MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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Special Edition
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Breakthrough

Spring 2018

Developing MDMA into a Prescription Medicine for PTSD

Every year in the U.S., 8 million people suffer from PTSD, and about 300 million people worldwide. With about 27% of suicides in the U.S. associated with PTSD, and 20 veterans committing suicide every day, there is an urgent need for more effective treatments.

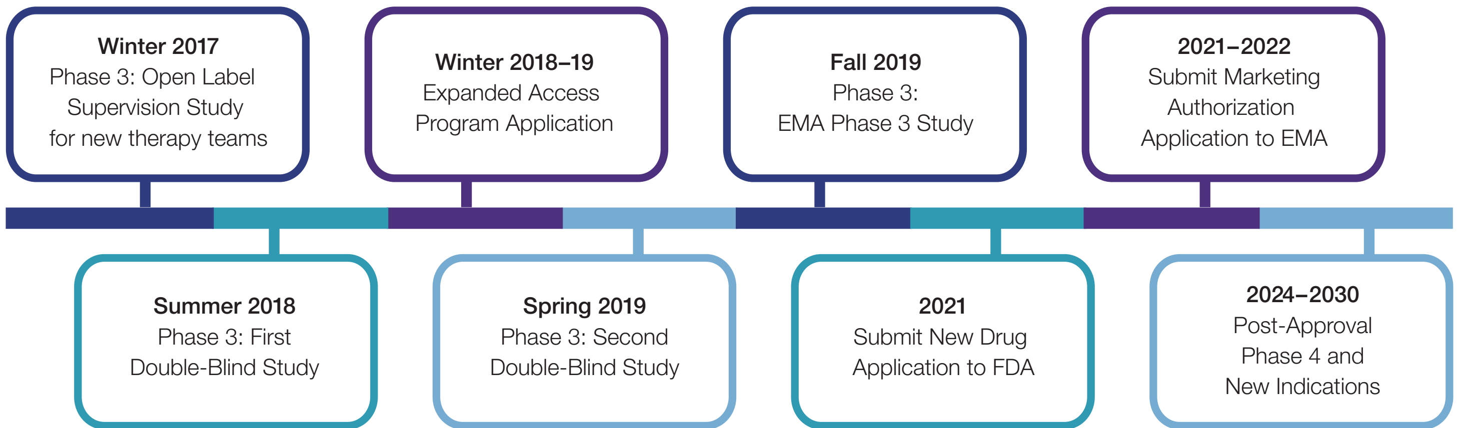
MAPS has raised $26.2 million of the $26.7 million needed for its FDA Phase 3 trials of MDMA-assisted psychotherapy for PTSD. MAPS is currently seeking an additional $5 million for European Medicines Agency (EMA) trials.

In MAPS' completed Phase 2 trials with 107 participants, among 100 participants who received therapy with active dose MDMA, 56% no longer qualified for PTSD two months following treatment. At the 12-month follow-up, 68% no longer had PTSD. All participants had chronic, treatment-resistant PTSD, and suffered from PTSD for an average of 17.8 years. Most subjects received just 2–3 sessions of MDMA-assisted psychotherapy.

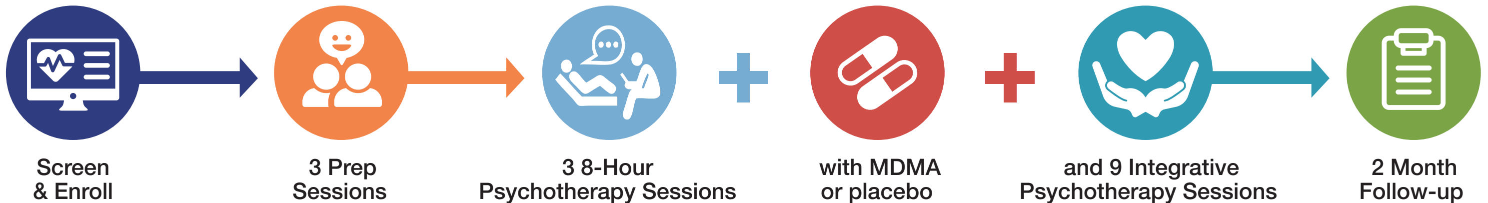
On July 28, 2017, MAPS concluded its Special Protocol Assessment process with the FDA, clearing the way for Phase 3 trials and confirming that if the results are successful, the FDA will approve the treatment. On August 15, 2017, the FDA granted **Breakthrough Therapy Designation** to MDMA-assisted psychotherapy for PTSD, acknowledging that it "may demonstrate substantial improvement over existing therapies" and agreeing to expedite its development and review.

On April 6, 2018, MPBC and MAPS Europe completed a Scientific Advice submission to the European Medicines Agency (EMA) as part of the process of obtaining approval for MDMA-assisted psychotherapy for PTSD in Europe.

Timeline for Regulatory Approval

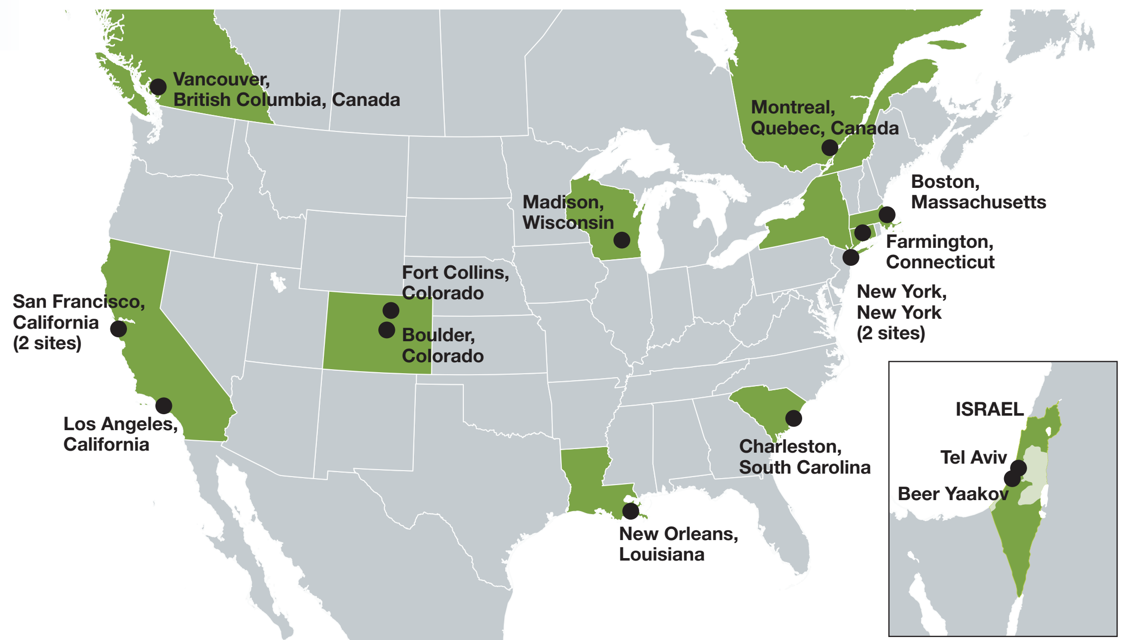


Phase 3 Study Design



Phase 3 Study Sites

Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD will begin in the summer of 2018, to enroll 200–300 participants across 16 sites in the U.S., Canada, and Israel. If the Phase 3 trials demonstrate significant efficacy and acceptable safety, FDA approval is expected by 2021.



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.

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From the Desk of Rick Doblin, Ph.D.

The Multidisciplinary Association for Psychedelic Studies (MAPS) is poised on the brink of initiating the most important and consequential research in our 32-year history: Phase 3 studies into MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) for the purpose of obtaining approval by the U.S. Food and Drug Administration (FDA) for prescription use. MAPS has resolved all regulatory issues and has obtained an FDA Agreement Letter, successfully concluding our Special Protocol Assessment process in which we negotiated all aspects of our Phase 3 protocol design and associated data that are required prior to prescription approval. The Agreement Letter is a written commitment by the FDA to approve MDMA-assisted psychotherapy for PTSD if our Phase 3 protocol design generates statistically significant results, and no new safety issues arise during Phase 3.

MAPS has also obtained Breakthrough Therapy Designation from the FDA for MDMA-assisted psychotherapy for PTSD, indicating that the agency considers MDMA-assisted psychotherapy for PTSD among the most promising treatments being developed. The FDA rejects about two-thirds of requests by pharmaceutical companies for Breakthrough Therapy Designation. MAPS has also raised almost all of the funds we're trying to raise for Phase 3 for the FDA trials, with $26.2 million of $26.7 million already donated or pledged in multi-year commitments.

Our culture is going through a transformative process that bodes well for the mainstreaming of the medical uses of psychedelics and marijuana.

Currently, MAPS is in the final stages of training about 80 therapists to work in 40 male/female co-therapist teams at 15 or 16 Phase 3 sites in the US, Israel, and Canada. To prepare for the Phase 3 trials, each new co-therapy team is working with one PTSD patient in an open-label protocol in which all participants receive MDMA (not placebo), with supervision and feedback provided by MAPS' therapist training team. Due to MDMA's status as a controlled substance, we can only provide therapists with experience administering MDMA-assisted psychotherapy to PTSD patients inside a protocol that has been approved by the FDA and the Drug Enforcement Administration (DEA). We anticipate completing the training of all of our Phase 3 therapists by Fall 2018, with Phase 3 starting at most of our sites this August and taking roughly two years to complete.

MAPS is also in the midst of negotiations with the European Medicines Agency (EMA). We have just learned that the EMA will schedule an in-person meeting in London between EMA officials and MAPS and MAPS Public Benefit Corporation (MPBC) staff in early June. The purpose of this meeting will be to discuss what data EMA will require for prescription approval in the European Union in addition to the data we will be gathering for the FDA. We anticipate coming to agreement with EMA before the end of this year. If we can raise the roughly $5 million we're currently estimating we'll need for new data for EMA, we can begin Phase 3 in Europe in the summer of 2019—and I think we can. We can then complete Phase 3 trials in Europe in 12 to 16 months, depending on how many subjects EMA will require to be treated in Europe and how many Phase 3 sites we establish.

MAPS is thinking globally, and working to start small Phase 2 MDMA-assisted psychotherapy for PTSD studies in Brazil, Colombia, Australia, and other countries where regulations may permit approval for prescription use based on MAPS' US and European Phase 3 data, with locally trained therapists. MAPS is even involved in preliminary explorations regarding initiating this research in China. Russia, unfortunately, is still completely blocking research with MDMA and other psychedelics, but perhaps one day Russian politicians will realize that they are falling behind in the race to obtain prescription approval for psychedelic-assisted psychotherapy.

MAPS' 18-year effort, which started in 2000, to end the 50-year federal monopoly on the supply of DEA-licensed cannabis legal for use in FDA-regulated research, is also approaching what feels likely to be a successful conclusion. Ever since his appointment by President Trump, Attorney General Jeff Sessions has blocked the DEA from issuing licenses to the roughly 26 applicants who have submitted the necessary paperwork. We

have been waiting since August 2016, when the DEA under President Obama filed a rule in the Federal Register indicating that it would approve new licenses to grow cannabis for federally-regulated research. Congressional pressure on Sessions is now building in both the Senate and the House of Representatives, with Senators Hatch and Harris sending a letter to Sessions demanding that all license applications be either approved or rejected by August 11, 2018. In his Senate testimony in October 2017 and again in April 2018, even Sessions has indicated that he supports ending the federal monopoly. The wait for actions rather than just words may soon be ending, though of course nothing is certain.

Once the federal marijuana monopoly does end, MAPS will have access to a supply of cannabis that could ultimately be sold as a prescription medicine. First, we'll need to complete our study of four different kinds of cannabis (THC, CBD, combined THC and CBD, and placebo) in 76 veterans with chronic, treatment-resistant PTSD, now taking place in Phoenix, Arizona, with Site Principal Investigator Dr. Sue Sisley. Then we can analyze the data and determine if it makes sense to try conducting additional drug-development research with cannabis for PTSD and, if so, how MAPS could raise the roughly $25 million we'd need for that research effort.

Our culture is going through a transformative process that bodes well for the mainstreaming of the medical uses of psychedelics and marijuana. One prominent example of this is journalist Michael Pollan's brand new book on psychedelics, *How to Change Your Mind,* which as of today has reached #1 on Amazon's bestseller list. With the continued support and donations of those who want to see us complete our work, our goal of obtaining approval for the prescription use of MDMA and marijuana is becoming much more than a dream.

Psychedelically yours,

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

COVER ART: QUILT CREATED BY MDMA THERAPY TRAINING PROGRAM PARTICIPANTS

This quilt is an experiential art project created during Part D of MAPS' MDMA Therapy Training Program. The purpose was for therapy teams to work individually and collaboratively on one piece of canvas. The quilt panels were created over a five day period, starting with interpersonal exploration, process from a Holotropic Breathwork experience, and feelings about the therapy. Each therapist worked individually on half of a panel for the first two days, then worked in pairs for one day, and merged unto each other's side of the panel for two days. The project was an exercise mimicking the process of therapy done in pairs: there is room for the individual; room to collaborate; and room to weave experiences and observations in a way that enhance and add richness to what each person brings to the experience.

"It was wonderful to see the pieces develop and the teams working together often into the night. And as a bonus, the pieces are beautiful."—Marcela Ot'alora, M.A., L.P.C., Therapy Training Team

Research News

Treating PTSD with MDMA-Assisted Psychotherapy

mdmaptsd.org

MDMA capsules from MAPS' completed Phase 2 trial of MDMA-assisted psychotherapy for PTSD in Boulder, Colorado.

Phase 3 Trials: Open-Label Lead-In Study Begins

In MAPS' completed Phase 2 trials, 61% of 107 participants who completed three sessions of MDMA-assisted psychotherapy no longer qualified for posttraumatic stress disorder (PTSD) after two months following treatment. At the 12-month follow-up, 68% no longer had PTSD. All Phase 2 participants had chronic, treatment-resistant PTSD, and had suffered from PTSD for an average of 17.8 years.

On August 16, 2017, the FDA granted Breakthrough Therapy Designation to MDMA for the treatment of PTSD. The FDA grants this designation for treatments that (1) are intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition; and (2) preliminary clinical evidence indicates may demonstrate substantial improvement over existing therapies.

As of April 4, 2018, MAPS Public Benefit Corporation (MPBC) clinical research staff have completed 13 of 14 Study Initiation Visits for an open-label lead-in study of MDMA-assisted psychotherapy for PTSD at planned Phase 3 sites across the United States and Canada. The purpose of this study is to provide the final training for our Phase 3 co-therapy teams. Each new co-therapy team will work with a single participant at their respective study site with supervision provided by MAPS' therapy training team.

Eleven open-label study sites have been granted Schedule I licenses by the U.S. Drug Enforcement Administration (DEA), and six open-label study sites have received the study drug. The study site in Fort Collins, CO, has conducted experimental treatment sessions with two participants, and the New Orleans, LA, study site has completed their first experimental treatment session; other sites will begin open label enrollment soon.

MAPS' Phase 3 trials, starting in the summer of 2018, will

assess the efficacy and safety of MDMA-assisted psychotherapy in adult participants with PTSD at sites in the U.S., Canada, and Israel. Over a 12-week treatment period, participants will be randomized to receive 12 90-minute non-drug preparatory and integration sessions, along with three day-long sessions of either MDMA or placebo in conjunction with psychotherapy, about a month apart. The primary endpoint will be the Clinician Administered PTSD Scale (CAPS-5), as assessed by a blinded pool of independent raters.

MAPS' Phase 3 trials will be conducted at the following study sites:

Los Angeles, CA | private practice
San Francisco, CA | research institution
San Francisco, CA | private practice
Boulder, CO | private practice
Fort Collins, CO | private practice
Farmington, CT | research institution
New Orleans, LA | private practice
New York, NY | research institution
New York, NY | private practice
Charleston, SC | private practice
Madison, WI | research institution
Boston, MA | research institution
Montreal, Canada | private practice
Vancouver, Canada | research institution
Israel | research institution

These Phase 3 trials build on the promising results of MAPS' completed Phase 2 trials, and are the final phase of research required by the FDA before deciding whether to approve MDMA as a legal prescription treatment for PTSD, which MAPS estimates could happen by 2021. Once approved, MDMA will be required to be used in only conjunction with psychotherapy in a clinical setting.

MAPS and MPBC are excited to reach this milestone toward bringing healing to those suffering from PTSD with MDMA-assisted psychotherapy. Donations are currently being sought to reach MAPS' goal of raising $26.7 million to complete the Phase 3 studies required to gain approval from the FDA for MDMA-assisted psychotherapy.

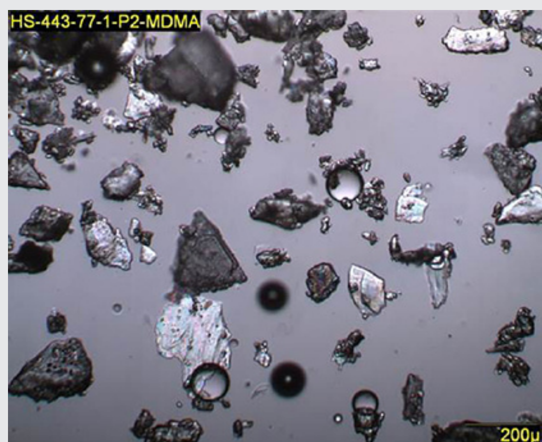
Approval from the European Medicines Agency (EMA) will likely require additional funds. MAPS began negotiations with EMA on March 1, 2018, and will travel to London, UK, to meet with EMA in Summer 2018. Additional expenses of $5-$10 million will include research for other regulatory agencies around the world, therapist training, Expanded Access, and FDA-required Phase 4 studies in adolescents with PTSD. With $26.2 million in hand or in multi-year pledges, there's still a funding gap we need to close.

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

GMP MDMA Imported to U.S.

On March 13, 2018, the MDMA that will be used in MAPS' upcoming Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD was successfully imported into the United States from our third-party pharmaceutical vendor in the UK. The compound, manufactured by Onyx Scientific Ltd. using a synthetic precursor, is certified under current Good Manufacturing Processes (cGMP), and was synthesized using the same route that will be used to manufacture MDMA for post-approval sales. The product will also be used for planned toxicology and clinical pharmacology studies. As the MDMA dosing regimen is three single-dose treatments per patient, the planned amount of drug product needed for commercial distribution is far lower than approved medications requiring daily dosing.

Drug product formulation studies are complete for the immediate release solid oral dosage form. Hydroxypropylmethyl cellulose (HPMC) capsules will be prepared by third-party cGMP drug product manufacturer, Sharp Clinical Services, Inc. (US). The final formulation includes only MDMA, mannitol, and magnesium stearate. Based on preliminary studies conducted with our previous MDMA supply for Phase 1 and Phase 2 trials, the drug product achieved greater than 80% dissolution at 15 minutes, indicating that the active compound is immediately and completely released from the capsules within 15 minutes. Based on only small differences in formulation, the Phase 3 and commercial formulations are anticipated to be comparable.



Results Published by The Lancet Psychiatry: MDMA-Assisted Psychotherapy for Veterans with PTSD

On May 1, 2018, the results of MAPS' pioneering U.S. Food and Drug Administration (FDA)-regulated clinical trial of MDMA-assisted psychotherapy for the treatment of post-traumatic stress disorder (PTSD) in veterans, firefighters, and police officers were published in the peer-reviewed journal *The Lancet Psychiatry.*

The publication has already received widespread international media attention in *The New York Times, CNN, Reuters, Fox News, Agence France Presse, British Forces News, Stars & Stripes,* and much more.

The double-blind, placebo-controlled, Phase 2 pilot study in 26 participants found that one month after their second day-long experimental session, 68% in the full-dose MDMA group did not qualify for a diagnosis of PTSD, compared to 29% in the low-dose MDMA (active placebo) control group. The course of double-blind treatment included 13.5 hours of non-drug psychotherapy and 16 hours (two day-long experimental sessions) of either full-dose or low-dose MDMA-assisted psychotherapy. On average, the positive results were sustained one year later.

Led by Michael Mithoefer, M.D., and Ann Mithoefer, B.S.N., in Charleston, South Carolina, the trial was one of MAPS' six completed Phase 2 pilot studies of MDMA-assisted psychotherapy for PTSD. Trial participants included veterans (22), firefighters (3), and police officers (1), all with service-related PTSD.

"The MDMA alone or the therapy alone don't appear to be as effective," explains Dr. Mithoefer. "The MDMA seems to act as a catalyst that allows the healing to happen."

"I was actually able to forgive myself," explains study participant Nigel McCourry. "There are also still some challenges I have to face from time to time related to the PTSD. But now I am able to work through them without getting stuck."

The study replicated previous research showing an acceptable risk profile for MDMA, with the most frequently reported adverse reactions during experimental sessions being anxiety, headache, fatigue, and muscle tension. Adverse reactions one week following treatment included anxiety, fatigue, and insomnia. Temporary elevations in pulse, blood pressure, and temperature were also recorded during MDMA sessions, and did not require medical intervention.

"At least one in two PTSD patients cannot tolerate or do not respond adequately to existing treatments, so there is an urgent need for better treatments for the millions of military veterans and others with PTSD," said Dr. Mithoefer. "These results are further evidence that MDMA, used just two times at monthly intervals, can make psychotherapy much more effective and better tolerated. I'm excited that Phase 3 trials will soon confirm whether this therapy can be approved for widespread use in a few years."

The Lancet Psychiatry article was authored by Michael Mithoefer, M.D., Ann Mithoefer, B.S.N., Allison Feduccia, Ph.D., Lisa Jerome, Ph.D., Mark Wagner, Ph.D., Joy Wymer, Ph.D., Julie Holland, M.D., Scott Hamilton, Ph.D., Berra Yazar-Klosinski, Ph.D., Amy Emerson, B.A.., and Rick Doblin, Ph.D.

THE LANCET
Psychiatry

Articles

3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for post-traumatic stress disorder in military veterans, firefighters, and police officers: a randomised, double-blind, dose-response, phase 2 clinical trial

Michael C Mithoefer, Ann T Mithoefer, Allison A Feduccia, Lisa Jerome, Mark Wagner, Joy Wymer, Julie Holland, Scott Hamilton, Berra Yazar-Klosinski, Amy Emerson, Rick Doblin

Summary

Background Post-traumatic stress disorder (PTSD) is prevalent in military personnel and first responders, many of whom do not respond to currently available treatments. This study aimed to assess the efficacy and safety of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for treating chronic PTSD in this population.

Methods We did a randomised, double-blind, dose-response, phase 2 trial at an outpatient psychiatric clinic in the USA. We included service personnel who were 18 years or older, with chronic PTSD duration of 6 months or more, and who had a Clinician-Administered PTSD Scale (CAPS-IV) total score of 50 or greater. Using a web-based randomisation system, we randomly assigned participants (1:1:2) to three different dose groups of MDMA plus psychotherapy: 30 mg (active control), 75 mg, or 125 mg. We masked investigators, independent outcome raters, and participants until after the primary endpoint. MDMA was administered orally in two 8-h sessions with concomitant manualised psychotherapy. The primary outcome was mean change in CAPS-IV total score from baseline to 1 month after the second experimental session. Participants in the 30 mg and 75 mg groups subsequently underwent three 100–125 mg MDMA-assisted psychotherapy sessions in an open-label crossover, and all participants were assessed 12 months after the last MDMA session. Safety was monitored through adverse events, spontaneously reported expected reactions, vital signs, and suicidal ideation and behaviour. This study is registered with ClinicalTrials.gov, number NCT01211405.

Findings Between Nov 10, 2010, and Jan 29, 2015, 26 veterans and first responders met eligibility criteria and were randomly assigned to receive 30 mg (n=7), 75 mg (n=7), or 125 mg (n=12) of MDMA plus psychotherapy. At the primary endpoint, the 75 mg and 125 mg groups had significantly greater decreases in PTSD symptom severity (mean change CAPS-IV total scores of –58·3 [SD 9·8] and –44·3 [28·7]; p=0·001) than the 30 mg group (–11·4 [12·7]). Compared with the 30 mg group, Cohen's *d* effect sizes were large: 2·8 (95% CI 1·19–4·39) for the 75 mg group and 1·1 (0·04–2·08) for the 125 mg group. In the open-label crossover with full-dose MDMA (100–125 mg), PTSD symptom severity significantly decreased in the group that had previously received 30 mg (p=0·01), whereas no further significant decreases were observed in the group that previously achieved a large response after 75 mg doses in the blinded segment (p=0·81). PTSD symptoms were significantly reduced at the 12-month follow-up compared with baseline after all groups had full-dose MDMA (mean CAPS-IV total score of 38·8 [SD 28·1] *vs* 87·1 [16·1]; p<0·0001). 85 adverse events were reported by 20 participants. Of these adverse events, four (5%) were serious: three were deemed unrelated and one possibly related to study drug treatment.

Interpretation Active doses (75 mg and 125 mg) of MDMA with adjunctive psychotherapy in a controlled setting were effective and well tolerated in reducing PTSD symptoms in veterans and first responders.

Funding Multidisciplinary Association for Psychedelic Studies.

