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Number 3



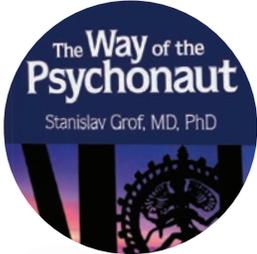
MAPS

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

2020 Annual Report
BULLETIN

Autumn 2020

MAPS ONLINE STORE



THE WAY OF THE PSYCHONAUT: ENCYCLOPEDIA FOR INNER JOURNEYS

Written by psychedelic therapy pioneer Stanislav Grof, M.D., Ph.D., *The Way of the Psychonaut* summarizes his life's work, the human psyche, and the spiritual quest for generations to come.

Two-volume
book set

Kindle
eBook

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All proceeds from
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research and education:
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MAPS

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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

MAPS furthers its mission by:

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

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

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

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NOW HIRING

Make your mark on the psychedelic renaissance!

MAPS, MAPS Public Benefit Corporation (MAPS PBC), and MAPS Europe are seeking qualified, mission-driven candidates for a variety of open positions.

To view all current job listings, please visit maps.org/careers



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maps.org/instagram



maps.org/youtube



maps.org/linkedin



maps.org/reddit

COVER ART: AUTUMN SKYE

Healing

36" x 24"

Acrylic on canvas, 2013

"Throughout history, society has looked to the arts to guide and inspire our individual and collective narratives. Artwork has the capacity to be an anchor in the storm and a touchstone of beauty amid an otherwise bleak reality. While the world is at the precipice of momentous change, artworks have the potential to be maps which can help guide humanity forward into new and positive ways of seeing and being.

And so I offer my art to you, from my heart to yours, with the prayer that it may touch some part of you and spark your own creative passion. May it fan the flame in you of peaceful revolution and timely change. We have so much work to do, and while I don't presume to know what your unique piece of the puzzle is, I am grateful to you for playing your part."

Autumn Skye's childhood was spent traveling the boundlessly majestic landscapes of North America, developing a deep wonder for nature and the diversity of humanity. She's been translating this inspiration through artwork since she was old enough to hold a pencil. Recognizing her curious imagination, creativity was always supported by her family.

Autumn Skye's meticulous and poignant paintings continue to gain expanding recognition, attracting collectors and students from around the globe. As a self-taught artist, she has dedicated innumerable hours in creative exploration. Her style gracefully weaves together refined realism, iconic imagery, profound symbolism, and subtle geometries.

She teaches and exhibits worldwide, and otherwise now lives and paints on the beautiful Sunshine Coast of British Columbia, Canada. Considering herself immensely blessed, Autumn Skye strives to support others through inspiration and creative empowerment.

autumnskyeart.com

autumnskyeart@gmail.com



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From the Desk of Rick Doblin, Ph.D.

ON BEHALF OF THE NOW roughly 100 staff members at MAPS and MAPS Public Benefit Corporation (MAPS PBC), I would like to express enormous gratitude to the thousands of MAPS donors who have contributed over \$100 million in support of our research and educational efforts since I founded MAPS in 1986. The inspiring news about the results of MAPP1, our first of two Phase 3 studies of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD), that I am sharing would not have been possible without the generosity and trust of MAPS donors, the dedication and expertise of MAPS and MAPS PBC staff, and the compassionate therapy provided by almost 100 therapists who have worked to treat participants with PTSD in our Phase 2 and Phase 3 clinical trials.

In March 2020, MAPS' Data Monitoring Committee (DMC) conducted an unblinded interim analysis of the data from MAPP1 when 60% of the participants had reached their primary outcome measure, and all 100 participants had been enrolled. The DMC reported great news: we had a 90% or greater probability of obtaining statistically significant results after all 100 participants had completed the study, meaning we didn't need to add more participants to the study. Shortly after the interim analysis, the COVID-19 lockdown resulted in the halting of treatment for a period of time. We negotiated with the FDA so that we would end the study when 90, instead of 100, participants had one baseline measure of their PTSD symptoms, plus at least one outcome measure of their PTSD symptoms after at least one experimental session. While a study with fewer than 100 participants decreases the likelihood of statistical significance, the outstanding results of the interim analysis suggested that even with just 90 participants, we had a very good chance of obtaining statistical significance upon completion of the study.

In August 2020, we gathered the last data from the 90th participant in MAPP1, which took place at 15 study sites (two in Israel, two in Canada, and 11 in the United States). For the last several months, we have been through the process of monitoring (double-checking) all of the data and sending queries regarding the data to the researchers and study coordinators in order to reach "data lock" where the data gathering is considered complete. We need to go through such a rigorous process in order to prepare for the FDA to audit all of our data should we proceed to submit an FDA New Drug Application (NDA) seeking permission for the prescription use of MDMA-assisted psychotherapy for PTSD patients.

After we reached the point of "data lock," we then submitted the data to our statisticians for analysis. At this point, the statisticians and MAPS PBC staff were all still blind to which participants were in the control group who received therapy with an inactive placebo and which participants were in the experimental group who received therapy with MDMA. Only after the data had been analyzed were the statisticians permitted to uncover the blind and see which group was the control group and which was the experimental group.

It's now with an enormous sense of pride, satisfaction, and relief that I can share that we learned that MAPP1 was statistically significant and is therefore considered a successful Phase 3 study. MAPS is on track towards our goal of obtaining FDA approval if we can successfully complete our second Phase 3 study and other associated safety studies that the FDA has required. We now can say with certainty that the \$30 million recently raised by MAPS, the Psychedelic Science Funders Collaborative (PSFC), author Tim Ferriss, and all other donors in our Capstone Campaign will be sufficient to generate all of the research data we need prior to submitting an NDA to

I would like to express enormous gratitude to the thousands of MAPS donors who have contributed over \$100 million in support of our research and educational efforts since I founded MAPS in 1986.

the FDA, and then to Health Canada and the Israeli Ministry of Health. In order to bring the therapeutic potential of MDMA-assisted psychotherapy for PTSD to the estimated 350 million people around the world who suffer from PTSD, MAPS is now launching a new \$30 million campaign to raise the funds necessary to conduct Phase 3 research in Europe for approval by the European Medicines Agency (EMA) and to globalize regulatory approval in most countries of the world.

While the therapeutic use of MDMA was pioneered around 1976 by Leo Zeff, Ph.D., (a.k.a. The Secret Chief) and I have known since 1984 that MDMA-assisted psychotherapy was excellent at treating PTSD when I used this modality with someone suffering from PTSD, it's only now in 2020 that we have been able to generate evidence supporting safety and efficacy in the context of an FDA-regulated Phase 3 clinical trial. It's tragic that so much suffering could have been avoided since 1986 when the Drug Enforcement Administration (DEA) rejected the recommendation of the DEA Administrative Law Judge that the therapeutic use of MDMA-assisted psychotherapy remain legal. Our current timetable for the potential of FDA approval is the first half of 2023, 37 years after the DEA kept both the therapeutic and social use of MDMA illegal.

We believe that potential FDA approval of MDMA-assisted psychotherapy for PTSD will be followed by regulatory approvals around the world. This will be followed by the establishment of thousands of psychedelic clinics with therapists cross-trained to provide therapy assisted by MDMA and other psychedelics, including ketamine and psilocybin, as other sponsors obtain approval from regulators. Eventually, in a post-prohibition world, there could be a licensed regulatory system for adults to legally access psychedelics to take on their own without supervision by therapists, with access to minors only with permission from their parents or guardians.

We are now in the midst of a renaissance of psychedelic research, a flourishing of non-profit and for-profit psychedelic companies, and successful psychedelic drug policy reform efforts such as the Oregon Psilocybin Program Initiative and the initiatives in Washington D.C., Ann Arbor, Santa Cruz, Oakland, and Denver that have made psilocybin mushrooms and/or plant psychedelics the lowest law enforcement priority. With the continued support of MAPS members, we have the precious and much-needed opportunity to obtain FDA approval for MDMA-assisted psychotherapy—first for PTSD and then for a wide range of other clinical indications. Our efforts are leading the way, helping other psychedelic organizations and psychedelic drug policy reform efforts toward the long-term goal of mass mental health, eventually moving toward a world with net-zero trauma and increased spirituality, tolerance, and care for the environment.

Onward to completing Phase 3 and way, way beyond!



Rick Doblin

MAPS Founder and Executive Director

We believe that potential FDA approval of MDMA-assisted psychotherapy for PTSD will be followed by regulatory approvals around the world.

Welcoming Amy Emerson and Joe Green to the MAPS Board of Directors

MAPS IS DELIGHTED TO WELCOME Amy Emerson and Joe Green to the MAPS Board of Directors (maps.org/about/board). Amy and Joe both understand that MAPS has a larger mission than just drug development, and are highly committed to mass mental health, drug policy reform, harm reduction, public education, and legal access to psychedelics for those who don't necessarily have a diagnosis but seek personal growth, relationship work, spiritual and/or celebratory experiences. It is with both great pleasure and honor we announce their additions to the MAPS Board of Directors, which now comprises eight people: five men and three women.

Amy Emerson started as a pro bono consultant at MAPS in 2003 when she approached MAPS Founder and Executive Director Rick Doblin, Ph.D., at a conference where he was speaking and offered to help monitor MAPS' clinical research. Rick's response was, "What's monitoring?" revealing how crucial Amy's pharmaceutical drug development experience was for the professionalization and growth of MAPS' research on MDMA-assisted psychotherapy for PTSD. Amy was the key for why MAPS built its own clinical research group rather than hiring contract research organizations (CROs) at an exorbitant cost. She built MAPS' clinical department while managing the MDMA Clinical Development Program with a focus on the PTSD indication. Her hard work and dedication have led her to her current position as CEO of MAPS Public Benefit Corporation (MAPS PBC). Amy brings decades of pharmaceutical development and research experience in Phase 1 through Phase 3 randomized controlled trials, including supporting three successful regulatory approvals for new biologics. Her professional experience at Novartis, Chiron, and other pharmaceutical companies (1993–2009) spans various fields including immunology, oncology, and vaccines. Amy is passionate about being a mother and bringing the potential of psychedelics for healing further into the consciousness of the world, leaving a better world for the following generations. With the growth of MAPS PBC, which currently has over 75 staff, and MAPS, with less than 30 staff, adding Amy to the MAPS Board of Directors ensures that the interests of MAPS PBC are formally represented in the deliberations of the MAPS Board of Directors.

Joe Green is a social entrepreneur who has spent his career addressing significant challenges by marrying technology with community organizing. Joe is the Co-Founder and President of the Psychedelic Science Funders Collaborative (PSFC), a community of philanthropists that supports research and clinical trials of psychedelic medicines, as well as patient access to these treatments. PSFC was born in 2017 out of a realization

that psychedelic medicine has the potential to make an enormous impact and has an achievable path to regulatory approval but has been systemically underfunded. Joe and PSFC have collaborated closely with MAPS, including being key partners in the successful \$30 million Capstone Campaign this year. Joe co-founded Causes, which empowered more than 100 million people to make an impact; NationBuilder, a leading software provider for organizers; and FWD.us, which has mobilized the tech community around immigration and criminal justice reform. He is currently the Chairman and Co-Founder of Treehouse, which builds communal housing apartment buildings in Los Angeles, and Chairman of Or Haleb, a center for Jewish meditation. Joe's expanding networks foster relationships with drug policy advocates, business experts, generous donors, and a plethora of professionals from outside the psychedelic realm. Joe has been instrumental connecting people in his extensive network of connections who have professional experience relevant to the work of MAPS and MAPS PBC. Joe's valuable prior political experience will help guide MAPS' activities as we work on both clinical drug development research and drug policy reform. Joe also has substantial previous business experience to help guide MAPS as we plan on the potential, and increasingly likely, FDA-approved prescription use of MDMA-assisted psychotherapy for PTSD. Joe brings a critical mind that helps us refine our motives and methods, and he pushes us to achieve better results for our mission, the community, patient access, and commercialization.



MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Annual Financial Report

Fiscal Year 2019-2020

June 1, 2019 – May 31, 2020

MERETE CHRISTIANSEN, MAPS ASSOCIATE DIRECTOR OF DEVELOPMENT
 RICK DOBLIN, PH.D., MAPS FOUNDER AND EXECUTIVE DIRECTOR
 TESS MARIN SHELLEY, MAPS DEVELOPMENT SPECIALIST



FISCAL YEAR 2019-2020 (JUNE 1, 2019 - MAY 31, 2020) was MAPS' most prolific year to date, both in funds raised and expenditures. This growth is primarily related to the Phase 3 studies of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) and the required buildout of the MAPS Public Benefit Corporation (MAPS PBC) subsidiary organization in preparation for potential U.S. Food and Drug Administration (FDA) approval and global expansion of the MDMA drug development program. With the successful completion of raising \$30 million in donations for the Capstone Campaign, MAPS achieved a pivotal milestone in funding projected expenses for completing the research necessary to request FDA approval and subsequent approval by the Israeli Ministry of Health and Health Canada. While we celebrate this success, our attention remains on the continued need for funding the operations of MAPS, as well as key programs including the campaigns for Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD with the European Medicines Agency (EMA) and broader global access, health equity, and harm reduction (see "What's Next?" on page 9 for more detail).



STATEMENT OF FINANCIAL POSITION JUNE 1, 2019 – MAY 31, 2020

ASSETS & LIABILITIES	ACTUALS FY19-20
Assets	
Cash and Equivalents	\$1,711,476
Pledges and Receivables	\$15,244,323
Other Current Assets	\$11,496,822
Total Assets	\$28,452,621
Liabilities	
Accounts Payable, Accrued Expenses and LTD	\$2,888,716
Total Liabilities	\$2,888,716
Net Assets	
Unrestricted	\$2,957,092
Board Restricted (Designated for Phase 3 MDMA/PTSD)	\$4,705,917
Temporarily Restricted	\$17,900,896
Total Net Assets	\$25,563,905
Total Liabilities and Net Assets	\$28,452,621
San Francisco Foundation* Balance	
Temp Restricted & Unrestricted Funds	\$9,914,899

*The Curing Fund, MAPS' long-term account for our assets, is managed by the San Francisco Foundation and has been invested in the stock market. The portfolio was transitioned from a long-term to a short-term investment strategy in 2017 in anticipation of required drawdowns on funds allocated for Phase 3 research. The Curing Fund had a closing balance of \$9,914,889 at fiscal year-end.

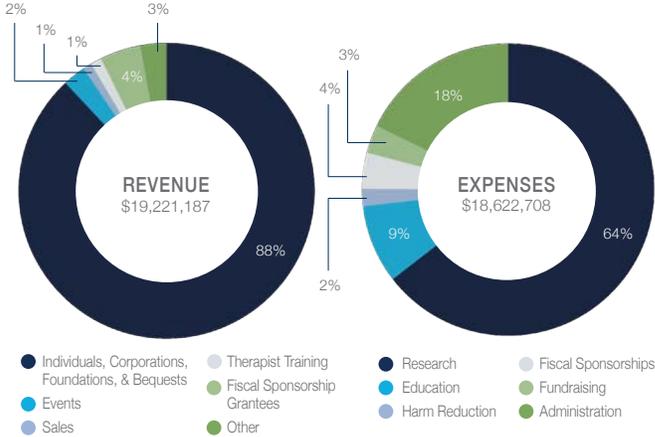
Support from individuals, corporations, bequests, and foundations in FY19-20 surpassed \$16.9 million, largely directed to the Capstone Campaign (see page 8 for a detailed report) and bolstered by MAPS' most successful year-end fundraising campaign to date, which took place in November and December 2019 (see page 8 for a detailed report). Thanks to our strong financial position, MAPS was able to deploy over \$14.7 million towards psychedelic research, harm reduction, advocacy, and education initiatives in FY19-20.

Programmatic spending for FY19-20 was 79.1%, primarily due to increases in administrative costs associated with adding additional accounting and IT staff, adding a second office, salary increases, and improving the overall quality of insurance and benefits for staff. Fundraising costs accounted for only 3% of expenditures, or in other words, MAPS efficiently spent only \$0.03 for every dollar raised.

