It’s my pleasure to share with you now the most important research update that has ever taken place in the Multidisciplinary Association for Psychedelic Studies (MAPS)’ entire 31-year history. On Friday, July 28, 2017, FDA sent MAPS an Agreement Letter for our Phase 3 clinical trial protocol of MDMA-assisted psychotherapy for people suffering from chronic, severe to extreme posttraumatic stress disorder (PTSD). This Agreement Letter marks the successful conclusion of a six-month protocol review under the FDA’s Special Protocol Assessment (SPA) process, during which FDA scrutinized our protocol in detail, impressing our staff with the rigorous nature of their evaluation.

Now that MAPS has obtained an Agreement Letter, we can proceed with Phase 3 research knowing that the FDA agrees with our protocol design, research methodology, the number of subjects, our primary outcome measure (the Clinician Administered PTSD Scale, or CAPS-5), and our Statistical Analysis Plan. Receiving an Agreement Letter after a successful SPA review process means that if our protocol does generate statistically significant evidence of safety and efficacy, that “as set forth in the SPA provisions in the FD&C Act, FDA will not change its position regarding the critical design elements agreed to as part of an SPA agreement unless a substantial scientific issue essential to determining the safety or effectiveness of the product has been identified after the trial begins.”

We can now start our Phase 3 studies in confidence, knowing that the protocol design itself is acceptable to the FDA. This is especially important since we have not been able to come up with a protocol design that fully solves the double-blind problem since psychedelics are drugs with powerful and recognizable effects on consciousness, or at least some noticeable side effect.

I thought I had solved the now-classic problem of the placebo in psychedelic research in my dissertation, by proposing to use low doses of the drug being tested and compare them to full doses. The low doses, I reasoned, could cause sufficient blinding by generating some confusion among subjects and therapists about whether a low dose or a full dose had been administered, while not providing a
full therapeutic effect which would make it difficult to compare outcomes and show a difference between the two groups.

MAPS’ series of Phase 2 studies demonstrated that the lower doses did indeed result in a substantial increase in the percentage of incorrect guesses by subjects, therapists and CAPS raters, so the blinding was sufficient. However, to our surprise, we also found that low doses—while they were sufficient to produce a more effective blind—tended to make subjects anxious and uncomfortable, feeling emotionally activated but still not quite able to suppress their fear responses to their trauma. Lower doses of MDMA actually had the effect of reducing the benefits of therapy compared to an inactive placebo, thereby making it easier to show a statistically significant difference between our full dose and the control condition. Therefore, we proposed to the FDA that our Phase 3 design involve administering the same psychotherapy to both groups while administering full doses of MDMA to one group and inactive placebos to the control group. Now that FDA has provided MAPS with an Agreement Letter, we know that our final results will not be challenged on the basis of an unsuccessful double-blind.

As of this writing, we are waiting for the FDA’s response to our application for Breakthrough Therapy Designation for MDMA-assisted psychotherapy for PTSD. While it’s not as crucial as obtaining the Agreement Letter regarding our Phase 3 protocol design, obtaining Breakthrough Therapy Designation would be terrific, potentially speeding up the review process for our Phase 3 data.

Now that we’ve passed this crucial turning point, the path to Phase 3 lies open before us like never before. FDA approval for the prescription use of MDMA-assisted psychotherapy for PTSD now depends on fundraising commitments from our supporters, with $25 million needed and $12.5 million already raised or pledged. It also relies on the compassion and therapeutic skill of the 80 co-therapists, most of whom we have newly trained, who will work on our over one dozen Phase 3 sites in the US, Canada, and Israel. With the continued financial support of MAPS members, MDMA-assisted psychotherapy is on track for FDA approval by 2021!

Psychedelically yours,

Rick Doblin, Ph.D.
MAPS Founder and Executive Director
Treating PTSD with MDMA-Assisted Psychotherapy

Phase 3 Trials: FDA and MAPS Discuss Protocol for Phase 3 Trials of MDMA-Assisted Psychotherapy for PTSD

On June 13, 2017, as part of U.S. Food and Drug Administration’s (FDA) Special Protocol Assessment process, MAPS submitted a revised Phase 3 protocol evaluating MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD). The protocol was revised based on discussions between MAPS and FDA during our May 11 Type A meeting and on FDA’s official meeting minutes we received on May 30. Based on our discussions during the May 11 Type A meeting and subsequent submission on June 13, FDA sent us an Agreement Letter on July 28, 2017. We expect to initiate our first Phase 3 clinical trial in the coming months, which will last 2–3 years and enroll at least 230 participants.

On November 29, 2016, the FDA hosted staff and researchers from MAPS and the MAPS Public Benefit Corporation (MPBC) for a formal End of Phase 2 Meeting to discuss clinical trials of MDMA-assisted psychotherapy for PTSD. During the 90-minute meeting at the FDA’s White Oak Campus in Silver Spring, Maryland, the FDA stated they are now ready for MAPS to move forward with Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD.