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Introduction

Post-traumatic stress disorder (PTSD) is a major public health problem, particularly among military veterans. Prevalence of PTSD in military personnel and veterans (17·1%)[1] and first responders (10–32%)[2] is much higher than the lifetime occurrence in the general population (8%). In addition to the severe psychological burden, chronic PTSD is associated with increased medical morbidity, occupational and relationship problems, decreased quality of life,[3] overall decreased life satisfaction and happiness, and increased risk of suicide.[4]

Treatment options for PTSD include pharmacotherapy and psychotherapies. The two medications approved by the US Food and Drug Administration (FDA) for PTSD, sertraline and paroxetine, reduce symptom severity with limited effectiveness,[5] especially in veterans. Off-label prescription of drugs, including antidepressants,

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New MDMA Articles Published in Peer-Reviewed Journals

In March 2018, the peer-reviewed journal *Progress in Neuro-Psychopharmacology and Biological Psychiatry* published a new article by Allison Feduccia, Ph.D., and Michael C. Mithoefer, M.A., of MAPS Public Benefit Corporation (MPBC), focusing on how fear extinction and memory reconsolidation could be some of the mechanisms underlying the beneficial outcomes seen in research into MDMA-assisted psychotherapy for reducing PTSD symptoms.

Feduccia, A. A., Mithoefer, M. C. (2018). MDMA-Assisted Psychotherapy for PTSD: Are Memory Reconsolidation and Fear Extinction Underlying Mechanisms? *Progress in Neuro-Psychopharmacology & Biological Psychiatry,* 221-228.

From the abstract: By reducing activation in brain regions implicated in the expression of fear- and anxiety-related behaviors, namely the amygdala and insula, and increasing connectivity between the amygdala and hippocampus, MDMA may allow for reprocessing of traumatic memories and emotional engagement with therapeutic processes. Based on the pharmacology of MDMA and the available translational literature of memory reconsolidation, fear learning, and PTSD, this review suggests a neurobiological rationale to explain, at least in part, the large effect sizes demonstrated for MDMA in treating PTSD.

Another article, "Potential Psychiatric Uses for MDMA", published in *Clinical Pharmacology & Therapeutics* by Michael C. Mithoefer, M.D., and Berra Yazar-Klosinski, Ph.D., was one of the journal's top 10 most downloaded papers in 2017. The paper received 2,339 downloads over the course of last year.

Yazar-Klosinski, B. B., Mithoefer, M. C. (2017). Potential Psychiatric Uses for MDMA. *Clinical Pharmacology & Therapeutics,* 194-196.

From the abstract: Phase 2 trials of MDMA-assisted psychotherapy have demonstrated initial safety and efficacy for treatment of PTSD, with potential for expansion to depression and anxiety disorders. In these trials, single doses of MDMA are administered in a model of medication-assisted psychotherapy, differing from trials involving daily drug administration without psychotherapy.

In November 2017, three more articles from MAPS staff and researchers were published in peer-reviewed scientific journals, including an update on MAPS' MDMA drug development program in *Psychopharmacology* and two letters to the editor about the need for more effective PTSD treatments in *Biological Psychiatry* and the *New England Journal of Medicine.*

Feduccia, A. A., Holland, J., Mithoefer, M. C. (2017). Progress and promise for the MDMA drug development program. *Psychopharmacology,* 1-11.

From the abstract: "Pharmacotherapy is often used to target symptoms of PTSD, but does not provide definitive treatment, and side effects of daily medication are often problematic…The most promising drug studied as a catalyst to psychotherapy for PTSD thus far is MDMA."

Feduccia, A. A., Mithoefer, M. C., Jerome, L., Holland, J., Emerson, A., Doblin, R. (2017). Response to the Consensus Statement of the PTSD Psychopharmacology Working Group. *Biological Psychiatry.*

From the abstract: "We are writing in response to the Letter to the Editor by John Krystal and colleagues…This timely research statement pointed out some of the barriers to translating a wealth of PTSD research into effective pharmacological strategies…The addition of two promising candidates—cannabis and MDMA—would make this report more comprehensive."

Mithoefer, M. C., Jerome, L., Monson, C. (2017). Posttraumatic Stress Disorder Correspondence. *New England Journal of Medicine.*

From the abstract: "MDMA therapy has been shown to produce lasting improvement in symptoms of PTSD and in personality changes supportive of recovery. Proposed mechanisms of action include fear extinction, greater ease in addressing emotionally upsetting material, and strengthening of the therapeutic alliance through increased empathy and self-compassion."

Therapist Training Study Enrolls 54th Participant

Ongoing study
Location: Charleston, South Carolina, and Boulder, Colorado
Principal Investigator: Michael Mithoefer, M.D., (Charleston), and Marcela Ot'alora, M.A., L.P.C. (Boulder)
Sub-Investigator: Annie Mithoefer, B.S.N., (Charleston)

On February 27, 2018, the 54th participant enrolled in our ongoing Phase 1 study of the psychological effects of MDMA when used in a therapeutic setting by healthy volunteers. Enrollment in this multi-site study is limited by invitation only to therapists in training to work on MAPS-sponsored clinical trials of MDMA-assisted psychotherapy for PTSD. On February 15, 2018, Senior Clinical Research Associate Charlotte Harrison of MPBC traveled to Colorado for a monitoring visit of the study site in Boulder, which included a thorough review of the study's documentation, database, files, and adherence to regulations.

MDMA Therapy Training Program: Update on Supervision Process *Training Program*

Location: Charleston, South Carolina, and Boulder, Colorado
Therapy Training Team: Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., Marcela Ot'alora G., M.A., L.P.C.

As of April 2018, the MDMA Therapy Training Program (**maps.org/training**) is supporting the final segment of training for Phase 3 therapy teams. Supervision of therapists is a major focus of active Phase 2 open-label trials in the US and Canada, and will continue to be an important aspect of the training program going forward. When therapy pairs treat their first study participant in the open-label trials, they receive feedback from a supervisor (an expert MDMA-assisted psychotherapy researcher) in regular meetings. Also, with the help of trained adherence raters, supervisors review video recordings of therapy sessions. The careful review of these therapy sessions

informs how a supervisor guides therapy pairs in their further training while aiming to improve treatment outcomes. MAPS' open-label trials currently include three supervisors and 12 adherence raters supporting 40 new therapy pairs. Completion of this program is a prerequisite for anyone working on a therapy team in a MAPS-sponsored Phase 3 trial. The MAPS Therapy Training Program plans to train approximately 300 therapists in anticipation of MDMA-assisted psychotherapy becoming an FDA-approved prescription treatment by 2021.

At this point, the training program is not accepting applications, however you can sign up to receive updates when future training opportunities become available. Learn more by visiting **maps.org/therapists**.

Cognitive Behavioral Conjoint Therapy for PTSD: Fourth Dyad Completes Long-Term Follow-Up Interview *Ongoing study*

Location: Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D.,
Sub-Investigator: Candice Monson, Ph.D.

On March 3, 2018, the fourth dyad (pair of participants) completed their long-term follow-up interview in our ongoing study of MDMA combined with Cognitive Behavioral Conjoint Therapy (CBCT) for PTSD at our Charleston, South Carolina site. The third dyad completed the six-month follow-up interview on October 25, 2017. This study has enrolled dyads with one participant diagnosed with PTSD and one concerned significant other who does not have PTSD but does experience psychosocial distress. MDMA will be administered to both participants to help facilitate communication and connection between participants and therapists.

The primary goal of this study is to develop a combined method of MDMA with CBCT for PTSD. This is the first MAPS-sponsored MDMA study conducted with VA-affiliated researchers and the first to employ measures developed for the DSM-5. There are several important reasons to include significant others in PTSD treatment, in addition to the data supporting the efficacy of CBCT for PTSD.

Startle Testing with MDMA: First Participant Receives Experimental Treatment *Ongoing study*

Location: Emory University in Atlanta, Georgia
Principal Investigator: Barbara Rothbaum, Ph.D.

On March, 15, 2018, the first participant completed an experimental session in our ongoing study of the effect of MDMA on startle testing in healthy volunteers. As of March 19, 2018, a total of 43 people have completed preliminary phone screening for enrollment opportunities. This study may be followed by another study exploring the combination of MDMA with Prolonged Exposure in PTSD patients.

MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

Social Anxiety Study Officially Completed

Study Completed
Location: Los Angeles, California
Principal Investigators: Charles Grob, M.D., and Alicia Danforth, Ph.D.

On July 10, 2017, investigators completed the formal closeout of our study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum. All treatment sessions and long-term follow-up interviews for this study have been completed. Led by Principal Investigators Charles Grob, M.D., and Alicia Danforth, Ph.D., this is a collaborative study between MAPS and the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. The data from this study are now being prepared to be submitted for publication in a peer-reviewed scientific journal.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted therapy for autistic adults diagnosed with social anxiety, (2) determining if additional studies in this area are warranted, and (3) initiating a new program of research into a possible beneficial use of MDMA building on collected case accounts.

MDMA-Assisted Psychotherapy for Anxiety Associated with Life-Threatening Illness

14th Participant Completes Long-Term Follow-Up Interview

Ongoing study
Location: Marin, California
Principal Investigator: Phil Wolfson, M.D.
Co-Therpaist: Julane Andries, L.M.F.T.

On March 19, 2018, the 14th of 18 participants completed their 12-month follow-up interview in our ongoing Marin, Calif., study of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness. This study is gathering preliminary data about the safety and efficacy of MDMA-assisted psychotherapy for anxiety associated with a diagnosis of a life-threatening illness.

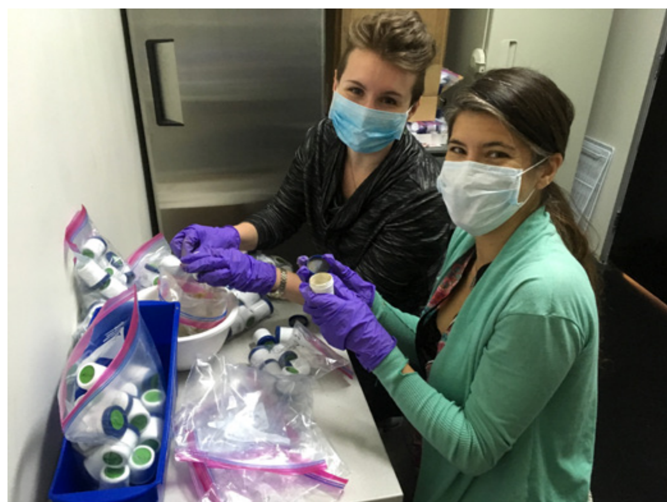
Goals for this study include (1) gathering data on the safety and effectiveness of MDMA-assisted psychotherapy for participants with anxiety associated with life-threatening illness; (2) determining if additional studies are warranted; and (3) initiating MDMA-assisted psychotherapy research for a new clinical indication.

Medical Marijuana Research

50th Participant Enrolls in Smoked Marijuana Trial for Chronic PTSD in Veterans

Ongoing study
Location: Phoenix, Ariz.
Coordinating Principal Investigator:
Marcel Bonn-Miller, Ph.D. (University of Pennsylvania)
Co-Investigator/Site Principal Investigator:
Sue Sisley, M.D. (private practice) and
Co-Investigator: Paula Riggs, M.D. (University of Colorado)

On March 28, 2018, the 50th of 76 participants enrolled and received study drug in the first-ever clinical trial of smoked marijuana (cannabis) for posttraumatic stress disorder (PTSD) in U.S. veterans. Taking place at the Scottsdale Research Institute (SRI) in Phoenix, Arizona, this clinical trial is evaluating the safety and efficacy of four different potencies of marijuana for symptoms of PTSD in 76 U.S. veterans. To learn more, visit the new recruitment website at **wecanstudy.org.**



Senior Clinical Research Associate Charlotte Harrison and Clinical Research Associate Alia Lilienstein, M.D., M.P.H., preparing study drug for the first-ever clinical trial of smoked marijuana (cannabis) for posttraumatic stress disorder (PTSD) in U.S. veterans on June 13, 2017, at the Scottsdale Research Institute in Arizona.

Ayahuasca Research

Data Collection Survey Underway *Ongoing study*

Principal Investigator: Jessica Nielson, Ph.D.

We are currently collecting responses for the revised version of our anonymous questionnaire about the potential risks and benefits associated with using ayahuasca as a therapy for PTSD. The results of the survey are currently being summarized and prepared for publication, at which point the survey will shift its focus to general ayahuasca use for a variety of conditions, including PTSD, depression and substance abuse/addiction. The data collection is being sponsored by MAPS, with Jessica Nielson, Ph.D., as the Principal Investigator.

Ayahuasca is a psychoactive brew or tea most commonly derived from *Banisteriopsis caapi,* a vine containing monoamine oxidase inhibitors (MAOIs), and the leaves of *Psychotria viridis* or other plants containing N,N-dimethyltryptamine (DMT), and often several other admixture plants. Ayahuasca is legal in many countries in South America.

The revised survey is a shorter and simplified version of the original survey, and we welcome participation from anyone that has tried ayahuasca in any context or setting, including those who took the first version of the survey. To participate in the survey, visit **surveymonkey.com/r/AyaPTSD**.

Ibogaine-Assisted Therapy for Drug Addiction

Observational Research Published in *American Journal of Drug and Alcohol Abuse* *Study completed*

Locations: Mexico and New Zealand
Principal Investigators: Thomas Kingsley Brown, Ph.D. (Mexico), and Geoff Noller, Ph.D. (New Zealand)

On May 25 and April 12, 2017, the promising results of MAPS-sponsored observational studies of treating opioid dependence with ibogaine-assisted therapy were published in the peer-reviewed *American Journal of Drug and Alcohol Abuse.* Sponsored by MAPS in Mexico and New Zealand, both studies show that ibogaine should be further studied as a potential treatment for opioid dependence in rigorously controlled studies.

Ibogaine is a psychoactive compound usually extracted from the West African *Tabernanthe iboga* plant. In animals, a single dose of ibogaine decreases signs of opioid withdrawal and produces sustained reductions in the self-administration of heroin, morphine, cocaine, nicotine, and alcohol. Ibogaine is illegal in the U.S., and legal but unregulated in Canada and Mexico. New Zealand, South Africa, and Brazil authorize the use of ibogaine by licensed medical practitioners. While its mechanism of action is not yet fully understood, it differs from that of standard opioid agonist treatments such as methadone and buprenorphine which maintain dependence, and thus may show promise as an innovative pharmacotherapy for opioid addiction.

Ultimately, the authors of the studies conclude that given the potential demonstrated by ibogaine's substantive treatment effect in opioid detoxification, its novel (though not yet fully understood) pharmacological mechanism of action, and its clinical effect in opioid-dependent participants who have not satisfactorily responded to other treatments, ibogaine has promise for future research and development as a novel pharmacotherapy for opioid addiction.

Download both articles for free at **maps.org/ibogaine**.

MAPS in the Media

The New York Times

Treating PTSD With MDMA? You Might Have Some Questions.

by Dave Philipps on May 2, 2018. *The New York Times* reports on the newly published results of MAPS' U.S. Food and Drug Administration (FDA)-regulated clinical trial of MDMA-assisted psychotherapy for the treatment of posttraumatic stress disorder (PTSD) in veterans, firefighters, and police officers. The New York Times speaks with MAPS-sponsored MDMA researcher Michael Mithoefer, M.D., and trial participants Nigel McCourry and Nicholas Blackston. "I was finally able to process all the dark stuff that happened," Nicholas Blackston, 32, a study participant who had been a Marine machine-gunner in Iraq, said in an interview. "I was able to forgive myself. It was like a clean sweep."

The New York Times

A Drug From the Dance Floor May Soon Help Ease Veterans' PTSD

Gutfeld on Using Ecstasy to Cure PTSD

by Greg Gutfeld on May 2, 2018. *The Five on Fox News* examines the history of MAPS, the current PTSD epidemic in veterans, and how MDMA combined with psychotherapy is showing promising results in treating PTSD. "I think every option should be on the table. If it's a therapy dog, if its psychotherapy, hyperbaric chambers, medical marijuana, MDMA, let's get it all fixed. Something that's taboo shouldn't prevent doctors from trying to help," states Jesse Watters of Fox News.

Active Ingredient in Ecstasy May Help Veterans with PTSD, Study Finds

by Susan Scutti on May 3, 2018. *CNN* covers MAPS' MDMA-assisted psychotherapy research by speaking with MDMA researcher Michael Mithoefer, M.D., about Phase 2 clinical trials results. "Unlike most other drug studies, MDMA is not being used as a daily drug. Taking it only a few times decreases side effects compared to daily dosing," and "eliminates the possibility of abuse, since it is administered directly by the therapists," explains Mithoefer.

Class A Ecstasy Drug Can Help PTSD, Says Study

Published on May 2, 2018. "If you were to design a drug to treat PTSD—MDMA would be it," says MAPS Founder Rick Doblin, Ph.D., in a new interview with *Forces Network.* Doblin discusses recently published results from MAPS' MDMA-assisted psychotherapy for PTSD Phase 2 clinical trials. "What made it so effective for therapy, is that it reduces activity in the amygdala—which is the fear-processing part of the brain, so when trauma is recalled the fear elements are muted so people can look at the trauma and process it," explains Doblin.

Support Grows for Ecstasy-Assisted Psychotherapy to Treat PTSD

by Nikki Wentling on May 2, 2018. *Stars and Stripes* covers MAPS' MDMA-assisted psychotherapy research results. MDMA researcher Michael Mithoefer, M.D., says, "results are further evidence that MDMA, used just two times at monthly intervals, can make psychotherapy much more effective and better tolerated."

Ecstasy Therapy May Help Service Veterans Suffering PTSD

by Kate Kelland on May 1, 2018. *Reuters* speaks to MAPS Public Benefit Corporation Clinical Data Scientist Alli Feduccia, Ph.D., about MAPS' MDMA-assisted psychotherapy for PTSD clinical trials, receiving designation for Breakthrough Therapy, and recently published results in the *Lancet Psychiatry*.

Ecstasy Ingredient Could Help Ease PTSD Symptoms, Study Finds

by Nicola Davis on May 1, 2018. *The Guardian* reports that MAPS' recently published research suggests that MDMA could help reduce symptoms among those living with post-traumatic stress disorder. "It is thought that the MDMA is catalysing the therapy, [rather than] just being effective on its own," said Dr Allison Feduccia, co-author of the research by the MAPS Public Benefit Corporation, a US-based charity focused on research into MDMA and psychotherapy, which funded the study.

Ecstasy May Help Some With PTSD, but Risks Remain

by Steven Reinberg on May 1, 2018. *WebMD* reports that people suffering from post-traumatic stress disorder might find some relief by using the popular party drug ecstasy, according to MAPS' recently published research. "Technically, this synthetic drug is called 3,4-methylenedioxy-methamphetamine (MDMA) and it alters mood and perception. When tried with 26 veterans and first responders with PTSD, it helped many of them, investigators found."

MDMA-Assisted Psychotherapy Improves PTSD Symptoms in Veterans, First Responders

by Matt Hoffman on May 3, 2018. *MD Magazine* reports an average of 20 US veterans commit suicide each day, and there is a lack of available US Food and Drug Administration (FDA) approved therapies for PTSD outside of a trio of selective serotonin reuptake inhibitors. "In a controlled setting, the use of MDMA adjunct to psychotherapy for patients with PTSD was found to be both effective and well-tolerated, with symptoms of the disorder reduced significantly after 12 months.

Can MDMA Treat Alcoholism? Scientists Begin First Clinical Trials

by Dana Dovey on April 26, 2018. *Newsweek* features the world's first clinical trials researching MDMA as an adjunct to psychotherapy as a potential treatment for alcoholism. MDMA researcher Ben Sessa, M.D., and researchers from Imperial College London are leading the clinical trials in the UK. "[MDMA] is able to break down many of the fear barriers that individuals may experience during therapy," reports *Newsweek*.

MDMA, Psychotherapy, and the Future of PTSD Treatment

by Tedx Talks on April 5, 2018. Brad Burge of MAPS presents on what it means to live with PTSD, provides a brief history of MDMA, and shares how MDMA-assisted psychotherapy is showing promising results for treating PTSD in a TEDx Talk for *TEDx Salem*. "Today I'm going to tell you about a new approach being developed to helping people overcome deeply engrained trauma, and it involves only 3 administrations of a drug that's been around for over 100 years," begins Burge.

Arizona Researcher Hopes Changes at VA Could Help Study Recruitment Efforts

by Lindsey Reiser on April 5, 2018. Marijuana researcher Sue Sisley, M.D., speaks with *AZ Family 3TV CBS 5* about recent U.S. Department of Veterans Affairs bureaucratic changes that may help MAPS' ongoing clinical trial of smoked marijuana for treating symptoms of PTSD in U.S. veterans, and in turn help more veterans, by allowing VA referrals to the study. "After seven years of struggle with the government, stonewalling at every turn, this week we enrolled our 51st veteran in the study," explains Sisley. "Let's make sure science is not being handcuffed by politics.

Bitcoin Mega-Philanthropist 'Pineapple' Talks About Psychedelic Research

by Gregory Ferenstein on February 28, 2018. *Forbes* interviews Bitcoin philanthropist and Pineapple Fund Founder about their dedication to help fund MAPS' ongoing MDMA research and personal experience receiving ketamine to treat Borderline Personality Disorder. "When I saw MAPS' work on MDMA-assisted psychotherapy after creating the fund, I was immediately convinced. I've personally experienced an incredible benefit and know it works. While ketamine is not MDMA, ketamine has allowed me to explore the depths of my emotions in a way that's impossible otherwise," explains Pine.

Bitcoin Could Bankroll MDMA Into the Mainstream as a Therapy Drug

by Sarah Sloat on January 14, 2018. *Inverse* speaks with the anonymous cryptocurrency philanthropist and Pineapple Fund Founder about their recent pledge to match all new donations to MAPS for Phase 3 trials of MDMA-assisted psychotherapy for PTSD in US dollars or cryptocurrency, up to $4 million in Bitcoin.

Breakthrough Therapy Designation: Streamlining the Path to Approval

MATTHEW J. NEAL

Matthew J. Neal

What springs to mind when you hear the word "breakthrough"? The light bulb? The printing Press? The telephone? Nuclear fission? What about fire? What about consciousness itself? That's more like it. When did we wake up? In all likelihood, immediately following our becoming conscious[1] was our awareness of trauma, danger, pain, and suffering. Whether it's the trauma of being born and entering the world, watching those around us leave the world through disease or other hardship, hordes of pillaging marauders, horse archers, tiger attacks, or the existential threat of life itself, life is suffering. For as long as we have been conscious beings, we have had to deal with trauma—both physically and mentally.

Therefore, discovering a method paired with a molecule—MDMA-assisted psychotherapy—that can heal trauma of the mind—post-traumatic stress disorder (PTSD)—is by nature healing suffering, easing suffering, changing the human condition. That is not only a breakthrough, but a miracle[2] of science, nature, and multidisciplinary collaboration.

Quoting Richard Carter's history of the discovery of the polio virus, Steven Pinker points out that on the day it was announced "people observed moments of silence, rang bells, honked horns, blew factory whistles, fired salutes, …took the rest of the day off, closed their schools or convoked fervid assemblies therein, drank toasts, hugged children, attended church, smiled at strangers, and forgave enemies." (Pinker, 2018, pp. 64–65) Perhaps it's time to understand the level on which this new breakthrough will change the human experience. In addition to healing individuals with PTSD, the ripple effect of mending this type of trauma on families, acquaintances, and even strangers, is going to be exponential and likely immeasurable. Maybe it is worth considering a day off to celebrate as a species. No gifts or cards, just a celebration of science and achievement in improving the human condition.

Many breakthroughs come in the form of multidisciplinary endeavor. No wonder that the first time in human history that a psychedelic compound has been run through a scientifically rigorous clinical trial process, it's been with a multidisciplinary approach, combined with the unstoppable will of one man (Rick Doblin), combined with the compelling mission, and so many other reasons.

In August of last year, the Multidisciplinary Association for Psychedelic Studies (MAPS) was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of PTSD with MDMA-assisted psychotherapy. That in and of itself is a breakthrough: a breakthrough for thorough, well-communicated, and transparent scientific rigor. That a small non-profit organization was able to make that happen is even more astounding.

