MAPS News

Celebrating 35 Years of MAPS and Introducing Our New Logo

This year marks the 35th anniversary of the Multidisciplinary Association for Psychedelic Studies (MAPS)! On April 8, 1986, MAPS was founded as a non-profit organization by Rick Doblin, Ph.D., to develop medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. While we celebrate our accomplishments, we are also taking this time to set intentions and goals for the decades to come.

Since 1986, MAPS has shown a commitment to change and innovation for the benefit of mass mental health. As we look towards the future, we hope to continue to transform minds and build a global community which collectively values healing for all.

In that spirit, we are excited to introduce our new, reimagined MAPS logo:

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

We could not have achieved 35 years of groundbreaking work without supporters like you. We invite you to join our growing number of monthly donors, who are an instrumental part of our work and allow us to execute our vision to make psychedelic treatments safe, legal, and accessible.

We hope you'll join us in continuing this journey, both inwardly and outwardly, into the next 35 years of the psychedelic renaissance and mainstream integration.

Research

MAPS' Phase 3 Trial of MDMA-Assisted Therapy for PTSD Achieves Successful Results for Patients with Severe, Chronic PTSD

- *The highly statistically significant results and excellent safety record suggest MDMA-assisted therapy will be an effective treatment for severe, chronic PTSD*
- *67% of participants who received three MDMA-assisted therapy sessions no longer qualified for a PTSD diagnosis and 88% experienced a clinically meaningful reduction in symptoms*
- *The pivotal Phase 3 trial treated 90 patients with severe, chronic PTSD from any cause with an average duration of 14 years and replicated the results of Phase 2 trials*
- *Study participants included patients with PTSD caused by combat-related events; accidents; abuse; and sexual harm; 84% have a history of developmental trauma*
- *MAPS is hopeful that these results will facilitate FDA approval in 2023 for this Breakthrough-designated therapy*

The first Phase 3 trial of MDMA-assisted therapy for post-traumatic stress disorder (PTSD) replicated and expanded on Phase 2 results indicating MDMA-assisted therapy may be an effective and cost-saving treatment for PTSD resulting from any cause. Nature Medicine is expected to publish the peer-reviewed paper detailing the results of the study sponsored by the Multidisciplinary Association of Psychedelic Studies (MAPS) and conducted by MAPS Public Benefit Corporation (MAPS PBC), a wholly-owned subsidiary of MAPS. In this first Phase 3 trial of any psychedelic-assisted therapy, participants who received MDMA-assisted therapy reported a significant reduction in PTSD symptoms compared to those who received placebo with therapy ($p<0.0001$), successfully achieving the prespecified primary endpoint for the trial. In fact, 67% of the group who received MDMA, compared to 32% of the group who received placebo, no longer qualified for a PTSD diagnosis after three treatment sessions. In addition, participants treated with MDMA-assisted therapy had statistically significant reductions for the key secondary endpoint of functional impairment relative to placebo with therapy ($p=0.0116$).

Jennifer Mitchell, Ph.D., photo © New York Times

Jennifer Mitchell, Ph.D., lead author of the paper, calls attention to the results for those with the dissociative subtype of PTSD, with depression, or who reported a history of alcohol or substance use. "People with the most difficult-to-treat diagnoses, often considered intractable, respond just as well to this novel treatment as other study participants. In fact, participants diagnosed with the dissociative subtype of PTSD experienced a greater reduction in symptoms than those without the dissociative subtype."

Mitchell added that MDMA serves as a catalyst to therapy: "MDMA is an experiential therapeutic and therefore necessitates the appropriate set and setting to truly guide change and recovery. While many forms of PTSD therapy involve recalling previous trauma, the unique ability of MDMA to raise compassion and understanding while tamping down fear is likely what enables it to be so effective."

The randomized, blinded, Phase 3 trial, designed under a Special Protocol Assessment with the FDA, treated 90 patients with severe, chronic PTSD. Participants were randomized to receive three sessions of either MDMA or placebo with identical talk therapy. Forty-six participants received MDMA therapy and forty-four participants received therapy with placebo. The primary efficacy endpoint was based on the change from baseline in an independently assessed clinical interview of PTSD severity after 18 weeks. The assessors also measured average change in functional impairment in work/school, social, and family life. Among the participants in the MDMA-assisted therapy group, 67% no longer qualified for PTSD diagnosis after three MDMA-assisted therapy sessions and 88% of participants experienced a clinically significant reduction in symptoms, while in the placebo group, 32% no longer qualified for PTSD diagnosis at the two-month follow-up and 60% experienced a clinically significant reduction in symptoms.

