

# Research Edition

# BULLETIN

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## From the Desk of Rick Doblin, Ph.D.

RIGHT NOW, IN THE 30TH year of the Multidisciplinary Association for Psychedelic Studies (MAPS), we're preparing for the most important reality check of our entire history. We're analyzing our Phase 2 data from our international series of pilot studies into the use of MDMA-assisted psychotherapy in people suffering from chronic, treatment-resistant posttraumatic stress disorder (PTSD), studies which we began in Spain in 2000 and continued in the U.S., Switzerland, Israel, and Canada. We're also busy designing the protocols for our two multi-site Phase 3 clinical trials. These are required to prove safety and efficacy of MDMA-assisted psychotherapy for PTSD prior to the U.S. Food and Drug Administration (FDA)'s approval of prescription use.

We are preparing to submit our Phase 2 data and proposed Phase 3 protocols to the FDA for our End of Phase 2 meeting, the purpose of which is to come to agreement with the FDA on the design of our Phase 3 studies. If our assumptions are accurate, we project the approval of MDMA-assisted psychotherapy for PTSD in 2021 by both the FDA and the European Medicines Agency (EMA). Whether our Phase 2 data is sufficient, and our proposed Phase 3 designs are accepted, is the reality check we're eagerly anticipating.

We currently estimating that our Phase 3 costs will total about \$25 million, of which we've raised or been pledged over \$10 million. Over the next five years, we have a major fundraising challenge ahead of us, but it is attainable. We also have a major challenge ahead training over 100 therapists to work in

co-therapist teams to treat approximately 450 participants with PTSD in our Phase 3 studies. That challenge is also attainable.

We must rise to these challenges—and together we will—because the need is so great for new treatments for PTSD, to break the cycles of multi-generational trauma that perpetuate conflicts, fear, and hatred through time. A recent commentary by Stanford neuroscience researchers Boris Heifets and Rob Malenka, published July 14, 2016, in the mainstream journal *Cell*, concluded by saying: "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 30th year of MAPS' existence is also a major reality check for our efforts to sponsor FDA-approved medical marijuana drug development research, as we've finally obtained all the regulatory approvals we need to start our first medical marijuana drug development study. We'll evaluate four different potencies of marijuana with varying ratios of THC and CBD to treat 76 U.S. veterans with chronic, treatment-resistant PTSD. We'll enroll subjects in two locations, at Johns Hopkins University in Baltimore, Maryland, and at a research facility in Phoenix, Arizona. The study is being funded by a \$2.15 million grant to MAPS from the Colorado Department of Public Health and Environment (CDPHE), the first government grant MAPS has ever received.

The marijuana for the study is being produced at the University of Mississippi, which has grown marijuana for research

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since 1968. We are purchasing the marijuana at cost from the National Institute on Drug Abuse (NIDA), which has a Drug Enforcement Administration (DEA)-enforced monopoly on the federally legal marijuana required for FDA drug development research. This is first time NIDA has been willing to sell us marijuana since 1992, when MAPS was working with Dr. Donald Abrams at the University of California, San Francisco, for a study of marijuana for nausea control and appetite stimulation in HIV patients with AIDS wasting syndrome. We obtained FDA and Institutional Review Board (IRB) approvals for that study, but NIDA refused to sell us the marijuana, preventing the study from starting. Sadly, it's taken 24 of our 30 years to persuade NIDA to sell us marijuana for our drug development research!

We'll be getting another reality check soon in MAPS' efforts to end the obstructive NIDA monopoly. Starting in 2000, MAPS began partnering with Prof. Lyle Craker at the University of Massachusetts-Amherst to obtain a DEA license to grow marijuana for drug development research. In 2005, after the DEA rejected his application, Prof. Craker sued the DEA in an internal DEA Administrative Law Judge (ALJ) hearing. In February 2007, Prof. Craker won the case when the ALJ recommended to the DEA Administrator that it would be in the public interest for the NIDA monopoly to end. The DEA Administrator did not respond to the recommendation for almost two years, finally rejecting it a week before the inauguration of President Obama. In 2013, Prof. Craker disappointingly lost his U.S. Court of Appeals case against the DEA when the judges

ruled that NIDA had an adequate supply for researchers.

Still undeterred, Prof. Craker is now within weeks of submitting a new application to the DEA for a license to grow marijuana and produce marijuana extracts for FDA-regulated medical research. We're trying again now with optimism because we can more clearly demonstrate that NIDA does not have an adequate supply, a position supported by a new pro bono legal analysis by the major Washington, D.C., law firm Covington & Burling. NIDA has not been able to provide MAPS with the strains and potencies of marijuana we requested. Furthermore, NIDA marijuana can only be used for research, not for prescription sale, and cannot be used in FDA-approved Phase 3 studies. Before the Obama Administration leaves office, there is a very good chance it will order the DEA to end the NIDA monopoly and issue a license to Prof. Craker, and to other private producers as well.

With the continued support of our members, MAPS will proceed with confidence to our upcoming reality checks, further refine our strategies, and continue our work to mainstream the therapeutic uses of psychedelics and marijuana.



With appreciation,

*Rick Doblin*

Rick Doblin, Ph.D.

**MAPS Founder and  
Executive Director**

## MAPS: Who We Are

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

MAPS furthers its mission by:

- Developing psychedelics and marijuana into prescription medicines.
- Training therapists and 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 federal governments, 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](http://maps.org/donate)



**MAPS**  
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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# Research News

## Treating PTSD with MDMA-Assisted Psychotherapy

mdmmaps.org

### Preparing for Phase 3 Trials

As of July 2016, we are preparing to submit the data from our Phase 2 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) to the U.S. Food and Drug Administration (FDA). Our submission will include data from 136 participants in our Phase 2 trials. Later this year, we'll meet with FDA officials in Washington, D.C., to agree on the design of our Phase 3 trials—with 400 or more additional participants—which we anticipate starting in early 2017. As long as we receive the funding needed to complete the research, we anticipate FDA approval of MDMA-assisted psychotherapy as a treatment for PTSD as early as 2021.

### Final Subject Completes Long-Term Follow-Up Interview in U.S. Veterans Study

*Ongoing study*

**Location:** Charleston, South Carolina

**Principal Investigator:** Michael Mithoefer, M.D., with Co-Therapist Annie Mithoefer, B.S.N.

**Estimated study budget:** \$1,429,000

**Already raised:** \$1,429,000

This study has been fully funded.