Here's what I know for sure, based on my experience. It is really $@&! hard to get a drug approved. Years of rigorous science. Years of rigorous analysis. Years of

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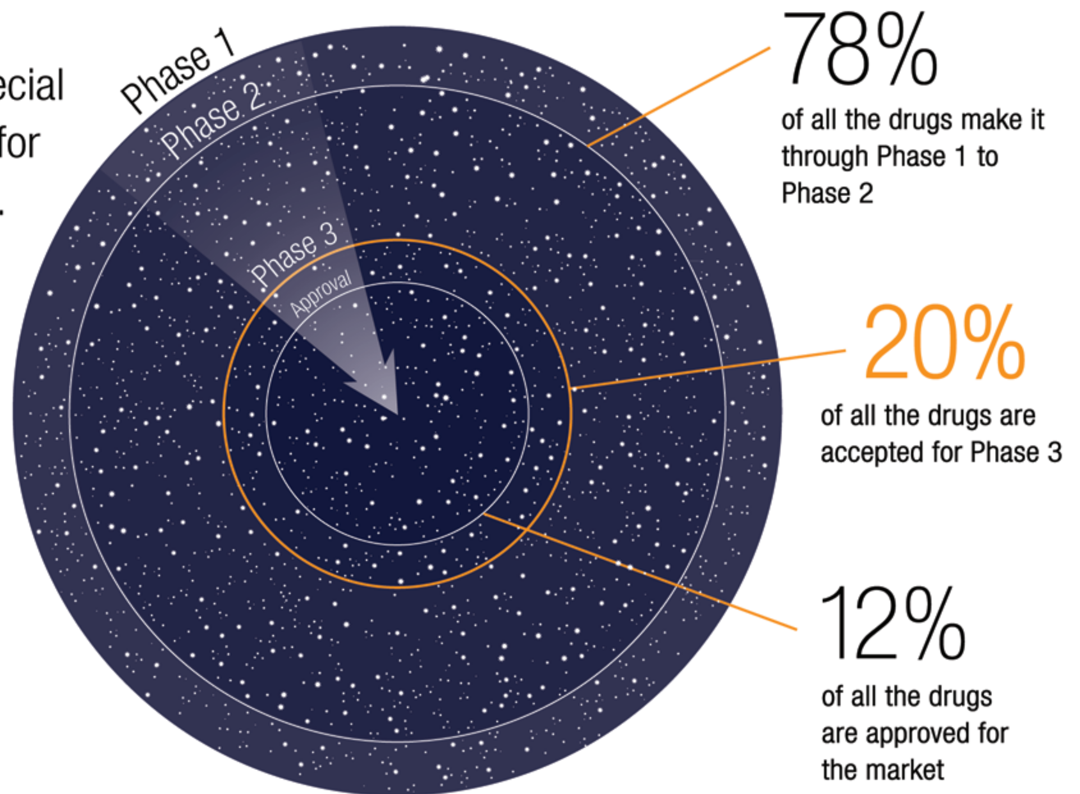
[1] Depending on your religious background and many other factors that try to figure out consciousness

[2] Miracle in this instance is a somewhat loaded term. For my purposes, I mean something we don't yet understand, not that there was necessarily divine intervention involved…though, I can't completely dismiss that notion given the possibilities that exist in the universe…truth is, I really don't know…and neither do you…isn't that fun?

The Universe of FDA Drug Approval

On July 28, 2017, MAPS and the FDA reached agreement on the Special Protocol Assessment for Phase 3 clinical trials.

The chart depicts all studies that have entered the FDA drug approval process as represented by stars. Studies are placed according to how much of the approval process they completed. This means that all stars in the outer layer represent studies that did not advance after the Phase 1 trials. Stars in the inner layer represent drugs that have been approved by the FDA for the market.



78%
of all the drugs make it through Phase 1 to Phase 2

20%
of all the drugs are accepted for Phase 3

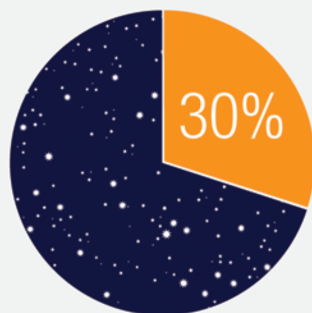
12%
of all the drugs are approved for the market

Source: Wong CH, Shaw K., Lo A. (2018) Estimation of clinical trial success rates and related parameters. Biostatistics (prepublished). Numbers from 2000 to 2015, with oncology excluded.

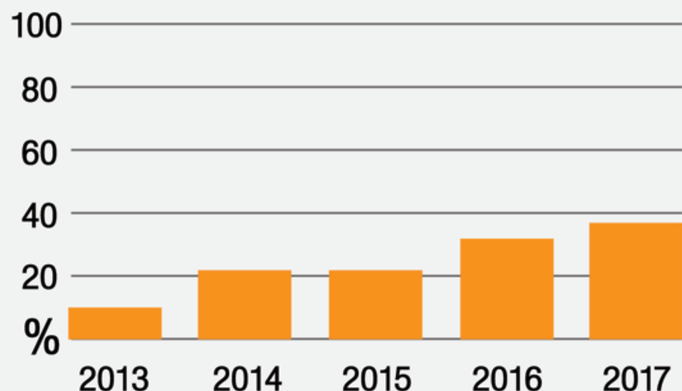
BREAKTHROUGH THERAPY DESIGNATION (BTD)

On August 16, 2017, the FDA granted Breakthrough Therapy Designation to MDMA-assisted psychotherapy for PTSD.

approximately 30% of the requests for BTD are granted by the FDA



The BTD program was launched in 2012. The chart below shows the percentage of novel drugs designated as Breakthrough Therapies for each year.



Source: FDA.gov novel drugs summaries for the years 2013-2017

rigorous planning and brainpower. To watch MAPS work towards its mission is to witness the coming together of the right minds, the right ideas, the right conversations, and the right circumstances over and over and over again, every step of the way. MAPS is all about synchronicity and willpower. From the organization's humble beginnings and mission of human wellness, it has achieved the legitimacy that comes with this type of recognition from a federal health authority.

By pursuing the scientific, federally regulated route to legitimizing psychedelic therapy, MAPS is using the rules of the system to break new ground. This required following the rules and also knowing what questions to ask along the way. MAPS challenges authority with a thoughtful and fact-based approach, instead of just rebellion for rebellion's sake. This attitude has enabled MAPS to get answers to questions that have not been asked before, since nobody else has brought this substance through the process. Any number of hurdles were overcome due to the right effort by the right people, many of whom genuinely have had a personal interest in the outcome because of their own experiences with trauma, mental illness, or psychedelics.

Is there something to be said for a personal breakthrough that comes through the psychedelic experience having an impact on understanding fundamentally, what a drug does? This is another part of the breakthrough of MDMA-assisted psychotherapy—that many of the therapists in the Phase 3 trials have actually had the chance to experience the treatment themselves, in MAPS' ongoing Therapist Training Protocol. How many of the scientists that are studying current psychiatric medicines and their effects on the human psyche know what it's like to use these treatments themselves?

When I asked a good friend and former colleague, Julie Lepin (currently Senior Vice President of Regulatory Affairs at Celgene Corporation) about Breakthrough Therapy Designation (BTD), her response spoke volumes: "It's a pretty big deal," she said. "BTD reflects the FDA's assessment that the early data provided are outstanding (knock-your-socks-off as I heard one reviewer describe the need) and likely reflect a significant therapeutic advance. In having BTD they commit to working closely with the sponsor to progress the new therapy because of this perceived advancement, so that patients in need can get early access to it."

There is an exciting and daunting future ahead for the MAPS Public Benefit Corporation (see my previous article in MAPS' Spring 2016 *Bulletin* for more about how the benefit corporation works). There is a tremendous responsibility to carry out the mission of the organization with ethics, integrity, transparency, and social good for all mankind. MPBC has the heart of a non-profit, with the structure of a for-profit business anchored to a social benefit mission to change the way humans heal from trauma.

MAPS and the MAPS Public Benefit Corporation had already attained legitimacy through the diligence and perseverance of the team at MAPS, as well as the undeniable efficacy of the treatment we have seen so far in Phase 2 trials. But progress through protocol reviews and favorable results in small studies are typical in early stages of drug development, and sometimes even through the later stages for products moving through the regulatory lifecycle. By highlighting a treatment through BTD, and distinguishing it among other treatments, is something very special. As a founding Board member of MPBC and advocate of the work that MAPS has done since 1986 to bring us to this point, I could not be prouder to be associated with this progress. PTSD and mental illness have touched my family in a real way, and I am proud to imagine a day in the not-so-distant future where this treatment will be readily available for those in need.

Where will MAPS be in 50 years? In one of my favorite books about long term thinking, The Clock of the Long Now (Brand, 2000), Stewart Brand outlines how a thought experiment spawned innovation. The idea is of humankind facing the complex, yet simply stated question: "How do we build a clock that would last 10,000 years?" Well, where would we put it? How would we tell others who came after us how to maintain it? Where do we get replacement parts? This barely scratches the surface of some of the questions Brand explores. The yield is technology, innovation, and breakthroughs of all kinds simply because that is what humans do:

We try to solve problems. As Steven Pinker points out in Enlightenment Now, "progress is an outcome not of magic but of problem solving."

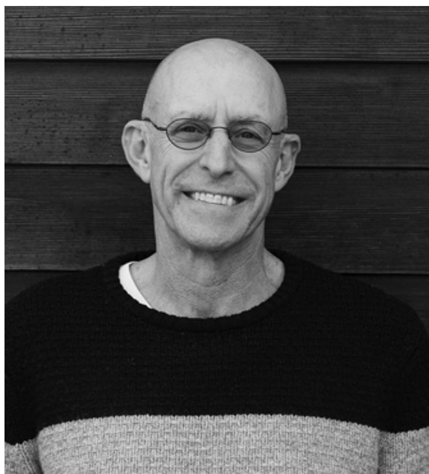
MAPS is trying to solve a big problem: the problem of healing trauma. We now have institutional proof that what many have thought for a long time could be a breakthrough of infinite importance, can be officially filed (with paperwork and everything) as a Breakthrough with a capital B. And that is a big deal.[3]

Matthew J. Neal *currently works as the Sr. Director of Product Management in Regulatory Solutions at PAREXEL and serves on MPBC's Board of Directors. He previously spent more than a decade at Amgen, Inc. as Director of Operations in Global Regulatory Affairs & Safety with a focus on Human Therapeutics to dramatically improve people's lives. Prior to that, he lived in Philadelphia where he was one of the pioneering members of the Regulatory Submissions Department for GlaxoSmithKline. Matthew has been publishing and submitting electronic dossiers to the FDA since 1996, and submitted the very first fully electronic NDA for GSK in 1999. Matthew holds a Master's Degree in Communication from Temple University. He can be reached at matt@mapsbcorp.com.*

[3] In conjunction with the Breakthrough Therapy Designation, MAPS also received a Special Protocol Assessment – which, in some ways, is more of a big deal than Breakthrough Therapy—doesn't sound as sexy, but it's a big deal. It basically means that based on the protocol design, assuming that we have the anticipated outcomes that were illustrated in the Phase 2 trials, just on a larger scale and without any new significant safety concerns, that we have an approvable product in MDMA-assisted psychotherapy. (https://en.wikipedia.org/wiki/FDA_Special_Protocol_Assessment)

How to Change Your Mind: An interview with author Michael Pollan

BRAD BURGE, MAPS DIRECTOR OF STRATEGIC COMMUNICATIONS



Michael Pollan

Michael Pollan is the author of seven previous books, including *Cooked, Food Rules, In Defense of Food, The Omnivore's Dilemma* and *The Botany of Desire,* all of which were *New York Times* bestsellers. A longtime contributor to the *New York Times Magazine,* he also teaches writing at Harvard and the University of California, Berkeley. In 2010, *TIME* magazine named him one of the 100 most influential people in the world. *How to Change Your Mind: What the New Science of Psychedelics Teaches Us about Consciousness, Dying, Addiction, Depression, and Transcendence* was published on May 15, 2018, and is now available at **maps.org/store**.

Brad Burge (BB): *How to Change Your Mind* has been described as your "most personal book," a kind of "participatory journalism." What are the two greatest insights you've gleaned from your research, which was at the same time both intimate and academic?

Michael Pollan (MP): I didn't start out planning to write a first-person book about psychedelics, but after interviewing participants in the "cancer anxiety" studies at Hopkins and NYU, and hearing about their literally life-changing experiences in the course of a single psilocybin session, I became intensely curious to have such an experience myself. Volunteers were returning from their journeys with a new understanding of their mortality; many of them had completely lost their fear of death. The dissolution of ego that often occurs on a high-dose experience had allowed them to "rehearse" their death and come to terms with it. I also talked to people who had stopped smoking after a single psilocybin trip for reasons that seemed ridiculously banal: "Smoking suddenly seemed stupid" or "I realized there was nothing more precious than my breath." It's hard to credit these abrupt shifts in perspective, so I decided I had to interrogate the experience in the first person. This made all the difference, a case when participatory journalism proved essential to fully grasping the story.

It's hard to credit these abrupt shifts in perspective, so I decided I had to interrogate the experience in the first person.

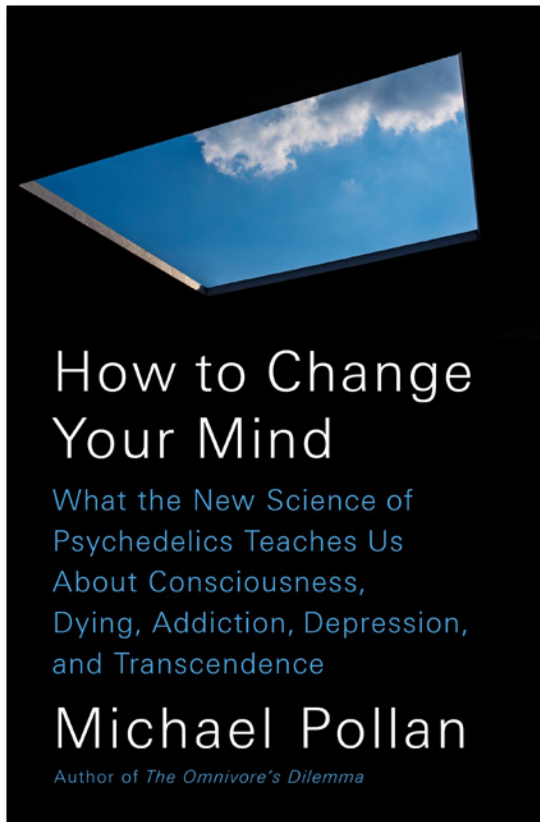
BB: In the book you write that realizing that there had been a recent explosion of research into psychedelics was what prompted you to open your mind to them after many years. In your hundreds (thousands?) of conversations with people over the course of your research, how do you think the culture is shifting with respect to psychedelic science, medicine, and spirituality?

MP: I started reporting on psychedelic therapy in 2013 and in the five years since the public, and the mental health community, have moved much faster than I ever would have thought possible. What was a pretty fringe approach toward mental illness in 2014 is now being taken seriously by the mental health establishment, by regulators, by philanthropists (as MAPS well knows), by investors, and by the press. When I published my piece in *The New Yorker* in 2015, "The Trip Treatment," I guessed FDA approval was 15 or 20 years away. Now I'd say it's probably less than five, which is in-

credible. So far, at least, the work has encountered much less resistance than I expected. That has a lot to do with the striking success of the Phase 2 trials, which is hard to argue with.

BB: Based on both your research and personal experiences, do you think that using MDMA, psilocybin, or LSD to assist psychotherapy in mental health treatment could replace or transform how psychiatry works as a field of a medicine? How do you think these substances differ from each other, and how to they compare?

MP: A great many of the researchers I interviewed for the book, both inside and outside the community of psychedelic science, are convinced these medicines have the potential to transform mental health care. They represent not just a new drug, but a radical new paradigm for psychiatry. In the past, psychiatry has either concerned itself primarily with the mind, in talking therapy, or with the brain, with psychiatric drugs. Some have said psychiatry went from being "brainless" to being "mindless." Psychedelic therapy promises to marry the mind and the brain in a new kind of therapy—"psychedelic assisted psychotherapy"—that holds enormous promise in the treatment of several serious illnesses. But it is also a challenge to a field that sees therapy and meds as mutually exclusive, and a field that is committed to interminable therapies, whether with drugs or weekly sessions. It's going to be fascinating to watch how this shakes out.



Available now at **maps.org/store.**

BB: How did your personal experiences, which you include in the book as your aptly-named "travelogue," influence the direction of your research, and what you were able to include in the book?

MP: My first-hand experiences helped me put flesh on an abstraction like "ego dissolution" or "mystical experience." The whole idea of the default mode network—which is downregulated during the psychedelic experience, and probably accounts for the loss of ego—also became more concrete for me after having the experience. (I also got to do some neural feedback with my Default Mode Network that was fascinating.) And I think my trips allowed me to connect better with the dozens of patients and volunteers I interviewed. We could speak one another's language, about an experience often described as "ineffable." The experiences presented a terrific literary challenge—how do you evoke a psilocybin or LSD trip on the page, without sounding like a lunatic? (You can decide if I succeeded.)

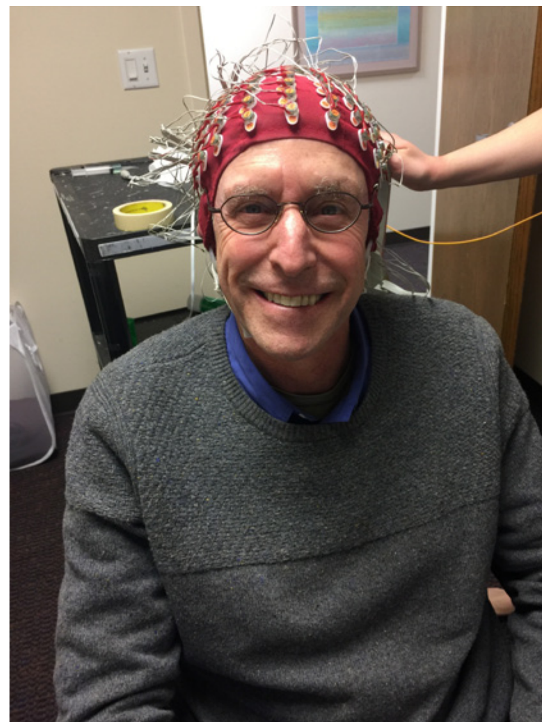
I also think the experiences changed me—changed my relationship to my ego (which I no longer think of as identical to my self, but more a "character" that needs to be managed and sometimes demoted); made me a better meditator; generally made me more open and less defended, etc., etc. My wife, who had trepidations when I embarked on this journey, eventually became quite supportive. Initially she worried that my involvement in psychedelics might somehow change me. (What she didn't foresee is that it might change me for the better!)

BB: How do you think psychedelics' apparent ability to promote mystical or spiritual experiences, and/or to expand our awareness to parts of our minds and bodies that were previously hidden, relate to their potential as healing tools for anxiety, trauma, and addiction?

MP: There seems little question that the mystical experience, so-called, is a key driver of a successful psychedelic treatment. The temporary loss of one's ego, which I take to be the hallmark of the mystical experience, achieves several things: it allows subconscious material (including trauma) to surface; it brings down the walls that sepa-

rate us from other people and nature; and it broadens one's conception of his or her "self-interest" to take in the interests of others, whether people close to you, your community, or humankind as a whole. The ego, and our attachment to it, is at the root of much suffering and mental illness; to realize it's not the only way to be in this world is to realize we can break out of all sorts of destructive patterns of thought, including the patterns and habits that underlie depression, addiction, and anxiety. Breaking mental habit seems to me the key, and psychedelics have the potential to do that.

BB: In your view, what is the biggest challenge facing the field of psychedelic research right now? Based on your extensive research and interviews, what hope do you think there is for overcoming these challenges, and how likely do you think it is that they'll be overcome?



MP: I think the community has to guard against overconfidence and, just in case, be prepared for a backlash. It also has to realize that the general public still associates these medicines more closely with mental illness rather than health. There's much work to be done educating the public as to the science and potential of these medicines. It seems unlikely the moral panic of the 1960s could be reignited, but a sloppy researcher, an adverse event, or some other negative story has the potential to blow things up. Tom Insel, the former head of the National Institute of Mental Health, is an example of an establishment figure who thinks there's great promise in this research. But the community would do well to remember his admonition from the stage at Psychedelic Science 2017 last year: "Don't screw it up!"

BB: What differences and similarities do you see between MDMA- and psilocybin-assisted psychotherapy? Do you think they are two completely different approaches, or do you think they complement one another in some way?

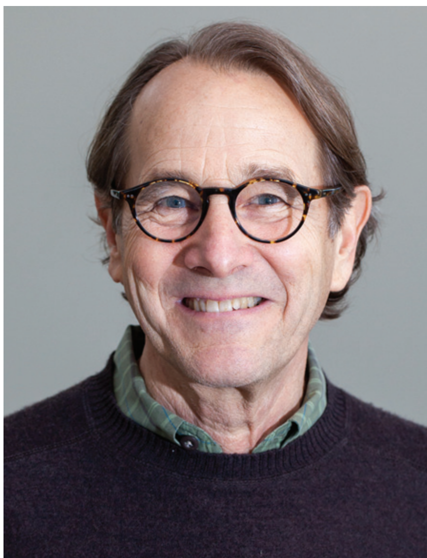
MP: I didn't dig as deeply into MDMA therapy as I did the classical psychedelics—psilocybin, LSD etc., but my sense is there are important differences and important similarities. The phenomenology of the experiences are quite different, obviously. But both give the patient/volunteer access to unconscious or suppressed material, bringing it into an observable space where, with the help of the therapist, it can be explored. I met several therapists who used MDMA at the beginning of the therapeutic relationship to establish bonds of trust before administering one of the classical psychedelics—this suggests that the two medicines are potentially complementary. Already we're seeing some sorting of the indications the two kinds of drugs are used for—MDMA for PTSD, for example, psilocybin for depression and addiction—suggesting some fundamental differences in their mode of action. I sometimes wonder if they weren't both Schedule 1 substances, would we put them in the same basket? I'm not sure.

BB: What's next for you?

MP: I've got many months traveling the country talking about *How to Change Your Mind,* so I'm not onto another project yet. For me a book tour is a valuable R&D laboratory—I hear the questions and reactions of my readers, and often come away with an idea of what they want to know and what I need to write next. My book tour might turn out to be a kind of Rorschach test for psychedelics, giving us a good fix on where exactly the American public stands on this revolutionary science and medicine. I can't wait to find out!

MAPS-Sponsored Research at the 2017 Annual Meeting of the International Society for Traumatic Stress Studies: Signs of Breaking Through Resistance

MICHAEL MITHOEFER, M.D.



Michael Mithoefer, M.D.

MDMA-ASSISTED PSYCHOTHERAPY WAS GRANTED Breakthrough Therapy Designation by the Food and Drug Administration (FDA) only one year after our End of Phase 2 meeting with the agency. I recently heard a Multidisciplinary Association for Psychedelic Studies (MAPS) consultant with many years of experience in the pharmaceutical industry say, "This never happens!"

The fact that it did happen is a result of the expertise and exceptionally hard work of the MAPS and MAPS Public Benefit Corporation (MPBC) teams, the advantages of a relatively small and nimble organization, and the support of so many people who see the importance of this effort. It's also a sign of growing acceptance by the medical and scientific community that this is rigorously conducted and sorely needed research; a far cry from the days when what we heard so often was, "You'll never get approval to do clinical research with MDMA!" Before I discuss other signs of this sea change, a brief review of some of the challenges along the way will illustrate how big a change it is.

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In 1990, Charlie Grob, M.D., Director of the Division of Child and Adolescent Psychiatry at UCLA, published a letter criticizing one of George Ricaurte's MDMA neurotoxicity studies reported in the *Archives of General Psychiatry.* Sasha Shulgin then sent a copy of the letter to Rick Doblin, who promptly introduced himself to Charlie. That's when their respective long-time determinations to pursue psychedelic research came together to bear fruit. Within two years, Charlie, Rick, and Gary Bravo submitted a Phase 2 protocol to the FDA to study MDMA for treating anxiety in patients with terminal cancer. Even for these patients with limited life expectancy, the FDA judged that the possible risk of neurotoxicity was too great to allow the study without more safety data. However, the FDA was willing to consider a Phase 1 trial in healthy volunteers to investigate the physiological effects and pharmacology of MDMA. Later that year, a Phase 1 protocol was accepted, and Grob went on to successfully complete the first of three U.S. Phase 1 trials investigating the effects of MDMA.

This is an example of what we have seen from the FDA consistently regarding psychedelic research—a rigorous approach based on science rather than politics, and a willingness and ability to reply to protocol applications without undue delay. (Responses from other regulatory agencies and institutions have not always been so rational or unbiased.) These Phase 1 studies provided the basis for the Phase 2 treatment trials that were to follow. Despite this success, Charlie judged that (in his words) "the MDMA neurotoxicity campaign run by NIDA was quite intense at that time

and had further poisoned the MDMA debate" (Grob personal communication 2018), so he focused his attention on psilocybin research instead, and did not proceed to a Phase 2 MDMA study for more than a decade.

The first Phase 2 study of MDMA-assisted psychotherapy was started in Spain, sponsored by MAPS and led by Jose Carlos Bouso and Marcela Ot'alora in 2000, the same year we started writing a protocol for a similar study in the U.S. Two years later, for political reasons, the study in Spain was forced to shut down by the drug police. Our U.S. protocol, having been approved by the FDA in November 2001—30 days after we submitted it—had since become mired in other regulatory delays. We had been unable to obtain an Institutional Review Board (IRB) review at the Medical University of South Carolina (MUSC) because MDMA research was still considered too controversial. I was told later by the Chair of Psychiatry at MUSC that they were afraid of a punitive audit by the federal government that, they said, could shut down all the research at the university for months.

