

Special Edition
BULLETIN



Pathway to Approval: MDMA-Assisted Psychotherapy for PTSD

November 2016 End of Phase 2 Meeting with FDA Launches Phase 3 Planning

On November 29, 2016, we met with the U.S. Food and Drug Administration (FDA) to plan our upcoming Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD). The outcome was as encouraging as we'd hoped: the FDA is ready for MAPS to move forward with the final stages of research for a New Drug Application (NDA). We plan to sponsor two Phase 3 studies at 14 sites in North America and Israel.

January–August 2017 Special Protocol Assessment and Breakthrough Therapy

We are currently planning and designing our Phase 3 program with consistent feedback from the FDA. We are progressing through the Special Protocol Assessment (SPA) process, a rigorous and lengthy review of the Phase 3 trial design that will provide greater confidence that the Phase 3 data will be accepted at the time of the NDA. The first round of SPA comments have been received and key design elements of the Phase 3 protocol have been accepted. The FDA has encouraged MAPS to apply for Breakthrough Therapy Designation, which, if approved, could expedite the clinical development of MDMA-assisted psychotherapy for PTSD.

Summer 2017 Negotiations with European Medicines Agency

In preparation for eventual marketing of MDMA-assisted psychotherapy for PTSD, we'll need to ensure that European regulatory requirements are met. These negotiations will begin in Summer 2017 and continue until we obtain approvals for Phase 3 clinical trials in the EU, anticipated to start in mid-2019.

Fall 2017 Phase 3: Open Label Supervision Study

Thirty participants will be enrolled in our open label study for supervision of MDMA-assisted psychotherapy for severe PTSD beginning in the fall of 2017. Open label means that all participants will receive MDMA, not placebo. This study will contribute to overall safety data and will further calibrate the therapeutic approach of the therapy pairs across the 14 sites that will conduct the double-blind placebo-controlled Phase 3 study.

April 2018 Phase 3: First Double-Blind Study

Between 100 and 150 participants will be enrolled in our double-blind placebo controlled Phase 3 study (MAPP1) of MDMA-assisted psychotherapy for severe PTSD beginning in the spring of 2018. We expect to conduct an interim analysis of our data in the winter of 2018, and complete the study in the spring of 2019. Participants who receive placebo will be invited to participate in our open label crossover study (Spring 2019).

Spring 2019 Phase 3: Second Double-Blind Study

The second Phase 3 study will serve as the confirmatory study for the first Phase 3. Between 100 and 150 participants will be enrolled in our second double-blind placebo controlled Phase 3 (MAPP2) study of MDMA-assisted psychotherapy for severe PTSD beginning in the spring of 2019, with interim analysis of our data occurring in the fall of 2019. We expect the study to be complete in the winter of 2019, and as in our previous studies, participants who receive placebo will be invited to participate in our open label crossover study. We anticipate completing collection of all Phase 3 data in January of 2020.

2021 Submit New Drug Applications to Regulatory Agencies (U.S. and Europe)

A pre-NDA meeting with FDA will be requested in Winter 2020. Phase 3 data will be submitted on an ongoing basis in order to expedite FDA review. Ongoing meetings with the FDA are expected as part of the Investigational New Drug (IND) process.



(L to R) Rick Doblin, PhD, Amy Emerson, Berra Yazar-Klosinski, PhD, Michael Mithoefer, MD, and Scott Hamilton, PhD, met with the FDA on November 29, 2016 to plan MAPS' upcoming Phase 3 trials of MDMA-assisted psychotherapy for PTSD.

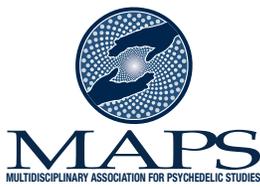
2015–2021 Therapy Training Program

The five-part training program is led by MAPS-sponsored researchers Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., and Marcela Ot'alara, M.A., L.P.C. The program is a prerequisite for anyone working on a therapy team in a MAPS-sponsored Phase 3 trial, and includes an online course, in person trainings, home study assignments, a final evaluation, and clinical supervision. Training began in 2015 and will continue through Phase 3 to prepare for post-approval licensure. Therapist training will continue in order to support the start of an Expanded Access Program and a Phase 3 study for the European Medicines Agency.

Fall 2018 Expanded Access Program Application

Our application for Expanded Access will be submitted to the FDA in Fall 2018. The program starts in Summer 2019. FDA regulations enable manufacturers of investigational drugs to provide patients access to the drug under certain situations if they cannot participate in a clinical trial, but have a serious disease or condition that may benefit from treatment with the drug. The primary intent is to provide treatment, rather than to collect data about the study drug.





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.

THIS SPECIAL ISSUE OF THE MAPS *Bulletin*, on the occasion of Psychedelic Science 2017 (psychedelicsscience.org), highlights the tremendous progress that the field of psychedelic research has made since our previous Psychedelic Science conferences in 2010 and 2013. There is now more psychedelic research taking place than at any time in the last 50 years. Advances in psychedelic research over the last several decades have reached the point that the U.S. Food and Drug Administration (FDA) is formally reviewing protocols for Phase 3 drug development clinical trials that will evaluate psychedelic-assisted psychotherapy for a variety of conditions. These upcoming studies will lead to prescription access, should they demonstrate both safety and efficacy.

We've now seen a decade of thoughtful, well-researched news reports about psychedelics in the full range of international media outlets, from *The New York Times* and BBC to Fox News and Redstate.com. These reports have widely disseminated balanced, much-needed information about the risks and benefits of psychedelics in a variety of medical, religious, scientific, and cultural contexts, building bipartisan support for expanded research into their beneficial uses.

We're also seeing a growing acceptance of—and need for—MAPS' Zendo Project and other psychedelic harm reduction services at festivals around the world. Psychedelic harm reduction reduces the number of "bad trips" by providing compassionate care for people going through challenging psychedelic experiences, in the process reducing public fears about psychedelics and creating a model for a post-prohibition world.

An astonishing number of people from all aspects of our society have been profoundly impacted by their experiences of ayahuasca, the psychedelic tea from the Amazon. Ayahuasca use has been growing in acceptance for decades, especially since 2006, when the U.S. Supreme Court approved the religious use of ayahuasca by the União de Vegetal (UDV) Church, and the 9th Circuit Court of Appeals' subsequent approval of its use by the Santo Daime Church. Growing public acceptance of medical marijuana and majority support for marijuana legalization further reinforce public openness to psychedelics, due to their shared status as Schedule 1 drugs.

All of these factors have contributed to Psychedelic Science 2017 (as far as we can tell) being the largest psychedelic conference in history, with over 2,500 attendees from at least 39 countries. It will be even larger than the historic 2006 International Symposium on the 100th Birthday of Albert Hofmann and the 2008 World Psychedelic Forum, both sponsored by Gaia Media in Basel, Switzerland, and each with about 2,000 attendees.

Now is a time of great potential for integrating psychedelics into Western culture, at a time of great need. We need more tools that can enable people to process fear and challenging thoughts and emotions more directly, in order to respond effectively to the challenges of violence, inequality, and environmental damage; to help overcome multigenerational trauma;

to face death with equanimity and life with joy; to build empathy and compassion; and so much more. One way forward can be through experimental mysticism research with psychedelics, with which we can develop inclusive spiritualities—the antidote to fundamentalism.

It's now incumbent on advocates, skeptics, researchers, regulators, journalists, and all people worldwide to all look as deeply, critically, and fairly as they can at the emerging information about the risks and benefits of psychedelics. This issue of the MAPS *Bulletin*, and all of Psychedelic Science 2017, is an invitation to engage in dialogue with all the rigor and open-mindedness we can muster. Psychedelics are tools that humanity needs to be legally available—to heal our deepest wounds, to develop emotionally and spiritually, and to survive and thrive in the 21st century and beyond.

Now is a time of great potential for integrating psychedelics into Western culture, at a time of great need.



Rick Doblin

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

Psychedelic Studies: Implications for Psychiatric Research and Care

PAUL SUMMERGRAD, M.D.



Paul Summergrad, M.D.

THE DECEMBER 2016 ISSUE OF the *Journal of Psychopharmacology* contained two important randomized controlled studies on the use of psilocybin to treat mood and anxiety (including adjustment disorders) in carefully selected and supervised patients with later stage malignancies.

Ross et al. (2016) studied 29 cancer patients using a two-session, double-blind, crossover (seven weeks after administration of dose 1) design employing psilocybin first then niacin second, or niacin first and psilocybin second. They found that psilocybin produced an immediate and ongoing anxiolytic and antidepressant response, with 83% in the psilocybin-first group (vs. 14% in the niacin-first group) meeting criteria for antidepressant response seven weeks after dose 1. These findings were sustained for most subjects at six months. Subjects' mystical or spiritual experiences were highly correlated with clinical response.

Griffiths et al. (2016) studied 51 cancer patients using a two-session, double-blind, crossover (five weeks after administration of dose 1) design employing high-dose psilocybin first then very low-dose (placebo-like) psilocybin second, or very low-dose (placebo-like) psilocybin first and high-dose psilocybin second. High-dose psilocybin produced large decreases in clinician- and self-rated measures of depressed mood and anxiety. At follow-up at six months about 80% of participants continuing to show clinically significant decreases in depressed mood and anxiety. Subjects' mystical or spiritual experiences were also highly correlated with clinical outcomes.

In both studies, adverse events were limited and there were improvements in attitudes toward death and the experience of deeply meaningful spiritual experience. These studies build on prior smaller studies, including a psilocybin study that found a trend to decreased psychological distress in people with life-threatening illness (Grob et al., 2011).

The February 2017 issue of *Clinical Pharmacology and Therapeutics* published an article about the potential psychiatric uses for MDMA. The article summarized the results of a series of published and unpublished Phase 2 studies (Mithoefer et al., 2011; Mithoefer et al., 2013; Oehen et al. 2013) into the use of MDMA-assisted psychotherapy for subjects with chronic, treatment-resistant posttraumatic stress disorder (PTSD),

reporting that “In phase II PTSD studies, 2 months after two to three active-dose MDMA treatments, 55% of chronic PTSD subjects no longer met the PTSD Diagnostic Criteria ($N = 100$) and 66.2% were in remission at least 12 months postdrug ($N = 65$).”

The difficulty of blinding subjects or study personnel to the effects of drugs with such dramatic effects as psilocybin or MDMA is an ongoing issue in these studies.

What are the implications of these and similar studies with other agents for ongoing research and clinical care with psychedelic agents? If the agents used in these studies were new investigational compounds, given the paucity of agents that have rapid effects on depressed mood or on chronic, treatment-resistant PTSD, there would likely be rapid dissemination of the results, expansion of trials to larger and other clinical populations, and attempts to develop additional compounds with similar mechanisms of action. If, after further study, initial findings were confirmed, discussions of compassionate use for individuals with severe and unremitting illness or rapid movement to approve for clinical use would likely occur.

The history of psychedelics and their legal status as highly restricted compounds, of course, make this a more complex issue. While the use of psilocybin and related compounds in spiritual ceremonies has a very long history in many traditional and non-Western cultures, the more recent history of widespread non-clinical use, or even more disturbingly their use in unethical and dangerous research designs surreptitiously funded by national security authorities, makes the status of these compounds more complex and suspect (Nichols, 2015; Select Committee on Intelligence, 1977). Despite extensive evidence of the safety of these compounds in well-selected individuals under careful supervision, as in these studies, their prior history and the general history of expansion of indications for clinical agents, including their clinically questionable use after approval for specific indications, is an important cautionary tale.

Beyond the clinical utility of these agents in individuals who are facing critical existential issues in end-of-life settings or who are suffering from PTSD, it is likely that studies will expand into other important clinical populations such as those with treatment-resistant depression, where an initial proof of concept study showed similar responses to those reported in these studies (Carhart-Harris et al., 2016).

There are, however, other important considerations in research with psychedelic agents. Psychiatric illnesses are both highly complex neurobiologic conditions and among the most intimate of human illnesses, touching as they do on our

deeply held sense of self and human agency. Both of these issues are highlighted in research with psychedelic agents. These compounds have important value in understanding the neural networks that support a well-delineated sense of self and other, and potentially in antidepressant or anxiolytic mechanisms of action. Psilocybin neuroimaging studies have suggested changes in the coupling of the posterior cingulate cortex and the medial prefrontal cortex (Carhart-Harris et al., 2012) and coupling of the medial temporal lobe and the neocortex (Lebedev et al., 2015), while studies of MDMA’s mechanism of action implicate the medial temporal lobes (Carhart-Harris et al., 2015; Gamma et al., 2000). However, neuroimaging studies with psilocybin, MDMA, and other psychedelic agents are in their early stages.

As important as these imaging studies may become for our understanding of these mechanisms, so is the experience of these agents by the study participants. Many participants rated their psilocybin experience as among the most profound and meaningful of their lives. The benefit of these experiences on mood and anxiety seemingly continued to affect them months later, despite only a single administration of psilocybin and their serious medical conditions. Participants who received MDMA reported profound experiences that catalyzed durable

healing from PTSD. It is unclear at present to what degree this benefit is due to the power of these experiences, ongoing changes in neural mechanisms, or other causes.

The experiences of salience, meaningfulness, and healing that accompanied these powerful spiritual experiences and that were found to be mediators of clinical response in these carefully performed psilocybin studies, and the experiences of fear extinction that were catalyzed by MDMA, are also important to understand in their own right and are worthy of further study and contemplation. None of us are immune from the transitory nature of human life, which can bring fear and apprehension or, conversely, a real sense of meaning and preciousness if we carefully number our days. Understanding where these experiences fit in healing, well-being, and our understanding of consciousness may challenge many aspects of how we think about mental health or other matters, but these well-designed studies build upon a recent body of work that confronts us squarely with that task.

Given the strength of these recent reports, more extensive studies to replicate these outcomes are called for, as are studies in more diverse clinical populations. Since, it is difficult to blind these agents adequately, consideration should be given to including research groups that have had less prior involvement in this area to minimize placebo responsiveness. Finally, the com-

Understanding where these experiences fit in healing, well-being, and our understanding of consciousness may challenge many aspects of how we think about mental health or other matters, but these well-designed studies build upon a recent body of work that confronts us squarely with that task.

plex history and legal status of psilocybin, MDMA and related agents suggests that additional thought should be given as to how to deal with the unique legal, ethical, and regulatory issues surrounding clinical use of these agents. Careful discussion now with ethicists, regulatory, legal, and clinical research authorities may be helpful to understand how psilocybin, MDMA and potentially related agents can be provided to select clinical populations should more extensive trials confirm the work reported in these studies. 🌱

Disclosure

This paper is adapted from Summergrad (2016) published in the December *Journal of Psychopharmacology*. Used with permission.

Declaration of conflicting interests

The author declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The author receives personal fees from CME Outfitters, Pharmasquire, and universities and associations for non-promotional speaking; royalties from Harvard University Press, Springer, and American Psychiatric Press; and consulting fees from Owl, Inc. and Quartet Health, Inc., all outside the submitted work.

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A New Era for Psychedelic Medicine

AMANDA FEILDING



Amanda Feilding

AFTER MANY DECADES, DURING WHICH psychedelic research has been stifled by repressive drug laws and stigma, we are finally re-opening the doors to this fertile field. As the potential benefits of responsible use of psychedelics in therapeutic settings are uncovered, and the media awakens to these discoveries, a new enthusiasm for what psychedelics can offer both science and society is taking hold.

The combination of advancing neuroscientific knowledge, modern brain-imaging technology and psychedelics provides a unique microscope to the mind, allowing us to map changes in consciousness to changes in neuronal and physiological activity. This opens up a new universe in which we can explore novel pathways to treat many of our most intractable illnesses, and to expand our understanding of consciousness itself.

My own passion for exploring these issues was born over fifty years ago, after gaining a new understanding of the physiological changes underlying altered states of consciousness brought about by LSD. In 1998 I set up the Beckley Foundation to scale the political wall that had kept psychedelics out of contemporary medicine since the late 1960s. Through the Foundation I have initiated and carried out innumerable collaborative programs with scientists and universities around the world, to investigate the effects of cannabis and psychedelics on consciousness and well-being. This research has expanded our understanding of these substances, which has contributed to global drug-policy reform by providing an evidence-base to inform policy decisions. The Foundation has also, through its seminars and reports, stimulated a shift in global attitudes to drug-policy.

One of my key collaborative ventures has been the Beckley/Imperial Research Programme, which I set up with Dave Nutt in 2005. This programme, which successfully combines psychedelics with brain-imaging, has broken considerable new ground. In 2016, we published our results from the first-ever LSD brain-imaging study, generating many fascinating findings, and fulfilling my promise to Albert Hofmann

to reintegrate his “problem child” into the scientific world.

The study shed light on many phenomena reported by users of psychedelics. It increased our understanding of the mechanisms underlying ‘ego-dissolution’, and its significance in the therapeutic process. It also revealed the neurological changes underlying the richness and intensity of the multi-sensory LSD experience. We saw increased blood-flow to the visual cortex, and dramatically increased connectivity between the visual cortex and over 20 regions across the rest of the brain, not usually involved in the visual process (see Figure 1).

Feelings of ‘ego-dissolution’ correlated with a ‘loss of integrity’, or reduced communication between the regions of the Default Mode Network (DMN). The DMN is particularly important in regulating our conscious experience. It is a high-order brain network involved in autobiographical memory, planning the future and self-awareness, and is most active when our minds wander during those times when we are not engaged in specific tasks. When functioning normally, the DMN affords a relative stability to one’s sense of self, but an overactive network can result in maladaptive thought patterns and compulsive behaviours. A common underlying mechanism of many mental illnesses is abnormal hyperactivity of the Default Mode Network (see Figure 2).

When, through the action of a psychedelic, the blood-supply to the DMN is reduced, there is an increase in cross-talk between diverse regions of the brain which normally don’t communicate with each other. This creates a more chaotic, fluid and creative state of consciousness, which breaks the rigidity of the neurotic patterns of thought and behaviour that underlie conditions such as depression and addiction.

A second Beckley/Imperial study also published last year and led by Robin Carhart-Harris, investigated the use of psilocybin in overcoming treatment-resistant depression. Our study group had suffered from chronic depression for an average of 18 years and had failed to show improvements from at least two previous treatment courses. This study had the remarkable success rate of 67% of subjects attaining remission from depression after the first week of treatment with psi

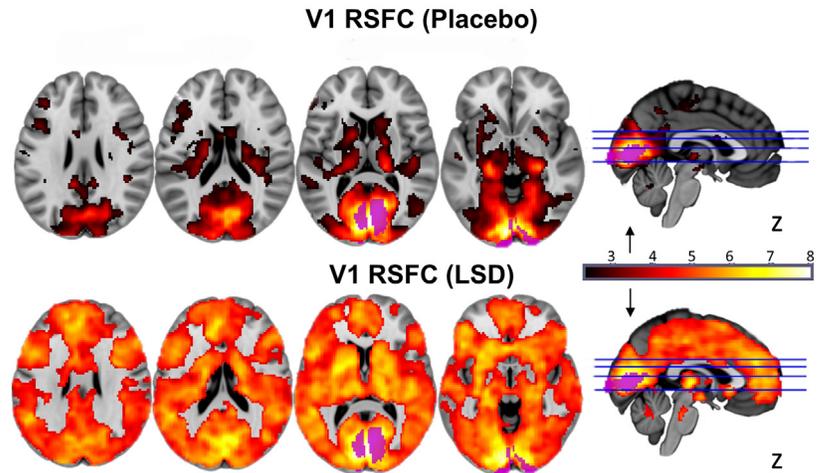


Figure 1. LSD increases the connectivity between the human visual cortex and the rest of the brain.