In the Phase 3 trial, the investigators observed no serious safety or tolerability issues in the MDMA group. MDMA did not increase the risk of suicidal thoughts or behaviors and did not increase cardiovascular risk or abuse potential relative to therapy with placebo. As expected from previous clinical trials, temporary increases in blood pressure and pulse were observed

during MDMA sessions; adverse events such as muscle tightness, decreased appetite, nausea, sweating, and feeling cold were transient.

PTSD is a profoundly challenging condition with unmet medical need. Bessel van der Kolk, M.D., a leading PTSD researcher and author of the foundational book on PTSD, The Body Keeps the Score, served as Principal Investigator for the Boston study site. He explains, "The experience of having been traumatized profoundly alters perceptions; self-experience; and capacity to plan, imagine and anticipate. For 88% of people who receive this treatment, we can expect to see a treatment response. This can lead to fundamental shifts in our subjects' perspective on self-capacity, affect regulation, and attitude towards those around them. It takes a great deal of courage to address one's PTSD, particularly when other treatments have failed. These results open the door to a potentially powerful new pathway to healing—once MDMA-assisted therapy has been approved as a treatment for PTSD."

Bessel van der Kolk, M.D.

Listed as a Schedule I drug, MDMA presently is defined as having "no medical benefit" and, therefore, is not currently accessible as a potential treatment for PTSD or other conditions except as administered in clinical trials. "As a result of this study and through the persistent and consistent application of scientific rigor, we have demonstrated that MDMA-assisted therapy is likely to provide relief for people diagnosed with PTSD," noted MAPS Executive Director Rick Doblin, Ph.D. "Far from having no medical benefit, MDMA, when combined with talk therapy in this protocol, has the potential to catalyze the therapeutic process and generate positive mental health outcomes."

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Michael Mithoefer, M.D., who serves as Senior Medical Director for Medical Affairs, Training, and Supervision, led the team that developed the therapy manual and trained the 70 therapists who provided the treatment in the Phase 3 study. He celebrated their efforts, stating, "The therapists and expert research team who have brought us here are at the vanguard of what may be a revolution in mental health care. The success of this pivotal study is a major step toward regulatory approval, and we hope these results will attract many more researchers and clinicians to join the effort to further explore and deliver MDMA-assisted therapy so we can together address our national—and global —mental health crisis."

Michael Mithoefer, M.D.

MAPS PBC develops and delivers therapy training programs and is responsible for the development of MDMA as a medicine. MAPS PBC CEO Amy Emerson describes its mandate: "MAPS Public Benefit Corporation is establishing a new paradigm in drug research, development, and commercialization in which we center our efforts wholly on the beneficiaries of our healing modality rather than shareholders. This approach commits us to open science and open books as we research best practices for psychedelic-assisted therapy. Ultimately, any proceeds from our work will be reinvested to generate more research, more training, and more affordable options for treatment."

Amy Emerson, CEO of MAPS PBC

A second Phase 3 clinical trial is currently enrolling participants. Prior to the hopeful approval in 2023 of MDMA-assisted therapy for PTSD, the FDA has granted permission for an expanded access program in which 50 patients can receive the treatment prior to FDA approval. MAPS plans to conduct additional studies to explore the potential of the treatment for other mental health conditions and with other treatment protocols such as group therapy and cognitive-behavioral conjoint therapy for couples. Additionally, MAPS is funding a formal commitment to health equity: a holistic plan to create more pathways to access MDMA-assisted therapy for those historically marginalized by the mental health field and society at large.

MAPS Wins Appeal and Authorization to Study MDMA in Healthy Volunteer Therapists

- *Phase 1 clinical trials of MDMA-assisted therapy for health-care providers will measure development of self-compassion, professional quality of life, and professional burnout among clinicians delivering the treatment to patients*
- *The study, one of few legal means by which therapists can experience the treatment they provide in MDMA-assisted therapy for PTSD, was placed on clinical hold by the FDA for 20 months.*
- *FDA's Office of Neuroscience granted the appeal on the grounds of scientific merit, the absence of unreasonable risk to participants, and appropriate investigator qualifications*

Berra Yazar-Klosinski, Ph.D., Chief Scientific Officer of MAPS PBC

Shannon Carlin, M.A., L.M.F.T. Director and Head of Training and Supervision of MAPS PBC

