassionate care while our cardboard yurt remains in temporary storage, we are transcending the physical space of our structure to contribute to building supportive, informed, and complete containers that can carry forward these gifts and lessons out into the world. With this in mind, Zendo Project has begun to expand and update our curriculum and training, identifying target audiences in various community settings. We are currently modifying our signature public training to provide more extensive general psychedelic harm reduction education to meet demand from growing communities of psychedelic explorers. Recognizing campus microcosms, we have also begun to develop a curriculum unique to the needs of the university setting and all its various parts. We are engaged with medical, legal, and mental health professionals to conduct needs assessments which will enable us to precisely devise offerings that bridge the gaps in our constituents' current understanding and previous training.

Thanks to Sara Gael, M.A., former MAPS Director of Harm Reduction, becoming a founding member of the Denver Psilocybin Mushroom Review Panel in February of 2020, we are currently in discussion with the City of Denver's first responder departments to create pilot trainings related to psilocybin decriminalization for their 3,600 first responders. This follows the panel's September 2020 vote to invite MAPS to lead their psychedelic harm reduction training initiative. The first responder departments include paramedics, police, fire, Sheriff's Department, and the expanding mental health co-responder units, the leaders of each expressing a desire to mandate these foundational trainings for all of their existing and incoming employees.

We envision a world where communities are educated, resourced, and engaged in applying harm reduction principles to support individuals exploring psychedelic states

KATRINA MICHELLE, Ph.D., L.C.S.W., began working with MAPS in August of 2020 as Harm Reduction Director. She received her Ph.D. in Psychology with a Transpersonal specialization from Sofia University at The Institute of Transpersonal Psychology in 2017 after completing her dissertation on “Exploring Resistance to Spiritual Emergence.” She served for three years as Executive Director on the board of The American Center for the Integration of Spiritually Transformative Experiences (ACISTE). Katrina graduated from Stony Brook University with her Masters in Social Work and a specialization in student community development and has maintained an integrative psychotherapy practice, *The Curious Spirit*, in New York City since 2008. Katrina serves as faculty at Columbia University School of Social Work and The Institute for the Development of Human Arts (IDHA) and is currently working on producing her first documentary film, “When Lightning Strikes,” with the intention to educate the mainstream about spiritual emergence.

The Zendo Project provides professional comprehensive harm reduction education and support for communities to help improve public safety, reduce adverse outcomes, and inform and transform difficult psychedelic experiences into opportunities for learning and growth. We envision a world where communities are educated, resourced, and engaged in applying harm reduction principles to support individuals exploring psychedelic states; recognizing that challenging experiences can be opportunities for self-exploration and healing.

The collective trauma that has been unearthed by events of the past twelve months can be viewed from a myopic lens as destructive or from a reformist lens as revolutionary. Moving forward as a culture whose wounds have torn open as they rose to the surface, we can no longer band-aid and turn our heads. This collective trauma can only be resolved by a collective commitment to healing. Lessons from the Zendo Project teach us that we all have a part to play—that we really can make a tremendous difference in someone else’s journey, because when we zoom out, we realize we really are all on the same trip.

People are not separate from their environments. It is through empowering each member of our community to support the other in being seen and held through the struggle that we all benefit. It is our intention that by offering educational tools to carve out intentional infrastructures at the community level, we will contribute to the healing of each person touched by the ripple of evolutionary change. As a culture of distraction, perhaps this past year has served as our initiation into depth. Committing to the rest of this journey together is the best way forward. It is an invitation and an opportunity to heal our core wounding at the individual, societal, and even ancestral levels. As we usher in a new means of medicine, we are no longer suppressing symptoms, but diving into truth. And that, they say, will set us free.

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Moral Injury and the Promise of MDMA-Assisted Therapy for PTSD

AMY LEHRNER, PH.D., AND RACHEL YEHUDA, PH.D.



MARCO* JOINED THE ARMY FOR many reasons: to be a part of a family with common purpose and values, to defend his country, and to protect those more vulnerable. When he was deployed to Iraq, Marco believed that he would be fighting in a just war and upholding his core values. He returned haunted by the many times he stormed into people's homes at night, turning the house upside down looking for weapons, taking fathers away from crying families to military prisons. He remembers convoys that were mobbed by hungry civilians hoping for handouts, whom he and his fellow soldiers beat back with clubs. He remembers his rage and hunger for revenge after friends were killed and his violence against locals who might have harbored insurgents. He witnessed and participated in the death of civilians, women, and children. Marco was affected by combat with opposing forces, certainly, but his pain is rooted in a deep sense of guilt and shame over actions he took that violated his core beliefs about right and wrong. He judges himself harshly, believing that he deserves to suffer and that any self-forgiveness represents a slippery moral slope towards justification of acts he believes are unforgivable. He fears that he is a monster, capable of horrible violence, and that he must keep this part of himself hidden to protect others, as well as himself. He believes that if anyone knew about his actions, they would condemn him. He has lost his faith in God, withdrawn from his family, and lives in a world of isolation and pain.

Marco was affected by combat with opposing forces, certainly, but his pain is rooted in a deep sense of guilt and shame over actions he took that violated his core beliefs about right and wrong.

Where moral injury creates isolation and profound alienation, MDMA may allow for the healing connection required to tend to the wounds left by betrayal of one's core morality.

The concept of moral injury is not new (Shay, 2014), but it has received increased attention in the United States after decades of war in Iraq and Afghanistan. Moral injury has been called a wounding of the soul, a scar that will always be borne. In academic research, moral injury has most recently been defined as “perpetrating, failing to prevent, bearing witness to, or learning about acts that transgress deeply held moral beliefs and expectations” (Litz et al., 2009). For many Veterans, war zone experiences, including the killing of others, violates moral or religious beliefs and creates a profound sense of internal alienation and conflict. These experiences may also include receiving orders or supporting actions that were perceived as unjust or immoral, and witnessing or perpetrating atrocities. One national survey of U.S. combat Veterans found that 11% reported moral transgressions, 26% reported witnessing transgressions by others, and 26% reported betrayal of moral code by trusted authorities (Wisco et al., 2017). Similarly, refugees and survivors of genocidal violence may struggle to reconcile themselves with things they did to survive, which may include betrayal of others and their own moral compass (Nickerson et al., 2015).

Moral injury, although it often occurs in the context of life threat and heightened physiological arousal, is distinct from posttraumatic stress disorder (PTSD) in the critical aspects of perpetration, complicity, or transgression. The moral and spiritual conflict that ensues can be distinguished from the helplessness and powerlessness associated with the traumatic victimization that leads to PTSD. For many reasons, this construct has received much less attention than PTSD, even though combat related guilt and the presence of moral injury have been associated with increased risk for suicide, poorer mental health, and reduced quality of life in Veterans and refugees (Hendin & Haas, 1991; Maguen et al., 2012; Nickerson et al., 2015). To recognize the guilt and shame of soldiers challenges the narrative of bravery, service, and sacrifice that militaries and nations promote in order to support volunteer armed services and communicate the honor of fighting for one's country. To acknowledge the pain of moral injury requires a reckoning with humanity's dark side — with things that we humans can do when threatened, when angry, when trying to survive. We ask our soldiers to shoulder and carry this knowledge, but as a society we cringe at bearing witness, at considering our own complicity, and at the question of how to hold compassion and to bring healing to these wounds of the soul.

As indications for MDMA-assisted therapy expand, there is excitement about its potential for treating moral injury. The Center for Psychedelic Psychotherapy and Trauma Research, in collaboration with MAPS, is conducting a trial of MDMA-assisted therapy for Veterans with PTSD in a Veterans Affairs outpatient clinic setting. This study includes assessments of moral injury and self compassion which will provide the first data on the impact of MDMA-assisted therapy on this construct. The two currently promoted gold standard psychotherapies for PTSD, Prolonged Exposure (PE; Foa et al., 2007) and Cognitive Processing Therapy (CPT; Resick et al., 2016), are grounded in fear conditioning and cognitive models of PTSD, respectively. The fear conditioning model postulates that during a life-threatening trauma, hypothalamic-pituitary-axis activation associated with the fight-flight-freeze response contributes to a pairing of multiple contextual stimuli (e.g., dark alley, odor of garbage, cold temperature) with the trauma memory, which in turn leads to avoidance of trauma cues and emotions. The cognitive model postulates that PTSD is driven not by the traumatic experience itself, but by distorted or maladaptive thoughts or appraisals about the event (e.g., “it was all my fault,” “men cannot be trusted,” or “crowds are dangerous”). Neither of these models encompass the core conflict of betrayal of one's own moral compass, which is neither fear-based nor a reflection of distorted or inaccurate thoughts about the event.

PE and CPT involve either the repeated recounting of trauma memories in order to extinguish conditioned responses to trauma cues and process primary emotions, or the collaborative evaluation of trauma related cognitions in order to arrive at more balanced and reality-based assessments. Neither of these approaches explicitly grapple with the experience of perpetration or collusion that is embedded in moral injury. In fact, many individuals complete these treatments without ever being asked about or disclosing their deeply shameful experiences of moral injury. Recounting in detail the perpetration of a morally repugnant act, as in PE, may only exacerbate feelings of shame and self-loathing. Suggesting that the anguish over killing another represents a cognitive distortion, using cognitive restructuring in CPT, is likely to be deeply invalidating. Contextualizing this act does not change the fact that it happened, nor does it absolve the person from responsibility. When someone has crossed a line that they cannot undo, they need this anguish validated, rather than having their behavior excused or minimized. This anguish may be the last indicator they have of their own goodness and decency.

Morality and spirituality are social experiences; they reflect shared norms and values, rituals and beliefs. Social emotions such as shame and guilt can function to promote prosocial behavior and encourage repair and amends when such norms are violated. All major religions address wrongdoing and offer paths towards forgiveness and redemption. But when individuals feel that their actions are unforgivable, their transgressions unacceptable, and amends impossible, the path to healing becomes murky. This person begins to feel like an inhuman monster and to self-exile from the community. Shame produces an impulse to hide because to be shunned and expelled from the society of decent people is one of the worst punishments that humans can levy. The experience of shame is one of self-condemnation, but it is rooted in the judgment of the other. This deep shame — and associated emotions of guilt, fear, anger, or self-hatred — is a profoundly difficult experience to explore in therapy. The fear of condemnation by the other, and the desire to avoid such emotional pain, lead many to never seek healing for such wounds, even after years of therapy.