- Parahippocampus (PH)
- Retrosplenial cortex is less connected to PH

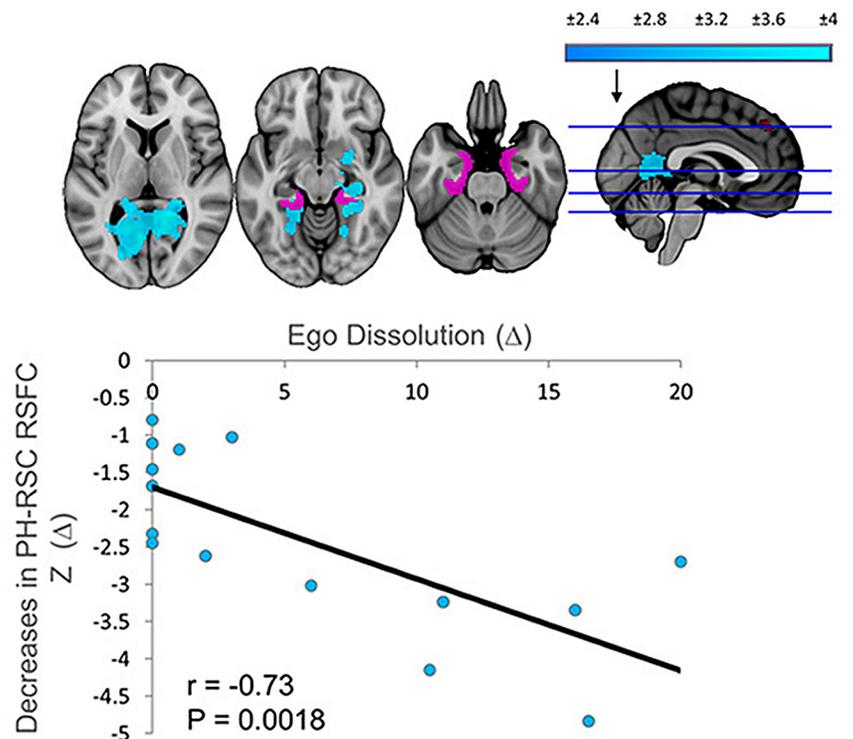


Figure 2. LSD decreased the connectivity between the parahippocampus (PH) and retrosplenial (RSC) cortex (an important region of the default mode network), and this decrease correlated with increased ratings of ego-dissolution.

locybin, and 42% remaining depression-free for at least three months (see Figure 3).

The success of this study reinforced that of the Beckley-sponsored Johns Hopkins study, which began in 2008, to investigate the efficacy of overcoming treatment-resistant nicotine addiction with psilocybin-aided psychotherapy. This pilot study had an amazing 80% success rate at 6 months, and has now led to an expanded double-blind study.

Opening up another promising avenue of research, the Beckley/Sant Pau Research Programme, led by Jordi Riba, has found that two components of ayahuasca—harmine and tetrahydroharmine, stimulate neurogenesis i.e., the birth of new neurons, in hippocampal stem cells *in vitro*. If this can be replicated *in vivo*, it may lead to new treatments for neurodegenerative disorders such as Alzheimer’s and Parkinson’s disease (see Figure 4).

The Beckley Scientific Programme is researching many of the effects of psychedelics, such as their interaction with music; their capacity to enhance mindfulness; the importance of the mystical experience; and the mechanisms underlying visual hallucinations. We are also conducting an exciting new study to investigate the subjective and neural effects of the under-researched molecule DMT, which will allow us to compare its mechanisms of action with those of LSD and psilocybin. In the pipeline is a study investigating the efficacy of LSD-assisted psychotherapy in overcoming alcohol addiction, for which we are currently applying for ethical approval.

An increasing number of studies suggest that psychedelics can help treat those conditions that often elude modern medicine—conditions characterized by rigid thoughts and behaviours, such as chronic depression, addiction, posttraumatic stress disorder, and obsessive-compulsive disorders. One of the remarkable characteristics of psychedelics is how one, or possibly two doses can bring about long-lasting positive change. The psychedelic experience is like a reset-button—it shakes the rigidity and prepares the ground for new seeds to grow.

LSD, psilocybin and ayahuasca have all shown long-lasting

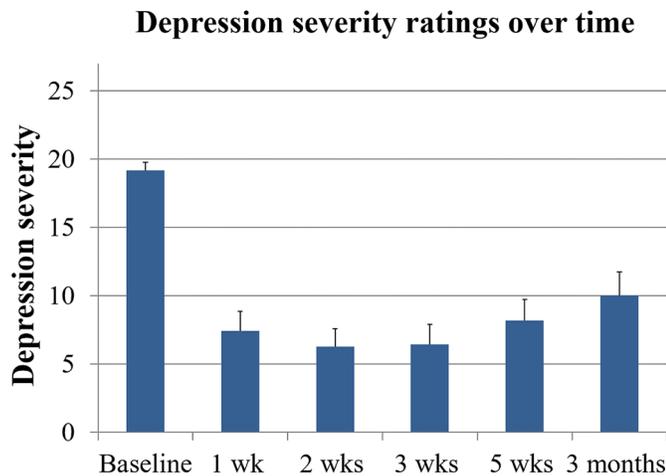


Figure 3. Depressive symptoms were markedly decreased following 2 sessions of psilocybin-assisted psychotherapy, and remained significantly reduced after 3 months.

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Figure 4. β -carbolines found in ayahuasca actively stimulate the proliferation and growth of neuronal progenitor cells into new neurons. A: No effects are seen after treatment of progenitor cells with a saline control. B and C: following the addition of harmine and tetrahydroharmine there is a marked increase in the growth of new neurons. (Color pdf available at maps.org/bulletin)

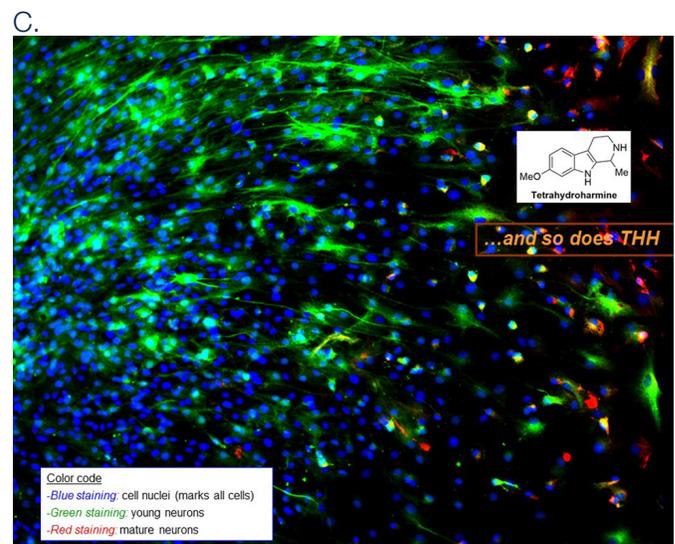
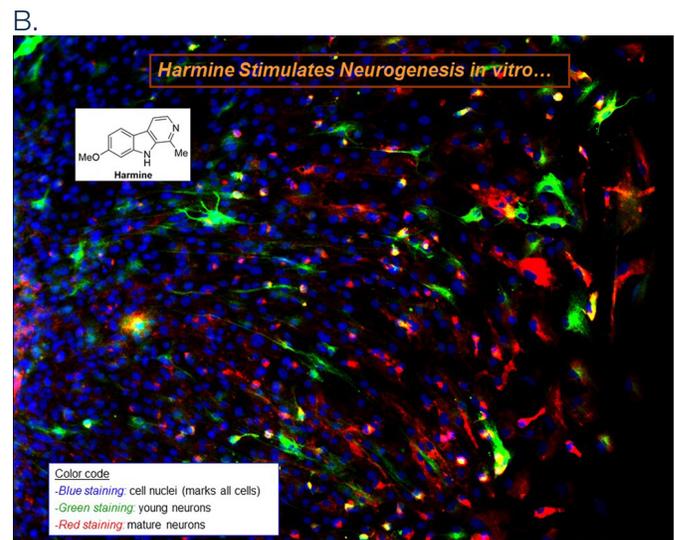
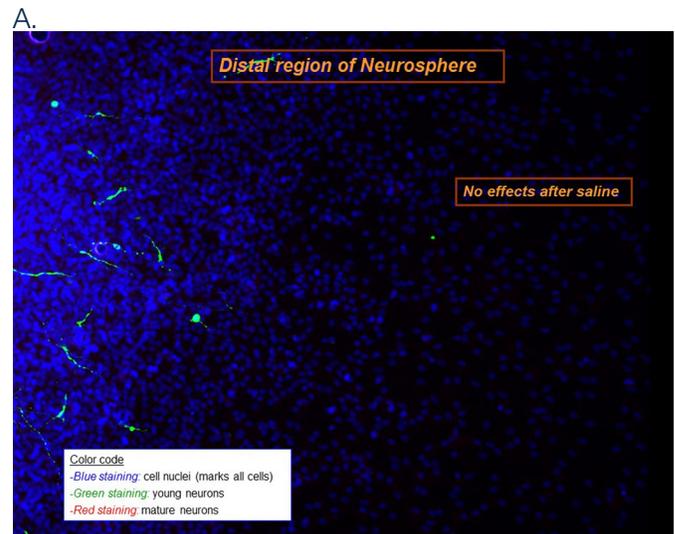
positive effects. Our studies showed that the personality traits of optimism and openness increased for at least two weeks after ingestion of LSD, and the extent of these long-term changes correlated with the extent of the network disintegration and desegregation experienced under LSD.

Our studies with ayahuasca have shown that regular use increases the qualities of openness, optimism and mindfulness. Another observation has revealed a shrinking of the posterior cingulate cortex (PCC) – one of the brain-regions involved in representing the self and self-awareness – among regular ayahuasca users. What's more, a smaller PCC correlated with higher scores on several mindfulness-related traits: self-transcendence, transpersonal feelings, and spirituality.

As this new era of psychedelic research progresses, it will be essential to understand the minutiae of the physiological and neuronal changes underlying the psychedelic state. It is also imperative that we create the political environment to support this research, and to facilitate the licensing and prescription of these potent medicines, and help make available clinics that will provide psychedelic-assisted psychotherapy to those in need.

After forty years of near-total stagnation, the psychedelic state is finally beginning to be understood. It won't be long before our small-scale studies are followed by large scale clinical trials, which we hope will demonstrate once and for all, just how valuable psychedelic substances can be for the future of medicine.

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.

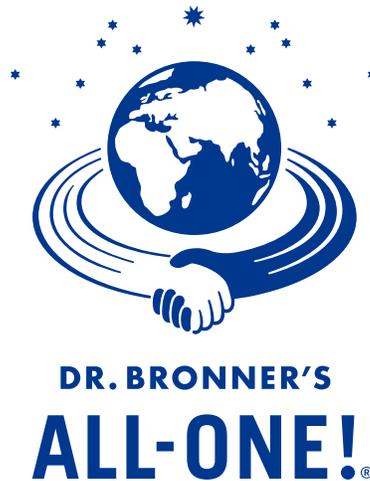


Why We're Donating \$5 Million to MAPS

DAVID BRONNER, CEO OF DR. BRONNER'S, BOARD MEMBER OF MAPS



David Bronner



OUR FAMILY COMPANY, DR. BRONNER'S, donates a lot of resources to social justice NGOs and campaigns, including over \$1 million to various state-level cannabis legalization campaigns in 2016. Collectively, well north of \$40 million was raised in the 2016 election cycle alone to end prohibition and stop the enormous waste of taxpayer and law enforcement resources from ruining the lives of upstanding citizens and their families. Even with the Trump administration, momentum is growing to recognize medical cannabis at the federal level and remove it from Schedule 1 of the Controlled Substances Act. Now, we have the opportunity to legalize MDMA as a U.S. Food and Drug Administration (FDA)-approved medicine, to be available in all 50 states, for a total cost that is substantially less than what we as a movement are investing into legalizing medical and recreational cannabis.

Along with many thousands of people, it's been our honor and pleasure to support the Multidisciplinary Association for Psychedelic Studies (MAPS)' strategy to fund FDA-approved clinical research on the effectiveness of psychedelic medicine

for diverse conditions, and to change the political climate that makes this type of research so difficult to conduct. The amazing team at MAPS have overcome obstacle after obstacle to bring us to this great moment: not only the FDA's recent go-ahead for Phase 3 studies of MDMA-assisted psychotherapy for treatment-resistant posttraumatic stress disorder (PTSD), but also the FDA's final guidance on the Phase 3 study design and protocol. MAPS has mapped out a detailed five-year game plan and a \$25 million budget, with FDA approval nearly assured when the research and funding are complete. Much of this expense is frontloaded in the first two years, so in order to be assured that the cash flow is there as needed, we need to get pledges lined up before we begin the studies.

This is the crucial moment to step up for one of the most important causes on the planet. There is tremendous suffering and pain that the responsible integration of MDMA for treatment-resistant PTSD will alleviate and heal. Plus, once MDMA is an FDA-approved medicine, legal use for other conditions is close behind. The FDA's approval of MDMA will also pave the



Dr. Bronner's is a family-run business that has been supporting MAPS since 2005. L to R: Michael Milam, Chief Operating Officer; Trudy Bronner, Chief Financial Officer; Michael Bronner, President; and David Bronner, Cosmic Engagement Officer (CEO).

way for other psychedelic medicines to follow, such as psilocybin for end-of-life anxiety and ibogaine for opiate addiction. To help inspire our allies to close the funding gap, my family has pledged \$1 million a year for five years—\$5 million total—by far our largest gift to an NGO partner to date. In part we were inspired by the incredible example of Ashawna Hailey, former MAPS Board member, who gave MAPS \$5 million when she died five years ago. MAPS has banked those funds for Phase 3, and coupled with our gift, that leaves a \$15 million gap for other angel donors to close. Smaller donations add up huge if enough people throw down.

We face enormous challenges globally, and psychedelics—used responsibly—can help us solve them. MAPS' larger goal is to see psychedelic medicine responsibly integrated into American and global culture, readily available to those who need it most, while helping the rest of us open our hearts and minds to each other and to the miraculous living world we live within. MAPS intends to use the profits generated from selling MDMA once it's an FDA-approved medicine to train therapists

and set up treatment clinics around the world, and to expand its research and move other psychedelics through the formal FDA regulatory approval process. Thus, our investment now into making MDMA a legal medicine will turn MAPS and the broader field of psychedelic science into a self-sustaining organism, exponentially increasing MAPS' ability to impact and change the world. I hope you are as inspired as we are to help them do it. 🌍

David Bronner is President of Dr. Bronner's Magic Soaps, the top-selling natural brand of soaps in North America. He graduated with a degree in Biology from Harvard University in 1995. David dedicates resources to different issues on behalf of the company's mission to make products of the highest quality, and to use profits thereof to help make a better world. He can be reached at info@drbronnner.com.

Psychedelic Science 2017: Interview with Conference Director Brad Burge

WESLEY THORICATHA



Brad Burge

PSYCHEDELIC SCIENCE 2017

APRIL 19-24, 2017 • OAKLAND MARRIOTT CITY CENTER • CALIFORNIA

NEXT MONTH IN OAKLAND, CALIFORNIA, hundreds of psychedelic researchers, scientists, advocates, and experts will converge at Psychedelic Science 2017, a major psychedelics conference hosted by the Multidisciplinary Association for Psychedelic Studies (MAPS). This five-day event will not just include workshops and presentations from the world's leading psychedelic researchers but will also involve a sunset cruise, a marketplace, and the world's first Psychedelic Comedy Banquet featuring comics like Duncan Trussell, Shane Mauss, and Adrienne Airhart. Wesley Thoricatha of Psychedelic Times recently caught up with Brad Burge, Director of Communications and Conference Director for MAPS, to talk about the event, its history, its purpose, and what exciting things are in store this year.

Thanks for taking the time to speak with us, Brad. I know you are busy preparing for the conference. Can you give us an overview of what Psychedelic Science 2017 will entail and what MAPS hopes to accomplish with conferences like this?

Most of our focus at MAPS is on clinical research of the therapeutic benefits of psychedelics and cannabis, with our main effort right now being Stage 3 clinical trials of MDMA psychotherapy for PTSD, working closely with the FDA and other government regulators to make this research happen and make psychedelics available as a legal prescription treatment. Once every three or four years, we put on the Psychedelic Science conference, and this will be our third event of this kind. The reason we don't hold this event annually is that we are a smaller organization, so we have to apportion our time and resources with care. Our aim with the conference is twofold. Firstly, we hope to create conditions to fertilize this field by bringing scientists together, enabling collaborations, and sharing scientific research. The other purpose is to contribute to the general public education surrounding psychedelics and marijuana and create a forum where people can come together from around the world to talk openly about their benefits—not just therapeutically but also creatively and spiritually.

This year features the world's first Psychedelic Comedy Banquet. What went into the thinking behind putting this on?

It's been something we've been thinking about for some time, blending together comedy and psychedelics. It seems to just be happening! Joe Rogan played a big role when he started speaking on his podcast about his psilocybin and DMT experiences and invited guests like Rick Doblin to speak about psychedelic science. More comedians have been talking about it in their acts as things like ayahuasca and microdosing have become more popular. I think that comedy is a really powerful way to mainstream and legitimize topics because you can laugh about it and take it less seriously, which leads to discussing it more openly. Often with psychedelic therapy, we are talking about

really serious things; it's not all glitter and rainbows. People go through really heavy stuff like dealing with trauma or coping with depression, anxiety, life threatening illness. Comedy is a way to lighten up the discourse.

Of all the presenters and workshops, is there one in particular that you are personally most excited about?

Of course all the science and research is really exciting, but I'm really glad we were able to get on the Plant Medicine Track a speaker coming from South Dakota, Sandor Iron Rope. He is part of the Native American Church, and he will be speaking about [the] indigenous perspective on how peyote can be used and the conservation of peyote in North America. Peyote is the source plant for mescaline, which is the source for MDMA and MDA and many other substances. It's one of the plant medicines with the longest history of cultural uses in North America, so I'm really glad Sandor Iron Rope will be part of the event.

This is a very exciting time for psychedelic research and therapy, thanks in large part to MAPS' efforts over the years. How is your organization processing the steady and significant inroads psychedelic research is making into mainstream science and culture? Is the atmosphere one of excitement or cautious optimism?

Both, definitely. We try to convey as much as possible the feeling of excitement and optimism that we have as a result of all the success and expanding research, but we always try to balance that because we need so many more resources to complete the research that we started and make MDMA a medicine. We need to raise another 20–30 million dollars over the next four years to complete the Phase 3 trials and make MDMA a medicine, and we want to deepen our relationships with the Department of Defense and the DEA and the current administration to garner greater support for our work with veterans. So as excited as we are, we are thinking about how we deal with our next phase of growth and where the next level of public support is going to come from. One of my favorite quotes sums this sentiment up: "Watch out for insurmountable opportunities." 🌀

Note: This interview was originally published on Psychedelic Times (psychedelictimes.org) and is reprinted with permission. To learn more about Psychedelic Science 2017, visit psychedelicsscience.org.

Wesley Thoricatha is a writer, visionary artist, permaculture designer, and committed advocate for psychedelic therapy as a means to a more meaningful and harmonious world.

Begin with the end in mind
then work backward to plan for reaching ambitious goals
—Ashawna Hailey, who left \$5.5 million to MAPS in her will

Help create a world where psychedelics are integrated into society by including MAPS in your end of life plans. If you tell us about your plans, you can join our *Next Horizon Society*, and we will invite you to receptions, learning opportunities, and other special events.

Please contact MAPS Development Officer
Jade Netanya Ullmann to discuss your plans.
jade@maps.org
831.429.6362 x111





Beatriz Caiuby Labate, Ph.D.