The U.S. Food and Drug Administration (FDA) Office of Neuroscience granted the Multidisciplinary Association of Psychedelic Studies (MAPS)' appeal of the clinical hold on the Phase 1 study after almost two years of clinical hold. Initially placed on clinical hold by the FDA in 2019, the MT2 study protocol is a Phase 1, open-label, multi-site research study to assess the safety and psychological effects of MDMA-assisted therapy in healthy volunteer therapists undergoing training to treat patients suffering from posttraumatic stress disorder (PTSD) with MDMA-assisted therapy, developed by MAPS Public Benefit Corporation (MAPS PBC), a wholly-owned subsidiary of MAPS. Personal experience is widely considered to be an important element in preparation and training to deliver psychedelic-assisted therapies.

The hold, lifted on May 11, 2021, was placed by the FDA due to concerns about the scientific merit of the study, risk-to-benefit ratio for healthy therapist participants, and the credentials of clinical investigators. If MAPS' appeal was not granted, the hold would have required that the Lead Facilitator in each two-person facilitator team hold an M.D., Ph.D., or equivalent degree and that the physician be on-site instead of on-call during the treatment sessions.

The evidence-based decision from the FDA Office of Neuroscience granting MAPS' appeal notes that this study does not differ in risk or investigator qualifications from MT1, a prior, similarly designed Phase 1 study approved in 2009, and therefore the rationale for a clinical hold is not supported.

Though drug development is often thought of as a linear progression, Phase 1 and Phase 2 investigations can provide valuable data while Phase 3 trials are ongoing. "Even though we are in the midst of Phase 3 studies to treat PTSD, Phase 1 studies are an important area of scientific research and inquiry to generate exploratory and safety data to support new indications. We appreciate the Office of Neuroscience seeing the scientific merit of these data," says Berra Yazar-Klosinski, Ph.D., Chief Scientific Officer for MAPS PBC. Other indications such as eating disorders and social anxiety are already in Phase 2 studies, and a number of reports suggest the potential for additional future indications.

While the MT1 and MT2 studies do not provide pivotal safety or efficacy data to support the PTSD treatment indication, they serve to increase understanding of MDMA's clinical effects in a therapeutic setting as well as enhance therapist training, and may therefore prove beneficial in the treatment of patients. As is typical for therapeutic treatments, these studies serve as a vital part of the MDMA Therapy Training Program by providing therapists with personal knowledge of the treatment; the knowledge gained from firsthand experience is invaluable, difficult to replicate, and illegal outside a clinical trial. Participants in MT1 reported the experience was an invaluable part of their training that improved their ability to provide treatment to PTSD participants in Phase 3 clinical trials. "Allowing therapist trainees to enroll in MT2 will support the goals of the MDMA Therapy Training Program to provide comprehensive training to future providers. This work builds capacity to deliver quality, accessible care to patients, pending approval of MDMA-assisted therapy as a legal prescription treatment," says MAPS PBC Director and Head of Training and Supervision Shannon Carlin, M.A., L.M.F.T.

> This is MAPS at its best, negotiating with the FDA in an evidence-based manner with existing and new data that we analyzed specifically for our response.

"This is MAPS at its best, negotiating with the FDA in an evidence-based manner with existing and new data that we analyzed specifically for our response," explains MAPS Executive Director Rick Doblin, Ph.D. "For three decades, we have sought to educate the FDA in our novel approach rather than simply

Participate in Research

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

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

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

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

accept FDA requirements that are unjustified by the evidence. The dedicated work and incisive strategy of our Clinical Development team continues to improve the regulatory landscape for all future patients of psychedelic-assisted medicines."

MAPS PBC completed three requests to remove the clinical hold containing detailed information addressing the scientific benefit of the study, safety data from previous trial participants demonstrating positive risk-to-benefit ratio, and rationales for allowing licensed therapists with masters level, not doctoral level, degrees to serve as Lead Facilitator with a physician on-call. The successful dispute resolution comes after months of ongoing efforts and the engagement of the experienced legal team at Hyman, Phelps & McNamara, P.C. and lead attorney Josephine Torrente, J.D.

The Office of Neuroscience granting the appeal is encouraging for future negotiations with the FDA on requirements. "We choose to dispute MT2, not solely for its specific impact on MT2, but in an attempt to resolve an ongoing issue with the FDA regarding investigator qualifications across studies," MAPS PBC Regulatory Affairs Manager, Allison Coker, Ph.D., notes. "The Office of Neuroscience's agreement with our assessment establishes a precedent that can serve as guidance for developing requirements for investigators in future studies. Along with our clinical safety data, we hope this decision may also support our proposals for use guidelines post-approval."

