MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Volume XXVIII
Number 3

2018 Annual Report
BULLETIN

Winter 2018

GIVE THE GIFT OF HEALING TRAUMA.

MAPS

Marcela is a MAPS-sponsored researcher who recently completed a Phase 2 trial of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) in Boulder, Colorado. Now, Marcela is leading a Phase 3 trial and hopes to make it a legal treatment by 2021.

You can help make psychedelic medicine a reality for millions of people suffering from PTSD.

MAPS.ORG/SUPPORT

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, PO Box 8423
Santa Cruz, CA 95061
Phone: +1 831.429.6362
Fax: +1 831.429.6370
askmaps@maps.org
maps.org

Editor: Brad Burge
Design: Sarah Jordan
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Visit **maps.org/store** for information about donations and purchases.

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COVER ARTIST: MICHAEL DIVINE

Michael Divine

Front and back cover:
Only Love Can (Reign Over Me)
Acrylic/Canvas, 54" x 32"

The paintings I make create a backdrop to our lives—these ordinary and extraordinary lives that we lead. They reflect back both the mundanity and the extraordinariness. They become points of departure, growth, and intimacy. It was challenging sometimes to go back to this painting when there'd be strife or despair and I'd be left feeling like I'm wringing light from painted diamonds.

And so that is this painting: it is simply me lifting you, me—all of us—up as best I can.

Looking for a title, I'd been calling it Rain then Violet had used the word "Reign". I recalled "Love Reign Over Me"—a song from The Who—and though I'm not much of a fan of The Who, I found this bit of writing from Pete Townshend regarding the song to be relevant:

> *"Love Reign Over Me refers to Meher Baba's one time comment that rain was a blessing from God; that thunder was God's Voice. It's another plea to drown, only this time in the rain. Jimmy goes through a suicide crisis. He surrenders to the inevitable, and you know, you know, when it's over and he goes back to town he'll be going through the same shit, being in the same terrible family situation and so on, but he's moved up a level. He's weak still, but there's a strength in that weakness. He's in danger of maturing."—Pete Townshend (From the liner notes of Quadrophenia)*

In those crystalline moments of realization, when we see everything so clearly. It's all just light and shadow, contrast, an ebbing and flowing. It's just life. And we can keep our heads hung low but, really, it's love that makes us look up, that causes us to open our eyes. To see. I think that only love can do that and it is some spark within us—this unquenchable fire—that is ignited again.

*

I mostly live and paint in California. In my work, I look for the most beautiful expression of the varieties of human experiences, exploring and inspired by the vast spectrum of that dance. To view more details of this painting as well as many others, I invite you to visit my website: **TenThousandVisions.com**. If you'd like to contact me, you can write me here: **Michael@TenThousandVisions.com**.

Reports from Allied Organizations

We have invited the directors of COMPASS Pathways, Heffter Research Institute, and the Usona Institute to speak for themselves and share with the MAPS Bulletin readership the progress of their drug development programs and plans for the future. Articles from COMPASS and Heffter are included in this issue. Usona has elected to share their article in an upcoming publication.

Since its inception, MAPS has espoused the principles of open science by openly sharing information with researchers, therapists, doctors, practitioners, companies, organizations, enthusiasts, and explorers seeking to increase their scope of understanding of psychedelics. The nature of MAPS' relationship with COMPASS Pathways is the same as with any other research organization in the psychedelic space: to share scientific information openly and freely in order to advance our nonprofit mission (**maps.org/mission**).

MAPS has chosen for reasons of ethics and responsibility to develop psychedelics into prescription medicines through a public benefit corporation, wholly owned by the non-profit MAPS. In this way, social benefit is built into the charter and structure of the organization, and any potential profit will be channeled back into funding future psychedelic research, rather than to individual investors. However, this is not the only way forward.

Until recently, the psychedelic research field has been occupied almost solely by non-profit organizations and academic institutions. As we move into a new era of psychedelic research and medicine there is, and will continue to be, increasing interest from for-profit companies to participate in expanding psychedelic research and medicine. MAPS' responsibility as a leader in this field is to create a standard of care and to model governance in a way that remains responsible, ethical, and accessible.

From the Desk of Rick Doblin, Ph.D.

This issue of the Multidisciplinary Association for Psychedelic Studies (MAPS) Bulletin presents our annual financial report for Fiscal Year 2018 (June 1, 2017–May 31, 2018). As you will see, this has been MAPS' most successful year ever. Astonishingly, we have now raised $27 million for U.S. Food and Drug Administration (FDA) Phase 3 research into MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD)!

In the last few months, we have made unprecedented progress in growing public acceptance for research into psychedelic psychotherapy, especially MDMA-assisted psychotherapy for PTSD. The most satisfying moment for me was on October 8 in Orlando, Florida, when I spoke at the annual conference of the International Association of Chiefs of Police (IACP), along with Jon Lubecky, a veteran who was successfully treated for PTSD in our Phase 2 research; Dr. Zhenya Gelfand, a psychiatrist working at our South Carolina Phase 3 site; Tony Coulson, our retired senior DEA official consulting for MAPS. Together, we discussed how MDMA-assisted psychotherapy could be used to help police officers suffering from PTSD. (President Trump decided unexpectedly at the last minute to speak at the same conference and his talk was scheduled at the same time as ours!) After our talk, one police therapist approached us to mention his interest in going through our therapist training program. It was an incredible experience to speak at IACP, and to feel that our presence was both welcomed and appreciated.

Two days after the police chiefs conference, I was back home speaking in Cambridge, Mass., at the Broad Institute, a genomics research center with scientists from MIT and Harvard, at a conference sponsored by the Harvard Brain Science Initiative, Harvard Medical School, the Broad Institute, the Gift Holotropic Association, and MAPS. Also speaking was Michael Pollan, author of the New York Times bestseller *How to Change Your Mind* (a book which has changed lots of minds), along with psychedelic researchers Matt Johnson from Johns Hopkins, Robin Carhart-Harris from Imperial College London, Dr. Franklin King from Massachusetts General Hospital, Anja Loizaga-Velder from the Nierika Institute in Mexico, and moderator Julie Holland. From IACP to Harvard, psychedelic research has obtained academic respectability and mainstream acceptance.

The remarkable progress we are making in public education was exemplified in an excellent seven-minute video from The Economist ("How MDMA is being used to treat PTSD," October 11) and a CBS Evening News "Eye on America" special report (September 18), and much more. You can view these and other recent news items on our website (**maps.org/media**).

Excitement about MDMA-assisted psychotherapy for PTSD research is growing internationally as well as in the U.S. At the end of September, our therapist training team led a six-day therapist training program in the Netherlands for about 60 therapists from 14 different countries. This training was preparation for our efforts to conduct Phase 3 MDMA-assisted psychotherapy for PTSD trials in Europe through the European Medicines Agency (EMA).

Before I went to the European training, I was in China speaking about our research efforts to Chinese psychiatrists and PTSD experts at a conference organized by the Chinese Society of Psychiatry and Chinese Medical Association. Joining me was Dr. Moshe Kotler, Principal Investigator of our completed Israeli Phase 2 MDMA trial. Amy Emerson, Executive Director of the MAPS Public Benefit Corporation (MPBC), was also in China speaking to Chinese psychiatrists and PTSD experts two weeks before Dr. Kotler and I arrived. Our presentations were sufficiently inspiring, and there is now interest among Chinese therapists and researchers in participating in our therapist training program. Our travel was funded by a MAPS donor who wants to help bring MDMA-assisted psychotherapy for PTSD research to China.

By the time you are reading this, MAPS' Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD will finally have begun screening participants. This is a momentous milestone for MAPS. We anticipate our U.S. Phase 3 trials will take about two years to complete, at which point the data will be submitted to the FDA along with our request to approve MDMA-assisted psychotherapy as a legal treatment for PTSD. We anticipate that our European Phase 3 trials will start in the second half of 2019 or early 2020, depending on how long it takes for regulatory approvals, and for MAPS to raise another $9 million in donations to fund the European trials.

We've also recently enrolled the 76th and final participant in our Phase 2 clinical trial of four different varieties of smoked cannabis for veterans with chronic, treatment-resistant PTSD. We will be able to remove the blind and begin data analysis in the first few months of 2019.

The greatest challenge we now face is to successfully manage our organizational growth, with over 45 staff at MAPS and MPBC combined, and more to come as we scale up for Phase 3 trials, Expanded Access, and therapist training. As we approach 2019, the opportunities are ever-increasing, as is the need to make psychedelic-assisted psychotherapy a legally available treatment for PTSD and many other conditions. With the continued support of MAPS donors, I am confident that next year will be even more astonishing than this one.

Psychedelically yours,

Rick Doblin

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

Annual Financial Report

Fiscal Year 2017–18 (June 1, 2017– May 31, 2018)

RICK DOBLIN, PH.D.

It's my pleasure and responsibility to present the Annual Report for the finances of the Multidisciplinary Association for Psychedelic Studies (MAPS). Each year, MAPS, a 501(c)(3) non-profit organization, presents its year-end consolidated financial report with details about our income and its sources, as well as our expenses and how they are allocated and projects prioritized. We do this as a commitment to transparency and an invitation to dialogue.

This report describes our most recently completed Fiscal Year from June 1, 2017 to May 31, 2018 (FY18) and consolidates financial information from MAPS, MAPS Inc. (MAPS' Canadian non-profit), and MAPS' wholly-owned for-profit subsidiaries the MAPS Public Benefit Corporation (MPBC) and MAPS Europe BV.

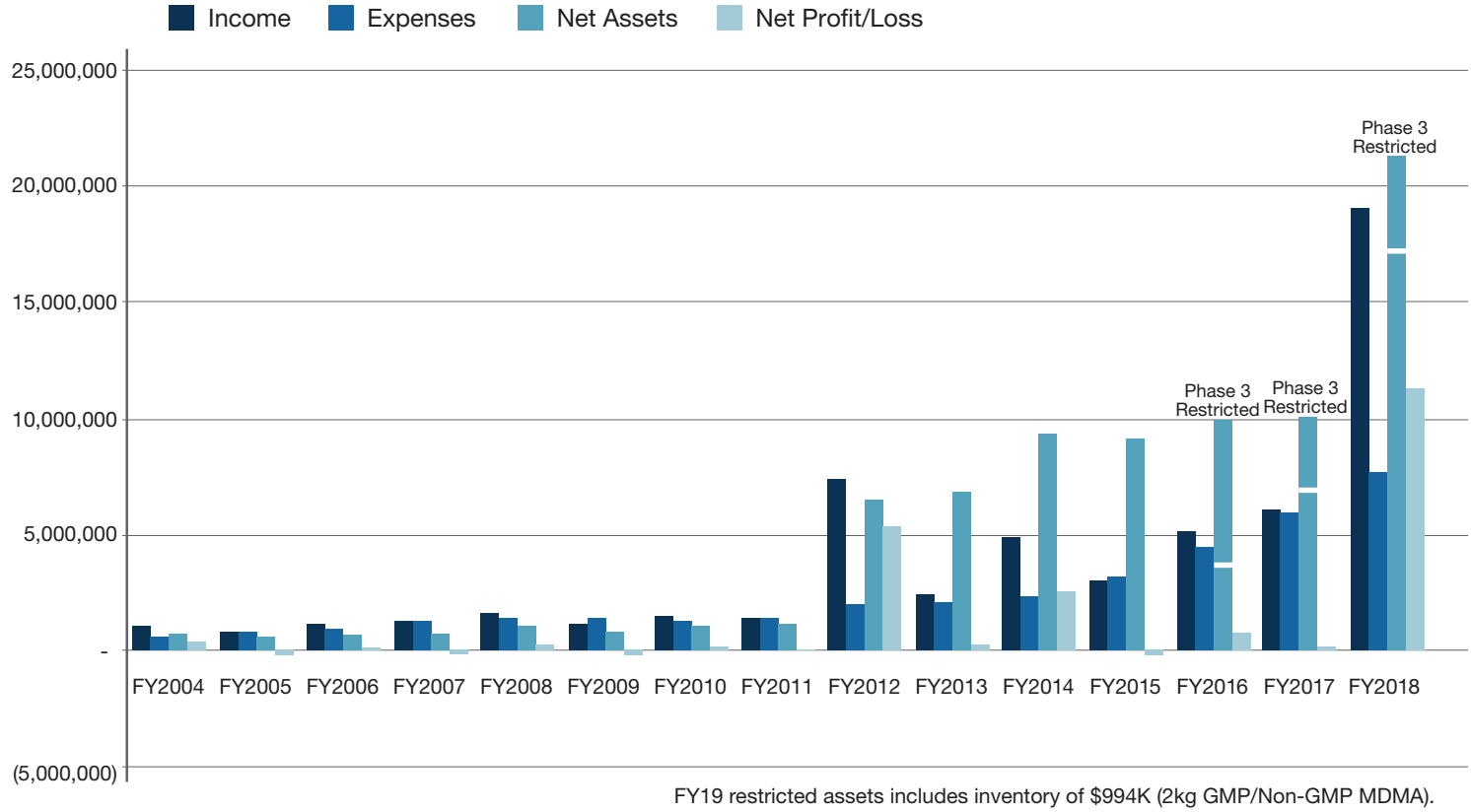
MPBC was created in December 2015 to conduct MAPS' clinical research and eventually to market MDMA as an FDA-approved prescription medicine for PTSD, an outcome we currently anticipate will take place in 2021 (additional information can be found at **mapsbcorp.com**). MAPS Europe BV was created in February 2018 to conduct MAPS' clinical research and eventually to market MDMA in Europe with approval by the European Medicines Agency (EMA), estimated in 2022. MAPS' top priority project is working to obtain worldwide approval for the legal prescription use of MDMA with approvals for indications beyond PTSD as funding permits.