Community Forums at Psychedelic Science 2017: A Vibrant Dialogue Between Scientists and Practitioners

BEATRIZ CAIUBY LABATE, PH.D.

PSYCHEDELIC SCIENCE 2017

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I AM THE CURATOR OF the Plant Medicine Track, and also of a series of community forums in Psychedelic Science 2017. As an anthropologist working on a conference that is largely geared towards biomedical research, I am pleased that we are bringing together the cutting edge of scientific research on psychedelics and creating a plural and inclusive space that hopes to actively strengthen local and international communities of people with kindred interests.

Among the Community Forums we are hosting are: *Exploring Legal Strategies, Harm Reduction and Best Practices for the Ayahuasca Community* (led by Robert Heffernan, Ben Christie, and Andrea Langlois); *Ayahuasca Researchers Meeting: Ayahuasca Science in the Twenty-first Century* (led by Helle Kaasik); *Ibogaine Safety* (led by Christine Minanga Fitzsimmons, Jamie McAlpin, and Clare S. Wilkins); and *Ayahuasca Best Practices, Sustainability and Reciprocity* (led by Matthew Watherston, Deanna Rogers, Adam Andros Aronovich, and Tanya Maté.)

Through these forums we are promoting ties between scientific researchers, and creating the opportunity for them to share experiences and challenges around their work. At the same time, their goal is to foster a dialogue between academics, therapists, religious leaders, facilitators, activists, artists, enthusiasts, indigenous representatives, and other voices. Finally, these forums hope to give back to the community, in more accessible ways, part of the knowledge that is being produced in academia.

In these spaces, we will openly discuss best practices and ethics associated with the rapid expansion of the uses of ayahuasca and iboga. We will also address the sustainability of these plant medicines and our responsibility to take into account the perspectives of people who live where these substances originate, and to reciprocate in fair ways.

This is important, because purely scientific discussions often omit some of these aspects. This happens either because science takes a long time to gather “data” or due to the fact that, often, researchers are afraid to openly address controversial aspects of their work. Yet, as a collective interested in advancing the public understanding of psychedelics, we must contemplate the conflicts and problems that exist—such as the need for

screening, interaction with drugs or pharmaceuticals, legal risks, proper training of therapists or ritual leaders, commodification, proselytism, sexual abuse, accountability, the proliferation of dubious “alternative” treatments and medicines, the emergence of pseudo experts, and other challenges in this growing field.

Above all, by giving space to multiple voices, we recognize that science does not happen in a vacuum, but rather is inserted in a specific socio-cultural context. Currently, the context of psychedelic science and knowledge is one of prohibition and stigma. No one can deny that investigations that might alter current drug schedules are constantly being obstructed and suffer from a lack of funding. As we incorporate the perspectives of practitioners and discussions around cultural and legal aspects, we are also creating a better scenario for the development of the science of psychedelics.

Scientists must be educated about the cultural contexts and sensitiveness surrounding these substances; practitioners need to understand the challenges involved in psychedelic research; scientists and practitioners must collaborate to improve the quality and utility of research; policy makers need to reevaluate restrictions on scientific research; and all parties need to promote benefit maximization and help strengthen informal and cultural controls for safe psychedelic use.

Besides gathering data and producing “scientific evidence,” we need to create dialogues between science, culture, and society, to better navigate the perilous regulatory waters. 🌀

Beatriz Caiuby Labate has a Ph.D. in Social Anthropology from the State University of Campinas (UNICAMP), Brazil. Her main areas of interest are the study of psychoactive substances, drug policy, shamanism, ritual, and religion. She is Visiting Professor at the Center for Research and Post Graduate Studies in Social Anthropology (CIESAS), in Guadalajara, Mexico. She is also co-founder of the Interdisciplinary Group for Psychoactive Studies (NEIP), and editor of NEIP’s website, neip.info. She is author, co-author, and co-editor of seventeen books, one special-edition journal, and several peer-reviewed articles. For more information, see bialabate.net. She can be reached at blabate@bialabate.net.

Sharing Our Stories: Psymposia at Psychedelic Science 2017

LEX PELGER



Lex Pelger



PSYCHEDELIC SCIENCE 2017
APRIL 19–24, 2017 • OAKLAND MARRIOTT CITY CENTER • CALIFORNIA

PSYMPOSIA IS EXCITED TO JOIN in making Psychedelic Science 2017 an even more in-depth learning experience for the community. Thanks to the generosity of MAPS and The Beckley Foundation, who are hosting the event, our stage will be located in the Marketplace (free and open to the public) from April 21–23, and provide a platform for people to explore psychedelics from a variety of angles, to share their personal transformative stories, and to engage in timely conversations on the big issues facing the psychedelic research community.

Political activist and poet Muriel Rukeyser once said, “The Universe is made of stories, not of atoms.” In the psychedelic research world, anecdotal evidence sometimes slips through the cracks, yet it also serves as some of our most powerful data. The Psymposia Stage at Psychedelic Science 2017 is a platform for attendees to share your story, so we’ll have opportunities for “open mic” storytelling the entire weekend.

We’ll also feature a wide range of familiar faces and fresh voices including young people from Latin America, Asia, and South America who’ve received scholarships to attend the Psychedelic Science 2017 conference; authors, artists, and academics sharing insights into their lives and work on the streets, behind a desk, or in the lab; conversation circles exploring issues like addiction, harm reduction, microdosing, mental health, regulation, and diversity; and short talks from a variety of ex-

perts on plant medicines, clinical applications, and the value of subjective experiences in science.

THE BLUE DOT TOUR

On the road to Psychedelic Science 2017, starting in early April, we began the Blue-Dot Tour. This cross-continent, zig-zagging storytelling adventure stopped in cities and towns that are hotbeds of activism: blue dots in red states. Of course, we also visited some blue dots in blue states, and we’re looking for hosts from Mexico to Canada who want to see a communal education night in their community.

The tour provided educational spaces—outside computers and classrooms—for the community to come together to share their experiences, good, bad, or ugly. Whether it was new insights from psychedelics, healing through opiates, spirituality through dissociative compounds, or any other experience with psychoactive substances, we captured people’s stories from across America.

Our group started by organizing conferences and lecture nights, and while we still treasure pulling those together too, it’s the storytelling nights that blossomed into the true communal magic. It’s amazing to see what our community brings when you simply put a naked microphone on the stage and ask for a share.

Along the way on the Blue Dot Tour, we screened the excellent and persuasive new film by MAPS Board member Robert Barnhart, *A New Understanding: The Science of Psilocybin*, which takes a powerful look at the healing enabled through this formerly suppressed and now re-emerging medicine.

In these turbulent and divisive political times, we feel that some of the best solutions emerge from community events, partnerships and platforms that bring people together to share honest insights, stories, and lessons learned the hard way. It's a vital part of activism: hearing from our elders, finding our peers, shifting conversations towards healing, liberty, and taking an honest look at both the benefits and the risks of psychoactive substances.

An important aspect of fulfilling this vision is seeking diversity in the community, including women, people of color, and other underrepresented voices. On the tour, I sat down with as many old-timers, autodidacts, and underground wisdom seekers as I could find to record out there on the road. So if you'd like to see a storytelling session or educational night for your community, student group, or conference, let Psymposia know and we'll be glad to facilitate however we can. On the Blue Dot Tour, we found many new stories to showcase—which leads me to our other recent exciting news.

THE PSYCHEDELIC SALON 2.0

Psymposia will be contributing new content to the venerable Psychedelic Salon podcast. We'll be infusing it with our own mix of talks, interviews, and conversations on psychedelics, drug war reform, harm reduction and overall "psychoactivism."

Send us news about your events, recommendations about who to interview, and anything else from the community you'd like to hear shared on the air. Reach out to Psymposia magazine if you want to submit your own experience, or come out of the closet by posting a video to the **#PsychedelicsBecause** campaign.

"I want to be involved in the psychedelic field in some way—what should I do?"

We're often asked this question and here's our answer: Follow your passion and do what you love! The beauty of psychedelics is that it's truly a multidisciplinary field: science, art, comedy, harm reduction, education, community building, and networking all form invaluable pieces of the puzzle.

You don't have to be a researcher, therapist, or neuroscientist to make a difference. We started out as students and activists who met at the *Horizons: Perspectives on Psychedelics* conference, and we decided to organize our own conference the following year at the University of Massachusetts-Amherst, which

we livestreamed around the world. The conference had a big impact, and encouraged us to continue organizing events across the country. If you have an idea that you think will make a positive change, take action! Ideas without action are like seedlings without water.

So, we encourage you to look at what's out there. If there's a gap you think is missing, fill it in. For us, we saw a lack of honest drug education and critical conversations out there, so we started our own online magazine last year at **psymposia.com**. While still in its infancy, our team has grown organically to include writers and editors in Tel Aviv, Portland, London, Boston, Queens, Burlington, and Baltimore. Our projects combine science with stories to bring a positive change and encourage people to think about society, medicine, and law.

"Symposia" are defined as friendly, lively, and free flowing gatherings of conversation and music. In that spirit, Psymposia aims to create a platform—in person and online—to bring groups together for critical conversations and the free exchange of stories, perspectives, and ideas.

HAVE STORIES? WILL TRAVEL

If you'd like to see a storytelling stop in your hometown, university, or loft please reach out to us at hi@psymposia.com.

If you would like to support our work, consider making a pledge to our crowdfunding campaign at **patreon.com/psymposia**. For as little as \$2/month, you can help us continue growing and spreading the message far and wide. Thank you for your support!

We also send a very big thank you to our friend Lorenzo Hagerty for giving us such a wonderful opportunity to revive the Psychedelic Salon.

Finally, we want to end with our gratitude to MAPS and The Beckley Foundation for pulling together the Psychedelic Science 2017 conference, inviting us to contribute an entire stage all weekend, and for MAPS' 31 years of work threading MDMA and other psychoactive substance (through the eye of a needle) towards FDA-sanctioned medicines for healing. 🌱

*With a background in science, **Lex Pelger** writes about drugs & as the host of Psymposia, he organizes psychoactive education & storytelling events. In his lectures, he covers how drugs work in the brain, shares stories of their actual use in the field & teaches about the dark racist history of the War on Drugs. His main project is a large graphic novel about cannabis and the endocannabinoid system (based on Moby Dick) titled "Anandamide or: the Cannabinoid". See the first finished chapter about Queers, AIDS, Reagan & the birth of the modern medical marijuana movement at lexpelger.com.*



Emily Williams, M.D.

Towards Breakthrough Healing: A History and Overview of Clinical MDMA Research

EMILY WILLIAMS, M.D.

IN NOVEMBER 2016, THE U.S. Food and Drug Administration (FDA) green-lit Phase 3 clinical trials proposed by MAPS to further investigate MDMA-assisted psychotherapy for the treatment of posttraumatic stress disorder (PTSD). This means we are closer than ever before to the reclassification of MDMA for legal clinical use as a prescribed medication. But how did we get here? Why—over a century since the first synthesis of MDMA—are we still working to demonstrate its safety and efficacy?

MDMA was first synthesized and patented by the German pharmaceutical company Merck in 1912 as one in a series of chemical intermediaries to produce a compound to stop abnormal bleeding. Merck first studied MDMA itself in animals in 1927, and then again in 1952 and 1959, but decided not to initiate research in humans throughout this period. After a brief series of toxicity studies in animals by the U.S. Army in 1953–4, MDMA was largely disregarded and thought to have no potential medical benefit.

In 1976, MDMA was rediscovered by medicinal chemist Alexander Shulgin, Ph.D. Its use was then spread by psychiatrists and psychologists who reported seeing benefits to its use as an adjunct to psychotherapy for individuals and couples in MDMA-assisted therapy sessions. MAPS founder Rick Doblin, Ph.D., learned about MDMA in 1982 as an adjunct to psychotherapy, but at that time it was already gaining in popularity in the party scene, leading the U.S. Drug Enforcement Administration (DEA) to identify it as a drug of abuse. Doblin then embarked on a valiant, but unsuccessful, effort to preserve the therapeutic use of MDMA by petitioning the DEA, but the agency ultimately criminalized the compound in 1985.

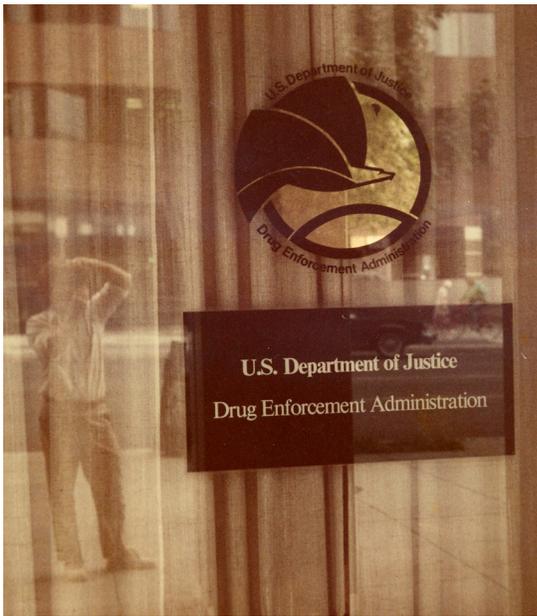
Doblin realized that the path to legitimizing psychedelic-assisted psychotherapy would be proving its efficacy via rigorous clinical trials sanctioned by the FDA. This provided Doblin with the motivation for the establishment of a non-profit medical research organization—the Multidisciplinary Association for

Psychedelic Studies, or MAPS—in 1986. MAPS began funding animal toxicity studies and human safety studies at Stanford University and Johns Hopkins University in the late 1980s (Emerson et al. 2014).

Nearly a decade later, the first FDA-approved, double-blind, placebo-controlled U.S. Phase I dose-response safety study of MDMA was published by Charles Grob, M.D., in 1996, working with MAPS. Since that time, MAPS has funded and conducted twelve clinical trials around the globe investigating MDMA-assisted psychotherapy for PTSD, anxiety related to advanced-stage illness, social anxiety in autistic adults, and a (still ongoing) study of healthy subjects via the MDMA therapist training program, with plans for additional studies of MDMA therapy for race-based trauma and transgendered people as well.

Because of MDMA's ability to decrease the fear response and increase empathy and interpersonal trust, early clinicians recognized that it could be especially useful in treating PTSD, a disorder characterized by patients' emotional activation when accessing traumatic memories. In hopes of investigating this potential link, MAPS sponsored the first clinical trial of MDMA-assisted psychotherapy for the treatment of PTSD in 2000, with a pilot study of female survivors of sexual assault with treatment-resistant PTSD in Spain. Unfortunately, the study was discontinued in 2002 due to pressure from the Madrid Anti-Drug Authority after only six subjects were treated with a single dose of MDMA ranging from 50 to 75mg (low to medium doses by comparison to current studies).

In 2004, the FDA and DEA approved the first U.S. clinical trial of MDMA in humans as an Investigational New Drug (IND) for the treatment of PTSD. This randomized, placebo-controlled Phase 2 trial, led by Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., in Charleston, South Carolina, was published in the *Journal of Psychopharmacology* in 2010. The study employed the male/female co-therapist pair method, which has become the standard in MDMA-assisted psychotherapy clini-



Rick Doblin caught a reflection of himself in the window when he petitioned the DEA to preserve the therapeutic use of MDMA in 1984. (left) after learning about the benefits of using it as an adjunct to psychotherapy with Leo Zeff (above).

cal trials, and treated patients with two full-dose MDMA experimental sessions using 125mg (with a 62.5mg supplemental dose offered two hours after the initial dose). The results were impressive. In a sample of 20 subjects with chronic, treatment-refractory PTSD (meaning they had failed two or more courses of conventional therapy), 83% no longer qualified for PTSD as measured by the Clinician-Administered PTSD Scale (CAPS), versus 25% of the placebo group at the end of treatment. In the long-term follow-up study, approximately 75% of patients still showed meaningful sustained reductions in their PTSD symptoms an average of three and a half years later and many patients no longer met criteria for PTSD (Mithoefer et al. 2011, 2013).

In 2006, a second Phase 2 study of MDMA-assisted psychotherapy for PTSD was sponsored by MAPS, this time conducted in Switzerland by Peter Oehen, M.D. This small study treated twelve subjects with three full-dose MDMA sessions (125mg initial dose + 62.5mg supplemental dose) compared with low-dose active placebo sessions (25mg + 12.5mg), and was published in 2012.

Though the reduction in CAPS for this group was not statistically significant due to the small size of the study ($p=0.066$), the effect size was similar to the first study by the Mithoefers, with further improvement in CAPS scores at the one-year follow-up.

The positive outcomes and lack of any serious adverse events in these first studies paved the way for the expansion of the MAPS research program and the further investigation of MDMA-assisted psychotherapy for PTSD and other psychiatric disorders. In Colorado, a Phase 2 study of 23 subjects with PTSD led by Marcela Ot'alara, M.A., piloted an intern training program in which one member of the co-therapist team is a healthcare intern, with the other being an experienced clinician. This study also aimed to determine optimal dosing of MDMA by comparing 125mg and 100mg doses of MDMA with a

40mg active placebo, then allowing patients to choose 100mg or 125mg dosing options in the second stage of the study. As of March 2017, this study, along with a separate MAPS-sponsored team in Israel, have nearly completed 12-month follow up visits. In November 2016, the team in Vancouver, Canada led by Ingrid Pacey, M.D., concluded their investigation of MDMA-assisted psychotherapy in six subjects with PTSD. This study compared full-dose 125mg MDMA with inactive placebo and the data will be included in a meta-analysis of MDMA-assisted psychotherapy results. A second Phase 2 study led by the Mithoefer team in Charleston, South Carolina, also recently concluded. This study—MAPS' largest Phase 2 trial—focused on a population of 24 U.S. military veterans, firefighters, and police officers, and compared 125mg and 75mg doses with a 30mg active placebo dose. The results from this study are currently pending publication, and will be presented at Psychedelic Science 2017.

While MDMA was used clinically with much success in couples therapy prior to its scheduling, until very recently MDMA-assisted

psychotherapy studies focused only on individuals. In 2016, Michael Mithoefer, M.D., and Candice Monson, Ph.D., began an exciting new phase in MDMA research, with a pilot study of MDMA-assisted Cognitive Behavioral Conjoint Therapy (CBCT) in couples. This study, now ongoing, includes one member of a couple with chronic PTSD, a significant other with no PTSD diagnosis, and significant relationship strain related to the PTSD symptoms. This study is expected to exhibit the improved communication and interpersonal connectedness reported in early publications on MDMA therapy.

MAPS has also funded and obtained approval for studies focused on other psychiatric disorders besides PTSD. In 2014, MAPS began a Phase 2 clinical trial of MDMA-assisted therapy as a treatment for social anxiety in adults on the autism spec-

*We are in the midst of a
psychedelic research renaissance.*

trum, led by Charles Grob, M.D., and Alicia Danforth, Ph.D., at the Los Angeles Biomedical Research Institute in Los Angeles, California. This study has been completed, and a protocol rationale paper was published in 2015. Also ongoing through MAPS is a clinical trial led by Phil Wolfson, M.D., in Marin, California, investigating the safety and efficacy of MDMA-assisted psychotherapy for anxiety in 18 subjects diagnosed with life-threatening illness. Additionally, a recently-approved MAPS-sponsored Phase 1 pilot study at Emory University led by Barbara Rothbaum, Ph.D., is investigating the effect of MDMA on fear extinction learning in healthy volunteers. This study aims to provide important insight into why MDMA may be beneficial for treating PTSD and will supplement an upcoming study combining MDMA with Prolonged Exposure, an evidence-based psychotherapeutic approach to treating PTSD.