On November 30, The New York Times published a feature article announcing the outcome of our End of Phase 2 meeting with the FDA. Trial participants Ed Thompson and CJ Hardin spoke with the NYT about how MDMA-assisted psychotherapy helped them overcome treatment-resistant PTSD. “It changed my life,” explains Ed. “It allowed me to see my trauma without fear or hesitation and finally process things and move forward.” CJ speaks about the results from his treatment, stating, “The MDMA sessions showed me a light I could move toward. Now I’m out of the darkness and the world is all around me.”

There are no roadblocks to moving forward with Phase 3 as the FDA gave favorable feedback to MAPS and MPBC responses to FDA questions. MAPS and MPBC staff are optimistic and excited to reach this milestone toward bringing healing to those diagnosed with PTSD through MDMA-assisted psychotherapy. Donations are currently being sought to reach MAPS’ goal of raising $25 million, with $12.5 million already raised, to successfully execute the Phase 3 studies required to gain approval from FDA for MDMA-assisted psychotherapy by 2021. There is now a clear path ahead to make MDMA a legal medicine for millions of people suffering from PTSD.

PTSD Study in Boulder Officially Completed

Study completed
Location: Boulder, Colorado
Principal Investigator: Marcela Ot’alora, M.A., L.P.C.
Estimated study budget: $895,000
This study has been fully funded.

On February 24, 2017, investigators gathered for the formal closeout of our Phase 2 study of MDMA-assisted psychotherapy in 23 subjects with chronic PTSD in Boulder, Colorado, led by Principal Investigator Marcela Ot’alora, M.A., L.P.C. The closeout was conducted by Senior Clinical Research Associate Charlotte Harrison, and included a thorough review of the study’s documentation, database, files, and adherence to regulations. All treatment sessions and long-term follow-up interviews for this study have now been completed. The final results are being prepared for publication, which is expected in 2017.

Twenty-three subjects will be included in our per protocol analysis, while all 28 subjects, including five who dropped out or were excluded for not meeting study criteria, will be included in our intent-to-treat analysis.
In addition to obtaining Phase 2 data on the safety and effectiveness of MDMA-assisted psychotherapy for PTSD, this study compared outcomes between different combinations of male/female co-therapist teams and dose response.

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.

**Israeli PTSD Study Officially Completed**

**Study completed**

**Location:** Beer Yaakov, Israel

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

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

This study has been fully funded.

On July 16, 2017, the 10th and final participant completed their 12-month follow-up interviews in our Israeli Phase 2 study of MDMA-assisted psychotherapy for PTSD. On February 2 and February 7, the eighth and ninth participants completed their 12-month follow-up interviews, and the seventh participant completed their 12-month follow-up interview on December 8, 2016. All treatment sessions and long-term follow-up interviews for this study have now been completed. Led by Principal Investigator Moshe Kotler, M.D., this Phase 2 study has treated 10 subjects with chronic, treatment-resistant PTSD from any cause. Data from this study will be included 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.

**Canadian PTSD Study Officially Completed**

**Study completed**

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

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

**Estimated study budget:** $425,000

Alfredly raised: $46,000 + $22,500 raised by partners

**Needed to complete this study:** $353,500

On November 27, 2016, investigators gathered for the formal closeout of our Phase 2 pilot study of MDMA-assisted psychotherapy for PTSD in Vancouver, Canada. Conducted by Clinical Data Scientist Alli Feduccia, Ph.D., the closeout included a thorough review of the study’s documentation, database, files, and adherence to regulations. All treatment sessions and long-term follow-up interviews for this study have now been completed. Led by Principal Investigator Ingrid Pacey, M.D., this small pilot study gave Canadian therapists experience delivering MDMA-assisted psychotherapy for PTSD, with data collected from six participants. The final results are being prepared for publication as a part of a global meta-analysis of MDMA-assisted psychotherapy results.

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.

**Therapist Training Study Enrolls 31st Participant**

**Ongoing study**

**Location:** Charleston, South Carolina, and Boulder, Colorado

**Principal Investigators:** Michael Mithoefer, M.D. (Charleston), and Marcela O’t’alora, M.A., L.P.C. (Boulder)

**Sub-Investigator:** Annie Mithoefer, B.S.N. (Charleston),

**Estimated study budget:** $687,000

**Already raised:** $160,000

**Needed to complete this study:** $527,000

On July 12, 2017, the 31st of 100 participants enrolled in our ongoing Phase 1 study of the psychological effects of MDMA when used in a therapeutic setting by healthy volunteers. Enrollment in this study is limited by invitation only to therapists in training to work on MAPS-sponsored clinical trials of MDMA-assisted psychotherapy for PTSD. The new participants were enrolled at the Boulder, Colorado, study site led by Principal Investigator Marcela O’t’alora, M.A., L.P.C. Michael Mithoefer, M.D., is serving as Principal Investigator at the site in Charleston, South Carolina with Sub-Investigator Annie Mithoefer, B.S.N.