Recently developed therapies for moral injury, such as Adaptive Disclosure (Litz et al., 2017) and Impact of Killing (Maguen et al., 2017), were developed based on the insight that for these injuries, healing requires an acknowledgment of transgression, a true expression of remorse, and a process of self-forgiveness and compassion. These treatments may provide a framework for a path to recovery, but unfortunately, the very nature of moral injury can prevent those who need treatment the most from engaging in them. The profound shame, self-loathing, and fear of judgment from a therapist often leaves patients unable to share their morally injurious experiences in the first place, or to open themselves to the possibility of forgiveness and redemption, ultimately reinforcing a sense of hopelessness and despair.

MDMA-assisted therapy holds the potential to unlock these barriers and open the path towards healing from moral injury. The conceptualization of moral injury as a web of moral and spiritual conflicts that block acceptance and self-forgiveness demands development of treatments that can help patients face and untangle this complex web. The empathogenic effects of MDMA (Kuypers et al, 2017), which brings forth feelings of safety, trust, and compassion, are precisely what is needed to address the shame and self-punishment of moral injury with a compassionate other. Where moral injury creates isolation and profound alienation, MDMA may allow for the healing connection required to tend to the wounds left by betrayal of one's core morality. MDMA-assisted therapy may thus help patients tolerate disclosure, face the potential for judgment by the therapist, and then take in the therapist's acknowledgment of their pain and their humanity. MDMA-assisted therapy may help patients find and ultimately embrace the seeds of self-forgiveness and self-compassion within themselves.

In working to find self-forgiveness, therapies for moral injury often include imaginary engagements with a respected moral authority, with those who have been wronged, and with earlier versions of the self. These strategies seek to help patients gain perspective and internalize a compassionate other. For many this work also involves questions of faith and spirituality, an exploration of the possibility of forgiveness and acceptance. The transpersonal experiences facilitated by MDMA, in which people may engage with parts of self, with absent others, and with spiritual connection, have the potential to heighten and catalyze these experiential approaches to healing, where therapists so often fear to tread.

Meaningful treatment for moral injury involves a painstaking walk through a field full of landmines, carefully balancing the importance of honoring the underlying values that were violated while letting go of the self-punishment and loathing that impede self-forgiveness and block opportunities to move forward and live by those values. MDMA-assisted therapy for moral injury remains to be further developed and studied, but the window of tolerance for intense and distressing emotions and memories opened by MDMA holds the promise of experiencing safety in disclosure and an opportunity to grapple honestly with these conflicts without being shut down by shame. As therapists, study participants, and patients take courage to seek the darkest places together, we look forward to the opportunity for MDMA-assisted therapy to help shine a light of healing and compassion.

* *Marco represents a composite of Veterans with moral injury*

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RACHEL YEHUDA, PH.D., is a Professor and Vice Chair of Psychiatry, and Professor of Neuroscience at the Icahn School of Medicine at Mount Sinai. She is also the Mental Health Patient Care Center Director at the Bronx Veterans Affairs. She has published several hundred scientific papers and compiled over 10 books examining diverse aspects of traumatic stress, and has studied PTSD and resilience in combat Veterans, survivors of genocide, interpersonal violence and terrorism, as well as in animal models. Her work has focused on neuroendocrinology, neuroimaging, genomic and molecular biological studies of trauma, experimental therapeutics (pharmacological and psychotherapy trials), biomarkers, genetic and epigenetic heritability, gender differences, and suicide.

A Way Out of the Valley

Towards a Psychedelic Industry That is Regenerative and Just

DAVE MCGAUGHEY



Part of what draws many of us to this work is the hope that psychedelics could help us break this cycle of extraction.

CAPITALISM HAS NEVER INTERSECTED WITH something like psychedelics. The power of psychedelic medicine, the complexity of psychedelic treatments, the suggestibility of patients experiencing it, and the trove of participant data it produces present unprecedented risks. How will these unique aspects of psychedelic medicine intersect with the perverse incentives that profit maximization can create?

At Auryn Project, we explored these questions in *We Will Call It Pala*, a graphic story about a commercialized psychedelic future gone awry. The story frames a fundamental risk to psychedelic business: regardless of the entrepreneur's intention, scaling with conventional capital will corrode their mission over time, often at great cost. In the time since the story came out, the psychedelic industry has exploded. Approximately \$450 million has been invested into psychedelics, almost all of it on conventional terms. The growth is not necessarily bad. The question is whether these entrepreneurs and investors see psychedelics as more than the next item on the assembly line of wealth.

Setting aside so many other ethical questions, it is worth zooming in on a meta dynamic that is at play. Power concentrated in large, centralized corporations has a diminishing effect on a community. Simply think of where the dollars go from a main street business versus a large corporation: In one case, money recirculates in the community. In the other case, money flows to a centralized office many states away to be reinvested elsewhere or distributed as shareholder returns. This siphoning of resources from communities contributes to growing inequality.

Inequality is a primary driver of “diseases of despair” — substance use disorder, depression, suicidality. By extracting from communities, psychedelic medicine delivered without mandates for community investment will perpetuate the root cause of the diseases that it treats. It is like holding someone underwater and offering them a snorkel. It is essential that they can breathe, but there will be no true healing until they are helped up.

Part of what draws many of us to this work is the hope that psychedelics could help us break this cycle of extraction. It is particularly painful to think that the opposite may happen instead.

Given the scope of the mental health crisis, compounded by a global pandemic, climate change, and systemic inequality, the funding needs to scale psychedelic medicine are great. If channeled through business structures that preserve a company's mission as it grows, for-profit capital can play an essential role in delivering psychedelic healing in ways that are equitable, regenerative, and just.

Today, such business and financing structures are at the forefront of a movement for a new economy. They are at work in parallel industries like regenerative agriculture, healing the land while empowering stakeholders — not just shareholders — to benefit from company success. New economy models allow a range of funding options that include financial returns for investors, channeling capital through structural safeguards that turn businesses into engines for positive change.

Here are four examples — each applicable in some way to psychedelics — that help to illustrate the point:

Business Structure: Organically Grown Company

- In order to protect its mission of delivering food that is healthier for the planet and for people, Organically Grown Company transferred the controlling stake of the business into a Perpetual Purpose Trust.
- The Trust is made up of a committee elected by all stakeholders — employees, farmers, customers, investors, and allies in the community where the business is located.
- This model allows the company to raise capital through offering non-voting preferred stock to “evergreen” investors who will be among several stakeholder groups who receive a profit redistribution.
- The structure ensures that the company will never be sold and makes profits a tool, not an end in itself, in service of the company's mission.
- The Perpetual Purpose Trust is built on a model called Steward Ownership, considered a gold standard for preserving the mission of a business.

Funding Structure: Seed Commons

- In order to bring wealth building opportunities and economic resilience to traditionally marginalized communities, Seed Commons has built a national network of local loan funds that use carefully constructed “non-extractive” terms.
- Their model of non-extractive finance ensures that loan repayment begins only after a company's operating costs are covered, including paying market-rate salaries to all its workers.
- Seed Commons invests in cooperatives and other shared ownership structures that facilitate stakeholder gover-

nance and more equitable wealth creation but typically have a difficult time accessing capital.

- Seed Commons also supports businesses with cooperative conversions, providing business owners with an opportunity to “exit to community” by selling their company to their employees.

Funding Mechanism: Revenue-Based Financing

- Revenue-Based Financing is a form of debt financing where an investor receives a percentage of company revenue until a certain return multiple is reached, rather than receiving equity in exchange for capital.
- This enables high quality companies to grow at steady rates while staying committed to their mission and remaining independent. It offers investors some of the upside of venture financing with some of the risk mitigation of debt while providing a way for entrepreneurs to receive growth capital without having to give up ownership and control.
- Revenue-Based Financing helps companies maintain steadier growth curves and protects them from the requirement for a large liquidity event in the form of an exit — a sale to a larger corporation or an initial public offering (IPO) — which can significantly diminish a company's ability to prioritize its mission.

Funding Mechanism: Revenue-Based Financing

- To see a compelling example of new economy principles in action we need look no further than MAPS. Concerned that the incentives of conventional pharmaceutical structures are fundamentally misaligned with healing, MAPS has developed its pharmaceutical company as a Public Benefit Corporation wholly owned by the non-profit.
- MAPS' ability to fund raise the large amounts of money required for drug development is a testament both to the organization and its leadership as well as to the unique energy around psychedelics. Funders of MAPS believe in the nonprofit's mission enough to do what many on the outside have said was impossible: resource the organization with the money required to take MDMA through Phase Three clinical trials to become available as a prescription medicine.
- It is as much their mission as their model that makes MAPS structurally situated to focus on healing, acting always in the best interest of the people whom would benefit from the medicine.



Deploying capital into business or financing structures like those above is sometimes called “catalytic” impact investing. Instead of saying, “We need to earn X return. What can we invest in to make an impact?” catalytic investors say, “We want to make Y impact. What forms of capital make sense?” The full range of funding options available span the array of investment from philanthropic giving to, in certain cases, venture capital. The point is to center the intended impact over funding structure and to remain diligent ensuring the investments are meeting that goal.

Much of the essential infrastructure to deliver psychedelic healing will not provide venture-style returns. In other industries this dynamic often means that such work will simply not get funded, relying instead on a patchwork of government or resource-starved nonprofits and small businesses. Just because a company will not create a 10x return doesn’t mean it is not a good investment. Plenty of “good” companies fail to reach the required growth rate for venture capital and are abandoned before they can become self-sustaining. In the case of psychedelics, what is needed is “patient-focused patient capital” — investments that operate on a flexible time frame (“patient” capital) with creative terms that put quality patient care first. Such an approach allows psychedelic companies to be driven by more than the short term return requirements of investors,

a mandate which can have a corrosive effect on company culture, business practices, and mission.

Few things offer higher leverage in shaping the future of psychedelics than bringing such investors in. Yet until investors are willing to provide catalytic capital, building new economy businesses in psychedelics will remain out of reach. Today, dozens of investors are stepping up, working to find and fund the models for psychedelic medicine where a focus on healing — not profits — is the point.

Longtime philanthropic funders in psychedelics like Dr. Bronner’s and Riverstyx Foundation are leading in catalytic investing as well. Following their example, millions of dollars of catalytic capital are being committed to this space. The higher that number climbs, the more entrepreneurs will feel there is a path for them to grow their businesses without compromising their missions. This alternative path for psychedelic business does not need to change the industry as a whole. It just needs to show that there is a better way. That better way will draw the kinds of people to it worth working shoulder to shoulder with for a lifetime.