MAPS' FY18 Annual Report demonstrates our efforts to strategically leverage the resources that MAPS supporters have so generously empowered us to use to transform psychedelics and marijuana into approved prescription medicines. Medicalization of psychedelics and marijuana is an essential part of our larger mission to mainstream these substances for a wide range of beneficial uses for a diverse and inclusive population of people.

MAPS' annual financial reports, audits, and IRS 990 forms can be found at **maps.org/about/fiscal**. If you have any questions or comments about anything in this financial report, or would like to become more involved, we invite you to contact **askMAPS@maps.org**.

MAPS needs your help to expedite legal access for many millions of people in the US and around the world to the healing and spiritual potentials of psychedelics and marijuana. You can donate any time at **maps.org/donate.**

Chart 1. MAPS FISCAL YEAR 2004–2018 CONSOLIDATED INCOME, EXPENSES, & ASSETS



FY19 restricted assets includes inventory of $994K (2kg GMP/Non-GMP MDMA).

OVERVIEW

Income in FY18 was the highest in MAPS' entire 32-year history. MAPS' net revenue in Fiscal Year 2018 (June 1, 2017 – May 31, 2018), totaled $19,066,615 from 3,433 donors, as well as events, sales, and investments. This total includes $18,279,144 in contributed revenue, $254,082 from events/sales, $742,213 from a grant from the Colorado Department of Public Health and Environment (CDPHE) for our marijuana/PTSD study, $563,743 from Fiscal Sponsorship income, and $243,680 in restricted donations and earned income by MAPS' Zendo Project providing harm reduction services at festivals and offering an advanced training program.

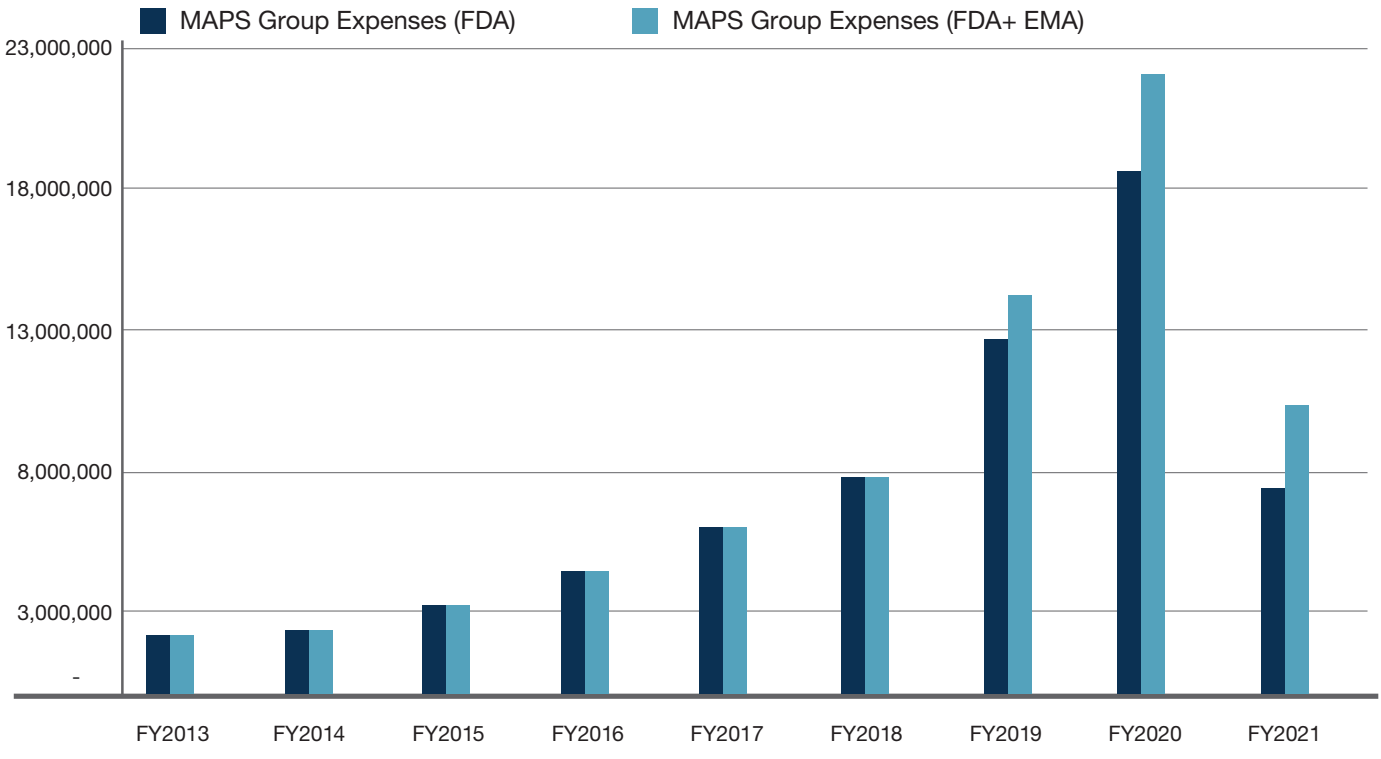
Expenses in FY19 totaled $7,774,908, also the largest in MAPS' entire history. FY18 expenses were over $1.8 million more than FY17, over $3.3 million more than FY16, and over $4.5 million more than in FY15. The dramatic increase in expenses over the last four years is primarily a result of MAPS' transition from Phase 2 to Phase 3 studies of MDMA-assisted psychotherapy for PTSD, along with the expansion of our MDMA program to include several Phase 2 studies of MDMA-assisted psychotherapy for PTSD, social anxiety and end-of-life anxiety, and a study for smoked marijuana for symptoms of PTSD. In FY17, MAPS increased its net assets by $230,450 and in FY18 MAPS increased its net assets by $11,291,707.

For historical information on overall annual income, expenses, and net assets, see Chart 1. Chart 1A presents historical information and projections for MAPS consolidated expenses for the MDMA drug development program for FDA only and for FDA + EMA. Charts 2 and 4 present detailed information on FY18, with Chart 3 projecting annual income, expenses, and net assets for FY19. Total amounts of restricted funds are listed in Chart 5 on a by project basis. Chart 6 is a detailed discussion of MAPS' expenses for FY18 on a project by project basis. With Charts 7 and 8 show long-term cost estimates for developing Phase 3 MDMA-assisted psychotherapy for PTSD into a legal prescription treatment by FDA and EMA respectively.

The largest variable that impacts expenses for FDA and EMA approval is the number of subjects we'll need to enroll in Phase 3 trials. This depends on the magnitude of the treatment effect with the larger the effect size, the fewer number of subjects needed for statistical significance. We anticipate that we will be able to make MDMA-assisted psychotherapy for PTSD into a legal prescription treatment in Europe through the EMA for approximately one-third the cost of the FDA program. This is because EMA will consider the data collected in the FDA studies as confirmatory data to support approval, requiring only one additional Phase 3 study while FDA is requiring two Phase 3 studies, along with other safety data.

MAPS has achieved an enormous success in fully funding projected expenses for FDA approval, but there are still funding gaps anticipated in FY19 including $1.15 million in operational expenses (with $921,000 left to raise) and funding for EMA Phase 3 research (estimated to require $9 million, of which we have raised roughly $900,000). Fortunately, we now have a clear path to FDA approval for the prescription use of MDMA-assisted psychotherapy for PTSD so our cost-estimates are becoming

Chart 1A. MAPS GROUP EXPENSES FISCAL YEAR 2013–2021



more precise. Nevertheless, we won't know how many subjects we are going to need for Phase 3 until the interim analysis of our first Phase 3 study, which we anticipate will take place in mid-2019.

REVENUE REVIEW FOR FISCAL YEAR 2017–18

The search for funding for Phase 3 trials of MDMA-assisted psychotherapy for PTSD for FDA approval was a major priority in FY18. MAPS had projected contributed revenue of $6.1 million for FY18, but received an additional $12.1 million above what was projected, for a total of $18.2 million in contributed revenue. This windfall of support allowed MAPS to fully fund anticipated expenses for FDA Phase 3 MDMA/PTSD research, a staggering $26.7 million project.

Marked increases in FY18 compared to FY17 were seen in individual contributions (526%), foundation contributions (420%), fiscal sponsorship income (88%), and harm reduction income (88%). Revenue from events and sales decreased by 76%, which can be attributed to Psychedelic Science 2017, the largest psychedelic science conference ever convened, taking place in FY17. In FY18, a loss of -$719,080 was realized in investments and other income, largely attributed to liquidation of cryptocurrency and the rapidly fluctuating value.

Major factors in overall revenue for FY18 include the outstanding support from the cryptocurrency community, especially the Pineapple Fund and several anonymous donors.

For an in-depth discussion of funding sources, see the Sources of Revenue section, and the article by Pine of the Pineapple Fund on pages 36–37. In FY18, MAPS raised $15,278,393 for research of which $14,500,365 was raised for MDMA-related research and $778,028 was raised for marijuana and other research projects.

Major support totaling $14,422,145 was received for MAPS' Phase 3 MDMA-assisted psychotherapy studies. This includes $14,395,477 for Phase 3 General Support which has been used to design the Phase 3 protocol and prepare submissions to FDA, prepare sites for the trials, and recruit staff; and $26,668 towards the production of the GMP MDMA study drug for the research. MAPS also received $78,220 for other MDMA research projects.

For research other than with MDMA, MAPS raised $727,858 for our study of marijuana for treating PTSD in 76 US veterans, funded by a $2.15 million cost reimbursable grant

Chart 2. CONSOLIDATED STATEMENT OF ACTIVITES
FY2018 Actuals June 1, 2017– May 31, 2018 (Unaudited)

Revenue	Actuals (unaudited) May 31, 2018	Projected 2018 Board
Support from Individuals, Corporations, & Bequests	12,116,354	12,238,437
Support from Foundations *(See Note 1: FY18 Income)*	5,919,110	5,742,278
Event Registration	150,341	130,064
Sales	103,741	105,000
Government Grants (CDPHE Grant)	742,213	1,041,922
Fiscal Sponsorship Income	563,743	298,102
Harm Reduction Income	243,680	229,122
Net Investment & Other Income	-719,080	-500,000
Total Revenue and Support	**$ 19,120,102**	**$ 19,284,924**
Cost of Goods Sold	53,488	29,672
Net Revenue	**$ 19,066,615**	**$ 19,255,252**
Expenses		
Research	4,796,961	5,595,510
Education	978,561	677,797
Harm Reduction	237,792	200,762
Fiscal Sponsorships	499,962	244,514
Total Programs	**6,513,275**	**6,718,582**
Fundraising	386,897	439,794
Administration	874,736	948,807
Total Expenses	**$ 7,774,908**	**$ 8,107,183**
Change in Net Assets	**$ 11,291,707**	**$ 11,148,069**

Chart 3. STATEMENT OF ACTIVITES (PROJECTED)
FY2019 Projected June 1, 2017– May 31, 2018

Revenue	Projected for FY19
Support from Individuals, Corporations, & Bequests	1,664,940
Support from Foundations *(See Note 1: FY18 Income)*	1,070,250
Event Registration	210,375
Sales	114,115
Government Grants (CDPHE Grant)	693,558
Fiscal Sponsorship Income	500,000
Harm Reduction Income	250,000
Net Investment & Other Income	480,000
Total Revenue and Support	**$ 4,983,238**
Cost of Goods Sold	58,837
Net Revenue	**$ 4,924,401**
Expenses	
Research	9,553,159
Education	924,928
Harm Reduction	250,000
Fiscal Sponsorships	475,000
Total Programs	**$ 11,203,087**
Fundraising	473,504
Administration	980,593
Total Expenses	**$ 12,657,183**
Change in Net Assets	**– $ 7,732,782**

from the Colorado Department of Public Health and Environment (CDPHE), the income of which will be recognized monthly as received over the next two years.