**Conjoint Therapy for PTSD:**

**Four Pairs of Participants Receive Treatment, Follow-Up Interviews Begin**

**Ongoing study**

**Location:** Charleston, South Carolina

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

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

**Estimated study budget:** $325,000

**Already raised:** $165,000

**Needed to complete this study:** $160,000

On July 7, 2017, the fourth dyad received their first experimental treatment in our study of MDMA combined with Cognitive Behavioral Conjoint Therapy (CBCT) for PTSD at our Charleston, South Carolina site led by Principal Investigator, Michael Mithoefer, M.D., and Sub-Investigator, Candice Monson, Ph.D. The fourth dyad was enrolled on June 29. Three dyads have finished receiving experimental treatments, and will now move on to follow-up interviews. On March 11, the first pair...
Fear Extinction Learning with MDMA: FDA and DEA Clear Study to Proceed
Ongoing study
Location: Emory University in Atlanta, Georgia
Principal Investigator: Barbara Rothbaum, Ph.D.
Estimated study budget: $276,000
Funds already raised by Rothbaum/Emory.

On November 30, 2016, the FDA cleared the upcoming MAPS-sponsored Phase 1 study on the effect of MDMA on fear extinction learning in healthy volunteers. Principal Investigator Barbara Rothbaum, Ph.D., a leading PTSD researcher, will conduct the study at Emory University in Atlanta, Georgia. On January 3, 2017, the Institutional Review Board (IRB) at Emory University approved the first protocol amendment for the study. On June 5, the U.S. Drug Enforcement Administration (DEA) conducted a formal inspection of the study site at Emory University. The DEA has approved the study through the site initiation visit is taking place in August 2017. This study will be followed by another study exploring the combination of MDMA with Prolonged Exposure in PTSD patients.

MDMA Therapy Training Program: Group Trainings Take Place in New York and Colorado
Ongoing Training Program for FDA, EMA and Expanded Access
Location: Charleston, South Carolina and Boulder, Colorado
Therapy Training Team: Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., and Marcela Ot’alora G., M.A., L.P.C.
Estimated study budget: $905,000
Already raised: $399,000
Needed to complete this study: $506,000

From March 18–23, 2017, 42 trainees from 7 U.S. states, 3 Canadian provinces, Israel, and the Netherlands participated in MAPS’ MDMA Therapy Training Program (Part D) in Stony Point, New York. From April 1–7, another 42 Phase 3 therapists from the U.S., Canada, and Israel were trained at the YMCA of the Rockies, Estes Park, Colorado.

These were the first times MAPS offered a Part D training, which consists of five and a half days of experiential learning in non-directive therapy, working with a co-therapist, bodywork, art, and non-ordinary states of consciousness. One day at each training consisted of Holotropic Breathwork™. Trainees got to experience non-ordinary states induced by breathing, alternating with the experience of sitting for another person. As is the case with MAPS’ Therapist Training Study, it is important for therapists to understand non-ordinary states of consciousness before treating subjects with MDMA-assisted psychotherapy. Holotropic Breathwork™ provides an accessible avenue for more trainees to gain this kind of hands-on training. Experiential work continued with role plays of situations that take place during MDMA-assisted psychotherapy sessions.

Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., shared case studies highlighting the non-directive approach as well as some of the unique challenges Phase 3 therapy teams might face, such as transference/countertransference and working with transpersonal experiences. Marcela Ot’alora G., M.A., L.P.C., led a dialogue on team development. MAPS Public Benefit Corporation (MPBC) Executive Director Amy Emerson and MPBC Clinical Data Scientist Alli Feduccia, Ph.D., joined the training staff to provide important information about screening, study design, and protocol. MPBC Training Program Coordinator Shannon Clare Carlin oriented trainees on the therapeutic use of music in psychedelic psychotherapy. MAPS Founder Rick Doblin, Ph.D., joined each group for the first several days of the training. Prior to these Part D trainings, 44 trainees gathered in Stony Point, New York, to participate in Part B of the MDMA Therapy Training Program from January 15–21.

The program is a prerequisite for anyone working on a therapy team in a MAPS-sponsored Phase 3 trial. 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.

At this point, the training program is not accepting applications, however you can sign up to receive updates when future training opportunities become available. Learn more by visiting maps.org/therapists.
MDMA-Assisted Therapy for
Social Anxiety in Autistic Adults

Social Anxiety Study Officially Completed

Study completed
Location: Los Angeles, California
Principal Investigators: Charles Grob, M.D., and Alicia Danforth, Ph.D.
Estimated study budget: $358,000
Already raised: $13,000 raised + $15,000 raised by partners
Needed to complete this study: $330,000

On July 10, 2017, investigators gathered for the formal closeout of our study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum. On April 28, the 12th and final participant completed the final follow-up visit and unblinding in our ongoing study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum. All treatment sessions and long-term follow-up interviews for this study have now been completed. Led by Principal Investigators Charles Grob, M.D., and Alicia Danforth, Ph.D., this is a collaborative study between MAPS and the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, with plasma biomarker collaboration with researchers at Stanford University.

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

18th and Final Participant Completes Treatment in Marin Study

Ongoing study
Location: Marin, California
Principal Investigator: Phil Wolfson, M.D.
Co-Therapist: Julane Andries, L.M.F.T.
Estimated study budget: $700,000
Already raised: $253,000
Needed to complete this study: $447,000

On May 1, 2017, the 18th and final participant received their last experimental treatment in our ongoing Marin, Calif., study of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness. As of July 17, seven participants have completed their 12-month follow-up interviews. Led by Principal Investigator Phil Wolfson, M.D., with Co-Therapist Julane Andries, L.M.F.T., this study is gathering preliminary data about the safety and efficacy of MDMA-assisted psychotherapy for anxiety associated with a diagnosis of a life-threatening illness.