On July 30, 2016, the 24th and final participant completed their 12-month follow-up interview in our largest Phase 2 study of MDMA-assisted psychotherapy for 24 U.S. veterans, firefighters, and police officers with chronic, treatment-resistant PTSD. Led by Principal Investigator Michael Mithoefer, M.D., and co-therapist Annie Mithoefer, B.S.N., in Charleston, South Carolina, the data from this study are now being prepared for analysis and publication in a peer-reviewed scientific journal. "When we applied to the FDA for our first study in October 2001, primarily aimed at treating people with crime-related trauma such as childhood sexual abuse, rape, or other assault, we didn't know that the Afghanistan and Iraq wars would be starting soon," writes Dr. Mithoefer in his article in the Winter 2015 *MAPS Bulletin*. "Since then, the need for additional treatments for returning veterans with PTSD has become painfully and increasingly pressing."

Approximately half of the 24 subjects have also enrolled in our ongoing sub-study, in collaboration with researchers at the Medical University of South Carolina (MUSC), of the physiological effects of MDMA-assisted psychotherapy. This sub-study is using heart rate variability (HRV) and functional magnetic resonance imaging (fMRI) to explore correlations with clinical outcomes.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy in people suffering from war-related trauma; (2) comparing the effectiveness of the treatment for people with war-related trauma



*Study participant and U.S. Marine Corps veteran Nigel McCoury accepts a dose of MDMA in one of his experimental treatment sessions in Charleston, South Carolina.*

versus for people with trauma related to sexual abuse, assault, and other causes; (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind; and (3) increasing awareness and support for our work by assisting a population with mainstream public recognition.

### 17th Participant Completes Long-Term Follow-Up Interview in Boulder Study

*Ongoing study*

**Location:** Boulder, Colorado

**Principal Investigator:** Marcela Ot'abora, M.A., L.P.C.

**Estimated study budget:** \$771,000

**Already raised:** \$771,000

This study has been fully funded.

On July 6, 2016, the 17th participant completed their 12-month long-term follow-up interview in our Phase 2 study of MDMA-assisted psychotherapy for subjects with chronic, treatment-resistant PTSD in Boulder, Colorado. 23 subjects will be included in our final analysis, while all 29 subjects, including six who dropped out or were excluded for not meeting study criteria, will be included in our intent-to-treat analysis. All subjects have now completed active study participation. Long-term follow-up data will provide additional information to guide the design of our upcoming Phase 3 trials. The final study results were prepared for publication in the first half of 2016, with publication expected later in 2016. In addition to obtaining Phase 2 data on the safety and effectiveness of MDMA-assisted psychotherapy for PTSD, this study is also comparing outcomes between different combinations of male/female co-therapist teams. Study participant Hania Withem presented a brief address at MAPS' 30th Anniversary Banquet and Celebration on April 17, 2016, at the Scottish Rite Center in Oakland, Calif. (read her story on page 8).

Goals for this study include (1) gathering evidence for the

safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD from a variety of causes, (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind, (3) exploring whether using intern co-therapists can reduce costs while maintaining treatment effectiveness, and (4) training the next generation of psychedelic psychotherapists.

## Final Experimental Treatment Completed in Israeli Study

*Ongoing study*

**Location:** Beer Yaakov, Israel

**Clinical Investigator:** Moshe Kotler, M.D.

**Estimated study budget:** \$509,000

**Already raised:** \$509,000

This study has been fully funded.

On March 24, 2016, the final open label experimental treatment session was completed in our Israeli Phase 2 study of MDMA-assisted psychotherapy for PTSD. In addition to being the final experimental session in this study, it was also the final experimental session in Phase 2 of MAPS' plan to develop MDMA-assisted psychotherapy into a legal treatment for PTSD. Led by Principal Investigator Moshe Kotler, M.D., this Phase 2 study has treated 10 subjects with chronic, treatment-resistant PTSD from any cause. "We are in the final stages of the Phase 2 research in Israel, having worked over the last few years with a variety of participants, their stories, feelings, body experiences, and the traumas that these reflect," reports co-therapist Keren Tzarfaty, Ph.D. "As these intense processes unfold and old layers melt, we have been witnessing new seeds of healing and growth, love and hope, seeds of wholeness." Once the final evaluations are complete, we will gather data for inclusion in an international meta-analysis of the safety and efficacy of MDMA-assisted psychotherapy for the treatment of PTSD.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD mostly related to war and terrorism, (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind, (3) working in direct association with the Israeli Ministry of Health, and (4) exploring the use of MDMA-assisted psychotherapy in other cultural contexts.

## Enrollment Concluded in Canadian Study

*Ongoing study*

**Location:** Vancouver, British Columbia, Canada

**Principal Investigators:** Ingrid Pacey, M.D.

**Estimated study budget:** \$470,000

**Already raised:** \$46,000 + \$69,000 raised by partners

**Needed to complete this study:** \$355,000

On November 2, 2015, enrollment was concluded in our study of MDMA-assisted psychotherapy for PTSD from sexual assault, violent crime, military service, or any other cause, taking place in Vancouver, Canada. The final results are being prepared for inclusion in our End-of-Phase 2 submission to the U.S. FDA. Led by Principal Investigator Ingrid Pacey, M.D., in

Vancouver, B.C., this small pilot study gave Canadian therapists experience with a MAPS-sponsored Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD, with data collected from three women and three men. All participants have completed treatments and are in long-term follow-up.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD from a highly skilled co-therapist team, (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind, and (3) initiating the first Canadian research into the potential benefits of psychedelic psychotherapy in over 40 years.