At the close of the fiscal year, liabilities, and net assets exceeded \$28.4 million, which includes over \$15.2 million in outstanding multi-year pledges and receivables. MAPS ended FY19-20 with a positive change in net assets of more than \$568,000, despite a 68% increase in expenditures from the previous fiscal year. Unrestricted funds, essential for the continued functioning of MAPS' core operations, totaled over \$2.9 million at the close of the fiscal year. With an operating budget of approximately \$4 million, unrestricted funds remain a primary funding priority in FY20-21.

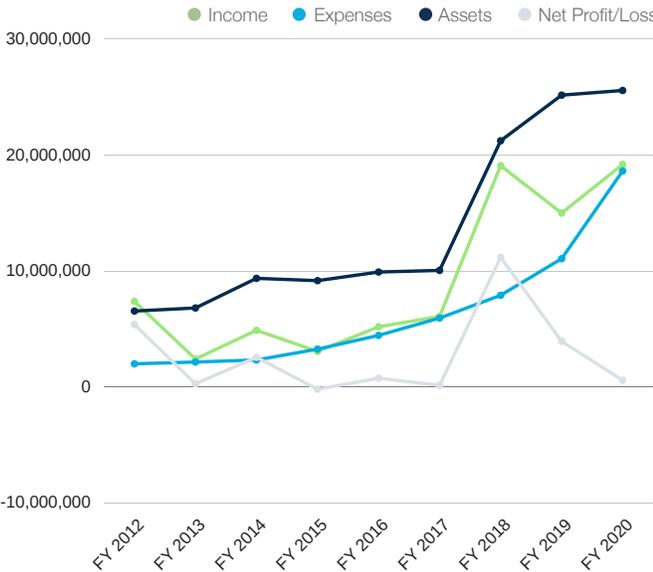
The financial results of FY19-20 are preliminary and pending the results of the annual audit, which is currently underway. To learn more, visit maps.org/about/fiscal

REVENUE & EXPENSES
JUNE 1, 2019 – MAY 31, 2020



INCOME, EXPENSES, & ASSETS

The following charts contain the consolidated income, expenses, and assets between MAPS, MAPS Public Benefit Corporation, and MAPS Europe over time.



STATEMENT OF ACTIVITIES

REVENUE	ACTUALS FY19-20
Assets	
Support from Individuals, Corporations, Foundations, and Bequests	\$16,922,268
Event Registration	\$478,094
Sales	\$184,008
Government Grants (CDPHE Grant)	\$8,125
Fiscal Sponsorship Income	\$858,079
Therapist Training Income	\$230,618
Net Investment and Other Income	\$539,995
Total Revenue and Support	\$19,221,187
Cost of Goods Sold	\$29,877
Net Revenue	\$19,191,310
EXPENSES	
Research	\$12,013,858
Education	\$1,619,233
Harm Reduction	\$358,040
Fiscal Sponsorships	\$740,040
Total Programs	\$14,731,171
Fundraising	\$575,794
Administration	\$3,315,743
Total Expenses	\$18,622,708
Change in Net Assets	\$568,602

Capstone Campaign

In 2020*, MAPS began its most critical and ambitious fundraising campaign of its 34-year history: the Capstone Campaign. With a goal to raise the final \$30 million needed to make MDMA a medicine, we were able to raise the first \$10 million from an initial round of support from our Board of Directors, the Psychedelic Science Funders Collaborative (PSFC), and core allies.

The second \$10 million was presented in the form of a 90-day challenge grant organized by author Tim Ferriss and PSFC. With the support of over 3,600 donors, the Capstone challenge grant was unlocked! Gifts to the challenge ranged from \$1 to \$1.9 million, and we deeply appreciate everyone who helped realize this goal.

We extend a special recognition of those who made the \$10 million challenge grant possible; Tim Ferriss who committed the first \$1 million for the Capstone Challenge matching grant, and was joined by the Steven & Alexandra Cohen Foundation (\$5 million), James Bailey (\$1 million), Blake Mycoskie (\$1 million), Peter Rahal (\$1 million), and John A. Griffin (\$1 million).

Thanks to this outpouring of generosity and support from our community, we are able to fund the FDA-regulated Phase 3 clinical trials and other activities required to make MDMA-assisted psychotherapy a medicine for PTSD in the United States, Canada, and Israel. The Capstone Campaign also funds the training of more therapists and preparations for prescription sales, in order to bring this much-needed treatment to patients.



\$30,106,218	RAISED
\$30,000,000	GOAL
3,623	TOTAL DONORS
3,152	NEW DONORS
90	DAYS

**This edition of the Annual Report captures financial data between June 1, 2019 - May 31, 2020. The Capstone Campaign ran in FY19-20 and FY20-21. The results of the campaign are presented in full on this page, but funds raised in FY20-21 are excluded from the aforementioned aggregate reports.*

Year-End Fundraising Campaign / General Operations

MAPS ran its year-end fundraising campaign, Expanding Psychedelic Medicine, from November 19 - December 31, 2019. Over 1,450 donors from 36 different countries helped us exceed our initial fundraising goal, raising a total of \$908,943 for psychedelic research and education!

We extend a special recognition of those who made the matching grant possible; John A. Griffin (\$100,000), Frank Kavanaugh (\$25,000), Matt Khoury (\$15,000) and the TinMan Fund (\$10,000).

The annual year-end fundraising campaign is a cornerstone for MAPS' general operating support. Funds raised support the seemingly unglamorous, but critical, administrative functions behind all of our projects, including research, education and outreach programs, psychedelic harm reduction, and policy and advocacy work.



\$908,943	RAISED
\$400,000	GOAL
1,468	TOTAL DONORS
807	NEW DONORS
43	DAYS

Zendo Project Campaign / Harm Reduction

The Zendo Project (zendoproject.org), the harm reduction program operated by MAPS, held our annual fundraising campaign to expand psychedelic peer support services at festivals and events. A total of 478 generous donors raised \$108,418 for psychedelic peer support services and education, bringing us to 108% of our \$100,000 fundraising goal. We extend a special recognition of those who made the matching grant possible: the Riverstyx Foundation (\$30,000), Connor Hill (\$15,000), and Dan McMurtrie (\$10,000). Our success is motivating and inspiring. We are so grateful for another year of providing peer support at festivals and events around the world!



\$108,418	RAISED
\$100,000	GOAL
478	TOTAL DONORS
309	NEW DONORS
46	DAYS

What's Next? / Funding Priorities

Over 350 people volunteered with the Zendo Project at Burning Man 2019 in Black Rock City, Nevada. Donations from the Zendo Project annual fundraising campaign helped to provide peer support services and education, train volunteers, secure supplies, and facilitate outreach at Burning Man, the Zendo Project's largest annual event. We are grateful to our volunteers and supporters who help make our work possible.

The Zendo Project is working towards a fully sustainable model where program expenses are entirely covered by event venues and producers or recovered through training fees. Until the Zendo Project achieves full sustainability, we rely on support from individual donors to bring psychedelic harm reduction to the places where it is needed most.

General Support

MAPS continues to prioritize public education, policy reform, and building community support networks. The educational programs and fundraising activities operated by MAPS are the lifeblood that fuel our research, training, advocacy, and community-building initiatives. MAPS anticipates its annual operating budget to grow to \$5 million.

European Medicines Agency (EMA) and Global Access

MAPS is seeking regulatory approval for legal access to MDMA-assisted psychotherapy across the world. Regulatory approvals from the FDA, Health Canada, and the Israeli Ministry of Health are anticipated by early 2023, depending on how COVID-19 impacts enrollment. The next priority in MAPS' global strategy is to receive EMA approval upon completion of a successful confirmatory clinical trial conducted across 10 sites in seven European countries. Data collected for regulatory approvals through the FDA and EMA will be used as a basis for approval in dozens of additional countries with some requiring no additional studies and some requiring small confirmatory studies. Approval in Japan and China will require additional Phase 3 studies that are not currently budgeted. MAPS anticipates the funding need for EMA and broader global access to be \$30 million.

Health Equity

MAPS believes that providing MDMA-assisted psychotherapy comes with a responsibility to deliver on the public benefit promise of the organization: everyone deserves an equal opportunity to heal, to live life without PTSD. As part of MAPS' efforts to catalyze equal access to healing for all who suffer from trauma, MAPS is launching a unified approach to embed health equity into everything we do. The Health Equity Program will create treatment and training access opportunities for those historically marginalized by the mental health field and society at large. This program funds therapist training, expanded access, and community building, with a particular focus on developing an MDMA therapist network that accurately reflects the diverse demographics of the countries where MDMA may be a medicine. MAPS is seeking \$4.5 million over the next three years to establish the foundation of this critical program.



MAPS continues to prioritize public education, policy reform, and building community support networks.

FISCAL YEAR 2019-2020 DONORS

These pledges and donations were made between June 1, 2019 and May 31, 2020. Our gratitude goes to all of those who contributed to make this work possible. We share this list in part to show that a community has gathered to make a difference.

\$5,000,000+

Steven and Alexandra Cohen Foundation

\$1,000,000 – \$4,999,999

Blake Mycoskie
Elizabeth Koch
George Sarlo
James Bailey
John A. Griffin
John Gilmore
Peter Rahal

Psychedelic Science Funders Collaborative (PSFC)
Tim Ferriss

\$500,000 – \$999,999

Cody Swift and Miriam Volat, RiverStyx Foundation

David Bronner, Dr. Bronner's Magic Soaps
Frank and Susan Kavanaugh

\$100,000 – \$499,999

Adam Wiggins
Alex and Rachel Lloyd
John and Gwen Smart Foundation

Joseph Kert Green
Julie and Jeff Brody
Justin Rosenstein
Mike Novogratz
The Libra Foundation
Vinny Smith

\$50,000 – \$99,999

Inkinen Family DAF
Open Society Foundations (OSF)

\$25,000–\$49,999

Google, Inc.
Jeffrey Kwatinetz
Ron Beller
Threshold Foundation

\$10,000 – \$24,999

AmazonSmile Foundation
Andrew Weil
Anne St Goar and Shippen Page
Aubrey Marcus
Audra Foster
Chris Ergen
Claudine Liss
Connor Hill
Courtney Hull
Daniel McMurtrie

David Adam Roth
Eldona Hamel
Fred J. Brotherton Charitable Foundation
George Wiel
Gil Penchina

Joshua Mailman Foundation, Inc.

Kirsten Waerstad
Kwang Ho Kim
Madeleine and Lyndon Rive
Madeline Farver Berky
Maeve Rockefeller

Matt Khoury
Max Kerr

Moshe Tov Kreps
Ramez Naam

Rockefeller Family Fund

Ryan Zurrer
Samwell Freeman
Scott Faber

The Lopker Family Foundation and QAD

The TinMan Fund
Tom Latchford

\$1,000 – \$9,999

Adam Goetsch
Adam Hupp

Aerin Lim
Alan Bader

Alan Feiger
Alison Whitmire

Amy Pico
Andrej Cvoro

Andrew Kirk Gradison
Andrew Koraleski

Andrew Ryan
Andrew Wiggins

Ankush Gera
Ann Parrish

Anne Kate Becker
Anne Kiehl Friedman

Apple, Inc.
Ariel Poler

Arthur Corey Sarkisian
Ashley Gordon

Bailey Gimbel
Barden Family Giving

Benjamin Halper
Bessel A. Van Der Kolk

Bill and Melinda Gates Foundation
Bill Freimuth

Billie-Grace Ward
Brandon Law

Brandyn Schwalm
Brian J. Smith Giving Fund

Brooke Stone
Brookstein Family Philanthropic Fund

Bruce Linton
Buckmaster Foundation

Caleb Whitten
Cameron Cheever

Candra Docherty
Cannabis Buyers Club Berkeley (CBCB)

Carla R. Lilley
Carly Taylor

Carol and Wally Marks
Carolyn Ferris

Carolyn Mary Kleefeld
Cartograph LLC
Cesar Caro Aguilar
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Research News

MDMA-Assisted Psychotherapy

MAPS and MAPS Public Benefit Corporation Announce Positive Result from Phase 3 Trial of MDMA-Assisted Psychotherapy for PTSD

IN NOVEMBER 2020, MAPS Public Benefit Corporation (MAPS PBC) completed data analysis of the first of two Phase 3 trials of MDMA-assisted psychotherapy for treatment of posttraumatic stress disorder (PTSD). The results confirmed Phase 2 results and prior expectations from an independent interim analysis which determined there was a 90% or greater probability that the trial, when completed, would be of sufficient size to detect statistically significant results. Further, no unexpected or serious safety signals emerged during the course of the trial.

The results indicate MDMA-assisted psychotherapy for PTSD may be an effective treatment for PTSD resulting from various types of trauma, including trauma occurring in childhood and in patients with dissociative subtype of PTSD, pending assessment by the U.S. Food and Drug Administration (FDA). Based on these results, MAPS will begin discussions with the FDA on ways to accelerate the timeframe for approval of this modality.

The Phase 3 trial, the first of its kind in scope and size, treated 90 participants who received 3 day-long MDMA or placebo sessions one month apart and 12 90-minute non-drug psychotherapy sessions over approximately 3.5 months. The severity of PTSD symptoms was measured using the Clinician-Administered PTSD Scale for the DSM-5 (CAP-5); measurements were taken before and after completion of treatment. Of these 90 participants, approximately half received MDMA-assisted psychotherapy. The other half of participants, the control group, received placebo with identical therapy. A second Phase 3 clinical trial is currently enrolling participants.

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 site of the study. He noted, “The experience of having been traumatized profoundly alters perceptions; self-experience; and capacity to plan, imagine and anticipate. Since the results of this study mirror previously published results, we can expect to see 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 powerful new pathway to healing once MDMA-assisted psychotherapy has been approved as a treatment for PTSD.”

Phase 3 Trials of MDMA-Assisted Psychotherapy for PTSD: Seeking Research Volunteers

We are currently seeking research volunteers for our second Phase 3 clinical trial of MDMA-assisted psychotherapy for PTSD. Volunteers will help contribute to scientific knowledge and will help us better understand if MDMA-assisted psychotherapy works for treatment of PTSD. MAPS conducts clinical trials under the guidance and regulations of the FDA in collaboration with federal regulators, including the Drug Enforcement Administration (DEA). To learn more about our clinical trials or apply to be a study participant, please visit our website: mdmaptsd.org.

We are recruiting participants in the following locations:

- Los Angeles, California | Private Practice
- San Francisco, California | Private Practice
- Boulder, Colorado | Private Practice
- Fort Collins, Colorado | Private Practice
- New Orleans, Louisiana | Private Practice
- Charleston, South Carolina | Private Practice
- Boston, Massachusetts | Private Practice

Not yet recruiting:

- San Francisco, California | Research Institution
- New York, New York | Private Practice
- New York, New York | Research Institution
- Madison, Wisconsin | Research Institution
- Vancouver, Canada | Research Institution
- Be'er Ya'akov, Israel | Research Institution
- Tel Aviv, Israel | Research Institution

The trials are the final phase of research required by the FDA before deciding whether to approve MDMA as a legal prescription treatment for PTSD. If approved, MDMA will be required to be used in conjunction with psychotherapy in an outpatient setting.

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

MDMA-Assisted Psychotherapy Will Be Cost-Effective in the Treatment of PTSD

A peer-reviewed study published on October 14, 2020, in the research journal *PLOS ONE* demonstrates that MDMA-assisted psychotherapy is remarkably cost-effective when compared to currently available treatments for PTSD. It is estimated that a public healthcare payer or private insurer making MDMA-assisted psychotherapy available to 1,000 patients with PTSD would reduce general and mental health care costs by \$103.2 million over 30 years.

Lead author Elliot Marseille, Dr.P.H., M.P.P., elaborates, “MDMA-assisted psychotherapy is conducted by a licensed psychologist and trained clinician over the course of twelve sessions with three sessions lasting six or more hours. The cost of that time is not inconsiderable, but in just over three years, healthcare providers will break even on the costs of mental health and general medical care. These estimates are promising yet likely too conservative: the study did not measure the value of increased productivity or lower disability payments as patients recover from PTSD and is constrained by the limited availability of data on the long-term trajectory of PTSD. Further research will be needed to determine the full financial, personal, and societal benefits of MDMA-assisted psychotherapy for PTSD.”