One day we could look out and see scores of psychedelic companies we can truly believe in. These companies will be a unifying force for the field. Instead of factions and divisions across psychedelics, there could be a cohesive movement built

on symbiotic relationships between clinicians, researchers, guides, Indigenous peoples, elders, and this new, deeply aligned form of business. At the heart of this segment of the industry would be the healers themselves. The entire ecosystem around them — of companies, service providers, experts, and funders — would be there to support their work.

Looking at the direction of the industry today it is easy to feel that this will not happen. But after conversations with dozens of investors and entrepreneurs across psychedelics I have a growing conviction that it will. That feeling emerged after we published *We Will Call It Pala*. Our intended audience had been the anchoring psychedelic community — the clinicians, researchers and guides who have carried this healing work in the West through the decades of prohibition. We were surprised when the people most impacted by the story were entrepreneurs. They said the story resonated with them. They saw themselves in the protagonist and asked, “How do we make sure we don’t contribute to that future?”

The intention behind that question, shared by the investors stepping up to fund a better way, provides a window into what makes psychedelics unique. There is a reason to believe a psychedelic industry could be different from every other industry on earth. Many of the people working in psychedelics today have had deep personal experiences with these substances. For some, these have been among the most profound and meaningful of their lives. This alone will not bend the psychedelic industry towards justice. It just shows us that there is a crack in the wall, a place where we can see the light shine through. From here the future is in our hands; a once-in-a-lifetime opportunity not only to see psychedelic medicine delivered to the world, but to treat our broken economic system along the way. In the end, this will not be a story about complex financing structures. It will be a story of how together we finally find a way to heal.

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Health Equity, Our Entheogenic Duty

RACHEL KNOX, M.D., M.B.A.

AS WE EMBARK INTO 2021, we find ourselves at an inflection point of global proportion. People are sicker and more distressed than ever, but there is a silver lining, a glimmer of momentous hope. Significant healing is within reach, but only if we get this one thing right: health equity in drug policy reform.

The impetus behind certain interests in cannabis and psilocybin legalization and regulation is what concerns me most. On one hand, COVID-19's acute toll on the economy has resulted in serious considerations for cannabis legalization. On the other hand, governments and other stakeholders have long recognized the economic impacts of both the suppression and legalization of these entheogens. Whichever the case, we must ensure that both legalization and regulation, wherever and whenever they happen, recompense the people who prohibition hurts most: Black, Indigenous, and Latinx people, and patients. We can only make the necessary amends if we put their needs first.

Continue reading to explore with me the meanings of health and health equity as we navigate the intersection of ecological sustainability, the War on Drugs, drug policy reform, and psilocybin legalization.

Ecological Sustainability

What is health? It's remarkable, really, how variable the definition of health seems to be. According to the World Health Organization (WHO; 1946), "health is a state of complete physical, mental, and social wellbeing and not merely the absence of disease or infirmity." With all due respect to the WHO, I disagree. Health is a state, but it is not inherently good; it's not inherently wellness or wellbeing. Health, at any given time, be it good health or bad health, is the net of all determinants of wellbeing, and a function of sustainability.

Let's unpack this, beginning with a comprehensive review of ecological sustainability, as understanding ecological sustainability is prerequisite to understanding health.

Total sustainability is best explained by the ecologist Robert Goodland, former Lead Specialist of the Environment Department of the World Bank. He describes sustainability as the sum of four comprehensive pillars: Economic Sustainabil-

ity, Environmental Sustainability, Human Sustainability, and Social Sustainability. Goodland articulates that sustainability is not only the prevention of ecological harm, or the avoidance of depleting natural resources — it requires maintenance, and maintenance requires capital investment (Goodland, 2002). That means making investment in human capital — in the education, skill development, knowledge, and leadership of human beings, as well as in their physical, mental, and spiritual fitness. It's investment in environmental capital — in preserving clean water, land, air, forests, and mineral-dense soil. It's investment in economic capital — in maintaining the value of currency and its fair distribution across a society. And it's investment in social capital — in infrastructure and the systems required to establish and maintain the basic frameworks for society.

If any one of these pillars is lacking, the balance that is ecological sustainability becomes compromised.

State of Human Health

So what does the current state of human health suggest about our commitment to total sustainability?

One in 10 American adults is suffering from heart disease or diabetes (Center for Disease Control and Prevention [CDC], n.d.); 1 in 5 from chronic pain (Dahlhamer et al., 2018), irritable bowel syndrome (IBS), or mental illness such as anxiety, depression, or posttraumatic stress disorder (PTSD; National Alliance on Mental Health [NAMI], n.d.). One in 3 American adults is ailing from insomnia, high blood pressure, or pre-diabetes (University of Pennsylvania School of Medicine, 2018; CDC, n.d.); 2 in 5 will develop cancer (American Cancer Society, 2020); 1 in 2 suffer from chronic headaches (WHO, 2016); and 1 in 1.5 are managing some form of chronic stress (American Psychological Association [APA], 2017).

These conditions are a result of human injury caused by poor diets, chronic prescription drug use, isolation, and emotional stress. They are the result of environmental injury caused by chemical pollution, habitat destruction, deforestation, depletion of non-renewables, and overharvesting renewables. They are the result of economic injury caused by soaring debts, predatory economics, and brutal capitalism. And they are the

result of social injury caused by selective investment and disinvestment; systemic and institutional racism and classism; and inequitable policies, regulations, and distribution of resources and services.

Our leading causes of disease reflect an ecological problem in that they are caused by the products, services, and circumstances that our industrial complexes and their politics create and perpetuate as they develop more Frankenfoods and drugs, more urban metropolises, and more technologies in a race against the balance of our own nature and towards profits.

The state of our health is a reflection of our ecosystem, which is really a reflection of our priorities and is inextricably tied to ecological sustainability.

This all leads me to my favorite, holistic definition of health. Health is the composite state of one's mental, physical, spiritual, and ecological wellbeing. It is also the state of community wellbeing and the state of a society's wellbeing, and all three — the health of individuals, communities, and all of society — are functions of total sustainability.

Translated another way, optimal health is the net sum of economic, environmental, human, and social determinants. I call these the four determinants of wellbeing.

State of Black, Indigenous, and Latinx Health

Now, let's juxtapose what we know of the health of the general population against what we need to acknowledge and understand deeply about our Black community.

Adults in America's Black community are 1.2 times more likely than white adults to die from cancer and 1.3 times more likely to be obese, a major risk factor for cancer, diabetes, heart disease, and other metabolic disorders. Black people are 1.5 times more likely to develop high blood pressure, a leading cause of heart disease and stroke; 1.6 times more likely to develop diabetes and 2.1 times more likely to die from it; and 1.2 times more likely to develop asthma and 2.8 times more likely to die from it (U.S. Department of Health and Services Office of Minority Health, n.d.).

Regarding mental health, Black adults (including those identifying as mixed-race Black) are more likely to have feelings of sadness, hopelessness, and worthlessness than white adults, while Black and mixed-race youth are more likely to attempt suicide than white youth (CDC, 2018).

This is the Minority Health Disparity Gap, and we've known about it for a long time (Healthy People, 2020). Healthy People 2010 and 2020 had audacious goals to close it, but COVID-19 has made it strikingly apparent that our society has not invested in the wellbeing of our Black community, nor in our Indigenous or Latinx communities, and perhaps doesn't actually know how.

A History of Omission

American society and its leadership have a nasty habit of erasure. This is remarkably evidenced in our secular history books, which reduce the treatment of Black and Indigenous people and their experiences in America to a few chapters that cover America's discovery and exploration, the Trail of Tears, slavery, the Underground Railroad, and the Civil Rights Movement in as few words as possible.

One of the reasons our Western, conventional medical system is failing so many patients is because medical care addresses symptomatology and rarely the source of illness. It doesn't know how to heal people, because it ignores the root causes of disease. Similarly, we will not find our way out of racial disparity by treating its symptoms. We have to treat it at its root cause, which is all but substantially hidden within the annals of America's history of the War on Drugs.

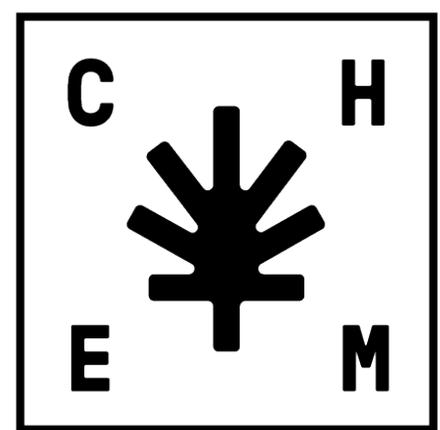
The War on Drugs criminalized entheogens like cannabis and psilocybe, and the irony is two-fold. First, each held significant cultural, economic, and spiritual value



Doctors Knox



ADVENT ACADEMY



at one time. Cannabis was a therapeutic staple, well stocked in household medicine cabinets and prescribed liberally by medical doctors, while hemp was a highly valued American cash crop grown by enslaved Black people at the height of its production. Psilocybe, on the other hand, played a significant role in Indigenous sacraments and healing throughout North, Central, and South America. But what compounds the irony is this: Black, Indigenous, and Latinx (BIL) people were stripped of their access and knowledge by prohibition, then had their craft and practices weaponized against them through their criminalization. The disproportionate enforcement of prohibition laws in BIL communities, a process that imprisoned bread winners and heads of household, has contributed to intergenerational marginalization and disinvestment in the wellbeing of these communities, negatively impacting all four determinants of wellbeing.

It has been a particular degree of greed, cruelty, racism, scarcity mindset, and denial that is the root cause of ongoing health disparity.

What is Health Equity, Really?

Through systemic racism and the War on Drugs, Black, Indigenous, and Latinx people have been disproportionately denied the assurance of access to wellbeing.

Equitable access to wellbeing is what's known as Health Equity, and it is created and maintained by the impartial and intentional distribution of attention and investment across all four determinants of wellbeing, such that they are optimized and balanced within and across a total population, resulting in healthy infrastructures, healthy economies, healthy environments, and healthy people, communities, and societies.

Health Equity achieves wellbeing for all people and can be measured. This also means that we can hold authorities accountable to reporting just how well our social frameworks facilitate wellbeing according to the 4 Pillars of Health Equity.