Goals for this study include (1) gathering data on the safety and effectiveness of MDMA-assisted psychotherapy for 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

20th Participant Enrolls in Smoked Marijuana
Trial for Chronic PTSD in Veterans

Ongoing study
Location: Phoenix, Arizona
Coordinating Principal Investigator: Marcel Bonn-Miller, Ph.D. (University of Pennsylvania)
Co-Investigators/Site Principal Investigator: Sue Sisley, M.D. (private practice)
Co-Investigator: Paula Riggis, M.D. (University of Colorado)
Estimated study budget: $2,156,000
Already raised: $2,156,000 grant awarded by the State of Colorado

As of July 10, 2017, a total of 20 of 76 participants have enrolled and received study drug in the first-ever clinical trial of smoked marijuana (cannabis) for PTSD in U.S. veterans, and participant screening is ongoing. Taking place at the Scottsdale Research Institute (SRI) in Phoenix, Arizona, this clinical trial will evaluate the safety and efficacy of four different potencies of marijuana for symptoms of PTSD.

On March 10, before enrolling a single subject, Johns Hopkins University elected to not participate as a clinical trial site for this study. JHU researchers wanted to focus just on the science but MAPS felt it necessary to focus both on the science and on the politics of the quality of NIDA’s marijuana and on ending NIDA’s monopoly on the supply of federally legal marijuana for FDA-regulated research. The funding agency, the Colorado Department of Public Health and Environment, signed a new contract with MAPS with SRI in Phoenix being the sole site where all subjects are now being recruited.

Application Submitted to DEA for License to Grow Medical Marijuana

MAPS is currently working with Professor Lyle Craker, Ph.D., of the University of Massachusetts-Amherst to end the
NIDA monopoly on marijuana for research by obtaining a license from the DEA to grow marijuana for research. MAPS and Prof. Craker have been working since 1999 to obtain this DEA license.

On August 11, 2016, the DEA announced their intention to grant licenses to additional marijuana growers for research. Craker reapplied for his license on February 14, 2017, and received a set of questions from the DEA on March 24. Craker responded to the DEA’s questions on April 12, and has not yet received a response.

It is now up to Attorney General Jeff Sessions and the Trump administration to end the obstructive NIDA monopoly, encourage independent marijuana research, and take action in granting Craker’s license.

Statement on the Adequacy of Marijuana Provided by NIDA for Phase 2 Clinical Trials for PTSD in Veterans

MAPS is testing the safety and efficacy of four different potencies of smoked NIDA cannabis to manage symptoms of chronic, treatment-resistant PTSD in 76 veterans in a placebo-controlled clinical trial. Prior to initiating enrollment in the study, laboratory testing of the NIDA cannabis was conducted over five months. To maintain transparency to the public and to ensure the reporting of accurate information, MAPS has released the results of the five rounds of secondary analytical testing of the chemical composition of NIDA cannabis (see below).

All six batches of cannabis tested negative for harmful microbes, mycotoxins, pesticides, arsenic, cadmium, and mercury. Two batches tested negative for lead. Four batches tested positive for low levels of lead. Based on exposure limits set by the World Health Organization (WHO) Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues, the International Programme on Chemical Safety, the American Herbal Pharmacopoeia’s Cannabis Inflorescence monograph, and the study protocol, the amount of possible lead exposure from NIDA cannabis was found to be well within the guidelines provided, and thus was considered safe for use in this clinical trial.

All test results were reviewed by an independent Institutional Review Board (IRB). Based on the NIDA-provided document Microbiology Safety Testing of Cannabis (Cannabis Safety Institute, May 2015) as well as test results that showed absence of harmful microbes and mycotoxins, and subsequent consultation with plant experts, MAPS concluded that the cannabis is safe for use in this clinical trial based on exposure limits and dispensation procedures specified by the amended study protocol. Only physically healthy participants who are not immunocompromised and without allergies or past adverse reactions to marijuana will be enrolled in this study. To our knowledge, there is no known case of NIDA cannabis contamination which interfered with a clinical trial or was the cause of an adverse event in a patient enrolled in the study.

Of the six batches tested, only one batch differed significantly from the potency information provided by NIDA in the certificate of analysis. It is believed the discrepancy in test results is due to homogenization issues as well as the analytical sampling technique used with the fine particulate nature of the specific batch. For this reason, treatment outcomes from a range of potencies will be reported from relevant cannabis treatment groups at the end of the trial.

Release specifications for NIDA cannabis, such as pass/fail or upper limits guidance for impurities, have not been set. NIDA is currently working with the FDA to identify appropriate tests and limits for marijuana used in Investigational New Drug (IND) studies. Despite the absence of federal guidance on quality, NIDA states that their cannabis is within the acceptable range of quality according to several common sets of guidelines for microbial contamination of dietary supplements. Two independent Schedule I-licensed and ISO17025 accredited analytical laboratories tested samples of cannabis provided by NIDA.