Berra Yazar-Klosinski, Ph.D., Deputy Director and Head of Research Development and Regulatory Affairs for MAPS PBC and co-author, developed the protocols studying MDMA-assisted psychotherapy. She notes, “A growing body of evidence suggests that MDMA-assisted psychotherapy may be more effective than currently available treatments for PTSD, a notoriously difficult-to-treat condition. Previous research has focused on safety and efficacy and indicates statistically significant improvements over psychotherapy with a control, demonstrating reduction in symptoms for 82% of participants. This study should compel healthcare providers to include MDMA-assisted psychotherapy as a covered treatment for PTSD following FDA approval.”

Rick Doblin, Ph.D., Executive Director of MAPS and a study co-author, states, “The profound personal toll of PTSD can include deterioration in physical health, relationships, and ability to participate in social activities along with the anxiety, insomnia, and suicidal ideation that mark the condition. By demonstrating a return of an average of 5.5 quality-adjusted life-years over 30 years, we have shown that MDMA-assisted psychotherapy has the potential to reduce more than the personal burden of PTSD, contributing to improved health outcomes and reduced healthcare burdens for payers and providers.”

A growing body of evidence suggests that MDMA-assisted psychotherapy may be more effective than currently available treatments for PTSD, a notoriously difficult-to-treat condition.

The cost-effectiveness of MDMA-assisted psychotherapy from the U.S. healthcare payers’ perspective was constructed with a decision-analytic Markov model to portray the costs and health benefits of treating patients with chronic, severe, or extreme, treatment-resistant PTSD. Efficacy was based on the pooled results of six randomized controlled trials with the 105 subjects who participated in Phase 2 trials and a four-year follow-up of 19 of those subjects. Other inputs were based on published literature and on assumptions when data were unavailable. Results are modeled over a 30-year analytic horizon and conducted extensive sensitivity analyses. The model calculates expected medical costs, mortality, quality-adjusted life-years, and incremental cost-effectiveness ratio.

The safety and efficacy of MDMA-assisted psychotherapy 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.

MDMA-Assisted Psychotherapy May Have Lasting Benefits for PTSD, Results Published in *Psychopharmacology*

On June 10, 2020, MAPS announced the publication of the long-term follow-up results of six Phase 2 clinical trials of MDMA-assisted psychotherapy for the treatment of PTSD in the peer-reviewed journal *Psychopharmacology*. The paper is the most comprehensive analysis yet published of the safety and durability of treatment outcomes following MDMA-assisted psychotherapy for PTSD.

The results show that for a majority of participants, the benefits of MDMA-assisted psychotherapy for PTSD extended at least 12 months after the treatment sessions. Sponsored by MAPS, the controlled, randomized, double-blind trials found that, two months following their last session, 56% of 100 participants no longer met diagnostic criteria for PTSD. In the newly published analysis, 91 participants were interviewed at least 12 months later. Of these participants, 67% did not qualify for a PTSD diagnosis. One of the studies included data from an average of 3.8 years after treatment.

“Trauma exposure has emerged as one of the most pressing public health issues of our time and is now at the forefront of global consciousness due to the COVID-19 pandemic and rising visibility of systemic oppression,” said

Berra Yazar-Klosinski, Ph.D., paper co-author and Deputy Director and Head of Research Development and Regulatory Affairs at MAPS. “Although our Phase 3 trials are not yet completed, these long-term data support the hypothesis



that MDMA-assisted psychotherapy may provide significant advantages in treatment outcomes, safety, and durability over available PTSD treatments. This is the breakthrough that the world needs right now.”

The trials were conducted by independent investigators in South Carolina (two trials), Colorado, Canada, Switzerland, and Israel. Trial participants included women and men with chronic, treatment-resistant PTSD from a wide variety of causes.

PTSD symptoms were assessed using the Clinician-Administered PTSD Scale (CAPS-IV) at baseline, one to two months after their last MDMA-assisted psychotherapy session, and at least 12 months after their final session. The course of double-blind treatment included one to three eight-hour MDMA-assisted psychotherapy sessions spaced three to five weeks apart, combined with weekly non-drug psychotherapy sessions. Outcomes were assessed by blinded Independent Raters.

Based on these results, in August 2017, the FDA granted breakthrough therapy designation to MDMA-assisted psychotherapy for PTSD, acknowledging that it “may demonstrate substantial improvement over existing therapies” and agreeing to expedite its development and review. The FDA also considered MAPS’ prior published Phase 2 results when it agreed to MAPS’ expanded access program in January 2020.

The follow-up study found that long-term adverse events were minimal although the benefits were sustained. The most common harm reported at the long-term follow-up was worsened mood, reported by less than 4% of study participants. Further assessment of the long-term benefits and risks of MDMA-assisted psychotherapy is needed in future trials that include control groups.

FDA Agrees to Expanded Access Program for MDMA-Assisted Psychotherapy for PTSD

On December 20, 2019, the FDA agreed to MAPS’ application for an expanded access program for MDMA-assisted psychotherapy for PTSD.

The purpose of the expanded access program is to allow early access to the potential benefits of treatment with MDMA-assisted psychotherapy to people for whom currently available treatments have not worked, and who are unable to participate in Phase 3 clinical trials.

The expanded access protocol will allow 50 patients to receive MDMA-assisted psychotherapy, following the MAPS treatment protocol (maps.org/treatmentmanual). MAPS hopes to expand the number of patients eligible to receive treatment in the expanded access program in the future. MAPS has proposed to the FDA that after the first 35 patients, patient data will be submitted for the agency to consider whether to expand the program.

The expanded access protocol differs from MAPS’ ongoing Phase 3 clinical trials in that it is limited to treatment-resistant patients with moderate to severe treatment-resistant PTSD. Other differences are that the FDA is requiring at least one therapist of each therapy pair to have a medical or clinical doctorate degree (M.D., Ph.D., or equivalent), there is no control group, and patients are responsible for the costs of their own treatment.

Up to 10 qualifying treatment sites will participate in the expanded access program. Over 120 site applications have been received to date. Once the program begins, patients can apply to the individual expanded access sites.

“The resurgence of research into using drugs such as MDMA to catalyze psychotherapy is the most promising and exciting development I’ve seen in my psychiatric career,” said Michael Mithoefer, M.D., Senior Medical Director for Medical Affairs, Training and Supervision for MAPS PBC. “Combining the powerful effects of pharmacology with the potential depth of psychotherapy is a compelling model for harnessing advances in neuroscience and psychopharmacology without ignoring the complexity, richness and innate capacity of the human psyche. I’m delighted that the expanded access program will now allow some patients access to this modality as MAPS’ Phase 3 research continues.”

MAPS’ expanded access protocol received Institutional Review Board (IRB) approval on November 4, 2020, and must still be confirmed by the DEA.

Israel Embraces Research on MDMA-Assisted Psychotherapy for PTSD

On February 3, 2019, Israel became the first government to approve a compassionate use program for MDMA-assisted psychotherapy for PTSD, which will allow 50 patients to receive the treatment outside of Phase 3 clinical trials. Patients with PTSD will be eligible to receive treatment at sites throughout Israel, including Rambam Medical Center in Haifa and psychiatric hospitals in Be’er Yaakov, Lev Hasharon, Be’er Sheva, and Sheba-Tel Hashomer. The U.S. FDA followed Israel on December 20, 2019, when the agency agreed to an expanded access program for MDMA-assisted psychotherapy for PTSD, also for 50 patients with PTSD.

“The Israeli Ministry of Health is constantly looking for new tools to get better results in psychological and psychiatric treatment,” says Bella Ben-Gershon, Director of Psychological Trauma for the Israeli Ministry of Health. “After seeing the very promising results of the completed MDMA-assisted psychotherapy research in Israel, we now believe that it is crucial to allow more citizens who suffer from PTSD to have access to this new treatment.”

Israel is also the first national government to financially support MDMA-assisted psychotherapy research. In February of 2019, the Israeli Ministry of Health granted \$500,000 in medical and hospital services to MAPS in support of the compassionate use of MDMA-assisted psychotherapy for PTSD in Israel.

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

On August 25, 2020, the FDA agreed to proceed with MAPS’ first randomized clinical trial protocol submitted in partnership with 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 Neurosci-

ence at the Icahn School of Medicine at Mount Sinai Hospital, through the investigator-initiated research program of the U.S. Department of Veterans Affairs (VA).

The study will be a Phase 2, open-label randomized controlled comparative study on the effectiveness of MDMA-assisted psychotherapy in U.S. veterans with chronic PTSD.

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 institutional and DEA approvals.

Startle Testing with MDMA: Thirty-Four Veteran Participants Complete Enrollment in Experimental Treatment

On July 30, 2020, MAPS completed enrollment in our study of the effect of experimental treatment with MDMA on startle testing in thirty-four healthy participants. Led by Principal Investigator Barbara Rothbaum, Ph.D., this study was conducted at Emory University in Atlanta, Georgia. Dr. Rothbaum presented a subset of findings at the 36th Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) on November 12, 2020.

An 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

Taking place in the United Kingdom, Germany, Portugal, Norway, the Czech Republic, and the Netherlands, this open-label Phase 2 study of MDMA-assisted psychotherapy for PTSD will serve as the lead-in to the planned Phase 3 study in Europe and to validate assumptions made for statistical power calculations supporting the planned Phase 3 clinical trial. This study will also provide cross-cultural validation data on the updated version of the Primary Outcome measure, the CAPS-5, which will be used in the Phase 3 study. In addition, the study will gather supportive data on the safety and effectiveness of manualized MDMA-assisted psychotherapy while providing an opportunity for clinical supervision to planned Phase 3 therapy teams. This study will be the first multi-center study of MDMA-assisted psychotherapy for PTSD in Europe and will explore reproducibility of findings from FDA-regulated Phase 2 trials to confirm the Phase 3 study design.

The study site in the Czech Republic is currently screening participants, screening at the first of two Netherlands sites

will begin imminently, and screening at the Norway site is expected to start before the end of the year. The sites in the United Kingdom and Germany require further permissions before they can begin screening, most likely in early 2021, and the study set-up in Portugal is still in an early stage. Data gathered in European trials would provide support for a planned Marketing Authorization Application for potential approval by the European Medicines Agency (EMA). For more information, please visit: mapseurope.eu/research.

Therapist Training Study: New Protocol Amendment Accepted by the FDA

On May 12, 2020, a new protocol amendment that increases the number of study participants to a total of 120 was accepted by the FDA. This protocol amendment was submitted to the IRB on April 30, 2020. This study is our ongoing Phase 1 study of the psychological effects of MDMA when used in a therapeutic setting by healthy participants. Enrollment in this multi-site study is on hold due to COVID-19 and is limited by invitation only to therapists in training to work on MAPS-sponsored clinical trials of MDMA-assisted psychotherapy for PTSD. The Boulder, Colorado, study site is led by Principal Investigator Marcela Ot'alara G., M.A., L.P.C., the Charleston, South Carolina, is led by Principal Investigator Zhenya Gelfand, M.D., and the Santa Fe, New Mexico, study site is led by Principal Investigator George Greer, M.D.

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 psychotherapy 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 Hepatic Impairment 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. 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

From September 25 - November 1, Marcela Ot'Alora G., L.P.C., and Bruce Poulter, M.P.H., delivered a three-weekend course on MDMA-assisted psychotherapy in collaboration with Naropa University. The 9-day course included training in contemplative psychotherapy from Naropa faculty.

Annie Mithoefer, B.S.N., and Michael Mithoefer, M.D., provided an online training from November 5-6 and November 9-12. The November training included trainees from Netherlands, Germany, Norway, Portugal, United Kingdom, Canada, Somaliland, South Africa, and the United States. In October, therapists preparing to work in Europe participated in virtual training calls focused on culturally-informed care for refugee participants, led by Adele Meyer and Nooria Mehraby, M.D.

Over the summer, the training program launched the first of a series of Phase 3 Quarterly Consultation groups. These virtual group supervision calls are facilitated by trainers Marcela Ot'Alora, L.P.C., Bruce Poulter, M.P.H., Annie Mithoefer, B.S.N., and Michael Mithoefer, M.D., and cover therapeutic topics, peer discussion, case presentations, and consultation. Therapists have appreciated gathering in this community of their peers to learn from each other's insights and challenges delivering MDMA-assisted psychotherapy. These are the MDMA Therapy Training Program's first experiment with group supervision; we look forward to offering group supervision on the upcoming expanded access protocol as well, which will be facilitated by Associate Supervisors who have recently completed supervision training.

Sign up for the MDMA Therapy Training Program Newsletter to receive updates on future trainings: mapspublicbenefit.com/training.

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.

MAPS in the Media

THE WALL STREET JOURNAL.

New PTSD Treatments Emerge as Cases Rise Among Some Groups

Andrea Petersen • September 21, 2020

The Wall Street Journal reports on the development of cutting-edge PTSD treatments that are on the horizon, including MDMA-assisted psychotherapy, as mental healthcare professionals brace for an increase of PTSD symptoms in the population due to the pandemic, especially frontline workers and young adults. Contrasting limitations with currently approved FDA treatments for PTSD, the article highlights promising results from a 2019 review of six MAPS-sponsored Phase 2 trials of MDMA-assisted psychotherapy for PTSD published in the journal *Psychopharmacology*, in which 54% of participants who received treatment no longer met the criteria for PTSD.

The Washington Post Magazine

Who Will Benefit From Psychedelic Medicine?

Whitney Joiner • September 21, 2020

The Washington Post Magazine explores the call for inclusion and social justice within the burgeoning world of psychedelic medicine, highlighting MAPS' efforts to expand racial equity and access, and announcing the MAPS health equity initiative launching this fall to benefit marginalized peoples. The article features interviews with therapists of color who worked on the MAPS-sponsored study of MDMA-assisted psychotherapy for PTSD with participants of color at the University of Connecticut, and insights from presenters at the Psychedelic Medicine and Cultural Trauma Workshop hosted by MAPS in Kentucky last year. "If you want this [treatment] to be accessible to people of color, you can't use the same strategies that marginalized them in the first place," says Jamilah R. George, M.Div.

Women's Health

Fresh Perspective

Kristin Canning • September 30, 2020

Women's Health magazine speaks with Amy Emerson, CEO of MAPS Public Benefit Corporation (MAPS PBC), to learn about the advantages of combining MDMA with psychotherapy to treat PTSD. Emerson says research shows MDMA can "turn down activity in the amygdala, or the part of the brain that ramps up fear, and turn up activity in the prefrontal cortex, which controls logic," making it a beneficial adjunct to therapy. Additionally, Emerson explains the therapeutic value of memory reconsolidation, or "examining and refiling a traumatic memory, so it no longer feels like a current threat."



The Great Power And Great Responsibility Of Using Psychedelic Medicine

Kaia Findlay and Anita Rao • September 10, 2020

Host Anita Rao of NPR's Blue Ridge Public Radio speaks with Ismail L. Ali, J.D., MAPS Policy and Advocacy Counsel, about psychedelic medicalization, indigenous plant medicines, and culturally responsible policy reform. "They've often been used in community intergenerationally as rites of passage, or as initiations, or as containers in which various kinds of political, social, personal, healing and community work can be done," explains Ismail L. Ali, J.D., about indigenous plant medicine traditions.

Vox

The Case for Funding Psychedelics to Treat Mental Health

Sigal Samuel • October 9, 2020

"If you want to invest in the mental health of people around the world, making us all more resilient to future crises, what can you do? Believe it or not, your best bet might be to fund drug development for psychedelic-assisted mental health treatments," says Vox in an article exploring a new in-depth philanthropy report by Founders Pledge. The Founders Pledge research team analyzed data from trials of MDMA-assisted psychotherapy for PTSD and psilocybin-assisted therapy for depression, leading their research team to recommend funding psychedelic drug development from the non-profit organizations MAPS and Usona Institute.

QUARTZ

Wall Street Donors Are Racing to Back Psychedelic Therapy

Olivia Goldhill • August 21, 2020

The completion of MAPS' Capstone Challenge continues to spread through the media, highlighting the shift in acceptance of psychedelic therapy. The success of the \$30 million fundraising effort to fund the final research required to seek U.S. Food and Drug Administration (FDA) approval of MDMA-assisted psychotherapy for PTSD represents the growing support for new and innovative mental health treatments. "Should psychedelics be legalized, the drugs will present both a transformative mental health treatment and a major industry," explains Quartz.