## 13th Participant Enrolled in Therapist Training Study

*Ongoing study*

**Location:** Charleston, South Carolina

**Principal Investigator:** Michael Mithoefer, M.D.

**Estimated study budget:** \$429,000

**Already raised:** \$35,000

**Needed to complete this study:** \$394,000

On July 5, 2016, the 13th participant was enrolled in our ongoing Phase 1 study of the psychological effects of MDMA when taken in a therapeutic setting by healthy volunteers. Enrollment in this study is limited to therapists in training to work on MAPS-sponsored clinical trials of MDMA-assisted psychotherapy for PTSD, with enrollment by invitation only. The Principal Investigator of this study is Michael Mithoefer, M.D. On May 9, in preparation for expanding our MDMA-



*Therapists attended an eight-day training led by Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., and Marcela Ot'alora, M.A., L.P.C., in Fort Collins, Colorado, April 24–May 1, 2016.*

assisted psychotherapy for PTSD development program into Phase 3, we submitted an amendment to the study protocol to the FDA. The amendment included increasing total enrollment to 100 participants and adding a second site in Boulder, Colorado, under the direction of Marcela Ot'alora, M.A., L.P.C., in order to increase enrollment to cover training needs over the next five years. The FDA gave clearance for the third protocol amendment on June 21, 2016. "We felt quite strongly that we should go through the therapist's training," says study participant Dr. Mathew Hoskins in a recent interview with Inverse. "We're asking our participants in our study to do really quite a lot."

Are you interested in learning more about being a Phase 3 MDMA-assisted psychotherapy for PTSD researcher? Learn more at [maps.org/training](http://maps.org/training) or email [askMAPS@maps.org](mailto:askMAPS@maps.org).

## Therapist Training Program: Group Training

### Takes Place in Colorado *Training Program*

**Location:** Charleston, South Carolina

**Principal Investigator:** Michael Mithoefer, M.D., with co-therapist Annie Mithoefer, B.S.N.

From April 24–May 1, 2016, 19 therapists participated in a one-week training in the techniques of MDMA-assisted psychotherapy for PTSD in Fort Collins, Colorado. Led by MAPS-sponsored researchers Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., and Marcela Ot'abora, M.A., L.P.C. trainees learned the modality of MDMA-assisted psychotherapy as outlined in the *Treatment Manual*, watched videos of therapy sessions from Phase 2 trials, and dialogued with therapists in training about the therapeutic approach. MAPS' four-part training program includes two in-person trainings, and is required for co-therapists who will be working on MAPS' Phase 3 trials of MDMA-assisted psychotherapy PTSD, which are planned to start in 2017. In-person trainings will be provided in September 2016, October 2016, and January 2017 to accommodate the co-therapists preparing for Phase 3 trials.

On May 25, 2016, MAPS issued the 8th edition of our *Treatment Manual for MDMA-Assisted Psychotherapy in the Treatment of PTSD*. The *Treatment Manual* provides researchers with a standardized method of MDMA-assisted psychotherapy to be used as a model in conducting manualized clinical trials. This manual is intended only for use with subjects of an approved clinical trial who have provided their informed consent.

The MAPS Therapist Training Program plans to train approximately 300 therapists before 2021, when we anticipate completing Phase 3 clinical trials investigating MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD.

## Conjoint Therapy: DEA, FDA, and IRB Approve Study Protocol

*Study in development*

**Location:** Charleston, South Carolina

**Principal Investigator:** Michael Mithoefer, M.D.

**Sub-Investigator:** Candice Monson, Ph.D.

**Estimated study budget:** \$200,000

**Already raised:** \$165,000

**Needed to complete this study:** \$35,000

On June 14, 2016, the U.S. Drug Enforcement Administration (DEA) approved the protocol for our upcoming study of MDMA combined with Cognitive-Behavioral Conjoint Therapy (CBCT) for treating PTSD. On March 16, 2016, the Independent Review Board (IRB) approved the protocol, and the U.S. Food and Drug Administration (FDA) accepted the protocol on January 26, 2016. Taking place in Charleston, South

Carolina, and led by Principal Investigator Michael Mithoefer, M.D., and Sub-Investigator Candice Monson, Ph.D., this will be a pilot Phase 1/Phase 2 open-label study exploring Cognitive-Behavioral Conjoint Therapy (CBCT) integrated with MDMA-assisted psychotherapy for the treatment of chronic post-traumatic stress disorder (PTSD). Candice Monson, a developer of CBCT, was introduced to MAPS by the U.S. Department of Veterans Affairs National Center for PTSD.

The study will enroll 10 pairs of participants, with one participant diagnosed with PTSD and one concerned significant other who does not have PTSD but does experience psychosocial distress. This is the first MAPS-sponsored MDMA study conducted with VA-affiliated researchers and the first to employ measures developed for the DSM-5. There are several important reasons to include significant others in PTSD treatment, in addition to the data supporting the efficacy of CBCT for PTSD. MDMA will be administered to both participants to help facilitate communication and connection between participants and therapists.

The primary goal of this study is to explore a combined method of MDMA with CBCT for PTSD. The study has received approval from all necessary government agencies, and will begin screening local participants residing around South Carolina for enrollment this summer.

## Over \$152,721 Raised for Purchase of GMP MDMA Supply for Phase 3 Trials

On April 17, 2016, MAPS' 30th Anniversary Banquet and Celebration was held at the Scottish Rite Center in Oakland, Calif, with the goal of raising funds toward the purchase of one kilogram of 3,4-methylenedioxymethamphetamine (MDMA) certified under current Good Manufacturing Practices (GMP). Additional fundraising efforts towards the purchase of GMP MDMA took place during the spring and early summer of 2016, with 82 Global Psychedelic Dinners held in 16 countries. In total, the money raised around the 30th Anniversary and the Dinners was over \$152,721.

This supply of GMP MDMA will be used for our upcoming Phase 3 trials of MDMA-assisted psychotherapy for PTSD, which will begin in 2017. The GMP MDMA will not be any purer than our existing supply, but has been created with complete documentation and validation of all manufacturing procedures as required by the FDA and the European Medicines Agency (EMA) for use in Phase 3 trials. The purchase of GMP MDMA will cost \$400,000. If you would like to host a Global Psychedelic Dinner to help raise the remaining funds, visit [psychedelicdinners.org](http://psychedelicdinners.org), or give now at [maps.org/donate](http://maps.org/donate).

## MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

### 11th Participant Treated; IRB Approves Two Additional Subjects

*Ongoing study*

**Location:** Los Angeles, California

**Principal Investigators:** Charles Grob, M.D., and Alicia Danforth, Ph.D.

**Estimated study budget:** \$400,000

**Already raised:** \$13,000 raised + \$15,000 raised by partners

**Needed to complete this study:** \$372,000

On June 29, 2016, the IRB approved an amended protocol to enroll two additional subjects in our ongoing study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum. On February 27, 2016, the 11th participant received their last blinded experimental session. Sponsored by MAPS, this is a collaborative study between MAPS and the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, with blood plasma biomarker analysis conducted by researchers at Stanford University. "During the actual drug-assisted treatment sessions, both structured and unstructured tasks will be employed, including but not limited to listening to preselected music, working with art supplies, writing in journals, silent introspection, and engaging in rapport building interactions with therapists," write the researchers in the March 2015 article published in *Progress in Neuro-Psychopharmacology & Biological Psychiatry*. "In addition, subjects will complete the TASIT, which is an interactive, video-based assessment of social inference skills. The co-therapists, always one male and one female to manage potential transference during therapy, will emphasize creating and communicating a setting of safety and support for the subject during periods of inner focus."