MAPS received additional revenue of $762,288 from its educational initiatives. This includes $243,680 from psychedelic harm reduction crowd funding, services and training, $254,082 from events and sales, and $563,743 in Fiscal Sponsorships (see Notes 1 and 2).

The balance of MAPS' funds raised in FY17, in the amount of $2,928,417, which included $274,718 from educational events, trainings, and harm reduction initiatives, was designated for unrestricted use.

SOURCES OF REVENUE IN FISCAL YEAR 2017–18

About 94% of net revenue was contributed by 3,433 individual donors and family foundations. In FY18, number of donors increased by 44%, and there was a 482% increase in amount raised compared to FY17.

The most obvious source of this major windfall was the Pineapple Fund, which contributed $1 million worth of Bitcoin to MAPS in December 2017. This inspired an additional $1 million worth of Bitcoin from an anonymous donor. In the same month, MAPS also received a donation of LUN tokens worth $769,203. The Pineapple Fund then offered a $4 million matching grant for FDA Phase 3, for the period of January 10 to March 10, 2018, which inspired yet another $1 million donation worth of Bitcoin from James Evans. MAPS completed the match, raising over $8 million for Phase 3. The Pineapple Fund also included roughly $339,118 in unrestricted money to cover volatility and fees during the transfer and liquidation of the donated Bitcoin. MAPS raised approximately $2.7 in cryptocurrency donations above and beyond the $8 million raised from the Pineapple Fund matching grant. You can learn more about the philanthropist behind the Pineapple Fund in their article on pages36–37. Other notable sources of Phase 3 funding in FY18 came from The Sarlo Foundation ($1,000,001), Dr. Bronner's ($800,000), Britt Selvitelle ($1,000,000), the RiverStyx Foundation ($800,000), and the efforts of Clay Rockefeller and Rebecca Lambert, in honor of their late father, Richard Rockefeller. At the very end of FY18, Clay, Rebecca, and their cousins collectively donated $500,000 to complete funding for FDA Phase 3.

MAPS had the most successful Year-End Fundraising and Zendo Project Crowdfunding Campaigns to date in FY18. Year-End Fundraising brought in $460,246 from over 800 donors in 28 countries. Matching grants were provided by three anonymous donors ($30,000), Justin Rosenstein ($15,000), The Sarlo Foundation ($10,000), and Bonnie Brunet & Martin Rist ($5,000).

From July through September 2017, 374 donors raised over $102,000 for the Zendo Project. This campaign raised twice as much as the campaign in 2016 and raised more than any Zendo fundraising campaign to date. Cody Swift of the RiverStyx Foundation generously gave $30,000 towards the campaign and an anonymous donor offered a $20,000 matching grant.

In FY18, MAPS hosted or helped organize seven fundraising event and six cultivation events which raised $226,411. These events are often in the format of a small to medium dinner or reception and offer opportunities to build relationships with our core supporters, connect with new supporters, and establish new audiences in new places. These events included the CryptoCruise ($15,250); Legalizing Psychedelic Medicine in NYC ($57,842), Atlanta, GA ($10,215), and Boulder, CO

Chart 4. STATEMENT OF FINANCIAL POSITION

FY2018 Actuals June 1, 2017– May 31, 2018 (Unaudited)

Assets	**May 31, 2018**
Cash and Equivalents	4,066,136
Pledges and Receivables	3,256,471
Other Current Assets	14,580,003
Total Assets	**$ 21,902,611**
Liabilities	
Accounts Payable & Accrued Expenses	563,694
Total Liabilities	**$ 563,694**
Net Assets	
Unrestricted	4,057,530
Board Restricted	4,705,917
Temporarily Restricted	12,575,469
Total Net Assets	**$ 21,338,917**
Total Liabilities and Net Assets	**$ 21,902,611**

FY2018 Net Revenue

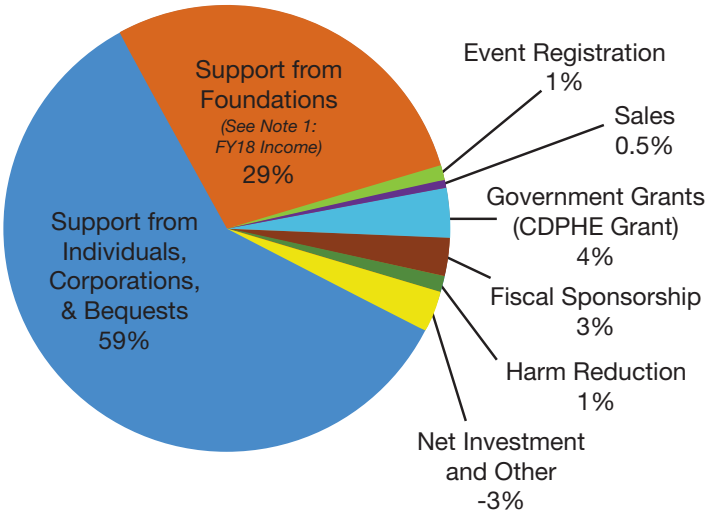


Chart 5. TEMPORARILY RESTRICTED , BOARD RESTRICTED, AND OTHER RESTRICTED FUND DETAIL

Fiscal Year 2017–2018 and 2018–2019 (at May 31)

	May 31, 2018			May 31, 2019		
Phase 3 Studies	**Temporarily Restricted**	**Board Restricted**	**Total Restricted**	**Temporarily Restricted**	**Board Restricted**	**Total Restricted**
Phase 3 Program General	11,256,896	4,705,917	15,962,813	4,847,562	4,705,917	9,553,479
Phase 3 GMP MDMA (book value of WIP)	574,557	-	574,557	994,315	-	994,315
Phase 3 Europe	246,983	-	246,983	-	-	-
Phase 3 MAPP1 Israel (FY17 Donation)	477,391	-	477,391	477,391	-	477,391
TOTAL Phase 3	**$ 12,555,826**	**$ 4,705,917**	**$ 17,261,743**	**$ 6,319,267**	**$ 4,705,917**	**$ 11,025,184**
Other Studies & Restrictions						
US MDMA Qualitative	5,698	-	5,698	-	-	-
MDA1 (Phase 2 End of Life Study)	15,349	-	15,349	-	-	-
LSD/Psilocybin General	4,643	-	4,643	-	-	-
Marijuana Opiate	15,000	-	15,000	15,000	-	15,000
Total Other Studies	**$ 19,643**	**$ 0**	**$ 19,643**	**$ 15,000**	**$ 0**	**$ 15,000**
Total Temporarily & Board Restricted Funds	**$ 12,575,469**	**$ 4,705,917**	**$ 17,281,386**	**$ 6,334,267**	**$ 4,705,917**	**$ 11,040,184**

($22,375); a Washington D.C. Dinner ($2,590); Exploring Psychedelic Medicine in Fort Collins, CO ($7,514); ArcView Dinner in Los Angeles ($35,828); and Psychedelic Possibilities Benefit in Austin, TX ($35,047).

Although there was a decrease in number of donors between FY16 and FY17, FY18 saw a considerable increase in donors to 3,433 (44% increase) with a renewal rate of 35%. This can be partially attributed to the aftermath of Psychedelic Science in April 2017. The conference drew many first-time contacts into MAPS' database, with a fair portion being converted into donors in the following fiscal year. The conference also re-engaged lapsed donors who hadn't given in some time.

Another reason for the increase in donors is due to ever-growing grassroots campaigns, which typically bring in new donors at a rate of 50-60%.

Monthly donors are some of MAPS' most dedicated supporters. It's noteworthy that monthly donors – people who set up automatic donations on a monthly basis – increased from 181 in FY17 to 232 in FY18 contributing $54,805 in revenue. This subset of donors provides a consistent foundation of funding, which has been steadily increasing in the last several years.

In FY18, MAPS has maintained its usual Foundation relationships and slightly increased its number of grant proposals. Grant revenue of $6,161,184 was received from family foundations and donor advised funds. In most cases, we have pre-existing relationships with the courageous and visionary donors.

MAPS' long term account for our assets, The Curing Fund, is managed by the San Francisco Foundation and has been invested in the stock market. At the end of FY17, the MAPS Board of Directors reallocated the portfolio to a short-term investment strategy based on cash flow forecasts that showed drawdowns beginning in December 2017. The Curing Fund began FY18 with a balance of $7,181,216. As projected, drawdowns on the fund of $450,000 began in December. These were more than offset by an additional $6,833,027 in new contributions added through the liquidation of cryptocurrency donations – primarily from December 2017 to March 2018. The success of MAPS' cryptocurrency and other fundraising efforts over the balance of the year eliminated the need for further drawdowns on The Curing Fund and led to a closing balance of $13,477,459 at fiscal year-end.

MAPS continued its long-running Fiscal Sponsorship program in FY18 with donations totaling $563,743. This program supports projects that are in alignment with MAPS' mission and vision but are being conducted by organizations that do not have a 501(c)(3) designation. MAPS monitors the project budget, takes a small fee, and sends the donor a receipt for their contribution.

Product sales and event registrations combined generated $254,082 and remain important aspects of our work. A total of 2,408 orders were placed in FY18, reaching more than 25 countries. Events and products serve to draw new supporters, strengthen our relationships to current supporters, and promote our message.

Note 1:
FY18 FISCAL SPONSORSHIP DETAIL

	Total Raised	Total Disbursed
Asociación de Estudios Científicos	12,300	11,685
Ayahuasca Foundation (Peru)	65,050	62,750
Better Living Through Chemicals	4,600	9,120
Bluelight	27,602	7,287
Catharsis on the Mall	11,720	11,560
Cosmic Sister	2,940	2,799
From Shock To Awe	125,030	118,731
Huxley's Exit	5,000	4,750
Ibogaine Stories	23,500	22,800
ICEERS	8,636	7,226
Nierka	88,875	54,150
Open Cannabis Project	26,480	22,757
The Mission Within	35,000	35,000
Psychedelic Family	220	-
Sacred Plants of the Americas (excludes MAPS Grant of $5,000)	22,498	15,347
Takiwasi	120,000	114,000
Sub-Total	**579,451**	**499,962**
Fiscal Sponsorship Management Fees/Adjustment	15,708	-
Total	**$ 563,743**	**$ 499,962**

Note 2:
FY18 HARM REDUCTION DETAIL

	Income	Expense
Zendo	4,500	23,623
Outreach	940	9,576
Staff Retreat	-	3,344
Seattle Fundraiser	4,325	3,343
Trainings	13,922	16,618
Amplify	-	65
Bronner Camp Fees for Burning Man	50,421	250
Burning Man 2017	488	79,801
Burning Man 2018	1,059	33,973
Insomniac	11,435	16,537
Harm Reduction General	142,524	14,663
Afrika Burn	2,540	2,040
Envision	4,600	13,927
Lightning in a Bottle	6,927	14,802
Reform	-	1,424
Youtopia	-	3,806
Total	**$ 243,680**	**$ 237,792**

EXPENSE REVIEW FOR FISCAL YEAR 2017–18

In Fiscal Year 2018, total expenses were $7,774,908. Program costs totaled 83.8% of all expenses. Programs included Research expenses of $4,796,961, Education and Communication expenses of $1,216,352 which includes Harm Reduction of $237,792 and Fiscal Sponsorships of $563,743. Fundraising expenses were $286,897 and Administrative expenses were $874,736.

Our primary expenditure in FY18 was for MDMA-assisted psychotherapy research with expenses of $3,978,141. Of that amount, MAPS spent $3,679,741 on beginning Phase 3 research into MDMA-assisted psychotherapy for PTSD and associated projects. We also completed our study looking at the safety and efficacy of using MDMA-assisted psychotherapy for social anxiety in adults on the autism spectrum ($20,872), with the paper recently published in *J. Psychopharmacology,* and completed our study of MDMA-assisted psychotherapy for end-of-life anxiety ($34,650), with the paper awaiting submission for publication. An additional $90,843 was spent on the study blending MDMA-assisted psychotherapy with Cognitive Behavioral Conjoint Therapy (CBCT) conducted by Candice Monson, Anne Wagner, Michael and Annie Mithoefer, and $11,060 on the study blending MDMA-assisted psychotherapy with Prolonged Exposure Therapy (PE) at Emory University.