This spring, MAPS hosted the Psychedelic Science 2020 Webinar Series, hosted by Bia Labate, Ph.D., where leaders of the psychedelic renaissance discussed the latest advancements in psychedelic research, medicine, therapy, policy, and advocacy, as well as their applications to our lives now and in the near future.

The following highlights from the webinar series are lightly edited for clarity.

Ketamine Therapy: Current Applications in Mental Health Treatment



"Ultimately, insurance coverage is intimately tied to FDA approval, so medical insurance doesn't have to cover ketamine treatment for depression until it becomes FDA approved."

– Raquel Bennett, Psy.D.



"It seems like right now more than ever, we are needing this support, collective healing, and thinking about the metaphor of the ketamine experience of going really inward."

– Veronika Gold, M.A., M.F.T.



"Psychedelics and ketamine are not a magic bullet or quick fix—it really is important to manage expectations because it needs to be a treatment tool in the context of a bigger treatment plan."

– Gita Vaid, M.D.

Psychedelics and the Brain

"I think there is a massive potential behind induced neuroplasticity; however, so far, this has only been shown in animals and we need to test whether this also holds true for humans."

– Katrin Preller, Ph.D.



Decriminalizing Psychedelics

"We are part of an intergenerational struggle to take psychedelics back to their historic place in our communities, reduce criminal penalties, and treat drug use, and psychedelics in particular, in a public health way rather than with a criminal justice approach."

– Sean McAllister, J.D.



"The impact of a person's drug use is much more impacted by the context of the drug itself that the drug is used in, and many drugs perceived as bad have important medical and even perhaps spiritually healing uses when done in a safer context than on the street under prohibition."

– Ismail Lourido Ali, J.D.





"From an evidence-based perspective, decriminalization seems to be one of the most effective ways of reducing drug harms, especially, and perhaps counterintuitively, for drugs with higher risk profiles."

— Natalie Lyla Ginsberg, M.S.W.

Psilocybin Mushrooms in Culture and Consciousness



"Psilocybin makes nicer people and better citizens, reduces criminality, and, I think, benefits society."

— Paul Stamets

Towards Legal Psychedelic Psychotherapy



"We are growing a lot internally to support not only the Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD, but also other initiatives and other indications because we don't want this only for PTSD—we want it for further indications, and we're looking at other drugs that will possibly develop in the future for other indications also."

— Amy Emerson



"Our real goal is mass mental health; it's not to maximize the amount of money that we make through selling MDMA, and it's not just to stay within a medical frame."

— Rick Doblin, Ph.D.

Psychedelic Peer Support: Models of Community Care

"The harm reduction approach accepts, for better or for worse, that licit and illicit drug use is part of our world, and chooses to minimize its harmful effects rather than simply ignoring or condemning them."

— Kwasi Adusei, DNP, PMHNP-BC

"If we are going to actualize the benefits of psychedelics on this planet, we need to adequately address the risks."

— Sara Gael, M.A.

"I think one of the most courageous things that we can do in this world is saying, 'I need help.'"

— Ryan Beauregard

Treating PTSD with MDMA-Assisted Psychotherapy

"MDMA and all psychedelic drugs are very responsive to the set and setting, and we were able to capture this set and setting dependence of MDMA function in our animal studies."

— Gül Dölen, M.D., Ph.D.

"MDMA-assisted psychotherapy manifests itself as a non-directive approach to the patient—you don't tell a patient what to do, but you guide the patient by just supporting the patient and facilitating the unfolding of whatever experience that is manifesting itself."

— Eric Vermetten, M.D., Ph.D.



We extend gratitude to the webinar speakers for their dedication to psychedelic education, the webinar attendees, and the MAPS volunteers who helped edit the transcripts of the webinar sessions.

We look forward to continuously expanding our online educational offerings, and hope to see you at the next MAPS webinar series!

For updates about upcoming MAPS events, please subscribe to the MAPS Newsletter (maps.org/newsletter) and check the MAPS Event Calendar (maps.org/calendar).



A Wholly Public Benefit Model

ANA LADOU, MAPS PBC CHIEF OPERATING OFFICER
KRIS LOTLIKAR, MAPS DEPUTY DIRECTOR



*“You never change things by fighting the existing reality.
To change something, build a new model that
makes the existing model obsolete.”*

— Buckminster Fuller

Psychedelics Go Mainstream

ALMOST FIFTY YEARS AFTER THE start of America’s War on Drugs, psychedelics have finally gone mainstream. On September 18, 2020, Compass Pathways pursued an initial public offering on the New York Stock Exchange, raising over \$100 million and quickly achieving a market capitalization of over \$1 billion (Statement, 2020). Less than two months later, voters in Oregon approved ballot measures to decriminalize drugs and permit the supervised use of psilocybin; voters in Washington D.C. joined those in other cities to decriminalize possession of psychedelic substances. These moments are milestones for the fields of psychedelic medicine, research, and policy. What was once seen as a fever dream of enthusiastic hippies has been decidedly embraced by the most buttoned-up financial institutions. This new era of billion-dollar psychedelic companies has us asking ourselves: where does MAPS fit, and how can we take advantage of this moment in history and the opportunity to create a better world?

Wholly Public Benefit Model

MAPS was established in 1986 as a 501(c)(3) non-profit research and educational organization to develop medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. In 2014, MAPS launched MAPS Public Benefit Corporation (MAPS PBC) as a subsidiary focused solely on completing the clinical research necessary to make MDMA an approved medicine by the U.S. Food and Drug Administration (FDA) and, eventually, to take this medicine to market. The non-profit organization wholly owns 100% of the public benefit corporation, so MAPS is the only shareholder and therefore, MAPS PBC’s only goal is to pursue MAPS’ mission while maximizing public benefit.

Over the last 34 years, MAPS’ wholly public benefit model has created tremendous public value and innovation. Without the constraint of focusing on profits for shareholders or just a few individuals, we can take intelligent risks, follow science, and focus on healing outcomes, while holding a meaningful seat at the table for questions of equity and access to be incorporated into our strategic planning. MAPS’ wholly public benefit model has allowed us to develop a thoughtful, a long-term strategy to bring MDMA-assisted psychotherapy to market, achieving breakthrough therapy designation with the FDA in the process, without sacrificing any primary endpoints (i.e., objectives) of its clinical studies for posttraumatic stress disorder (PTSD), an affliction that affects upwards of eight million Americans and 350 million people across the planet (Hoppen & Morina, 2019; Sareen, 2020).

Within our wholly public benefit model, MAPS evaluates the needs of all our stakeholders—patients, researchers, therapists, donors, staff, and policy makers—to create a platform for everyone to benefit, unlike companies prioritizing shareholders or the few who are putting up the capital. The wholly public benefit model aims to consider the collective over the individual, and honor the psychedelic traditions of generosity and transparency.

Turning Traditional Business Model on its Head

This fall, MAPS PBC launched the second Phase 3 trial of MDMA-assisted psychotherapy for PTSD in the U.S., Canada, and Israel, and opened enrollment for Phase 2 trials in multiple European countries. In addition to the clinical trials, we have been given breakthrough designation by the FDA, allowing for an expanded access/compassionate use program to provide the treatment to some patients prior to approval and in turn

allowing more locations to start the MAPS PBC protocol early. As we review results from the first Phase 3 study, we are embarking on a number of pathways to innovate patient access and go-to-market strategies with a clear-eyed focus on public benefit. Similar to how MAPS has defined public education around the healing properties of psychedelics over the last 34 years, MAPS PBC is defining the road ahead for psychedelic research and patient access. The mainstreaming of psychedelics didn't happen overnight and it didn't happen by accident; MAPS, along with other leaders in the field, has been methodically and persistently building the case for this moment over the last three decades, and will continue to transparently share all of our materials in a bid for trust and building a new paradigm in psychedelic clinical research.

Traditional pharmaceutical companies invest billions of dollars in research and marketing for new medications, often ignoring off-patent medicines like MDMA in favor of drugs that they can invent and make millions of dollars from. Their ability to engage in cutting-edge research for select patient populations is further impacted by their duty to maximize profits for shareholders. This has not served them well in building trust with the public. MAPS has solved the problem of prioritizing financial returns over human returns by turning the traditional business model for drug development on its head and creating a wholly public benefit model.

Business as *Unusual*

As with any strategy, there are trade-offs. MAPS is funded entirely by donations, solely on the merits of our work and its potential to create a public benefit. MAPS and MAPS PBC's work have world-changing potential, but bringing it to the whole world comes with a high price tag. Since MAPS' founding, Rick Doblin, Ph.D., has continually inspired donors to support the next project, then demonstrate progress and success, and then raise funds for the next phase of work. The challenge has always been to share the vision of healing over profits, but it has kept MAPS and MAPS PBC dynamic, focused, and accountable. MAPS PBC's next phase is to develop thoughtful go-to-market strategies that prioritize patient safety and equitable access rather than the highest profit possible, and any sales revenue will go towards further research, supporting public education, harm reduction, and drug policy reform, rather than providing returns to shareholders.

MAPS and MAPS PBC continue to attract and keep talent without offering millions in stock options. The reality is that there are an increasing number of people for whom meaningful work and the potential to leave a legacy is at a premium. Many members of the MAPS and MAPS PBC staff are leaders in their fields, have come out of retirement, or left

behind highly paid consultant positions to join us because they believe the eventual impact on the mental healthcare system will be historic. They innovate alongside the cadre of pro bono advisors who work for free for MAPS and MAPS PBC because they also believe public benefit is more important than personal wealth. These growing and evolving teams get to work with amazing teammates, and also have the opportunity to leave a meaningful legacy for humanity.

MAPS PBC is years ahead of any other effort within the field of psychedelic science, with our first successful Phase 3 clinical trial now behind us and commercialization rapidly approaching. We know that faster and bigger aren't always better, and having a thoughtful strategy going to market is key to our long term strategy; we balance this intentionality with the reality that millions of PTSD patients are waiting.

Historical Legacy of Psychedelic Medicine

Our wholly public benefit model aligns with the historical legacy our work is built upon as MAPS' success derives from the hard work and ideas of many others. This model is consistent with the history of psychedelic healing, which is steeped in and informed by Indigenous practices, traditional healers, early psychedelic researchers, breath-workers, somatic healers, and many others who have led the way. MAPS did not invent psychedelics. MAPS did not invent psychedelic therapy. MAPS did not even invent MDMA. It is important not to repeat the mistakes of the past by appropriating knowledge and know-how of others for individual gain. The "rediscovery" of psychedelics by Western culture has inspired a new wave of researchers, writers, botanists, and artists who became interested

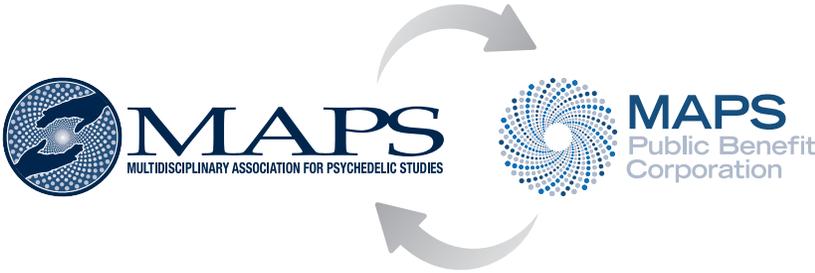
in psychedelics for their wide array of uses: psychiatric healing, artistic inspiration, and even spiritual growth and enhancement.

We all hold a piece of the puzzle, and our hope is that we can work together as partners, instead of competitors, in building out the ecosystem. With our multidisciplinary approach and wholly public benefit model, we endeavour to collaboratively focus on the root causes of the challenges we face

together. Thanks to the generosity of each of our donors, we have been able to focus solely on a public benefit buildout of a fledgling but resilient psychedelic-assisted therapy ecosystem: a mycelial network of psychedelic therapy clinics across the United States, and now in Canada, Israel, and Europe. We believe that by working together—as did our predecessors in these psychedelic endeavors—we can achieve better results for humanity. MAPS' support of other organizations, through fiscal sponsorship and grants, has ensured that we are not the only organization engaging in research because our hope is that together, we can shift the way mental health services are

The mainstreaming of psychedelics didn't happen overnight and it didn't happen by accident.

brought to communities. Our dedication to open science and to creating, establishing, and researching best practices for psychedelic-assisted therapy and therapist training will ensure that future generations of researchers—including the new generation of for-profit companies—will have access to and benefit from our training materials, drug compound chemistry, research protocols, and any other materials we develop (Cooperation over Competition, 2018). In a sense, we have already “gone public” through our commitment to creating a new model for the delivery of mental health services to all people who may benefit.

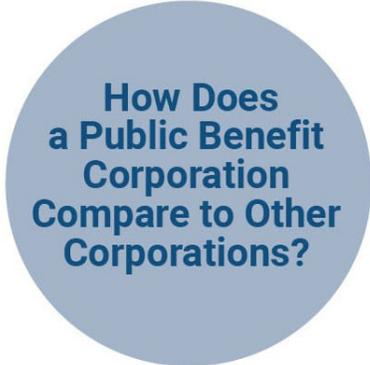


We believe that by working together—as did our predecessors in these psychedelic endeavors—we can achieve better results for humanity.

Multidisciplinary Roots

The “M” in MAPS stands for *multidisciplinary* because MAPS combines scientific research and drug development with education and advocacy. We recognize that public health and criminal legal reform are inextricably linked, and we will not forget how we got here: the racist War on Drugs that repressed scientific advancement, destroyed countless lives, and ultimately held back psychedelic medicine breakthroughs for decades. We are proud that MAPS PBC just completed the first half of a successful Phase 3 trial for MDMA, a Schedule I controlled substance that was declared to have no medical value in 1985. We are not going to be able to address the health disparities plaguing mental health if we don’t change the drug laws, too, so we are determined to change laws and treat patients in equal measure. Perhaps the most important aspect of our wholly public benefit model is MAPS’ ability and willingness to take risky political positions and stand by what we believe is right for the public benefit. In part because of MAPS’ freedom from investors, who sometimes discourage controversial stances to avoid turning off their potential customers, many of MAPS’ early “controversial” positions have slowly become mainstream.

Non-Profit Corporation	Public Benefit Corporation	Traditional Corporation
Tax Exempt Status	Pay Taxes	Pay Taxes
Operate for Charity	Operate for Profit	Operate for Profit
Does not profit as an organization	Spends profits on a specific benefit	Spends profits any way desired
Not obligated to be transparent with progress	Obligated to be transparent with progress	Does not operate specifically for a benefit or charity
No shareholders or stocks	Shareholders and Stocks*	Shareholders and Stocks



*MAPS Public Benefit Corporation is owned by one shareholder. MAPS Public Benefit Corporation (MAPS PBC), is a wholly owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS). MAPS funds MAPS PBC to cover the costs of research, clinical trials, programs, and operations. MAPS PBC’s proceeds further MAPS’ mission.

Defining Public Benefit

When your goal is radical change, there are bound to be obstacles. Operating within a wholly public benefit model in the pharmaceutical space raises questions and increases complexity. How do we define and track our success in achieving public benefits and outcomes? How do we meet our financial needs while listening to all stakeholders? How do we maintain our values and principles while working inside economic systems that are built around profit and extraction? Over the next year, MAPS intends to define in specific terms how we will measure and report our public benefit. This will allow our community to better engage with the work we do and hold us accountable.

Psychedelics are undoubtedly stepping out of the shadows. But that does not mean that MAPS and MAPS PBC are abandoning unique approaches to problem solving. We dream of a future where pharmaceutical companies begin asking themselves whether a model focused on healing and public benefit has the potential to outperform the old paradigm, not only for specific shareholders but for the public at large. MAPS' 34-year track record of collaboratively creating a new ecosystem has been accomplished with the faith and trust of our supporters, staff, and volunteers. Thanks to them—and each of you—we will continue to develop and implement the wholly public benefit model, and co-create a future that challenges all of our beliefs about what is possible.