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

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

### Tenth Participant Treated in Marin Study

*Ongoing study*

**Location:** Marin, California

**Principal Investigator:** Phil Wolfson, M.D.

**Estimated study budget:** \$627,000

**Already raised:** \$214,000

**Needed to complete this study:** \$414,000

On June 6, 2016, the tenth participant was treated in our ongoing study of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness in Marin, Calif. Led by Principal Investigator Phil Wolfson, M.D., with co-therapist



*Principal Investigator Phil Wolfson, M.D., study participant Wendy Donner, and co-therapist Julane Andries in Marin, Calif.*

Julane Andries, LMFT, this study is gathering preliminary data about the safety and efficacy of MDMA-assisted psychotherapy for treating anxiety in 18 subjects diagnosed with a life-threatening illness. "I can live my life right now," explains study participant Wendy Donner. "That is such a gift for me."

On May 3, MAPS was a proud participant in Silicon Valley Gives, an online fundraising effort led by the Silicon Valley Community Foundation with proceeds supporting this trial. On April 3, investigators announced that the first participant has been scanned in an additional fMRI brain imaging study of the physiological correlates of MDMA-assisted psychotherapy in subjects with anxiety associated with life-threatening illness. The brain imaging sub-study is a collaboration between the MAPS-sponsored study and Michael Silver, Ph.D., at the Helen Wills Neuroscience Institute at the University of California, Berkeley.

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

## Medical Marijuana Research

### Marijuana for PTSD: Researchers Prepare for First-Ever Trial of Medical Marijuana for PTSD in Veterans

*Study in development*

**Location:** Baltimore, Md., and Phoenix, Ariz.

**Coordinating Principal Investigator:** Marcel Bonn-Miller, Ph.D. (University of Pennsylvania)

**Co-Investigators/Site Principal Investigators:** Sue Sisley, M.D. (private practice) and Ryan Vandrey, Ph.D. (Johns Hopkins University)

**Co-Investigator:** Paula Riggs, M.D. (University of Colorado)

**Estimated study budget:** \$2,156,000

**Already raised:** \$2,156,000 grant awarded by the State of Colorado

From June 6-16, 2016, a series of investigator meetings and initiation visits took place in preparation for our upcoming study of smoked marijuana for symptoms of PTSD in U.S. veterans. Principal Investigators, study coordinators, and study

physicians met in Palo Alto, CA, Baltimore, MD, and Phoenix, AZ, to discuss study procedures, receive training on the electronic platforms to be used in the study, and review protocols for recruitment, enrollment, and study publicity. Discussions at these meetings led to an amendment to the study protocol to clarify several study procedures and adjust study measures. Once the amendment has been approved by the Institutional Review Boards (IRBs) at the Scottsdale Research Institute (Phoenix) and Johns Hopkins University (JHU), we will be able to begin recruiting and enrolling participants. We currently expect that this study, the first-ever randomized controlled trial of whole plant medical marijuana (cannabis) as a treatment for PTSD in U.S. veterans, will begin in August 2016.

On April 19, 2016, the U.S. Drug Enforcement Administration (DEA) formally approved the study. The DEA's approval marks the first time a clinical trial intended to develop smoked botanical marijuana into a legal prescription drug has received full approval from U.S. regulatory agencies, including the DEA, FDA, and IRBs. The randomized, blinded, placebo-controlled study will test the safety and efficacy of botanical marijuana in 76 U.S. military veterans with treatment-resistant PTSD. The study is funded by a \$2.156 million grant from the Colorado Department of Public Health and Environment (CDPHE) to MAPS, which is sponsoring the study. MAPS' study protocol will be replicated using vaporization by the Canadian medical



*Medical marijuana for PTSD study investigators, study coordinators, and study physicians met in Palo Alto, Calif, in June, 2016.*

marijuana producer Tilray, and by the University of Sydney using Tilray extracts in orally administered capsules.

The Principal Investigator for this study is Marcel Bonn-Miller, Ph.D., of the University of Pennsylvania. Paula Riggs, M.D., of the University of Colorado, is serving as an additional Co-Investigator to help ensure the study's scientific integrity. The study site in Phoenix, Arizona, will be led by Co-Investigator/Site Principal Investigator (PI) Sue Sisley, M.D. Half of the study's 76 subjects will be treated at the Phoenix site, with the other half treated at Johns Hopkins by Co-Investigator/Site PI Ryan Vandrey, Ph.D.

On February 20, 2016, Sue Sisley, M.D., gave a presentation to commissioners of the American Legion in Washington, D.C., about MAPS' efforts to initiate our clinical trial of medical marijuana for PTSD in U.S. veterans. The talk, titled

"Barriers to Researching Medicinal Marijuana," was presented to the American Legion's Veterans Affairs and Rehabilitation Commission, TBI and PTSD Committee, as part of their 2016 conference. "I have heard great feedback from the American Legion commissioners who attended saying they felt that it was incredibly successful," reports Dr. Sisley. "They did not believe any issue related to marijuana would be so warmly embraced. They kept thanking me for opening their eyes to a very legitimate injustice of science being shackled by politics."

## Ayahuasca Research

### Data Collection Survey Underway

*Ongoing study*

**Principal Investigator:** Jessica Nielson, Ph.D.

A new anonymous questionnaire is gathering preliminary data about the potential risks and benefits associated with taking ayahuasca as a therapy for PTSD. The data collection is being sponsored by MAPS. Jessica Nielson, Ph.D., is the Principal Investigator for this study. To participate, take the survey at [surveymonkey.com/r/AyaPTSD](http://surveymonkey.com/r/AyaPTSD).