Since the classification of MDMA as a Schedule I substance in 1985, there have been over 5,000 articles written about the compound in academic journals, and over 1,100 volunteers have taken MDMA in clinical settings. Many groups across the globe are passionately working to answer important questions developing from this seminal research, such as: How does MDMA produce its benefits in therapy? What changes occur in brain activity while under the influence of MDMA? What are its potential risks and side effects? What is the abuse potential? There have been many studies of the acute effects of MDMA on healthy subjects, highlighting a wide range of results including fMRI data showing specific patterns of increased and decreased cerebral blood flow (Carhart-Harris 2014, 2015), PET scans of neurotransmitter release and receptor activity (Vollenweider 2002), and data demonstrating pro-social and increased emotional verbal content with MDMA (Baggott 2015). As with all carefully designed and implemented research, each question answered leads to more questions to be asked.

Reflecting on the research completed, in-process, and planned for the future, it is particularly notable that these studies detailed above have been wholly the result of private funding, thanks to the heroic efforts of MAPS. Because of the hard work and dedication by the clinicians and scientists noted above, and many others whom we did not have space to list, we are in the midst of a psychedelic research renaissance. For the first time in decades, students are able to pursue careers investigating treatments based on trusting the healing process, and on letting go of expectations. As Stanford neuroscientists Boris Heifets, M.D., Ph.D., and Robert Malenka, M.D., Ph.D., wrote in their compelling commentary paper published in *Cell* in 2016: “The world’s populations need more compassion and empathy for one another. The study of MDMA provides one small but potentially important step toward reaching that goal.” This approach to healing and healthcare is needed now more than ever. 🌱

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Emily Williams, M.D., is a psychiatry resident at the University of California, San Francisco in the NIH-funded Resident Research Training Program (R25 MH060482). She is currently conducting an analysis of the effects of MDMA on therapeutic alliance as well as serving as co-PI on a MDMA-assisted psychotherapy for PTSD Phase 3 clinical trial site. She also works as the independent clinical rater for the MAPS-funded study on MDMA for end of life anxiety in Marin, CA. In addition to her clinical and research work, she has a passion for harm reduction and serves as a supervisor for the Zendo Project which provides psychedelic harm reduction for events and festivals. She can be reached at emilynicolewilliams@gmail.com.

Being Present for the Journey: Experiences of MDMA-Assisted Psychotherapy

KAREN DIAMOND

JOHN SAUL



Karen Diamond

Karen Diamond and John Saul were both participants in MAPS-sponsored studies. Here they share their personal stories of what brought them to our studies and how their lives have changed in the months following their MDMA-assisted psychotherapy experience.

★

Karen Diamond was a subject in MAPS' study of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) in Boulder, Colorado.

I WAS BORN TO HEROIN-ADDICTED parents who divorced when I was two. Beginning around age 5, I was repeatedly molested by neighbors. At age seven, my father committed suicide and at 12 my mother followed suit. I came home from school and found her in bed. From 13–39, I used nicotine, marijuana, alcohol, cocaine, heroin, and pills to manage my emotional pain and PTSD symptoms. After having my first child at 27, I started decades of therapy and tried a myriad of antidepressants. I have worked hard on myself to create a good life. But even with a loving husband of 32 years, two amazing children, and now a grandson, I just wasn't able to enjoy it. This is what motivated me to try MDMA-assisted psychotherapy.

Here's an excerpt from a letter I wrote to my friends and family after the first session.

It's like doing years of therapy in one day. It's not scary, I never felt out of control, and didn't feel 'high.' Though there was a bit of visual vividness when I opened my eyes, and I did have these metaphorical 'visions' in my mind while lying there feeling deeply connected to the music, everything was always in my control. If I started to see something I didn't want to look at I could (and did) easily move away from it. For me, that was the sexual abuse. And I will be revisiting that for sure.

The great thing is that I was able to take the principles that I have intellectually known after decades of therapy, and make a huge gut connection that feels permanent...in part due to the medicine, and partially due to the gentle and supportive way the therapists were with me on the journey. It's like a big AHA! moment happens and is reinforced by the medicine and the therapy style. What I experienced during the active treatment, is what I always kind of knew, but what I now not only KNOW, but BELIEVE. AMAZING!



John Saul

The core of that for me is that I felt broken and unworthy. Now know I am whole and worthy. All the things that happened still happened, but I was not broken. And the things that happened to me had nothing to do with me. And dammit—I made it! A beautiful bud on a strong stem, some outer leaves crushed and bruised, but still able to bloom. :)

Don't get me wrong, this is not a totally instantaneous process, it will take some continued work on my part to rewire my reactions to things. But it feels so doable, and I can only imagine how much more I will get out of the remaining two sessions.

As I mentioned in my letter, MDMA didn't create hallucinations, but more something I would call "felt metaphors"—a way of seeing events and feeling emotions with a new perspective that allowed me to explore the traumatic events and the impact they had on me in a way that I was unable to do with traditional therapy and antidepressant drugs.

MDMA-assisted psychotherapy helped me to see my parents and sexual perpetrators as their own people on their own journey with their own issues. To realize that the ways in which they were not there for me, were not capable of being there for me, the ways in which they were horrible to me and could not control their behaviors, had nothing to do with me—that it wasn't personal—not so much to forgive them, but to let go of them, to move on.

Since finishing treatment over a year ago, I don't wake up dreading each day. Overall I'm feeling happier, more secure, and able to enjoy my life. I'm experiencing fewer intrusive thoughts, and a reduced startle reflex. Even when I get frightened, the adrenaline doesn't spike through my body like it used to. No more waking up at night in a sweat with my heart pounding. Less need to try to control everything—my kids, my husband, holidays. It's easier to make decisions and I have less anxiety. When it does come up I can face it, instead of trying to repress and avoid it. I don't hate myself anymore, a.k.a., I love myself.

I just turned 60, and I still have a lot of things I am working on changing, and other things I'm learning to accept as they are about myself. But what stands out is my dramatically increased ability to enjoy my life, figuring out who I am, what I like and don't like, without the PTSD ruling my moods and behaviors. Here's to enjoying and being present for my journey through the next 30+ years!

Karen Diamond was born in Stafford Springs, Connecticut, and has lived in Colorado since 1976; it's home. Her work history runs the gamut from restaurant work to sign language interpreting to running art shows. Currently she owns her own business selling a unique product for women called the P-Mate. Family is everything to Karen, so fortunately, her two children and grandson live close. Her current goal in life is to find and release her inner artist. "I know she's in there and she's beginning to find her way out."



Karen Diamond and her grandson, Miles, enjoy a ritual of watching trains together. "When he hears he whistle he tells me and we run around like crazy getting our shoes on and into his car seat and drive the few blocks to try to catch it as it goes by. We manage to see it about half the time, but we enjoy the whole process even when we've just missed it."

John Saul was a subject in MAPS' study of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness in Marin, California.

IT'S SEVERAL MONTHS BEFORE I discovered the MAPS-sponsored study. I watch yet another capsule of expensive medicine skitter across the floor. It escapes under a heavy piece of furniture. "I give up," I say to myself. This has become routine. My disease, systemic sclerosis, also known as "scleroderma" has all but paralyzed my fingers and made them slick as hard plastic.

I felt something beyond compassion, beyond humility. I felt gratitude and love on a different scale. "This is some real learning," I thought.

Every morning as I awake, I hope to find that the last 950 days have been a bad dream, but it's never the case. I take 20 minutes to force a decision: "Get. Out. Of. Bed." I do it. I'm skinnier than the day before, but I feel like 400 lbs. I feel arthritic, stiff, feverish. Like I've got the flu, every day. I feel toxic, like I've bathed in pesticide. My skin crawls and burns. My feet and hands pound as the blood forces through the capillaries. My heart skips and slams for a few beats, I'm short of breath. Fatigue drags me toward the floor. My inner voice says, "I can't do it. Just let me sleep." I email two clients to reschedule. The office will have to stay quiet today. My business is hemorrhaging money.

"Oh, it's 9:45 am. Time for a little warm-cozy." I break the 10 mg Percocet in half and chew it down with a glass of water. I pocket another 10 mg for the afternoon. 10 minutes later, I change my mind and get ready to go into the office. "Maybe I am getting better." I am fooled by the opiate, but it's doing its job.

So went my life and my business for three and a half years, circling the drain. "I will never feel the high of a hard trail run. I won't enjoy my body feeling strong after a week of weight lifting and yoga. I'll never sail my boat again. My friends have stopped the invitations and written me off. Another 51 degree day, but I can't feel my feet. My hands are white. I can't move them." Suicide stops by for a visit: "Hey, man. Let's go for a walk in the woods. It'll do you some good."

That's the shape I was in when I unfolded the *San Francisco Chronicle* and saw the article, "Ecstasy therapy approved for trial in Marin County." Some weeks later, Dr. Phil Wolfson said, "John, you certainly qualify for the study. You'll have to produce a clean urine test. That means no opiates. Here is a tapering schedule." When I got home, it was 3:30 pm. "Well, the last one went down at 9:00 am. That's it. I'm not putting another one in my mouth." I put the remaining pills on a shelf in plain view. I knew I had picked a big fight. I had tapped the core of my personal will.

It was a foregone conclusion: the FDA-approved study, sponsored by MAPS and titled: "MDMA assisted psychotherapy for anxiety associated with life-threatening illness" was going to be one of the major waypoints in my life. The scientists will get their measures, and I am going to pivot my entire life on this experience. It was fact, and I was finished with the opiates. They had done their job. The ensuing five weeks of opiate-withdrawal is its own story. It was hard. My will prevailed, motivated by the "carrot" of knowing that I will ingest a generous dose of a powerful psychoactive compound in a comfortable, safe place with two of the best, most experienced, compassionate, and capable healers on the planet. And, hopefully, I will reclaim my life.

January 7, 2016: Adventures wake me up and stop time. Second MDMA-assisted psychotherapy session: one of the best days of my life. This day of work on the couch was a level up: Advanced Intermediate.

This time, as compared to my first session, I demanded more of myself to think, write notes, and prepare. I set intentions. I re-read my notes: "Check your commitment to the truth." I asked more of myself in terms of committing to the work. I asked more from the medicine. I asked specific things from my compassionate healers, and in turn, they asked more from me. Then, they gave more of themselves than I could ever have imagined. I popped the tab and said to the medicine: "Get in there. Go to town." The memories of the day take my breath away.

It wasn't too long before I noticed that objects in the room were vying for attention and admiration. Plants, paintings and musical instruments seemed busy and brimmed with personality.

My healer-guides allowed me to soak in it. Their faces said, "We love you, and we know." "Settle-down. Go inside for awhile." I settled into the couch, got warm, drifted inside my head, and slowly turned the pages of the picture book, forward and backwards.

The compassionate healers were in it with me. In addition to guiding me, calling on me to do the work, and keeping me comfortable and safe, they were "on the road" with me for the day, helping me to find and observe Truths in my life. The communication lines were wide open.

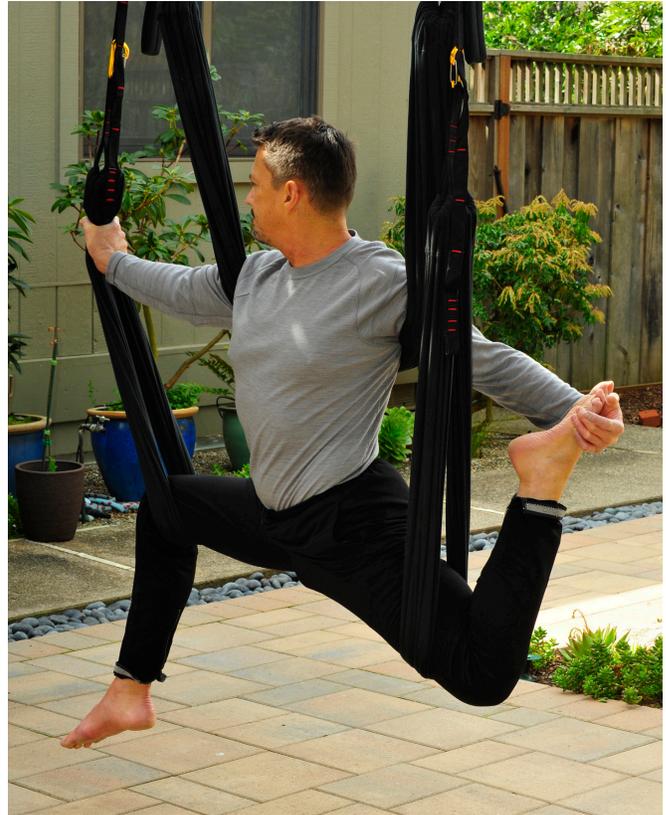
Then it was time to do some work. A gentle but firm shoulder urged me there. "That" topic again. Let's lift the curtain and look at it again, except there is no curtain. It's floating and slowly rotating right in front of me. "It's Ok. Look at it." It is clear and detailed. It is real and without interference. "You see?" "Yes." "You know?" "Yes, I know."

We talk about the most uncomfortable things, yet I feel something beyond comfort. Beauty radiates from sadness. I witness raw emotion, like I grabbed a live power-line and watched it arc into my body. Awestruck. I felt something beyond compassion, beyond humility. I felt gratitude and love on a different scale. "This is some real learning," I thought. In my head and in my heart, a huge iceberg of sorrow, grief, disappointment and anxiety cracked off and began to drift away. Throughout the day, 18 years of whatever lacked in my upbringing was gently placed into my heart. Then, over the next 72 hours, it catalyzed in there, right where it belongs.

It's been one year since concluding my part in the study. Through many different means, I am physically about 90% better than as described earlier. A large part of improving physically is to make gains emotionally, mentally, and spiritually, especially when living with an incurable, life-threatening illness.

When you get your "internal house" in order, learn to entertain only the Truth in your thoughts, learn the medicinal value of crying, learn to tap into the gigantic pool of empathy that exists as counterpoint to the loneliness, fear and anger that is the human condition, your life changes for the better.

My involvement in the MAPS-sponsored study was the pivotal event that helped me get in touch with this and reclaim my life. The study enabled me to wake up, pause, and tap into Love and Courage. I run on trails, beaches, and I do half-marathons again. I became certified to teach aerial yoga, and I enjoy a new line of work in answer to a calling to help others. I still drop pills onto the floor on a daily basis but they are vitamins, not opiates. 🌱



John Saul, shown here on his therapeutic yoga swing, became certified to teach aerial yoga after participating in the MAPS study, and is currently pursuing certification in traditional Iyengar yoga instruction.

John Saul is a 52-year-old ex-jock from Los Angeles. He competed in NCAA division-1 wrestling at CSU, Fullerton. He has lived in: Pasadena, California; Frankfurt, Germany; Sausalito, California; and now lives in Venice, California where he runs miles on the dry sand. A diagnosis of a life-threatening illness in 2012 prompted him to shift gears and answer a calling to help others by developing tools and resources for people knocked down by life-threatening or life-altering chronic illness. He also enjoys teaching a popular therapeutic modality: aerial yoga. He is currently pursuing certification in traditional Iyengar yoga.

A Psychedelic Renaissance: Historical Reflections on the Future

ERIKA DYCK, PH.D.



Erika Dyck, Ph.D.

IN FEBRUARY 2014 *Scientific American* shocked readers with an editorial that called for an end to the ban on psychedelic drug research.¹ The article criticized the mental health treatment industry for failing to advance therapies beyond the golden era of the 1950s, and lambasted drug regulators for prohibiting psychedelic drugs, including LSD, ecstasy (MDMA), and psilocybin; drugs, which had historically held clinical promise but were “designated as drugs of abuse.”² As the editors pointed out, the situation has created a paradox: “these drugs are banned because they have no accepted medical use, but researchers cannot explore their therapeutic potential because they are banned.... The decades-long research hiatus has taken its toll.”³ Lest there be any confusion as to where the editors stood on the issue, they continued with explicit instructions: “This is a shame. The US government should move these drugs to the less strict Schedule II classification...it would make it much easier for clinical researchers to study their effects.”⁴ The article brought public and scientific attention to a growing contention amongst researchers, and even some regulators, that the clinical potential among psychedelic drugs had been dismissed due to a moral panic about drug abuse.

But, this article was just the tip of the proverbial iceberg. In the past decade psychedelics have returned to the clinical arena with renewed optimism for their positive role in therapeutics, across a range of areas. Hundreds of published papers have looked back and criticized regulators, researchers, and consumers for distorting the truth about psychedelics. According to British psychopharmacologist David J. Nutt, LSD, among other psychoactive drugs, has tremendous therapeutic potential yet existing restrictions in both laboratories and clinical trials have prevented the meaningful exploration of its scientific potential. He laments the “daunting bureaucratic labyrinth” that dissuades “even the most committed investigator.”⁵ Meanwhile, California-based neuroscientist Mark Geyer argues that the modern culture of scientific research discourages investigators from asking big picture questions in science. Taking time to ponder the intersections of spirituality, consciousness and brain science seems to have moved beyond the grasp of even the most successful researchers whose time is increasingly devoted to securing grants, filling out ethics forms, and logging hours in the lab accumulating data. In other words, the context of modern scientific enterprises has refocused attention on data accrual and away from larger questions of ontology. Franz

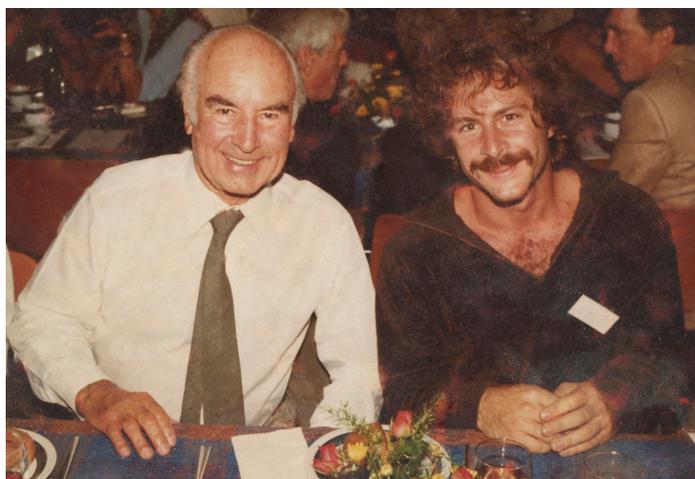
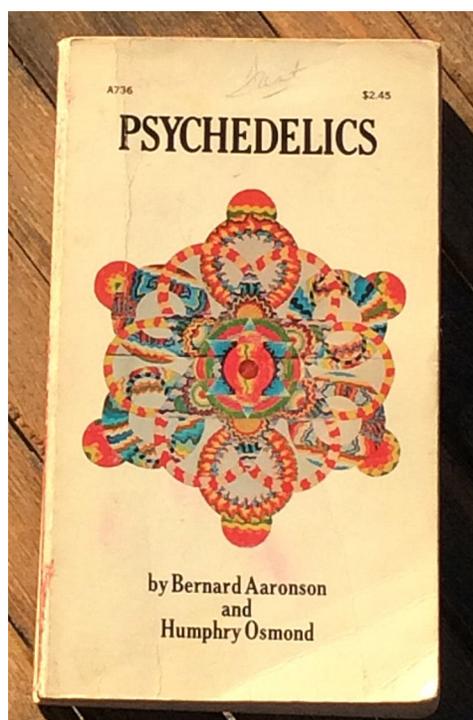
¹Editorial, “End the Ban on Psychoactive Drug Research,” *Scientific American* (2014) 310 (2), pp. 1–2.

²*Ibid.*, p. 1.

³*Ibid.*

⁴*Ibid.*, p. 2.