ANA LADOU serves as the Chief Operating Officer (COO) for MAPS Public Benefit Corporation (MAPS PBC) where she oversees IT, People Operations and Culture, Facilities, Corporate Communications, Governance, and GxP QA and Compliance. Prior to joining the MAPS team, she led organizations with local, national, and international reach where her strengths in relationship building, collaborative leadership, and process development ensured efficiency and innovation. Ana graduated from Columbia University in New York and launched her career in marketing at Miramax Films. She went on to hold leadership roles at a number of technology firms and nonprofits where she became known for her ability to work across an organization to deliver credible and visionary strategies. She is committed to her Vipassana mindfulness and Nonviolent Communication (NVC) practices, and making our world a more compassionate and equitable home for all living beings.

KRIS LOTLIKAR serves as the Deputy Director for MAPS. Kris is an experienced entrepreneur and futurist. Kris founded Renewable Choice and served as President for fifteen years. Renewable Choice was a leading supplier of renewable energy to global corporations and clients included over 150 companies from the Fortune 500. It was awarded Green Power Supplier of the Year four times between 2011 and 2016 by the EPA. Renewable Choice was acquired by Schneider Electric in 2017. Kris has maintained a life-long commitment to drug policy reform since founding Students for Sensible Drug Policy (SSDP) twenty-two years ago. SSDP has grown to a UN-recognized NGO with a presence on 300 campuses in 32 countries. Kris has served on the Board of Directors for SSDP, the League of Young Votes, the Flex Your Rights Foundation, and the Arcview Group.

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Developing Ethical Guidelines in Psychedelic Psychotherapy

SHANNON CARLIN, M.A., AMFT, MAPS PBC DIRECTOR AND HEAD OF TRAINING AND SUPERVISION

SARAH SCHELD, M.A., MAPS PBC TRAINING AND SUPERVISION ASSOCIATE

The content of this article may be triggering to those who have been impacted by trauma or ethical violations of a sexual nature.

“Ethics is reverence for life rooted in right relationship with another.”

— Kylea Taylor, M.S., LMFT, *The Ethics of Caring*

Ethics: Nonmaleficence

A CODE OF ETHICS FUNCTIONS to define and articulate the moral standards of a group, such as a profession or workplace. Ethical codes in healthcare prioritize a commitment to the dignity of patients and clients (Center for the Study of Ethics in the Professions, 2020). One of the earliest known codes of ethics, written as early as the third century, is the Hippocratic Oath, a set of ethical standards for physicians (Hippocrates, 1923):

Into whatsoever houses I enter, I will enter to help the sick, and I will abstain from all intentional wrong-doing and harm, especially from abusing the bodies of man or woman, bond or free.

Many of the early ethical codes, in both Western and Eastern culture, were based on a religious sense of morality. Hippocrates, for example, began the Oath with a declaration to Apollo and the Greek gods and goddesses of medicine. Modern codes are more pragmatic, focusing on practices that have been shown to demonstrate efficacy (Wear et al., 1993). Still, early precepts, such as the Hippocratic Oath, have been fundamental in the evolution of medical ethics.

To this day, a primary tenet of healthcare ethics is *nonmaleficence*. In the 2006 book *Ethics in Health Administration*, Eileen E. Morrison offers this definition of nonmaleficence: “to use the most appropriate treatment for the condition and have provided that treatment with the least amount of pain and suffering possible” (p. 46). Morrison explains that efforts to alleviate suffering in the long term almost always introduce some amount of suffering in the short term. The responsibility of health care providers is to make ethical decisions regarding the potential risks and benefits of treatment procedures, and to provide participants with information and options whenever possible so that they too can make informed choices about their care.

Therapeutic Relationship, Transference, and Countertransference

Attending to the commitment of nonmaleficence in psychotherapy requires therapists to develop relationships with participants that are appropriate and likely to cause the least amount of suffering. The relationship between a participant and their therapist is called the therapeutic relationship; it is an important component of therapy and requires careful attention from therapists. Many psychotherapies emphasize a relational component of therapy: ideally participants can explore various ways of relating, express themselves authentically, establish a deeper sense of safety, and practice healthy boundaries. Through the process of therapy, participants internalize experiences of safety, expression, and boundaries, and apply these experiences in situations and relationships throughout their lives.

One of the ways this relational repatterning happens is through a process called *transference*, in which the participant's feelings about a past situation or person in their life are redirected, or *transferred*, onto the therapist. Sigmund Freud first described transference in 1895, since which the field has created various interpretations and applications of the concept.

Through the process of transference, the participant may, at times, perceive the therapist as a representation of an attachment figure or other symbolic person from the participant's life. In this process of redirection, the participant may explore or test the relationship with the therapist. For example, a participant who had experienced sexual abuse may explore trust and safety with her therapist. This can look countless ways; for example, the participant might explore trust by deciding how close to sit to the therapist in the therapy room, asking if the therapist would hold her hand, or asking if the therapist is attracted to her. Therapists are trained to respond to transference in ways that are likely to support the participant's therapeutic process and unlikely to cause undue harm. In responding to transference, the therapist takes great care to maintain the safety and integrity of the therapeutic container.

The therapist is also responsible for managing their own feelings, including feelings towards the participant, referred to as *countertransference*, while upholding professional boundaries in service to the participant's safety and dignity. By attending to transference and countertransference appropriately, the therapist supports an ethical therapeutic relationship and nonmaleficence.

Speaking to the healing power of therapeutic relationships built on trust, Courtney Hutchinson and Sara Bressi (2018) write, "First and foremost, trauma survivors have experienced ruptures in trust—trust in the safety of the world, in the goodness of others, in their own inherent value. Too often, these ruptures are then tragically repeated and reproduced in relationships with important others, clinicians, and institutions." An ethical practice promotes an environment of safety, support, and trust, where participants can heal from life experiences that were not safe, supportive, or worthy of trust.

Considerations for Psychedelic Psychotherapy

Although psychedelic substances have been used therapeutically for centuries, and the practice of psychedelic-assisted psychotherapy is several decades old, the modality is only now slowly gaining acceptance in standard clinical practice. Clinical trials and regulatory approval of psychedelic medicines are creating legal avenues for psychedelic psychotherapy.

While psychedelic psychotherapy incorporates standard psychotherapeutic principles, aspects of the modality require unique clinical skills and competencies. First of all, psychedelic psychotherapy involves the combination of psychotherapy and a psychedelic substance, requiring collaborative delivery of medical and mental health care. Medical professionals working in the field of psychedelic psychotherapy need

Through the process of therapy, participants internalize experiences of safety, expression, and boundaries, and apply these experiences in situations and relationships throughout their lives.

to be aware of the therapeutic process and approach. Mental health professionals working with psychedelics need to be able to recognize potential medical issues, monitor vital signs, and know when to call for medical attention.

Unlike the typical format of weekly one-hour (or 50-minute) sessions, psychedelic sessions are much longer; for example, MAPS' MDMA-assisted psychotherapy sessions are eight hours long, designed to match the duration of drug effect and the intention to support deep process. Additionally, many psychedelic psychotherapies adopt a co-therapy model: two practitioners working together with each participant, again designed to support the depth of work.

In addition to these logistical differences, psychedelic substances can evoke direct experiences of insight, aspects of self, traumatic memories, somatic sensations, and spirituality. MAPS' approach to MDMA-assisted psychotherapy aims to provide an environment of safety and support for individuals to engage with their own *inner healing intelligence*, a person's innate wisdom and ability to move toward wholeness and authenticity. Practitioners support participants in arriving at their own insights and finding trust in the wisdom of their own body and mind to heal. Psychedelic therapists help participants navigate the psychedelic experience and work with non-ordinary states as a resource in the therapeutic journey.

Psychedelic states present the possibility for greater openness and empathy, which are viewed as assets in therapeutic work leading to authenticity, transparency, self-acceptance, perspective, and connection. It's important to understand, however, that with greater openness and empathy, a person in a psychedelic state may also be highly suggestible, especially prone to the suggestion or influence of others. This introduces an even greater need for client-centered approaches, therapeutic skill in navigating transference and countertransference, and professional boundaries in psychedelic therapy. Psychedelic psychotherapy heightens the importance of trust, trustworthiness, and safety.

The process of therapeutic relationship and the dynamics of trust place a significant amount of power and responsibility in the hands of the practitioner. Many psychotherapeutic ethical codes speak to the need for practitioners to be aware of the power differential in therapeutic relationships and to use their role power consciously and ethically. Cedar Barstow, author of *Right Use of Power* (2008) and a reviewer of the MAPS Code of Ethics, writes, "not only do we all have the capacity to misuse power, but we are all subject to the addictive trance of elevated power that reduces our empathy and inhibitions and pulls us toward prioritizing our own needs and interests because our

higher role or rank allows us to." Psychedelic therapies may also shift the power dynamics between participants and therapists toward greater balance and reciprocity. The therapeutic approach of MDMA-assisted psychotherapy is described as "inner directed," meaning the participant's inner healing force guides the therapeutic process. Instead of directing or interpreting unconscious material, the practitioner respects the participant as the authority of their consciousness and healing, and offers guidance only to support the participant in moving through their process. "Placing clinicians as alternatively facilitators and 'empathic witnesses' disrupts inherent power dynamics in the therapeutic alliance" (Hutchinson & Bressi, 2018, p. 427).

Developing a MAPS Code of Ethics for Psychedelic Psychotherapy

Given that psychedelic substances induce non-ordinary states of consciousness, extra care and attention must be given to support these states and use them skillfully as a therapeutic tool. With these unique aspects in mind, specific training and guidance is needed to support the ethical practice of psychedelic psychotherapy. The groundwork for ethical codes in non-ordinary states has been laid out through the efforts of groups such as the Council on Spiritual Practices, who developed their first version of a "Code of Ethics for Spiritual Guides" in 1996. Learning from the work of others, the MDMA Therapy Training Program sought to develop a Code of Ethics for its practitioners.

In early 2018, the MDMA Therapy Training Program began developing a Code of Ethics, aiming to define the ethical guidelines and agreements of practitioners working on MAPS protocols. Drafting the Code of Ethics took a full year of research, reflection, and review. The Code was edited by the authors of this article: Shannon Carlin, M.A., AMFT, MAPS Public Benefit Corporation (MAPS PBC) Director & Head of Training and Supervision, and Sarah Scheld, M.A., MAPS PBC Training and Supervision Associate. More than a dozen reviewers and contributors from the fields of psychology, psychedelics, medicine, and ethics contributed their experience and perspective, including: Cedar Barstow, MEd, CHT, Marca Cassity, BSN, LMFT, Karen M. Cooper, M.A., R.N., Leia Friedman, M.S., Shai Lavie, MFT, Ismail Lourido Ali, J.D., Annie Mithoefer, BSN, Michael Mithoefer, M.D., Angella Okawa, LMFT, Marcela Ot'olora G., LPC, Bruce Poulter, R.N., Dominic A. Sisti, Ph.D., Kylea Taylor, M.S., LMFT, Verena Wieloch, LPCA, LCAS, and several others who generously provided feedback and wisdom.

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One reviewer, Kylea Taylor, authored the book *The Ethics of Caring*, which describes a method she calls InnerEthics, a practice that supports clinicians in navigating ethical issues and reflecting on their own therapeutic work with expanded states of consciousness. Taylor writes:

The deeper a client moves into a state of consciousness which has an inner or transpersonal focus, the greater the need for a professional's adherence to the ordinary ethical issues and the greater the need for professional self-reflection, supervision, and an ethic of care.

The MAPS Psychedelic Psychotherapy Code of Ethics was published in April 2019, appearing in the Spring edition of the *MAPS Bulletin*. The updated and re-named MAPS Code of Ethics for Psychedelic Psychotherapy has twelve sections:

1. Safety
2. Confidentiality and Privacy
3. Transparency
4. Therapeutic Alliance and Trust
5. Use of Touch
6. Sexual Boundaries
7. Diversity
8. Special Considerations for Non-Ordinary States of Consciousness
9. Finances
10. Competence
11. Relationship to Colleagues and the Profession
12. Relationship to Self

The remainder of this article will focus specifically on the ethical guidelines for sexual boundaries. The reason for this focus, knowing that every section of the code has deep and meaningful history and context worthy of discussion, and that sections are interdependent and inform one another, is to highlight an area that continues to present ethical challenges and social taboos across the disciplines of healthcare and many professions. Additionally, though the Code has undergone minor edits since its original publication, the guideline around sexual intimacy with former clients has specifically undergone significant modification, which is described and explained below.

Practicing integrity in therapeutic relationships requires confronting past experiences and beliefs about love, attachment, and relationship—those of the therapist, client, and society.

Love in Therapy

Psychotherapy is an intimate process, clients risk sharing their fears and grief and practicing trust and connection. Judith A. Schaeffer describes that, in therapy, clients risk being loved and expressing love, which both provide direct experiences counter to the thought that one is unlovable or incapable of loving. The loving attention of a therapist can support a participant's experience of safe and healthy love. Too often experiences of love are entangled in relationships of abuse and neglect. Therapists must work proactively to ensure that their relationships with clients do not repeat familiar patterns of abuse and neglect. Practicing integrity in therapeutic relationships requires confronting past experiences and beliefs about love, attachment, and relationship—those of the therapist, client, and society.

Judith A. Schaeffer (2019) writes:

[T]ransference love arises when clients perceive their therapist as someone from their past and thus transfers love related to an unresolved affiliate conflict from the past to the present. Countertransference love arises when a therapist does this. It also arises simply when a therapist receives a client's transferred feelings, thoughts, and sensations.

Fortunately, what usually comes alive in therapy is non-erotic transferred love. However, that form of love may evolve into other forms: the erotic, the eroticized, and the perverse. And these forms can be initiated by either client or therapist. Similarly, they can be received and responded to by either client or therapist.

Many people carry shame, trauma, and repressed feelings about sexuality. MDMA can be used as a therapeutic tool to support the healing of sexual trauma. MDMA's subjective effects include feelings of openness, empathy, connection to others, and heightened sensuality, which can aid in revisiting traumas with a new/renewed sense of resource and safety.

Psychedelic states may also intensify sexual feelings felt by the participant towards the therapist and sexual feelings felt by the therapist towards the participant, requiring a greater level of therapist self awareness and regulation as well as meaningful training and supervision in how to work with sexual feelings in psychotherapy. Kylea Taylor reflects that psychedelic sessions can open up powerful emotions not only for participants, but also for practitioners, who should not underestimate the unconscious fears and longings that can be catalyzed when holding space for others in expanded states of consciousness.

As with any powerful tool, when used with care, skill, and clear intention, MDMA can be a valuable healing resource.

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Professional Sexual Boundaries

Ethical codes within the field of mental health consistently prohibit sexual relations between professionals and clients who are currently in treatment. However, professional organizations have varying views on when, if ever, it might be considered acceptable for a therapist to engage sexually with *former* clients. For example, the American Psychological Association and the California Association of Marriage and Family Therapists both state that therapy providers must not engage in sexual intimacies with former clients for at least two years after termination of therapy (CAMFT Code of Ethics, 2020; Ethical Principles of Psychologists and Code of Conduct, 2017). The American Psychiatric Association simply states, "sexual activity with a current or former patient is unethical" (The Principles of Medical Ethics, 2013). The CAMFT Ethics Committee recently made substantive revisions to their Code of Ethics, including requirements for therapists to assess certain factors prior to engaging in a sexual relationship with a former client to avoid potential harm or exploitation (Griffin, 2020).

When MAPS began drafting the Code of Ethics, we were faced with this same question: when, if ever, is it ethical for an MDMA-assisted psychotherapy provider to engage sexually with a former participant? As the organization set out to formalize its standards for the clinical practice of MDMA-assisted psychotherapy, we were faced with widely divergent examples in the field of psychotherapy. When we looked into the rationale behind the two year post-termination period, we found that some organizations further clarified the rule by adding that, in addition to the two year period, the practitioner must also demonstrate that the relationship does not involve any exploitation, making this an "almost never rule" (Sturm, 1998). The American Psychological Association additionally claims that permanently prohibiting sexual involve-

ment may compromise the client’s autonomy in choosing their personal relationships (Behnke, 2004). Yet some would argue to support a permanent ban on sexual involvement with clients, claiming that because of the power imbalance, the client may not be in a position to clearly evaluate the risks of becoming intimately involved with their practitioner (Sturm, 1998).

After much consideration and consultation, the MDMA Therapy Training Program determined that practitioners working in the MAPS modality should *never* engage sexually with clients or former clients, at any point during or following treatment.