## Ibogaine Treatment for Drug Addiction

### Data Prepared for Publication in Scientific Journals

**Locations:** Mexico and New Zealand

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

All treatments have been completed in our two observational studies of ibogaine-assisted therapy for drug addiction, which took place at independent treatment centers in Mexico and New Zealand. We anticipate that data from both studies will be published in peer-reviewed scientific journals this year. Both of these studies observed the long-term effects of ibogaine treatment for opioid dependence, and the data from each study will be compared to evaluate how ibogaine treatment varies between different centers. Goals for these study included (1) gathering preliminary evidence about the safety and potential benefits of ibogaine-assisted therapy for opiate addiction, (2) comparing the safety and effectiveness of different ibogaine treatment centers, and (3) initiating and encouraging psychedelic research in New Zealand.

If you would like to apply to participate in our study of **MDMA-Assisted Therapy for Social Anxiety in Autistic Adults**, and reside in the Los Angeles area, visit [mdma-autism.org/participate](http://mdma-autism.org/participate).



Hania Withem

# Speaking My Truth: My Experience of MDMA- Assisted Psychotherapy

HANIA WITHEM, STUDY PARTICIPANT

WHEN I WAS ASKED TO speak at the Multidisciplinary Association for Psychedelic Studies (MAPS) 30th Anniversary Banquet in April 2016, I said yes, I would be happy to, even though it was a very scary prospect. How could I have said no to helping an organization that has enabled me to live a happy, productive life? So I wrote speech after speech, trying to find the right tone and to convey, with honesty, the impact this gift has had on my life. Nothing I wrote seemed to work, but I figured that as time approached, I would eventually be satisfied with what I had written.

The day of the banquet, I took the train to Oakland, Calif., and halfway there met with Nigel McCourry, another trial par-

icipant. We both had speeches prepared. We decided to write the outline of our speeches on note cards, and we arrived at the banquet venue determined to be understood. I was incredibly nervous at the idea of standing and speaking in front of a large audience, but was intent on giving it my best shot. As I was getting ready to sit at my table, I briefly met with Aubrey Marcus and, in my near panic state, asked him what he thought people would want to hear from me. Without missing a beat, and with a huge smile on his face, Aubrey said: "Truth." And so it was that when my turn to speak came, I shoved my note cards in my pocket on my way to the podium and started speaking my truth, from the heart.

## 30<sup>th</sup> ANNIVERSARY Banquet & Celebration

Over 900 people joined us in person at our 30th Anniversary Banquet and Celebration on April 17, 2016, at the Scottish Rite Center in Oakland, Calif. At this historic gathering, the global psychedelic science

community came together to celebrate the progress we've made since our founding, and to help build the future of psychedelic medicine with a fundraiser to support our \$400,000 purchase of one kilogram of pharmaceutical grade (GMP) MDMA for Phase 3 clinical trials and other research around the world. **Watch the live video of the event including Hania's address at [maps.org/live30](https://maps.org/live30).**



It seemed like a simple enough notion. However, at the time, it didn't occur to me that the reason why that resonated so deeply within me was because the whole concept of MDMA-assisted psychotherapy revolves around the idea of truth. I had spent my entire adult life hiding from the truth by avoiding any recollection of my past. I had somehow convinced myself that if I denied the circumstances I experienced growing up, I would be able to move on and live a relatively peaceful life. I did not, at the time, understand that I was setting myself up for a life of struggle that would interfere with my everyday life. After more than two decades of hardship, I was incredibly fortunate to be accepted into the MAPS clinical trial of MDMA-assisted psychotherapy for the treatment of posttraumatic stress disorder (PTSD).

The question I get asked most often is this: What is the process like? Imagine this, if you can: You are in a room surrounded by beautiful things, artwork and little treasures and beautiful flowers. There is quiet music playing, soothing music that makes you feel safe and comforted. You are sitting on a couch, and there are two people in the room with you. They are the two people you have been meeting with, and that you fully trust to guide you along on this journey of self-discovery. Everything is real. Nothing is hidden or mysterious.

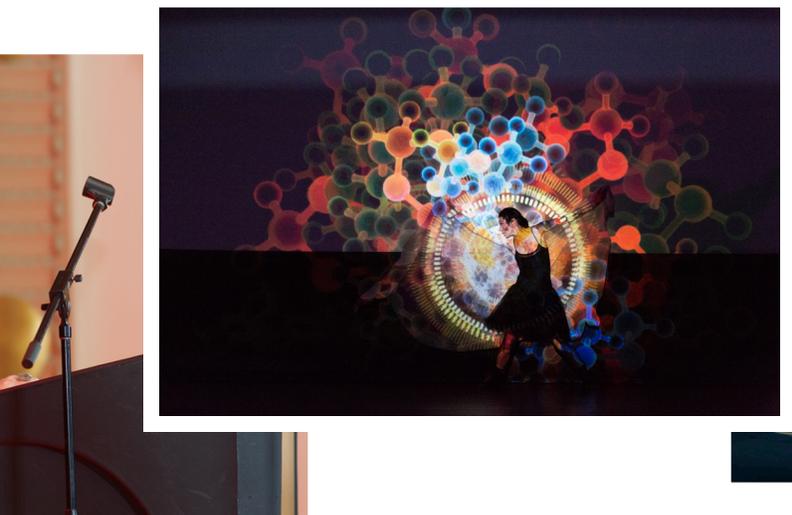
You take the medicine, and even though you know, deep down, that you are going to be traveling back to the past, to revisit your worst nightmares, you also know that you are not alone. Every feeling you experience becomes a stepping-stone to the next feeling or thought that will reveal itself to you.

Everything is quiet, everything is felt, everything is deliberate, and the entire experience is centered around the truth of who you are and what your experience was in the past. You have the absolute certainty that you were there, that you were a part of all of it, and that you were instrumental to everything that happened then and has happened since. It doesn't mean that any of it was your fault; it simply means that you were not just a spectator, but a thinking and feeling being who at the time made the only choices that seemed possible. When you are able to see your experience for what it was, instead of your recollection of all the awful feelings and emotions that became associated with it, it becomes something that you can place into the timeline of your life. Instead of memories floating around you, to be reawakened at the slightest sound or sight or smell, your past becomes a part of your story, to revisit only when you wish.