MAPS had initially planned to store the packaged cannabis at refrigerated temperatures prior to dispensing to participants. However, refrigerated storage was reported to exacerbate mold growth. Total Yeast and Mold (TYM) testing was conducted to determine appropriate storage conditions and dispensation procedures for study cannabis. Though many legal medical marijuana states have set varying acceptable levels of TYM, there is no agreement on whether TYM should be a required test. After review of testing, dispensation procedures were revised to limit likelihood of yeast and mold growth.

This 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 research.

Ayahuasca Research

Data Collection Survey Underway

Ongoing study

Principal Investigator: Jessica Nielson, Ph.D.

As of May 31, 2017, we have received a total of 351 completed responses for our anonymous questionnaire about the potential risks and benefits associated with using ayahuasca as a therapy for PTSD. A total of 171 participants (49%) reported a past or current diagnosis of PTSD, and 162 (46%) reported no history of a PTSD diagnosis.

The results of the survey are currently being summarized and prepared for publication, at which point the survey will shift its focus to general ayahuasca use for a variety of conditions, including PTSD, depression and substance abuse/addiction. The data collection is being sponsored by MAPS, with Jessica Nielson, Ph.D., as the Principal Investigator for this study.

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

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Ibogaine Treatment for Drug Addiction

Observational Research Published in American Journal of Drug and Alcohol Abuse

Study completed

Locations: Mexico and New Zealand

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

The promising results of two observational studies into treating opioid dependence with ibogaine, a naturally occurring psychedelic compound, have been published in the peer-reviewed American Journal of Drug and Alcohol Abuse. Sponsored by MAPS in Mexico and New Zealand, both studies show that ibogaine should be further studied as a potential treatment for opioid dependence through rigorously controlled studies.

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

The results are particularly notable given the growing opioid epidemic, which the U.S. Centers for Disease Control and Prevention estimate caused 91 deaths per day in the United States in 2016, and which has been recognized as a health policy priority by the White House’s Commission on Combating Drug Addiction and the Opioid Crisis.

The Mexico study, published on May 25, showed that ibogaine administration was associated with substantive effects on opioid withdrawal symptoms and drug use in subjects for whom other treatments had been unsuccessful. Using the Addiction Severity Index and Subjective Opioid Withdrawal Scale as primary outcome measures, the study enrolled 30 participants who received ibogaine treatment at an independent clinic in Mexico. 12 out of 30 participants reported 75% reductions in their drug use 30 days following treatment, and 33% reported no opioid use three months later. The paper is co-authored by Thomas Kingsley Brown, Ph.D. (University of California, San Diego) and Kenneth Alper, Ph.D. (New York University School of Medicine).

As one participant in the Mexico study reported: “Iboga could give an opiate addict several months to half a year of freedom from craving, and a period of time in which to get their life together and learn to face things straightforwardly, directly and honestly. Iboga will not do the work for you.”

The New Zealand study, published on April 12, showed that a single ibogaine treatment could reduce opioid withdrawal symptoms and achieve either cessation from opioids or sustained, reduced use for up to 12 months following treatment. The results indicate that ibogaine may have a significant pharmacological effect on opiate withdrawal. All participants in the study described their ibogaine experience in positive terms. The analysis includes data from 14 out of 15 participants enrolled, with one participant disqualified and one who died during treatment while under the supervision of a qualified medical practitioner. The paper is co-authored by Geoffrey E. Noller, Ph.D., (Dunedin School of Medicine); Chris M. Frampton, Ph.D. (University of Otago); and Berra Yazar-Klosinski, Ph.D. (MAPS).

Historically, a number of other ibogaine treatment deaths have occurred outside of medically supervised environments. Although there was no evidence that the deceased participant had a preexisting cardiac condition, the coroner’s report suggested that the death was likely related to ibogaine ingestion, though not necessarily to cardiotoxicity. Though an experienced physician, the practitioner “nonetheless was adjudged to have failed in their duty of care” through a failure to appropriately monitor the patient, according to a second investigation into the death. The authors acknowledge the potential shortcoming of ibogaine treatment highlighted by the mortality associated with the therapy, especially in non-medical settings, specifically concerns about potential cardiovascular complications related to ibogaine’s metabolism in the body.

Although the Mexico study had no adverse events, the authors acknowledge specific limitations to this study including the number of participants, the lack of a control group, and the reliance on self-reporting. The authors of both studies emphasize the need for further studies, stating that randomized controlled clinical studies are required to further explore ibogaine’s potential as a legal, regulated treatment option in the U.S.

Ultimately, the authors of the studies conclude that given the potential demonstrated by ibogaine’s substantive treatment effect in opioid detoxification, its novel (though not yet fully understood) pharmacological mechanism of action, and its clinical effect in opioid-dependent subjects who have not satisfactorily responded to other treatments, ibogaine has promise for future research and development as a novel pharmacotherapy for opioid addiction. Download both articles for free at maps.org/ibogaine.
Sitting, Not Guiding: The Power of Non-Directive Support
ERICA ZELFAND, ND AND TIMOTHY CRESPI, LPC, CADC

An hour after eating psilocybin mushrooms at a festival, Olivia notices her left hand is shaking. She can stop it with effort, but prefers to just let it do its thing. She isn’t angry, yet it feels strangely good to shout fragmented thoughts and hum Dave Brubeck’s “Take Five.” The hand-shaking has progressed; now she’s flapping her whole left arm like a hemiplegic bird trying to take flight. The people around her have noticed and are keeping a distance.