The vulnerability required to do healing work deserves tremendous respect and should be held with care always. MAPS sought an ethical standard that would do justice to the trust and vulnerability that participants share with their therapists.

The MAPS Code of Ethics for Psychedelic Psychotherapy states that therapy providers “do not engage in sexual intercourse, sexual contact, or sexual intimacy with a participant, former participant, their spouse or partner, or their immediate family member, at any point during treatment or following termination.” Therapy providers who are found to violate this Code face the consequence of losing their MAPS certification to practice MDMA-assisted psychotherapy.

Addressing Sexual Ethics Violations

In the MAPS protocols, sexual engagement between providers and participants is never ethical and it is strictly prohibited. It is the therapist’s responsibility to uphold professional boundaries.

However, shortly after MAPS commenced initial research on the Code of Ethics, in April 2018, the organization learned of a serious ethical violation that had taken place between a MAPS therapist and a study participant. In 2015, a therapist working on a Phase 2 trial of MDMA-assisted psychotherapy for PTSD entered into an inappropriate relationship with a participant, which became sexual. In research settings, participants report grievances to the Institutional Review Board (IRB), the independent ethics committee designated to protect the rights of research participants; however, the scope of the IRB is limited in its ability to address grievances beyond the active phase of clinical trials. The participant in this situation filed a grievance with the IRB, but since the study was complete and the investigators were no longer working on research protocols, there was little action the IRB could take in response to the grievance. The participant then reported the grievance to MAPS. At the time the organization didn’t have a formal process for handling grievances directly; clinical trial Sponsors refer to the IRB which has structures and procedures to handle grievances. However, the lack of meaningful support and responsive action motivated MAPS to respond to the grievance and provide resources for the participant to access care while

addressing the ethical violation. For more information, please see MAPS’ Public Announcement of Ethical Violation by Former MAPS-Sponsored Investigators (2019). This ethical breach highlighted the crucial need to bring honest attention to the real potential for such violations, and to create structures to prevent and address ethical transgressions.

Clear grievance procedures are needed for participants in psychedelic psychotherapy. MAPS is aware that there are gaps for participant protection in psychedelic research and clinical settings. While ethical review in research settings is handled by IRBs, the ethical oversight of clinical practice beyond research is typically handled by professional associations and licensing boards. As the modality of psychedelic psychotherapy enters into standard clinical practice, new guidelines, associations, and perhaps new credentialing boards will be needed to protect consumer and provider liability.

In light of this, MAPS has been developing procedures for addressing grievances, which has included hiring an Ethics and Compliance Officer, establishing pathways for receiving grievances, and policies for appropriate review and response to grievances. Community members in the psychedelic field are currently working to establish professional associations focused on psychedelic therapies. The establishment of standing ethics boards specializing in psychedelic psychotherapy could go further to provide meaningful resources to clients who have been harmed by ethical violations—resources such as funds and appropriate referrals for reparative psychotherapy, referrals to peer support groups, education and support to family members and others who may be impacted, not to mention resources for providers in the wake of grievances filed against them, to encourage and support authentic self-reflection and responsibility.

The MDMA Therapy Training Program is committed to ethical practice. The Code of Ethics is now a foundation for our training curriculum. All therapy providers and study staff members working on MAPS protocols are oriented to the Code and sign their agreement to uphold its tenets. Structures to enforce the Code and support participants, such as a Participant Bill of Rights, are in development. The Code of Ethics will remain a living document to grow and adapt with the ongoing integration of feedback and evolution of needs over time.

Participant safety is the first priority in the field of healthcare.



Supporting Providers in their Ethical Commitments

Participant safety is the first priority in the field of healthcare. In service to participant safety, it is essential for practitioners to understand the legal and ethical parameters of therapeutic work. Clinical training programs relay the rules against sexual involvement with clients, and impress a strong warning never to have sex with a client, yet a significant number of care professionals still cross that line. This is a violation of trust in a profession that requires so much trust from patients and clients.

Data from a national pool of mental health professionals shows that the incidence of sexual contact between clients and practitioners in the United States ranges between 7–12% (Alpert & Steinberg, 2017). Given that these cases are self-reported, it's likely that the prevalence may even be higher.

Kenneth S. Pope and colleagues conducted extensive research in the 1980s exploring the topic of sexual attraction to clients. In Pope's survey of over 500 therapists, 87% reported having been sexually attracted to a client, and although only a minority acted on their feelings, many felt guilty, anxious, or confused about their attraction. About 50% of psychotherapists claimed they did not receive any guidance or training concerning sexual attraction to clients, and only 9% reported that they had received adequate training or supervision on the matter (Pope et al., 2006).

Pope highlights the need for training programs to acknowledge and examine the phenomenon of sexual attraction to clients and to provide clinicians with tools to recognize and work with this form of countertransference. Clinical training programs should support trainees in acquiring the knowledge and skills necessary to recognize and respond appropriately to sexual attraction, both attraction expressed by the client as well as attraction felt by the therapist. Competence in working with erotic transference supports clinicians in their ability to uphold professional boundaries, and further, in the ability to actually use erotic transference as a therapeutic tool.

Sexual attraction is a common human experience, especially in intimate settings. Psychotherapists don't tell clients to simply stop feeling a feeling and to be sure not to act on it,

instead, they help clients explore feelings and develop tools to work with them so they can know themselves better and make conscious decisions. Therapists are provided basic instruction in how to respond to a client's expression of attraction to the therapist, but they are provided very little, if any, guidance to work with their own attraction to a client. The clinical field must break the taboo and do for therapists what therapists aim to do for clients, provide safe and open spaces to develop tools and work with feelings, including sexual feelings, and especially sexual feelings in the therapeutic environment.

In addition to focused efforts to create procedures and resources to support *clients* who have been harmed by ethical violations, clinical programs should also put resources towards preventing ethical infringements through meaningful training, supervision, and ongoing support for clinicians. When asked how to address sexual ethics violations in psychotherapy, many leaders in the field respond that the focus must be on a preventative approach, working with providers to foster open dialogue and authentic support in the times it is most needed.

Ongoing supervision, peer consultation, and support groups can be non-judgmental spaces for providers to talk about the most challenging aspects of their work, which is so important for the ongoing safety, integrity, quality, and sustainability of their practice and their own well-being. As with many health care professions, isolation and burnout are common for psychotherapists.

While ongoing supervision and resources for self and community care are essential throughout a practitioner's career, practitioners must also take responsibility for their own projections, countertransference, and personal needs in relation to participants, engaging in ongoing self reflection, and receiving and integrating feedback from supervisors and peers.

Thankfully, more and more people are addressing issues of sexual abuse and gender-related discrimination in psychedelic spaces. By promoting safe spaces to gather feedback, listening to the stories of survivors, and openly discussing the ethical challenges facing providers, we create healing environments worthy of trust.



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SARAH SCHELD, M.A., is Training and Supervision Associate at MAPS Public Benefit Corporation (MAPS PBC). In her role with the MDMA Therapy Training Program, Sarah supports supervision and training for MDMA-assisted psychotherapy providers, and program and curriculum development. She received her M.A. from the California Institute of Integral Studies' East-West Psychology program, focusing on psychedelic and Gnostic studies. Sarah has trained extensively in somatic experiential psychotherapies such as Hakomi and Somatic Experiencing, and spoken publicly on somatic and trauma-informed approaches to psychedelic psychotherapy. In addition to her dedication to therapeutic trauma work, Sarah enjoys engaging in trauma healing through art and storytelling; with a professional background in production design and filmmaking, her writing and film work explore the archetype of rape and sexual violence. She is passionate about the role of trauma awareness and the skillful use of psychedelic medicines in individual and collective healing. She lives in Occidental, California.

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Living Our Values

MAPS Establishes an Ethics and Compliance Program

LESLIE BOOHER, J.D., M.B.A., MAPS LEGAL AND POLICY ASSOCIATE
in conversation with

SETH WHITELAW, J.D., LL.M., S.J.D., MAPS CHIEF ETHICS AND COMPLIANCE OFFICER



SINCE MAPS WAS FOUNDED, THE principles of transparency, trust, and accountability have governed how the organization works to achieve our mission of developing medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. Those principles were passed down to MAPS Public Benefit Corporation (MAPS PBC) to guide the development of MDMA-assisted psychotherapy. These principles define how we act in relationship to the wide variety of stakeholders with interests in our work.

Addressing the impact of trauma is a significant obstacle, but one worth tackling for the greater engagement and fullness of life it can offer. Our work applying research-based, psychedelic-assisted therapies requires some reimagining of not just the preexisting symptom management paradigm in mental healthcare, but also some aspects of conducting business and relating to the public. As MAPS Founder and Executive Director Rick Doblin, Ph.D., often says, “We are taking not just a new approach to mental health, which is psychedelic-assisted psychotherapy, but a new approach to marketing medical treatments and drugs. And so, we have a great responsibility on our shoulders.”

However, like most things in life, the words transparency, trust, and accountability come easily, while living them every day is much harder.

MAPS’ growing size, progress in clinical trials, increasing breadth of activities, and public awareness makes centralizing complex roles a worthwhile endeavor. So, to meet this expansion and remain consistent to our principles, MAPS decided it was vital to establish a formal Ethics and Compliance Program with a Chief Ethics and Compliance Officer taking the lead.

Dr. Seth Whitelaw, our new Chief Ethics and Compliance Officer, joined the MAPS family in June. As a food and drug lawyer, Seth has worked with numerous drug and medical device companies as both an in-house compliance officer and a consultant. He also teaches ethics and compliance for Mitchell Hamline School of Law and is the editor of a compliance publication, *Policy & Medicine Compliance Update*. Most recently, he served as a compliance expert for the plaintiffs in the ongoing Opioid Multidistrict Litigation. The father of two grown sons, he lives in West Chester, Pennsylvania, with his wife and four dogs.

Seth’s work on the ongoing implementation of an Ethics and Compliance Program is critical to MAPS’ mission, so we are pleased to share his perspective about his role and an overview of the program.

Leslie Booher (LB): How would you describe your role?

Seth Whitelaw (SW): I have struggled with how to describe what I do for people who are not familiar with my role or an Ethics and Compliance Program. However, if you think of MAPS as building, I am helping MAPS, and its subsidiaries, build and maintain a solidly supported ground floor that meets the local building codes (compliance) so that floor does not collapse. Since MAPS has significant aspirations, I help put the framing in place for the organization to successfully grow and be a leader. And like any building, there always is maintenance to do, so compliance is really a journey and not a destination.

Put another way, a former CEO of mine, J.P. Garnier, describes the role as having three primary components: missionary, diplomat, and police officer. A compliance officer needs to be a true believer in the goal of achieving the organization's objectives in the right way. They also need to convey the hard messages with diplomacy and tact lest the message becomes about the messenger. In the role of police officer, enforcing accountability must be tempered with justice and kindness. Sometimes mistakes are just mistakes.

LB: What skills and interests are important for your role?

SW: You need to be a quick study and always learning. The Chief Ethics and Compliance Officer doesn't always have the answers but needs to know how to get them. One of things I love most about teaching law school is that my students teach me as much as I hope I teach them. Everyone I've met so far in MAPS has been both patient and generous explaining things that are second nature to them but are new to me.

Finally, you need to be innately curious and willing to ask "why" when things don't make sense. However, that curiosity also needs to be tempered with skepticism and not accepting the easy answer of "because we've always done it that way." However, at MAPS, that does not seem to be an issue, as we are always challenging the status quo—in a good way.

LB: So, are ethics and compliance your responsibility?

SW: Yes and no. While I am the most visible face of the program, behaving ethically and compliantly is the responsibility of everyone in MAPS. When I first started in this role at another company more than 25 years ago, it was designated as the Compliance Coordinator. In some ways, that title is more appropriate because I help coordinate our ethics and compliance efforts, but I cannot do it alone. Ethics and compliance truly is a team sport, or as I have heard you say, "teamwork makes the dream work."

LB: If MAPS has a strong ethical foundation, why do we need an Ethics and Compliance Program?

SW: Yes, MAPS does have a strong ethical foundation. So many organizations that I have worked with are at the same point in the product development cycle and size as MAPS, but do not have that foundation. Instead, they are so focused on getting the product approved and on the market that they neglect the culture and values of the company. MAPS never did that, but rather framed its mission, including its efforts around MDMA-assisted psychotherapy and its efforts to change drug policy and make it more equitable for all, around its culture and values.

However, a strong culture and values are not enough. We need to have consistency. We also need to demonstrate to legislators and regulators that we indeed are being true to our values. Or to paraphrase William Duncan Vandiver, "I'm from Missouri, show me." The Ethics and Compliance Program provides a framework to accomplish both of these goals.

We also need the program because in this complex world, there is a broad spectrum of legal and regulatory requirements that organizations, especially drug development organizations, need to comply with beyond just the requirements of the U.S. Food and Drug Administration (FDA) or the Drug Enforcement Administration (DEA). These other legal and regulatory requirements often intersect with, or in some cases overlap, one another. Having an Ethics and Compliance Program helps ensure that we see the forest and not just the trees to avoid missteps.

LB: What makes up an Ethics and Compliance Program?

SW: Without going into too much detail, the framework, as it has evolved since the mid-1980s, encompasses eight standard elements of an organizational program of due diligence, reasonably designed to prevent and detect violations of law. Those elements, put simply, are: (1) having policies and procedures, (2) having a compliance officer, (3) avoidance of improper delegation of organizational authority, (4) communication of standards and procedures to staff, (5) monitoring, auditing, and reporting functions, (6) consistent enforcement, (7) effective response and mitigation, and (8) ongoing risk assessment. (To learn more see pharmacongress.com/wp-content/themes/ipc/documents/LS_Compliance_From_the_Beginning.pdf).

Although eight elements apply to all organizations, they require tailoring and adaptation because industries and individual organizations face different circumstances and develop tailored standards over time. The core issue is that the program must work to catch and prevent transgressions. It cannot be a paper-driven exercise, but something that lives and breathes, and is embedded in how we live and work. Therefore, the program must be practical, and more importantly, sustainable.

Because so many ethics and compliance issues are not black and white, for our Ethics and Compliance Program to work, it also must achieve a balance between our freedom to get the job done and the risks associated with getting it wrong. In the end, if we do it right, the program will help make us more consistent and efficient, which is good for everyone, including our study participants, future patients, and donors.

LB: You said ethics and compliance is a journey and not a destination, so where is MAPS on that journey and what does success look like?

SW: We are still in the early stages. We are working on putting the necessary framework and processes in place, which Rick Doblin has said are crucial for MAPS' continued growth and expansion. While it is hard to describe in terms of a single instance or outcome, success, to me, means having both an organizational framework and a culture where it is second nature to manage risk, protect MAPS' reputation, and, most importantly, to identify as many of our stakeholders as possible and work to protect and respect their interests and ours, even in the face of challenges and tough decisions.

While we still have much to do, we are heading in the right direction. Together, I believe we truly will change the world of mental health, and more broadly, the healthcare system. It is an exciting time to be a part of MAPS and I am honored to be a part of it.

*Together, I believe we truly
will change the world of
mental health, and more
broadly, the healthcare system.*

LESLIE BOOHER, J.D., M.B.A., is the most recent addition to the MAPS Policy and Advocacy Department. Leslie received her bachelor of science in business administration and her master of business administration from Southeast Missouri State University, as well as her juris doctor from University of California, Berkeley, School of Law. Before joining MAPS, Leslie gained litigation experience at large and small law firms, from both the plaintiff and defense sides. Leslie is excited because her work at MAPS combines many of her passions: learning and educating others about our shared human physiology and psychology, striving for social contentment through imaginative socio-economic structures, aspiring for criminal justice reform, and calling attention to the unique role that altered states of perception play in conceptualizing, contextualizing, and coping with our own consciousness. She's currently interested in topics like behavioral economics, novel economies, technology and privacy, peer support, and rural community issues.