- **Human Equity:** the impartial optimization of individuals' knowledge, skills, ability, capability, and adaptability; and that of their physical, mental, and spiritual fitness.
- **Economic Equity:** the impartial assurance of access to the possession of economic resources (income, savings, assets, capital, etc.), and personal and collective agency over the flow of these resources through a household and community.
- **Environmental Equity:** the impartial guarantee of the existence of, access to, and maintenance of clean air, clean water, clean land, clean soil; clean, safe, and natural outdoor spaces; and clean, safe, and consistent housing options.
- **Social Equity:** the impartial assurance that social infrastructures facilitate 1) fair and continual access to economic, environmental, and human resources, services, and justice; and 2) social participation, cooperation, trust, cohesion, and personal and collective productivity.

Psychedelics and Health Equity: Integrous Stewardship of Psychotropic Legalization and Regulation

So, here's the nexus. Through their prohibition, entheogens like cannabis and psilocybe (i.e., psilocybin) have been weaponized against people, and chiefly those identifying as Black, Indigenous, and Latinx, resulting in health disparity. As such, these communities should be the first to benefit from their legalization and regulation. Restitution is the reason why we should be decriminalizing, legalizing, and regulating the economies of psychotropic commodities, followed closely by their incredible medical utility for all of humanity. And this is why regulatory frameworks must be equity-centric, decolonized, and stewarded with integrity.

This is not only the social responsibility of local, state, national, and international governments. It is the responsibility of every stakeholder — every regulator, every operator, and every ancillary service provider — in the nascent cannabis and

Through systemic racism and the War on Drugs, Black, Indigenous, and Latinx people have been disproportionately denied the assurance of access to wellbeing.

psilocybin industries to ensure that the regulatory frameworks, economies, tax structures, and utility of cannabis, psilocybe, and their derivatives serve health equity. They should be seen as the principal investment vehicles to optimize determinants of wellbeing and total sustainability in all communities beginning with those most negatively impacted by the War on Drugs. Prohibition harmed BIL people and communities, so legalization must heal them. To argue against this is callously reductive and reprehensible, and many do (Jaeger, 2020).

Ethnobotany and Decolonization

Besides coming to terms with America's — and, really, our global — racist history, addressing health disparity at its root cause will require a drastic “unknowing” also referred to as *decolonization*.

Prohibition of plant medicines, like entheogens, deprived all people of all colors from accessing natural, safe, effective, affordable, and holistic medicine. It has denied all people of life-saving therapies and experiences. And it is just as important to understand that the cultural appropriation, control, and in some cases erasure, of Indigenous craft, practices, and medicine by Western authority — i.e., the colonization of plant medicine — has deprived us all from cultivating a collective appreciation and respect for traditional knowledge and from properly honoring, crediting, and rewarding Indigenous people globally who originally fostered that knowledge. We all need to be freed from this debt.

One way to do this is through edifying Western, or conventional, scientific and medical standards of exploration, study, and validation with the promotion of Ethnobotany, coupled with eliminating the thinking and knowing reflective of Western perceptions of superiority over traditional and Indigenous knowledge, science, and medicine. We must eliminate the pervasive methodologies used to control, suppress, hide, adulterate, co-opt, or market Indigenous wisdom, especially for capitalistic gains.

To put this into perspective, try to imagine what it might feel like to witness the legalization, regulation, and commoditization of a plant medicine once traditional to your community, but that has since been arbitrarily denigrated, made illegal, and even used to disproportionately marginalize and criminalize you. Add to this your systemic exclusion from the economic opportunities birthed through its now-legal market, and the reality that little-to-none of the billions to trillions of dollars that its market generates get passed back to your community, the very community out of which the plant medicine originated. This is what is happening with many plants and plant medicines historically cultivated by marginalized Indigenous people all over the globe.

The stark truth is that plant medicines are being commercialized, and some legalized, for the benefit of white wellness. From who “wellness” is marketed to, to where it can be accessed, American “wellness” is primarily consumed by white Americans in predominantly white communities. From yoga to palo santo and everything in between, the commercializa-

tion of healing and “wellness” is really the commoditization of global Indigenous knowledge and wisdom, and of Indigenous science and medicine, but not to their credit nor reward.

Oregon Voted, Now Oregon Must Work

With the passage of Measure 109 in 2020, my home state of Oregon is tasked with the regulatory development of a psilocybin-assisted therapy program and the psilocybin industry the program will intrinsically create. The state has an opportunity and responsibility to erect both a first-of-its kind and best-in-class Psilocybin-Assisted Therapy program and a psilocybin industry that are Indigenous-led, equitable and decolonizing, patient-centered, science-informed, and rooted in sensible market economics.

At a minimum, Oregon's framework should ensure that Black, Indigenous, and Latinx people have equitable access to psilocybin therapy and that they benefit from it.

BIL people have suffered disproportionate and intergenerational psychological trauma as a result of the War on Drugs and systemic racism more broadly. In my work I have recognized this trauma as a significant barrier to BIL people's use of cannabis as medicine for fear of continued stigma and discrimination. Given the therapeutic potential of psilocybin to treat the very trauma the War on Drugs and systemic racism have cumulatively caused, there is a duty to dismantle stigma and to treat the trauma with this breakthrough therapy. Oregon must ensure that BIL communities have 1) awareness, 2) education, 3) local access, 4) affordable therapy, 5) treatment specialists and researchers who look like them, and 6) the assurance that Oregon has an interest in monitoring, measuring, and reporting the short and long-term impact of psilocybin therapy in its BIL communities as the program evolves.

Oregon's framework should also ensure that historically marginalized BIL healers, entrepreneurs, and workers have equitable access to economic opportunities as licensed operators throughout the entire psilocybin supply chain, from cultivation to treatment administration. Economic justice is not only a determinant of wellbeing, but wherein psilocybin is a traditional Indigenous medicine, racial justice is the assurance that the Indigenous peoples of the Americas be among the first to benefit economically from its sale and distribution. Oregon must prioritize and protect Indigenous influence and participation in its psilocybin market.

If healing is what we're after, and if we believe that entheogens such as cannabis and psilocybin are our gateways to health, wellbeing, and inspired living, we must steward their decriminalization, legalization, and regulation integrally. We must guarantee that the programs and markets these processes create lead to impactful and measurable pathways to actuating health equity across all communities, beginning with those most harmed by the War on Drugs. It is the nature of these entheogens to integrate and to heal. Let us follow their lead; it's our entheogenic duty.

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Four-Inch Headlines

How new psychedelic news outlets are shaping culture and industry

REILLY CAPPS



WHY DOES PSYCHEDELIC JOURNALISM MATTER? It matters because something as controversial as these substances — as nuanced, daunting, easily misconstrued, liable to be demonized or lionized — needs dedicated reporters who believe these substances are important — whether they’re currently legal or illegal, regarded by the outside as cures or poisons — and whether anyone in the rest of the media world cares or not.

After all, the mainstream, Western media has had a love-hate, up-and-down relationship with psychedelics. LIFE Magazine started covering psychedelics in 1957, when Gordon Wasson reported on the “magic” mushrooms of the Indigenous Mazatec Mexicans. For the next decade, the media covered psychedelics with open curiosity and, at times, reverence. They featured musicians using LSD for creativity, spiritualists finding god, and studies suggesting psychedelics could make you healthier.

An advertising-driving media, though, runs in cycles, and it runs on juicy stories. So if yesterday’s hero can be today’s villain — that’s a good story. By the late 60s and early 70s, the media soured on psychedelics, and tales of teen girls jumping out windows were more likely to sell papers. They were also following the lead of politicians like Richard Nixon, who called Timothy Leary “the most dangerous man in America” and drug use “public enemy number one.” The press’ sour relationship with psychedelics, and their tendency to exaggerate the downsides, actually helped psychedelics get banned.

By the 70s and 80s, the mainstream media tended to either ignore psychedelics or recycle old stories about the drugs driving you crazy. Even when there was psychedelic news, the media culture wasn’t set up for it. Respectable places like the Washington Post drug-tested new reporters, and pitches on psychedelic culture tended to go nowhere.

Folks who had actually tripped, had been shaken and stirred by the fantastical, shattering, absurd heights of megadoses were stunned. “Why this is not four-inch headlines in every newspaper on the planet I cannot understand,” marveled DMT philosopher Terence McKenna, “because I don’t know what news you were waiting for, but this is the news I was waiting for.”

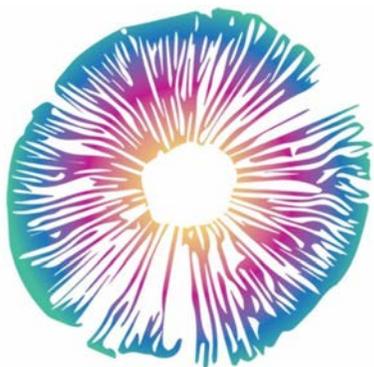
As the Internet came online, psychedelic news finally found an opening it would never let go of. Most news came not from pro journalists but from passionate psychonauts like David Wilder of Think Wilder, now nearly 15 years old and still the best psychedelic news aggregator. “When I was starting out, there wasn’t a whole lot of information,” emails Wilder. “As a result, I ended up learning a lot of lessons [about using psychedelics] the hard way. My blog and YouTube channel help people learn how to avoid making the same mistakes that I made.”

It wasn’t hard to keep up with the news. Even just a few years ago, the above-ground psychedelic news could only fill a few column inches, and professional reporters had to scrounge for stories. “In 2017, when I started covering psychedelics full-time, it was pretty easy to keep up with all the comings and goings. A few new studies, a news item here or there, and that was about it,” emails Troy Farah, who co-hosts the Narcocast podcast.

“Why this is not four-inch headlines in every newspaper on the planet I cannot understand, because I don’t know what news you were waiting for, but this is the news I was waiting for.”



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psychedelics
today

But those lean times for psychedelic news are history. Catalyzed, in large part, by MAPS, the psychedelic news today comes in tidal waves: psilocybin and MDMA-assisted therapy are fast-tracked to become legal treatments for depression and PTSD; a half-dozen jurisdictions have decriminalized some psychedelics; Oregon approved psilocybin therapy; psychedelic-focused companies are traded openly on Canadian exchanges; celebrities flaunt their psychedelic use; retreats thrive in Jamaica, Mexico and The Netherlands. “It’s getting to be impossible to keep up,” emails Farah.

Mainstream media are once again poking around psychedelics, even stodgier outlets like 60 Minutes and The New York Times. A few older, edgier organizations cover psychedelics extremely well and regularly: VICE, Rolling Stone, The Guardian, Playboy. And cannabis-friendly outlets, such as Marijuana Moment, Leafly, High Times, Merry Jane, and Rooster, staffed by journalists aware that psychedelics are cousins of cannabis, crank out regular content.