"While the term 'dispute' may seem adversarial, this process can actually strengthen the relationship and trust between us and our review Division and ensures the Division has support on this project from the Office of Neuroscience," MAPS PBC Chief Executive Officer Amy Emerson explains. "This decision demonstrates how our strategic, data-driven strategy in challenging the FDA rulings can be successful."

Allison Coker, Ph.D.,
Regulatory Affairs
Manager of MAPS PBC

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

The Institutional Review Board (IRB) has approved MAPS' protocol for a Phase 2, open-label randomized controlled comparative study on the effectiveness of MDMA-assisted therapy in U.S. Veterans with chronic PTSD. Led by esteemed PTSD researcher Rachel Yehuda, Ph.D., Director at the Mental Health Patient Care Center, James J. Peters VA Medical Center, and Professor of Psychiatry and Neuroscience at the Icahn School of Medicine at Mount Sinai Hospital, the study is moving through the investigator-initiated research program of the U.S. Department of Veterans Affairs (VA). On August 25, 2020, the FDA agreed to proceed with the protocol.

The study will enroll 60 veterans and will collect further information on whether there is a difference in two versus three sessions of MDMA-assisted psychotherapy for safety and therapeutic outcome. This study will also act as a training ground for VA clinicians and therapists on the MAPS modality, and will include blood collection samples for later analysis of hormones, molecules, and other biological markers that may be related to having or recovering from PTSD. Dr. Yehuda and her team plan to conduct this trial at the VA pending DEA approval.

First Participant Completes Second Experimental Session in Open-Label, Phase 2, Multicenter Feasibility Study of Manualized MDMA-Assisted Psychotherapy with an Optional fMRI Sub-Study Assessing Changes in Brain Activity in Subjects with PTSD in Europe

We are very excited to share updates for the open-label lead-in study of MDMA-assisted therapy for PTSD in Europe, including news about enrollment progress. Data gathered in European trials is required for a planned Marketing Authorization Application to the European Medicines Agency (EMA).

In early May, the first participant completed the second experimental MDMA-assisted therapy session at our first study site in the Netherlands. This participant is expected to complete their final study visit within the next few weeks. The second participant at this study site has completed their first experimental session and is on track to complete the second experimental session at the end of May. Screening has begun for potential patients at our second study site in Maastricht, Netherlands.

Our study site in the Czech Republic currently has its first potential participant in the screening process, and screening additional potential patients is ongoing.

At our study site in Norway, the research team is continuing to screen potential patients. Two participants are currently at various stages in the screening process. If any are eligible to proceed, the first experimental session is expected to take place in mid-June.

Further study sites in Germany, the UK, and Portugal are starting and are expected to begin patient recruitment before the end of summer 2021.

An Open-Label, Multi-Site Phase 2 Study of the Safety and Feasibility of MDMA-Assisted Psychotherapy for Eating Disorders

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

This study will explore the safety and feasibility of MDMA-assisted therapy and adjunctive caregiver involvement in the treatment of individuals with AN-R and BED. The addition of a supportive caregiver as a treatment ally with every participant reflects this most recent development in science and practice. Supportive caregivers enrolled in the study will receive non-drug psychotherapy support. The study will enroll 12 participants who meet the Diagnostic Statistical Manual for Mental Disorders Edition 5 (DSM-5) criteria for AN-R, and 6 participants who meet DSM-5 criteria for BED, for a total of 36 participants (12 AN-R, 6 BED, and 18 caregivers).

The study will take place at three study sites. The study site in Vancouver, Canada, will include six BED participants, with Qualified Investigator Christian Schütz, M.D., Ph.D., M.P.H, overseeing the study. The study sites in Toronto, Canada, and Denver, Colorado, will each include six AN-R participants, with Michael Verbora, M.D., overseeing as Qualified Investigator in Toronto, and Co-Clinical Investigators Adele Lafrance, Ph.D., and Mike Rollin, M.D., overseeing the site in Denver.

A Phase 1 Open-Label Study of MDMA Tolerability and Pharmacokinetics in Participants with Moderate Compared to Matched Control Participants with Normal Hepatic Function

MAPS is sponsoring an open-label Phase 1 study of MDMA's effect on hepatic impairment (liver disease). While the study site is prepared, this study has not yet enrolled any participants and enrollment is on hold due to COVID-19.