SETH WHITELAW, J.D., LL.M., S.J.D., has almost 30 years of industry experience in the life sciences and health care sectors, as an attorney, compliance officer (C.R. Bard, Inc., GlaxoSmithKline, and Misonix, Inc.) and industry consultant (Deloitte, Whitelaw Compliance Group LLC). Most recently, he served as a compliance expert in the Opioid Multidistrict Litigation. In addition to being a Food and Drug Law Institute (FDLI) fellow and having worked for both the FDA's Office of Chief Counsel, he has a J.D. from Washington & Lee School of Law, an LL.M. from George Washington University Law School, and a doctorate in Health Law from Widener University School of Law. Currently, Dr. Whitelaw is the Editor of the *Policy & Medicine Compliance Update* and teaches corporate governance and compliance at Mitchell Hamline School of Law where he is the Senior Fellow & Adjunct Professor, Life Sciences Compliance.

Prioritizing Public Benefit Means Healing for All

Announcing MAPS' Health Equity Plan

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

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“Of all the forms of inequality, injustice in health is the most shocking and most inhumane because it often results in death.”

— Dr. Martin Luther King, Jr. (1966)

COMMUNITIES EXPERIENCING THE HIGHEST RATES of trauma usually access mental health services at the lowest rates. Social marginalization is a primary determinant for poor health, and marginalization and historical trauma often compound post-traumatic stress disorder (PTSD). Years of neglect and underinvestment have limited access to affordable healthcare services, and created inadequacy in culturally competent and effective care. Conversely, programs designed to serve those who are most marginalized by society end up benefiting the widest net of people, often described as the "curb-cutting effect" (Blackwell, 2017). With potential U.S. Food and Drug Administration (FDA) approval of MDMA-assisted psychotherapy on the horizon, MAPS has developed a Health Equity Plan to work to safely and effectively deliver this potentially life-saving care to as many people as possible.

Our initial plan includes fundraising and allocating \$5.5 million to four main initiatives over the next three years: 1) developing scholarships for training therapists from historically marginalized communities, 2) supporting clinics and patients in the expanded access program with a treatment access fund,

3) building inclusive and equitable community, outreach, and education, and 4) hiring new team members at MAPS and MAPS Public Benefit Corporation (MAPS PBC) dedicated to implementing the health equity plan and integrating health equity into all parts of MAPS and MAPS PBC's work. We have already raised \$675,000 from a number of foundations including Libra Foundation, Riverstyx Foundation, Open Society Foundations, Dr. Bronner's, the Psychedelic Science Funders Collaborative (PSFC), and individuals including Gwyneth Paltrow, Bob Parsons, Craig Nurenberg, and Rachel Ratliff.

The backbone of our Health Equity Plan is expanding the therapist training to include, uplift, and train therapists, supervisors, and trainers from communities who experience high rates of trauma and insufficient access to care. In therapy, and especially in psychedelic therapy, a leading determinant of outcome is the establishment of a safe container through a trusting therapeutic alliance. Research shows that racial and ethnic alignment among healthcare providers and their patients can improve survival, safety, and trust for patients. We are committed to developing a network of MDMA therapists, supervisors,

and trainers who are reflective of the diverse demographics of the countries where we expect MDMA to be approved as a medicine.

Achieving health equity requires creating access to PTSD treatment for communities who experience the most trauma. In the United States, Indigenous, Black, and Latinx Americans experience some of the highest rates of trauma (Alegría et al., 2013; Roberts et al., 2011). Sexual orientation and gender identity also influence vulnerability to trauma; transgender and gender non-conforming people in the United States experience particularly high rates of PTSD (Mizock & Lewis, 2008; Roberts et al., 2012). MAPS will prioritize training therapists who are Indigenous, Black, Latinx, trans and gender non-conforming, queer, and therapists who are not able-bodied, who come from refugee or immigrant communities, who have been formerly incarcerated, who work in rural communities, and/or who are economically marginalized. We especially value people's perspectives with multiple intersecting marginalized identities, as they experience even higher barriers to effective care, as well as access to therapist training.

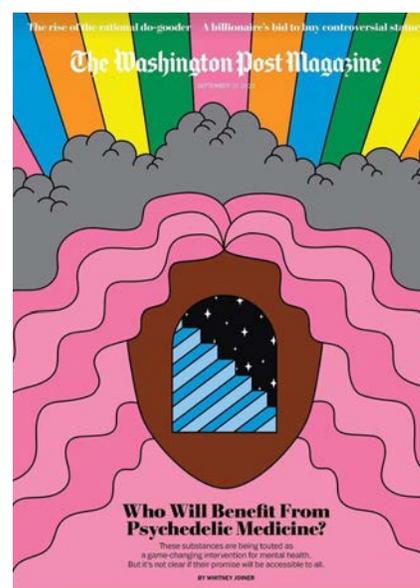
MAPS' Health Equity Plan creates an expanded access patient access fund and allocates funding to support the start-up costs of expanded access clinics. This plan will provide subsidization for MDMA-assisted psychotherapy treatment costs for expanded access patients who need financial assistance. This plan also supports expanded access clinics in the many costs required to get started, ranging from preparing and designing treatment rooms to purchasing and installing drug storage equipment. Expanded access will also allow more therapists to gain experience in MDMA-assisted psychotherapy, providing more opportunities for therapists from underrepresented communities to develop into MDMA therapy trainers and supervisors.

Additionally, our Health Equity Plan allocates ongoing resources, including staff, to community building, outreach, and education. This includes content creation, social media outreach, educational and community-building events, and workshops that will all include a broad understanding of cultural and historical trauma, psychedelic education, and harm reduction. Currently, MAPS is hosting a workshop series for therapists who attended MAPS' MDMA Therapy Training for Communities of Color, which will culminate in the creation of an organizer toolkit to support therapists and organizers building in communities of color.

The outcome disparities that result from "healthcare as usual" are unconscionable, and we are ready to do our part to reverse them. In one egregious example, a 2020 study documented that Black newborns are three times more likely to die in the hospital than white newborns if they are cared for by white physicians; when Black newborns are treated by Black physicians, this disparity drops significantly (Greenwood et al., 2020). These are newborns—imagine the health disparity in therapy for adults with lifetimes of different experiences.

We will be releasing more information soon about how to apply for therapist scholarships and the patient access fund, and we are excited to be in the process of onboarding more staff to dedicate resources to the core work of health equity. As COVID-19 has tragically demonstrated, no one is healthy if we are not all healthy, and the same applies for mental health. Equity and parity in access to mental health care is fundamental for collective human flourishing.

As COVID-19 has tragically demonstrated, no one is healthy if we are not all healthy, and the same applies for mental health.



The Washington Post Magazine features an article about access to psychedelic medicine and MAPS' Health Equity Plan as the cover story in September 2020.

NATALIE LYLA GINSBERG, M.S.W., is Director of Policy and Advocacy at MAPS, where she works to disentangle science from political partisanship, and to create safe, equitable and regulated access to psychedelics, and all criminalized substances. She is also partnering with Israeli and Palestinian colleagues to develop a psychedelic peace-building study. Natalie is particularly inspired by psychedelics' potential to assist in healing intergenerational trauma, for building empathy and community, and for inspiring creative and innovative solutions. Natalie received her B.A. in history from Yale, and her master's of social work (M.S.W.) from Columbia.

ISMAIL LOURIDO ALI, J.D., is Policy and Advocacy Counsel for MAPS, where he advocates to eliminate barriers to psychedelic therapy and research, develops and implements legal and policy strategy, and coordinates support for clinical research in Latin America. Ismail earned his J.D. at the University of California, Berkeley School of Law in 2016, where he served as co-lead of Berkeley Law's chapter of Students for Sensible Drug Policy and worked for the ACLU of Northern California's Criminal Justice and Drug Policy Project, and the International Human Rights Law Clinic at Berkeley Law.

RITIKA AGGARWAL, M.F.T. CANDIDATE, is Executive Support and Operations Coordinator at MAPS Public Benefit Corporation (MAPS PBC). Ritika earned her B.A. in feminist studies and psychology from the University of California, Santa Cruz. While in Santa Cruz, she founded and co-directed the local chapter of NORML/Students for Sensible Drug Policy and worked with the Wo/Men's Alliance for Medical Marijuana. For the past ten years, she has been a legal advocate for people incarcerated in California prisons, helping to secure the release of over 100 people with life sentences.

FEDE MENAPACE, M.B.A., serves as Director of Strategy for MAPS. In his role at MAPS, Fede aims to build bridges across different organizations in the psychedelic medicine field to further MAPS' cause of providing broad and safe access to mental health treatments for those who are most in need. Fede also works on internal strategy projects to identify and execute growth opportunities for MAPS and its subsidiaries. Fede received his M.B.A. from the Stanford Graduate School of Business and his M.S. in structural engineering from the University of Michigan, Ann Arbor.

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Drug Decriminalization

Breaking our Addiction to Criminal Punishments

THESHIA NAIDOO, J.D.

THE UNITED STATES HAS DEVELOPED an unhealthy dependence on criminal punishment. For more than a half century, if there was a difficult societal problem, more often than not, policy makers have labeled it as criminal and “declared war” on it. If that approach did not solve the issue, legislators doubled down by increasing criminal penalties. And if this approach did not work, they shifted punishment to systems outside of the legal system, making it harder for those suffering criminal convictions to ever fully rejoin society. And if this strategy did not work, they increased penalties again. In the process, these policies destroyed communities—often Black and Brown communities—filled our jails and prisons beyond their capacities, and gave nearly unchecked, deadly power to police forces that did not have the trust of the communities that they were sworn to serve.

Nowhere is that destructive pattern more evident than with the War on Drugs. The criminalization of drug possession and use was not preordained or scientifically based; it was a policy choice born out of a particular time and societal situation, based on who was perceived to be consumers of those drugs (A Brief History of the Drug War, 2020). Substances like opium and cocaine were restricted close to the same time that alcohol use and sale were prohibited (Against Drug Prohibition, 2020). In the case of alcohol, what became widely recognized as a disastrous policy decision was eventually reversed, but the penalties associated with many other substances remained, and over the coming decades, steadily intensified.

The effects of the decision to apply criminal penalties to drug possession have been staggering. In 2018 alone, U.S. police agencies made over 1.6 million drug arrests—and more than 85% of these arrests were for possession only (Stellin, 2019). Hundreds of thousands of people in the U.S. are held in custody awaiting trial on a drug offense, and hundreds of thousands more are placed under government supervision based on a drug offense. Conviction for a drug offense imposes barriers to employment, housing, financial aid, legal immigration status, voting, jury service, and even the ability to be a parent. A

criminal conviction for a drug offense isn’t over after “serving time”—it is a perpetual ulcer that eats away at nearly all of the foundational elements of a person’s life.

The racial inequality that is evidenced throughout the criminal legal system is particularly prevalent in the War on Drugs (National Research Council, 2014). Prosecutors are twice as likely to pursue a mandatory minimum sentence for Black people, and Black and Indigenous people are more likely than any other group to be killed by law enforcement. For noncitizens, including legal permanent residents, possession of even a small amount of drugs can trigger automatic detention and deportation. The stigma that comes with drug criminalization becomes particularly toxic when combined with racial stereotypes and implicit bias. Communities of color have been at the front lines of the drug war, and they have been its most frequent casualties.

As with so many other forms of unhealthy dependence, the U.S. invests more and more in the criminal system, only to see diminishing results. After decades of pursuing the criminal approach—imposing ever higher penalties, spending ever more resources, and inflicting ever more human damage—drugs continue to be available, the demand for drugs remains constant, and overdose rates continue to climb (Centers for Disease Control and Prevention, 2020).

Frustrated with the ineffectiveness and destructiveness of this approach, some jurisdictions are turning away from the criminal system as a response to drug use. Cities, counties, and even states are deciding to decriminalize drug use and possession. Drug decriminalization refers to the removal of criminal penalties for possession of any drug for personal use. Decriminalization does not distinguish between drug type, and applies to all substances including psychedelics, cocaine, methamphetamine, and others.

The racial inequality that is evidenced throughout the criminal legal system is particularly prevalent in the War on Drugs.

It can be accomplished in two ways: a) de jure: changing or repealing laws that treat drug use and possession as a crime; or b) de facto: changing practices and policies, such as enacting non-enforcement or non-prosecution policies for drug possession offenses, even if the underlying law remains intact.



Decriminalization is distinct from legalization, which entails the legal regulation of drug-related activities, including cultivation, production, distribution, and sale. It is a policy focused on the consumers of psychoactive substances and it is often paired with an increase in access to treatment or other social services.

The policy of decriminalization is neither new nor radical. Twenty-nine countries, most notably Portugal and the Czech Republic, have successfully decriminalized possession of various drugs and have achieved meaningful improvements in treating problematic drug use and reducing the harms wrought by the criminal system (Csete, 2011; Decriminalisation Across the World, 2020; Domoslawski, 2011). Support for eliminating criminal penalties for drug possession is growing across the U.S. and around the world. Leading medical, public health, and human rights groups have endorsed drug decriminalization, including the United Nations, World Health Organization, International Federation of Red Cross and Red Crescent Societies, American Public Health Association, Human Rights Watch, Movement for Black Lives, National Association for the Advancement of Colored People (NAACP), Latino Justice, National Latino Congreso, Organization of American States, and many others (It's Time for the U.S. to Decriminalize Drug Use and Possession, 2017).

The road to all-drug decriminalization has had many preparatory steps (Bronner, 2020). The Drug Policy Alliance (DPA) has been at the forefront of decades-long efforts—replacing jail and prison sentences with drug treatment; reclassifying drug possession from a felony to a misdemeanor offense; promoting pre-arrest and pre-plea diversion programs; decriminalizing or altogether legalizing marijuana; enacting 911 Good Samaritan laws that allow for limited decriminalization of drug use and possession at the scene of an overdose for those who are witnesses and call for emergency medical assistance; and supporting recent efforts at the local level to treat possession of drugs, including psychedelics, as the “lowest law enforcement priority.” Some district attorneys have adopted a “decline to prosecute” policy for drug possession offenses (Prudente & Jackson, 2020; Swan, 2020). As a result of these steps, millions of people across the country already live in jurisdictions where

drug possession has been de facto decriminalized—and most of them probably do not even realize it.

The latest, and most significant step towards drug decriminalization happened in Oregon on election night. Measure 110 (voteyeson110.org), the Drug Addiction Treatment and Recovery Act, makes Oregon the first state in the nation to decriminalize possession of all drugs for personal use. Instead of facing arrest, jail, and being saddled with a criminal conviction, a person in possession of a small amount of drugs would now be subjected to a fine and incentivized to seek social services. The measure redirects funds to build a health-oriented infrastructure and increase access to social services.

With Oregon's Measure 110, the policy of all-drug decriminalization steps onto the national stage in the U.S. in a way that it never has before. The landslide victory (by a 17-point margin) on election night has demonstrated decriminalization's strength as public policy (General Election, 2020). It has withstood intense scrutiny and debate, gained the support of mainstream groups across the political spectrum (Endorsements, 2020), and sailed to victory. Available empirical evidence from international models strongly suggests that decriminalization does not lead to a significant increase in rates of drug use (Hughes & Stevens, 2010). Moreover, the criminal system is not a necessary or even desired conduit to treatment. Voluntary, community-based treatment has been proven to be as effective, if not more effective, than criminal-based options.

Decriminalization is also a potent tool to ending racial disparities in the criminal system. In the case of Measure 110, a study by the Oregon Criminal Justice Commission estimated that its adoption would decrease racial disparities in drug arrests by 95%, and convictions of Black and Indigenous Oregonians would drop by 94% (IP 44 Racial and Ethnic Impact Statement, 2020). Replicating these results in other jurisdictions would be a critical step in addressing the systemic racism in policing that sparked this summer's historic protests.

Imposing criminal penalties on those who use and possess drugs was a policy decision. We have lived with the consequences of that decision, with people of color bearing the greatest brunt, for more than a century. Over those years, the U.S. has become more and more addicted to the idea that so-



cietal problems can be solved by increasing criminal punishment. The road to recover from that flawed policy choice has been long, with many intermediary steps. Dealing with any form of unhealthy dependence takes dedication and sustained effort.

Beginning with small localities, building to large metropolitan areas, and culminating in a statewide initiative before voters, it is clear that decriminalization is a policy whose time has finally arrived.