This situation could end in a number of different ways. Some options include:

(A) A medical team appears, ties Olivia to a stretcher as she screams at them to let her go, and administers a benzodiazepine to sedate her.

(B) A police officer asks Olivia to settle down. She becomes terrified, panics, and hits him with her flapping arm. He wrestles her to the ground and places her in handcuffs.

(C) A well-intentioned yoga teacher appears and tells Olivia she’s having a Kundalini awakening. He instructs her to chant Sat Nam, squeeze her pelvic floor muscles, and visualize a serpent swirling around her spine.

(D) An experienced Zendo Project volunteer introduces herself and offers Olivia a safe space to have her experience away from the watchful eyes of other attendees. She sits with Olivia in a tent adjacent to medical as Olivia marches, tics, and repeats nonsensical phrases.

Which scenario is most healing for Olivia?

In the first scenario, Olivia wakes the next morning feeling both ashamed and violated. In the second, she gets a criminal record. In the third, Olivia takes on somebody else’s agenda, which may or may not be healing for her. In all three of these scenarios, she is restrained or restricted in one form or another.

In Scenario D, however, Olivia comes back the next day to the Zendo Project tent to thank the volunteer. She explains that she was often physically restrained as a child and was
taught that come what may, she had to hold in her emotions and keep a cool exterior. Being able to shake, move, and blurt out random things with no filter last night was the most healing experience of her life. Today she feels tired but light in a way she’s never felt before.

As Zendo Project volunteers, we work at festivals like Lightning in a Bottle, Burning Man, Envision Festival, and the Electric Daisy Carnival to provide a supportive environment for those going through difficult emotional or psychological experiences related to psychedelic use, but who are not in need of medical care. Our mission is to transform difficult psychedelic experiences into opportunities for learning, healing, and growth.

Sponsored by MAPS, The Zendo Project works collaboratively with medical, security, law enforcement, and other emergency service personnel to determine the best course of action for an attendee in distress. If an attendee shows signs and symptoms of potential medical distress, they are evaluated by medical. If an attendee becomes violent, security may be involved. At the events that Zendo attends, other emergency service departments are most often familiar with the harm reduction approach and everyone works together to support the emotional, psychological, and physical safety of the individual. This work in turn helps reduce drug-related arrests, sedation, and restraint. We’re here, in other words, to make sure stories like Olivia’s end up in Scenario D.

It’s easy for most people to understand the shortcomings of Scenarios A and B. Yet despite our chuckles over the yogi in Scenario C, many of us inadvertently mimic him (in subtler forms) when we interact with people on psychedelics.

The Zendo Project principle of “Sitting, Not Guiding” is therefore an important touchstone for our work, reminding us to get out of the way and let a person’s healing process unfold without our embellishments. Doing this entails not only checking our egos, but also taking a heroic leap of faith, trusting both in the healing power of psychedelics and in the human organism’s inherent propensity toward balance. Seldom do we understand a guest’s core wound or the meaning of their trip, but by providing them with a safe environment and a supportive presence we may nevertheless help them find wisdom, healing, and transformation. Our most therapeutic intervention—both as Zendo Project sitters and as healers—is quite often no intervention at all.

This sounds simple, but it’s surprisingly hard work. It can be challenging to watch our own reactions to a guest, perhaps even feel personally triggered by a guest’s process, and continue to hold space without acting on our impulses. Especially for those of us who are therapists, or generally identify as “doers” in the world, it can be quite the task to bear witness without leading, forcing, or guiding.

The importance of non-directive support is modeled in recent studies on psychedelic-assisted psychotherapy. In few, if any, of the clinical trials on MDMA, psilocybin, ayahuasca, or other entheogens do the therapists lead or choose the content of a client’s process. This ensures reproducibility of the study methods and standardization of the findings. More importantly, however, a non-directive approach allows the client to reconcile unconscious material in the order and nature in which it bubbles to the surface for healing.

Psychedelics can unveil unconscious material while heightening one’s sensitivity. This can place users in a highly suggestible state, making it very easy for us, despite our best intentions, to muddy the waters. Stroking somebody’s back, for instance, may appear to be a soothing intervention, but it may actually be annoying, distracting, or even triggering. Likewise, instructing a user to take deep breaths and relax their jaw might interrupt a process in which they build up pressure to the point of pain, allowing them to discover and reconcile a muscular holding pattern organically, without assistance. Direct interventions can be a powerful adjuvant to healing, but they can also be a hindrance. During a difficult emotional or psychological experience, skilled healers can often discern when it’s best to intervene and
when it’s best to be non-directive. When in doubt, however, it’s often more effective to be hands off.