We went on to obtain approval from Western IRB without difficulty, but three months later their approval was withdrawn because of concerns raised by a new study from Johns Hopkins University, published in *Science* with an accompanying press release and considerable fanfare, claiming that MDMA caused fatal dopamine toxicity in 20% of primates studied. Our published response expressing skepticism about the study was dismissed by the study authors (among them George Ricaurte, again) and apparently largely ignored by many readers. It seemed they were not persuaded by our scientific reasoning or our assertion that if 20% of people at raves were dying every weekend we probably would have heard about it. Speculation ensued in the medical literature about the looming epidemic of Parkinson's disease expected to result from widespread "Ecstasy" use. As a result, despite Rick Doblin's persistent efforts to find another IRB, we were not able to do so until almost exactly a year later.

On September 12, 2003, Ricaurte's paper was retracted because the researchers discovered that they had mislabeled the bottles, and had not administered MDMA at all in their study. What they had administered to the unfortunate baboons and squirrel monkeys was methamphetamine, a prescription medicine known to cause dopamine toxicity in high doses. Suddenly, when it wasn't MDMA causing the toxicity, the fears about Parkinson's disease seemed to evaporate. Eleven days after the retraction, we received IRB approval from Copernicus IRB in North Carolina.

Meanwhile, my Schedule I research registration application, submitted July 3, 2003, and required for me to obtain and administer MDMA in clinical research, had still not been approved by the Drug Enforcement Administration (DEA). After more than a year of calls, letters, and emails back and forth, and two resubmissions of the approximately 500-page application because it had been misplaced internally at the DEA, I faxed a letter to Senator Fritz Hollings with a chronology of all our communications with the DEA. I said I did not expect the Senator to have an opinion about whether or not the application should be approved, but I was requesting his help with the undue delays that were impeding science. Four days later, I got a call from the South Carolina DEA Field Office to schedule a site inspection.

There was some additional delay as the central DEA office in Washington asked them also to do a background check on the therapist in the adjacent office. They said they were concerned that she could drill through the wall into the back of the safe to steal the MDMA. She was a good sport about my giving them her contact information: "OK," she said, "But tell them I'm not good with tools." Apparently the DEA investigation confirmed this because my Schedule I registration arrived in February 2004. We began screening the first research participant the following month. Since that time, although the regulatory process involved in doing research with a Schedule I drug re-

Resurgence of MDMA Clinical Research

First Phase 2 protocol approved by FDA for MDMA-assisted psychotherapy for PTSD.

October 2003

IRB approval granted.

April 2004

First participant enrolled.

As of 2016

Six Phase 2 MDMA/PTSD clinical trials completed.

August 2017

FDA grants Breakthrough Therapy Designation. Agreement on Special Protocol Assessment reached for Phase 3 trials.

mains frustratingly slow at times, we have never again had such extreme delays obtaining approval for any of the subsequent U.S. studies, and we have developed a successful working relationship with the DEA.

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In those earlier days, resistance to accepting the importance and legitimacy of MAPS' research was not limited to the DEA and some IRBs; it also seemed to be widespread in the medical and psychotherapy communities. Happily, this has changed radically in recent years, due in large part to our publishing very promising data in peer-reviewed journals. Media coverage no longer starts every report about the research with images of raves and Ecstasy pills. The public focus has gradually shifted to the results of our rigorously designed and conducted clinical trials, and to the profound stories of the research participants who have courageously spoken publically about their healing.

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A recent sign of this changing attitude was my invitation to speak at the International Society for Traumatic Stress Studies (ISTSS) 2017 Annual Meeting in Chicago. The last time that meeting was in Chicago had been ten years earlier. I applied to speak at the 2007 meeting, but was only accepted to do a poster presentation. While I was in Chicago that first time, I was interviewed on-camera at the CNN studio for one of the reports Sanjay Gupta did on our research, but my poster got relatively little notice at the conference itself. In contrast, in 2017, though I did not apply to speak, I was invited to give one of the "Master Clinician" addresses at the conference. In addition, the conference hosted a symposium entitled "Pharmacologic Agents as Treatment and Adjunct to Psychotherapy for PTSD" with presentations by two psychologists who have collaborated with us on MAPS-sponsored studies.

One of these presenters was Anne Wagner, Ph.D., who organized the symposium and spoke about the promising results of our recently completed pilot study combining MDMA-assisted psychotherapy with Cognitive Behavioral Conjoint Therapy (CBCT) for PTSD. Candice Monson, Ph.D., who developed CBCT and is Director of Clinical Training at Ryerson University and an affiliate of the Women's Health Sciences Division of the Veterans Affairs (VA) National Center for PTSD, was also a co-therapist in the study in which both members of a couple received MDMA together during two MDMA-assisted therapy sessions embedded in a course of CBCT. To my knowledge, this is the first time FDA has allowed an investigational psychiatric drug to be administered to two people at the same time.

The other MAPS collaborator presenting on the panel was Barbara Rothbaum, Ph.D., professor at Emory University and the Atlanta VA Hospital, who spoke about her recent studies of MDMA as an agent to increase fear extinction and her upcoming study combining MDMA with Prolonged Exposure therapy for PTSD. The discussant for the panel was Paula Schnurr, Ph.D., Executive Director of the VA's National Center for PTSD, responsible for directing PTSD research and treatment in the VA system. In her discussion, Schnurr pointed out that she is approached every week with new ideas for better PTSD treatments, most of which she does not consider worth pursuing. She went on to say that MDMA-assisted treatment is an approach she does consider important to pursue, citing our promising data and the plausible mechanisms of action based on what is known about the effects of MDMA and the nature of PTSD.

My "Master Clinician" presentation also seemed to be very well received. Though there was one person in the room who went on a bit of a tirade against the research during the discussion period (with arguments I didn't quite understand), many people expressed excitement about the potential of MDMA-assisted psychotherapy. I explained our study design, our therapeutic approach, and the combined results of MAPS' completed Phase 2 studies, showing a large effect size across six studies at five different sites in four countries. This was an audience of trauma therapists who were trained and experienced in a variety of different methods, so I pointed out that while the format of our therapy with eight-hour sessions and our relatively non-directive (or client-directed) approach is quite different from existing trauma-focused treatments, we have consistently observed that elements of other therapeutic approaches often arise spontaneously in the course of our less directive method of therapy.

For example, our research participants often spontaneously engage in "imaginal exposure," something patients are instructed to do in Prolonged Exposure (PE) therapy, a form of Cognitive Behavioral Therapy (CBT). Our participants also invariably address relationships, family issues, and transference as in psychodynamic psychotherapy; they notice and correct cognitive distortions as in CBT; and they often become more aware of their own inner parts, and bring curiosity and compassion to addressing them, as in Internal Family Systems (IFS) therapy. Our approach includes a focus on the body, as is the case with Somatic Experiencing, Sensorimotor Therapy, Holotropic Breathwork, and other body-centered methods. In addition, there are often Jungian elements, such as powerful archetypal images and processing that resembles active imagination.

One of the challenges I've confronted in discussing possible therapeutic mechanisms of MDMA-assisted psychotherapy has been accounting for this variety of effects observed during PTSD research sessions. How does MDMA-assisted psychotherapy work? Does MDMA work by facilitating imaginal

exposure, by exposing underlying faulty schema and correcting cognitive distortions, by providing psychodynamic insights and increased awareness of transference, by increasing "Self" energy and allowing for effective work with internal parts, by stimulating somatic processing, by mobilizing Jungian archetypal forces, or by engendering mystical or transpersonal experiences? My suggestion to this group of therapists was that we may be in a situation akin to the fabled group of blind individuals describing an elephant according to which part of the elephant each of them could feel.

Parallel to the challenge of making sense of the spectrum of possible mechanisms of MDMA-assisted psychotherapy was the challenge of explaining our relatively non-directive/client-directed approach to a group of experienced trauma therapists and researchers, many of whom were experts in the most widely used manualized treatment methods. Although, these methods are more responsive to individual client differences than one might expect when in the hands of skilled therapists, they are much more standardized, directive, and tied to specific theories about PTSD than is our approach. In our approach, the working hypothesis (which we originally learned from Stanislav Grof) is that the therapeutic process is best directed by the individual's own inner healing intelligence. To many cognitive behavioral therapists, this may seem insufficiently standardized to be consistently effective or even to be studied adequately. Our data demonstrate that this is not the case. In my opinion, our approach is standardized in an important respect, although it is different from what is considered standardization in other treatments, which tend to prescribe the content of each therapy session. Each of our study participants receives the therapeutic experience that arises naturally according to their own healing intelligence, when they are provided a conducive set and setting and a catalyst for this intelligence to express itself. This may be a more relevant form of standardization than one dictated by therapists' assumptions about what may or may not fit a given participant's natural healing process. Instead, the role of the therapist becomes removing obstacles and supporting the healing process as it unfolds.

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As someone with experience practicing MDMA-assisted psychotherapy, all this makes perfect sense to me, but I wondered how it would be received by the ISTSS audience. Happily, I got some unexpected encouragement from an inspiring presentation by Kenneth Kendler, M.D., the day before my talk. Dr. Kendler is a highly respected, widely published professor of psychiatry who has spent decades thoughtfully studying psychiatric disorders. He made an elegant argument against reductionist explanations of etiology (the causes of illness) and in support of the conclusion that "psychiatric disorders are inherently multifactorial." I would add that it follows that if the origin of psychiatric disorders is multifactorial, so too should be their treatment. Our observations and results bear that out. Perhaps that's one reason many people in MAPS-sponsored MDMA-assisted psychotherapy studies who had failed to respond to years of existing pharmacologic and psychotherapeutic treatments for PTSD have responded so robustly to our multifactorial approach.

A few months after the ISTSS meeting, I was delighted to read additional support for this position from another psychiatric elder and leader in developing and teaching psychotherapy, Irvin Yalom, M.D.. Drawing on his many years of research and experience, Dr. Yalom writes, "The therapist must strive to create a new therapy for each patient." I'd take this even further, and say that the therapist must strive to allow and encourage each patient to create a new therapy for themselves. It appears that MDMA, used wisely, can be a powerful ally in this endeavor.

Michael Mithoefer, M.D., *is a psychiatrist practicing in Charleston, SC, where he divides his time between clinical research and outpatient clinical practice specializing in treating PTSD with an emphasis on experiential methods of psychotherapy. He is a Grof-certified Holotropic Breathwork Facilitator and is trained in EMDR and Internal Family Systems Therapy. He and his wife, Annie Mithoefer, recently completed a MAPS-sponsored Phase II clinical trial testing MDMA-assisted psychotherapy for PTSD. A paper about their study was published in July 2010 in the* Journal of Psychopharmacology. *Before going into psychiatry in 1995 he practiced emergency medicine for ten years, served as medical director of the Charleston County and Georgetown County Emergency Departments, and has held clinical faculty positions at the Medical University of South Carolina. He is currently board certified in Psychiatry, Emergency Medicine, and Internal Medicine.*

From Print to Presentations: The Importance of Communicating Findings from Psychedelic and Cannabis Studies

ILSA JEROME, PH.D., MPBC RESEARCH AND INFORMATION SPECIALIST
ALLISON FEDUCCIA, PH.D., MPBC CLINICAL DATA SCIENTIST

Allison Feduccia Ph.D. (left)
Ilsa Jerome, Ph.D. (right)

Posttraumatic stress disorder (PTSD) is a condition that disrupts and constricts people's lives, and remains a topic of interest to researchers and health professionals. The increasing scope of PTSD research is occurring in the face of treatments with high dropout rates that are ineffective for many, has led to a growing number of published reviews and thought pieces addressing the nature and treatment of PTSD. When published in established, peer reviewed journals, these articles can serve as key references for healthcare professionals and are used as guideposts for understanding treatments and research for PTSD. Websites with medical news and perspectives are also frequently referenced by healthcare professionals to access the latest information, including information on conditions such as PTSD.

MAPS is working to develop MDMA-assisted psychotherapy as a PTSD treatment, with Phase 3 trials starting in the summer of 2018, and Breakthrough Therapy Designation received from the U.S. Food and Drug Administration (FDA) in August 2017. Two review articles published in 2017 addressing PTSD or its treatment failed to mention MDMA-assisted psychotherapy or cannabis, despite both being under investigation in these clinical trials. Shortly afterward, a misleading and uninformed opinion piece in the prominent health-related news site Medscape criticized MAPS' studies of MDMA-assisted psychotherapy as inherently problematic because of "bias" in the research. The author, Dr. Jeffrey Lieberman, considered MDMA to be a "feel good" drug, by definition having high potential for abuse. After encountering these articles, we sprang into action, penning responses to both review articles and crafting a rebuttal to Lieberman's opinion piece, to reduce misinformation and ensure that the research is being recognized.

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First, a review in the *New England Journal of Medicine,* a respected medical journal with high impact in the medical and scientific community[1], surveyed causes and models for the etiology (cause and development) of PTSD. The section on treatment included descriptions of existing treatments and innovative approaches, including neurofeedback, transcranial magnetic stimulation and D-cycloserine, but failed to mention MDMA-assisted psychotherapy or cannabis.

On the heels of the *New England Journal of Medicine* report on PTSD, the psychiatric periodical *Biological Psychiatry* published a "consensus statement" on pharmacotherapy for PTSD [2]. The article was written expressly to describe the current state of available medications and the future of drug therapies for PTSD. The authors of the report stated that they searched for both completed and ongoing studies, reporting that

they used the national clinicaltrials.gov trial registry and accepted all ongoing and completed studies, both with and without reported results. The consensus statement asserted that there is a need to develop novel trial designs or methods that target specific symptoms of PTSD, and to examine optimal combinations of medications and psychosocial treatment. They called for a greater evaluation of "real life" treatment effectiveness. While the piece mentioned "cannabinoid receptor modulators," it failed to mention MDMA-assisted psychotherapy or cannabis as potential PTSD treatments, despite several trials for both being listed in the clinicaltrials.gov registry.

We responded to the omissions in the *New England Journal of Medicine* review by referring to findings from MAPS' Phase 2 studies, describing potential mechanisms of action for MDMA's use in therapy, including fear extinction and greater ease in facing emotionally upsetting memories, and providing clinicaltrials.gov reference numbers for MDMA and cannabis studies [3]. We also noted that in terms of risk analyses, ketamine (a legal prescription drug increasingly used off-label as an antidepressant and in psychotherapy) appears to have more risks than cannabis, notable since the authors expressed concerns about the abuse potential of cannabis, but not ketamine. In order to be considered for publication, letters to the NEJM had to be sent within three weeks of the article they referred to, leading to the rapid and intensive submission of our response.

Our response to the *Biological Psychiatry* consensus statement about PTSD was more expansive. We had the space to note the inconsistency of omitting MDMA-assisted psychotherapy and cannabis from the list of innovative treatments despite their meeting the authors' established criteria [4]. Our response noted the additional hurdles to research for Schedule I drugs, and the FDA's decision to grant MDMA-assisted psychotherapy Breakthrough Therapy Designation. These two responses, published in widely-read medical research journals, corrected the oversight of the original reviews and introduced MAPS' research to a wider audience of physicians and medical researchers.

The third article that we responded to was an opinion piece published on Medscape by Columbia University Psychiatry Chair, Dr. Jeffrey Lieberman [5], in the form of a video blog and written transcription. While not a peer-reviewed journal, Medscape reaches a broad cross-section of physicians, nurses, therapists, and other healthcare professionals, so we felt it important to respond. In the article, Lieberman opined that MDMA-assisted psychotherapy would not succeed as a treatment because MDMA can produce euphoria, and he believes in a division between "feel good" and "genuinely therapeutic" drugs. He also expressed wariness about research findings from MAPS' studies because of "bias," as if this were a problem unique to research on MDMA-assisted psychotherapy. In expressing concern for study participants developing tolerance to MDMA, Lieberman appeared unaware that our Phase 2 study designs involve administration of MDMA only a few times, not daily dosing.

The inaccuracies and moralizing of the opinion piece stoked the flames of our motivation to respond [6]. Unlike peer-reviewed journals, Medscape doesn't have a formal outlet for rebuttals beyond the limited user comment space on their website. Lacking this outlet, MAPS Director of Strategic Communications Brad Burge wrote to the editors at Medscape presenting our rebuttal and explaining the importance of clarifying the misinformation from Dr. Lieberman. Medscape's executive editor agreed our rebuttal was well-founded, and published our response as an original op-ed piece on Medscape.

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Education and outreach are a key part of MAPS' mission, and a service that we at MAPS Public Benefit Corporation (MPBC) are cultivating to bring our perspectives to the public. This includes participating as members of the research and science community. Peer-reviewed journal articles command more attention within the scientific community than news reports, and their impact lasts longer as well, since science journals remain in libraries and are routinely cited by other researchers in publications. For those reasons, we felt that correcting these omissions and inaccuracies would have a lasting impact.

All three responses were published. This is encouraging, possibly representing a shift in editors' and reviewers' attitudes concerning the proposed therapeutic uses of Schedule I drugs. Introducing physicians and medical researchers to the therapeutic potential of MDMA-assisted psychotherapy and cannabis in the treatment of PTSD will stimulate public interest, grow support for MAPS' work, and possibly even challenge other researchers to devise their own trials.

Responding to incomplete and/or inaccurate publications is but one step in sharing our findings. A bigger and even more significant step will be publishing results from our Phase 2 research, including studies of MDMA-assisted therapies in the treatment of PTSD, social anxiety in adults on the autism spectrum, and anxiety in people confronting life-threatening illness. Adding these publications to the existing public record will give MAPS' supporters and interested researchers a greater array of findings to cite, examine, and communicate to others. To that end, MPBC and MAPS have embarked on writing manuscripts reporting results from our Phase 2 MDMA clinical trials. Findings from our study of MDMA-assisted psychotherapy for veterans and first responders with PTSD, and findings from our Boulder, Colorado, study of MDMA-assisted psychotherapy PTSD study, have been submitted for publication.

Presenting posters or speaking at scientific conferences is another way we are fostering interest and understanding of our work. Many researchers are unfamiliar with the drug development programs for psychedelics, and still hold viewpoints based on the multitude of papers and inaccurate reports they have read, such as those treating findings from studies using high, often neurotoxic doses of MDMA given several times a day as if they are relevant for estimating the safety of MDMA-assisted psychotherapy. Over the past few years, MPBC staff have pre-

sented data from our Phase 2 MDMA studies at neuroscience conferences, military health research conferences, psychiatric Grand Rounds, and trauma conferences, and have supported collaborator presentations at various conferences and events. This education and outreach is helping to inform people in the scientific and medical community about the magnitude of the findings seen in the Phase 2 studies. Over 32 years of MAPS' work is now beginning to be acknowledged beyond a small circle of supporters. Much to our surprise and excitement, in 2016, Allison Feduccia, Ph.D., (who co-wrote this article) received the Mental Health Treatment Award on behalf of MAPS at the Canadian Military and Veteran Health Research (CIMVHR) Forum for a presentation on MDMA-assisted psychotherapy [7].

With a growing number of published papers and news reports, and with more communication of our results at scientific conferences, we are building strong and lasting support for research on MDMA, cannabis, and other psychedelic plants and compounds. This, in turn, will increase the pace of discovery and development of psychedelic-assisted therapies into prescription treatments. It may also extend beyond clinical applications to foster interest and support in reconsidering current drug policy. If this happens, we have a greater chance of meeting our goal of creating medical, legal, and cultural contexts for the careful uses of psychedelics and marijuana.

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L. (Ilsa) Jerome *earned a doctorate in psychology from the University of Maryland in 1999, with an interest in social cognition. Inside and beyond formal education, Jerome immersed herself in literature on psychopharmacology and what would soon become affective and social neuroscience. Ilsa was a member of the team that developed the initial 3,4-methylenedioxymethamphetamine (MDMA) Investigator's Brochure. Jerome was the Clinical Research and Information Specialist at the Multidisciplinary Association for Psychedelic Studies (MAPS). At MAPS Public Benefit Corporation (MPBC), Jerome has retained the title, focusing on archiving, communicating and sharing information about studies into the effects, risks and benefits of MAPS' primary study drugs, particularly MDMA and classic psychedelics. Seeking, understanding and communicating scientific information has been at the core of this role, while the details have changed. As clinical research and information specialist, Jerome has collected and summarized research as part of designing and developing the Investigator's Brochure and Phase 2 studies. She has assisted in the revision and management of Psychedelic Bibliography scope and content, supported and communicated with medical monitors, and communicated with researchers within and outside of MAPS and sending findings into the world as published reports. She believes in the necessity of interpreting and sharing research knowledge that will best help MPBC produce transparent, thorough and honest documents and reports, and that spotting good questions is as important as knowing good answers. Ilsa is fascinated by sound and music, and fragrance and olfaction. She spent a couple of years as a DJ at a university radio station, but remains emphatically unhip. She can be reached at ilsa@mapsbcorp.com.*

Alli Feduccia, Ph.D., *received a bachelor's degree in Biological Psychology in 2009 from Louisiana State University. After earning a Ph.D. in Neuropharmacology from the University of Texas at Austin by utilizing rodent models to study the effects of MDMA on behavior and neurochemical release, she held a postdoctoral research position in the Preclinical Development Group at Ernest Gallo Clinic and Research Center at the University of California San Francisco where her experiments aimed to discover novel treatment strategies for alcohol dependence by elucidating the mechanisms of action of medications used to treat substance use disorders. In 2012, she received a Postdoctoral Research Training Award from the National Institutes of Health that enabled her to work on clinical trials at NIAAA/NIDA investigating novel therapeutics for alcoholism, as well as, human fMRI studies oriented to understanding the neural underpinnings of addiction. At MAPS PBC, Alli is currently serving as the Clinical Data Scientist, performing various tasks to ensure clinical data is analyzed and communicated in the highest quality for regulatory documents, scientific publications, and public presentations. She also makes online e-learning modules and creates content for a web-based learning management system to host training and educational material for site and therapy teams, Zendo Project, and other public educational outreach. Alli is passionate about starting a MAPS-sponsored trial of ayahuasca for treatment of alcohol use disorders and is currently applying her translational perspective to the development of a new protocol. Recognizing this as a monumental time in history, Alli highly regards the opportunity to participate in efforts to generate scientifically based evidence on the therapeutic and spiritual potential of psychedelics. She can be reached at alli@mapsbcorp.com.*

Clinical Supervision in MDMA Therapy Training: An Ethical Commitment

SHANNON CLARE CARLIN, M.A., MPBC MDMA THERAPY TRAINING PROGRAM MANAGER

Shannon Clare Carlin, M.A.

In 2016, the MDMA Therapy Training Program was redesigned to prepare dozens of therapists for working on the Phase 3 clinical trials that will soon be started by the Multidisciplinary Association for Psychedelic Studies (MAPS). Since, then the program has trained over 200 therapists and researchers, 80 of whom are co-therapists embarking on MAPS-sponsored MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) clinical trials in 2018.

Supervision is a primary focus of MAPS' current open-label Phase 2 trials, and will continue to be an important piece of the training program going forward. Amongst the 2016 program updates, we added clinical supervision as the final process of initiating new MDMA-assisted psychotherapy providers. In MAPS' MDMA clinical trials, therapy sessions are always conducted by two therapy providers, in a co-therapy pair. Clinical supervision (or just "supervision") entails close oversight and support of the first study participant treated by each co-therapy pair. There are many forms of study monitoring, including sponsor visits to study sites, data monitoring, medical monitoring, and adherence rating. These are all typical functions for conducting sound clinical research. Supervision adds an element of clinical support and oversight specific to the application of the therapeutic method, as outlined in the *Treatment Manual* (**maps.org/treatmentmanual**). Supervisors offer insight and feedback as therapy pairs put into practice the knowledge gained through their training.

Supervision is an ethical commitment to providing competent care to clients by supporting the development of practitioners, and an industry standard in the training of therapists. It is also a requirement for gaining licensure to practice psychotherapy in most jurisdictions, and a common practice in many certificate programs. MAPS and the MAPS Public Benefit Corporation (MPBC) are dedicated to ensuring the integrity of MDMA-assisted psychotherapy trials. As the number of study sites expands, currently 16 in the US, Canada and Israel, so do our efforts to maintain consistent and high-quality care across the sites.

The extra support that supervision provides allows newly trained providers to obtain guidance and ask questions during their first experiences treating clients in a new modality. The lived experience of a supervisor provides invaluable insight for supervisees. A senior practitioner has knowledge beyond the curriculum of the training program, and understands the practicalities of applying a therapeutic model in the real-world.

In MAPS-sponsored trials, the supervisor role is filled by lead therapists, researchers who are experienced in providing MDMA-assisted psychotherapy. They are intimately familiar with the therapy method and protocol. The current supervisors have all published results from MAPS-sponsored Phase 2 trials, and are the trainers in our MDMA Therapy Training Program. They currently include Annie Mithoefer, B.S.N., Marcela Ot'alora, L.P.C., and Michael Mithoefer, M.D.

Supervision in our current active open-label Phase 2 "lead-in" trials is closely linked to adherence rating. Adherence rating is the process of evaluating video-recorded therapy sessions according to specific criteria, assessing how closely co-therapy pairs adhere to the *Treatment Manual* and study protocol. Both adherence rating and supervision ensure a standardized therapeutic approach across many sites with dozens of providers. This standardized method increases data efficacy in clinical trials, as well as consistency and quality of care for study participants. The ratings serve as an internal cross-check, ensuring that the modality outlined in the protocol is indeed the same modality used at each study site. Adherence ratings also provide a feedback loop for training, highlighting areas where providers need more support, and where the training program can update its curriculum for future cohorts.