But none of that is enough to keep up with the torrent of news from a culture now bursting at the seams of the straitjacket once thrown around it.

Thankfully, a large number of psychedelic news organizations have popped up to cover the culture, science, and — especially — the financial aspects of the emerging psychedelic industry. These websites, podcasts, social media feeds, subreddits, and newsletters are being created by all manner of people: established journalists, eager investors, and passionate hobbyists. Some are polished and professional, some corporate and slick, some homespun and quirky. Overall it creates an information ecosystem that matches — if not exceeds — all the action and news in the psychedelic space, and creates huge opportunities for psychedelic-focused journalists, publishers, and readers.

A look at a small batch of the new publications help give you a sense of who’s running these outlets and why. For many, love of psychedelics — not money, fame or recognition — is their motivation.

Madison Margolin and Shelby Hartman were cannabis journalists who decided they wanted to give psychedelics what nearly every beautiful thing in the world has, from racehorses to flower gardens: a sharp, sensually aesthetic, almost luxurious physical magazine — the *Sunset* or *Vanity Fair* of tripping. “We saw an absence in the media sphere of an outlet for people who are psychedelically curious,” says Margolin, managing editor. *DoubleBlind* is built to be a gateway drug for neophytes, mixing how-to’s for newby trippers with stories to bewitch Internet-dwellers with short attention spans — about witchcraft, BDSM, and asking “Could Giving Acid to Dolphins Help Us Talk to Aliens?” (Answer: might as well try.) Margolin wants to attract new psychonauts but also “keep psychedelics weird.” “If the mainstream is getting into psychedelics,” Margolin says, “how can we actually make the mainstream more psychedelic and accepting of weirdness and, you know, chaos — the beauty of entropy and uncertainty.”

There is also a growing group of news outlets whose founders are determined to give voice — not to the whole subculture, — but to some particular facet of psychedelics important to them. For example: *Psychedelics Today* — a blog, podcast and online education hub — was founded by folks who believe the modern materialist mindset is “killing us and harming the planet,” in the words of co-founder Joe Moore, and sought to raise the profile of Stanislav Grof. Moore knew Grof’s breath work often inspires a larger worldview — that the Self and the Cosmos are connected, that there is Something More. Moore hopes these ideas can “help evolve humanity, science and medicine” — to basically save us all. Another site, *Chacruna*, an educational nonprofit, speaks for nature and the folks who know her best, intent on being a bridge between the ceremonial use of sacred plants and the Western psychedelic world of molecules and clinical trials, hipsters and outlaws. “Plants matter,” executive director Bia Labate often says (Labate is also Chief Editor of this *MAPS Bulletin*). *Chacruna*’s articles come from shamans and ayahuasqueros talking about indigenous rights, wisdom, and strug-

gles, and Western academics often highlight underrepresented voices such as women, queer folks and people of color. Psymposia, a website and podcast with an anarchic, anti-capitalist bent, often highlights the shadow side of psychedelics, calling out new businesses for unethical moves or just general un-coolness, such as dropping the traditional culture and meaning of psychedelics to make them palatable to investors. And the Third Wave, which teaches courses on microdosing, is hyper-focused on the practice of taking small amount of psychedelics as an adjunct to self-improvement and self-acceptance.

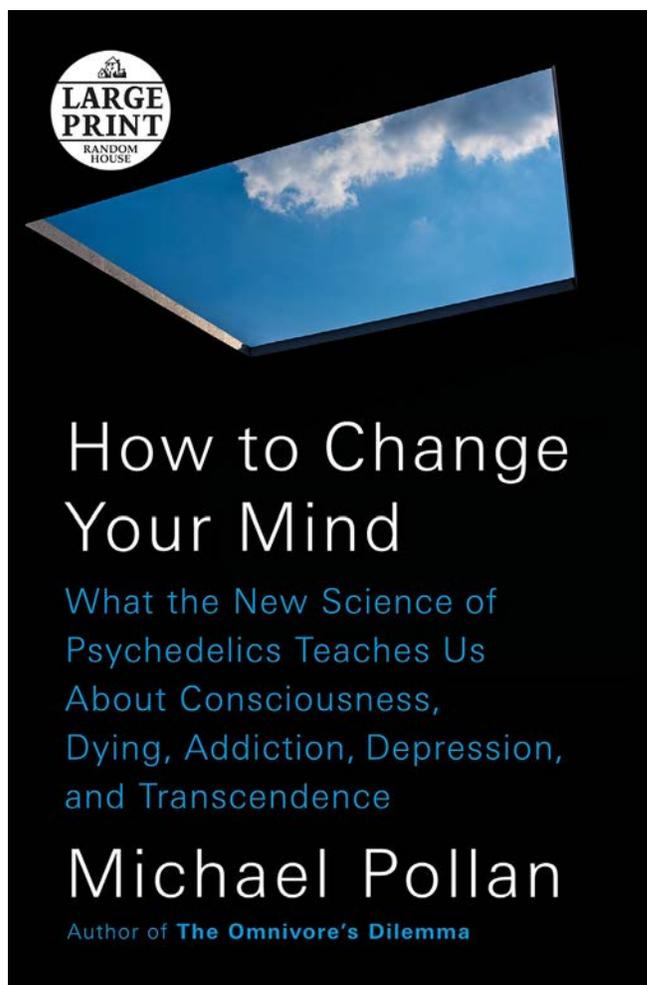
And then there is the rapidly-expanding class of outlet that did not exist at all until just a few years ago: the psychedelic business site. PsilocybinAlpha, Truffle Report, Shroom Investor, Psychedelic Finance, PsyTech, Microdose, and more, all survey the business landscape, offering interviews and commentary. Some are more promotional than journalistic and revel in the zooming stock prices of psychedelic startups. (No small thing. ATAI Life Sciences, a biotech company exploring ibogaine, has raised over \$210 million, and Compass Pathways, focused on psilocybin-assisted psychotherapy, is now valued at more than two billion dollars.) In the coming era of big psychedelic money — an era old psychedelic fans barely imagined — these business-focused websites will connect and cohere the industry to itself. Many outlets have ties to companies they cover, creating platforms for CEOs and investors to talk to one another about opportunities and IPOs.

Other news sites are partly laying the groundwork for future money-making endeavors. Psychedelic Invest, for example, was started by psychedelic investors keeping track of their own industry with a stock index of every public psychedelic company. An arm of the company brings private deals to accredited investors. There are plans to have a tradeable psychedelic index fund “when the market matures,” messages co-founder Cody Shirk. Another outlet, Psychedelic Spotlight, full of interviews and news items, is owned by Global Trac Solutions, a newly formed psychedelic company which has not yet announced its business plans.

All these publications — and more on the way — ensure that a subculture that was once ignored when it wasn’t being spat on — is now drenched in news aimed at every type of user — fans of plants and foes of capitalism, microdosers and macrodosers, therapists and shamans and investors.

And then you have to ask: is it strange that drugs once totally reviled are far, far more likely to be celebrated now? If Aldous Huxley was right to call these “heaven and hell” drugs, journalists are once again super focused now on the heaven. And so concerns remain, particularly among journalists, about balance.

“Journalism about psychedelics has definitely grown in scale and sophistication, but it still has a long way to go to become a journalistic beat,” emails Michael Pollan, journalism professor at the University of California-Berkeley. Pollan’s 2018 bestseller, *How to Change Your Mind*, is credited with bringing the Psychedelic Renaissance to mainstream attention.



“Much of the stuff out there — the online magazines — are still more evangelical than journalistic, and could benefit from a somewhat more rigorous and skeptical approach — from the voices of people who are not necessarily already in the psychedelic tent. Evangelical journalism is great for pumping up the choir, but it can repel people who are fearful or simply uninformed,” Pollan goes on. “From the outside, it can look like a cult.”

“Psychedelics are an exciting science,” messages the journalist Troy Farah. “But publications that herald this new era also have a responsibility to champion facts over anecdotes and not exaggerate the potential of entheogenic substances.”

A few new outlets see the lack of balance and seek to correct it. Lucid News aims at “accurate and fair” psychedelic journalism, not boosterism or sensation, its editors write on their mission statement, asking reporters and editors to reveal their own biases and conflicts of interest, and to seek out balance. “They add real, legit reporting,” says Ifetayo Harvey, a contributing writer. “There’s something to be said about reported pieces given the lack of that in the psychedelic space.”

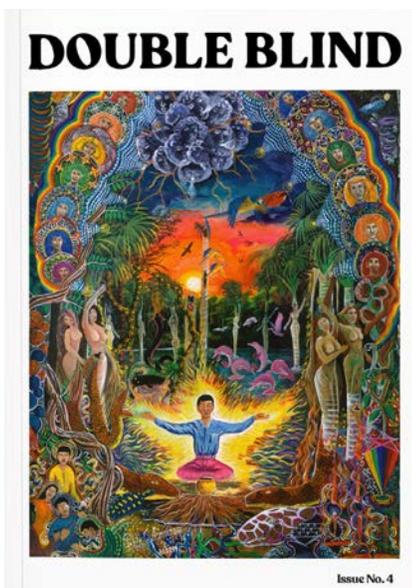
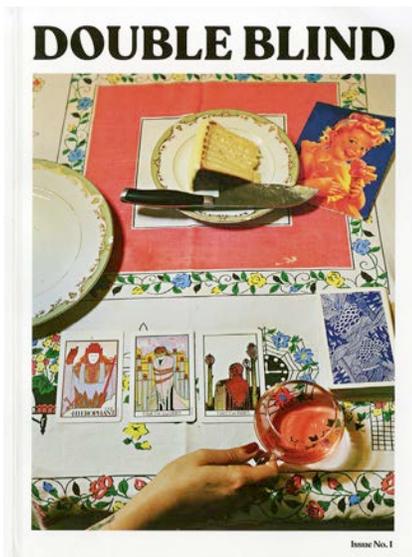
And Psychedelic Science Review, a new site, believed the psychedelic Internet was lousy with low-quality info: “subjective experience reports, poor analysis of high-quality research,

REILLY CAPPS worked as an EMT responding to 911 calls in Boulder, where he grew fascinated with the impact of alcohol and street drugs on his patients' health. His reporting for Rooster, a Colorado magazine, helped catalyze Denver's 2019 vote to decriminalize mushrooms. He co-founded the Denver Mushroom Cooperative, a hub for growers and users of all types of fungi. He has written about drugs for DoubleBlind, the Telluride Daily Planet and the Washington Post. He contributes articles, guides and website content to psychedelic companies, notably The Third Wave. Follow Reilly on Twitter: twitter.com/reillycapps

and general widespread misinformation,” in the words of Barb Bauer, lead science researcher. Her site sifts through piles of new studies and produces fact-based, objective scientific reporting, without editorializing or pushing an agenda.