This concept of non-directive therapy is not a new one: the American psychologist Carl Rogers outlined the approach in his 1951 publication *Client-Centered Therapy*. At a time when therapists were endowed with the task of “fixing” their “broken” patients, Rogers boldly argued that clients have their own innate capacities for healing. Realizing that this was also true in situations other than the traditional psychotherapeutic setting, Rogers later used the term “Person-Centered Approach” to describe his philosophy.

We also see this principle in naturopathic medicine. Beyond “First, Do No Harm,” naturopathic doctors (NDs) are further guided by the philosophy of the *Vis Medicatrix Naturae*, or the “Healing Power of Nature.” This speaks not only to the medicinal power vested in natural substances like psilocybin and DMT, but also to the propensity toward equilibrium and health inherent in every living organism. As creations of Nature, our bodies, minds, and spirits have incredible healing capacity.

Whether we’re sitting with Zendo Project guests at Burning Man or with study participants in psychedelic-assisted psychotherapy sessions, it’s important to trust in both the healing power harnessed in these medicines and in the healing capacity vested in the human organism. Our role, then, is to create the optimal environment for fostering that healing to its fullest potential.

We can still, thankfully, support our guests without guiding or leading them. We can communicate through open questions, like “How are you feeling?” as opposed to closed ones like, “Are you hungry?” We can likewise let them know what’s available to them (a blanket, a glass of water, a snack, etc.) and let them decide for themselves what they need. We can sit or walk alongside them in silence. As they talk to us, we don’t have to interpret what they’re saying or lead them to any epiphanies. We can simply listen with contact and empathy, occasionally reflecting back to them what we’ve heard. We don’t need to solve any existential crises, nor do we need to nudge, redirect, or rush the healing process. On the contrary: Simply by holding space, we invite the magic to unfold on its own.

Erica Zelfand, ND, is a family physician specializing in integrative and functional medicine. She sees patients of all ages in her private practice at Somatic Center Portland and is deeply committed to a patient-centered, root-cause-oriented, nature-honoring approach to healing. She is adjunct faculty at the National University of Natural Medicine, as well as an engaging public speaker, a writer, and a mentor to both medical students and functional medicine physicians. She loves lecturing on the clinical applications of psychedelic medicine and volunteering both as a sitter and medical lead with the Zendo Project. To learn more, visit EricaZelfand.com.

Timothy Crespi, MA, LPC, CADC, is a somatic-oriented counseling psychologist. After earning a Master’s in Transpersonal Counseling Psychology from Naropa University, Timothy completed additional trainings in Gestalt Therapy, couples therapy, Applied Existential Psychotherapy, Contemporary Reichian Psychotherapy, and Alcohol and Drug Counseling (CADC). In addition to his work as a Zendo Project supervisor, Timothy is also a source of support for volunteers and staff at festivals. He is the founder of Somatic Center Portland, an integrative healing center located in southeast Portland, Oregon. To learn more, visit SomaticCenterPortland.com.
At Psychedelic Science 2017, the international scientific community came together from April 19–24 in Oakland, California, to explore new research into the benefits and risks of MDMA, LSD, psilocybin, ayahuasca, ketamine, ibogaine, medical marijuana, and more. The historic six-day global gathering featured three days of conference presentations, three days of workshops, a Sunset Cruise on the San Francisco Bay, the Psychedelic Comedy Banquet, and much more.

“America’s premiere psychedelics conference.” — The New York Times

“The psychedelics state of the union.” — New York Magazine

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Psychedelic Science 2017 was the largest psychedelic conference in history, with over 3,000 attendees from 40+ countries.

227+ Conference Presentations
12 Full-day Workshops

150 Volunteers
4,000+ Volunteer hours

15+ entertainment acts
1,500+ books sold

14 Community and Partner Forums
45+ Poster Presentations
15 Film Screenings

60+ Marketplace Exhibitors

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MAPS in the Media

The New York Times
Molly at the Marriott: Inside America’s Premier Psychedelics Conference
by Casey Schwartz
May 6, 2017 - The New York Times reviews Psychedelic Science 2017, a six-day international gathering hosted by MAPS and The Beckley Foundation. The New York Times speaks with MAPS Founder Rick Doblin, Ph.D., and MAPS Policy and Advocacy Manager Natalie Lyla Ginsberg to discuss the success and cultural impact of the conference. “We are not the counterculture,” explains Doblin, “we are the culture.”

EAST BAY EXPRESS
World’s Largest Psychedelic Drug Conference “Psychedelic Science 2017”
by Blake Gillespie
April 19, 2017 - East Bay Express reports that in 2017, psychedelics are undergoing concurrent waves of cultural renaissances. One only has to look at the potpourri of workshops by researchers and specialists worldwide that will descend on the Psychedelic Science 2017 conference: MDMA-assisted psychotherapy is the front-runner in medicalization, the family tree includes issues such as ayahuasca retreats, ketamine-assisted psychotherapy, psychedelic harm reduction at festivals, holotropic breathing, and LSD microdosing.