Marijuana research expenses totaled $762,034. In FY16, after seven years of struggle, MAPS finally received DEA and IRB approval to move forward with its study examining the efficacy of smoked marijuana in 76 veterans with chronic, treatment-resistant PTSD. This research is funded by a $2.156 million grant from the Colorado Department of Public Health and Environment (CDPHE). In February 2017, the first participant was enrolled and received cannabis. As of the writing of this report, we have enrolled 75 of the 76 subjects.

Chart 6. MAPS FY 2017–18 ACTUALS COMPARED TO FY 2018–19 PROJECTED DETAIL EXPENDITURES (Unaudited)

Research	MAPS FY 2017–18 Actual	MPBC FY 2017–18 Actual	Consolidated FY 2017–18 Actual	Consolidated FY 2018–19 Projected
Ayahuasca				
Ayahuasca General	2,824	1,931	4,755	5,000
Ayahuasca PTSD	-	343	343	5,000
Ayahuasca Addiction	-	-	-	-
Total Ayahuasca	**$ 2,824**	**$ 2,274**	**$ 5,097**	**$ 10,000**
Ibogaine				
General	104	-	104	-
IOA-3 Ibogaine (Mexico)	1,364	109	1,474	-
IOA-4 New Zealand	-	-	-	-
Total Ibogaine	**$ 1,468**	**$ 109**	**$ 1,577**	**-**
LSD/Psilocybin				
LSD General (Includes MAPS Grant to Peter Gasser)	50,030	82	50,112	-
LSD Creativity	-	-	-	-
LSD Swiss End of Life Study	-	-	-	250
Total LSD/Psilocybin	**$ 50,030**	**$ 82**	**$ 50,112**	**-**
Marijuana				
General	67	3,332	3,399	-
MJP-1 Cannabis PTSD	15,028	743,607	758,635	693,558
Total Marijuana	**$ 15,094**	**$ 746,940**	**$ 762,034**	**$ 693,558**
MDMA/PTSD Key Phase 2 Research Studies				
MP1: Charleston, Pilot	-	250	250	-
MP8: Charleston, Veterans	33	25,983	26,016	36,500
MP8-S1: MDMA PTSD-US Vets Substudy	-	1,518	1,518	-
MP1-E2: Charleston Relapse	-	7	7	-
MP4: Canada	(100)	813	713	36,500
MP9: Israel	45,311	27,719	73,030	36,500
MP10: England FMRI MDMA/PTSD	-	-	-	-
MP12: Boulder	59	39,379	39,439	36,500
MDMA Phase 2 Research Studies, other				
MAA1: Autism Anxiety, Los Angeles	417	20,456	20,872	20,000
MDA1: End-of-Life Anxiety, San Anselmo	59	34,591	34,650	30,000
MPVA1: PTSD, Cognitive-Behavioral Conjoint Therapy	-	90,843	90,843	25,000
MPVA2: CPT Cincinnati	-	-	-	-
MPVA3: PTSD, PET, Charleston	-	-	-	-
MPVA4: PTSD, Prolonged Exposure Therapy, Emory	100	10,960	11,060	100,000
PTSD, Prolonged Exposure Therapy, Toronto	-	-	-	100,000
MP11- Australia	-	-	-	25,000
Memory Reconsolidation Study	-	-	-	3,100
MDMA Phase 3 Research Support				
MDMA Therapist Adherence	83	53,038	53,122	104,864
MDMA Lit Review & (Investigator Brochure)	-	2,821	2,821	43,983
MDMA Treatment Manual	-	117	117	-
MDMA End of Phase 2	-	14,288	14,288	-
MDMA International - Other	13,082	8,556	21,637	-
MP18 Phase 3 Europe Lead-in & Start-up	-	6,291	6,291	703,159
EU Phase 3 Program General	6,110	63,397	69,508	254,088
MP16/MP17 Phase 3 Lead-in	3,913	1,143,830	1,147,743	957,422
Phase 3 Systems (CTMS/eTMF/eCTD)	-	220,444	220,444	196,181
Phase 3 GMP MDMA	10,121	39,285	49,406	488,909
Clin Pharm (PK Studies)	-	-	-	959,770
Phase 3 Preclinical Toxicity Studies	-	2,551	2,551	1,565,809
Phase 3 Program General	57,358	441,423	498,781	306,432
Phase 3/EA Therapist Training	65	119,865	119,930	219,768
Phase 3 MAPP1	14,580	663,329	677,909	3,566,836
Phase 3 MAPP2	-	-	-	85,366
Phase 3 MAPP3	4	2,643	2,646	-
MT1: Therapist Training (Phase III)	64	285,125	285,189	156,442
Expanded Access Training	-	8,538	8,538	199,816
Phase 4 Commitments	-	-	-	-
NDA Process	-	-	-	220,000
Clinical Research General	67,989	430,830	498,819	346,750
Total MDMA	**$ 219,248**	**$ 3,758,892**	**$ 3,978,141**	**$ 10,824,695**
Total Research	**$ 288,664**	**$ 4,508,297**	**$ 4,796,961**	**$ 11,528,253**

Education	MAPS FY 2017–18 Actual	MPBC FY 2017–18 Actual	Consolidated FY 2017–18 Actual	Consolidated FY 2018–19 Projected
Conferences, Events & Initiatives				-
Advocacy	119,520	-	119,520	154,520
Atlanta	2,421	-	2,421	2,500
Psychedelic Science 2017 (Close-out Payments)	107,872	-	107,872	-
Beyond Psychedelics (Prague)	1,390	-	1,390	-
Breaking Convention	4,532	-	4,532	-
Catharsis on the Mall	8,142	-	8,142	8,142
DPA	10,207	-	10,207	10,207
Float Conference	1,777	-	1,777	-
Grants (Gil Karni & Institudo Plantando Consciencia)	27,376	-	-	-
Harm Reduction (see note 2)	237,792	-	237,792	250,000
Horizons	4,056	-	4,056	5,000
LSD 75	11,528	-	11,528	-
Special Events	46,723	-	46,723	90,000
Events Staff, Education Staff, & General Expense	78,355	-	78,355	80,000
End NIDA Monopoly	45,382	-	45,382	50,000
Total Conference, Events & Initiatives	**$ 707,072**	**-**	**$ 707,072**	**$ 650,369**
Communications				
Web & Multimedia	150,769	-	150,769	155,292
Media	34,735	-	34,735	35,778
Publishing	87,218	-	87,218	89,835
Email Newsletter	4,054	-	4,054	4,175
Social Media	56,650	-	56,650	58,349
Media Communications	122,370	-	122,370	126,041
Marketing	3,371	-	3,371	3,472
Communications General Expense	50,113	-	50,113	51,617
Total Communications	**$ 509,280**	**-**	**$ 509,280**	**$ 524,559**
Total Education	**$ 1,216,352**	**-**	**$ 1,216,352**	**$ 1,174,928**
Fiscal Sponsorships *(see note 1)*	499,962	-	499,962	475,000
Total Programs (Research, Education, Fiscal Sponsorships)	**$ 2,004,978**	**$ 4,508,297**	**$ 6,513,275**	**$ 11,691,996**
Fundraising				
Events	63,725	-	63,725	65,637
Campaigns	59,554	-	59,554	86,341
Donor Meetings	40,314	-	40,314	41,524
CRM Implementation (Salesforce)	-	-	-	50,000
Fundraising Staff and General Expense	223,303	-	223,303	230,002
Total Fundraising	**$ 386,897**	**-**	**$ 386,897**	**$ 473,504**
Operations				
Business Expenses (includes Group Insurance & Txn Fees)	51,619	12,087	63,707	58,096
Audit, & Tax	21,193	21,193	42,385	40,656
Accounting and Finance	82,666	77,017	159,684	187,164
Legal and Tax Advisory Services ($50K Projected Zendo Related)	7,770	-	7,770	62,878
Information Technology	40,417	-	40,417	156,737
Facilities and Equipment	2,796	-	2,796	4,237
Human Resources	47,344	38,394	85,738	75,000
Occupancy (Allocated to Depts.)	11,478	25,917	37,395	44,889
Office Supplies, Utilitites, Phones, Post, Printing, Misc	57,445	3,691	61,136	63,168
Staff Development	7,077	2,687	9,764	12,289
Travel	12,386	-	12,386	12,758
Operations Staff & Other Expense (Contingency)	273,549	78,011	351,560	366,755
Total Operations	**$ 615,739**	**$ 258,997**	**$ 874,736**	**$ 1,084,626**
Total Expenses	**$ 3,007,614**	**$ 4,767,294**	**$ 7,774,908**	**$ 13,250,125**
Programs Ratio (Education/Total Expense)	66.7%	94.6%	83.8%	88.2%

Education expenses of $1,216,352 includes events, conferences, publications, communications, psychedelic harm reduction, and fiscal sponsorships. Conferences, events, and initiatives had expenses of $707,072. In FY17, MAPS provided sponsorship, speakers, tables, formal representatives and/or promotional support for over 70 outreach events, doubling the number from FY17.

Communications expenses of $509,280 include active engagement in public education through media contacts, website and social media presence, publishing three MAPS *Bulletins,* 12 email newsletters and the MAPS Podcast hosted by Zach Leary. We maintain maps.org, mapsbcorp.com, mapscanada.org, zendoproject.org, psychedelicscience.org, psychedelicdinners.org, and mdma-autism.org. In FY18, MAPS received 549 unique media mentions from online and print publications, more than ever before. Media outlets include: *Time, Forbes, Rolling Stone, New York Magazine, The Washington Post, Playboy, The New York Times, Fox News, Breitbart, Stars and Stripes, Reuters, The San Francisco Chronicle* and many more.

The Zendo Project psychedelic harm reduction program incurred costs of $237,792, with $113,774 of that to support Zendo's work at Burning Man. The Zendo Project provided services at seven major festivals including: Burning Man, Insomniac events with Project Open Talk, Envision, and Lightning in a Bottle. The Zendo Project provided support to over 670 guests at two locations at Burning Man 2017. Zendo's location was highlighted on Burning Man's official map of Black Rock City and Zendo collaborated closely with medical staff, law enforcement from the Bureau of Land Management, and Black Rock City Rangers. A public 3-hour training on the principles of psychedelic harm reduction was hosted for several hundred people. Zendo staff also hosted two integration sessions.

Fundraising expenses were $386,897, an increase of 86% from

FY17. However, current fundraising expenses account for only 2% of all contributed revenue for FY18, which is better than national averages (10-20%). MAPS efficiently spends $0.02 in fundraising for every $1 raised. Of the fundraising expenses, $223,303 is primarily for staff, mail and delivery, donor research, and database costs; with another $40,314 for donor meetings and cultivation efforts; and another $123,280 in campaign and fundraising event expenses.

Operational costs were $874,736. These are the unglamorous but necessary expenses of staffing, office rent, taxes, fees, accounting, information technology, equipment, supplies, and postage. Operations accounts for 11% of MAPS expenses.

PROJECTIONS FOR FISCAL YEAR 2018–19

In FY19, our focus remains on the multi-site Phase 3 studies required for FDA approval of MDMA-assisted psychotherapy for PTSD as a legal prescription treatment. We also anticipate a growing focus on Phase 3 studies required for European Medicines Agency (EMA) regulatory approval. The first Phase 3 study for FDA will have been initiated by the time this Bulletin arrives in MAPS members' mailboxes. We anticipate submitting our New Drug Application to the FDA in 2021. We are currently training potential European researchers, selecting potential study sites, and preparing regulatory submission in hopes of initiating studies in Europe near the end of FY19, however this is dependent on raising the $9 million needed to fund these studies.

In FY19 there are projected total research expenses of nearly $11.6 million with approximately $1.49 million of this amount earmarked for European studies, about $1.17 million for our education programs including the Zendo Project and Fiscal Sponsorships, with approximately $1.55 million for Fundraising and Administration.

Estimated spending in FY19 is projected to be over $13.25 million, an increase of nearly $5.5 million over FY18, and by far the largest expenditures in a single fiscal year in MAPS' entire 33-year existence due to the ongoing Phase 3 studies.

MAPS' fundraising ability has significantly increased now that MAPS has obtained an FDA Agreement Letter successfully concluding our Special Protocol Assessment (SPA) process and been granted FDA Breakthrough Therapy Designation for MDMA-assisted psychotherapy for PTSD, and published Phase 2 results in high impact journals like The Lancet Psychiatry and Psychopharmacology. MAPS has received some major support in FY19, including grants and pledges of $500,000 from Good Ventures, $500,000 from the efforts of Clay Rockefeller and Rebecca Lambert, $100,000 from Lauren Sherman who contributed to MAPS Canada, and $100,000 from Abby Rockefeller.