Historically, burgeoning subcultures have gotten the press coverage they deserve. And Michael Pollan says he is confident that a cadre of rigorous journalists will emerge and turn psychedelics into a regular journalistic “beat.” However: we’re in a new, uncertain time for journalism. Google, Facebook and Twitter post stories and then suck up all the ad revenue, like paperboys who pocket all the subscription money. Will there be enough resources to fund the kind of journalism psychedelics needs? Creative solutions are needed. Outlets such as DoubleBlind and Psychedelics Today earn much of their revenue not through ads, but by selling courses on, for example, how to grow mushrooms or integrate trips. Chacruna is one of several sites that has a membership program. A lot of sites ask readers for donations.

It matters. Psychedelics are developing the kind of press corps they need if they are finally going to get the four-inch-headlines Terence McKenna wanted — with solid journalism alongside those headlines: features that add context, graphs to track company revenue, and sidebars to point out psychedelics’ shadow sides. Psychedelics deserve to be covered thoroughly. Not like a fringe, sideshow, fluke — but like a real thing, like the astounding substances they absolutely are.



Psychedelic Journalism List

TV

Hamilton’s Pharmacopeia

Psychedelic content, written

DoubleBlind
 Psychedelics Today
 Psychedelic Times
 Think Wilder
 Psychedelic Science Review
 Reality Sandwich
 Lucid News
 Psymposia
 Chacruna Chronicles
 Psychedelic Press

Cannabis outlets that cover psychedelics well

Marijuana Moment
 Leafly
 High Times
 Merry Jane
 Rooster

Psychedelic companies with active blogs

Third Wave
 Synthesis

Financial/business websites

PsilocybinAlpha
 Psychedelic Spotlight
 Truffle Report
 Shroom Investor
 Psychedelic Finance
 PsyTech
 Microdose

Mainstream outlets that cover psychedelics well

Rolling Stone
 Vice
 AlterNet
 The Conversation
 The Guardian
 Playboy

Examining *Drug Use for Grown-Ups: Chasing Liberty in the Land of Fear*

KERTHY FIX IN CONVERSATION WITH CARL HART, PH.D.



IN A POWERFUL MOMENT OF social change, America is at a turning point as it searches its soul around social justice, liberty and the history that created this country. In this interview with Dr. Carl L. Hart, Ziff Professor at Columbia University and former chair of the Department of Psychology, Dr. Hart challenges all reasonable people to examine how we've allowed ourselves to be criminalized for the drugs we enjoy.

As one of the world's preeminent experts on the effects of so-called recreational drugs on the human mind and body, Dr. Hart's forthcoming book entitled *Drug Use for Grown-Ups: Chasing Liberty in the Land of Fear* eviscerates the irrational myths that surround compounds like PCP, bath salts, methamphetamine, and heroin. His powerful voice challenges us to remember our unity with all people — especially the poor and certain racial groups — who are being targeted with mass incarceration and murder. And to be open about our own drug use as an act of civil disobedience to disrupt a system that uses drug law terror to limit our freedoms.

Kerthy Fix: Tell me about your new book?

Carl Hart: First of all, this is a book for and about grown-ups. I have to define what I mean when I use the term “grown-ups.” These are autonomous, responsible, well-functioning, healthy adults. They meet their parental, occupational, and social responsibilities. Their drug use is well planned in order to minimize any disruptions of important life activities. These individuals get ample sleep, eat healthy diets, and exercise on a regular basis. They don't put themselves or others in dangerous situations as a result of their drug use. These are all grown-up pursuits, examples of how grown-ups take care of themselves. As you may know growing up is difficult and it's not guaranteed. This book is for those who have managed to grow up.

At its core, the book is an invitation for grown-ups to contemplate their own Liberty. In other words, do you have

the freedom to do as you please — as long as you don't infringe on others' rights, of course? Do you have the freedom to alter your consciousness as you see fit? Clearly, you do not. So the question is: why not? In the book, I show how Americans have made a bargain to sell out certain people's liberty when it comes to personal drug use. This is not only wrong but will inevitably lead to us forfeiting even more fundamental rights.

Another goal of the book is to get the country to reconcile its practice with its promise. The Declaration of Independence, our founding document, is a radical reification guaranteeing each person “Life, Liberty and the pursuit of Happiness.”

What does this mean in practical terms?

Life? It means that I can do, with my life, what I choose. Liberty? This provides me with freedom from tyranny, freedom from political oppression, or simply the freedom of choice. The pursuit of Happiness? Well, this means that I am free to pursue happiness as I see fit, even if it includes taking psychoactive substances. Of course, these rights are dependent upon me not interfering with the Rights of others. The point is that the government doesn't have the right to tell me what to think, what to put in my body, or how to live. Importantly, drug laws, banning person drug use, are out of step with the principles that we claim make us American.

What recommendations do you offer?

I urge readers, especially privileged-class readers, to get out of the closet about their own drug use. I urge them to blatantly disregard law that prohibit adult drug use. Such laws are ruthlessly unjust and they are inconsistent with the nation's promise of Liberty. Massive civil disobedience, like the one I am proposing, is how people like Rosa Parks, Martin Luther King Jr., helped to make our society more just. Clearly, we still have a lot of work remaining. I hope this book helps.

It seems as though your position on drugs and drug policy has evolved since you started studying the brain and drugs some 30 years ago. Can you explain this?

When I began studying drugs, I believed that drug use damaged the brain and ruined people's lives. I now know that there is virtually no evidence indicating that drug use causes brain abnormalities in otherwise healthy individuals. I also now know that many other complex factors are responsible for the turmoil that is inappropriately blamed on drug use.

Are you advocating for the legalization and regulation of all recreational drugs? Why?

Yes, I am advocating for the legal regulation of drugs like cocaine and heroin and methamphetamine and so forth. My research has clearly shown that most of the harm attributed to drugs flow from their being illegal. During alcohol prohibition, for example, hundreds of thousands of people were maimed or killed due to drinking alcohol produced in illicit stills. There was no quality controls on the drug and drinkers were forced into the shadows, both of which can increase toxicity. This problem went away when Prohibition was repealed. Similarly, today most people who overdose on opioids do so because of tainted opioids obtained in the shadows of the illicit market. Legally regulating the market would dramatically reduce opioid overdoses, because it would introduce a level of quality control and decrease opioid users' social isolation. Furthermore, responsible adults should be permitted to alter their consciousness with drugs, should they so choose, just as they are allowed to engage in consensual sexual activities, operate automobiles, and own firearms.

You write for the first time about your own drug use. What made you write so personally and openly about this part of your life?

My conscience would no longer allow me to remain silent about my drug use, nor could I remain silent about the absurdity of punishing people for what they put into their own bodies. How could I remain silent when countless people are subjected to harsh punishments for merely using drugs? What kind of man would I be if I didn't publicly voice solidarity with these individuals? I'd be a hypocrite and a coward. I should know because I had been living as such for many years. I refuse to do so any longer.

It's clear after reading *Drug Use For Grown-Ups* that so much of what we think we know about drugs isn't rooted in science or fact. For example, you explain PCP and ketamine are chemical siblings, but messaging is starkly different around these drugs. What is at the root of this bias and why is it important?

The legal status and social perceptions of psychoactive drugs are rarely determined by pharmacology, or science, alone. Oftentimes, if a specific drug is perceived to be used primarily by a despised group, exaggerated media stories, connecting use of the drug with heinous crimes, addiction, among other adverse effects, dominate the airwaves. For another example, consider Powder and crack cocaine. Powder is either snorted intranasally or dissolved in saline or water before injecting it intravenously. Crack is smoked. The resulting effects are essentially the same, regardless of the form of cocaine ingested. Simply put, powder and crack are the same drug. But our perceptions about the users of the different forms of cocaine differ. We tend to associate powder with wealthy white users, whereas crack evoke images of poor Black, menacing users. In 1986, these perceptions influenced passage of legislation that established penalties that were one hundred times harsher for crack infractions than for powder infractions. A whopping 80 percent of those sentenced for crack offenses are black, even though most users and dealers of the drug are white. Similarly, heroin and morphine are basically the same drug. Heroin is made by slightly modifying morphine's chemical structure, and both produce nearly identical effects. Yet, heroin is banned and morphine is used medically to control pain. At the root of this bias is our need to vilify individuals deemed politically inconvenient — e.g., the poor, specific racial minorities — and to justify the subjugation of this group.

You also debunk misconceptions and point out lies spun about drug "epidemics."

Media reports frequently claim that we are experiencing an opioid overdose "epidemic." People are dying because of ignorance, not because of opioids. For those who may not know, opioids are pain medications like oxycodone and heroin. Some people also use these drugs to get high. Perhaps that's one reason opioids have been blamed for the recent "overdose crisis." Consider the year 2018, for example. More than 45,000 Americans died with at least one opioid drug in their bodies. Now, does this mean an opioid drug caused all these deaths? I think not.

Please don't get me wrong. I am not suggesting that opioid overdose isn't a real risk. It is. But the odds of this occurring have been exaggerated. For example, it's certainly possible to die after taking too much of a single opioid drug, but such deaths account for only about a quarter of the thousands of opioid-related deaths. Tainted opioid drugs and opioids taken in combination with other sedatives (including alcohol or a benzodiazepine) cause the vast majority of these deaths. In other words, many deceased drug users likely didn't know that the drug they took contained contaminants. Others didn't know

*People are dying
because of ignorance,
not because of opioids.*

that combining an opioid with another sedative increases the risk of overdose. The bottom line is this: People are not dying because of opioids; they are dying because of ignorance. *Drug Use for Grown-Ups* contains important information to remedy society's ignorance about drugs, information that will help keep drug users safe.

One particularly eye-opening and heartrending section of your book discusses how drug use is often wielded as a justification for stopping, searching, and detaining black people as well as excusing excessive force and murder.