The primary objective of this study is to evaluate the effect of moderate hepatic impairment on the pharmacokinetics of oral MDMA and its active metabolite 3,4-methylene-dioxyamphetamine (MDMA). The secondary objective of this study is to evaluate the effect of moderate hepatic impairment on the safety and tolerability of oral MDMA. Led by Principal Investigators Janel Long-Boyle, Pharm.D., Ph.D., and Robert M. Grant, M.D., M.P.H., this study will be conducted at the University of California, San Francisco.

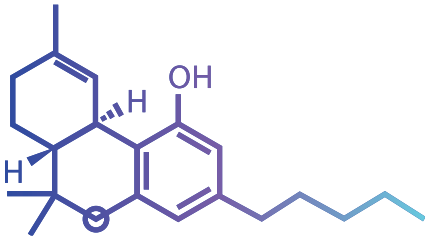
MDMA Therapy Training Program Update: Summer 2021

On Friday, May 14, 2021, the training team officially welcomed the Summer Cohort. This cohort is our largest to date, with a total of 309 trainees currently enrolled. Trainees are joining from across the globe, including those from Canada, Australia, New Zealand, South America, and Europe. Trainees are based in 30 different states in the US. Equally significant are the number of scholarships awarded and the efforts of the training team to expand the reach of the training program. A total of 80 scholarships were allocated to eligible trainees, totaling $317,500. More than one-third of the cohort are practitioners of color. More than 25 trainers are supporting the Summer Cohort.

We are accepting applications for our fall 2021 cohort and future training cohorts. Please visit our training website to learn more about the MDMA Therapy Training Program. Qualified applicants are encouraged to submit our training application.

MAPS Health Equity Scholarships are available for the fall 2021 MDMA Therapy Training Cohort! Thanks to the MAPS Health Equity Fund, the MDMA Therapy Training Program is honored to offer a number of full and partial scholarships for tuition costs to eligible practitioners for the fall 2021 training. The MAPS Health Equity Scholarship is part of MAPS and MAPS PBC's larger commitment to increasing inclusion and equity in our programs and advancing the initiatives outlined by the MAPS Health Equity Fund.

First Controlled Trial of Cannabis for the Treatment of PTSD Raises No Safety Concerns, Further Research is Needed to Determine Efficacy



Molecular compound of cannabis

- *Widespread anecdotal reports of benefit have led to self-treatment of the symptoms of posttraumatic stress disorder (PTSD) with cannabis among Veterans and others; the safety and potential efficacy of such treatments have not previously been studied through randomized clinical trials.*
- *All three active concentrations of smoked cannabis and the placebo cannabis were generally well tolerated.*
- *While the strongest response was to a 9% THC concentration, the study did not find a statistically significant difference in change in PTSD symptom severity between strains with 9% THC, 11% CBD, 8% THC / 8% CBD combination versus placebo.*
- *The cannabis concentrations available for this clinical trial were not reflective of the quality of cannabis available through either legal or informal markets.*

A peer-reviewed paper published on March 17, 2021, in PLOS ONE analyses the results of a randomized cross-over clinical trial of the Short-Term Impact of 3 Smoked Cannabis Preparations Versus Placebo on PTSD Symptoms. The study was funded by a $2.2 million grant from the Colorado Department of Public Health and Environment (CDPHE) to the Multidisciplinary Association of Psychedelic Studies (MAPS) and was conducted by MAPS Public Benefit Corporation (MAPS PBC), a wholly-owned subsidiary of MAPS. Though no statistically significant difference was shown between the groups, all showed improvement in PTSD symptoms during treatment with the THC group having the largest response.

"This study served as the first randomized placebo-controlled trial comparing the therapeutic potential of varying ratios of THC and CBD for treating symptoms of PTSD" said Dr. Marcel O. Bonn-Miller, Coordinating Principal Investigator and lead author of the study. "These data, coupled with those of a recently completed accompanying study also funded by CDPHE, provide better insight into why individuals with PTSD are turning to predominantly-THC-cannabis as a treatment. We now require larger randomized placebo-controlled trials to determine minimally-effective doses of THC needed to safely treat individuals suffering from PTSD while also mitigating risks of cannabis dependence in this vulnerable population."

"One of the biggest take-aways from this study is that Veterans with PTSD can use cannabis at self-managed doses, at least in the short term, and not experience a plethora of side effects or a worsening of symptoms," said Mallory Loflin, Ph.D., co-author of the paper and Volunteer Assistant Professor of Psychiatry at UC San Diego School of Medicine. "That's what most providers are worried about when their patients with PTSD decide to try cannabis."