Chart 7. MDMA/PTSD COST PROJECTIONS: Two Phase 3 Trials for FDA

Phase 3 MDMA/PTSD Research Projects	Actuals 2014–15	Actuals 2015–16	Actuals 2016–17	Actuals 2017–18	Projected 2018–19	Projected 2019–20	Projected 2020–21
End-of-Phase-2 Meeting w/ FDA	2,060	69,462	105,614	-	-	-	-
GMP MDMA Supply	205	125,262	305,170	370,352	465,485	12,000	12,000
MDMA Therapist Training-Protocol (MT-1)	-	77,197	153,350	285,189	-	-	-
MDMA Literature Review	-	-	10,000	117	43,983	45,941	57,797
MDMA Therapist Adherence Criteria	-	-	26,000	51,933	47,000	45,588	-
Phase 3 Therapist Training	52,549	154,553	308,406	129,628	-	-	-
Phase 3 Program General	-	92,354	359,089	435,654	306,432	249,764	247,716
Clinical Research General	30,114	103,101	180,451	430,830	296,750	236,614	256,040
Phase 3 Systems	-	-	-	220,444	148,299	115,108	107,750
ClinPharm (PharmocoKinetics & ECG Studies)	-	-	-	-	959,770	60,851	-
Preclinical Toxicity Studies	-	-	-	2,551	1,565,809	455,376	-
MP16/MP17 Phase 3 Lead-in	-	-	-	1,157,981	957,422	-	-
Phase 3 Trial 1: MAPP1 (n=100)	-	423	185,670	640,476	3,543,622	1,450,570	223,069
Phase 3 Trial 2: MAPP2 (n=100)	-	-	-	-	85,366	2,885,473	1,539,252
Phase 3 Trial 1: MAPP1 Expanded (n=50)	-	-	-	-	23,214	1,898,039	-
Phase 3 Trial 2: MAPP2 Expanded (n=50)	-	-	-	-	-	1,656,180	703,777
Phase 4 Commitments	-	-	-	-	-	15,500	171,825
NDA Process	-	-	-	-	220,000	354,060	255,806
Overhead (7% Allocation for Projected)	-	-	76,595	184,676	486,633	617,311	207,447
Total Phase III MDMA/PTSD Research	**$ 84,928**	**$ 622,353**	**$1,710,345**	**$ 3,909,830**	**$ 9,149,785**	**$10,098,375**	**$ 3,782,479**
Total Phase III Projected Costs	**$ 26,940,469 over four years including overhead of $ 1.5M**						

CONCLUSION

FY18 was an exceptional year, successfully setting the stage for Phase 3 research on MDMA-assisted psychotherapy for PTSD. Expenses were greater than any other fiscal year to date, yet MAPS managed to raise enough contributions and multi-year pledges to completely fund FDA Phase 3 studies, increasing our net assets temporarily by over $11 million. However, as Phase 3 kicks into high gear in FY19, expenses will grow substantially. The inspiring news about FDA granting MAPS Breakthrough Therapy Designation for MDMA-assisted psychotherapy for PTSD has motivated supporters to step up, confident in the impact of their gift to heal trauma and legitimize MDMA-assisted psychotherapy as a legally available treatment available by prescription.

As MAPS initiates its Phase 3 MDMA/PTSD studies for FDA, research and educational expenses will continue to increase each year until FY20 when we'll complete gathering the Phase 3 data. In FY21, MAPS' FDA Phase 3 research will shift to much less expensive data analytic work and submitting a New Drug Application to FDA.

MAPS' currently has raised the estimated $26.7 million needed to complete Phase 3 studies for FDA. Now, our fundraising focus turns to EMA Phase 3 studies, which we anticipate will cost approximately $9 million, of which about $900,000 is already raised. MAPS is seeking to raise these funds by the end of FY19. It will be substantially less expensive if we can enroll subjects for the one Phase 3 study for EMA and continue until we have treated enough subjects, than if we have to stop the study to raise more funds.

In FY19, we have conducted discussions with EMA for scientific advice about the study designs for the Phase 3 study, and discussions with FDA and DEA regarding our Breakthrough Therapy Designation. MAPS still needs to demonstrate statistically significant evidence of efficacy in our Phase 3 studies with an acceptable safety profile before FDA will authorize prescription use, but the Breakthrough Therapy Designation allows for discussions about potential commercialization issues prior to the completion of the Phase 3 studies. These discussions will focus on topics related to Expanded Access (compassionate use for PTSD patients prior to actual approval for prescription use), brand names, manufacturing of commercial quantities of GMP MDMA, the Risk Evaluation and Mitigation Strategies (REMS) that will control how MDMA-assisted psychotherapy will be provided by prescription, as well as other topics related to commercialization of MDMA-assisted psychotherapy for PTSD.

We are not there yet, but with the continued support from the MAPS community, the legal prescription use of MDMA will become more than a dream.

If you have questions or comments about anything in the financial report, or would like to become more involved, we invite you to contact **askMAPS@maps.org**.

Chart 8. MARKETING AUTHORIZATION IN EUROPE: MDMA/PTSD Phase III Cost Projections

Phase 3 MDMA/PTSD Research Projects	Actuals 2017–18	Projected 2018–19	Projected 2019–20	Projected 2020–21	Projected 2021–22
GMP MDMA Supply - Clinical Batch	-	23,424	-	-	-
MDMA Therapist Training-Protocol (MT-1) EU	-	130,000	-	-	-
MDMA Therapist Adherence Criteria	-	57,864	56,470	61,821	-
Phase 3 EU Therapist Training	-	219,768	-	-	-
Phase 3 EU Program General	53,564	254,088	328,214	306,489	658,111
Healthcare Economics Analysis & HTA Assessment	-	50,000	-	-	-
Phase 3 Systems	-	47,882	67,304	67,304	-
MP18 Phase 3 Lead-in	-	703,159	262,669	-	-
Phase 3 Trial 3: MAPP3 (n=70)	8,933	-	2,585,990	794,069	-
Phase 3 Trial 3: MAPP3 Expanded (n=35)	-	-	-	1,217,053	-
MAA Process (EMA)	-	-	-	500,000	-
Overhead (7% Allocation for Projected)	-	104,033	184,972	59,912	-
Total Phase III MDMA/PTSD Research	**$ 62,497**	**$ 1,590,218**	**$ 3,485,620**	**$ 3,006,649**	**$ 658,111**
Total Phase III EMA Projected Costs	**$ 8,803,094 over 4 years including overhead of $ 350,000**				

MAPS FISCAL YEAR 2017–2018 DONORS

These pledges and donations were made between June 1, 2017 and May 31, 2018. Our gratitude goes to all those who contributed to make this work possible. We share this list in part to show that a community has gathered together to make a difference.

Donors in *italics* donated to MAPS Canada rather than to MAPS US.

$1,000,000 & ABOVE

Pineapple Fund ($5,297,904)
RiverStyx Foundation ($2,030,000)
Anonymous ($1,017,255)
George Sarlo ($1,010,001)
James Evans ($1,000,050)
Dr. Bronner's ($1,000,000)
Britt Selvitelle ($1,000,000)

$100,000–$999,999

Anonymous ($769,203)
The Libra Foundation ($610,000)
Anonymous ($500,000)
Anonymous ($400,000)
Christian Halper ($300,000)
Mental Insight Foundation ($300,000)
William H. Donner Foundation ($300,000)
Neva Goodwin ($250,000)
Rebekah Mercer ($250,000)
Jason Dorsett ($209,979)
Anonymous ($175,000)
Christopher & LuAnne Hormel ($100,000)
Adam Wiggins ($100,000)

$50,000–$99,999

Carey & Claudia Turnbull ($52,844)
Paul & Emily Eastham ($51,130)
Peggy Dulany ($51,041)
Cyan Banister ($50,113)
Robin Toor ($50,000)

$25,000–$49,999

M. Allen Hopper ($45,000)
Laura & Ed W. Littlefield ($40,000)
Tim Luckit ($25,376)
Fundamental ($25,000)
George Goldsmith & Katya Malievskaia ($25,000)
Aubrey Marcus ($25,000)

$10,000–$24,999

Jennifer Allen ($21,956)
Google, Inc. ($20,875)
Joshua Bezoni ($20,100)
Rodrigo Niño ($20,000)
Fred & Kate Weber ($20,000)
Anonymous ($20,000)
Anonymous ($20,000)
Anonymous ($17,508)
Robert J. Barnhart ($16,735)
Dean Nolan ($15,699)
Justin Rosenstein ($15,000)
Lauren Sherman ($15,000)
Anonymous ($15,000)
Paul & Kristina Eklund ($12,000)
William F. Harrison ($11,000)
Hub Spoke and Wheel ($10,850)
Anonymous ($10,820)
Anonymous ($10,100)
Anonymous ($10,050)
Devon Aoki ($10,000)
Arizona Natural Pain Solutions ($10,000)
Robert Bienstock ($10,000)
Chris Kalcovski ($10,000)
Ronald A. Mis ($10,000)
Lisa Orange & William Pugh, Jr. ($10,000)
Maeve Rockefeller ($10,000)
René Ruiz ($10,000)
Hilary Silver ($10,000)
Spark Directed Fund ($10,000)
Anonymous ($10,000)
Anonymous ($10,000)

$1,000–$9,999

AAA ($1,000)
Sean Abraham ($7,500)
Jeya Aerenson ($1,000)
Swami Ajaya ($1,200)
Alternative Telecom Solutions ($1,000)
AmazonSmile Foundation ($7,949)
James Anderson ($3,600)
Eric Angell ($1,000)
Apple, Inc. ($1,000)
Allan M. Badiner ($1,000)
Normand Boivin ($1,000)
Erik Bouchard ($1,575)
Rose Marsh Boyle ($2,000)
Bonnie Brunet & Martin Rist ($5,000)
Breast Cancer Choices, Inc. ($1,000)
John H. Buchanan ($4,500)
Sheila Burgel ($1,200)
Tim Butcher ($2,701)
Diane Byler ($1,550)
Jonathan Cain ($2,500)
Camp Walter ($1,000)
James Stewart Campbell ($1,000)
Diana & Matt Chapman ($1,000)
Martin Chilcutt ($2,000)
Carolyn Cline ($1,000)
Chris Coburn ($1,000)
Ryan Crane ($2,500)
Jay Cranfill ($1,010)
John & Barbara Crary ($1,000)
Clay Creasey ($1,000)
Matteo de Nora ($8,000)
Joshua Dirlam ($1,000)
Vinh Do ($1,100)
Candra Docherty ($2,000)
Mark Drayton ($1,693)
Robert Eisenberg ($2,000)
Hal Elrod ($2,500)
Howard Fallon ($1,250)
Kevin S. Feldman ($1,000)
James Ferrari ($1,000)
Daniel Finster ($1,000)
Audra Foster ($8,500)
Bill Freimuth ($1,000)
Chris Freund ($1,618)
Mack Fuhrer ($4,250)
Robert Gansser ($1,000)
John Garand ($1,000)
The Gardner Grout Foundation ($2,500)
Steve Gehrman ($1,000)
Nimrod Gileadi ($1,520)
Bailey Gimbel ($3,700)
Fiona Glaser ($7,791)
Elliot Godzich ($4,200)
Neal Marshall Goldsmith ($2,400)
Elisha A. Gottstein ($1,000)
Jerry Greenfield ($1,000)
Emily Marie Grossell ($1,000)
Adam Growald ($2,000)
Michael Hamann ($1,000)
Gale Hayman ($1,000)
Russell Haywood ($4,400)
John Heilemann ($2,500)
Kevin Herbert ($2,000)
Christopher James Hewitt ($1,200)
Highfield Foundation ($2,500)
Julie Holland ($1,625)
Ed Hunsinger ($1,000)
Adam Hupp ($2,120)
Shawnna & Steve Huser ($1,000)
Marty Jakle ($1,000)
Chris & Dana Jenks ($1,100)
Philip Jensen ($2,500)
Shawn Joyce ($1,000)
Lucas Jushinski ($2,500)
Meghan Kennedy ($2,600)
Max Kerr ($4,750)
Lars King ($1,500)
Carolyn Mary Kleefeld ($5,000)
Rebecca Lambert ($5,000)
Shane Leather ($3,000)
Salyer Jess Lee ($1,000)
Tom Lehrer ($1,000)
David L. Lewis ($1,000)
Robert & Nancy Ley ($1,000)
Carla R. Lilley ($1,400)
Niklas Lindgren ($1,200)
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To discuss your plans, please contact Jade Netanya Ullmann at giving@maps.org.