Examples of adherence criteria include such statements as "Therapists inquired about the participant's knowledge regarding PTSD and/or provided education about it as needed" and "Therapists created and communicated a setting of safety and support." Each criterion is rated "Yes" or "No." There are 24 adherence criteria for Preparatory Sessions, 20 for Experimental Sessions, and 12 for Integrative Sessions. Additionally, there are eight Competence Criteria for each session type. The *Adherence Rater Manual* is currently being updated, and will soon be available online.

Adherence raters undergo a six-month training to learn how to view and rate therapy sessions according to the adherence criteria. Adherence rater trainees are graduate students or professionals in the mental health field who are competent in patient confidentiality. Twelve Adherence raters are currently working on open-label Phase 2 trials in the US and Canada. Another 19 trainees are nearly complete with their six-month training for adherence rating of upcoming Phase 3 trials in the US and Canada. Additionally, a group of bilingual Adherence Raters will be trained to conduct ratings for future trials in Israel and across Europe.

To assist in the added function of supervision, adherence raters collaborate with supervisors to streamline the process of watching hundreds of recorded therapy sessions, rating therapist adherence and providing feedback for the co-therapy pair. While supervisors are the experts on the therapeutic modality, the adherence raters support them by pinpointing timestamps of interest and summarizing the activity of the session.

The technology required for adherence rating and supervision is elaborate. Audio-visual equipment at each study site records every moment of a therapy session and can be immediately uploaded to a secure video server only accessible to authorized users. Within 24 hours of the therapy session, the video is processed into a secure portal for adherence raters and supervisors to access through an encrypted link. Comments are made directly into the video portal, and adherence ratings are entered into the study database. Each piece of equipment and step of the process is supported by an MPBC staff member who closely monitors that everything is working properly and securely.

After successful upload of the video and completion of the adherence rating, the supervisor views the therapy session, reviewing the adherence ratings, timestamps, and comments from the adherence rater. The supervisor then makes their own assessment and adds their own comments to the video portal. Finally, the supervisor provides feedback to the co-therapy pair through regular supervision meetings via video conferencing. These supervision meetings take place before each experimental session so that therapists can make improvements and incorporate feedback before the next treatment.

At the time of this writing, nine co-therapy pairs have enrolled study participants in the US open-label Phase 2 trial, and are meeting regularly with their supervisor. In the coming weeks and months, dozens more co-therapy pairs will join them. The newly designed supervision process is effectively supporting co-therapy pairs in their growth and ability to conduct competent and compassionate treatment for participants enrolled in MDMA-assisted psychotherapy clinical trials.

Shannon Clare Carlin *is passionate about life and growth. She cares deeply about humankind and the natural world. Shannon is dedicated to working with people through addiction, trauma, relationship, and the body. She received her Master's Degree in Integral Counseling Psychology from the California Institute of Integral Studies in 2014, including a practicum working with youth on moderation management for drug and alcohol use. At MPBC Shannon serves as MDMA Therapy Training Program Manager, overseeing administration and program development to educate professionals and researchers to provide MDMA-assisted psychotherapy for PTSD in approved settings. Shannon is also committed to psychedelic harm reduction, and continues to provide integration services through the Zendo Project. Shannon served as co-therapist on the MAPS-sponsored Phase 2 trial researching MDMA-assisted psychotherapy for anxiety associated with life-threatening illness, and will be a co-therapist at the Phase 3 site in Los Angeles, researching MDMA-assisted psychotherapy for severe PTSD. She is a dancer and California native. An adventurer at heart, Shannon can be found running in nature or swimming in a body of water. She can be reached at shannon@mapsbcorp.com.*

The Right to Science and Freedom of Research with Scheduled Substances:

MAPS at the United Nations 61st Commission on Narcotic Drugs

NATALIE LYLA GINSBERG, M.S.W., MAPS POLICY & ADVOCACY DIRECTOR

Natalie Lyla Ginsberg, M.S.W.

On March 15th, 2018, the Multidisciplinary Association for Psychedelic Studies (MAPS) and the government of the Czech Republic hosted a panel event at the United Nations 61st Commission on Narcotic Drugs in Vienna, entitled the "Right to Science and Freedom of Research with Scheduled Substances." The event educated delegates about both barriers to and potential for increased research with psychoactive substances currently scheduled by the Single Convention on Narcotic Drugs. Originally drafted in 1961, the Single Convention is the primary international drug control treaty; the substances included on its list are internationally criminalized, outside of limited exceptions for research and medical use.

MAPS hosted the event and participated in the UN Commission on Narcotic Drugs thanks to the United Nations Economic and Social Council (ECOSOC), which granted MAPS official consultative status in the spring of 2017, after a two-year application process. In addition to co-sponsoring the event with the Czech government, MAPS also partnered with fellow non-governmental organizations (NGOs) including the International Center for Ethnobotanical Education Research and Service (ICEERS), Veterans for Medical Cannabis Access (VMCA), the Foundation for Alternative Approaches to Addiction (FAAAT), and Associazone Luca Coscioni.

Our panel was moderated by former Italian senator Marco Perduca, who currently coordinates international activities for the Associazone Luca Conscioni. In April 2018, Perduca also organized the World Congress for Freedom of Scientific Research (**freedomofresearch.org**) at the European Parliament in Brussels, and invited MAPS' founder and executive director Rick Doblin to speak.

Dr. Ludovica Poli, International Human Rights Law Professor at the University of Turin, opened the panel by reviewing existing international frameworks as they pertain to the human right to science. She explained that the right to "enjoy the benefits of scientific progress and its applications" is enshrined in the International Covenant on Economic, Social and Cultural Rights, part of the International Bill of Human Rights. Part III, Article 15 declares that:

> *The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity…[and] the steps to be taken by [States] to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.*

Dr. Poli explained that when the bill was drafted in the 1950s, science was heralded as a powerful vehicle to implement human rights, thanks to excitement around new medical and agricultural advances. By the 1970s, however, the international community had grown more fearful and suspicious of science and technology impinging on human rights.

The next presenter on our panel was psychologist Dr. Jose Carlos Bouso, Scientific Director of ICEERS. Bouso focused on the limitations of the Western clinical model of research on psychedelic plants, He argued that the largest barrier to this research is the regimented methodology of Western science, which is compounded by the dominant political and scientific ideology that stigmatizes psychedelic plants. These stigmas, he said, have given birth to onerous, bureaucratic requirements for research, and even

Vienna, Austria: Panelists at the United Nations Commission on Narcotic Drugs side event, Right to Science and Freedom of Research with Scheduled Substances (left to right): Jindrich Voboril (National Coordinator for Drug Policy of the Czech Republic), Michael Krawitz (Founder and Excecutive Director of Veterans for Medical Cannabis Access), Natalie Ginsberg, (Policy & Advocacy Director for MAPS), Dr. Jose Carlos Bouso, (Scientific Director for ICEERS), Dr. Ludovica Poli (Law Professor at University of Turin) and Marco Perduca (Coordinator of International Activities at Associazone Luca Conscioni)

more problematically, have also produced a hierarchy of research that assigns more value to some types of evidence over others.

The randomized, double-blind, placebo-controlled trial is the gold standard of scientific research, but, Dr. Bouso asks, how can you give a shaman placebo ayahuasca? According to Dr. Bouso, it is "impossible to differentiate the traditional medicine from the culture." He believes this lack of distinction makes modern clinical research poorly suited to replicate or evaluate traditional practices with psychedelic plants.

Next, I presented an update about MAPS' clinical drug development research and the barriers we face, particularly in researching cannabis, from my perspective as MAPS' Policy and Advocacy Director. Many in attendance were surprised to discover that MAPS encounters more difficulty conducting research with cannabis than with MDMA, due to the U.S. government's monopoly on cannabis for federally regulated research. Since 1967, the National Institute on Drug Abuse (NIDA) at the University of Mississippi has been the only federally legal cannabis cultivator, despite the proliferation of legal state cannabis programs. Because there are no private cannabis producers, there is no cannabis eligible for the Phase 3 drug development research in the U.S. In the U.S., though the Drug Enforcement Administration (DEA) announced its intentions to grant more licenses in the summer of 2016, current Attorney General Jeff Sessions is not allowing those licenses to be granted.

By comparison, the UK has issued private cannabis cultivation licenses although it has not yet legalized medical cannabis. For example, UK-based GW Pharmaceuticals developed and now sells Sativex®, the first cannabis-derived medicine to receive prescription approval, which has helped GW Pharmaceuticals maintain its approximately $3 billion market value. In April 2018, an FDA advisory panel also determined their support for GW's new cannabis product, Epidiolex®.

In my presentation, I also explained that the greatest difficulty for MDMA research is funding: though the U.S. government has spent millions of dollars on research trying to discover the harms of MDMA, it has not funded any research into its potential benefits. At the time of MDMA's scheduling in 1986, the chairman of the World Health Organization (WHO) Expert Committee on Drug Dependence was Dr. Paul Grof, who happened to be the brother of Dr. Stanislav Grof, one the founders of the field of psychedelic therapy. At the time, Dr. Grof objected to MDMA's placement in Schedule I, which should be reserved for drugs with no medical use and a high potential for abuse, explaining that the only research referenced in the scheduling decision was on a different but related compound (MDA) that had been administered to rats in frequent and high doses. At the time of MDMA's scheduling, the WHO's 22nd Report of the Expert Committee on Drug Dependence stated that "No data are available concerning [MDMA's] clinical abuse liability, nature and magnitude of associated public health or social problems." Though MDMA had been administered legally in therapeutic settings for over a decade, the committee determined that there were insufficient controlled, clinical data supporting MDMA's therapeutic use. Since then, MAPS has privately fundraised and sponsored the only therapeutic research with MDMA since its scheduling.

In the next panel presentation, Michael Krawitz—longtime UN cannabis activist and VMCA founder and executive director—provided heartfelt testimony about American veterans' demand for more cannabis research in order to find alternatives to current treatments for a variety of conditions. Medical practitioners and insurance companies are resistant to recommending cannabis without clinical research, which leaves veterans, in Krawitz's words, "stuffed full of oxycodone." He described how the two U.S. Food and Drug Administration

(FDA)-approved psychiatric medications for PTSD (sertraline/Zoloft® and paroxetine/Paxil®), list suicidality as a side effect, and wonders how an acceptable "side effect" can be the same as the worst symptom. In many states, he added, if veterans test positive for cannabis, they can lose access to treatment and their other medications.

Krawitz explained that the current placement of cannabis in the most restrictive schedule, which makes cannabis research extremely difficult or impossible in most countries, has not been reviewed since 1935. The treaty, he emphatically explained, "was created in antiquity." For context, the inaugural U.S. "drug czar" from 1930–1962, Harry Anslinger, who helped launch the global war on drug users, wrote at the time that most cannabis users:

> *…are Negroes, Hispanics, Filipinos, and entertainers. Their Satanic music, jazz, and swing, result from marijuana use. This marijuana causes white women to seek sexual relations with Negroes, entertainers, and any others.*

Krawitz concluded on an encouraging note. In June 2018, the 40th meeting of the WHO Expert Committee on Drug Dependence will review current scientific knowledge about the cannabis plant and its various preparations and components, and may recommend changes in cannabis' international scheduling if the committee draws different conclusions based on the substantial research that has occurred since 1935.

The panel concluded with comments from Jindrich Voboril, National Coordinator for Drug Policy of the Czech Republic. Voboril is known as one of the world's most progressive "drug czars," as he is a vocal advocate for harm reduction, decriminalization, and other evidence-based approaches to the drug regulation. I first connected with Voboril at the 2016 UN Commission on Narcotic Drugs, where he expressed support for MAPS' research and interest in learning more about our treatment model. He has worked for decades with people who use drugs and who struggle with problematic substance use.

On the panel, Voboril spoke about the Czech Republic's rich history of supporting psychedelic research, and current possibilities for research in his country. Voboril described how Czechoslovakia hosted LSD research long after other countries shut down programs, starting in the 1950s when Dr. Stanislav Grof began his LSD research in Prague. When Czech research came to a temporary halt in 1974, Voboril explains that it "was not because there wasn't a will to continue, but because [there was] no money." The Czech Republic has restarted its psychedelic research program in recent years, and is currently the only national government funding research on psychedelics that is not focused exclusively on their potential harms. Voboril explained that it is "very much up to the boldness of the country to make the move forward" because "conventions are administrative barriers, [and] cannot stop us from research."

In 2017, Voboril attended the MAPS MDMA Therapy Training Program in California, along with several Czech therapists and researchers who will be hosting a MAPS-sponsored European Phase 3 site. Voboril concluded his presentation with this observation:

> *As a person from the treatment area, I don't understand—if there is a medicine, why not use it? How can anyone point to the conventions and say it's not possible, because we know it's possible? As much as we are critical of the Conventions, still even under the Conventions, [the] people who were drafting it were swearing that this will be accessible to all substances that we call drugs for medical purposes, so I see no reasons this should be stopped.*

As if in response to Voboril's call to be bold, the first comment from the audience was posed by a member of the American delegation who works for the FDA, offering his support and time! He identified himself as "the guy who writes the federal registry notice at the FDA" and who was "on the human use committee for cannabis use at one time." He continued:

> *I just want to say thanks very much. I don't disagree with [you that there are] the barriers [you list, but] there is another side of the story, on the government side, and I'll just have you know that at the FDA, our job, our purpose, is to make safe and effective medicines available. Our number one thing. We're not on a different team, we're on the same team…I'm available if you have any questions."*

Amidst a less-than-encouraging experience at the Commission on Narcotic Drugs over all, where countries failed for the first time in the CND's 61 years to find consensus, this side event offered hope and a way forward for many of us in the room. The need for more medical research should not be controversial, and fortunately representatives from across the political spectrum agree. Our work ahead internationally, similar to our work in the U.S., will continue to focus on providing frameworks for those who vocally support eliminating research barriers to actually take political action.

Natalie Lyla Ginsberg, M.S.W., *earned her Master's in Social Work from Columbia University in 2014, and her Bachelor's in History from Yale University in 2011. At Columbia, Natalie served as a Policy Fellow at the Drug Policy Alliance, where she helped legalize medical marijuana in her home state of New York, and worked to end New York's racist marijuana arrests. Natalie has also worked as a court-mandated therapist for individuals arrested for prostitution and drug-related offenses, and as a middle school guidance counselor at an NYC public school. Natalie's clinical work with trauma survivors spurred her interest in psychedelic-assisted therapy, which she believes can ease a wide variety of both mental and physical ailments by addressing the root cause of individuals' difficulties, rather than their symptoms. Through her work at MAPS, Natalie advocates for research to provide evidence-based alternatives to both the war on drugs and the current mental health paradigm. She can be reached at natalie@maps.org.*

From the Personal to the Political: Why Psychedelic Therapy is a Bipartisan Issue

SGT(R) JONATHAN M LUBECKY, MAPS VETERANS & GOVERNMENTAL AFFAIRS LIAISON

SGT(R) Jonathan M Lubecky
image: Kyra Wiener

For me, this is personal. I fight this battle so a son can have his father at his graduation, so a daughter can be walked down the aisle, so a wife can watch her husband bounce his grandchild on his knee, rather than a ten-year-old being handed a folded flag "on behalf of a grateful nation," as my son almost was.

If you had told me ten years ago that I would be attending the Conservative Political Action Conference (CPAC) to extol the virtues of psychedelic therapy, I would have thought you were crazy. Yet that is exactly what I did from February 21-24, 2018. It was far more successful than I could have imagined.

I know that the idea and reality of news organizations such as Breitbart covering psychedelic research concerns some supporters of the Multidisciplinary Association for Psychedelic Studies (MAPS), which was clear from a few comments MAPS received on the very positive Breitbart article about MDMA-assisted psychotherapy research it shared a few months ago. However, in order to effectively change public opinion, we need to be speaking to the *whole* public, which means that we also need bipartisan support and bipartisan news coverage of the critical research MAPS is conducting. The reality of the situation is that at this time, Republicans control the White House, the Senate, and the House of Representatives. It is imperative that the research be expanded, which also means those on the political right must understand what MAPS is, and even more importantly, what MAPS is not.

We all know how important the research MAPS conducts is to those who are suffering. For me, it is personal. I once had severe posttraumatic stress disorder (PTSD) from my service in Iraq, with multiple suicide attempts. I found MAPS at a critical time, and my relationship with MAPS has been transformative. I was a participant in the MDMA trial in 2014. More recently, I started doing interviews in the media to spread the word. However, while the mainstream media and left-leaning media were open to the idea of covering psychedelic research, the conservative media was not. Thanks to polarization and tribalism, especially on social media, a large segment of the American population was not hearing about the research. So, MAPS launched a concerted effort to get more conservative media outlets to cover the research. The first opening was when the U.S. Food and Drug Administration (FDA) declared MDMA-assisted psychotherapy a Breakthrough Therapy, and almost every media outlet did a story on it. Even Breitbart ran an article, in part because the reporter actually knew me personally and I had told him how it helped me. This was the first event that broke news of MAPS's research into the conservative world.

Two other major events occurred that made my outreach at CPAC far more successful than originally anticipated. The first was the Mercer Family Foundation's donation of $1 million to MAPS, signaling true bipartisan support for the work that MAPS conducts. The second, sadly, was the school shooting in Parkland, Florida. CPAC is very supportive of the 2nd Amendment, so due to the shooting, mental health and ways to treat the mentally ill were constant topics throughout the conference. These two events opened the doors to numerous conservative media personalities and programs reporting on MAPS at CPAC.

Jonathan Lubecky was Veterans Coalition National Co-Chair for Rand Paul's 2016 presidential campaign (above); and currently advocates for MAPS research alongside Ismail Ali, MAPS' Policy & Advocacy Counsel (right).

Matt Boyle of Breitbart Radio interviewed me about ending the National Institute on Drug Abuse (NIDA) monopoly on marijuana for research, and about the MDMA treatment, as well as several local conservative talk radio programs. Patriot Radio on SiriusXM now has a few shows that are interested in covering MAPS more regularly, looking at all their research, not just at PTSD. This will allow MAPS to spread the word to a wider audience; and right now, this audience is listening. Truly, the list of those listening at CPAC was astounding: I discussed MAPS and psychedelic research with Sean Hannity, Andrew Wilkow, Breitbart, Nigel Farage (UK MP), Matt Schlapp (President of the American Conservative Union, which organizes CPAC), Sheriff David Clarke, Grover Norquist, and others.

The expansion and continuation of MAPS critical research endeavors deserves support, irrespective of party affiliation. Reducing suffering is not a Republican or Democrat issue, it is an American issue. We have the science to convince them of the value of psychedelic research; however, we also need to convince their constituents in their home states or districts. That base has preconceived notions concerning drugs in general, and concerning psychedelics in particular. The way to change their mind is to talk to them, with accurate information reported through the media outlets they trust. No Democrat will ever convince Jeff Sessions or Donald Trump to end the NIDA monopoly or support MAPS' work, but their bases can, and so can Republican politicians. Obtaining bipartisan media coverage is a critical component of accomplishing this task.

For me, this is personal. I fight this battle so a son can have his father at his graduation, so a daughter can be walked down the aisle, so a wife can watch her husband bounce his grandchild on his knee, rather than a ten-year-old being handed a folded flag "on behalf of a grateful nation," as my son almost was.

For these reasons, I am happy to announce that MAPS has hired me to be their Veterans & Governmental Affairs Liaison. I will continue to attempt to bridge the divide and inform veterans, elected officials, and others of the truly groundbreaking research that MAPS is sponsoring. Rick Doblin, Michael Mithoefer, and Annie Mithoefer saved my life, not because they hoped I would help, but because I needed saving. I now have the perfect job: I get to help my brothers- and sisters-in-arms, work in politics, and ensure that those who are suffering get the treatment they need.

Sgt(R) Jonathan Lubecky *served 4 years in the US Marines Corps and 8 years in the US Army. He was was deployed to Iraq from 2005 to 2006 and returned home with severe PTSD, as well as a brain injury. Lubecky participated in MAPS' Phase 2 study of MDMA-assisted psychotherapy for PTSD and experienced a 50% reduction in his symptoms. He is now working as a political consultant. He can be reached at jonathan@maps.org.*

I Tried MDMA-Assisted Psychotherapy, and I Still Have PTSD: Here's What I Think About It

KRISTINA CIZMAR EKLUND

Kristina Cizmar Eklund

If you've heard of MDMA-assisted psychotherapy for treating posttraumatic stress disorder (PTSD), you've probably also heard that a huge percentage of those who've tried it reach full recovery. But what about the people who don't—people like me?

I'm a middle-aged woman with complex trauma and treatment-resistant PTSD. Diagnoses aside, I am a seemingly normal high-functioning human being who survived rather horrific childhood abuse, sexual and otherwise.

Like it or not, these things from my past impact my present day. At various times in my adult life, I've struggled with unhealthy relationships, addiction, sudden emotional swings, episodes of depression and suicidal ideation, avoidance behaviors, poor posture from a lifetime of shame, chronic migraines, and digestive problems. The hardest to live with by far has been the flashbacks, which can happen at any time including while I'm driving, shopping, or at work. Flashbacks are more than just memories. Traumatic flashbacks are times when I experience events from my childhood as if they are happening *in the present*. Even this might not sound that bad really—after all, my childhood is over and I do know that. But traumatic flashbacks are much worse than you can possibly imagine if you've never had one. These flashbacks are fresh experiences of terror, happening in the here and now as if I am that helpless child with nowhere to go and no safe person to turn to. There *is no way out,* and *there will be no help.*

When I heard of MDMA-assisted psychotherapy, I had already lived through more than nine years of flashbacks and trauma processing, interspersed with several plateaus where I inevitably thought, "This time, for sure, I'm fully healed!" I had tried every treatment I could find—things like craniosacral, acupuncture, EMDR, Somatic Experiencing, Trauma Releasing Exercises (TRE), various energy healing techniques, and trauma-informed therapy and support groups. Most things helped a little, but nothing provided the kind of relief I hoped for.

When I first tried MDMA-assisted psychotherapy, I was on the verge of a new wave of flashbacks around the single most terrifying event of my childhood—an event so unbearably soul-killing, painful, and lonely that I know if I had to go through these flashbacks the "old-fashioned" way, I would have committed suicide. Period.

So, I sought out something drastically different. Make no mistake about it: PTSD can be as life threatening as cancer. I read up on MDMA-assisted psychotherapy in the way someone with a terminal illness might latch on to some new promising cure. The research was ongoing, but for me the results were already strong enough to offer me hope.

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When the morning of my first session arrived, I had to drag myself out of the house. Of course I rationally wanted to do this, but I also felt the dread of not wanting to go into the awful things that would surely come up. Knowing my other option was to let flashbacks come up randomly, with no support, I made it to the therapy room. I am no stranger to therapists' couches, so once there I settled in. This was set up differently—so I could lie down with covers and get cozy if I wanted to.

I recognized and appreciated the care taken to convey that I was in charge—that

this treatment was not being put on me, but rather was chosen by me, and that I could also change my mind at any time, and know that that too would be honored. My therapist handed me the bowl with the medicine, and I took it of my own free will.

Trauma doesn't heal in a linear fashion. It circles around in tighter and tighter circles, throwing up one buried unbearable emotion at a time, starting with terror and shame. At least, that's been my experience. Analyzing my experience is what I do. It's what I've always done. Since childhood, analyzing has been my #1 survival strategy, because when I analyze something I create distance between myself and that thing. The result? I'm pretty good at analyzing, and sometimes I've lived at a safe distance from my own life.

There's no way I could describe a full MDMA-assisted psychotherapy session in a linear fashion. What I wish to offer here are a few snippets of the sessions, in imperfect order. Each session was a container for a multitude of healing experiences. It would take a book to try to share them all.

I lay down, pulled a blanket over myself, and noticed the music. Music has such a beautiful way of eliciting emotion and is a key element of the sessions, in a way I appreciate but don't fully comprehend. I've always loved the way the lyrics or even the pure emotion of a song have the power to offer me companionship—a kind of empathy that transcends time and space.

It wasn't long before a young version of myself—the one who bore the brunt of my childhood pain, spoke up loud and clear. This was not imagined or contrived, but simply organic and genuine. The words seemed to be spoken in a younger version of my own voice. These words revealed numerous sad faulty beliefs that had been embedded in my psyche since childhood. The words that came also revealed the pain of being left behind and pushed away by present-day me—who really just wanted to move on and "get over it" (which, by the way is the #1 most unhelpful thing to suggest to an adult survivor of childhood sexual abuse).

The words I spoke the most often in that first session were directed towards my therapist. Perhaps I should be ashamed to share those words here. But truthfully, I'm more ashamed to live in a world where children who are molested are shamed rather than protected or supported. So, I will share the words that came:

"And you don't want to have sex with me?!"

Okay, so let me get this straight: Someone is being really exceptionally nice to me, *and* (thanks to MDMA-assisted psychotherapy) I'm letting that niceness sink in to my being, *and* they don't want to have sex with me in return?! But why else would they be *that nice* to me?! My young self was terribly confused by this.