There have been numerous cases during which police cited the fictitious dangers posed by drugs to justify their deadly actions. This gimmick was used when police (or a proxy) killed Trayvon Martin, Michael Brown, Laquan McDonald, Philando Castile, Terence Crutcher, George Floyd, among a host of others. In each of these cases, the deceased's toxicology findings, combined with his behavior, revealed drug levels that I believe were too low to have contributed to his death. In other words, drugs didn't make them act so violently that lethal force was reasonable or necessary; nor did they cause some fatal medical condition.

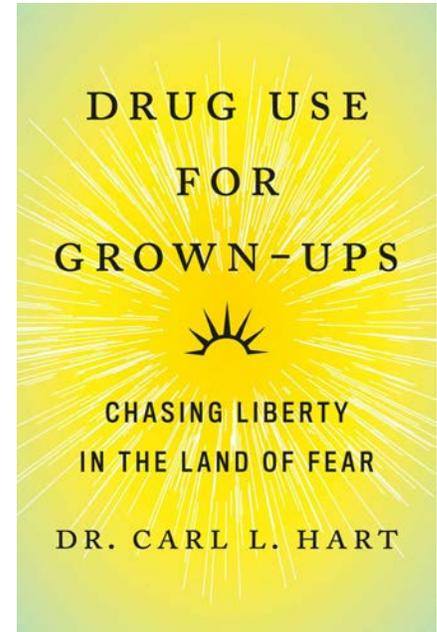
Even the mere accusation that an acquaintance might be a drug seller is enough to justify police breaking down your door in the middle of the night. That's what happened to 26-year-old Breonna Taylor. Just after midnight on March 13, 2020, police entered her apartment, under the auspices of a legal search warrant, in search of her ex-boyfriend, a suspected drug dealer. He wasn't there. But her new boyfriend was there and he fired a shot at the entering plainclothes officers, fearing they were intruders. Police also fired. They fired multiple shots, hitting Ms. Taylor eight times and killing her. Back in 2006, police killed 92-year-old Kathryn Johnson under similar circumstances.

You write about your travels speaking to drug experts and activists around the world. Which countries are getting things right and how has that led to better outcomes?

Several countries are on the right path, including the Netherlands, Portugal, Spain, and Switzerland, although no country is perfect. Still, in these countries, the first intent of drug policy is to keep users safe, not infantilize them, and to respect their autonomy. Each of these countries have accepted the basic fact that humans will always seek to alter their consciousness through drug use. As a result, they have put in place policies that do not criminalize this pursuit but instead, enhances its safety. Each of these countries, has lower rates of drug-related deaths, as well as other negative effects, than in the United States.

In the November election, four states legalized recreational marijuana while two legalized medical marijuana. DC decriminalized psychedelic plants; Oregon went much further – decriminalizing all illegal drugs, a historic first. What was your response to these ballot initiatives passing?

All these developments are steps in right direction. The Oregon decriminalization law is, by far, the most significant. Essentially, Oregonians will no longer be arrested for merely using a drug, no matter whether the drug is marijuana, cocaine, heroin or some other substance. This is an excellent initial step. *Drug Use for Grown-Ups* lays out additional drug policy measures that should be taken in our continuing quest to "secure the Blessings of Liberty to ourselves and our Posterity," as the Constitution states.



DR. CARL L. HART, Ziff Professor at Columbia University and former chair of the Department of Psychology, is one of the world's preeminent experts on the effects of so-called recreational drugs on the human mind and body. He is also a Research Scientist at the New York State Psychiatric Institute. Dr. Hart has published numerous scientific and popular articles in the area of neuropsychopharmacology. His book *High Price: A Neuroscientist's Journey of Self-Discovery That Challenges Everything You Know About Drugs and Society* was the 2014 winner of the PEN/E.O. Wilson Literary Science Writing Award. His new book is entitled, *Drug Use for Grown-Ups: Chasing Liberty in the Land of Fear*.

KERTHY FIX is a documentarian, who together with Paul Kloss, is following Dr. Hart's work as well as some of the other trailblazers changing the drug landscape in America in a film called "Ecstatic."



Beyond Oregon

A New Drug Policy Horizon in the U.S.

ISMAIL LOURIDO ALI, J.D., NATALIE LYLA GINSBERG, M.S.W.,
AND LESLIE BOOHER, J.D., M.B.A.

Note: The authors received the sad news of Sheri Eckert’s passing while we were making our final edits to this piece. In offering this reflection, we hope to acknowledge and honor her inspiring work in imagining, actualizing, and passing Measure 109 in Oregon.

FOR OVER THREE DECADES, MAPS has worked to end the global war on drugs through medical research, education, and advocacy. We have focused on changing federal and international drug policy and breaking psychedelic stigma by creating legal, medical contexts for psychedelic healing. To provide some guidance and recommendations for the rapidly expanding community of psychedelic drug policy reformers, MAPS published our Considerations on the Regulation and Decriminalization of Psychedelic Substances in 2019.

Our broad priorities for psychedelic policy reform remain consistent at the international, federal, state and local levels; we supported civil society activists around the world to pressure the UN Commission of Narcotic Drugs to follow WHO’s recommendations to recognize the medical benefits of cannabis (which they partially did), sued US Federal agencies to increase access to cannabis for research, and encouraged grassroots efforts toward full decriminalization. We talk to elected officials, coalesce with leadership from campaigns, and research nitty-gritty details of legislative language to provide recommendations.

As part of our continued commitment to contribute to building the psychedelic ecosystem, MAPS maintained open conversation with the Measure 109 and 110 campaigns in Oregon to understand the initiatives’ content and context, providing strategic support throughout the qualification, voter education, and implementation processes. Oregon’s citizens voted the two groundbreaking measures into law last year; implementation will take place over the next two years:

- **Measure 109** - The Oregon Psilocybin Services Act - passed with 56% of the vote. The Measure’s passage establishes the Oregon Psilocybin Services Program, a regulated, legal market for psilocybin products to be sold and used in supervised services as a limited exception to the criminalization policy of psilocybin production and distribution in Oregon. Measure 109 maintains some of the elements of medical protocols utilized in clinical trials of psychedelic-assisted therapies (i.e. requiring a secure container, licensed facilitator, and non-drug preparation and integration time). Some elements of delivery of traditional medical care are adjusted, including barriers to access created by diagnosis requirements for patients and requirements of therapeutic licensure for guides. It is important to note that M109’s legal standing is most similar to state-legal adult-use cannabis programs, which remain illegal under federal law.

- **Measure 110** - Oregon's Drug Addiction Treatment and Recovery Act - passed with 58% of the vote. This is possibly the most promising drug policy reform in the United States to date, as it is the closest we have come to repudiating the "war on drugs" criminalization mentality and replacing it with one rooted in by public health, compassion, and non-coercive treatment that permits the possibility of full-spectrum support. Notably, Measure 110 was the first successful effort in the United States to decriminalize the personal use of a number of substances including MDMA, LSD, ketamine, methamphetamine and heroin while adopting the first state-level decriminalization of schedule 1 plants, cacti, and fungi.

Advocates and lawmakers in other states have enthusiastically started to move toward replicating these policies elsewhere. Working together, we can create a future where all drugs are fully decriminalized and medical access, personal use, and spiritual practice coexist. We offer the following analysis to expand on some of what we are excited about - and what we are cautious about - in the hopes of learning with and from advocates seeking similar reforms. Such reforms should seek to:

- Resist stigma by divesting from coercion, pathologization, and criminalization,
- Lower barriers to entry while maintaining quality of care, and
- Protect consumers while regulating responsibly.

Resist stigma by divesting from coercion, pathologization, and criminalization

Stigma and criminalization are two dangerous exacerbating factors for drug use. To approach a safer social baseline that has been impossible under prohibition, decriminalizing drugs should always be paired with social support measures including fact-based education, unarmed and appropriately trained crisis response, legal and accessible rapid substance analysis, and access to qualified therapeutic care for those who seek it.

Treatment or addiction recovery support is often based in shame rather than evidence; one-size-fits-all; and coerced by the threat of a loss of life, safety, or freedom. This unfortunate status quo of ill-suited, often-forced interventions for substance use fails many of the people it purports to help. Instead of being compassionate and supportive, this type of treatment perpetuates a policing-oriented mindset and undermines personal autonomy and agency - key aspects of healing and recovery. Measure 110 specifically protects against coercive treatment by providing an option to waive the fine that would normally come with an infraction for anyone who participates in a substance use screening but putting no other requirements on the person.

Under Measure 109, rather than conditioning access on a medical diagnosis, all adults will be eligible to use supervised

psilocybin, absent contraindication. This theoretically expands access to psilocybin services for adults in Oregon far beyond the diagnosis-based treatment that FDA approval for psilocybin would include. Permitting access to psychedelic services without the prerequisite of pathology will better empower people to choose psychedelic interventions in the pursuit of health and well-being.

Because criminalization often exists at the edge of regulation (for now), advocates should continue to engage with the question of how regulated use and decriminalization can remain in lockstep. Indeed, an outcome where people could pay for facilitated psilocybin use in a licensed center — but could not forage for mushrooms in a park — would still be unjustifiable. Although many advocates were initially concerned that decriminalization was taken out of Measure 109, we were relieved that Measure 110 passed concurrently, permitting possession of up to 12 grams of psilocybin or psilocin. These limits provide meager protections, but the additional commitment to provide non-coercive treatment instead of jail for people caught with drugs is a step in the right direction. Future efforts should ensure that these reforms are paired together.

Like many laws that create legal, licensed, regulated markets, policy that exempts license-holders from drug prohibition laws while a) not changing the status of non-licensed activity and b) giving regulatory authorities and law enforcement broad permission to enforce licensure violations may incentivize state actors to allocate resources to punish behavior that occurs outside of licensed systems. Oregon will now implement significantly reduced criminal penalties for possession of small amounts of psilocybin (misdemeanors or license violations) and exempt those in the regulated market from criminal penalties — yet continue to penalize manufacturers and distributors outside the licensure system with charges as severe as felonies.

The same freedom of choice doesn't yet exist for other substances, threatening the safety and well-being of people who use those substances rather than, or in addition to, psychedelic ones. Future reforms can weave decriminalization and regulation together in a way that maximizes opportunity and healing without sacrificing justice and fairness.

Lower barriers to entry while maintaining quality of care

In order to receive a facilitator license under Measure 109, an applicant need only hold a high school diploma or equivalent; receiving the facilitator license cannot be conditioned on holding a higher degree. This stands in contrast to FDA's recent requests to require advanced professional degrees among the credentials of people facilitating MDMA-assisted therapy for PTSD and psilocybin therapy for other indications. Intentionally lowering barriers to entry for prospective facilitators and providing opportunities for meaningful work to those who do not have access to higher education can be done responsibly.