MDMA has shown me that as long as I stay true to who I am, and speak only my truth, I will be able to live a more authentic life, free of the fear and the worry that used to guide my every step. Marcela Ot'olora and Bruce Poulter, the two therapists who have guided me along this journey, continue to remind me, whenever I forget, that the full reality of my experience is what has led me to the life of fulfillment and love I live today. 🌱

*Hania Withem was a participant in MAPS' clinical trial of MDMA-assisted psychotherapy for posttraumatic stress disorder and currently lives and works in Fort Collins, Colorado.*

*From left: A full house in the Scottish Rite performance hall; MAPS supporters gathering prior to the banquet; MAPS Public Benefit Corp Executive Director Amy Emerson addresses the audience; Phadroid performs with music and graphics by Android Jones; and Rick Doblin presents on the manufacturing of one kilogram of pharmaceutical grade MDMA.*



*Image credits: Geneva Shanti / Devon Tackels / Bobby Lee*



# GLOBAL Psychedelic Dinners

In celebration of MAPS' 30th Anniversary, supporters from around the world gathered with their communities by hosting or attending Global Psychedelic Dinners starting in March, 2016. The Global Psychedelic Dinners culminated into MAPS' 30th Anniversary Banquet and Celebration at the Scottish Rite Center in Oakland, CA on April 17, 2016.

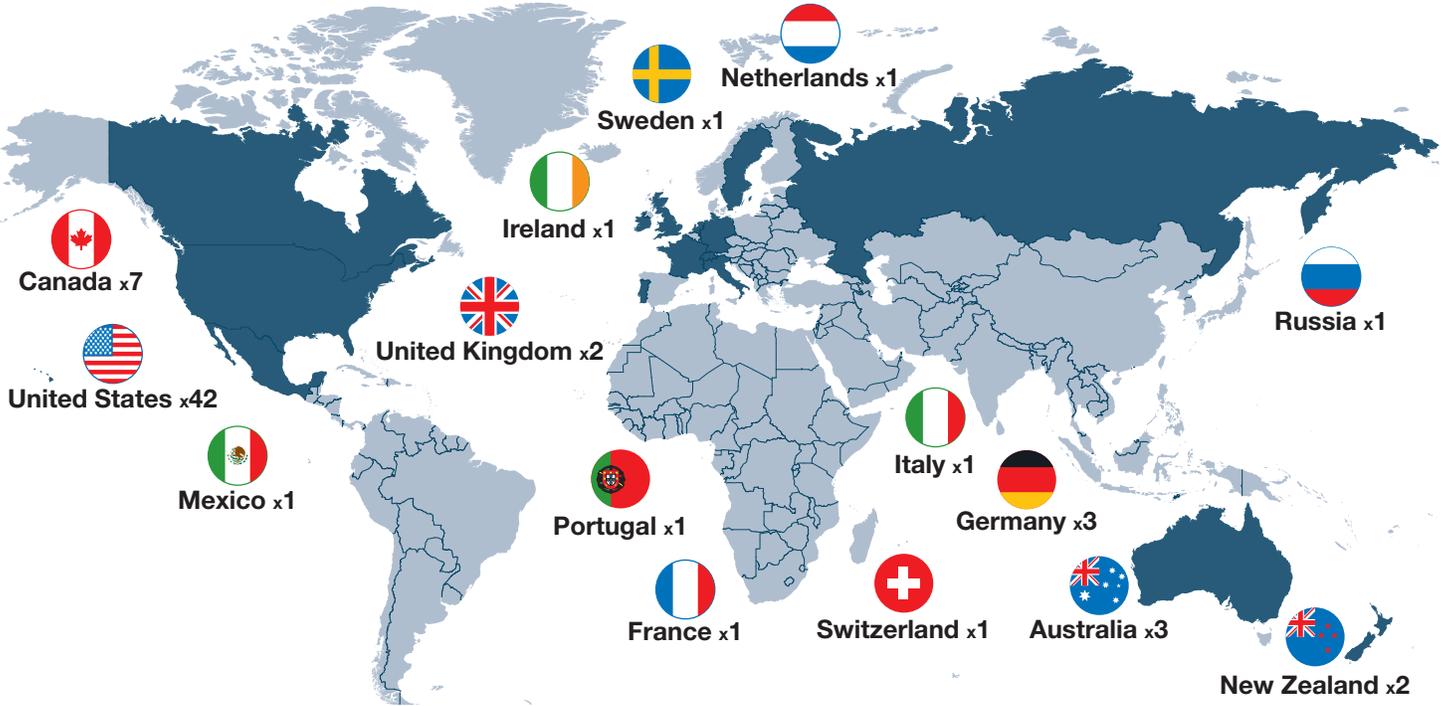
**Thank You** to all 82 gracious hosts and fundraisers, with special thanks to those who each raised over \$1,000 at their dinners!

|                             |                      |         |
|-----------------------------|----------------------|---------|
| Lars King / CTR             | Victoria, Canada     | \$5,202 |
| Jeff Breau / Evolver        | New York, NY         | \$5,182 |
| Tamara Rutherford           | Santa Barbara, CA    | \$3,985 |
| PRISM                       | Melbourne, Australia | \$2,425 |
| Rebecca Matthews            | Berkeley, CA         | \$2,205 |
| Matthew Blau                | Brattleboro, VT      | \$1,965 |
| Magaly Mauer & Kevin Garcia | Miami, FL            | \$1,673 |
| Joel Kirkpatrick            | Portland, OR         | \$1,241 |
| Gabriella Aime              | Plant City, FL       | \$1,200 |
| Robin McDuff                | Hilo, HI             | \$1,110 |



*From left: Ryan Keating and Terra Celeste discuss community building at Ryan's dinner in Salt Lake City, Utah; Rob Carr tends to a raffle at Joel Kirkpatrick's dinner in Portland, Oregon; Kwasi Adusei's guests continued their evening with live music from the band Marco Benevento in Buffalo, New York; Rick Doblin attended Illiez Planche's dinner in Montreal, Canada; PRISM hosted a large audience for presentations at the University of Melbourne, Australia;*

**82 Global Psychedelic Dinners in 16 countries** took place during Spring and early Summer of 2016. To date, over **\$45,000** has been raised from nearly **400** donors at the dinners, and in total we have raised **\$152,721** for the purchase of pharmaceutical grade MDMA for our Phase 3 trials of MDMA-assisted psychotherapy for PTSD and other MDMA research worldwide. If you are interested in hosting a dinner, visit [psychedelicdinners.org](http://psychedelicdinners.org).