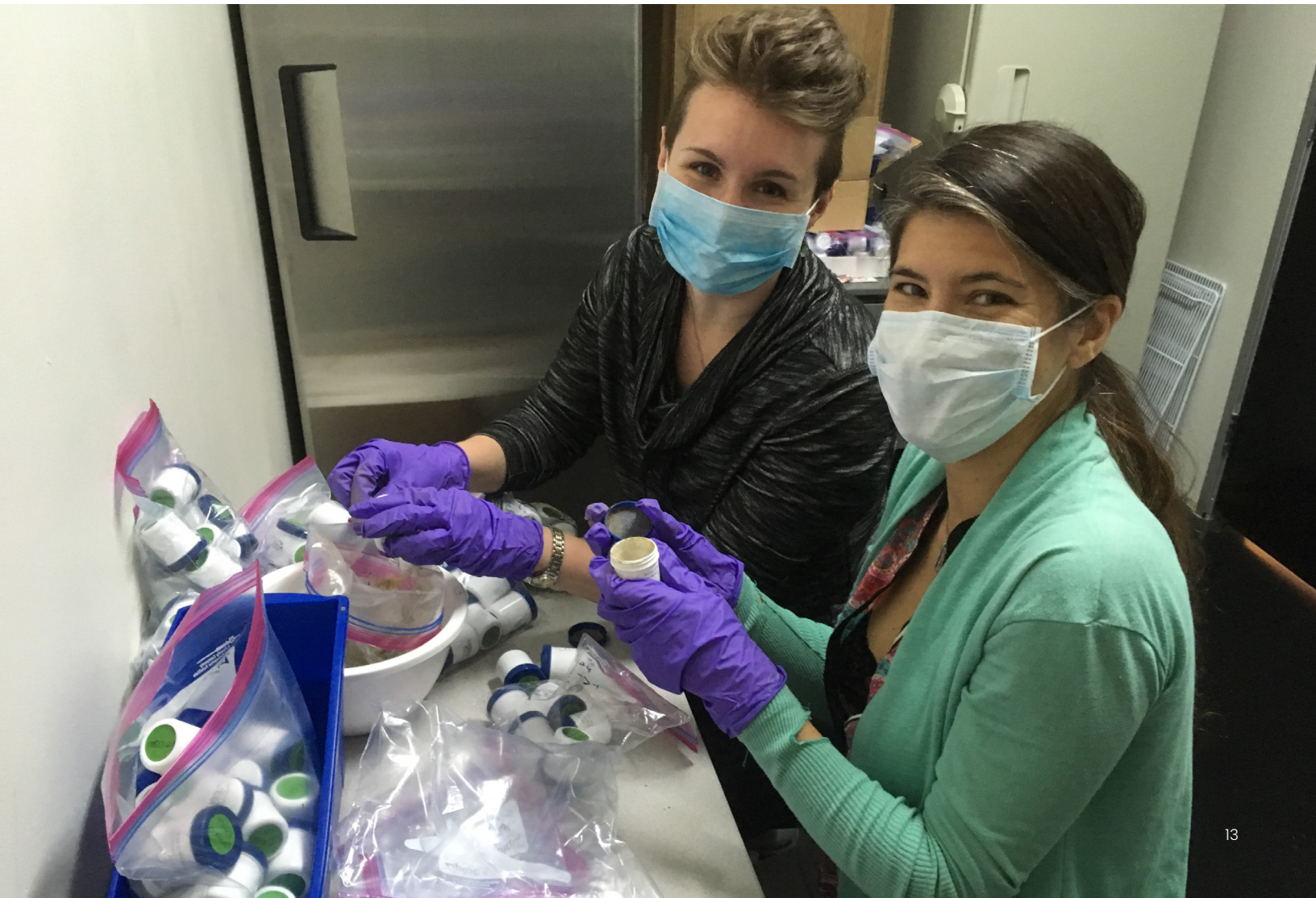
Co-author, Site Principal Investigator, and President of The Scottsdale Research Institute Sue Sisley, M.D.,notes that "This study's safety data and other research in PTSD patients in Colorado using real-world cannabis flower are promising. Despite the absurd restrictions federal prohibitionists have placed on research for more than 50 years, we are squarely focused on launching further Phase 2 trials with imported cannabis of tested, higher potency, fresher flowers that will provide a valid comparison for the millions of Veterans and others with PTSD who are looking for new options."