⁵“End the Ban on Psychoactive Drug Research,” *Scientific American* (2014) 310 (2): 33. Consulted at <http://www.scientificamerican.com/article/end-the-ban-on-psychoactive-drug-research/>



Humphry Osmond coined the term “psychedelic” in 1957 and later co-authored a book of the same name (left); Albert Hofmann, the first person to synthesize and ingest LSD (above left), shares a meal with MAPS founder and executive director Rick Doblin (above right).

Vollenweider’s work in Switzerland attempts to defy that trend, as he compares psychedelic reactions with subjects who had been administered LSD and subjects who had reached a similar state of consciousness through meditation. Using brain imaging techniques and questionnaires, Vollenweider has explained how the now well-established mantra of randomized controlled trial methodology all but paralyzes such attempts to raise what are essentially philosophical questions in brain science, which steers him towards other questions and other methods for exploring the relationship between spirituality and the brain.⁶

The psychedelic renaissance may then be less of a re-awakening and more of a realigning psychedelics with their own richer, deeper, and more culturally sensitive past. Over sixty years ago, as MAPS readers well know, Albert Hofmann at Sandoz Pharmaceutical Laboratories in Switzerland first synthesized LSD in 1938 and personally experienced its effects in 1943. In what was later described as a voyage into madness, or a chemically induced psychosis and spiritual awakening; Hofmann’s drug opened up a new era of hallucinogenic research. Over the next 15 years over a thousand studies using LSD or mescaline appeared in medical and scientific publications. Claims varied widely as to the drug’s inherent value, its therapeutic potential, or the most lucrative target areas for its use, but for over a decade the popular and scientific reports were generally positive, even optimistic.

Many of these studies were confined to laboratory settings,

and retained a careful focus on the chemical substances, rather than cultural rituals that might be associated with a longer tradition of healing or psychoactive exploration. Indeed German psychiatrists worked diligently to isolate mescaline from peyote in the 1930s, and with it, they interrogated mescaline as a substance free from the indigenous traditions that venerated the sacred cactus. Similarly, in 1957 when psychiatrist Humphry Osmond introduced the term “psychedelic” in the *New York Academy of Sciences* it was described as a scientific concept, a newly discovered phenomenon offering insights into the human psyche that might offer important research and therapeutic potential. Despite recognition of a longer history of so-called psychedelics in indigenous healing or spiritual encounters, drugs like LSD and mescaline were increasingly regarded as pharmaceutical substances, products of the modern, western, and increasingly lucrative psychopharmaceutical complex.

However, the psychedelics were destined to have trouble convincing regulators and researchers that they could consistently perform well in controlled and later randomized trial conditions, or that their therapeutic power followed a regular schedule of prescribed use. The psychedelics were different from their contemporary psychopharmaceutical counterparts, but perhaps in an effort to evaluate and justify their scientific merit, some of the more subtle, abstract, or philosophical benefits were discarded as too culturally specific, too anecdotal, or too difficult to repeat.

Despite the promising results from the 1950s, concerns

⁶For an in-depth study of both Franz Vollenweider and Mark Geyer, see: Langlitz, Nicolas. *Neuropsychodelia: The Revival of Hallucinogen Research since the Decade of the Brain*. Los Angeles: University of California Press, 2013.

emerged that the drug was an enticing substance for abuse, or that it was an altogether dangerous chemical given its capacity for conjuring visual hallucinations or producing psychosis. Critical scientific reports combined with negative media exposure made the continuation of scientific pursuits of psychedelic research more difficult. Much of that research halted largely as these substances had become synonymous with countercultural activities, hedonism, drug abuse, and a black market in acid. By the end of that colourful decade LSD was considered in many jurisdictions as a prohibited substance and its clinical applications moved to the margins of acceptable medicine.

Meanwhile, many psycho-active substances with more lucrative applications enjoyed widespread commercial success after performing well in the new gold standard for rigorous pharmaceutical tests: the randomized controlled trial. LSD, and other psychedelics for that matter, routinely failed to satisfy researchers seeking a set of conventional or repeatable responses. These drugs, instead, confounded the trial methodology and committed psychedelic researchers fought back against a method that did not allow for a more holistic or contextualized set of experiences to constitute an effective psychopharmacological intervention. In other words, LSD reactions were difficult to quantify or even classify in therapeutic terms, and neither the methodology nor their single-dose applications convinced commercial distributors that it was worth pursuing.

Psychedelic investigators in the so-called 'golden era' had not yet articulated a coherent plan for regulating these substances in a manner that balanced the appetite for non-clinical use with the desire to retain psychedelics within the clinic. Famously ex-Harvard University psychologist Timothy Leary proselytized the use of LSD, exclaiming that everyone should take it, and in fact he is rumoured to have recommended its use even more indiscriminately—by putting it in water supplies—but no specific thought was given to how much, or whether such a move should only be done on public holidays, whether they should use microdoses, or combine it with 'car free' days. While others, like Abram Hoffer in Saskatchewan recommended that it be tightly controlled and regulated by governments, permitting its use exclusively in medical contexts. Others were more elitist, suggesting that understanding psychedelics required experimentation, but that experimentation should involve intellectuals, physicians, theologians, neuroscientists, etc.—a particular strand of highly educated individuals who might then

harness the powers of psychedelics to improve society. These discussions over how to best regulate and control the use of psychedelics fell moot by the end of the 1960s as black market versions circulated freely and the political climate of the Cold War gave rise to the damaging association between psychedelics and subversive behaviour.

In the 21st century, both researchers and consumers collectively have more experience with psychopharmaceuticals than ever before. Indeed, in the 1950s, the marketplace was only really beginning to embrace the psychopharmacology with real intensity. As Nikolas Rose suggests, this period also witnessed the dawn of the 'psy-ences'—a term that he uses to describe the pervasiveness of psychiatry,

*As we look forward to this new chapter in
psychedelic science, we might also take the
opportunity to look back and consider how the
historical context of scientific research shaped our
understanding of psychedelics in the past.*

psychology, and social work in the everyday lives of citizens.⁷ A return of psychedelics is perhaps for this generation of consumers neither off-putting nor obscene, but rather a response to the culmination of a cultural shift towards chemically altering our consciousness as a natural response to modern living. As we look forward to this new chapter in psychedelic science, we might also take the opportunity to look back and consider how the historical context of scientific research shaped our understanding of psychedelics in the past.

Historically, scientists were keen to separate the drugs from their cultural, spiritual, and healing contexts, even when they later compensated for this isolation by designing careful guidelines for establishing 'set and setting'. Our accumulated knowledge about psychedelics has demonstrated that the experiences readily invoke reactions that are not necessarily reducible to scientific categorization. Perhaps it is time for psychedelic science to emphasize the *psychedelic* elements of this approach, and to embrace a more holistic framework of understanding, interpreting, measuring, and ultimately treating modern human experiences. 🌀

Erika Dyck, Ph.D., is a Professor and Canada Research Chair in the History of Medicine at the University of Saskatchewan, Canada. She is the author of *Psychedelic Psychiatry: LSD from Clinic to Campus* (2008), and *Facing Eugenics: Reproduction, Sterilization and the Politics of Choice* (2013). She has numerous articles on the history of psychedelics, and edited *A Culture's Catalyst: Historical Encounters with Peyote and the Native American Church in Canada* (2016). She can be reached at erika.dyck@usask.ca.

⁷Rose, N. (2003). Neurochemical selves. *Society*, 41(1), 46-59.

Research Update: Phase 2 Clinical Trial of Marijuana for Symptoms of PTSD in U.S. Veterans

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES (MAPS)

AS OF MARCH 2017, SIX participants have received marijuana (cannabis) provided by the National Institute on Drug Abuse (NIDA) in the ongoing Phase 2 clinical trial sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS) at the Scottsdale Research Institute (SRI) in Phoenix, Arizona. MAPS is testing the safety and efficacy of four different potencies of smoked NIDA cannabis to manage symptoms of chronic, treatment-resistant post-traumatic stress disorder (PTSD) in 76 veterans in a placebo-controlled clinical trial.

Dr. Sue Sisley at SRI is actively recruiting U.S. military veterans in the Phoenix area. For more information, visit maps.org/participate/participate-in-research.

The initiation of this trial is a remarkable milestone, as MAPS first submitted their Investigational New Drug application to the FDA in November of 2010. Over the past seven years the study encountered numerous setbacks in gaining approvals from regulatory agencies, however, the research team was able to overcome all these obstacles, beginning screening in January of 2017. Enrollment for participation in the study is ongoing, and expected to last through February 2018 in Phoenix, Arizona. Data are expected to be available in January 2019.

Previously, the clinical trial was a multi-center study at both Johns Hopkins University (JHU) in Baltimore, Maryland, and at SRI in Arizona. Recently, JHU elected no longer to participate in the trial to focus on other research projects.

MAPS' clinical research focus is the drug development of

whole plant marijuana. The goal is to turn whole plant marijuana into a prescription medication approved by the FDA that would be covered by insurance companies. At this time, the Drug Enforcement Administration (DEA) has yet to issue a Schedule I facility a license to produce cannabis for use in Phase 3 clinical trials, thus preventing drug development research from moving forward.

As MAPS is committed to ensuring the safety of study participants, the study was slightly delayed due to testing and analyzing of the cannabis being used in the clinical trial. Prior to initiating enrollment in the study, laboratory testing of the NIDA cannabis was conducted over five months. All test results were reviewed by an independent Institutional Review Board (IRB). Testing showed an absence of harmful microbes and my-

cotoxins, and the amount of possible lead exposure from NIDA cannabis is well within available guidelines. After consultation with plant experts, the study team, and medical monitors, MAPS concluded that the cannabis is safe for use in this clinical trial based on exposure limits and dispensation procedures. For full test results, see our official statement at maps.org.

This study is funded by a \$2.156 million grant from the Colorado Department of Public Health and Environment (CD-PHE) to the California-based

non-profit MAPS, which is sponsoring the research. MAPS is committed to sponsoring rigorous clinical research to develop cannabis into a prescription medicine through the Food and Drug Administration (FDA). 🌿



A study participant completes measures at his weekly visit and receives study drug for the next week.



Peter Gasser, M.D.

Research Update: Psychedelic Group Therapy in Switzerland

PETER GASSER, M.D.

AFTER THE REALISATION OF TWO pilot studies in Switzerland with MDMA and LSD, the two investigators of these projects, Dr. Peter Oehen and myself respectively, applied for licenses for individual treatments with MDMA and LSD, otherwise known as limited medical use of non-registered drugs, or compassionate use.

From 2014 until now, the Swiss Federal Office for Public Health (Bundesamt fuer Gesundheit, BAG) has given individual permission for a total of 17 patients residing in Switzerland (10 for LSD and seven for MDMA). The studies Peter Oehen and I completed were both done with individual treatments for every participant. This was due to the original protocol we developed with MAPS, and also due to the fact that we were convinced that a request for a study in a group setting would have lowered the chances of regulatory approval.

In Switzerland, we have a tradition of conducting therapy with mind-altering drugs in group settings. Although three of the founding members of the Swiss Medical Society for Psycholytic Therapy (SAePT) were trained in the individual treatment setting approach with Stanislav Grof in Czechoslovakia (Juraj Styk) or with Hanscarl Leuner in Germany (Peter Baumann, Juerg Roth), they applied a group setting approach beginning in 1988 when they received their special permission for treatments with MDMA or LSD.

The three-year training SAePT offered from 1989 until 1992 was all done in a group setting. The vast majority of the treatments Styk, Baumann, Roth, and two other therapists did from 1988 until 1993 (nearly 200 patients in total) were done in groups. It was never clearly conceptualized why these therapists favoured group therapy, but they certainly would have learned

the advantages of group therapy in humanistic therapy approaches like Primal Therapy or Theme-Centered Interaction. Of course, they also knew that rituals in indigenous cultures (such as with peyote, psilocybin, and ayahuasca, for example) are also usually done in groups.

When Peter Oehen and I started with compassionate use, we treated in an individual setting like we did in the pilot studies. When we requested permission to treat the patients in groups, the authorities expressed concerns about safety and manageability of difficult situations. We agreed that first I would do a small group of three patients and report after the session. Because that group went well, BAG agreed to let us continue in groups, allowing us to decide on the setting, size, frequency, and structure of the groups corresponding to our therapeutic reflections and methods.

Peter Oehen and I decided to do the LSD and MDMA sessions together. That allowed us to be always two therapists in the group. For 2017, we planned four workshops for our patients. Until now we have directed groups of four to eight patients, and we include patients using LSD and MDMA in the same group. We encourage a quiet meditative setting so that the shorter duration of action of MDMA has not been a problem for the group dynamics to date.

The LSD or MDMA experience is embedded in a workshop of three days. The first day, we meet in the evening for about three hours for a sharing round and body awareness exercises, and for clarifying any questions about dosage, duration, and structure of the LSD or MDMA experience. We discuss anxieties if there are any, and everyone's intentions for the next day. The second day we meet at 9:30 a.m. Everyone finds a place



A group session with LSD and MDMA (above); and the next day's sharing round (right) are part of a three-day workshop offered in the current research of psychedelic group therapy in Switzerland.



where she or he will feel comfortable for the whole day, and ingests the substance at 10 a.m. Then we vary between music and a quiet meditative atmosphere, with about one third music and two-thirds silence. We then go their individual spaces and ask them how they are and offer touch, such as a gentle hold of the hand or putting the hand on the body, and guide them through their processes of psychic pain, grief, anxiety, anger, etc. For every workshop, we alternate with one of us as the dedicated leader who moderates the sharing rounds, plays the selected music, and sometimes gives advice to the whole group (like bringing attention inwards again, connect with breath, etc.). At 6 p.m., we eat a light dinner in the room while sitting on the floor. At 7 p.m., patients may leave the room and be brought home or to their hotel, or they may choose stay in the group room for another two to three hours and relax.

During the first few hours of the drug action (usually until approximately 3 p.m.) there is not (and should not be) much interaction between the patients. Extended interaction would disturb the deep inner process in the opening and plateau phases of the experience. However, in the last hours of the experience, being connected to physically real persons can play a role in healing.

On the third day, we meet at 9:30 a.m. for group sharing. Everyone talks in detail about their experiences of the day before. This is an important part of the workshop. We call it integration, with participants having to find words for the rich, overwhelming, associative, often ineffable, spiritual, and psychodynamic process they experienced. Integration is not only recounting and reporting to the others in the group, but also—and maybe even more so—a step towards understanding and

incorporating the drug session. There is also an important group dynamic that shows up on this third day, when participants can look to others who have had similar difficulties or who have experienced a certain situation or music in a different way.

It may be that the setting described here does not apply to high-dose psychedelic experiences (300µg LSD or more). Such experiences may be more effective in an individual patient setting, or in a group with individual sitter for each person who ingests the substance. For now, we have only had experiences with patients taking 200µg or less LSD, or 125mg MDMA.

Many psychological symptoms and difficulties are born out of dysfunctional relationships, and it is obvious to us as therapists that these symptoms and difficulties need helpful, good relationships to heal. This is one of the great values of group therapy. We are happy that we were able to convince the authorities and create this effective setting for psycholytic therapy. 🌀

Note: In this article, the terms “psycholytic” and “psychedelic” are used as synonyms.

Peter Gasser, M.D., is a physician for psychiatry and psychotherapy, working in private practice in Solothurn, Switzerland. He was trained in psychodynamic methods as well as in therapy with mind altering drugs, i.e. psycholytic (psychedelic) therapy. He is member of Swiss Medical Society for Psycholytic Therapy since 1992 and its president since 1996. He conducted a pilot study for LSD-assisted psychotherapy in people suffering from anxiety due to life threatening diseases. He holds a number of individual permissions from the Swiss Federal Office for Public Health for the treatment with LSD and MDMA. For more information, visit petergasser.ch.

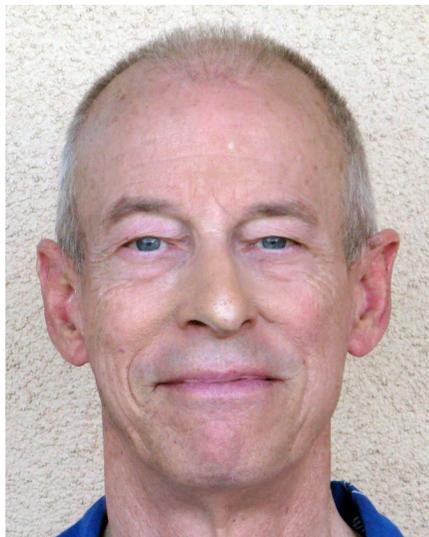
Heffter Research Institute: Psilocybin Research to Alleviate Suffering and Understand Consciousness

DAVID NICHOLS, PH.D.

GEORGE GREER, M.D.



David Nichols, Ph.D.



George Greer, M.D.



H E F F T E R
RESEARCH INSTITUTE

THE HEFFTER RESEARCH INSTITUTE FUNDS research with psychedelics to contribute to a greater understanding of the mind and to alleviate suffering. Heffter scientists believe psychedelics' unexplored potential requires careful scientific research to find their best uses in medical treatment.

Heffter-funded scientists have designed the leading studies on psilocybin, the active chemical in psychedelic mushrooms, at prominent research institutions in the U.S. and Europe, including Johns Hopkins, New York University, Harbor-UCLA, and the University of Zürich.

Two of these Heffter-funded studies—double-blind randomized control trials conducted at Johns Hopkins and New York University over five years and published December 1, 2016 in *The Journal of Psychopharmacology*—showed that a single dose of psilocybin, in conjunction with psychotherapy, reduced anxiety and depression in patients with life-threatening cancer diagnoses. These findings were the most profound to date in the medical use of psilocybin: A single treatment improved symptoms for months.

A statistical analysis found that patients' peak mystical experiences correlated with the positive therapeutic outcomes. Prior research has found that many study participants rate their psilocybin-occasioned experience as being among the five most personally meaningful and five most spiritually significant experiences of their lives.

Although it is impossible to say with 100 percent certainty how much of the alleviation of depression and anxiety was due to the psychospiritual effects and how much due to the biological effects of psilocybin, there is reason to believe that the shift in patients' life perspectives is behind the lasting effects of this therapeutic treatment.

Although the mechanism is not yet fully understood, the upshot is this: Psilocybin has been shown to be safe and non-addictive. Early results indicate that when used with medical screening and therapeutic support, it could be more effective at treating some significant psychiatric diseases than existing pharmaceutical approaches, and without having to take a medication every day.

This medicine has the potential to improve millions of lives!

The path has not been easy. It takes dedicated researchers, institutions, and funding to make this innovative research happen. The government has not yet funded this research, and drug companies don't see a way to profit from single-dose medicines that cannot be patented. Those practical hurdles, plus cultural stigma from the past, have slowed scientific progress in this area for decades.

A few scientists, with non-profit funding from Heffter, have kept the torch lit. This work has depended entirely on the generous support of individuals and family foundations. With that support, Heffter has been the primary funder of psilocybin research for more than 20 years.

Heffter researchers have made breakthrough discoveries over the past two decades. But a large, multi-site Phase 3 clinical research trial will be needed to demonstrate further psilocybin's safety and prove that its effects can be replicated nationwide.

Even after that trial is complete and the Food and Drug Administration approves psilocybin for prescription use for patients with anxiety and depression, additional research will be needed to understand how this medicine can be used to help myriad

other patients with conditions not yet being successfully treated by today's standard pharmacotherapy approaches.

Drawing on the scientific expertise and longstanding partnership of the world's leading investigators, Heffter mentors the next generation of psilocybin researchers and therapists, vets new approaches, supports proof-of-concept studies, and gathers the evidence base for therapeutic treatments that, pending FDA approval, will be available to patients in need.