Before prohibition and throughout its reign, including through our Zendo Project, people with and without professional degrees have offered sound support to people in altered states. Bolstering this lived experience with training, while protecting patients with regulations, will improve the safety, quality, and affordability of care.

Increasing opportunity for prospective facilitators is critical to accessibility, but Measure 109 also maintains many common barriers to entering the regulated market. For example, licensure is conditioned on subjective standards of good moral character and financial responsibility, excluding people with some criminal histories. Advocates must critically consider which barriers to entry actually protect people, and which could become tools for bias and systematic marginalization.

Lowering barriers to entry for practitioners brings up questions about how to ensure the safety of clients and maintain quality of care. Ongoing analysis, discussion, and reflection will provide the frameworks to conceptualize and address this tension. It will be essential to prioritize community and interdependence, while incentivizing concern and respect for others, in a paradigm in which legalization is so often reduced to meaning nothing more than “permission to commodify.”

Protect consumers while regulating responsibly

It will be important for advocates to watch — and influence — how a public entity like the Oregon Health Authority creates a new system of licensure and permits the delivery of psychedelic services to the public. Consolidating decision-making power about implementation in any one entity risks overcentralization and imbalanced power. Similarly, many are justifiably skeptical of the drug treatment and addiction recovery industry’s ability to appropriately adapt to non-coercive approaches.

Prospective psilocybin service clients in Oregon will be asked information about risk factors and contraindications to determine whether they can participate in a session, but the sessions are otherwise not medicalized. Anything with the appearance of therapy or medical care – even and especially if it does not automatically come with protections from HIPAA or stronger – should come with consumer protections like data security and personal privacy protections. Because the potentially sensitive nature of information disclosed about use of psychedelic services could have unanticipated implications for immigration status, family, employment opportunity, access to insurance markets, and other legal risks, gathering of information should always come with data and privacy protections proportional to its sensitivity.

This is true and important for any systems that collect health data. In the age of big data, insufficient privacy protections could increase the vulnerability of some clients, especially for non-US citizens, undocumented persons, those who have been incarcerated, and parents. Any system that interacts with sensitive, personal records must maintain the highest standards of confidentiality and personal privacy to ensure that vulnerable people are not targeted for their participation in the system. (This includes anyone aggregating and licensing or selling consumer data on people using psychedelics or other drugs, too.)

The intersection of drug policy reform and commercialization is essential to safely meet the existing demand, so it will

be essential for psychedelic reformers to actively engage with the emerging ecosystem to build a conscious system of exchange. Measure 109 includes a tax on psilocybin products, but not on psilocybin services, and advertising restrictions are likewise placed on products, but not on services. Promotions in Oregon theoretically won’t come with billboards advertising mushroom chocolates themselves—the billboards may just advertise the people handing you

the chocolates and their facilities. If MAPS’ experience with MDMA is any indication, the majority of the cost for services will be in the hours of licensed care, not the substance itself. We are still in the process of determining what advertising rules MDMA-assisted therapy will be subject to, so we’re watching this process closely.

Advertisement and promotion can be used to manipulate consumers, often at the expense of accurate information, and hope that Oregon can find a balance of education and access to information that puts the safety of its citizens first.

Conclusion: To balance, prioritize process

In the same way that MAPS must navigate DEA and FDA regulatory requirements for drug development to turn MDMA into a medicine, policy change at the state or local level will have to contend with the reality of integrating or rejecting existing systems. We recognize the challenge of navigating regulatory realities among a changing political landscape while staying in alignment with the needs of people who are seeking care. We commend our allies for beginning to clear these murky waters!

However, we still have a lot to learn. Since the Industrial Revolution, industry has been prioritizing business interests before people and planet; too-few examples in the cannabis industry contradict that norm, despite its origins in movements for justice and healing. Psychedelic advocates can learn from this and instead prioritize safety and support for those most

It will be essential for psychedelic reformers to actively engage with the emerging ecosystem to build a conscious system of exchange.



impacted by prohibition and insufficient access to mental health care. The lessons we can learn from social equity and community reinvestment programs encourage deep reflection on how the psychedelic ecosystem approaches restoration and reciprocity — with society in general and with Indigenous people and practices in particular.

Mechanisms for public feedback and community accountability are necessary to consider a multitude of voices for a safe, equitable, and workable outcome. Open, responsive, and critical dialogue between multiple stakeholders is a proven way to develop and adjust successful standards in this new era. This year, Oregon will convene a panel to discuss and recommend many of the details that its new program will administer. These panels will have added value if they are established before bills are written, incorporating the broadest base of stakeholders in developing the content and supporting implementation of them after passage.

We remain curious about how to best interact with existing infrastructure in the creation of new models. This new era is creating novel arenas of law and of healthcare, so some big questions remain, including how state-level systems will integrate or conflict with potential FDA approval of psychedelic therapies on comparable timelines, how services will be made available for indigent clients, and how finances and taxes will be managed on a macro level. MAPS looks forward to continuing to navigate these questions and more in the emerging psychedelic ecosystem.

ISMAIL LOURIDO ALI, J.D., MAPS Policy & Advocacy Counsel, advocates to eliminate barriers to psychedelic therapy and research, develops and implements legal and policy strategy, and supports MAPS' governance, non-profit, and ethics work. Ismail earned his J.D. at the University of California, Berkeley School of Law in 2016, after receiving his bachelor's in philosophy from California State University, Fresno. Ismail has previously worked for the ACLU of Northern California's Criminal Justice & Drug Policy Project, and Berkeley Law's International Human Rights Law Clinic. Ismail is licensed to practice law in the state of California, and is a founding board member of the Psychedelic Bar Association. Ismail is passionate about setting sustainable groundwork for a just, equitable, and generative post-prohibition world.

NATALIE Lyla GINSBERG, M.S.W., is the Director of Policy & Advocacy at MAPS, where she works to disentangle science from political partisanship, and to create safe, equitable and regulated access to psychedelics, and all criminalized substances. She is also partnering with Israeli and Palestinian colleagues to develop a psychedelic peace-building study. Natalie is particularly inspired by psychedelics' potential to assist in healing intergenerational trauma, for building empathy and community, and for inspiring creative and innovative solutions. Before joining MAPS in 2014, Natalie worked as a Policy Fellow at the Drug Policy Alliance, where she helped legalize medical cannabis in her home state of New York, and worked to end New York's race-based marijuana arrests. Natalie received her B.A. in history from Yale, and her master's of social work (M.S.W.) from Columbia.

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

Ask MAPS Anything

GRACE CEPE



Since its inception in 1997, the AskMAPS email inbox (askmaps@maps.org) has received thousands of inquiries about psychedelics, therapy, and research each year. MAPS' Communications Associate Grace Cepe connects with the psychedelic community and provides educational resources through AskMAPS. In this edition of the MAPS Bulletin, she answers a commonly asked question about our clinical trials and shares her response to a former gang member who reached out for help.

Hello! I'm very interested in participating in the Phase 3 clinical trials for MDMA-assisted therapy for PTSD, but when I enter my zip code in the application, I get notified that my zip code is not within range of any trial locations. Would it be possible for me to travel to a nearby clinical trial location to participate?

I understand that you are willing to travel to participate in our studies; however, clinical trials are highly regulated by the FDA and we are unable to override the distance criteria. In other words, qualified participants must live within range of each of the clinical sites for the Phase 3 trials of MDMA-assisted therapy for posttraumatic stress disorder (PTSD). The Phase 3 trials are expected to be completed in 2022, meaning that the FDA could approve the treatment as early as 2023.

You may try searching for more clinical trials at clinicaltrials.gov. This site lists most upcoming, ongoing, and completed clinical trials in all 50 states in the US as well as in 200 additional countries and you can search by condition, treatment method, and location. You may also find a few psychedelic-specific trials at the [psychedelic support research](#) page.

I grew up in a gang in Los Angeles which led me to being in-and-out of prison. I suffered from drug addiction and PTSD because of long term damage created by the consequences of a child trying to survive in a world. I want to focus on the huge PTSD that is being overlooked on the vast numbers of ghetto, inner city youth who are suffering from poverty, lack of education, and healthcare.

Thank you for sharing your story. You've gone through so much growing up in the streets of Southern California. I'm sorry that you're going through difficult times, but I'm happy that you're seeking alternative treatments for healing.

I wanted to share this article from The Verge about a neuroscientist, Chris Medina-Kirchner, who went to prison for selling drugs and is now a graduate student at Columbia University doing research with MDMA.

"...as perhaps the only scientist in the field who has experienced the impact of those laws from within the prison system, he's also creating a pipeline to help other formerly incarcerated people transition into scientific research."

Medina-Kirchner studies under Dr. Carl Hart, a neuroscientist who grew up in an impoverished area in Miami dealing drugs as a teenager, who now focuses his research on drug addiction, drug abuse, and its impact on the inner city communities.

Additionally, there's a gang rehabilitation and re-entry program in Los Angeles called The Homeboy Industries. If you're not in Los Angeles, Homeboy Industries created a Global Homeboy Network so that former gang members can find community-based organizations near their own neighborhood.

Lastly, here's a video about the Compassionate Prison Project,

"The Compassion Trauma Circle is where the men and women step inside the circle for each traumatic event they have experienced in their childhood, roughly based on the Adverse Childhood Experiences test created by Dr. Vincent Felitti and Robert Anda of the CDC."

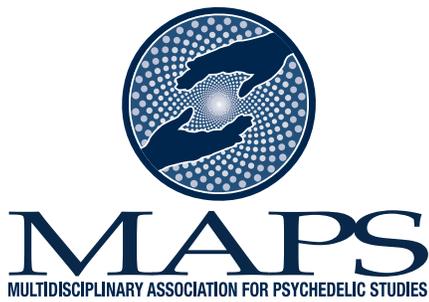
and an educational TED talk on "Adverse Childhood Experiences."

"Childhood trauma isn't something you just get over as you grow up. Pediatrician Nadine Burke Harris explains that the repeated stress of abuse, neglect and parents struggling with mental health or substance abuse issues has real, tangible effects on the development of the brain."

I hope these educational resources give you some clarity and self-compassion for your upbringing. Many people with similar stories like yours are using their experience to become experts in their field to help others and themselves. Thank you for the work that you do in your community and for your courage, perseverance, and strength to keep going.

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

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



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

*Seconded employee from MAPS

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

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

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