Inspired by preclinical evidence suggesting cannabis may be effective in the treatment of PTSD, this study was the first to evaluate its safety and efficacy in an FDA-regulated placebo controlled double-blind clinical trial in order to measure the effect size. Seventy-six predominantly male Veterans between the ages of 24 and 77 completed the study. In Stage 1, participants were randomized to receive prepared cannabis that was 9% THC,11% CBD, a mix of 8%THC and 8% CBD, or placebo. All preparations were supplied by the National Institute on Drug Abuse (NIDA) which, despite MAPS' best efforts for the last 20 years, still maintains the only license in the U.S. for production of cannabis preparations for federally regulated clinical trials. PTSD symptom severity decreased among all groups but demonstrated no statistical significance between the placebo group or the groups that received cannabis as measured by the Clinician-Administered PTSD Scale (CAPS-5).

"This study took seven years to obtain approval and three years to conduct at a cost of $2.2 million. The difference between anecdotal reports and these results may be the quality of the marijuana," said Rick Doblin, Ph.D, Executive Director of MAPS, "which highlights the need for further well-controlled clinical trials that more closely represent currently available marijuana products. Higher quality cannabis flower suitable for Food and Drug Administration (FDA) approval is currently unavailable domestically due to restrictions on production imposed by the U.S. Department of Justice and Drug Enforcement Administration and must be imported."

It is estimated that 6-10% of the general population and 13-31% of U.S. Veterans experience PTSD. The condition is associated with high rates of comorbid physical conditions, substance use disorder, depression, and suicidality. While currently approved treatments can be effective for some, the majority of military veterans with PTSD who receive one of the best practices psychotherapies for PTSD still qualify for a diagnosis of PTSD by the end of treatment. Self-treatment of PTSD with cannabis has been increasing alongside interest among patients, clinicians, and researchers to determine if cannabis may be an effective and appropriate treatment for PTSD.

NOTE: This study was supported by funding from the Colorado Department of Public Health and Environment (CDPHE). The content and opinions are those of the grantee/authors and do not represent the official views of CDPHE.



Policy and Advocacy

MAPS Celebrates California Senate Passage of Groundbreaking Psychedelic Reform Bill

- *California Senate Bill 519 decriminalizes the personal use and possession of psychedelic substances*
- *SB 519 will establish a task force to recommend regulatory systems California could adopt for safer personal use of psychedelic substances*
- *The historic Senate vote on June 1, 2021, advanced the most expansive psychedelic policy reform to pass through a state chamber*

Fifty years after the War on Drugs was officially declared and psychedelic substance prohibition began in contravention of evidence supporting therapeutic use, the California State Senate has taken the first Legislative step to dismantle psychedelic prohibition with a 21-16 vote on June 1, 2021, in favor of Senate Bill 519 Controlled substances: decriminalization of certain hallucinogenic substances sponsored by California State Senator Scott Wiener (D-San Francisco). The Bill will now move on to the State Assembly, where its members will have the opportunity to join the 91% of Americans who believe the War on Drugs has failed. SB 519 eliminates destructive criminalization policies and creates pathways which could, in the future, address the risks of currently-illegal substances through evidence-based policies such as harm reduction, education, and regulatory measures to combat adulteration.

"SB 519 reflects California's growing disillusionment with the War on Drugs, a decades-long public health disaster, and increasing desire for a more evidence-based drug policy paradigm. This is an exciting step toward a world where these substances can be used more safely, responsibly, and intentionally," said Ismail L. Ali, J.D., acting Policy Director for the Multidisciplinary Association of Psychedelic Studies (MAPS). "Ongoing criminalization of drugs and people who use them increases the dangers of drug use and traumatizes communities. As medicalization moves forward through clinical trials, MAPS is committed to ensuring that psychedelic drug policy does not perpetuate a dichotomy in which people using the same substances are celebrated in a medical context but criminalized outside of it."

Ongoing criminalization of drugs and people who use them increases the dangers of drug use and traumatizes communities.

Ali and members of the MAPS Policy and Advocacy Department offered expert advice and policy analysis to Senator Wiener, which included expanding the scope of content covered by the commission proposed by the legislation. Maurice Byrd and Dr. Bob Grant, both of whom were trained in MDMA-assisted therapy for PTSD by MAPS Public Benefit Corporation (MAPS PBC), provided expert testimony to the Senate in support of the framework proposed by SB 519.