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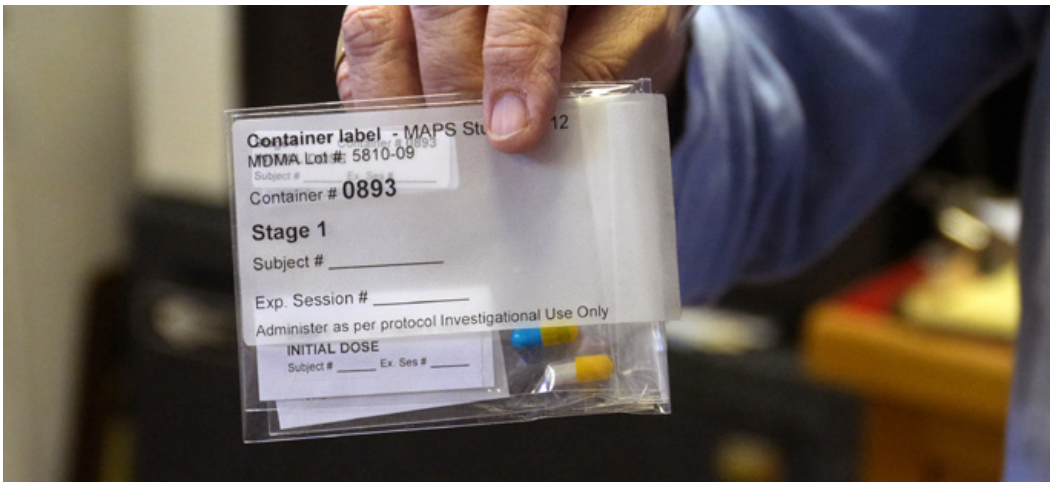
Research News

Treating PTSD with MDMA-Assisted Psychotherapy



MDMA capsules from MAPS' completed Phase 2 trial of MDMA-assisted psychotherapy for PTSD in Boulder, Colorado.

Phase 3 Trials: Study Initiation Visits for 8 Sites Completed

In MAPS' completed Phase 2 trials with 107 participants, 56% no longer qualified for PTSD after treatment with MDMA-assisted psychotherapy, measured two months following treatment. At the 12-month follow-up, 68% no longer had PTSD. Most subjects received just 2-3 sessions of MDMA-assisted psychotherapy. All participants had chronic, treatment-resistant PTSD, and had suffered from PTSD for an average of 17.8 years.

MAPS-sponsored researchers have completed study initiation visits for FDA-regulated Phase 3 trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) at eight United States locations.

MAPS Public Benefit Corporation (MPBC) clinical research staff have completed 14 Study Initiation Visits for an open-label lead-in study of MDMA-assisted psychotherapy for PTSD at planned Phase 3 sites across the United States and Canada. A total of 19 participants have completed treatment for this study. The purpose of this study is to provide the final training for our Phase 3 co-therapy teams. Each new co-therapy team will work with a single participant at their respective study site with supervision provided by MAPS' therapy training team.

Seven study sites are now enrolling and seven sites are fully enrolled. The study is expected to be completed in early 2019.

Phase 3 clinical trials starting Fall 2018 will assess the efficacy and safety of MDMA-assisted psychotherapy in adult participants with PTSD. Over a 12-week treatment period, participants will be randomized to receive 12 non-drug preparatory and integration sessions lasting 90 minutes each along with three day-long sessions about a month apart of either MDMA or placebo in conjunction with psychotherapy. The primary endpoint will be the Clinician Administered PTSD Scale (CAPS-5), as assessed by a blinded pool of independent raters.

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.

On August 16, 2017, the FDA granted Breakthrough Therapy Designation to MDMA for the treatment of PTSD. The FDA grants this designation for treatments that (1) are intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition; and (2) preliminary clinical evidence indicates may demonstrate substantial improvement over existing therapies.

MAPS' Phase 3 trials will be conducted at the following study sites:

Los Angeles, CA | private practice
San Francisco, CA | research institution
San Francisco, CA | private practice
Boulder, CO | private practice
Fort Collins, CO | private practice
Farmington, CT | research institution
New Orleans, LA | private practice
New York, NY | research institution
New York, NY | private practice
Charleston, SC | private practice
Madison, WI | research institution
Boston, MA | research institution
Montreal, Canada | private practice
Vancouver, Canada | research institution
Israel | research institution

MAPS and MPBC are excited to reach this milestone toward bringing healing to those suffering from PTSD with MDMA-assisted psychotherapy.

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

Therapist Training Study Enrolls 67th Participant

Ongoing study
Location: Charleston, South Carolina, and Boulder, Colorado
Principal Investigator: Michael Mithoefer, M.D., (Charleston), and Marcela Ot'alora, M.A., L.P.C. (Boulder)
Sub-Investigator: Annie Mithoefer, B.S.N., (Charleston)

As of October 10, 2018, the 67th participant officially enrolled in our ongoing Phase 1 study of the psychological effects of MDMA when used in a therapeutic setting by healthy volunteers. Enrollment in this multi-site study 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'alora, M.A., L.P.C. Michael Mithoefer, M.D., is serving as Principal Investigator at the site in Charleston, South Carolina with Sub-Investigator Ann Mithoefer, B.S.N.

Cognitive Behavioral Conjoint Therapy for PTSD: Sixth Dyad Completes Long-Term Follow-Up Interview, Study Close-Out Completed

Completed Study
Location: Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D.
Sub-Investigator: Candice Monson, Ph.D.

In May 2018, the sixth dyad completed their long-term follow-up interview in our study of MDMA combined with Cognitive Behavioral Conjoint Therapy (CBCT) for posttraumatic stress disorder (PTSD) at our Charleston, South Carolina site led by Principal Investigator, Michael Mithoefer, M.D., and Sub-Investigator, Candice Monson, Ph.D.. The study close-out was conducted in July 2018. This study has enrolled dyads with one participant diagnosed with PTSD and one concerned significant other who does not have PTSD but does experience psychosocial distress. MDMA will be administered to both participants to help facilitate communication and connection between participants and therapists.

The primary goal of this study is to develop a combined method of MDMA with CBCT for PTSD. This is the first MAPS-sponsored MDMA study conducted with VA-affiliated researchers and the first to employ measures developed for the DSM-5. There are several important reasons to include significant others in PTSD treatment, in addition to the data supporting the efficacy of CBCT for PTSD.

Startle Testing with MDMA: First Participant Receives Experimental Treatment *Ongoing study*

Location: Emory University in Atlanta, Georgia
Principal Investigator: Barbara Rothbaum, Ph.D.

On August 27, 2018, the eighth participant completed experimental treatment in our ongoing study of the effect of MDMA on startle testing in healthy volunteers. Led by Principal Investigator Barbara Rothbaum, Ph.D., this study is conducted at Emory University in Atlanta, Georgia. This research group is hoping to eventually conduct a subsequent study exploring the combination of MDMA with Prolonged Exposure in people with PTSD.

MDMA Therapy Training Program: Expanded Access *Training Program*

Therapy Training Team: Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., Marcela Ot'alora G., M.A., L.P.C.

In the fall of 2018, MAPS plans to apply for a special U.S. Food and Drug Administration (FDA) program called Expanded Access (EA), which allows the use of an investigational medical product (one that has not yet been approved by the FDA) outside of a double-blind clinical trial. The program's purpose is to grant access to potentially beneficial investigational treatments for people facing a serious or immediately life-threatening condition for which there is no satisfactory treatment currently available. The FDA's website has more information on its Expanded Access program.

MAPS has already had positive preliminary discussions about Expanded Access with DEA on December 19, 2017, and with FDA on December 20, 2017. If Expanded Access for MDMA-assisted psychotherapy for PTSD is approved, new sites in the U.S. meeting the requirements may obtain approval and undergo training to administer open-label MDMA-assisted psychotherapy to eligible patients with treatment-resistant PTSD, under a MAPS protocol. Qualified Expanded Access site applicants will have 1) a suitable facility to conduct MDMA-assisted psychotherapy and meet drug storage requirements, 2) qualified therapy team who have completed the MDMA PTSD Therapy Training Program, operated by MAPS Public Benefit Corporation (MPBC), 3) Medical Doctor who can obtain a DEA Schedule I license for MDMA. Sites must also gain DEA approval to manage, store, and administer MDMA, a controlled substance. As MAPS gets closer to application, the requirements will be better understood.

Currently, MPBC is updating its website, including web pages for the MDMA Therapy Training Program (**maps.org/training**) and an online training application for eligible sites and providers. Completed applications for potential sites to work on a U.S. FDA Expanded Access protocol for MDMA-assisted psychotherapy will be reviewed on an ongoing basis, starting late 2018 and continuing through the duration of the protocol, pending approval. Registration for the first training cohort will take place early 2019; training events will take place starting March 2019, in locations across the U.S.

We encourage each site, in choosing location and therapy teams, to consider diversity, inclusivity, and cultural and racial competence. One of the most robust ways to provide accessible care is to train therapists and practitioners from diverse backgrounds, including people of color and from the LGBTQ+ community. If you are a therapist from a marginalized community, we encourage you to reach out to us at **training@mapsbcorp.com**.

At this point, the training program is not accepting applications, however you can sign up to receive updates when future training opportunities become available.

Learn more at **maps.org/training**.

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

Marin: Study Closeout Completed in June 2018

Completed study
Location: Marin, California
Principal Investigator: Phil Wolfson, M.D.
Co-Therpaist: Julane Andries, L.M.F.T.

A close-out visit of MAPS' Phase 2 clinical trial of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness in Marin, Calif., took place on June 20-21, 2018. Associate Director of Clinical Operations Rebecca Matthews, Clinical Research Associate Alia Lilienstein, and Clinical Research Associate Joselyn Lindgren of MAPS conducted the visit. Led by Principal Investigator Phil Wolfson, M.D., with Co-Therapist Julane Andries, L.M.F.T., this study gathered preliminary data about the safety and efficacy of MDMA-assisted psychotherapy for anxiety associated with a diagnosis of a life-threatening illness. Goals for this study include (1) gathering data on the safety and effectiveness of MDMA-assisted psychotherapy for participants with anxiety associated with life-threatening illness; (2) determining if additional studies are warranted; and (3) initiating MDMA-assisted psychotherapy research for a new clinical indication.

Medical Marijuana Research

76th and Final Participant Enrolls in Smoked Marijuana Trial for Chronic PTSD in Veterans

Ongoing study
Location: Phoenix, Ariz.
Coordinating Principal Investigator:
Marcel Bonn-Miller, Ph.D. (University of Pennsylvania)
Co-Investigator/Site Principal Investigator:
Sue Sisley, M.D. (private practice) and
Co-Investigator: Paula Riggs, M.D. (University of Colorado)

As of October 10, 2018, 76 of 76 participants enrolled and received study drug in the first-ever clinical trial of smoked marijuana (cannabis) for treatment of symptoms of posttraumatic stress disorder (PTSD) in U.S. veterans, nearly completing enrollment. Taking place at the Scottsdale Research Institute (SRI) in Phoenix, Arizona, this clinical trial is evaluating the safety and efficacy of four different potencies of marijuana for symptoms of PTSD in 76 U.S. veterans.

Ayahuasca Research

Data Collection Survey Continues *Ongoing study*

Principal Investigator: Jessica Nielson, Ph.D.

We are currently collecting responses for the revised version of our anonymous questionnaire about the potential risks and benefits associated with using ayahuasca in treatment for PTSD. The results of the survey are currently being summarized and prepared for publication, at which point the survey will shift its focus to general ayahuasca use for a variety of conditions, including PTSD, depression, and substance abuse/addiction. The data collection is sponsored by MAPS, with Jessica Nielson, Ph.D., as Principal Investigator.

Ayahuasca is a psychoactive brew or tea most commonly derived from *Banisteriopsis caapi,* a vine containing monoamine oxidase inhibitors (MAOIs), and the leaves of *Psychotria viridis* or other plant containing N,N-dimethyltryptamine (DMT), and often several other admixture plants. Ayahuasca is legal in many countries in South America.

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

Ibogaine-Assisted Therapy for Drug Addiction

Observational Research Published in *American Journal of Drug and Alcohol Abuse* *Study completed*

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

On May 25 and April 12, 2017, the promising results of MAPS-sponsored observational studies of treating opioid dependence with ibogaine-assisted therapy were published in the peer-reviewed *American Journal of Drug and Alcohol Abuse.* Sponsored by MAPS in Mexico and New Zealand, both studies show that ibogaine should be further studied as a potential treatment for opioid dependence in rigorously controlled studies.

Ultimately, the authors of the studies conclude that given the potential demonstrated by ibogaine's substantive treatment effect in opioid detoxification, its novel (though not yet fully understood) pharmacological mechanism of action, and its clinical effect in opioid-dependent participants who have not satisfactorily responded to other treatments, ibogaine has promise for future research and development as a novel pharmacotherapy for opioid addiction.