Heffter is excited to investigate these other conditions that might be treated with psilocybin, including:

- Emotional distress accompanying diagnoses such as AIDS and Alzheimer's disease
- Addictions to cocaine, alcohol, and tobacco
- Depression that is not being successfully treated
- Obsessive-compulsive disorder and eating disorders
- Criminal recidivism

Heffter also seeks to understand behavior and consciousness. Questions include:

- What is the relationship between brain processes and subjective experience, including cognition, emotion, and spiritual experience?
- When psychedelic-assisted therapy produces enduring healing, what changes in brain function and neurochemistry have occurred?
- What effects can these drugs have on personality structure, creative problem solving, and pro-social behavior?
- Does microdosing with LSD have quantifiable cognitive effects?

Some of this research is already underway:

- At Johns Hopkins, following up on a pilot trial that had an 80 percent success rate, researchers are conducting a placebo-controlled clinical trial of 80 participants with nicotine dependence, using fMRI neuroimaging to help understand the neurobiological changes that occur when psilocybin is administered to smokers.
- At New York University, researchers are conducting a follow-up clinical trial of 180 patients with psychotherapy for alcohol dependence and two sessions with psilocybin or placebo. The study is expected to finish in 2019.
- At the University of Alabama, researchers are conducting a placebo-controlled pilot study of 40 patients

with cocaine dependence, deploying psychotherapy and fMRI neuroimaging before and after psilocybin treatment.

- Researchers at Johns Hopkins are seeking individuals with a regular, long-term meditation practice to participate in a research study looking at the combined effects of meditation and psilocybin.
- A joint New York University-Johns Hopkins study is recruiting practicing religious leaders for an investigation to advance scientific understanding of mystical-type experience and its effect on personal wellbeing, spirituality, and pro-social behavior.

Heffter is currently reviewing additional proposals to conduct further research, and continues to build partnerships with donors, medical professionals, and patient advocates who support Heffter's dual mission of alleviating suffering and understanding human consciousness.

Learn more about the Heffter Research Institute and how you can contribute to support this groundbreaking research at heffter.org.



A psilocybin study participant reclines during an experimental session.

David Nichols, Ph.D., is Co-Founder and President of the Heffter Research Institute. He was a Distinguished Professor of Medicinal Chemistry and the Robert C. and Charlotte P. Anderson Chair in Pharmacology at the Purdue University College of Pharmacy and adjunct Professor of Pharmacology at the Indiana University School of Medicine. He is currently an Adjunct Professor at the University of North Carolina, Chapel Hill. His research has investigated the relationship between molecular structure and the action of psychedelic agents

and other substances that modify behavioral states. He is recognized as one of the foremost experts on the medicinal chemistry of hallucinogens. He can be reached at dave@heffter.org.

George Greer, M.D., is Co-Founder and Medical Director of the Heffter Research Institute. He conducted over 100 therapeutic sessions with MDMA for 80 individuals from 1980 to 1985 with his psychiatric nurse wife, Requa Tolbert. Their review of this work remains the largest published study of the therapeutic use of MDMA. He is a Distinguished Life Fellow of the American Psychiatric Association and Past President of the Psychiatric Medical Association of New Mexico. He was also the Clinical Director of Mental Health Services for the New Mexico Corrections Department during the 1990s. He can be reached at ggreer@heffter.org.



Mendel Kaelen

Experience as Medicine: Insights from Studying Psychedelics and Music

MENDEL KAELEN

“MANY PEOPLE SIMPLY CANNOT BE CHANGED,” one university professor told me.

This was 2011. I was a neuroscience student at the University of Groningen in the Netherlands, and was writing an essay about therapy-resistant depression. “But,” he continued in a fatherly, slightly patronizing tone, “you’re still young, so please dream on.” His thick eyebrows slowly moved upwards again and then the professor (who was also a psychiatrist) initiated an enthusiastic discourse, trying to persuade me to shift the focus of my essay to the genetic determinants of social anxiety in mice.

When I handed in my essay, unfortunately the psychiatrist’s eyebrows did not move upwards again. I had followed his suggestion to dream on, and argued that the assumption that many people cannot be changed is false. In my argument, I referred to recent research with psychedelics and MDMA, a field of research that is becoming particularly fruitful. These compounds can facilitate immediate changes in mood, behaviour, and personality which can be long-lasting, even with just a single dose. This is unheard-of in psychiatry, and suggests not only a more effective type of medication but, more importantly, a different paradigm of therapy: a different view on what therapeutic change means, and how this change can be brought about.

Typically, during psychedelic therapy sessions, individuals are encouraged to focus their attention inwards while listening to music. The period of peak drug effects is often characterised by minimal verbal interactions, waves of intense emotionality, and eruptions of therapeutic insights. Although it is no overstatement to describe psychedelic therapy as a highly non-directive and client-centred approach, it does beg the question of whether the music itself may provide some form of direction. If so, understanding how music does this—and how it can best be used—is important, particularly when the therapy is being implemented on an increasingly large scale.

For my Ph.D., I have combined neuroscience and qualitative research to better understand the functions of music in psychedelic therapy. In our first studies, we demonstrated that

under the influence of the classic psychedelic LSD, people feel stronger emotions in response to music. This effect was associated with increased activation of a brain network specialised in attributing meaning and emotion to “sequences of sound”—including a region usually associated with language, known as Broca’s area.

Importantly, these changes happened mostly in response to music’s timbre (also known as tone color). To understand what timbre refers to, imagine one person playing the cello and another person playing the flute. When both produce exactly the same note and volume, then the sound quality you use to differentiate the instruments is what we call timbre. In our lives, we constantly use this acoustic property to give meaning not only to instruments, but to all objects and human voices we hear. Already, prior to birth, we are equipped with an outstanding capacity to pick up subtle details in timbre—a skill used to recognize and emotionally bond with our mother’s voice. Timbre has been called “the interface of sound and emotion” and the increased responsivity of the brain to timbre under a psychedelic may underlie the enhanced emotionality in response to music.

We also found that the combination of LSD and music targets a brain circuit associated with the construction of personal memories. The more information that flowed from a region called the parahippocampus to the visual cortex, the more vivid and autobiographical the mental imagery became. Interviews we conducted with individuals undergoing psychedelic therapy about their experience of the music are much in line with this. Participants frequently described the music as providing a sense of personal care and reassurance, and as if it guided them on a “journey.” “Every new song would bring a different image,” one participant said. “The music was the vehicle that transported me from one place to the other,” another explained. One described the music as “very sad and very beautiful,” and that within her flooding of tears, she found her self-blame to be replaced by self-compassion.

While it is satisfying to know that the music selection

worked well for the majority of participants in this study, we also learned from closely listening to those for whom the music did not work well. From this, we identified three ingredients in the music-experience that predict therapeutic changes: 1) Liking, referring to appreciation of the music's style and quality, 2) Resonance, referring to the degree of harmony between the music and the state of the listener, and 3) Openness, referring to the degree to which the listener was accepting the influences of the music, rather than wanting the experience to be different. The higher individuals scored on each of these, the stronger was their therapeutic response. This knowledge may help treatment providers improve their use of music to support the therapeutic process, which is highly dynamic and unique for each individual.

Throughout our life, we continuously acquire new experiences, and our brains remember those that are important to us. This produces something that we could call an "inner roadmap," that helps us give meaning to, and thrive in, a complex world. Some experiences, however, give birth to a roadmap that does not serve this goal. Emotional pains of all sorts can result in beliefs about ourselves and our world which are destructive—in particular, when they resist change. It is this inner roadmap, again unique for each individual, that people seek to change when entering psychotherapy.

Psychedelics may work in therapy by temporarily dissolving this inner roadmap, making any stimulus inhabit a whole new world of meanings. The environment in which these experiences take place do therefore need to be chosen carefully. Importantly, the environment can be designed strategically, such that it becomes an active element of the therapeutic procedure. I believe this is what is being done with music: In the absence of the usual roadmap, music functions like a navigator that suggests new routes to follow without using words. Instead, music bypasses the intellect to shift the person's awareness directly to those most intimate parts of their being. Subsequently, when the listener is open to the music's suggestion to be "carried away" in

this direction, the listener can become an explorer—one who travels through deep inner territories to discover or rediscover new aspects of oneself, and to experience those aspects in fuller emotional depth.

"This music drove the most beautiful experience of my life," one participant from our study stated. Experiences are the source of learning, and learning is the foundation for change—in particular when experiences are strong and personally meaningful. Utilizing experiences may therefore be the most effective way, and maybe even the only way, to update the inner roadmaps we use.

Psychedelics and music seem particularly effective in providing such experiences. Yet, there is much left to learn, and many opportunities open to explore. Further development of this paradigm of therapy, where experience is the basis for change, is therefore an invitation to those who are masters of experience—not only the psychotherapists, but also the musicians, the light-artists, the installation-artists, the design-artists, the architects, and so on.

All expertise in psychotherapy, art, science, and technology can be united into a framework that offers true life-changing experiences. 🌀

***Mendel Kaelen** is a neuroscientist based at Imperial College London specializing in the therapeutic function of music in psychedelic therapy. He is interested in understanding how environments can be utilised to facilitate therapeutic change. Together with artists and engineers he works to translate insights from science into innovative therapeutic applications. Current activities include the development of a music-therapy platform, the creation of music playlists and the design of therapy rooms for sessions with psilocybin and MDMA. He can be contacted through his website, mendelkaelen.com.*



Sara Gael, M.A.

Understanding and Working with Difficult Psychedelic Experiences

SARA GAEL, M.A.

MAPS DIRECTOR OF HARM REDUCTION, ZENDO PROJECT

CHALLENGING PSYCHEDELIC EXPERIENCES are not uncommon. The very nature of the psychedelic state, with its limitless sensations, expressions, and dynamics, can be disorienting, confusing, and at times frightening. The same elements that can influence someone's decision to explore psychedelics—change in perception, expanded awareness, and altered consciousness—can be the very things that can contribute to a difficult experience, challenging our beliefs and assumptions about ourselves and the universe.

UNDERSTANDING DIFFICULT PSYCHEDELIC EXPERIENCES

Psychedelic substances allow the subconscious—the part of our mind which stores our repressed memories, aspects, fears, and insecurities—to become conscious. The subconscious, sometimes referred to as the shadow, contains all the aspects of the self which society has taught us to hide, reject, or otherwise suppress. Given that the subconscious mind is comprised of the things we have suppressed, because they have been viewed as threatening or undesirable by a given culture or society, it is no wonder that when faced with these parts of ourselves, we may experience fear or challenge.

Various psychedelic substances have been used for thousands of years by different cultures to induce altered state experiences, which has been seen by many as a doorway into personal and collective healing. By seeing that which we have suppressed, we have an opportunity to heal it. When psychedelics are used in a ceremonial or therapeutic setting, difficulty is expected and even welcomed as part of the experience. With certain substances like ayahuasca or peyote, it is commonly understood that facing the fears and inner demons revealed by the medicine is a trademark of the experience. In psychotherapy sessions using MDMA, accessing and processing suppressed memories is the mechanism through which individuals are able to heal from trauma.

Becoming conscious of our repressed aspects and memories and integrating them into our awareness is at the core of the psychological and emotional healing process. Psychedelics can catalyze this healing process, which is why they hold so much promise in mental health treatment. In recreational environments, however, this knowledge can often be forgotten and

replaced with oft unspoken and misleading beliefs about the psychedelic experience, for instance that it is supposed to be fun, connecting, enjoyable, transcendent, peaceful, or euphoric. It can definitely be these things—and much more.

Because psychedelics are nonspecific amplifiers, the ingestion of these substances can allow us to expand our insight into every possible aspect of the human experience, everything from joy, bliss and love to fear and confusion, and hatred. If the individual under the influence is in a supportive environment free of shame and judgment they are more likely to be able to surrender to whatever the substance is revealing to them. One of the challenges with recreational environments like concerts, festivals, and parties is that these environments can be highly varied and unpredictable. Combined with a psychedelic this can create conditions in which the individual cannot surrender and can begin to resist, causing a spiral

of more struggle and challenge. Helping someone having a difficult psychedelic experience means creating a safe environment for the individual to surrender to the experience.

HOW TO HELP SOMEONE HAVING A CHALLENGING PSYCHEDELIC EXPERIENCE

Assisting someone who is having a challenging psychedelic experience is an opportunity to transform a potentially traumatic experience into an opportunity for learning and transformation. Since its inception in 2012, the Zendo Project, developed by the Multidisciplinary Association for Psychedelic Studies (MAPS), has assisted over 1900 guests and trained over 1500 individuals in the practices of peer counseling and psychedelic harm reduction. We have worked within the transformational festival community to create a safe space for those who might otherwise end up being hospitalized or arrested as well as less extreme cases, individuals who are looking to process and make sense of their journey. Many of our guests are brought in by their friends, who are uncertain how to provide support. Most people come to the Zendo because they are in some way feeling unsafe, disoriented, confused, or frightened. We often have guests who may themselves be having an enjoyable time themselves but their behavior



4 Principles of Psychedelic Harm Reduction



Safe space

If someone is having a challenging experience try to move them into a comfortable, warm, and calm environment.



Talk through, not down

Without distracting from the experience, help the person connect with what they are feeling.



Sitting, not guiding

Be a calm meditative presence of acceptance, compassion, and caring. Promote feelings of trust and security. Let the person's unfolding experience be the guide.



Difficult is not bad

Challenging experiences can wind up being our most valuable, and may lead to learning and growth.

is disruptive to others or inconvenient to the status quo—or consensual reality. Whatever the situation, we employ the following principles when providing peer support:

1. Create a safe space. The presence of a grounded, compassionate individual can go a long way in helping someone feel safe in a time of crisis. Approach with kindness and openness, creating an environment of acceptance and compassion. Let the person know that they are in a safe place and that their experience is welcome. Let them know that whatever is coming up for them emotionally or mentally is ok and invite them share their experience if they would like, making no expectations. If possible, move them to a quiet place with few inputs. Things like bright lights, loud music, and lots of people can contribute to disorientation. Rule out any potential medical complications. Learn about or receive training in the signs and symptoms of a medical emergency so that you can help determine if someone needs medical care.

2. Sitting and not guiding. Words can often confuse or get in the way. Use them sparingly unless the individual is desiring to engage in a dialogue about their process. Rather than analyze their experience, listen with an open mind and heart. If engaged in dialogue, ask questions which help the individual deepen into their experience. Listen from the heart and become curious about their reality. Allow the individual to come to their own insights or conclusions. It is ok to provide your perspective on their experience, but focus more on helping them come to their own insights through compassionate inquiry. Let go of your agenda and try not to get ahead of the process.

3. Talking through and not down. Help the individual turn toward their experience rather than away from it. Trust in the process and the person's inner guide. Trust that whatever is showing up for them is something that they are being invited to learn about. Never dismiss or invalidate someone's perceived reality. Try to avoid rushing the experience, trying to fix the scenario, or find a solution. Rather than provide answers or solutions, remain in a place of not knowing, or beginners mind. If the individual is behaving in ways that are destructive or violent, set boundaries around behavior while validating the emotions behind the behavior such as "I hear that you are angry. You are welcome to express your anger with your words and emotions, just not with violence."

4. Difficult is not the same as bad. Difficult life experi-

ences can be some of the most valuable learning opportunities. Strength, resilience, surrender, and deep wisdom are often forged in the fires lit in our darkest times. Remembering the philosophies discussed earlier in this article will help the sitter trust that however challenging the situation may seem, being a calm and grounded presence will go along way in helping someone who is struggling. Reminding the individual that their experience may be an opportunity for them to look at aspects of themselves that want their attention in order to be healed can be helpful. Inviting in the possibility that they will emerge from the experience with new insights and understanding.

The Zendo Project was developed in response to a need for more compassionate interventions for those who choose to use psychedelic substances. Outdated ways of working with these experiences such as restraint or sedation are most often unnecessary and can cause harm. These approaches are often rooted in simple misunderstandings as well as decades of stigma and fear around psychedelics. The Zendo Project believes that through education about psychedelics and their effects, we can teach others including medics, law enforcement, and security personnel ways to respond with compassion and help deescalate situations when they arise. We aim to invite honest conversations about drug use, which facilitate understanding and change the way we respond to those in need of support. 🌱

Note: This article originally appeared as a blog on Global Drug Survey (globaldrugsurvey.com). Please add your experience to their survey at globaldrugsurvey.com/GDS2017.

Sara Gael, M.A., is Director of Harm Reduction for MAPS' Zendo Project. Sara received her Master's degree in Transpersonal Counseling Psychology at Naropa University. She began working with MAPS in 2012, coordinating psychedelic harm reduction services at festivals and events worldwide with the Zendo Project. Sara was an Intern Therapist for the recently completed MAPS Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD in Boulder, CO. She maintains a private practice as a psychotherapist specializing in trauma and non-ordinary states of consciousness. Sara believes that developing a comprehensive understanding of psychedelic medicines through research and education is essential for the health and well being of individuals, communities, and the planet. She can be reached at sara@maps.org.



Natalie Lyla Ginsberg

Psychedelics and the Trauma of Daily Injustice

NATALIE LYLA GINSBERG

AFTER INTERVIEWING 8,000 PEOPLE in Atlanta, an Emory University study determined that there were higher rates of Post-Traumatic Stress Disorder (PTSD) in a violent neighborhood than in returning war veterans.¹ Trauma is the experience of feeling profoundly unsafe, emotionally or physically. So, PTSD comprises a set of behaviors and attitudes that develop as adaptive mechanisms. For example, hypervigilance, which can manifest in symptoms including debilitating anxiety, insomnia and violence. Trauma causes individuals to respond defensively, from a place of fear. The healing from a psychedelic experience comes from its capacity to move people to act more from a place of compassion and love, and less from a place of pain and fear.

Violence, poverty, neglect, and discrimination can all be traumatic experiences both on the individual and community levels. The most marginalized communities are therefore the most traumatized. Civil rights advocate and Professor at both UCLA and Columbia Law Schools, Kimberlé Williams Crenshaw, first coined the concept of intersectionality to highlight the fact that those who live at the intersection of multiple, marginalized identities experience compounded vulnerabilities. Crenshaw focuses specifically on the ways “race and gender intersect in shaping structural and political aspects of violence against women of color.”² For example, though women experience more violence than men, women of color experience more violence than white women, and trans women of color experience even higher rates of violence. *Intersectional trauma* describes the daily trauma of existing in a society that marginalizes your identity. Unfortunately, marginalized communities are also the most widely under-diagnosed and under-treated. Social injustice, devastatingly, both creates trauma and perpetuates it. For those with safe access, psychedelic experiences can serve as harm reduction for the trauma of daily injustice.

As Bessel Van Der Kolk reports,³ for every veteran that develops PTSD, there are 30 children who develop PTSD (of-

ten misdiagnosed as ADHD) from childhood abuse or neglect. Severe trauma from childhood usually has the most long-term impacts. According to one report, “adults who have experienced four or more traumas are more than 12 times as likely to attempt suicide, more than 10 times as likely to use injection drugs, and over seven times as likely to be an alcoholic. These individuals are also more than twice as likely to have a stroke, and nearly twice as likely to have cancer.”⁴ Even among military veterans, exposure to childhood trauma, or “adverse childhood experiences,” increases vulnerability to developing PTSD during military service. The same report states that “61.7 percent of adults in California have experienced at least one trauma, and one in six California adults have experienced four or more traumas.”

Almost one-third of U.S. military veterans suffer from PTSD, yet routinely receive inadequate support. Veterans are prescribed a number of ineffective pharmaceuticals, often including opiates. Twenty-two veterans are estimated to commit suicide each day, and many others die from prescription opiate overdoses. In fact, in 2015 the U.S. experienced more deaths from opioid overdoses than car accidents,⁵ and veterans are twice as likely to die from an opiate overdose as non-veterans.⁶ MAPS is proud to work with military veterans in our cannabis and MDMA studies to increase their access to safe, effective healing.