"MAPS has laid the groundwork for research showing psychedelics may have great promise in helping people deal with complex trauma, depression, anxiety, and addiction. The War in Drugs has fueled mass incarceration without making us safer or reducing substance use disorder," said Senator Wiener. "Alongside MAPS and a coalition of dedicated allies, we've developed a science- and health-based approach that both reflects the transformational potential of psychedelics and begins to repair the harms of the War on Drugs."

SB 519 is co-sponsored by combat veteran service organizations Heroic Hearts Project (HHP) and Veterans Exploring Treatment Solutions (VETS). MAPS, HHP, and VETS are part of a broad coalition of allies supporting psychedelic policy reform to increase justice, expand cognitive liberty, or support people living with the mental health conditions that, according to a growing body of evidence, are likely to experience benefits from their therapeutic use. In addition to HHP and VETS, the coalition also included New Approach PAC, Law Enforcement Action Partnership, the Indigenous Peyote Conservation Initiative, Decriminalize Nature, and Sacred Garden Community.

SB 519 decriminalizes, but does not legalize or regulate, the personal possession and use of psilocybin, psilocyn, MDMA, LSD, ketamine, DMT, mescaline (excluding peyote), and ibogaine, all of which are under investigation for their possible beneficial therapeutic use. The bill also decriminalizes substance analysis tools, and creates a commission to study and recommend regulatory models that may, in the future, be appropriate for these substances. While Oregon voters elected to decriminalize all drugs in 2020, no state Legislature has taken such a bold step to align state psychedelic policy with the potential benefits and risks of these substances which are supported by decades of research and, in the case of some substances, hundreds or thousands of years of ceremonial use.

MAPS hopes that in the future, such policies will include decriminalizing all drugs as well as more comprehensive reforms including funding for education and harm reduction, access to treatment, and unarmed, appropriately trained crisis response.

Public Education

Synergetic Press and MAPS Form Copublishing Partnership

Synergetic Press and the Multidisciplinary Association for Psychedelic Science (MAPS) are pleased to announce they have entered into a copublishing relationship effective May 1, 2021, which will greatly expand the availability of education about psychedelics and psychedelic therapy.

Since MAPS began their mission to open pathways for legal, cultural, and medical contexts for people to benefit from psychedelics in 1986, they have published many pioneers in the psychedelic movement including Stanislav Grof, Albert Hofmann, Myron Stolaroff, Claudio Naranjo, Torsten Passie, Beatriz Cauiby Labate, Phil Wolfson, and Annie Oak. As with MAPS, Synergetic Press has been a leading publisher of cutting-edge books in the field of psychedelics and consciousness. The collaboration rests in the mutually held value to make these authors' knowledge more accessible to a broader world-market. This newly formed alliance, along with Synergetic Press' other copublishing partner, Transform Press, places Synergetic Press as the leading publisher in the field of psychedelics.

"Now that the psychedelic renaissance has overcome political and financial obstacles to research, public education is the most important need," says Rick Doblin, Ph.D., founder and executive director of MAPS. "MAPS is delighted to partner with Synergetic Press to expand the reach of our publications so that people all over the world will be better prepared as psychedelics move into the mainstream."

The first title to be published under the copublishing arrangement is Psyche Unbound: Essays in Honor of Stanislav Grof, to be released in October 2021. Edited by Rick Tarnas and Sean Kelly, Psyche Unbound honors the life and legacy of Grof, a founder of transpersonal psychology and a pioneering figurehead in the practice of psychedelic therapy. Included are essays from a vast array of notable thinkers including Joseph Campbell, Huston Smith, Fritjof Capra, Frances Vaughan, Thomas Riedlinger, John Buchanan, Jenny Wade, Ralph Metzner, Paul Grof and Arlene Fox, William Keepin, Jorge Ferrer, Gerry Goddard, Ervin Laszlo, Christopher M. Bache, Tom Purton, Gregg Lahood, Jeffrey Kripal, Michael Mithoefer, and Charles Grob.

"I have watched Rick Doblin over the past thirty-five years take on what seemed impossible, that is, to change people's minds about psychedelics and pave a path to decriminalization, regulation, and medical research," shared Deborah Parrish Snyder, Publisher and CEO at Synergetic Press. "Today, he and his team have succeeded at getting very far down that road. The MAPS imprint has curated the leading voices of the industry, funding and publishing pioneering work in the field. We are proud to bring the groundbreaking books from MAPS into our ever-expanding catalog."

With this agreement, the MAPS backlist and new titles will be distributed to the trade through Synergetic Press and their distributor, Publishers Group West, part of Ingram Publisher Services.