No wonder I could never let kindness in. Before the session I had not been consciously aware that I had such a deep association between kindness and being sexually manipulated. These words came tentatively at first, and then eventually I asked the question with more confidence and even joy. "And you don't want to have sex with me!" My inner child was delighted by this revelation. Thankfully I was on a therapist's sofa, and not in a nightclub.

There is a heaviness that descends on my body and mind in my deepest trauma, when I was left for dead as a child. My body assumed the position I was in back then. My jaw started shaking like a wind-up toy that's been wound up well beyond its capacity, and it's now letting it all go. My arms and legs moved to escape. My therapist pushes against me so that my muscles could do what they were trying to do—reliving the movements from decades earlier. I faded in and out of conscious awareness as my jaw continued shaking at breakneck speed, beginning to release all that had been pent up in me. My therapist held my hand through the whole thing, and every time I flickered my eyes open, she was there, with kind attention. I could feel her attentive presence. I was no longer alone in this. Hours seemed to pass in this way.

I had brought a water bottle and a rehydration drink with me to the session, but they ran out. My therapist offered and then delivered to me a glass of water. It seemed to me as though her intentions of kindness and care flavored the water. I felt myself literally drinking in her care along with the water. This "care water" tasted even better than my own water had, and my therapist happily brought me as much as I wanted. All I had to do was ask, and there was more care water. I felt as though I was learning to ask for and receive care in an entirely new way.

> *Other trauma treatment modalities gave me hard-won baby steps towards healing; MDMA-assisted psychotherapy gave me an empowering rocket ride with me in the driver's seat.*

A song began to play that I didn't like. It grated on my nerves. I asked to skip the song, feeling good in the moment about exercising my free choice. My therapist made a note. I don't recall her words, but I made my own mental note of how curious this was—as though not wanting to hear some piece of music indicated there was something within me that I also did not want to hear.

The time came to leave the session. I felt quite fine. Lighter and happier in body and spirit. It was early evening and I felt tired and relieved. Mild confusion set in because although I've grown accustomed to paying for therapy, something new had been given to me, something money can't buy.

I had a vision, as though I was walking along the edge of a cliff. My path was smooth and beautiful, blue skies and sunshine, ambling onwards. Down below off the edge of the cliff to my left I could see the low shadows of the path I hadn't taken. It looked rocky down there, and I could see from above that it soon hit a dead end. I felt blessed to no longer be on that path.

Side effects I noticed: smiles and gratitude. And probably best not to drive for a day or so.

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So, what do I really think about MDMA-assisted psychotherapy? MDMA-assisted psychotherapy is light years ahead of every other current approach to healing trauma. That is what I think. And here's why.

MDMA-assisted psychotherapy helped me:

1. Process trauma more quickly, so that I could start to get my life back now. In just a couple eight-hour sessions I processed through what I could feel would have taken me many years to resolve.

2. Do the work of healing without feeling overwhelmed. During each session I could work with deep trauma with a clarity of mind that allowed me to stay present without being flooded by terror, despair, and other intense emotions.

3. Suspend the part of me that avoided going into the pain. I could approach what I needed to work on without fighting myself.

4. Feel with certainty that PTSD was neither a failure of my willpower nor a sign of weak character. My fear response was simply stuck doing what it does best—keeping me alive. Feeling this helped me shift from shame to self-appreciation.

5. Stay present during all subsequent flashbacks. The single most terrifying aspect of my flashbacks had always been that I would be 100% in the past, with no sense of present safety. After my very first session, this seems to have permanently changed. I still have flashbacks, but my present-day self who knows I survived and knows I have resources gets to stay present as a grounding self-witness.

6. Feel empowered to heal on *my* terms. There is a huge difference between making an appointment for a dedicated day to work on my trauma with skilled help, versus having random intrusive flashbacks. The latter often left me feeling just as powerless as I had been during the original trauma.

7. Feel how strong my body is, and always has been. I couldn't believe how much trauma and suppressed startle responses released from my body during the sessions. No wonder I would get tired so easily—it clearly took a lot of energy to hold all that in!

8. Experience what it could feel like to not have my body be constantly "on guard" for the next threat. I wasn't aware that I had been walking around with my eyes popped out and my hips shot forward. After the sessions, my body held on to a new memory of what normal could feel like, which continues to help me remain more aware of my body.

9. Receive care from another human being without feeling triggered. As someone who was abused by "caregivers," I had learned that things like relationships, feeling safe, and receiving care were sure signs of danger. So how could I make progress when the basic things I needed in order to heal were themselves trauma triggers? MDMA-assisted psychotherapy helped me bypass my conditioned fear and make relatively effortless progress on this previously impossible piece.

10. Allow "inner child" parts of myself to be seen and heard. These are the parts that had gotten locked away in my psyche, along with all the traumatic experiences, unprocessed emotions, and basic needs that I had no hope of meeting as a child. In other words, all the things in me that needed healing were given voice and a safe space to come forward in a way I'd never before experienced.

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If it's so amazing, then why do I still have PTSD? Yes, I still have PTSD after a couple sessions, but that doesn't mean I didn't benefit immensely. I did. And my work isn't over. My life keeps getting better, and then sometimes it gets worse again. The difference is that I have felt true support in my being, and I have felt healing happen rapidly. The music serves as a reminder.

In the time following my treatment, I married a man who also deeply appreciates the emotional power of music. I'm able to be more present and open with my daughter. Sometimes I'm able to focus solely on things that are important to me in the present day. And sometimes, still, I can't.

I continue to have traumatic flashbacks, but they are fundamentally different than before. I call them "lucid flashbacks"—because as with lucid dreaming, I have some present moment awareness, and can even exert some control or reach out for support while they are happening. This wasn't possible for me before.

I still have a lot of trauma releasing from my body. After the sessions it's harder to stay at a healing plateau than it used to be, which sometimes is a blessing and sometimes a curse. I know I could be continuing to heal faster if I had access to more sessions. But I don't crave this in the way I would have craved a drug when I struggled with addiction. I feel grateful for the sessions I had, grateful to still be alive, and grateful to the people behind MAPS for working to make this treatment widely available. I've been through so much trauma, and I have felt so frustrated trying to heal. I'm not unique. There are so many people, including fellow survivors of childhood sexual abuse, who could benefit from this treatment.

Other trauma treatment modalities gave me hard-won baby steps towards healing; MDMA-assisted psychotherapy gave me an empowering rocket ride with me in the driver's seat—still doing the work—but finally a vehicle capable of supporting me in getting where I want to go.

Healing doesn't have to be so hard.

***Kristina Cizmar Eklund** works as an analyst at a university, teaches Emotion Yoga, and offers workshops on working with shame. View more of her story athealingcsa.org/the-film. She can be reached at kristina@healingCSA.org.*

Cryptocurrency Philanthropy Catapults Fundraising for Phase 3 Trials

MAPS, LIANA GILLOOLY, AARON MANGAL, BRIAN NORMAND, WESLEY THORICATHA

On March 9, 2018, the non-profit Multidisciplinary Association for Psychedelic Studies (MAPS) announced the successful completion of a $4 million matching grant from the Pineapple Fund for U.S. Food and Drug Administration (FDA) Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD).

On January 10, 2018, the Pineapple Fund, created by an anonymous cryptocurrency philanthropist known only as "Pine," announced that they would match the next $4 million in donations to support MAPS' upcoming Phase 3 trials, with a deadline of March 10 (**pineapplefund.org**). The announcement inspired $4 million in new gifts from over 550 individuals, which the Pineapple Fund matched in Bitcoin (BTC), for a total of $8 million. 149 of these new gifts, totaling $1,093,330, were received in cryptocurrency.

MAPS staff partipated in multiple panels at CryptoPsychedelic Summit, an event in Tulum, Mexico, that brought together leaders in blockchain and psychedelic science to discuss new possibilities in research, innovation, and community building.

The Pineapple Fund made their first gift to MAPS on December 14, 2017, with a donation of 59.89 BTC valued at $1 million. Several days after announcing the Pineapple Fund's first gift, on December 18, MAPS received a second large donation of 51.54 BTC from another anonymous donor. Then, on December 20, MAPS received 88,000 Lunyr (LUN) tokens worth over $769,000 from yet another anonymous donor.

"Pine's extraordinary generosity has inspired many others to rise to the challenge of his $4 million matching grant," said Rick Doblin, Ph.D., MAPS' founder and executive director. "We can now truly say that MDMA-assisted psychotherapy will be a gift to the world from the psychedelic and cryptocurrency communities, with MAPS having been unable to obtain any government funding for our research."

MAPS was an early supporter of cryptocurrency donations, first accepting Bitcoin donations (**maps.org/donate**) in December 2013. Currently, MAPS is able to accept donations in Bitcoin, Bitcoin Cash, Ethereum, Monero, or Litecoin. Since then, MAPS has received cryptocurrency donations totaling more than $7.5 million in support of its work.

As of April 2018, MAPS has raised $26.2 million of the $26.7 million needed for its upcoming FDA Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD. MAPS now needs only an additional $500,000 to complete funding for the final stage of research needed to make MDMA-assisted psychotherapy a legal prescription treatment for PTSD in the U.S. MAPS is currently seeking an additional $5 million for European Medicines Agency (EMA) trials to supplement the data gathered for the FDA.

CRYPTOPSYCHEDELIC: BLOCKCHAIN AND PSYCHEDELICS COME TOGETHER IN TULUM

An interview with Brian Normand by Wesley Thoricatha

*The original, longer version of this interview was first published in Psychedelic Times (**psychedelictimes.com**). Reprinted with permission from Psychedelic Times.*

Aside from philanthropy, how might blockchain technology help the causes of psychedelic research, drug policy reform, and fundraising? To explore this intersection, a groundbreaking event called CryptoPsychedelic (**cryptopsychedelic.com**) was held in Tulum, Mexico on February 3, 2018. Hosted by leading psychedelic advocacy group Psymposia and blockchain consulting firm Decentranet [and co-sponsored by MAPS], this summit brought together leaders and innovators from both of these worlds to ask forward-thinking questions while encouraging new connections and partnerships. Right before the event, Wesley Thoricatha of Psychedelic Times spoke with Psymposia co-founder Brian Normand about CryptoPsychedelic and the exciting possibilities that the event would explore.

These are people who see things differently, who want to make positive, long-lasting changes in a system where we see a lot of corruption. Both worlds are comprised of people who are looking to make things better.

WT: How did the idea of CryptoPsychedelic come about, and what are you hoping to accomplish?

BN: I started getting involved in blockchain technology over the summer. I had an interest in it back in 2012 right when Bitcoin started coming out. I was interested in it at the time because of the financial crash, but it never stuck. But for some reason, this summer I started really diving into it. I had heard of this thing called the Crypto Cruise in San Francisco, which was a small fundraiser for MAPS that sounded interesting. Nothing really came of that [for me] other than finding out some of the people who were organizing it, but it stayed on my radar.

Fast forward to December 2017: my partner Mike Margolies moved out to Oakland and the person he ended up rooming with was the guy who organized the Crypto Cruise. His name is Matt McKibbin, and he founded a group called Decentranet that works in a variety of blockchain products, consulting, and related areas. We started talking immediately about, hey, we've had this cruise, why not plan a more formal event? Then the Pineapple Fund came around and that got huge amounts of attention, showing that people in the crypto world have the ability to fund projects at this scale.

We've had a very short time to plan it; everything has come together really within the last few weeks. CryptoPsychedelic is not really a conference—it's more of a summit where we want to ask questions about how each of these different fields can work with one another. Is there common ground here? Can crypto and blockchain be applied to psychedelic advocacy? Can it be applied to issues that we face with the war on drugs and prohibition? The idea of this event is to put people from these different communities in the same room and get them talking to one another. Our focus is on forming relationships and building a new community so that moving forward, we can get to know one another. That's really what we want to do with this event.

WT: I think there is some really compelling shared territory between these two worlds. With psychedelics you have the cognitive liberty movement, and with cryptocurrency it's all about economic liberty. At the core, it's about freedom, in a sense.

BN: Yeah, I think you hit on it with freedom: the ability to make your own decisions. One of the things I want to touch on as a common ground in both of these fields is regulation. This is a core issue that both the crypto world and psychedelics face. That's something that I would really like to explore—the parallels between both of these worlds, and the spectrum between government regulations and self-governance. I think you're going to see increasing regulation attempts in the U.S. in terms of ICOs and considering tokens securities. A lot of different things are going to start being talked about by regulators, but it's not going to stop the momentum, just like prohibition is not going to stop drug use. I think that's where these fields are sort of at right now. It's interesting to me how they both have the potential to invert existing paradigms.

WT: Yeah, absolutely. They seem to both be part of the new paradigm emerging within the old one, and so there's friction there of course, but both seem inevitable. Psychedelics will completely revolutionize the field of mental health and have a ton of cascade effects, just like crypto is going to completely revolutionize economics and banking and have a ton of cascade effects as well.

BN: I think there's a lot of crossover between people who are interested in crypto, decentralized applications, and use cases, and the people who are looking at psychedelics for mental health, cognitive liberty, PTSD, and all these things. These are people who see things differently, who want to make positive, long-lasting changes in a system where we see a lot of corruption. Both worlds are comprised of people who are looking to make things better.

WT: It's really exciting. So for this event, can you describe the format?

BN: There will be four conversation panels. One is going to focus on the science and research behind psychedelics. Another one is going to focus on drug reform advocacy, going beyond the research and using the science to inform different directions we're heading. Then we'll have a crypto panel and give an overview to the psychedelic people about what crypto is, where it is going, what the potential is—just an overview. Then we're going to mix both of those groups into a crypto-psychedelic panel. Not knowing what to expect is what's making this so fun. We don't have talks scheduled, and there are no presentations or speeches. It's really going to be an organic thing that just goes in whatever direction it goes.

CRYPTOPSYCHEDELIC: COLLIDING WORLDS

by Liana Sananda Gillooly

Over the past year, I have become integrated into the blockchain community, drawn by the technology's groundbreaking ability to transparently decentralize trust, and the community's emphasis on creating real improvements to our systems that can seismically shift the world.

I found that many of the original theorists and architects of this emergent technology were also psychedelics enthusiasts. The longstanding relationship between tech and psychedelics is well-documented, and even more overt in the crypto world.

I met Matt McKibbin through Natalie Ginsberg of MAPS ahead of the Cryptos & Psychonauts & Cannabis Cruise that he produced in the summer of 2017, which was the first time, to my knowledge, that leaders of these communities were brought together. Directly after the success of the dinner cruise, Matt determined that he would produce another event of a similar nature in Tulum, Mexico, in February. Fast forward a few months, and I had the great pleasure of introducing Matt to Mike Margolies, who was co-directing Psymposia at the time. Three days after they met, they excitedly informed me that they had partnered on the Tulum event, and decided to call it CryptoPsychedelic. Around this time, the Pineapple Fund made its first $1 million donation in Bitcoin to MAPS, bringing the relationship between these two communities to light.

I don't think any of us knew what to expect of the first-ever CryptoPsychedelic event. I found myself declaring that the point was to bring together two revolutionary communities of curious, intelligent, visionary people to see what kind of "brain-babies" could be made. If nothing else, this wouldn't be boring.

This event captured the crescendo both of these history-making communities are amidst. MDMA is in its final push through the FDA to become the first legal psychedelic medicine available in the US, while several cryptocurrencies have (at least briefly) exceeded the market cap of many mid-sized countries. Both of these tools have the potential to massively impact society. Timing is everything. I found myself reveling in the cosmic coincidence of the establishment of new wealth in a population keenly interested in social benefit, arriving at the pivotal moment when more capital than ever is needed to complete ground-breaking research into psychedelic therapies. The idea of staggering wealth landing in the hands of people supportive of our cause is truly exciting.

At the event, I discovered that most of the psychedelic and drug policy community were new to crypto, and many were skeptical of anything coming out of the tech community that claimed to hold the key to resolving major problems in the world. I also found that many psychedelic enthusiasts from the crypto world were unaware of the daily horrors of the illegal and racist war on drugs, and new to the great work of MAPS and long road of bringing groundbreaking therapies to the world. New synapses were created as these two networks collided.

Both groups were able to expand out of their respective echo chambers, becoming exposed to perspectives other than their own, exposing blind spots, and entertaining new avenues of growth.

I was aware of a deep tension felt by many of my peers in the drug policy world: Here is a population of people, generally perceived as privileged, seemingly creating wealth out of thin air, and declaring their intentions to transform the world with an intangible technology that is hard to grasp. And yet, our new allies, an inspiring group of mostly young crypto people shares the disillusionment of our current failing systems, and are ardently experimenting with building new models with the aim of rendering the existing model obsolete, have a unique set of capabilities that could hasten the ending of the drug war and legalizing of psychedelic therapy.

What emerged was a lot of mutually beneficial dialogue. Both groups were able to expand out of their respective echo chambers, becoming exposed to perspectives other than their own, exposing blind spots, and entertaining new avenues of growth. It was personal, and at times uncomfortable, as intentions and beliefs were carefully examined. Transformation can be messy. At times I found myself mediating between these communities, who spoke different dialects, and had their own way of going about improving the world. I felt my own perceptions tested. Ultimately, I left feeling like the work had only just begun, and feeling grateful for the willingness from all to do it, and the container to do it in.

There is a new technology emerging that stands to greatly impact our global systems and societal structures. These technologies take on the energy from which they were made. CryptoPsychedelic is an opportunity for us to purposefully imbue this emergent technology with the attributes inherent in the psychedelic experience: openness, connection, unity, unconditional love, and a sense of well-being. Additionally, our movement in mental health and drug policy reform can be fueled by a boon of resources, and influenced by whole systems thinking.

At CryptoPsychedelic, not only did we get to explore the ways in which these movements are impacting the world, we got to examine the ways in which these tools can impact each other.

CRYPTOPSYCHEDELIC: REFLECTIONS FROM MAPS STAFF

An interview with Merete Christiansen and Natalie Ginsberg by Aaron Mangal

After CryptoPsychedelic, Aaron Mangal caught up with Merete Christiansen, MAPS Executive Manager and Assistant to Rick Doblin, and Natalie Ginsberg, MAPS Policy and Advocacy Director, to reflect on their experience in Tulum and to explore what they're excited about at the intersection of cryptocurrencies and psychedelic science.

AM: How have you seen cryptocurrencies affect psychedelic research as a whole?

MC: Funding has been the most influential impact in my opinion. Cryptocurrencies are a relatively new form of value, and have brought wealth to many who previously did not have capacity to give to funding initiatives in such a major way. MAPS first started accepting Bitcoin donations in 2013. Since then, we've received well over $7 million in cryptocurrency donations.

AM: What are your thoughts on the mysterious cryptocurrency donor "Pine" and the Pineapple Fund?

NG: It's awesome. I'm really grateful. The $4 million matching grant from Pine was so inspiring to so many donors. It felt like Pine was activating the community, rather than just donating as an individual. In connecting to the crypto community I do think Pine was very helpful in inspiring donations by demonstrating the capacity for the crypto community to make change.

Something I heard at CryptoPsychedelic that I appreciated from the crypto community was a criticism of how traditional wealth is often held—people just sit on billions of dollars—which clogs up the system and prevents our financial system from flowing freely. I appreciate those in the crypto world who believe in moving that money now—there are such urgent problems that we simply cannot afford to wait. And by Pine just going "Here's $86 million dollars, boom, let's go!" Doing that in this way was just so inspiring.

The crypto community gets that it's time to make big change now. And they are not following the traditional model of just making money and sitting on it. They want to put that back into the community. This is not what everyone is doing, so this is why we need people like Pine to be inspiring that.

AM: What was the CryptoPsychedelic crowd like, and what were the conversations about?

MC: The event was unlike any event I've ever been to. Some psychedelic and crypto events are fairly niche events where most people there have a fundamental agreement on many topics. At CryptoPsychedelic, we brought two niche groups together that have many fundamental differences of opinion. It made for very interesting conversation! It was inspiring to see so many intelligent people learning from each other and having civil discourse about disagreements and differing opinions.

NG: It's true—people usually identified with either the cryptocurrency space or the psychedelic space, even though both spaces were interested in the other. It was quite funny because people were asking each other if they were a "cryp" or a "psych" person.

It was special to be in Tulum in such a beautiful venue for a summit that really facilitated us all connecting in meaningful ways. There were also some tensions because we do have very different approaches to work and what we're trying to do. But that was part of the process.

Lots of people who are in the crypto space say they don't trust anything, at least not the current systems, and cryptocurrency is their way of dealing with that. In the psychedelic world, it's kind of the opposite, where psychedelics are about trusting the universe and (in the extreme) trusting everything. So there's something really interesting about that tension, and how these communities are still clearly connected, and finding the value in each of these spaces.

Another tension I found was that the crypto space is very male-dominated, and especially white male dominated, and I'm concerned about what the implications are for this brand new developing space. I also saw a lot of openness around changing that which was really cool.

AM: What gets you most excited about the synergistic potential of cryptocurrency and the psychedelic research community?

MC: There is amazing potential in both the crypto and psychedelic spheres for innovation and new ways of interacting with ourselves and others. I'm excited about the opportunities that exist, especially for people who have been historically burdened and held back by our existing financial system, societal norms, and perpetuation of multi-generational trauma. Cryptocurrencies offer a new way of interacting financially, and if implemented responsibly, a new platform for participation on a global scale, raising up those who have been undeserved and undervalued. Likewise, psychedelics offer a potential for healing and self-growth that may be more effective than our current approaches to mental and physical healthcare by facilitating openness to new understandings of ourselves and our interconnectedness to each other and the planet.

The Zendo Project: Evolving Psychedelic Support Since 2012

RYAN BEAUREGARD

Ryan Beauregard

A HISTORY BEYOND THE ZENDO PROJECT

During the Zendo Project's Psychedelic Harm Reduction workshop at the Psychedelic Science 2017 Conference, I got to watch one of my elders and heroines share about the evolution of psychedelic support services since the 1960s. Annie Oak delivered a top-notch summary of the groups and leaders who have been present since this movement began. I highly recommend watching her talk, as part of the collection of videos from the conference available online (**psychedelicscience.org/videos**). Her recollection of this history has inspired me to share my perspective of the evolution of the Zendo Project since my involvement in 2013.

ABOUT THE ZENDO PROJECT

Creating a Community of Compassionate Care: The Zendo Project, started in 2012, is a psychedelic harm reduction community outreach program which provides tranquil spaces at events with trained volunteers to help those having a difficult psychedelic experience. Our goal is to help transform those experiences into ones that can offer valuable learning opportunities, and potentially even healing and growth.

FROM JUVENILE JANITORS TO COSMIC CUSTODIANS

In its infancy, the Zendo Project struggled to provide the staffing numbers to properly support an event. Whether it was having a limited number qualified volunteers or a lack of justification from the event's production team, we were often understaffed and under-resourced. In these earlier years, some medical and event security personnel saw us as an unnecessary part of event production. But as we continued to transform seemingly impossible situations into positive outcomes before the eyes of safety teams and production managers, our value was increasingly acknowledged and our reputation grew.

We have come to take pride in being what I sometimes call the cosmic custodians of the psychedelic festival scene. We exist to clean-up and care-take the resulting accidents that can occur when sleep deprivation, mental anguish, and trauma meet psychedelics. We have brought together a team that provides grounded, loving support for those facing the most unpleasant, challenging trips of their life.

Our veteran volunteers and staff who provide the Zendo Project's service are not here on a whim, not simply curious about the work. We're all extremely committed to the movement of psychedelic support. Over the last five years, I've seen us grow from a handful of volunteers and three annual events to a tribe of diverse and dedicated individuals giving our all, to ten distinct music and art gatherings in 2017.

OVER FOUR THOUSAND SUPPORTED

Our first year at Burning Man, in 2012, the Zendo Project supported over 100 guests. In 2013, we made our debut at Envision (Costa Rica), AfrikaBurn (South Africa), and Lightning in a Bottle (California). During those early years, our personnel was minimal, sometimes only two to four people at an event work-

ing around the clock. Some of our spaces in those days consisted of a three-person tent, or a leaky tropical lean-to with sarongs as makeshift walls. Fractal Planet, the art and music camp where we'd been based at Burning Man in 2012 and 2013, didn't return in 2014, and we made home with the camp organized by Dr. Bronner's, the international fair-trade soap and body products company (Dr. Bronner's has been a major supporter of MAPS and the Zendo Project, and their CEO, David Bronner, serves on the MAPS Board of Directors). Our 2014 location was almost hidden in comparison to our front-and-center presence at the previous year's sound camp, yet we still supported about 60 guests.

In 2015, we made the choice to set up and staff two locations at Burning Man, on opposite sides of the city, near what are called the 3:00 and 9:00 keyholes. We had a similar setup again in 2016, and in 2017 chose to consolidate our services to one location. This decision came with the support and suggestions of Burning Man's official Black Rock Rangers and Emergency Service Department, as well as the Burning Man organization, recognizing the value of our services in Black Rock City and wanting to utilize our support within their existing safety framework. From my perspective, this integration and appreciation came as a result of our longstanding relationship with the Burning Man organization, and our ongoing work at outside events where we continued to grow our cooperation and deepen our relationships with medics and security personnel.