CBS SF Bay Area
Psychedelic Drug Banned In The U.S. May Help Battle Addiction
by Susie Steimle
May 15, 2017 - CBS San Francisco Bay Area explores new research into the therapeutic benefits of psychedelics like ibogaine and MDMA for treating addiction and PTSD. Susie Steimle of CBS speaks with MAPS Founder Rick Doblin, Ph.D., and psychedelic researchers and study participants about ongoing research with ibogaine and MDMA combined with therapy as a potential treatment for a variety of mental health issues. “It just gives you a view into yourself that I had just never had before,” explains Andy Gold, MDMA-assisted psychotherapy study participant from a MAPS-sponsored clinical trial.

PLAYBOY
MDMA’s Long, Strange Trip from Club Drug to Military Medicine
by Seven McDonald
May 17, 2017 - Playboy features MDMA research conducted by MAPS. Underground MDMA-assisted psychotherapy patient Seven McDonald of Playboy speaks to MAPS Founder Rick Doblin, Ph.D., MAPS-sponsored researchers Michael Mithoefer, M.D., and Annie Mithofer, B.S.N., and study participant CJ Hardin about current clinical trials of MDMA-assisted psychotherapy for PTSD. “People ask all the time if this is a cure,” explains Michael Mithoefer. “I think a better term is maybe durable remission, because we don’t know. People can make so much progress and be free of symptoms that were debilitating before, yet if they get a strong enough trigger, it can happen that the symptoms come back.”

YouGov
Majority of Americans Ready to Embrace Psychedelic Therapy
by Gregory McCarriston
June 23, 2017
YouGov explores the therapeutic potential of psychedelics as treatments for depression, anxiety, and PTSD, providing new data providing new data collected by YouGov that, “shows that many Americans are ready to embrace psychedelic therapies.” Gregory McCarriston of YouGov explains that, “While more than half of all Americans may support research into psychedelics for therapeutic use, a 63% majority also said they would personally be open to medical treatment with psilocybin, ketamine, or MDMA if faced with a pertinent medical condition—assuming the substance is proven safe.”

Example questions from this nationally representative survey of 1,100+ U.S. adults (demographic breakdowns available at today.yougov.com)
Q: In general, do you support or oppose researchers being allowed to study illegal psychedelic substances (e.g., mushrooms, MDMA, ketamine, etc.) in medical trials to investigate their potential medicinal benefits, despite their illegal status?
53% Support
21% Oppose
27% Don’t know

Q: Please imagine that MDMA was approved as a prescription drug...If available to you, would you or would you not try this treatment if you were faced with a similar medical condition?
56% Would
21% Would not
22% Don’t know
Psychedelics: Medicine or Madness?
by Moshe Kasher

Could A Club Drug Be The Secret To Curing PTSD?
by Louisa Kamps
March 1, 2017 - Elle Magazine speaks to MDMA-assisted psychotherapy study participant Julie Nelson about her experience overcoming PTSD through a MAPS-sponsored clinical trial. Louisa Kamps of Elle also interviews MAPS-sponsored MDMA researchers Marcela Ot’alora, M.A., L.P.C., and Annie Mithoefer, B.S.N., about their personal experiences providing psychedelic therapy to help participants process trauma. “Researchers working on the new MDMA trials think that the drug provides relief by helping people deal directly with the emotional fallout of their trauma,” says Kamps. “We think MDMA removes obstacles and catalyzes recovery by helping people start to access their own healing capacity,” explains Mithoefer. “Rather than trying to avoid triggers, they’re “able look at them in a different light, communicate about them, and begin to let them go.”

MDMA and LSD May Soon Be Used to Treat Mental Disturbances
by Marcelo Leite
June 17, 2017 - Brazil’s largest newspaper, Folha de S. Paulo, covers MAPS’ MDMA-assisted psychotherapy for PTSD studies, highlighting research results presented at the recent Psychedelic Science 2017 conference. “After six days of presented works, the moment had come to commemorate the end of the 2017 Psychedelic Science Conference, which had united more than 3,000 people from 40 countries in Oakland, California, at the end of April. The mood was one of euphoria over the possibility of rehabilitating various drugs of dubious reputation,” says Marcelo Leite of Folha de S. Paulo.

Can Psychedelics Be Therapy? Allow Research to Find Out
by Aaron E. Carroll
July 17, 2017 - The New York Times explores psychedelic therapy as a potential treatment for PTSD, depression, addiction, and anxiety associated with life-threatening illness. Aaron Carroll of The New York Times reports on LSD, psilocybin, and MDMA research, highlighting MAPS’ clinical trials of MDMA-assisted psychotherapy for PTSD and LSD-assisted psychotherapy for anxiety associated with life-threatening illness. “With the potential to help curb more serious addictions and ease the symptoms of mental illnesses, it seems odd to continue to make it nearly impossible to research the therapeutic potential of psychedelics,” explains Carroll.
GIVE THE GIFT OF HEALING TRAUMA.

“[MDMA] made me feel like I deserve to be here, I deserve to be happy.”

—Hania, MAPS study participant

Hania was born in Beirut, Lebanon and lived in a war zone for the first 19 years of her life. MDMA-assisted psychotherapy helped her heal her trauma.

Join us today to make psychedelic medicine a reality for millions of people suffering from posttraumatic stress disorder (PTSD).

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