Shannon Clare Pettitt's guests enjoyed locally grown produce (right) at a beach bonfire dinner party (above); Kevin Garcia, Luna Suescún, Kevin Herbert, Magaly Mauer, Ph.D., and Jade Netanya Ullmann (l-to-r) at a dinner in Miami, Florida.



Rion Beauregard

# AfrikaBurn: An International Incubator for Psychedelic Harm Reduction

RION BEAUREGARD, ZENDO PROJECT SUPERVISOR

AFRIKABURN IS AN ANNUAL REGIONAL Burning Man event started in 2006 by a group of South Africans whose lives were forever changed at Burning Man. With the support of a few amazing individuals within the AfrikaBurn organization who recognize the need for a safe space for difficult psychedelic experiences, the Multidisciplinary Association for Psychedelic Studies (MAPS) has had the opportunity to send Zendo Project staff and volunteers to the event for the past four years to help create AfrikaBurn's Sanctuary space, facilitate harm reduction trainings, and work alongside rangers, medical, and security to create a safer environment for AfrikaBurn's approximately 10,000 attendees.

In 2013, AfrikaBurn's Sanctuary space was a humble three-person tent supported by the efforts of former MAPS Director of Harm Reduction Linnae Ponté. Year two saw the expansion and growth of the fledgling Sanctuary space alongside the Zendo Project. For the last two years that I've had the opportunity to volunteer at AfrikaBurn, the Zendo Project has provided one of the most integrated support systems of any of the festivals providing harm reduction services.

In my three years of working with the Zendo Project, I've seen a variety of psychedelic crisis scenarios, as well as cooperation and conflicts with the agencies responsible for keeping festival attendees safe. What our team has discovered through these different configurations is that success depends on building relationship. When we take the time to get to know the personality of a festival, and the individuals and teams that make them happen, we gain a better understanding of how to improve psychedelic harm reduction in the growing festival culture.

## MAKING RELATIONSHIP

In Lakota, there is a phrase, *aho! mitakuye oyasin*, which translates to "I honor all my relations." I believe this is a huge part of our work, not only as sitters for guests having challenging experiences, but also for those we work with on the medical, security, ranger, and production teams. We are making relationship with

all things, not just the easy or convenient things, but the things that we don't want to look at within ourselves, the parts of our culture that we'd rather bury away, and the shadows that can consume us if we don't shine light upon them. These are the same shadows that our guests in the Zendo often find themselves confronting.

As our volunteers know from their more intense shifts, we are learning how to make relationships with whatever arises. Sometimes this happens by sitting for someone who has taken an unfamiliar substance, holding space for someone's process that is scary or triggering, or witnessing the spectrum of human expression across many states of consciousness: rejoicing in "god-states" as well as enduring suffering.

Immersing ourselves in international festivals, we often get asked about our experience of the culture of that country.

When I answer honestly, I admit that most of what I experience is a homogenization of festival crowds: white, alternative, dressed in fur and feathers, covered in dust, and committed to a three- to seven-day bender of drugs, sleep deprivation, sexual pursuits, music, and play. Somehow in that mix, they expect transformation; often it comes, but not always as expected. Sometimes this transformation arrives in the form of a particularly overwhelming or difficult situation, and we end up in the care of our community.

AfrikaBurn's Sanctuary has grown from a small group of volunteers organized by the Zendo Project to a dedicated, locally organized team. It's a community that does an amazing job taking care of their own. Eventually, as the number of AfrikaBurn attendees who have been through Zendo Project trainings increases, and participants gain experience with peer-support trip-sitting through volunteering at Sanctuary, the festival community itself develops the capacity to provide psychedelic harm reduction services from within. As the Zendo Project gains experience and exposure, we hope that these ways of community care take on a life and momentum of their own so that everyone has a basic understanding of the Four Principles of Harm Reduction.



## CREATING A COHESIVE SAFETY TEAM

A key component of the Zendo Project’s philosophy of working with other agencies, including medical and law enforcement, is that we are on the same team: We are all here to keep people safe, and ensure the best outcome for our guests. Additionally, we want to positively impact the reputation of the festival, production team, and safety agencies. This year at AfrikaBurn, we had the pleasure of working, camping, and playing with other American imports—the Black Rock Rangers—a dedicated team of volunteers who provide mediation and safety (within reason), and serve as the eyes and ears of the community.

Working collaboratively in community delivers the connection needed to prevent burn-out. There is an intensity of presence, caretaking, and grounded sobriety that make the festival-going experience for the Zendo Project volunteer’s shift unique: Zendo Project volunteers pull all-nighters, fueled not by LSD or MDMA but by the intensity of the work. Working for days on end can grind away anyone’s positive attitude and energy, yet the family formed through working together constantly refuels our capacity for work and play.

Making relationships with ourselves and others is at the heart of what makes both this work and the psychedelic experience so alchemical: a journey into the unknown, witnessing familiar and unknown aspects of ourselves and the world at large, and ultimately—with care and intention—integrating the experience to improve our quality of life on this planet.

## ABOUT THE ZENDO PROJECT

The mission of the Zendo Project is to provide a supportive environment and education to help transform difficult psychedelic and psychological experiences into opportunities for learning and growth. We envision a world where communities provide safety and support for people having psychedelic and psychological challenges, and where harm reduction principles are used foremost to reduce the risks associated with substance use.

So far in 2016, the Zendo has been available to festival-goers at Envision Festival in Costa Rica, AfrikaBurn in South Africa, and Lightning in a Bottle in Bradley, Calif. Coming up, the Zendo Project will provide services at Burning Man 2016 in Black Rock City, Nev., (August 28–September 5), Symbiosis Gathering in Oakdale, Calif. (September 22–25), and Youtopia in San Diego, Calif. (October 13–16). 🌱

*Rion Beauregard received his Bachelor’s degree in Psychology from Claremont McKenna in 1998. He has been assisting with the Zendo Project since 2013 as a volunteer and supervisor. Rion worked as a wilderness mentor for at-risk youth and is the Founder and CEO of We Share Earth, a non-profit which aims to transform garbage into gardens and grief into growth. He brings his passion for Rites of Passage, ceremony, and grief work to his position with the Zendo, providing a grounded presence to individuals in extreme states.*

# \$15,000 Matching Grant!

## Donate to support the

# ZENDO PROJECT

## Psychedelic Harm Reduction

We’re asking for your help raising \$30,000 of the \$90,000 needed to expand the Zendo Project’s services at Burning Man 2016. More event producers are recognizing the need for psychedelic harm reduction services at their events and asking for our services—we need your help to get there.