From 2013–2016, our presence at AfrikaBurn (South Africa's regional Burning Man event) was focused on assisting the AfrikaBurn Rangers to set up and run their own sanctuary–a safe place for folks to land who need extra care and support in the middle of their psychedelic or psychological challenges. In 2015, Sara Gael, Brooke Balliett, and myself had the honor of connecting deeply with the international exchange program of AfrikaBurn rangers from the U.S. We had all interacted with one another over the course of the years on different Zendo Project calls or drop-offs, but for me, it was this experience that cemented our connection, deepening our relationship with the AfrikaBurn safety team. In my experience with sports teams, corporations, and non-profits, nothing creates cohesion in a team more than spending a week camping, eating, working, and playing together.

Since 2016, we've been increasing our presence at the events we attend, as well as forging new partnerships. In 2016, The same year, we began a partnership with the Drug Policy Alliance (DPA), providing peer support with one of the biggest production companies on the planet—Insomniac—best-known for their three-night 120,000+ person rave in Las Vegas known as the Electric Daisy Carnival (EDC). Since our first appearance at EDC 2016, where we successfully provided education at a multidisciplinary harm reduction booth, we subsequently began providing support services at a handful of other Insomniac events. Since then, the Zendo Project has also helped with Project #OpenTalk at eight Insomniac events. The goal of Project #OpenTalk, a collaborative initiative developed by Insomniac in collaboration with the Zendo Project, DPA, and Healthy Nightlife, is "connecting accurate and unbiased drug and sexual health information with crucial emotional support provided by trained peers together under one umbrella" (**insomniac.com**). From there, our involvement with Project #OpenTalk and Insomniac has grown to attending about half of the events they produce, and training their onsite "Ground Control" harm reduction staff in our model.

In 2017, thanks to our deepening relationships with event producers and expanded resources thanks to a successful crowdfunding campaign, we expanded even more. The Zendo Project's presence at Lightning in a Bottle increased from one location to two distinct locations. Last year, the Zendo Project supported over 1,500 people at seven events, including over 670 guests at Burning Man 2017, and over 250 at Lightning in a Bottle.

TRAININGS AND WORKSHOPS

In the last year, we've done six trainings outside of the festival circuit, including four private events, and two public workshops that provided Continuing Education credits. Our audience is no longer just festival-goers, but a diverse collection of business professionals, doctors, nurses, therapists, entrepreneurs, and event producers. Our last training in Washington, D.C., sold out, and still some people drove from over five hours away for the four-hour, standing-room-only training. Our services are greatly needed at festivals, so we have a constant stream of requests to attend events and train small organizations on how to provide their own version of psychedelic peer support services to their community. We continue to provide outreach, consultation, and resources to these individuals and groups.

These trainings have even extended to law enforcement. In 2016, Sara Gael gave a private informational session federal Bureau of Land Management Rangers at Burning Man. The overwhelming feedback after the training and throughout the event were of appreciation for the service we provide at the event.

As 2018 unfolds, we'll be holding a training specifically for emergency workers, and plan on delivering more trainings specifically for medical professionals and law enforcement personnel, to help those on the front lines provide more compassionate support to those in difficult psychedelic states. We'll also be making online trainings and psychedelic peer support certifications available to the public by the fall of 2018.

THE ZENDO PROJECT'S REPUTATION

Over the past three years, I've heard our name being used in the same way that Band-Aid™ or Kleenex™ is applied to their equivalent generic products. I get reports from festival-goers

about how thankful they were to have the Zendo Project at events we didn't attend, and have heard our name used as a verb in a forecast of a big night: "This acid is so strong, I'm going to get Zendo'ed!"

There is a question often posed to me by opponents of our work, as well as by curious devil's advocates: "Do you think the presence of the Zendo Project creates a safety net that encourages more irresponsible psychedelic use?" My response is, well, perhaps in the same way that the availability of emergency rooms may prompt some people not to wear their seatbelt, or to be careless with kitchen knives. While we're aware of this critique of safety nets in general, in the conversations we've had with the public, we've found that the Zendo Project is more likely to remind people to stay within certain boundaries than to encourage them to take larger doses of psychedelics—most would rather be out having fun with their friends than being cared for by us.

The Zendo Project is taking on the psychological waste and emotional discard of our culture, and performing the service of composting it into rich, nutritious soil, so that something new and beautiful may grow from it to feed our future.

Often, as party-goers pass by our tent or structure on their way to the big stage, groups will yell out, "We love you, Zendo!" and our unprompted volunteers at the greeter table will respond, "We love you, too!" Sometimes a friend or two will break off from the group and come to thank us for what we did for them or for their friend last night, or last year. Other times, the arrival of a high-energy and/or extremely disoriented guest brought in by medical or security staff helps remind passing groups of what can go wrong if the party gets too intense.

OUR TAGLINE

From the beginning, some within the community have been opposed to using the words "harm reduction." Over the past few years we've adopted the phrase "psychedelic peer support" to more accurately encapsulate the specific service that we're bringing to the community. Harm reduction as a practice involves such a wide range of services—including drug testing, drug education, and preventative measures—and the reality of our work is that we're dealing with individuals deep within their experiences and in need of immediate assistance from compassionate people in their own community.

ZENDO PROJECT AS A MOVEMENT

From our humble beginnings at Burning Man in 2012, to our integrated services with medical staff and Black Rock Rangers at Burning Man 2017, with our flyer being given out to every single one of the event's 70,000 attendees, we have seen our vision coming true. This encouragement of having been embraced by the public and event producers alike keeps us focused on continuing to provide these services to a larger and larger community.

Since the beginning, one of the biggest tragedies we've sometimes faced is having to pack up and remove our structure, staff, and support at the end of an event, while a guest is still needing care. We are acutely aware of the current lack of short- and long-term care for individuals facing psychotic breaks or spiritual awakenings who could greatly benefit from new approaches other than what pharmaceutical drugs and psychiatric wards can provide. As the Zendo Project expands, we're brainstorming, seeking creative paths, and making plans for providing more permanent spaces for people who need our care outside of festivals.

As new chapters unfold for the Zendo Project, and for the broader field of psychedelic harm reduction, we face new opportunities for growth, both as individuals and as an organization. We are continuing to streamline our logistics and operations so that the majority of our time and resources can be focused on what we are most passionate about in this work: being present, learning and improving in real time, and providing support simply by being grounded and compassionate when people are in crisis.

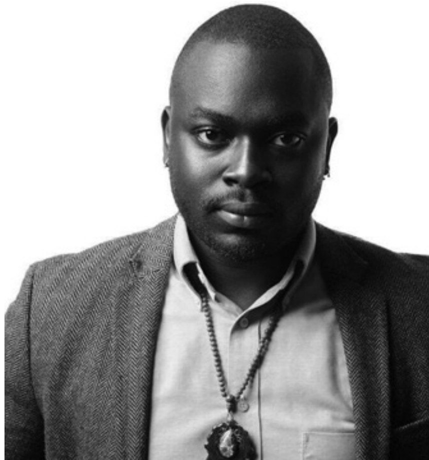
Although being at the bottom of the drain pipes can be hectic and chaotic work, those of us who find a home here are seemingly wired to be sustained by it. To use a metaphor from sustainable design science, the Zendo Project is taking on the psychological waste and emotional discard of our culture, and performing the service of composting it into rich, nutritious soil, so that something new and beautiful may grow from it to feed our future.

I—and all of us at the Zendo Project—share our deep gratitude for all the volunteers, donors, guests, and allies who have made it possible for us to show up at events all over the world and provide peer support for those in need. Please continue to follow our work and get involved by visiting our website, **zendoproject.org**. I'll see you out there.

Ryan Beauregard *received his B.A. in Psychology from Claremont McKenna College, and spent 10 years mentoring at-risk teens and families through wilderness survival skills and nature connection. His passion for community connection, the environment, and intrapersonal healing continued with his involvement in permaculture, natural building, and ancestral grief rituals. As a volunteer with the Zendo Project since 2013, Ryan has had the opportunity to connect and expand the scope of psychedelic harm reduction in communities and festivals all over the globe. As the Zendo Project Manager, he integrates his skills in psychology, design and and community engagement. He can be reached at ryan@maps.org.*

Psychedelic Integration Through Community Service: My Experience Starting a Psychedelic Society

KWASI ADUSEI



Kwasi Adusei

During a conversation I recently had with Colin Pugh of the Brooklyn Psychedelic Society, he asked a question that really resonated: "If society were more psychedelic, what would it look like?" One answer was obvious to me: It would be more giving!

Two years ago, in 2016, I hosted a Global Psychedelic Dinner (**psychedelicdinners.org**) to raise money for the Multidisciplinary Association for Psychedelic Studies (MAPS)' MDMA-assisted psychotherapy for PTSD research. Based on its success, I helped launch a psychedelic society in Buffalo, New York. From the beginning, I wondered what events could truly engage people in an effort to build community, foster discussion, and create opportunities for people to be truly psychedelic. How could we create not just a psychedelic society, but a society that was psychedelic, with psychedelic values? Again, the answer showed itself to me fairly quickly: by engaging in community service.

In my personal psychedelic travels, the inward journey found three common themes: take better care of yourself, take better care of others, and take better care of the planet. These themes highlight for me a quintessential truth of life, that we are all one. Based on this philosophy, the Buffalo Psychedelic Society placed a priority on community service. We began doing regular cleanups of city streets and parks. We started a community garden open to the public to source fresh fruits and vegetables. We volunteered in soup kitchens and homeless shelters when help was needed. We held fundraisers for community organizations, like Journey's End, whose mission is to welcome refugees without regard to ethnic origin or creed, and to assist them in becoming healthy, independent, contributing members of the community. We also provided psychedelic harm reduction at local festivals through a project called the Sanctuary, which we modeled after the Zendo Project (**zendoproject.org**). Engaging in service, and providing opportunities for others to be involved with service, became our ways of integrating our psychedelic experiences.

Free books collected as part of Hammock 'n' Read, a book recycling program.

This work also provided opportunities to educate those outside of the psychedelic community about the ever-growing movement, and the society grew to establish chapters in three cities: Buffalo, Rochester, and Batavia. Not only were we practicing psychedelic values, but by doing so, we were also helping to break the stigma associated with psychedelics.

In April of last year, the work I led created an opportunity for me to attend Psychedelic Science 2017 (p**sychedelicscience.org**) through the Perspectives Scholarship, which sponsored people of color to attend and help raise their voices within the movement. It was a blessing to be connected to the global psychedelic community. I met leaders in the space from cities across the United States, India, and Ghana, to name a few.

So motivated by the practice of community service, I sought to encourage other groups to integrate this model. The encouragement presented itself through the Global

Psychedelic Month of Service, which I led by reaching out to psychedelic group organizers around the world, and marketed to individuals through campaigns with The Third Wave, Psymposia, and Psychedelics Today. It occurred this past November 2017 and engaged seven organizations and 30 individuals from around the world, who carried out community service projects in the name of psychedelics. Notable was a four-week course created in Brooklyn, New York, by Katherine MacLean, called The Psychedelic Good Samaritan, which touched on topics of self-care, psychedelic integration, harm reduction, and education on the effects of psychedelics.

The success of that event inspired me to revisit a topic which I was introduced to at Psychedelic Science 2017, the issue of psychedelic plant conservation. Mother Earth provides us with healing medicines that have impacted cultures and individuals for millennia, but due to the widespread use of psychedelics, some of these medicines are experiencing a conservation crisis. When I encountered this idea, it took me aback—it was something I never truly considered. Issues of conservation are widespread in nature, even with potable water, so why wouldn't this be the case with psychedelics?

Community service volunteers reorganized a food pantry for Compass House, a children's shelter.

The notion motivated me to take on a new current endeavor, the Global Psychedelic Earth Day Cleanup, where we are encouraging psychedelic groups around the world to honor Mother Earth by organizing a community clean-up on Earth Day. In doing so, the project will draw attention to, and support for, the issue of psychedelic plant conservation.

Do you want to learn more about this problem? Are in interested in contributing to the cause? Visit **psychedelicearthday.dudaone.com** to find more information, make a donation, find a cleanup near you, or to add a cleanup of your own.

Let's celebrate Gaia, take care of our communities, and practice the psychedelic value of environmental awareness. Together, we can synchronize to accomplish something greater than ourselves.

Kwasi Adusei *is the founder of the Psychedelic Society of Western New York and one of the connectors and administrators of the Global Psychedelic Network (GPN). Through his work with the GPN, he has led projects that include Psychonauts of the World, which shares meaningful psychedelic stories from around the globe, with the intention of publishing them in a book as an avenue to raise funds for psychedelic research, the Global Psychedelic Month of Service which encouraged psychedelic groups and individuals from around the world to engage in a service project catered to the needs in their regions, developed a guide on starting psychedelic societies which consolidates methods and practices from the global psychedelic community into one resource, and leads a campaign to address drug checking initiatives across the country. Locally, Kwasi incorporated an organization known as Emergence-In to provide various harm reduction services, including psychedelic harm reduction at music festivals through a project called Sanctuary and provides opportunities for his community to practice of psychedelic values by engaging community service. Kwasi is also registered nurse and a doctoral student at the University at Buffalo, studying to be a Psychiatric Nurse Practitioner. He can be reached at kwasiadu@buffalo.edu.*

A psychedelic harm reduction training for Sanctuary volunteers.

The Beckley Foundation Brings Microdosing Under the Microscope

AMANDA FEILDING

Amanda Feilding

MY LONG-STANDING INTEREST IN LSD AND MICRODOSING

The ancient Chinese game of Go is challenging and complex. So complex, in fact, that artificial intelligence (AI) has only recently managed to beat the world champion—some twenty years after IBM's Deep Blue claimed victory over chess grandmaster Gary Kasparov. And yet, one of the most intriguing effects of my personal experimentation with LSD and microdosing during the 1960s was that it made me a better Go player: I found that if I was on LSD and my opponent wasn't, I won more games.

This positive effect is a clue as to why computers took so long to learn to play Go well. Go cannot be beaten by sheer computing force in the manner that Deep Blue played chess. Its complexity requires a very human ability to play it well: intuitive pattern recognition. Recognising patterns—what we might call insight—sits somewhere at the intersection between intelligence and creativity. Larger doses of LSD are well-known to produce a sense of insight: psychedelics can act as liquid open-mindedness, allowing users to look upon themselves, their behaviours, and their life histories with fresh eyes, seeing things that they hadn't realised before. Perhaps it is not so surprising after all, that a microdose, or a moderate dose, of LSD could allow me to better see the patterns implicit on the Go board before me.

The ancient Chinese game of Go requires logical thinking and creativity, two points of interest in the LSD microdosing study.

I am by no means alone in seeing benefits from microdosing. Increasing numbers of people are now taking LSD, not for hallucinations or ego-dissolving mystical experiences, but as a "psychovitamin" to improve their lives in all manner of ways. Advocates of microdosing swear by the practice, reporting more vitality and enthusiasm, an increased ability to get into the "flow," as well as feeling more connected to others, themselves, and their values. Others attribute their success in overcoming addiction to it. Reading through accounts of the experiences of microdosers, a theme that appears again and again is that these small amounts of LSD allow them to work better, think more creatively, and feel more alive to the present moment—what we might today call "living mindfully."

More palatable to the wider community than larger doses, this alternative way of using psychedelics has already attracted a large number of adepts, from Silicon Valley hotshots to individuals struggling with depression. Engineers, programmers, writers, and artists are sharing their stories in numerous blogs and news outlets, and microdosing is now beginning to be discussed outside the psychedelic community, awakening the potential of lifting the 50-year-old veils of taboo and stigma, giving us a second chance to integrate these substances into society in a safe and beneficial way.

In spite of its increasing number of adherents, all of the current evidence on LSD microdosing is anecdotal in nature. There are no published scientific studies exploring the mechanisms of action, benefits, or possible side-effects of the practice. And it is precisely because of this increasing number of adherents that scientific research is now all the more urgent.

THE WORLD'S FIRST MICRODOSING STUDIES

Since finally succeeding in carrying out the first brain imaging study with LSD in 2016, I have been wanting to extend our LSD research to include the microdosing phenomenon. As part of the Beckley/Imperial Research Programme, we are developing a protocol to investigate the physiological and psychological effects of repeated microdosing, with a particular focus on cognitive functions, creativity, and mood.

We will give four dozen participants eight treatments over a period of four weeks: twice-weekly microdoses of LSD or a placebo. As well as measuring microdose-induced changes in brain activity using EEG, we will assess the claims made by the microdosing community via the use of subjective reports, questionnaires, and tasks. Particular focus will be given to mood enhancement, cognitive flexibility, creativity, and both emotional and intellectual insight (such as the ability to resolve long-standing emotional or work-related problems).

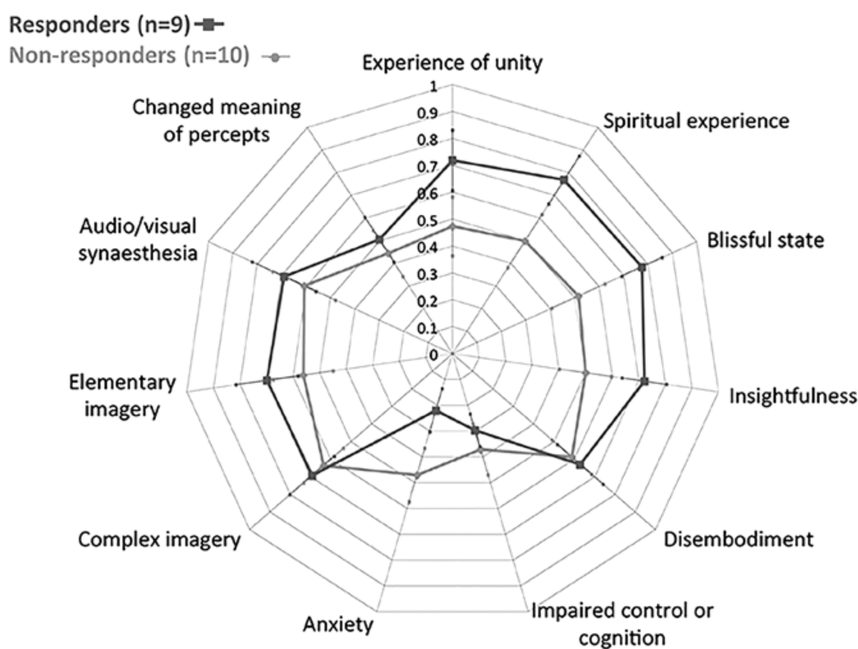
Many of the advocates of LSD microdosing—especially those working in artistic and technological fields—are most attracted by its positive impact on creativity and insight. But capturing a moment of insight, rather than relying on self-reported judgments, presents a considerable challenge. In facing this challenge, I was inspired by my personal experience as a Go player, which I was passionate about in the 1960s and 1970s. To win at Go, players must spot opportunities and weaknesses emerging in the constantly changing pattern of black and white stones on the board. Rather than relying on well-known sequences, or planning multiple moves ahead, top players intuit their way through the game, fusing logical thinking and creativity. For these reasons, Go allows us to measure intuition and the sense of insight—that Aha! moment of sudden clarity—in a new way.

On each microdosing day, alongside subjective reports, questionnaires, and formal tasks, participants will play a computerized Go game, to investigate creativity and intuitive thinking. As Go uses a well-established ranking system, a Go-playing AI is able to measure its human opponent's ability, and hopefully give us a simple outcome measure of how good their Go playing is.

THE BECKLEY FOUNDATION LSD RESEARCH PROGRAMME

I founded the Beckley Foundation 20 years ago, with the aim of researching the underlying mechanisms and potential beneficial applications of psychedelics for the improvement of the health, happiness, and well-being of humanity. This necessitated a focus on global drug policy reform to help overcome the deeply ingrained taboo on psychoactive compounds. It's been a long and hard struggle, but the gates are finally opening and we are now witnessing a renaissance in psychedelic science. Eminent academic institutions such as Imperial College London, Johns Hopkins, and NYU are beginning to demonstrate the incredible potential of psychedelic-assisted psychotherapy to treat mental illness.

The collaboration I set up with David Nutt and Imperial College in 2009 has provided invaluable insights into the mechanisms of action of LSD and other psychedelics such as psilocybin. Our results revealed how these compounds reduce neural activity within the brain's "Default Mode Network"—where overactivity has been linked to the rumination and repetitive negative thinking characteristic of depression and addiction—as well as a dramatic increase in connectivity between brain regions that do not normally communicate with each other. Might this point towards an explanation of why microdosing is said to heighten creativity and improve mood? It is too early to say for certain, but it warrants further investigation.

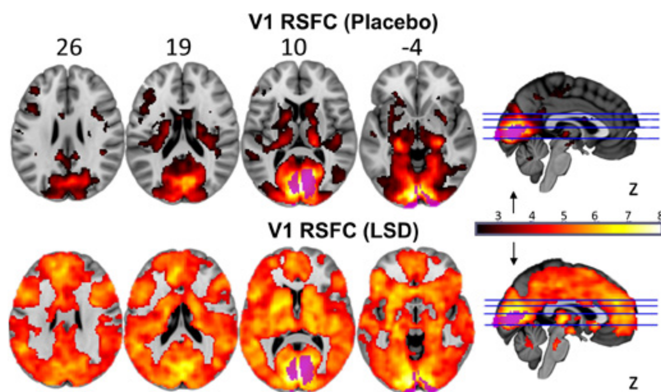


The Mystical Experience Web by Leor Roseman.

Our research has also demonstrated that the quality of the acute psychedelic experience plays a key role in the healing process. We found a strong link between the experience of "ego dissolution," or "mystical" quality of an LSD trip, and its efficacy

as a treatment for mental disorders. With a typical therapeutic dose, participants recount a "mystical" or "ineffable" experience, although some researchers prefer the deliberately secular term "peak experience" to describe the phenomenon within a scientific context.

While some people recognise these out-of-the-ordinary experiences—the dissolution of the sense of self, a sense of oneness with the universe—as crucial to their development and healing, it is precisely because of them that many are uneasy about engaging with LSD as a treatment. However, microdosing does not involve any ego-dissolving mystical-type experience, and yet anecdotal reports of its benefits on depression abound.



The Beckley Foundation's brain imaging study showed that LSD increases the connectivity between the human visual cortex and the rest of the brain.

The ability of LSD to provide an antidepressant effect, without the mystical, classically psychedelic component, suggests that there is much more to be understood about its mechanisms of action. Moreover, it may be the ideal way to rehabilitate the compound in the eyes of society at large: A pill that enhances energy, vitality, creativity, and mood, while allowing the user to retain full control of their focus and behaviour, could be a welcome addition to our current pharmacopeia in the midst of a rising tide of mental health disorders.

With this in mind, I set myself the task of developing a multi-armed international research programme that will thoroughly investigate the therapeutic potential of LSD, both at the microdosing level and with the higher doses typically used in therapeutic settings.

The Beckley LSD Research Programme will comprise several arms of complementary research carried out at different centres around the world. Within this programme we will investigate:

1) How LSD-assisted psychotherapy might help overcome treatment-resistant conditions, based on an excessively rigid and overactive default mode network, such as addiction, depression, OCD, and PTSD.

2) The effects of different doses of LSD (from 10mcg to 250mcg) on cerebral circulation, brain activity and connectivity; as well as on mood, cognitive functions, and creativity.

3) How repeated microdoses of LSD may differ from a single, higher dose, in producing prolonged effects on mood, cognitive functions, creativity, wellbeing, and associated changes in brain function.

4) The physiological effects of LSD in vitro on neural cells and cerebral organoids ("small brains" grown in the lab), with a particular focus on inflammation, neuroplasticity, and neurogenesis.

The programme will assess LSD's dose-response curve—a gold standard for measuring the effect of any drug treatment—using well-validated psychometric and pharmacological tools. Both full doses and microdoses seem promising prospects for treating a wide range of conditions. But we don't know, for example, if the subjective and cognitive effects of a full dose are just higher-intensity versions of a microdose, or if they are fundamentally different. By undertaking dose-response studies, we will help determine which doses are likely to produce the best results for different conditions and therapies. We will also yield important answers about the efficacy, safety, and tolerability of LSD.

In collaboration with leading scientists and universities in the US, the Netherlands, Brazil, and the UK, I am developing studies which will build a more complete picture of the potential of LSD. This will hopefully, not only increase our ability to heal sickness, but also enhance our understanding of consciousness itself, an aim which motivated my passion for this research 50 years ago.

As our research develops, it is my hope that Albert Hofmann's "problem child" will be rightfully rescheduled, and in time, become a licensed medicine and authorised therapeutic tool, ensuring wide access to its health-giving properties.

***Amanda Feilding** is the Founder and Director of the Beckley Foundation. Amanda established the foundation in 1998 to further research into the therapeutic and transformative potential of psychoactive substances forbidden by prohibitionist policies, and has since been called the "hidden hand behind the renaissance of psychedelic science and drug policy reform." Through the Scientific Programme, Amanda orchestrates collaborations with leading scientists worldwide, investigating cannabis, psilocybin, LSD, Ayahuasca, DMT and MDMA. These include clinical trials identifying the effects of psychoactive substances on cerebral circulation, brain function, subjective experience, and clinical symptoms. She co-directs the thriving Beckley/Imperial Research Programme with Prof David Nutt. She can be reached at amanda@beckleyfoundation.org.*

Black Masks, Rainbow Bodies: Psychedelics and Race

NICHOLAS POWERS

Nicholas Powers

Last time I sang the national anthem, I was on ecstasy. We huddled in the street. No one knew each other. We passed a joint, a woman waved the flag and it blew the smoke to where cops stood, holding an orange net.