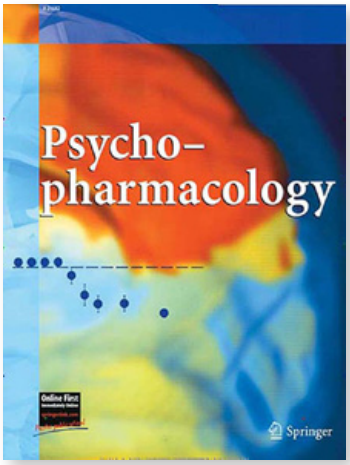
Download both articles for free at **maps.org/ibogaine**.

Participate in Research

MAPS sponsors clinical trials around the world that require human participants. 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 will open in Fall 2018. Please bookmark our Participate in Research page and check it frequently for updates.

maps.org/participate/participate-in-research



MDMA-Assisted Psychotherapy Shows Promise for Reducing Social Anxiety in Autistic Adults, New Study Shows

Results published in *Psychopharmacology*

On September 8, 2018, the results of the first clinical trial of MDMA-assisted psychotherapy for the treatment of social anxiety were published in the peer-reviewed journal *Psychopharmacology*. All 12 participants in the small pilot study were adults on the autism spectrum, a population that commonly experiences severe social anxiety.

Sponsored by the non-profit Multidisciplinary Association for Psychedelic Studies (MAPS), the study found significant and lasting reductions in social anxiety following two sessions of MDMA-assisted psychotherapy along with additional preparatory and integrative sessions without MDMA. The study also demonstrated the safety of limited doses of MDMA in a controlled therapeutic setting. In this study, MDMA-assisted psychotherapy was not intended to treat autism itself, but rather for social anxiety in adults with autism.

The research was conducted by Charles Grob, M.D., and Alicia Danforth, Ph.D., at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, and conducted in cooperation with the U.S. Food and Drug Administration (FDA), Drug Enforcement Administration, and ethics boards.

The study found reductions in the social anxiety that were significantly greater for participants who received MDMA-assisted psychotherapy than for those who received placebo (psychotherapy without MDMA). On average, participants in the placebo group experienced reductions of 19.3 points on the Liebowitz Social Anxiety Scale (LSAS), compared to 44.1 reductions in the MDMA group.

"What was particularly notable for many of the participants after treatment was their increased self-confidence when interacting in social settings, an endeavor that in the past they had experienced as overwhelming," said Dr. Grob. "We hope that our study will help to establish a foundation for future investigations exploring the safety and efficacy of MDMA in the treatment of social anxiety in vulnerable patient populations."

The rationale for the trial came from doctoral survey research conducted by Alicia Danforth about the MDMA experiences of adults with autism. In the survey, 91% of participants reported "increased feelings of empathy/connectedness" and 86% experienced "ease of communication" after using MDMA (or "Ecstasy") in non-clinical settings.

Similar to previous research for other conditions, the study indicated an acceptable risk profile for MDMA, with the most frequently reported adverse reactions during experimental sessions being anxiety and difficulty concentrating. Participants also reported fatigue, headaches, and sensitivity to cold. There were no unexpected serious adverse reactions. Temporary elevations in pulse, blood pressure, and temperature were also recorded during MDMA sessions, and did not require medical intervention.

"We hope that the good safety profile and encouraging reduction in social anxiety symptoms will inspire funding for new and larger studies," said Dr. Danforth. "We are looking forward to sharing what we learned with other researchers and communities committed to improving the quality of care for autistic adults and other populations struggling with social anxiety."

Participants reported reduced barriers to successful social interactions and increased confidence in school, at work, in friendships, and in romantic relationships following MDMA-assisted psychotherapy. "I felt like I was experiencing my best self and seeing the world for the first time and seeing myself for the first time," reported one participant. Another said: "I realized communication is not just about talking. Now, I take time to notice my emotions and others' emotions before talking."

Autism refers to a spectrum of congenital and pervasive neurocognitive variants. Autistic individuals frequently experience difficulty in the realm of social interaction, often including social anxiety. There are currently no FDA-approved pharmacological treatments for adults with autism with social anxiety, and conventional anti-anxiety medications are often ineffective in this population.

The *Psychopharmacology* article was authored by Alicia L. Danforth, Ph.D., Charles S. Grob, M.D., Christopher Struble, M.D., Allison A. Feduccia, Ph.D., Nick Walker, Lisa Jerome, Ph.D., Berra Yazar-Klosinski, Ph.D., and Amy Emerson.

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

Colorado Study Shows Benefits of MDMA-Assisted Psychotherapy for Treating Chronic PTSD

Results published in the *Journal of Psychopharmacology*

On October 29, 2018, the results of the largest-ever U.S. Food and Drug Administration (FDA)-regulated clinical trial of MDMA-assisted psychotherapy for the treatment of chronic posttraumatic stress disorder (PTSD) were published in the peer-reviewed *Journal of Psychopharmacology.*

Sponsored by the non-profit Multidisciplinary Association for Psychedelic Studies (MAPS), the double-blind, placebo-controlled, Phase 2 pilot study in 28 participants found that one month after their second day-long experimental session, 42.9% in the active-dose (100 mg and 125 mg) MDMA groups did not qualify for a diagnosis of PTSD, compared to 33.3% in the low-dose MDMA (40 mg active placebo) control group. The results were even more notable 12 months after the third active-dose experimental session, which found that one year following treatment with MDMA-assisted psychotherapy, 76% of participants no longer had PTSD.[1]

Led by Marcela Ot'alora, MA, LPC, in Boulder, Colorado, the trial was the largest of MAPS' six completed Phase 2 pilot studies of MDMA-assisted psychotherapy for PTSD. Trial participants included 28 people with chronic PTSD from military service, sexual assault, and other causes.

"Our study demonstrated that different therapy teams were able to get similarly robust results, further strengthening the case for MDMA-assisted psychotherapy as a promising option for the treatment of PTSD," said Principal Investigator Marcela Ot'alora. "Plus, the results of the study indicate that this treatment has the potential to greatly improve the lives of people suffering from PTSD, regardless of the source of their trauma. After treatment, a great majority of our participants have reported feeling more connected to themselves and to others, more joy, more compassion, and with new skills for facing life's challenges."

The study replicated previous research showing an acceptable risk profile for MDMA, with the most frequently reported adverse reactions during experimental sessions being anxiety, jaw clenching, headache, muscle tension, dizziness, fatigue, and low mood. Adverse reactions one week following treatment included insomnia, low mood, irritability, and ruminations. Temporary elevations in pulse, blood pressure, and temperature were also recorded during MDMA sessions, and did not require medical intervention.

In August 2017, based on the results of MAPS' Phase 2 trials, 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.

Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD began in September 2018, and will enroll 200-300 participants across 16 sites in the U.S., Canada, and Israel. If the Phase 3 trials demonstrate significant efficacy and an acceptable safety profile, FDA approval is expected by 2021.

The *Journal of Psychopharmacology* article was authored by Marcela Ot'alora G., MA, LPC; Jim Grigsby, Ph.D.; Bruce Poulter, MPH, RN; Joseph William Van Derveer III, M.D.; Sara Gael Giron, MA; Lisa Jerome, Ph.D.; Allison A. Feduccia, Ph.D.; Scott Hamilton, Ph.D.; Berra Yazar-Klosinski, Ph.D.; Amy Emerson, BS; Michael C. Mithoefer, MD; and Rick Doblin, Ph.D.

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[1]The course of double-blind treatment included 13.5 hours of non-drug psychotherapy and 16 hours (two day-long experimental sessions) of either full-dose or low-dose MDMA-assisted psychotherapy. After completing the initial double-blind portion of the study, participants who were initially randomly selected to receive active-dose MDMA then received a third day-long experimental session with active-dose MDMA and 4.5 additional hours of non-drug psychotherapy. Participants initially randomized to the low-dose group then received three day-long active-dose MDMA sessions and 18 additional hours of non-drug psychotherapy.

MAPS in the Media

The Economist FILMS

How MDMA is being used to treat PTSD

October 11, 2018. *The Economist Films* reports that an estimated eight million Americans suffer with PTSD and war veterans are only a fraction of this number. "It's a public health disaster costing billions of dollars to treat. There are treatments available but the drugs prescribed are only successful in 20% of cases. For those who don't respond to the available treatment there may be an alternative—MDMA—he active ingredient in the party drug ecstasy is being touted as a miracle cure for PTSD."

CBS NEWS

MDMA, the Main Ingredient in Ecstasy, Could Be Key in Helping Veterans With PTSD

by Jim Axelrod on September 18, 2018. *CBS News* broadcasts an investigative report on MAPS-sponsored studies of MDMA-assisted psychotherapy for PTSD, featuring an overview of scientific success through interviews with MAPS Founder Rick Doblin, Ph.D., and U.S. Army SGT (R) Jon Lubecky. Lubecky shares his personal story of overcoming PTSD after receiving MDMA-assisted psychotherapy, and Doblin explains how the treatment can help process trauma.

CBC radio

The Big Trip: Three Part Series

by Annie Bender on September 8, 2018. *CBC Radio's Day 6* reports on the therapeutic use of psychedelics.

RollingStone

Study: MDMA Could Help Autistic Adults with Social Anxiety

by Lilly Dancyger on September 25, 2018. *Rolling Stone* covers the results of the MAPS-sponsored study on MDMA-assisted psychotherapy for social anxiety in autistic adults.

Newsweek

MDMA Could Reduce Social Anxiety in Adults With Autism

by Aristos Georgiou on October 2, 2018. *Newsweek* reports that the results of the first clinical trial of MDMA-assisted therapy for the treatment of social anxiety have been published in the journal *Psychopharmacology.*

WebMD

Psychedelic Drugs to Treat Depression, PTSD?

by Matt Smith on September 18, 2018. *WebMD* reports on the growing number of studies investigating the therapeutic use of psychedelics to treat depression and PTSD.

America's Voice

Interview with Jon Lubecky

by Edward Woodson
September 22, 2018.

ROOSTER

An MDMA Therapist on How It Works and Why It's Better Than Current Treatments

by Sean Lawlor
October 1, 2018.

11ALIVE.com

This Is Why There's a Push to Make MDMA Legal

by Natisha Lance and Donesha Aldridge
October 2, 2018.

big think

A prescription for MDMA? We're getting closer

by Derek Beres
August 6, 2018.

AFP

From 'problem child' to 'prodigy'? LSD turns 75

October 12, 2018.

More Faces of Phase 3: Principal Investigators in MAPS' Clinical Trials of MDMA-Assisted Psychotherapy for PTSD

CHARLOTTE HARRISON

Charlotte Harrison

The MAPS Public Benefit Corporation (MPBC) has spent the last several months readying ourselves and our clinical trial sites for Phase 3 trials of MDMA-assisted psychotherapy for severe posttraumatic stress disorder (PTSD). In the US and Canada, sites have been enrolling and treating their first participants in our open-label lead-in studies—the training grounds in advance of Phase 3. Therapists are now in the process of receiving feedback from our experienced supervisors, and the sites are getting used to the high demands of our study protocols. We are gearing up to enroll our first Phase 3 participants this fall, which is a huge milestone in the journey towards approval of MDMA as a legal medicine.

In the Winter 2017 MAPS *Bulletin* (**maps.org/bulletin**), we introduced several of our investigators, and in this issue, we are following up to feature several more. The individuals below are saddled with the ultimate responsibility over the data generated from their study sites, participant safety and welfare, and research integrity. We feel incredibly lucky to be working with such qualified, dedicated, and experienced researchers, therapists, and doctors as our Clinical (Principal) Investigators.

Madison, WI

At the University of Wisconsin at Madison (UW), Dr. Christopher Nicholas, whom we featured in our last piece, shares the role of Clinical Investigator with Randy Brown, M.D., Ph.D. At UW, Dr. Brown serves as the Director of the Center for Addictive Disorders and is the Founding Director of the UW Addiction Medicine Fellowship Program. With a background in both family medicine and addiction, he also works as a consulting physician at the William S. Middleton Memorial Veterans Hospital, the UW Health Center HIV/AIDS Clinic, and Access Community Health Centers. He has been a prescriber of buprenorphine for opioid dependence since 2001. He is the Medical Director of the Overdose Prevention Program of the AIDS Resource Center of Wisconsin and a Director of the American Board of Addiction Medicine and the Addiction Medicine Foundation.

Dr. Brown's research focuses on the treatment and prevention of substance use disorders and their complications, including the preventing opioid misuse, supporting recovery through mobile technology, and promoting the prescription of medications to aid in alcohol and opioid use disorders in primary care settings. He has also worked on clinical trials using psilocybin. From Dr. Brown:

"I am excited by the possibilities of psychedelic-assisted therapies to improve outcomes for people struggling with complex mental health conditions and substance use disorders."