[maps.org/zendo2016](http://maps.org/zendo2016)



**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**

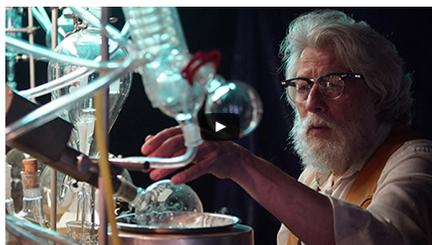
Be a calm meditative presence of acceptance, compassion, and caring. Promote feelings of trust and security. Let the person’s unfolding experience be the guide.



**Difficult is not bad**

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

# MAPS in the Media



## I am Rebel: The Love Drug

June 20, 2016. *National Geographic Channel* presents *I Am Rebel: The Love Drug*, a documentary exploring the history of MDMA in therapy, science, and culture. This

episode highlights the life and work of Alexander “Sasha” Shulgin, Ph.D., the pioneering chemist who recognized the therapeutic use of MDMA.



## Talks at Google by Rick Doblin, Ph.D.

March 7, 2016. *Talks at Google in New York City* hosts MAPS Founder Rick Doblin, Ph.D., for a presentation about psychedelic research and politics, the Zendo Project’s psychedelic harm reduction services at Burning Man and other events, and how MAPS is working to develop MDMA-assisted psychotherapy into an FDA-approved prescription treatment. “My career goal is to become a psychedelic therapist,” says Doblin, “We’re predicting that may be possible by 2021.”



## DEA Approves First Trial Of Medical Marijuana For PTSD by Christine Jun

May 16, 2016. *Popular Science* reports on the Drug Enforcement Administration (DEA)’s recent approval of MAPS’ clinical trial of medical marijuana for U.S. military veterans with chronic, treatment-resistant posttraumatic stress disorder (PTSD).



## Patients in Ecstasy Clinical Trial find Drug Beneficial by Don Lattin

March 19, 2016. Don Lattin of *The San Francisco Chronicle* interviews MDMA-assisted psychotherapy study participants Andy Gold and John Saul to discuss their experiences of overcoming anxiety associated with life-threatening illness after participating in a MAPS-sponsored clinical trial in Marin, Calif. The article outlines the history of MDMA being used as an adjunct to psychotherapy before and after its criminalization in 1985.



## MDMA as a Probe and Treatment for Social Behaviors

by Boris D. Heifets, M.D., Ph.D., Robert C. Malenka, M.D., Ph.D.

July 14, 2016. The peer-reviewed scientific journal *Cell* publishes a new review of current research into the use of MDMA as an adjunct to psychotherapy for a range of neuropsychiatric disorders. The article summarizes current knowledge about MDMA’s mechanism of action, highlighting its ability to catalyze prosocial, empathogenic effects which may help treat symptoms of medical conditions such as major depressive disorder, social anxiety in autistic adults, posttraumatic stress disorder (PTSD), and schizophrenia.

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.

Please contact MAPS at (831) 429-6362  
jade@maps.org



# FORTUNE

The DEA Just Approved a Way to Smoke Marijuana Legally for the First Time  
by Jen Wieczner  
April 22, 2016

# Rolling Stone

How LSD Microdosing Became the Hot New Business Trip  
by Andrew Leonard  
November 20, 2015

# U.S. News & World Report

Want to Legalize Medical MDMA? Attend a "Psychedelic Dinner"  
by Steven Nelson  
February 18, 2016

# 5 KPIX

Patients Legally Take Ecstasy While Receiving Therapy In Marin County  
by Emily Turner  
February 26, 2016

# Military Times

DEA Approves PTSD Marijuana Study  
by Patricia Kime  
April 21, 2016

# c&en

Psychedelic Compounds Like MDMA May be Good for More Than Just a High  
by Jyllian Kemsley  
March 28, 2016

# TECH TIMES

MDMA Used In Clinical Trial To Help People With Autism  
by J.E. Reich  
November 30, 2015

# The Washington Post

DEA Greenlights Marijuana Study to Measure Pot's Effect on PTSD  
by Andrew Blake  
April 22, 2016

# POPULAR SCIENCE

Mind-Altering Drugs Could Cure PTSD  
by Matt Giles  
December 22, 2015

# KQED

Making Psychedelics Mainstream: Interview with Rick Doblin  
by April Dembosky  
November 30, 2015

# 5280

Rolling in the Deep  
by Kelley McMillan  
January 4, 2016

# BUSINESS INSIDER

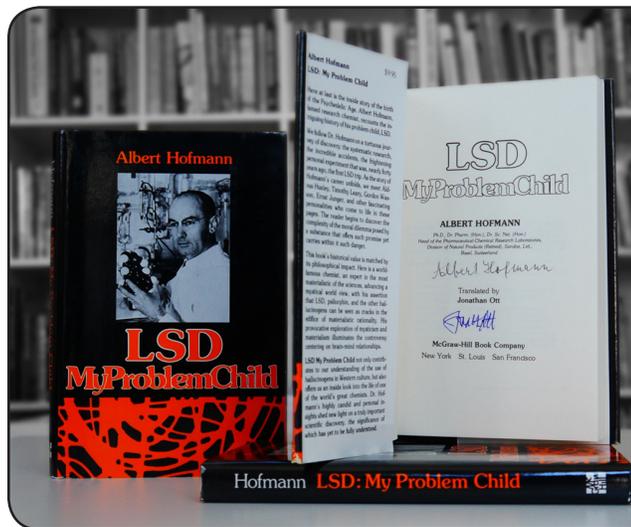
There's a Plan to Get the World's Biggest Club Drug Approved for Medical Use by 2021  
by Lydia Ramsey  
October 20, 2015

# SALON

Veterans Hope MDMA Can Cure Their PTSD  
by Christine Jun  
November 11, 2015

# BLAIRE

Psychedelic Therapy is Healing Mental Illness  
by Sarah Long  
November 6, 2015



## Rare signed Books

LSD My Problem Child by Albert Hofmann, Ph.D.  
Signed, Original, Hardcover

These rare collector's items are signed by author, chemist, and discoverer of LSD, Albert Hofmann, Ph.D., as well as translator Jonathan Ott. Proceeds support MAPS psychedelic research projects. **\$1,000**

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