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THESHIA NAIDOO, J.D., is Managing Director, Legal Affairs, with the Drug Policy Alliance (DPA). Naidoo has pushed for the creation and adoption of innovative criminal justice reforms, including playing a pivotal role in the advancement of policies and practices to reduce the role of the criminal legal system and promote a health approach to drug use. Naidoo crafts legislation and policies across the U.S. and supports campaigns to eliminate or reduce criminal penalties for drug offenses, protect immigrants from deportation based on drug offenses, reform civil forfeiture, and minimize the collateral consequences of criminal convictions. Most recently, Naidoo served as one of the chief architects of Oregon's Drug Addiction Treatment and Recovery Act of 2020. Naidoo received her B.A. from UC Berkeley and her J.D. from UCLA School of Law. Prior to joining DPA, she worked at a law firm and left to join the struggle to make drug laws and policies more just, compassionate, and effective.

The Intersection of the Microbiome-Gut-Brain Axis, PTSD, and Ayahuasca in Veterans

JESSE GOULD, KATE PATE, PH.D., AND CHRISTOPHER A. LOWRY, PH.D.



A COMMON THEME AMONG THOSE who eventually make their way toward psychedelic medicine is the realization that the current standard of care for mental health provides few reliably effective treatment options. Many of these same individuals acknowledge how little the lay audience and scientific communities seem to understand about what it means to be mentally healthy. For American military veterans, coming to terms with these kinds of realizations has become a painful and standard part of one's transition process, not to mention the endless paperwork and severely protracted timelines associated with their attempts to receive care within the U.S. Department of Veterans Affairs (VA). In large part, due to the groundbreaking research from the Multidisciplinary Association for Psychedelic Studies (MAPS), the scientific community is reevaluating the use of certain illicit substances like MDMA and ayahuasca, leading to the reemerging discussion of psychedelic-assisted therapy. The tremendous potential of these substances is providing hope for countless individuals who seek peace from their traumas. Heroic Hearts Project (heroicheartsproject.org) was founded to solve this disconnect between the mental health systems of the VA and exciting breakthroughs that are happening in psychedelic research.

Given the extreme nature of the profession, members of the military are at much higher risk for experiencing trauma and struggling with mental health issues such as posttraumatic stress disorder (PTSD), depression, anxiety, and addiction than their civilian peers. Because of this, the veteran population is a good barometer for measuring just how effective current treatment options are at helping individuals work through and beyond their traumas and improving mental health. It won't come as a surprise to most people that the current options are severely lacking. According to the latest VA report, veterans are 1.5 times more likely to die by suicide than Americans who never served in the military. For female veterans, the risk factor jumps to 2.2 times more likely (U.S. Department of Veterans Affairs, 2019). These numbers have stayed elevated for over 15 years, and despite billions of dollars in funding for a variety of federal initiatives, the VA has not been successful at effectively addressing veteran suicide. In fact, the veteran suicide epidemic may be getting worse: the total number of suicides among veterans has increased steadily during four of the last five years on record (U.S. Department of Veterans Affairs, 2019).



In May 2019, the Heroic Hearts veterans group participate in ayahuasca ceremonies in this maloka in Tarapoto, Peru. Photo Credit: Jeremy Lock

The VA's current standard of care for mental health issues like PTSD includes a form of psychotherapy and medication. Unfortunately for many veterans, the approach for determining mental health diagnoses is an overly simplistic psychological evaluation. Based on the answers provided, a veteran will receive a percentage rating based on the detected severity of PTSD. However, there is rarely any discussion of other important factors in a veteran's life, like their diet, sleep, quality of life, current employment, social support network, and other contributing elements. All of our interactions with veterans in the Heroic Hearts program strongly suggest that these are all important considerations for how well a veteran will adjust to a post-military life.

There are other factors that play a significant role in influencing a veteran's overall mental health, including brain trauma, toxic exposures, and pre-military trauma. Standard assessments fail to consider and/or measure these factors, which is critical because we now know that many symptoms of traumatic brain injury (TBI), specifically military-related blast trauma, and PTSD overlap, leading to the misdiagnosis of PTSD in those suffering from brain injuries. There are a cluster of symptoms collectively known as "Operator Syndrome," of which TBI and PTSD can be a part, but it's a complex collection of many factors, and it's affecting our special operations community at an alarming rate (Stewart & Trujillo, 2020). A partner veteran organization, HunterSeven Foundation (hunterseven.org), has been dedicated to bringing attention to the nuanced mental and physical health issues that veterans often face due to the extreme impact that toxic exposures from burn pits and other occupational hazards have on the body. It's nearly impossible to consider every exposure, every blast, every night of missed sleep that a service member accumulates over his or her career, but these examples should highlight the numerous ways in which the current assessments are falling short and potentially leading to misdiagnosing and misunderstanding serious issues.

*Our team believes
that ayahuasca, when
administered in a traditional
ceremonial setting, can be
extremely effective for
helping veterans overcome
mental health challenges,
including PTSD.*

Many of the veterans who go through our program share similar stories about their frustrating experiences with the VA. For perspective, the following is one such account from a veteran in the Heroic Hearts program.

After my own issues were starting to negatively impact my life I decided to go to the VA in order to seek professional therapy. Hours later, I ended up walking out of the office, having achieved nothing. I was told that I would have to learn to live with PTSD. They informed me that they could provide me with three therapy sessions but after that I would have to be open to going on medication if I wished to continue. I wasn't interested in medication, so I left. There was no discussion about any other aspects of my life or any real assessment of the issues I was struggling with.

Unfortunately, stories like these and stories of veterans finding themselves with more than ten prescription medications are far too common.

Through our work at Heroic Hearts Project, we have come to realize the breadth of what "mental health" really means. Although there can be commonalities among the symptoms that veterans experience, each person is unique and should be treated as such. Additionally, veterans and all individuals should have more agency with regard to their preferences for treatment rather than being told what to do. Currently available prescription medications are certainly a powerful tool and should be considered as an option for some, but psychedelics provide an alternative that may be more effective in some cases.

Over the years, our proprietary veteran program has evolved around this concept, which has primarily focused on helping veterans with PTSD find healing through ayahuasca.

However, we quickly began to realize that many of the veterans who came to us for healing displayed some, but not all, of the symptoms required for a PTSD diagnosis according to the Clinician-Administered PTSD Scale (CAPS-5) from the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), and yet they were still struggling mightily. What the veterans were experiencing was more complex and nuanced than what the CAPS-5 assessment was measuring, and each person had multiple influencing factors that contributed to how he or she dealt with trauma. What we witnessed was in stark contrast to our culture's stereotype that "problems"

with veterans are psychological in nature and all stem from one or more uniquely stressful or horrific events that imprinted on the individual's mind and subsequently affected behavior.

Service-related traumatic events often do play a major role in the psychological health of a veteran, but stopping here at the explanation is only a partial measure. The majority of the veterans in our program have had some form of combat-related trauma, but again, addressing just combat-related experiences falls short of a holistic approach to health. We believe that in order for veterans to fully heal and experience long-lasting results, more comprehensive approaches to physical, mental, and spiritual health are needed.

It's an exciting time to be participating in and studying psychedelic research. The field continues to grow, and new preclinical and clinical studies are being pursued on a regular basis. However, restrictions and legalities have made the research on these important medicines difficult or impossible in many parts of the world. With regard to ayahuasca, randomized, placebo-controlled clinical trials are few and far between. Observational research studies and anecdotal reports predominate in the literature, but even these are hard to come by. Thus, new empirical studies are increasingly important to pursue. Our team believes that ayahuasca, when administered in a traditional ceremonial setting, can be extremely effective for helping veterans overcome mental health challenges, including PTSD, and we have observed as much in our few short years of existence as an organization. "During the ayahuasca journey, individuals can explore sensations, emotions, and thoughts associated with trauma, so that symptoms are discharged and resolved. Ayahuasca also guides victims to resolve events that predispose them to PTSD" (Nielson & Megler, 2014).

The authors of this paper primarily focus on providing alternative options for healing to veterans in need. The authors also feel compelled to better understand how ayahuasca can benefit veterans struggling with PTSD, but also those struggling with TBI or other mental or physical health issues. To that end, this team has undertaken a novel study to investigate how ayahuasca consumption can lead to changes in the gut microbiome in veterans with PTSD, and how psychological, biological, and physiological biomarkers are correlated with these changes. This research is ongoing and preliminary data will be available in early 2021.

When Dr. Kate Pate, an author of this paper, initially approached Dr. Christopher Lowry, another author of this paper, about working with Heroic Hearts Project to evaluate and understand the intersection of ayahuasca, the gut microbiome, and PTSD, he jumped at the opportunity. His laboratory is grounded in the desire to develop novel therapeutic strategies to the prevention and treatment of anxiety disorders, affective disorders, and trauma- and stressor-related disorders, such as PTSD. In particular, Dr. Lowry shares a common interest in complementary and integrative health approaches to the treatment of trauma- and stress-related disorders, in part because these approaches tend to be more acceptable to many veterans, and, while the jury is still out, these complementary and integrative health approaches appear to hold great promise.



The first dose of ayahuasca during a ceremony with a Heroic Hearts veteran group in Tarapoto, Peru, in May 2019. Photo Credit: Jeremy Lock

But why study the gut microbiome in association with ayahuasca as treatment for PTSD? The interest is founded in our growing understanding that the microbiome-gut-brain axis plays a role in both physical and mental health. The authors are particularly interested in the relationship between the gut microbiome, inflammation, and mental health. To understand why, it's important to grasp a few tenets.

First, inflammation prior to or at the time of trauma exposure increases the risk of developing PTSD symptoms. For example, in a seminal study, the Marine Resiliency Study of 2,600 war zone-deployed Marines, those who had higher blood concentrations of C-reactive protein, a biomarker of inflammation, at boot camp had higher risk of post-deployment PTSD symptoms (Eraly et al., 2014).

Second, trauma and stressor exposures can alter the gut microbiome in ways that favor increases in inflammation. The mechanisms involved are not completely understood, but some are becoming more clear. One mechanism is through reduction of what is called "alpha diversity" of the microbiome. The consensus is that a microbiome characterized by high alpha diversity is a healthy microbiome (McBurney et al., 2019), and that stress, by decreasing alpha diversity, makes the gut microbiome more vulnerable to opportunistic pathogens. Opportunistic pathogens can cause gut inflammation, "leaky gut," resulting in translocation of bacteria from the gut into the body, and subsequently, systemic inflammation (which can be detected by increases in biological signatures of inflammation, including C-reactive protein; Myers et al., 2004). A second mechanism is that trauma and stressor exposures can increase proliferation of "pathobionts", microorganisms that typically behave themselves, but under some conditions become pathogenic (Chow et al., 2011; Reber et al., 2016;), leading to the cascade of effects described above, culminating in increased inflammation.

Inflammation increases stress-induced fear learning and impairs acquisition and recall of fear extinction

Although confirmation in human studies is needed (Michopoulos et al., 2017), evidence suggests that inflammation increases stress-induced fear learning and impairs acquisition and recall of fear extinction (Doenni et al., 2017; Jones et al., 2015; Quiñones et al., 2016; Young et al., 2018). Together, these studies suggest that targeting inflammation is a rational strategy for both the prevention and treatment of PTSD.

Hope for microbiome-based interventions

Dr. Lowry and colleagues have recently shown in mouse models that immunization with a soil-derived bacterium with anti-inflammatory and immunoregulatory properties can prevent development of a PTSD-like syndrome (Reber et al., 2016). These findings led his laboratory to conduct, together with the Rocky Mountain MIRECC in Denver, Colorado, a randomized, double-blind, placebo-controlled clinical trial evaluating the feasibility, acceptability, and safety of an eight-week administration of an anti-inflammatory and immunoregulatory probiotic in U.S. veterans with PTSD and mild TBI (Brenner et al., 2020). Although additional studies with larger group sizes are needed, the results show a trend for the probiotic to reduce plasma C-reactive protein concentrations, and a highly significant effect to reduce stress reactivity during a psychosocial stress test (Brenner et al., 2020). An alternative approach to probiotic administration is whole dietary intervention. Whole dietary interventions that increase intake of fruits and vegetables, nuts, seeds, and olive oil (essentially, an anti-inflammatory diet) decrease anxiety and depressive symptoms (Firth et al., 2019). Although the mechanisms through which whole dietary interventions decrease anxiety and depressive symptoms are not clear, increased consumption of diverse plants increases the alpha diversity of the gut microbiome (McDonald et al., 2018), and therefore may promote stress resilience.

Ayahuasca, the gut microbiome, and PTSD

The impact of ayahuasca on the gut microbiome is unknown. However, the anecdotal reports of the transformative effects of ayahuasca on PTSD symptoms lead us to believe that ayahuasca may impact the gut microbiome, either increasing the diversity of the gut microbiome, eliminating pathobionts, or preventing inflammatory responses to pathobionts, and that an altered microbiome may play a role in the transformative effects of ayahuasca. Thanks to the individuals involved in this collaboration, we can begin this journey of discovery, find answers, and, hopefully, help those in need.



The Heroic Hearts veteran group gathers around the opening fire ceremony, discussing intentions for their ayahuasca experience in Tarapoto, Peru, in May 2019. Photo Credit: Jeremy Lock

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JESSE GOULD is a military veteran leader in psychedelics. As Founder and President of the Heroic Hearts Project, he has spearheaded the research and acceptance of ayahuasca and other psychedelic therapy programs for military veterans. Jesse has raised over \$400,000 in scholarships from donors including Dr. Bronner's, partnered with the world's leading ayahuasca treatment centers, and is researching psychiatric applications with the University of Colorado Boulder and the University of Georgia. His mission is to help military veterans struggling with mental trauma and spread awareness of the benefits that ayahuasca therapies offer as an alternative treatment to pharmaceuticals. Jesse has spoken globally about the benefits of psychedelics on mental health and has been featured in the New York Times and Rolling Stone magazine and recognized as one of the Social Entrepreneurs To Watch For In 2020 by Cause Artist. The mission of Heroic Hearts Project has expanded internationally and represents the voices of veterans across the U.S., the United Kingdom, and Canada: heroicheartspj.org.

KATE PATE, PH.D., is a neurophysiologist, lover of mountain sports, entrepreneur, integration coach, and yogi. She has a broad scientific background, having spent over 15 years conducting research in a variety of fields within academic and industry settings. She is also the CEO and Founder of Coruna Medical, a military-specific medical device company. For the past five years, Kate's research has focused solely on military trauma medicine and mental health. She comes from a military family and has always been passionate about helping military service members and veterans in whatever capacity she could. This passion, coupled with her interest in plant-based medicines and her journey to find ways to heal from her own traumas, led her to cross paths with Heroic Hearts Project. Kate joined Heroic Hearts Project as the Director of Research in January of 2019 and has been working closely with the team to investigate the ways in which ayahuasca can benefit veterans suffering from traumatic brain injury, PTSD, and other mental health issues, and how changes in the gut microbiome following ayahuasca consumption may be correlated with long-term psychological and behavioral changes.

CHRISTOPHER A. LOWRY, PH.D., is an Associate Professor in the Department of Integrative Physiology, Center for Neuroscience, and Center for Microbial Exploration at the University of Colorado Boulder, with a secondary appointment in the Department of Physical Medicine and Rehabilitation and Center for Neuroscience at the University of Colorado Anschutz Medical Campus; a Principal Investigator in the Department of Veterans Affairs Eastern Colorado Health Care System, VA Rocky Mountain Mental Illness Research, Education, and Clinical Center; and Director of the Behavioral Neuroendocrinology Laboratory at CU Boulder. He is Co-Director, with Dr. Lisa Brenner, of the Military and Veteran Microbiome Consortium for Research and Education. Dr. Lowry's research program focuses on understanding stress-related physiology and behavior with an emphasis on the role of the microbiome-gut-brain axis in stress resilience, health, and disease.

In Memoriam

Throughout global challenges this year, some notable pillars of the psychedelic community have passed away. We appreciate each of their vital contributions to the broad field of psychedelics and wish their families well during their grieving processes.



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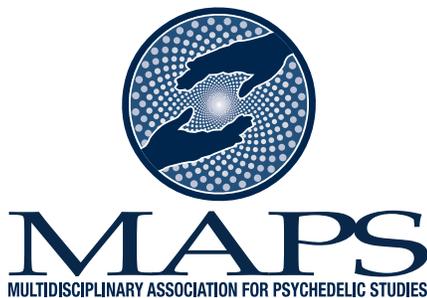


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