However inadequate military veterans’ current treatment, veterans still have access to some of the best PTSD services currently being provided. The majority of people in the U.S. and around the world suffering from PTSD do not even have a diagnosis, much less access to any treatment. In my experience as a social worker, PTSD diagnoses often help people recognize that their behavior is a reflection of their experience, rather than of themselves, which can inspire and grant them more agency to work towards healing. More concretely, diagnoses also facilitate treatment options and insurance coverage. As long as diagnoses serve as psychological education, and not as pathological la-

¹ Christiansen, Jen. “PTSD from your ZIP code: Urban violence and the brain.” *CNN*. March 27, 2014 <http://www.cnn.com/2014/03/27/health/urban-ptsd-problems/>

² Crenshaw, Kimberlé Williams. “Mapping the Margins: Intersectionality, Identity Politics, and Violence against Women of Color.” *Stanford Law Review* 43 (6):1241-99 (1991). <http://www.racialequitytools.org/resourcefiles/mapping-margins.pdf>

³ Van Nuys, David. PhD. “Brain, Mind and Body in the Healing of Trauma with Bessel van der Kolk MD.” *The Archive* No. 436. January 1st, 2015. <https://archive.org/details/436-brain-mind-and-body-in-the-healing-of-trauma-with-bessel-van-der-kolk-md> [at 2:30]

⁴ Katcher, Margaret. “Gabby Falzone Translates the Study of Trauma.” *Oakland North*. November 15th, 2016. <https://oaklandnorth.net/2016/11/15/gabby-falzone-translates-the-study-of-trauma/>

⁵ Center for Disease Control and Prevention (CDC). “Opioid Overdoses.” 2015. <https://www.cdc.gov/drugoverdose/>

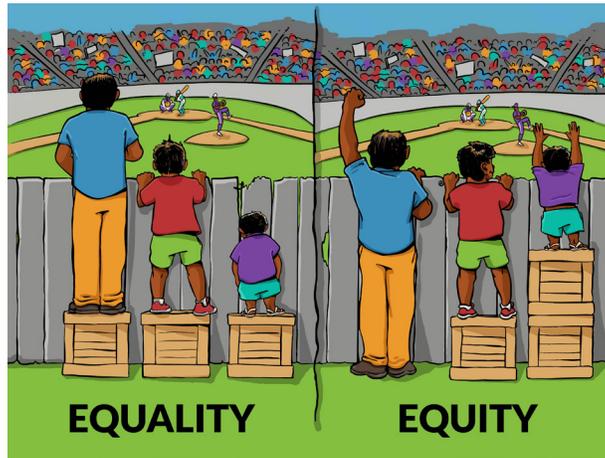
⁶ Bohnert AS1, Ilgen MA, Galea S, McCarthy JF, Blow FC, “Accidental poisoning mortality among patients in the Department of Veterans Affairs Health System.” *Med Care*. April 2011. 49(4):393-6. <https://www.ncbi.nlm.nih.gov/pubmed/21407033>

bels, they can be a helpful way to support individual development.

Research has demonstrated that the genetic, psychological, physical and economic effects of trauma can last generations,⁷ described as “intergenerational trauma” or “multigenerational trauma.” Intergenerational trauma is unique to each group and each person, but understanding that trauma is a shared, community experience is a necessary step towards healing traumatic cycles. Researchers have documented the lasting genetic trauma in Holocaust survivors’ offspring. The committed philosophy and campaign to “never forget” the Holocaust helps the Jewish community understand their shared trauma, which allows work towards healing.

Similarly, a majority of black Americans experience intergenerational trauma. Dr. Joy DeGruy has named the trauma experienced by descendants of African slaves in the Americas as “Post-Traumatic Slave Syndrome.”⁸ A majority of black Americans have ancestors who were kidnapped from West Africa, torn from their families, sold as slaves, stuffed as cargo onto slave ships, and beaten and raped by their owners, all the while raising children under these conditions. Further, many of these children were born of rape: one large scale genetic study demonstrates that on average black Americans have 24% European ancestry.⁹ When slavery finally ended, racism was codified in the Jim Crow laws. These laws enacted both physical and psychological terror, commonly including the lynching of black men. After decades, explicit segregation transformed into new tools of discrimination: the war on drugs and mass incarceration. Today, walking down the street or driving in a car automatically endangers Americans of color, and in particular, black Americans. Almost daily, we find law enforcement footage of unprovoked violence against black people, and law enforcement officers rarely receive consequences for their actions, even when their violence ends in death.

Dr. Monnica Williams, a pioneering trauma researcher, has demonstrated that racial trauma can manifest in standard PTSD symptoms. In the fall of 2015, Williams attended MAPS’ MDMA Therapy Training Program, and will speak at Psychedelic Science in April 2017 on a panel entitled *Injustice, Intersectional Trauma, and Psychedelics*. Joining Dr. Williams will be Dr. Jae Sevelius, an Assistant Professor and principal investigator at UCSF Center of Excellence for Transgender Health, who will



Artist Angus Maguire illustrates equality versus equity. Used with permission from the Interaction Institute for Social Change. Learn more at interactioninstitute.org and madewithangus.com.

speak about the intersectional trauma her transgender clients face, and the potential role played by psychedelic therapy. The other panelists will address the intergenerational trauma faced by indigenous Americans, and the potential role of restorative justice and psychedelic healing in addressing trauma stemming from systemic injustice. One of Psychedelic Science 2017’s many Community Forums will focus on “White Allyship and the Psychedelic Community,” where we engage in conversations about intersectional and intergenerational trauma both in white communities and communities of color.

The Open Society Foundation (OSF) has also provided MAPS with a grant to award Perspectives Scholarships to individuals from around the U.S. and globe to attend Psychedelic Science 2017 who represent underrepresented identities and perspectives. The Perspectives Scholarships includes those otherwise marginalized by their gender, race, nationality, religion, sexual orientation, age, or ability, and aims to ensure that their community’s unique perspective of trauma is reflected in this fast-growing field.

MAPS’ MDMA-assisted psychotherapy research is showing the vast potential for psychedelics to heal PTSD. At Psychedelic Science 2017 and beyond, we hope to explore how we can further develop psychedelics into tools for healing the trauma of systemic injustice, and ultimately contribute to stopping the cycles of trauma and injustice themselves. ●

Natalie Lyla Ginsberg is Policy and Advocacy Manager at MAPS. She 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.

⁷ Rodriguez, Tori. “Descendants of Holocaust Survivors Have Altered Stress Hormones.” *Scientific American*. February 3rd, 2015. <https://www.scientificamerican.com/article/descendants-of-holocaust-survivors-have-altered-stress-hormones/>

⁸ De Gruy, Joy. PhD. “Post-Traumatic Slave Syndrome.” <http://joydegruy.com/> [accessed 3.25.17]

⁹ Wade, Lizzie. “Genetic Study Reveals Surprising Ancestry of Many Americans.” *Science*. December 18th, 2018. <http://www.sciencemag.org/news/2014/12/genetic-study-reveals-surprising-ancestry-many-americans>



Jag Davies

Psychedelic Justice: How Do We Repair the Harms of Psychedelic Prohibition?

JAG DAVIES

**We are
the Drug
Policy
Alliance.**

PSYCHEDELICS CAN BE LIFE-CHANGING tools that can help people lead more meaningful and fulfilling lives. They can help us understand how changing ourselves—and the world around us—is possible.

When it comes to drugs and drug policies, the landscape has changed as quickly as any other issue in U.S. politics over the past few years. Despite the throwback drug war extremists now occupying the White House, the fact remains that a growing majority of Americans—including many prominent lawmakers from both sides of the aisle—now support making marijuana legal, significantly reducing the role of the criminalization in drug policy, and treating addiction as a health issue rather than a criminal one.

The Drug Policy Alliance (DPA) has played an instrumental role in many, if not most, of the major drug policy reforms over the past two decades—and we're increasingly turning our focus toward protecting the safety, wellness, and freedom of people who can benefit from psychedelics.

We believe people who use psychedelics shouldn't be vulnerable to criminal punishment—and we want to build a world where legal psychedelics make sense. This means:

1. *Exposing and overcoming ongoing barriers to scientific and medical research.* The potential benefits and risks of psychedelics need to be better understood, but the drug war and its ideology continue to drastically limit the scope of scientific research. That's why we're working to shift decision-making authority away from law enforcement, while empowering health and science experts. (For more on DPA's campaign to reform and eliminate the Drug Enforcement Administration [DEA], see drugpolicy.org/DEA.)

2. *Changing the conversation about how psychedelics are per-*

ceived and managed. Public support for legal access to psychedelics remains low due to unsubstantiated myths that are vestiges of the drug war. That's why we're working to educate the public about their histories, traditional uses, and clinical findings.

That's also why we're working with universities, festivals, nightlife venues, and other institutions to end zero tolerance policies—and to instead promote harm reduction and benefit maximization measures, such as drug checking and onsite peer counseling services like MAPS' Zendo Project. (Check out DPA's #SaferPartying campaign at drugpolicy.org/MusicFan for much more on this.)

3. *Repairing the harms of psychedelic prohibition and reducing the role of criminalization in psychedelic drug policy.* Psychedelic prohibition is a legacy of racism, colonialism, and the repression of indigenous cultures. This legacy continues today, with thousands of people every year getting handcuffed, arrested, branded for life as criminals, and serving time behind bars simply for using or possessing a psychedelic substance. These people are more likely to be young, non-white, and socioeconomically marginalized than most other people who use psychedelics.

While psychedelic-assisted psychotherapy could be approved within the next decade, that would not change the criminal penalties for people who use psychedelics outside of government-sanctioned, medically-supervised settings. That's why it's incumbent upon people who care about psychedelics to work toward ending the criminalization of people who use them outside of medical contexts, while also advocating for psychedelic-assisted therapy research.

We must ask ourselves: What would it mean if we end up in a world where psychedelics are legally accessible for a privileged few, while communities who have historically suffered

the worst harms of prohibition remain criminalized? For social change to be truly transformational, mustn't it lift up those who are the least privileged among us?

At DPA, we're working to end arrests and criminal penalties for people who use or possess psychedelics and other substances—a step several countries like Portugal and the Czech Republic have taken with enormous success—and to scale back draconian prison sentences for people convicted of making or selling them. We're also committed to exploring and evaluating small-scale models for legally regulating psychedelics outside of medical contexts, as well as protecting people who use psychedelics as part of a religious or spiritual practice.

From October 11–14, 2017, please join us in Atlanta for DPA's biennial International Drug Policy Reform Conference—it's one of the best ways for MAPS supporters to meet like-minded people and push reform opportunities forward. As in previous years, the Reform Conference will be co-hosted by MAPS and will foment discussion and debates about psychedelics through a series of forward-thinking panels with leading luminaries connecting the dots between psychedelics and other issues like criminal justice reform, marijuana legalization, drug treatment, and harm reduction.

Then on October 27, 2017, join us in Seattle, where DPA and the End of Life Liberty Project are co-organizing a day-long symposium on psychedelics and palliative care, hosted by the University of Washington's Schools of Law, Medicine, and Public Health.

For social change to be truly transformational, mustn't it lift up those who are the least privileged among us?

For those attending Psychedelic Science 2017, you can connect with me and my colleagues at DPA's community forum (Friday, April 21 at 4:30 PM). In addition, DPA's founder Ethan Nadelmann will speak on the "Psychedelics and Policy" panel, Audience Development Director Stefanie Jones will

speaking on the harm reduction panel, and Deputy Director of National Affairs Michael Collins will speak about marijuana research and policy reform.

DPA is a proud, long-time supporter of MAPS' work to demonstrate the safety and efficacy of psychedelics for science, therapy, spirituality, and personal growth. We are profoundly

grateful to MAPS for supporting our complementary work to reduce the role of criminalization in psychedelic drug policy and to diminish the pain that psychedelic prohibition continues to reap with every passing day.

Together, we can live to see a world where people who use psychedelics are no longer criminalized and stigmatized, where we are all free to share our full truths. 🌱

Jag Davies is the director of communications strategy at the Drug Policy Alliance (drugpolicy.org), the nation's leading organization promoting drug policies grounded in science, compassion, health and human rights. Jag worked at MAPS from 2003–2007, serving as director of communications and in other roles. He also previously worked for the American Civil Liberties Union (ACLU), where he coordinated local, state, federal and international efforts to end punitive drug policies that cause the widespread violation of constitutional and human rights. He currently lives in New York City and can be reached at jdavies@drugpolicy.org.

A Really Good Day: How Microdosing Made a Mega Difference in My Mood, My Marriage, and My Life

AYELET WALDMAN

An excerpt from the new memoir, published by Knopf (2017)



Ayelet Waldman

(Image by Claire Lewis)

Day 1

Microdose Day

Physical Sensations: Heightened awareness.

Mood: Excited. Nervous. Delighted.

Conflict: Who, me? Even the idea seems absurd.

Sleep: Hard time falling asleep. Woke up early.

Work: Astonishingly productive, lost track of time.

Pain: My shoulder—frozen for the past year and a half—is killing me.

Today I took my first microdose. My senses are ever-so-slightly heightened, a feeling all but unappreciable, so perhaps it's psychosomatic, though that word carries little meaning when anything that might be happening to me right now has inevitably to do with the interaction of mind and body. I feel a tiny bit more aware, as if my consciousness is hovering at a slight remove, watching me tap the keys on my keyboard, rub my ankles together, sip a mouthful of tea and swallow it. The trees look prettier than usual; the jasmine smells more fragrant.

It suddenly occurs to me that I feel mindful, a feeling I have tried to achieve through meditation, though I always come up with zip. I am finding it a little bit easier to notice both my thoughts and my body moving through space. Though, even as I write this, I fear the sensation has passed.

Even more thrillingly, for the first time in so long, I feel happy. Not giddy or out of control, just at ease with myself and the world. When I think about my husband and my children, I feel a gentle sense of love and security. I am not anxious for them or annoyed with them. When I think of my work, I feel optimistic, brimming with ideas, yet not spilling over. There's nothing hypomanic about this mood. My mind is not racing. I feel calm and content. Surely, the results cannot be evident so quickly? This is, in all likelihood, nothing more than the placebo effect. But even if it is all in my mind, even if the mood passes, I am grateful for this respite.

When I woke up this morning, I crept out of my house to the place where I hid the little cobalt blue dropper bottle that contains my microdose of diluted LSD. Careful not to hold it up to the light (LSD degrades when exposed to ultraviolet light—ironic, considering all the black-light posters users have stared at while feeding their heads), I shook the bottle a few times, filled the dropper, and carefully deposited two drops under my tongue.

“An intriguing and thorough look at the therapeutic possibilities of an illegal drug... An engaging and deeply researched primer on a taboo subject and a compelling case for more research on it.”

—Nora Krug, *The Washington Post*

This was certainly not the first time I had tried an illegal drug, though I have never been what you would call a regular drug user. I smoked marijuana a few times in high school, a dozen or so times in college, once or twice as an adult, and then not again until I was prescribed medical marijuana (I live in California), first to end my dependence on the sleeping pill Ambien and then to ease the pain of a frozen shoulder. I have used MDMA six or seven times.* In college, I tried cocaine twice, and those mushrooms that purported to be magic once. All together? More than some people my age, less than Presidents Obama and Bush.

Nor am I an avid user of legal recreational drugs. I don't like the taste of alcohol, and am too readily susceptible to its effects, so even when I'm not taking psychiatric drugs I rarely drink. Though I've certainly been mildly intoxicated, I remember being inebriated only twice: once in high school, when I threw red wine up on the shoes of a boy I liked (he drove me home, helped me up the stairs to my bedroom, muttered an awkward excuse to my mother, and disappeared from my life), and once in college, when I was convinced to try a beer funnel (I threw that up, too). Tea is my stimulant of choice, and on a workday I can go through a pot or two before noon, when I stop in order not to spend the night wide awake.

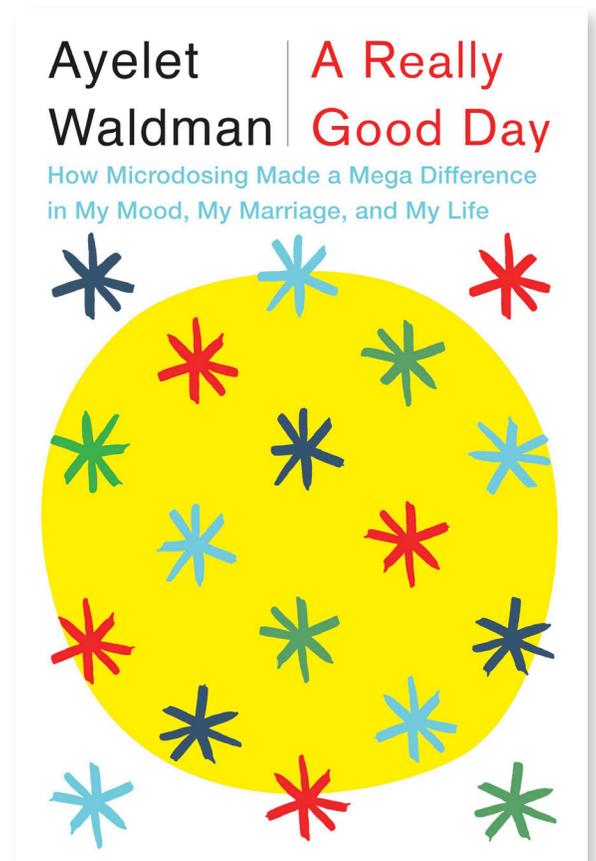
I have never purchased drugs from a drug dealer. Whatever illegal substances I've ingested have been passed to me at a party or given to me by friends. When I decided to try the protocol, despite living in Berkeley, a place I'd always assumed to be the psychedelic capital of the world, I had no idea how one would go about buying the drug. Should I wander down to People's Park and hit up one of the dealers who ply their trade among the homeless teens? How would that go?

“Hey, lady, smoke, shake?”

“Why, yes! Do you happen to have lysergic acid diethylamide? And do you take Visa?”

Having dismissed the possibility of a street hand-to-hand, I found myself in yoga class one morning, staring at the grubby-footed young woman on the mat next to mine. Her sweat-stained Interstate 420 T-shirt was a good sign, but then I noticed the Tibetan mandala tattoo on her ankle. How can you trust someone who inscribes permanently on her body something specifically designed to symbolize the transitory nature of the material world? I couldn't buy drugs from an idiot, especially a dirty one.

It then occurred to me that, like all middle-aged women in the Bay Area, I have a



Available for purchase at
maps.org/store.

* Stay tuned. You'll read more about how and why I've used MDMA later on in the book.

healthy supply of gay male friends, most (though by no means all) of whom are childless. Surely, they still knew how to party! Or at least maybe knew someone who knew someone who knew how to party. I started calling.

Unfortunately, it turns out that the gay men of my acquaintance no longer jet around from one circuit party to the next, but, instead, spend their weekends in the same domestic torpor as I do. Binge-watching episodes of *Orange Is the New Black* is the closest they get to criminality. My former-stoner friends were similarly useless. The guy who used to grow hydroponic weed in his dorm room closet? He's the third-grade room parent, his only remaining allegiance to the counterculture the Darwin fish bumper sticker on his Prius.