Hours before, I was in a TV studio when news came that America elected its first Black president. Instead of saying something witty, I held my head and felt a shaking inside. Walking outside, I felt the whole city shook as if some invisible wall had broken. Truck drivers honked horns. Hipsters and workers, the homeless and students, wealthy business men and cops all danced and hugged, hi-fived, kissed and shared beers.

I went to my friend Brad's apartment, he smiled like the Cheshire Cat and took out two huge pills of ecstasy. They looked like UFOs in his hand. "Ready to beam up," he asked. "Yes," I whispered, "Yes."

Soon, my head felt like was a balloon floating away. We walked to the Lower East Side and followed a woman, who waved an American flag. At the end of the block was Tompkins Square Park. Cops formed a line with orange netting to stop us from going in. We stood face to face, moments pulsed like an alarm. Our eyes struck their eyes like matches. Then music came on. We danced. We sang the National Anthem and partied, happy and free as the police stood, trapped inside their own net.

I open with that story because it's where two freedom movements, briefly meet in my life. The Black Freedom Movement, a living force of millions of people, whose ancestors were kidnapped from Africa. Chained together on slave ships, they fought for freedom from the plantation to the White House. The Psychedelic Movement began with Albert Hofmann on his bicycle tripping on LSD. Decades later, he was followed by hippies, musicians, and mystics exploring visions. Next were LSD soaked 90's underground raves. Now, 21st century doctors and activists inch psychedelics closer to legalization for medical use.

Here are two freedom movements, two separate worlds, and both go toward the same goal of a common humanity but never meet in mass, never share stories or organize together. It was as if a wall stood between them.

It's a wall built with a story; never use drugs or trust anyone who does. In the 60's and 70's, my mother was a young Puerto Rican staring at skyscrapers. Her high school friends were drafted into the Vietnam War and came home hollow-eyed and on the needle. Angry, she grew an afro that rose from her head like a black fist. She marched. She organized. It seemed that they were going to change the world until one by one, her comrades, stumbled from the Movement in a chemical fog. "The government let the drugs in to destroy us," she said, "I saw dealers a block away from a police station."

Inside her warning was the echo of ancestral voices warning us about your drugs. In Frederick Douglass' personal narrative, he wrote:

> The holidays are a gross fraud…Their object seems to be, to disgust their slaves with freedom, by plunging them into the lowest depths. Slaveholders…make bets on their slaves, as to who can drink the most whisky and

> in this way they get whole multitudes to drink to excess. We felt, and very properly too, that we had almost as well be slaves to man as to rum. So, when the holidays ended, we staggered up from the filth of our wallowing, took a long breath, and marched to the field.
> —Frederick Douglass, *A Narrative of the Life of Frederick Douglass, an American Slave* (1845)

When my mom was alive, Malcolm X was also alive. He said this to an audience in Harlem:

> We allow ourselves to be used by the white overlords downtown to bring their dope back here in Harlem to push it on our poor, unsuspecting people. Why we let the white man use to make drug addicts out of children, to make drug addicts out of babies, drug addicts out of mothers. We let the white man use us to bring that poison back here in Harlem and stick it into the veins of our people.
> —Malcolm X, "Crime In Harlem"

And Assata Shakur, who is nearly the same age as my mom, who lived in New York when my mom did, wrote this about drugs.

> In my tongue-tied, confused state of marijuana intoxication I was trying to communicate. I was feeling guilty and stupid, silly and politically backward. I was embarrassed to be bumbling down the street…too high to deal with reality much less change it. I had heard somebody say that revolutionaries get high on the revolution and that it was the best high in the world. "I'm gonna check out that high," I said.
> —Assata Shakur, *Assata: An Autobiography* (1987)

White supremacy using drugs to control us is etched into our history. In the Black radical tradition, you grow up seeing drugs as a trap. And whiteness itself is a drug we need to purge from ourselves. Purge the straight hair. Purge the skin-lightening cream. Purge the seeking of approval of whites.

In the Black Freedom Movement, drugs are a plot to destroy us, and pushers are chemical overseers. After the 70's activists were shot down by COINTEL and drugs flooded the hood, some saw dealers as entrepreneurs. Yet whether you were an activist or not, everyone saved their worst scorn for addicts, "crackheads," who were the living symbols of a new slavery.

My mom saw the addicts. She lived poor. Which meant that I lived poor. She sent me to a boarding school, which helped get me into a private college. She got me out. The deeper I entered the majority white world, I saw quirky, odd, fun, individuals. I did not see a puppet master. Some I loved. Some I hated. Yet when I entered a room where no one knew me, I saw that I wasn't seen; instead, between us was a warped stereotype. W.E.B. Du Bois wrote about this more than a century ago,

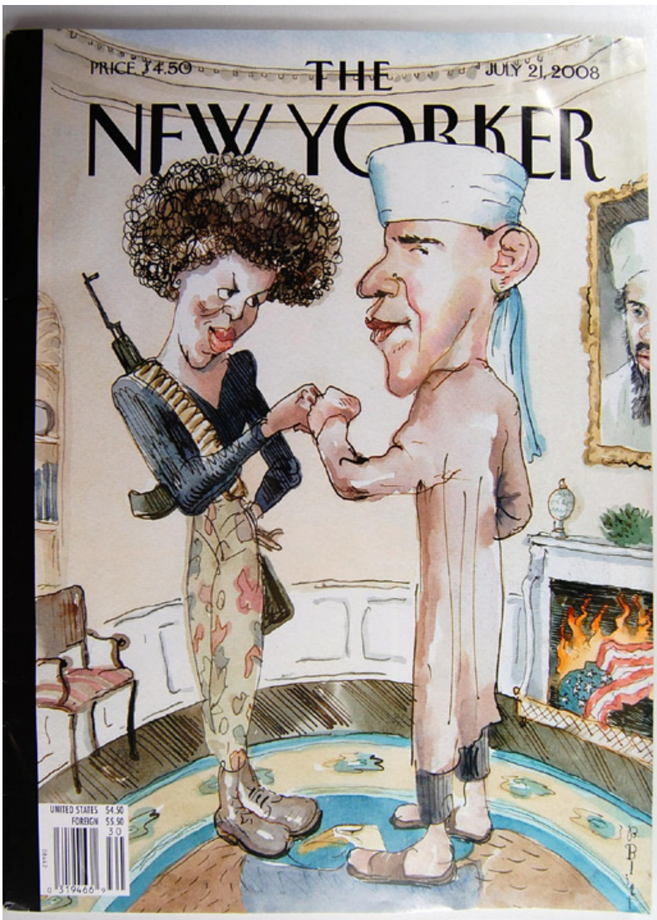
> It is a peculiar sensation, this double-consciousness, this sense of always looking at one's self through the eyes of others, of measuring one's soul by the tape of a world that looks on in amused contempt and pity. One ever feels his two-ness,—an American, a Negro; two souls, two thoughts, two unreconciled strivings; two warring ideals in one dark body, whose dogged strength alone keeps it from being torn asunder.
> —W.E.B. Du Bois, *Souls of Black Folk* (1903)

When my high school friend took me to visit his family and his sister's boyfriend, he shot me a look and said, "You know the only reason I can't get a job is because my skin is the wrong color and there's something between my legs." I knew he didn't see me. He saw a lazy coon who mooched off the system.

Or when I wanted to be left alone, I tied a bandana around my head to scare away people, even if came at the cost of reinforcing that racial fear.

I knew I was seen as a threat. And that's why, decades later, when Obama ran for office I knew I saw one image,

while racists saw another.



Stereotypes warp reality. Images become a wall between people. Du Bois also wrote:

> Why did God make me an outcast and a stranger in mine own house? The shades of the prison house closed round about us all: walls... relentlessly narrow, tall, and un-scalable to sons of night who must plod darkly on in resignation, or beat unavailing palms against the stone, or steadily, half hopelessly, watch the streak of blue above.
> —*W.E.B. Du Bois, Souls of Black Folk (1903)*

The Wall creates shadow. Its darkness is the body being eclipsed by image. It feels heavy, as if we're at the bottom of a toxic ocean. We hear off-color jokes at work. Our bodies are tense alarms. We fear sabotaging ourselves. We use smiles like crowbars to pry open stereotypes. We also, sometimes, don't think about race very often until Michael Brown. Until Sandra Bland. Until Eric Garner. Until someone like us is shot down in public and even if one never think about race, we feel a part of us die with them.

PART II

In college, I wore the mask of militancy. I had a Malcolm X poster on my wall. I sold weed. Pounds of it. I sold mushrooms and LSD. I sold so many drugs that I should have worn a lab coat.

I made enough money that I almost didn't care. But I did. I was falling into the trap my mom had warned me against. One afternoon I smoked a joint with my friend Dina and told her how ashamed I was at being a stereotype. She said, "You're selling weed to white kids, not that big of a deal. Think of it as reparations."

We laughed but it faded behind my smile. I grew dreadlocks to anchor myself. I went to Nation of Islam meetings and converted to Islam. I learned to be anti-Semitic. I was

homophobic. The mask of militancy shielded me from looking in the mirror.

And then came Brad. Gay. Jewish. From Long Island. He had no chill. He wanted weed and I was selling. He looked like a handsome owl. An intelligent light radiated from his face. Have you ever fallen in love, when you didn't want to? On paper, we were enemies. In real life, I felt brother-love. We smoked together. Debated. Prayed together. One night, we took LSD and read the Koran, wept over its poetry. I was so proud at feeling the Prophet's words, I told my Muslim friends and they yelled, "You don't read the Koran on acid!" I said, "I'm sorry. I didn't know. Okay, no LSD and Allah."

Brad had come of the closet in high school. He was helping me take off my mask. He didn't know it but I admired how brave he was to be openly gay. I wanted to be open, too. And one night I took mushrooms and went to the dock by the river. I sat there. The psilocybin lit my brain up like a starry night. Faces moved between the constellations. The sound of waves washed my ego away. Closing my eyes, in the receding tides of sound and memory, I saw Mom. She was young again, staring at me sternly and shaving off her afro. When she cut the last puff off, she vanished and I picked up the hair. I tried putting the afro back together, but a light made it hard to find. When I opened my eyes, the sun was rising over the river.

The light lifted me to a wordless, voiceless place. Thought dissolved into colors. All I saw was sacredness, sacredness, sacredness. I can't say it was a conversion. I can't say everything changed, but a heavy weight shifted inside me. I wasn't off balance.

The second psychedelic racial turning point for me came when I was in Europe. Train pass in hand, I zigzagged through nations. France here. Spain there. Part of our tour was going to Dachau, a former Nazi concentration camp. My girlfriend was coming to visit. Hmm, make love? Or go on a death tour? I spent the weekend with her. When I came back to campus, the staff was furious and told me to go to Dachau and give a report, so I took the train to Germany.

It's as eerie as it sounds. Heavy rattling wheels. Lights flashing in the windows. I got to Dachau on an off day. No crowds. Grey sky. The color seemed have been washed out. I took mushrooms out of my pocket and looked at the entrance. I knew what we were supposed to feel a script of sadness and guild. I thought it was more honest to listen to the spirits, so I ate the mushrooms and walked in.

Rows of buildings sat like giant coffins. Bare trees hung low. I touched the walls and fence and ovens. What if I had been here? Every rough brick was molded by a story. A racist story about us—I was saying "us" now. I wasn't inside myself but bobbing in a common humanity. The ego had dissolved into the silence where shadows of invisible bodies clawed at the walls. A cold hate blew from the past. A hate frozen into eternity by the last breath of the dead. I inhaled it and breathed it out.

Outside the crematorium, I thought of Brad. What if he'd been born in an earlier time? No. No. No. Not you. But I couldn't stop imagining him being shoved into the oven and I punched the wall. I punched it again. And again. And again. I punched and punched, bloody fists against the wall.

PART III

Psychedelics healed me. They healed my double consciousness. They healed my bigotry and homophobia. They gave me a transcendent vantage point. I saw how hatred began as fear and grew into stories like interlocking walls in a vast maze that we were lost in, searching for each other.

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Every year, we come here [to the Horizons: Perspectives on Psychedelics Conference] to celebrate our escape from that maze. To ask a question: Can they heal the world? At Horizons, doctors share new research on neurotransmitters, or how they gave MDMA and psilocybin to the terminally ill, to those with PTSD, and found success. I was invited to talk about race, so are we now asking, how can this medical model can be applied to racism? Can prejudice be treated with psychedelics as an institutional practice?

If so, we have to ask questions. Are MAPS or the Johns Hopkins Research Project or any of the other organizations going to hire minority staff and fund cultural outreach? Will they integrate the findings of those minority therapists into its methods and paradigms? Is it going to compile the testimony of the volunteers and create a case for social justice?

Is the white psychedelic medical movement going to turn to the world beyond these walls? Is it interested in expanding, beyond the pool of soldiers, firefighters, and the terminally ill to recruit from the criminal justice system? That revolving door of destroyed lives. Too many Black. Too many Latino. Too many white poor.

If so, it will have to go beyond my story, which is the

plight of a middle-class man of color. It must go into the spiritual depths of men and women of color, who are poor, who have been trapped in intergenerational trauma, who have been churned through prisons and joblessness and broken families. And whose pain has become their armor.

Are you going to challenge the narrative of psychedelics as party drugs, and of crack and meth as addictive, dirty, and criminal? Is the white psychedelic medical movement going to explore how implicit bias and hate show up in brain scans, and how LSD or MDMA or psilocybin can re-wire it? Will you work with Life After Hate, a group that rehabilitates formers Nazis and white supremacists?

Imagine the lives that could be saved. On my street, in Bed-Stuy, NYC, a girl was shot and killed. Three neighbors, shot by accident. We patch up wounds with prayer but the fear never leaves. Imagine one of the shooters, a young black man, entering a psychedelic therapy session. He's nervous and hides it with bravado. He curses. He's surly. Slowly, he talks about his family and fears. The therapist says he's ready and he takes MDMA in a guided session. Memory floods him as immense waves of buried feeling burst through his inner wall. He's on the floor, cradled by the therapist. Imagine him, days later, going to his victims and asking forgiveness.

That's why we need you. The real world needs you. During your therapy sessions and private trips, you've glimpsed the rainbow body underneath the masks we wear. You drew up from the well of the body our unconscious history. You know the source-light that connects our thoughts to time itself.

We need your psychedelic wisdom to heal the victims of the system and the ones who built the system. Tell the wealthy and privileged few that they are the Prodigal Sons of history, who left the home of our common humanity. And like the Prodigal Son, they cast the world's money to the wind. Now they see how lost they've become as capitalism breaks down. They buy security guards and alarm systems and armored buildings. They are scared. Tell them to let go of it. Tell them that the whole world is their home. All of humanity is their family and there's a celebration for their return. The people will heal them with joy.

Recently, I visited Brad in LA and a group of friends went to Venice Beach. We heard distant drums, smiled at each other and jumped into the hot, dancing vortex of bodies. It reminded me of the election night in New York, when the city was united in joy. Here on the beach were African drummers. Mexican families. White surfers. Tourists. Everyone danced in the sand. Everyone sang and sweated and rejoiced. Everyone was home.

Are you going to challenge the narrative of psychedelics as party drugs, and of crack and meth as addictive, dirty, and criminal? Is the white psychedelic medical movement going to explore how implicit bias and hate show up in brain scans, and how LSD or MDMA or psilocybin can re-wire it? Will you work with Life After Hate, a group that rehabilitates formers Nazis and white supremacists?

Will any of this happen? So far, there's no evidence it will. In the many years of this conference, this talk is the first on race. I haven't read of any race-specific studies. So, if there's no real research being done, why am I here? Either today is the start of a new outreach or I am token, a presenter of color to give a veneer of diversity. Regardless of why, I came to give you a message.

People who are scared build walls. Recently, I was in Ohio for a journalism conference and one student drove me through a town devastated by opioids. Shirtless men walked in drugged stupor across the park. Homes of blistered paint. Trash on the lawns. Families pushing shopping carts. Towns like that were bruises on the state map. "If I lived here," I told the student driver, "I would have voted for Trump too."

The West is becoming a walled-off fortress. Le Pen in France wants a wall. The Golden Dawn in Greece want a wall. Britain, with Brexit, wants a wall. Trump wants a wall. Here, there, everywhere are walls. Each brick is cast by the same story: us versus them, native versus foreigner, moral versus pervert.

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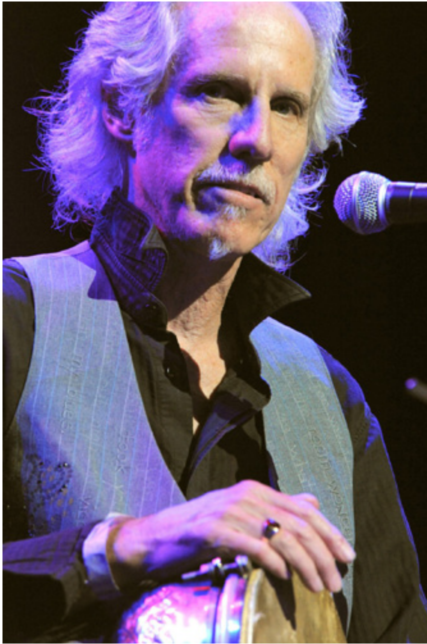


John Densmore

Breaking on Through: The Psychedelic Experience 50 Years On

JOHN DENSMORE

All this to say—if you are up against that wall—in a place where it feels like there are no options—and your intuition says it's right…go ask Alice.

I'm 73 years old, and still feeling quite good about myself. Well, I know I'm on the descent, but it's a nice ride…right now. I know it's going to get more difficult, but if I can just hang on to what I experienced 50 years ago, I'll make it to where I'm supposed to go.

So play the game "Existence" to the end…
…of the beginning, of the beginning

Fifty years ago, my friends and I were street scientists, experimenting with then-legal psychedelics. At Monday rehearsals, we would all share what happened on our weekend "trips." On one of those Mondays, Jim suggested we call our new group The Doors, after the Aldous Huxley book, *The Doors of Perception*. It seemed the esteemed British scholar had written a little book about his mescaline experience. The new name quickly became unanimous. All of us went through the gauntlet—tough moments that lasted for a few minutes, or quite a while. A few friends never came back fully to their former mental selves, and actually all of us were in some way changed forever—mostly in quite positive ways.

Lifting the veil is dangerous, but if the environment is supportive, the outcome can be life-changing. I only took the trip a few times, but the opening is still with me. I realized these experiments were extremely rigorous on the nervous system, so I found myself heading towards a less shattering route: meditation. But the initial couple of liftoffs have definitely impacted my life permanently.

Now, 50 years later, I still can touch the feeling of wonder that I got from these initial excursions. It's hard to describe anymore than that; kind of like trying to describe God. My 90-year-old cousin, who is a diligent thinker, laments the loss of the framework of organized religion. I told him that the impact of a tab of acid made a much bigger impression on my spiritual life than the communion wafer at mass. And I can't go back. Even though Pope Francis is challenging my renegade Catholicism because he is so wonderful, I still can't go back. The great mythologist Joseph Campbell says that the new mythology might take 100 years or so to fully form. So I comfort myself with a patchwork cosmology: a little Hinduism here, a dash of Buddhism there, and a whole lot of indigenous wisdom.

Let me be clear—I am not advocating indiscriminate drug use. But recent studies have shown that used carefully, some psychedelics can actually help treat addiction to other drugs. Plus, carefully conducted scientific studies from non-profit organizations and major universities are showing many physical and psychological benefits, including a powerful treatment for PTSD and anxiety in people with serious illness. Even the much-maligned weed is showing stunning evidence as an important medicine that fights diseases like epilepsy and cancer.

These are very exciting studies, but psychedelics still have a stigma: the old patriarchal, mistaken outlook that all drugs are the same. We now know that "Just Say No" is an extremely simplistic and misleading response to a very complex issue. As Ethan Nadelmann of the Drug Policy Alliance said years ago, the appropriate phrase is "Just Say Know." This is apparently lost on the new U.S. Attorney General, Jeff Sessions, who is trying to go back in time with tough policies that have failed. Sessions' predecessor, Eric Holder, has called this "dumb on crime."

Of course, there are those who will quickly judge this rant as a "hippie flashback." If that's what this is, then bring it on. I have raised a family, have grandkids, written three books, a significant amount of music, and many articles. No slacker's or stoner's rant is this. In fact, I'm very careful now about what I

John Densmore (above); and The Doors (l to r) Jim Morrison, John Densmore, Ray Manzarek, and Robby Krieger.

put into my system, and those early days of exploring my mind were key in forming my values and my spiritual path.

Now here's the cosmic part (you saw it coming): when I stepped outside while under the influence of LSD, I saw God in every leaf. OK, now you expect me to say I started eating those botanicals since I was so loaded, but what I really came away with is a sense (which is still with me) that this moment in time is not the only moment happening at this moment! This might sound like double-speak, but there are other realities going on right now outside of our awareness.

But before I stepped outside, I had a few minutes of absolute terror. My friend, who was also "tripping," pulled me out of it by laughing hysterically. You see, in those days, we didn't have doctors like today at Johns Hopkins hospital in Baltimore carefully monitoring our voyage. Due to our early experiments, and of course centuries-old shamanic cultures, researchers are now clear about the safe boundaries needed to make the excursions the most fruitful. Knowledge is often surrounded by danger. You have to get out on the edge to see the whole clearly.

Turn off your mind, relax and float down stream
It is not dying, it is not dying

Every night when we choose go to bed, we are accepting a "little death," giving up our conscious daily life. We know we need rest to reset our body for another day of sentient life. In effect, it's a small rehearsal for the big "D" coming at the end of our time here on planet Earth. When that time arrives, going peacefully is what we all want. For thousands of years, Tibetan Buddhists have believed it is crucial to be calm in the moments before crossing, or you won't get to where you're supposed to go. Now we are seeing terminal cancer patients receiving effective help via psychedelics with the "little death" rehearsal.

Lay down all thoughts, surrender to the void
It is shining, it is shining

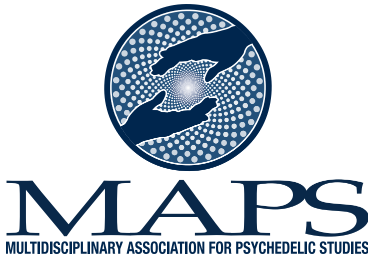
So once again, the U.S. government is very slow to get the message, and continues to interfere with the availability of traditional indigenous medicine. Bipartisan support for criminal justice reform has been halted. Medicine that has helped people for centuries is once again under attack. It's sad, because Vietnam vets that have been metaphorically stuck in the jungle have been finding their way out of years of mental and emotional torture thanks to medicinal plants.

Retired Sgt. Jonathan Lubecky, who served in Iraq, says about MDMA-assisted psychotherapy, "This treatment has made it possible for me to watch my son grow up. He will not be presented with a folded flag on behalf of a 'grateful nation' in recognition of a parent who took his own life." So unfortunately, there are more roadblocks to the "good" drugs, but thank God for human enterprise. No wall can keep out the human spirit, which seeks healing.

All this to say—if you are up against that wall—in a place where it feels like there are no options—and your intuition says it's right…go ask Alice. Make sure you have planned your excursion, have a guide, and this is really what you need to do. Then you will build a bridge or dig a tunnel into your soul and find yourself.

John Densmore *is a musician, author and activist. He is best known as the drummer of the rock band The Doors, and as such is a member of the Rock and Roll Hall of Fame. His memoir* Riders on the Storm *was a* NYTimes *bestseller. He can be reached at johndensmore.com.*

MAPS: Who We Are



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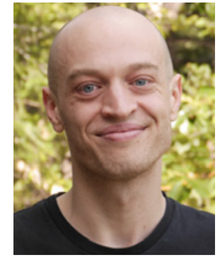
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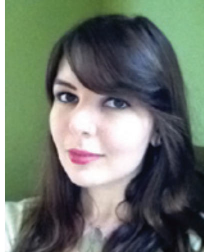
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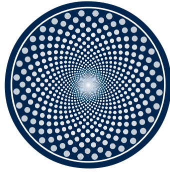
MAPS furthers its mission by:

- 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.



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MPBC's primary work is completing Phase 3 clinical trials required to develop MDMA-assisted psychotherapy into an approved treatment for PTSD. MAPS continues to conduct education and harm reduction projects, to raise funds for MPBC projects, and serve as parent organization and sole funder of MPBC. MPBC was incorporated on December 19, 2014.

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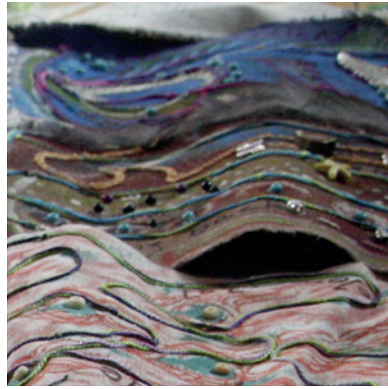

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