I was at a loss, so though Fadiman stresses the importance of discretion, I began tentatively bringing up the subject of microdosing in conversation. If the response was familiarity or even curiosity (or really anything other than befuddlement or disgust), I'd mention that I was looking for a reputable (or at least not entirely disreputable) source. After some time, an acquaintance told me that he had heard a story about an elderly professor who had been microdosing with LSD for years. He didn't know the professor's name or anything about him, but he'd pass a message along to the person who had told him about the professor. Maybe that person would reach out to the professor on my behalf. The entire tale had the ring of the apocryphal, and I had little faith that anything would result from this attenuated game of telephone with someone who I wasn't sure even existed.

I continued my fruitless quest. I even momentarily considered trying to log on to the dark web, but since I am only marginally more technologically savvy than my mother, who has yet to figure out how to turn on her cell phone ringer, I realized that with my luck I'd probably end up soliciting drugs directly from the DEA homepage. I only ever got as far as Googling LSD and finding endlessly threaded message boards where eager seekers were told by more experienced keyboard shamans that when they were truly ready the drug would come to them. Obviously, these guys were high. I gave up.

About a week later, I received a message from my acquaintance. The possibly mythical professor was sympathetic to my predicament. Moreover, he was nearing the end of his life and no longer had use for his remaining LSD. He would send it to me. The story seemed preposterous, but two days later, I opened my mailbox to find a brown paper package covered in brightly colored stamps, many of them at least a decade old. The return address read "Lewis Carroll." Inside the package, wrapped in tissue, was a tiny cobalt blue bottle. On a scrap of white paper, printed in sans-serif italics, was the following note:

*Dear Fellow resident of Berkeley,
Because of a request from an old friend, you will find 50 drops
of vintage quality in the small bottle. Take in two drops portions
(5 mcg per drop).
Our lives may be no more
Than dewdrops on a summer morning,
But surely,
It is better that we sparkle
While we are here.
L.C.*

Weird. Very, very weird. And yet also kind of adorable. And freaky. I was ready, and it had come to me.

My first order of business was to test the drug. When I began flirting with the idea of trying the protocol, I ordered an LSD test kit. Without the security of the FDA,

I wanted to make very sure that what I was taking was actually LSD and not some toxic substitute. Far too often, what is sold on the street as one drug is something else entirely. For example, as the precursor chemicals to MDMA (commonly known as Ecstasy or Molly) become harder to find, hundreds of new psychoactive substances, some of which are very dangerous, are being synthesized and sold under the name. According to the DEA, the vast majority of what is currently being sold as Molly is in fact something else, often a synthetic cathinone (known as bath salts), methamphetamine, or most likely a combination of a variety of substances, some benign, some very dangerous. My eldest child attends Wesleyan University, where a group of students ended up in the hospital after consuming what they had been told was pure Molly. The kids suffered respiratory distress, and at least one of them nearly died. It took six shocks with a defibrillator and an intubation to save that young man's life. It appears that what the kids took was not MDMA but AB-Fubinaca, a synthetic cannabinoid commonly known as "Spice" or K2, which is far more dangerous. Similarly, toxic substances have been sold as LSD, leading in at least a few cases to death. I was not about to consume a drug without testing it first, no matter how cute a note it came with.

From where did I order this testing kit, you might wonder? I already told you I'm too nervous for hand-to-hand purchases and too inept to log on to the dark web. I got my LSD testing kit from the Internet's largest purveyor of toilet paper, half-hour dramas, and discounted books. That's right, I bought it on Amazon. And it qualified for Prime two-day shipping!

Squinting at the fine print on the box through my reading glasses, I read through the directions twice—I didn't want to make any mistakes. I delicately squeezed a single drop from the cobalt blue bottle into the opening at the top of the test kit and squeezed the rubber sleeve, which broke the thin glass barrier between the drop and the testing solution, allowing them to mix together. The solution was meant to turn bright lavender in the presence of LSD, but I saw only the faintest shade of purple. I reread the directions. Stared again at the solution. Was it even purple I was seeing so very faintly, or was it my imagination? Suddenly I realized what the problem was. LSD is effective at infinitesimal doses. A single drop of pure LSD would contain a massive amount of the drug. For this reason, LSD, even in its liquid form, is always diluted. "Blotter acid," for example, the most common way LSD is sold, is a piece of paper, generally decorated with some kind of design, soaked in a diluted solution of LSD and perforated into little squares. One single confetti-sized square is designed to contain the standard dose—approximately one hundred to one hundred and fifty micrograms of LSD.* If a single drop of Lewis Carroll's solution contained a mere five micrograms of LSD, it had to have been so vastly diluted that it would barely register on the testing kit. After an hour of Web surfing (there seem to be a limitless quantity of Web sites offering information about psychedelic drugs, including how to test them), I made a decision to have faith that the contents of Lewis Carroll's bottle would not make me grow either very big or very small. Or kill me.

I took the drug, and went on to have a really good day. 🌀

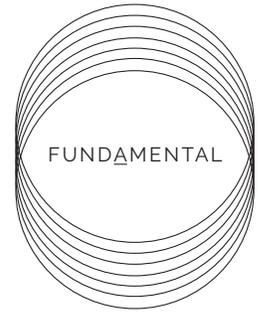
* Or at least that's what it says on the Web and in the thirty-two books about psychedelics I bought and neurotically pored over in anticipation of beginning this experiment because I am a good student and an anxious nerd and I like to do my research before taking anything resembling a risk. I haven't ever actually seen a tab of acid in person. According to DEA data from confiscated samples, the actual range of LSD on blotter is from thirty micrograms (if your dealer's a cheapskate) to a hundred and twenty.



Rodrigo Niño

FUNDAMENTAL: Crowdfunding Psychedelic Research

RODRIGO NIÑO



OVER THE PAST DECADE we have seen how the power of the internet has allowed us to connect in ways we never thought possible, yet disconnect in ways we never expected. Major technological advances of our time have brought forth universal struggles, like the mental health crisis that plagues our society today. From depression and anxiety, to addiction and trauma, many of those close to us are suffering. The exciting news is that current research on psychedelics is finally reaching the mainstream. Now it is time to do something about it.

Crowdfunding has been one of the great advantages of our time. Books have been published, elections have been funded, projects have been financed, and most importantly, communities have been built. I believe, however, that the true potential of crowdfunding has yet to be reached.

Imagine if each person suffering from a mental illness or witnessing someone close to them struggling with mental health could do something about it. If dollar by dollar, we could come together as a community and spark a mental health revolution by supporting the science and bringing it closer and closer to medicalization. Today that is possible.

My name is Rodrigo Niño; I was born in Colombia and have been living in the States with my family for over 19 years. I am a real estate developer and I do crowdfunding for commercial properties in Manhattan. I believe in democratizing access to investments and believe we can also democratize access to philanthropy. I came to this realization in a very particular way.

In 2011, I was diagnosed with cancer—stage 3 Metastatic Melanoma—at age 41. After two surgeries, my odds of survival were about 1 in 3 over the next five years. Imagine yourself facing a certain death. We know we are all going to die, yet only a few of us know, when we are going to die. And even worse, we don't even know how to die well. That realization can be profoundly traumatic. It can cause terminal patients to suffer from depression, increased suicidal tendencies, and demoralization. Doctors call this fear “end-of-life distress.”

I took it upon myself to research alternative medicines for end-of-life anxiety after learning that traditional medicine couldn't do much more for me. While healing from the second surgery at Massachusetts General Hospital in Boston, and after many sleepless nights of online research, I came across an article

in *National Geographic* about a brew produced by an indigenous tribe in the Amazon called ayahuasca.

According to some accounts I read, I learned that ayahuasca might help treat autoimmune diseases and certain types of cancer. It may have been wishful thinking, but the very next week I was on a flight to Peru.

After sitting in a ceremony that lasted all night in the middle of the Peruvian jungle with a *curandero*, I woke up feeling that my fear of dying was completely gone. I couldn't believe it. I had to understand how.

Upon my return to New York, I went on a mission to find scientific validation to determine, if what had happened to me was some sort of placebo effect caused by the hallucinations, or if in fact, I had been physiologically cured by this mystical brew.

In January 2015, I met Dr. Stephen Ross of Bellevue Hospital at New York University. He was working on a double-blind, placebo-controlled study to treat end-of-life anxiety in terminal cancer patients with psilocybin-assisted therapy.

His research, confirming that psychedelics like psilocybin could potentially reduce the symptoms of anxiety and depression associated with end-of-life distress, was exceptional. Diving deeper into the subject, I came across research from all over the world from the Beckley/Imperial Research Program to MAPS, which showed even more potential for a host of other mental illnesses. I knew then as I know now that this is some of the most important scientific work I had ever come across.

Dr. Ross and Dr. Roland Griffiths published their Phase 2 trial papers on December 1, 2016, in the *Journal of Psychopharmacology*. While this was taking place, Dr. Rick Doblin and MAPS received formal approval from the FDA to embark on the final phase towards approval of MDMA-assisted psychotherapy for PTSD. When I saw the story featured on the front page of *The New York Times*, as well as in *Newsweek*, *TIME Magazine*, and many other mainstream publications, I knew it was time. A revolution in mental health was possible. The results of these studies were unprecedented and the public reception was profound.

The most inspiring implication to me, however, is not only the revolutionary therapeutic benefit these powerful compounds have, but the fact that it is often correlated with mystical experiences, where patients report encountering an ultimate

reality of interconnectedness with all people and things.

In my research I found that traditional sources of financing for scientific research had little interest in funding trials of these natural compounds due to stigma and a lack of financial incentive. That's when I realized that donation based crowdfunding could enable families like mine—who have witnessed loved ones suffer from fear of dying, or a debilitating mental illness like depression, alcoholism, or PTSD—to finally be able to do something about it.

The frustration and impotence I saw in my family due to my ordeal is something that I believe no one should have to go through. My hope is that in a few years we have enough evidence

to medicalize these compounds and allow doctors to prescribe psychedelic-assisted therapies to so many of those in need. To reach that point, the crowd has the opportunity to come together to fund the research and directly support psychedelic science.

In the coming months, we will all be able to fund a mental health revolution through the FUNDAMENTAL crowdfunding campaign: a campaign with the goal of engaging a community of individuals to support scientific research related to the application of psychedelic compounds, and to help solve the global mental health crisis. Through this crowdfunding campaign, my intention is to enable *anyone* to support *everyone* who has suffered from mental illness or end-of-life distress like I did.

Take a moment. Think of someone you love. Think of someone you know who is suffering. Think of someone you've lost.

Because this is not just about funding another clinical trial. This is about finally taking the opportunity to do something for them.

It's time to fund a mental health revolution. Join the movement at fundamental.nyc.

Rodrigo Nino, CEO and founder of Prodigy Network, is a leading crowdfunding expert in commercial real estate. He is the sponsor of FUNDAMENTAL, which is focused on backing government-approved studies in the United States and around the world.

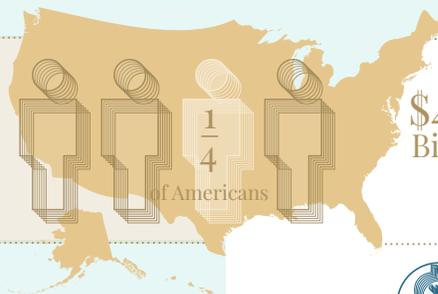


FUNDAMENTAL
is a continuous crowdfunding initiative for scientific research on psychedelic-assisted treatments for mental illnesses.

Our first campaign aims to fund specific studies on End of Life Anxiety, Alcoholism, and PTSD, led respectively by **Dr. Stephen Ross, Dr. Michael Bogenschutz, and Dr. Rick Doblin.**

The Problematic

Millions of people are suffering from various kinds of mental illnesses.



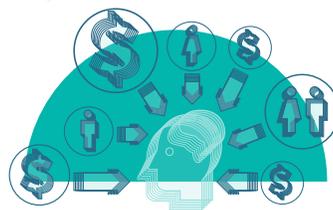
USD
\$400 Billion
Lost

One fourth of Americans are currently suffering from a mental issue, leading to over US\$400 billion in lost earnings and health care costs each year. Two thirds of those diagnosed will never seek treatment.

The Alternative

New studies offer promising relief for a variety of mood-altering illnesses, through an unlikely source.

A group of scientists at prestigious research institutions such as NYU, Johns Hopkins, MAPS and the Imperial College of London are conducting studies with psilocybin and other psychedelic compounds to treat issues such as cancer-related depression and anxiety, alcohol and drug addiction. So far the results are very promising, creating an opportunity for these ground-breaking treatments to be medicalized.



A FUNDAMENTAL Opportunity

Currently the research depends on the support of a few private donors and institutions, with little-to-no help from governments or pharmaceutical companies. Yet a steady stream of funding is essential to continue this research.

For the first time, thanks to technology, the friends and family of those afflicted by mental illness have the opportunity to contribute to a solution, by crowdfunding scientific research.

The FUNDAMENTAL Fund

Sponsored by Rodrigo Nino, a leading crowdfunding expert in commercial real estate, FUNDAMENTAL is focused on backing government-approved studies in the United States and around the world.

Crowdfunding is not only about funding the research.

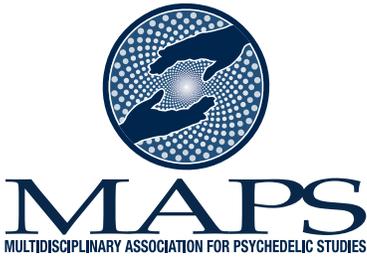
A community of individuals united in their connection to the goal will naturally form.

Legal Structure

Each tax-deductible donation will be deposited in a Donor Advised Fund, to ensure transparency and security for the crowd. Once the crowdfunding campaign is closed, the DAF will grant the funds to the aforementioned institutions with the exclusive purpose of supporting the research.



MAPS: Who We Are



Executive



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



Merete Christiansen,
Executive Associate
and Assistant to Rick
Doblin, Ph.D.

Clinical Research



Alia Lilienstein, M.D.,
M.P.H., Clinical
Research Associate
- Physician



Berra Yazar-Klosinski, Ph.D.,
Clinical Research Scientist

Communications and Marketing



Brian Brown,
Communications and
Marketing Manager;
Conference Manager



Brad Burge, Director of
Communications
and Marketing;
Conference Director



Sarah Jordan,
Publications Associate



Cara LaChance,
Social Media and
Multimedia Associate



Amy Mastrine,
Web Assistant



Bryce Montgomery,
Content Manager

Development



Erik Brown,
Development Manager



Tess Goodwin,
Accounting and
Development
Consultant



Jade Netanya Ullmann,
Development Officer
and Connector



Ryan Beauregard,
Zendo Project Manger



Sara Gael, M.A.,
Director of
Harm Reduction,
Zendo Project

Harm Reduction (Zendo Project)

Operations



Aidan Boling,
Operations Associate



Kynthia Brunette,
Event Volunteer Manager
and CRM Systems
Specialist



Jenni Vierra,
Administrative
Associate

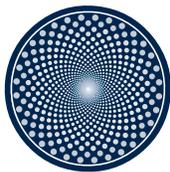
Policy and Advocacy



Ismail Ali,
Policy Fellow



Natalie Lyla Ginsberg,
Policy and Advocacy
Manager



MAPS Public Benefit Corporation

The **MAPS Public Benefit Corporation (MPBC)** is a wholly owned subsidiary of MAPS. The special purpose of MPBC is to balance income from the legal sale of MDMA with the social benefits of MAPS' mission by serving as a vehicle for conducting MAPS' psychedelic and marijuana research initiatives.

MPBC's primary work is completing Phase 2 studies of MDMA-assisted psychotherapy for PTSD, and preparing for the 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.

MAPS Public Benefit Corporation



Amy Emerson,
Executive Director and
Director of Clinical
Research



Michael Mithoefer, M.D.,
MDMA/PTSD Study
Clinical Investigator/
Medical Monitor



Annie Mithoefer, B.S.N.,
MDMA/PTSD Study
Co-Investigator



Allison Feduccia, Ph.D.,
Clinical Data Scientist



Colin Hennigan,
Clinical Data Manager



Charlotte Harrison,
Senior Clinical
Research Associate



Ilsa Jerome, Ph.D.,
Research and
Information Specialist



Rebecca Matthews,
Clinical Trial Leader



Shannon Clare Petitt,
M.A., MFTI, Therapy
Training Program Manger



Sarah Sadler,
Study Coordinator



Allison Wilens,
Clinical Study
Associate

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

MAPS furthers its mission by:

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

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

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

maps.org/donate

MAPS Store maps.org/store

Featuring books, DVDs, art prints, clothing and accessories, historical artifacts, and back issues of the *MAPS Bulletin*. All proceeds support psychedelic and medical marijuana research and education.



Psychedelic Science 2017 Shirt

Show your support for Psychedelic Science with this soft, v-neck shirt! Made from 65% polyester and 35% combed ring-spun cotton, in the USA by Next Level Apparel, and screen printed locally in Santa Cruz, by The Print Gallery. Available in charcoal, in most sizes.

\$30



Psychedelic Science 2017 Tumbler

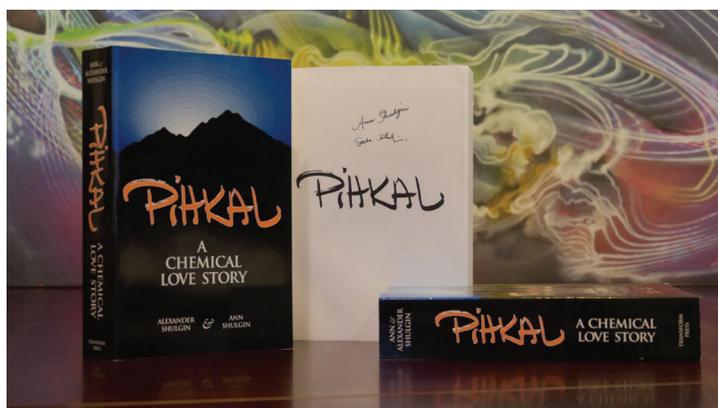
To commemorate Psychedelic Science 2017, artist Ipek Kotan created a limited edition of 500 hand-made porcelain tumblers, each with its unique number, with logos of PS17, MAPS, and Beckley, and signatures of Rick Doblin and Amanda Feilding.

"Having benefited so much from the therapeutic qualities of psychedelics in my own journey of healing, I feel both honored and privileged to be able to contribute to the psychedelic community."

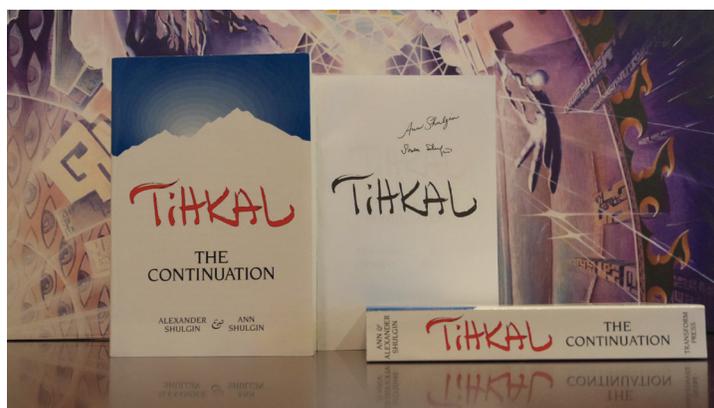
—Ipek Kotan, artist, ipekkotan.com

\$30

Rare Signed Books



PiHKaL (Phenethylamines I Have Known And Loved): A Chemical Love Story
by Sasha and Ann Shulgin **\$500**



TiHKaL (Tryptamines I Have Known and Loved): The Continuation
by Sasha and Ann Shulgin **\$500**

A limited edition of 100 copies of each title have been signed by Alexander "Sasha" Shulgin and Ann Shulgin.

PSYCHEDELIC SCIENCE 2017

APRIL 19-24, 2017 • OAKLAND MARRIOTT CITY CENTER • CALIFORNIA