New York, NY

Dr. Michael Bogenschutz is an experienced psychedelic researcher at New York University (NYU). In addition to his role as Clinical Investigator for MAPS MDMA-assisted psychotherapy trials, he is currently conducting a Phase 2 randomized, double-blind, controlled trial of psilocybin-assisted treatment of alcohol use disorder. He is also conducting NIH-funded studies on the effects of cannabidiol and topiramate in the treatment of alcohol use disorder and the use of strengths-based case management to facilitate engagement of patients with opioid addiction into treatment. His research interests focus on developing novel combinations of pharmacologic and psychosocial therapies to improve outcomes for patients with alcohol and substance use disorders, integrating addiction treatment into medical settings, and treating co-occurring psychiatric and addiction disorders. He currently serves as a Research Professor at NYU Langone Medical Center. Prior to joining NYU in 2015, he served at the University of New Mexico Health Sciences Center as a Professor of Psychiatry and Psychology, Vice Chair and Division Director for Addiction Psychiatry, and Vice Chair for Clinical Research in the Department of Psychiatry. There he founded and directed the addiction psychiatry fellowship program and served as Principal Investigator of the Southwest Node of the National Institute for Drug Abuse Clinical Trials Network for 10 years. From Dr. Bogenschutz:

"Psychedelic-assisted treatments are, in my opinion, the most exciting and promising development in psychiatry in decades. The idea that one or a few discrete experiences, combined with appropriate therapy, can lead to lasting or permanent benefit has the potential to revolutionize psychiatry. I've been doing clinical research with psilocybin since 2011. MDMA is an equally promising medication, which is very different from psilocybin but in some ways complementary in its clinical potential. We are excited to be starting research with MDMA at NYU and hope this work will lead to clinical breakthroughs in treatment for PTSD and other psychiatric disorders."

Montreal, QC, Canada

Dr. Emma Hapke is an attending psychiatrist at the Centre for Addiction and Mental Health in Toronto, Ontario, and a lecturer at the University of Toronto. Her specialty is in women's mental health and the treatment of developmental trauma, sexual trauma, and complex PTSD. She has extensive training in multiple modalities of psychotherapy and has worked clinically with ketamine-assisted psychotherapy. She is joining the MAPS research team as the Clinical Investigator at the Montreal site for Phase 3 and in developing a study in Toronto combining Cognitive Processing Therapy (CPT) with MDMA. From Dr. Hapke:

"As Albert Einstein said, 'We cannot solve our problems with the same thinking that created them'. The opportunity to access expanded and altered states of consciousness through psychedelics to facilitate deeper healing is one of the most promising developments in modern psychiatry. I'm honored to play my part in this paradigm shift from symptomatic management toward transformation and from the mind into the heart that is occurring in the field, in ourselves as individuals, and in our society as a whole."

Dr. Simon Amar is a Sub-Investigator at his private practice in Montreal, where the study will be held. He specializes in integrative, psychodynamic, and mindfulness-based psychotherapy. His deep interest in the healing potential of psychedelics began at Psychedelic Science 2013. There, he attended Michael and Annie Mithoefer's workshop on MDMA-assisted psychotherapy for PTSD, where he met his wife and co-therapist.

A view inside the study site in Montreal, Canada. Photo: Dr. Simon Amar

Since then, they have both passionately devoted themselves to becoming a part of MAPS research. From Dr. Amar:

"Unlike most psychiatric medications available to us today, this molecule provides a way of enhancing psychotherapy so that rather than just reducing symptoms, we are reaching a deeper level of healing. I feel inspired by the profound transformations people have experienced."

San Francisco, CA

For our research at the University of California at San Francisco (UCSF), two co-Clinical Investigators have teamed up to lead our studies: Jennifer Mitchell, PhD, and Josh Woolley, MD, PhD, two accomplished researchers in the field of mental health.

Dr. Jennifer Mitchell is a neuroscientist whose main research objective is innovation in the treatment of addiction and other mental health issues including PTSD, anxiety, depression, and impulsivity. At UCSF, she serves as an Associate Professor in the Departments of Neurology and Psychiatry. Her research group studies the mechanisms of expression of behavioral disorders through the use of translational tools, such as behavioral pharmacology, genetics, functional magnetic resonance imaging (fMRI), and transcranial magnetic stimulation (TMS), in order to identify new potential treatments. From Dr. Mitchell:

"I am honored to be assisting MAPS in their quest to test and develop MDMA for PTSD; this is an all too common and debilitating condition for which better treatments need to be identified and rapidly disseminated."

Co-Clinical Investigator Dr. Josh Woolley's current research focuses on examining the mechanisms of social connection, which does not always come easy to people suffering from PTSD, substance use disorders, and schizophrenia. At UCSF, Dr. Woolley serves as an Assistant Professor in the Department of Psychiatry and the Principal Investigator for the Bonding and Attunement in Neuropsychiatric Disorders (BAND) Lab. He is also a Staff Psychiatrist at the San Francisco

VA Medical Center. From Dr. Woolley:

"My long-term goal is to develop and test novel interventions for various debilitating deficits commonly found in individuals with mental illness. To this end I have developed a program of research focused on investigating the underlying psychological, behavioral, physiological, and neural mechanisms of these deficits and their treatment. Specifically, I have been examining the effects of intranasal oxytocin in schizophrenia, posttraumatic stress disorder, and substance use disorders. Recently, I have become intrigued by the therapeutic potential of MDMA combined with psychotherapy for difficult-to-treat psychiatric illnesses including PTSD. My multidisciplinary research group is currently conducting two studies that are centered around understanding the role of (1) intranasal oxytocin and (2) remote cognitive training on alleviating social cognitive deficits in PTSD as well as a pilot-study of psilocybin-enhanced group therapy for demoralization and complex trauma in long-term AIDS survivors. In the months and years to come, I am most excited to be able to better understand the underlying mechanisms through which MDMA coupled with psychotherapy may be useful for treatment of PTSD. I cannot express my gratitude for the heroic effects of organizations like MAPS that allow dedicated scientists to pursue cutting edge research in psychedelic medicine. I sincerely hope that my lab's work will help contribute to this impactful work."

Charlotte Harrison *earned her bachelor's degree in Greek and Latin in 2012 from Tufts University while pursuing pre-medical studies. After an exciting internship working on oncology trials at Clinical Assistance Programs (CAP), she decided her skills were better suited to clinical research. She monitored and managed clinical trials in supportive cancer care, nephrology, dermatology, and cardiology at CAP, MedTrials, and Harvard Clinical Research Institute. At MPBC, Charlotte is currently serving as a Senior Clinical Research Associate, supporting the management of MDMA and marijuana studies. She supports, trains, and monitors multiple sites, ensuring quality research and compliance. She is hopeful that her passion for improving the quality of life for those suffering with mental illness and determination to make scientific research more efficient will be beneficial to MAPS' important and necessary work. In her free time, Charlotte can be found doing yoga, snuggling her cats, or playing board games late into the night. She can be reached at charlotte@mapsbcorp.com.*

Cultivating Inner Growth: The Inner Healing Intelligence in MDMA-Assisted Psychotherapy

SHANNON CLARE CARLIN, M.A., MPBC ASSOCIATE DIRECTOR OF TRAINING & SUPERVISION

Shannon Clare Carlin, M.A.

Just as a seed has within it the knowledge to grow, humans have an innate capacity to heal, when given the right environment to do so. When help is needed to create that environment, psychotherapy, like a greenhouse, can provide a container conducive to healing.

The term "inner healing intelligence " refers to the knowledge and power within oneself to move towards wholeness and wellbeing. There are many terms that could be used here; various paradigms of thought would articulate these concepts in different ways; some might reference Spirit, truth, unity, and there are many other terms that can and do carry similar meaning. I once heard a participant call it the "inner champion," as she encountered what she experienced as its destructive counterpart, the inner critic. In this writing, I adopt the phrase "inner healing intelligence" and similar terms such as inner healer, deep knowing, innate wisdom. If you connect with the concept of an intrinsic ability to heal and grow oneself, I encourage you to consider any other name you like, and to think of that name as you read.

A seed has within it the intelligence to grow into a vibrant and blossoming plant. Given a nourishing environment, rich soil, water, air, and light, a seed will naturally develop into a mature and thriving plant. It will develop roots, establishing the ability to take in nutrients and water from the soil and stay grounded in the midst of erosion. Leaves develop to absorb energy from sunlight and carbon dioxide from air, so the plant can initiate photosynthesis and transform these ingredients into food. So long as the environment continues to provide what it needs, the plant will grow to full capacity, expressing its intrinsic qualities.

When the outside environment can't provide what is necessary, a plant demonstrates signs of poor health: wilting leaves, pale color, blossom rot. If the conditions aren't adjusted, the plant's health will continue to deteriorate as it strives to survive. When the outside environment doesn't have what the plant needs, a greenhouse can offer shelter, respite from extreme temperatures, and protection from the elements. The conditions inside the greenhouse are set specifically for the plant it intends to serve.

Like plants, our consciousness naturally flourishes when given a safe and supportive environment and encouragement. Accessing this inner healing intelligence is a process of honoring and expressing strength from within, coming from a place beyond mental chatter and negative self-talk, from alignment and clarity, even when our current experience may be of fragmentation and confusion. We can learn to hear our own voice of wisdom amidst the crowded room of the psyche. Cultivating the inner healer is part of cultivating deep relationship with oneself.

Unfortunately, many people are not in a place of encouragement and support. Like a plant in a time of flooding, or being perpetually whipped by harsh winds, being in an unsafe or unsupportive environment, whether for a short or long period of time, is a common characteristic of trauma. A traumatic event is one that causes (or threatens to cause) death, serious injury, or sexual and/or other kinds violence, which a person may experience directly or indirectly. During a traumatic event, instinct kicks in and the body's resources are allocated to respond to the trauma—survival is the primary concern. The body's trauma response is adaptive: in the face of threat, it is intended to save one's life.

60 Therapy Training participants from 14 countries gathered in Landgraaf, Netherlands from September 26 – October 3, 2018, to attend Part B of the MDMA Therapy Training Program: learning about "inner healing intelligence" and how the concept translates internationally.

What happens, though, when the threat is no longer present? This was the focus of Peter Levine's observation of animals in the wild when under attack by a predator: after surviving an assault, an attacked animal's body may shake and tremor, a natural release of energy. Within a few minutes, animals returned to their resting state and resumed normal activity. What do humans need to do in order to "shake off" trauma? What do we need in order to heal?

Doing difficult trauma processing requires a degree of safety. This is challenging for people with PTSD, since symptoms such as flashbacks and hypervigilance make it difficult to differentiate between past and present threat. It's especially challenging for people to find respite if they continue to be exposed to threats of injury. It's important to acknowledge that many people are living continuously at risk of harm, and for future research and clinical practice to inform how best to deliver MDMA-assisted psychotherapy to actively threatened populations.

Inner healing intelligence blossoms in a context of safety. Like the protection a greenhouse offers, effective trauma therapy fosters a safe and supportive environment for people who are processing traumatic events and their impact. MDMA-assisted psychotherapy is designed with the intention to create a space for a person to come back to recognizing their own power, their own capacity to heal, to love, and to live a full life. In a safe setting, supported by two clinicians, and with ample time, participants are offered the chance to address the core issues of their trauma.

Providing this context of safety and support is a primary task of MDMA-assisted psychotherapy. In addition to essential safety procedures, such as monitoring vital signs, the therapy team must work with each study participant to determine what conditions they require in their metaphorical greenhouse. In setting the specific conditions, it's important to consider medical and psychiatric history as well as culture, needs, beliefs, and identity. The participant plays a crucial role in designing and contributing to the container of safety. The power of inner healing intelligence is honored from the first study session, when a participant is greeted with interest and care, and their ability to make decisions about their treatment is valued, starting with obtaining their informed consent to be in the study. The participant is treated as an expert of their own experience and as having the capacity to access the knowledge they need to heal, whether it's through the cognitive mind, the body, emotions, or spiritual experiences. When a person who has been burdened with trauma has an internal experience of safety, they gain what they didn't have before: a reference point for healing. If they can find this mental and physical state of refuge—their greenhouse—they will have found a place to do healing work.

Just like the therapy team helps create a safe environment in preparation for, during, and after the MDMA therapy sessions, the MDMA itself simultaneously contributes to that sense of safety during the processing of trauma. From my experience with participants in recent trials, MDMA seems to reduce hypervigilance (always being on alert) and allow them the ability to face traumatic memories while remaining connected with the present reality, in which they know they are safe. With the assistance of MDMA, participants are better able to tolerate the process of trauma therapy.

The protocol for MDMA-assisted psychotherapy affords substantial time for participants to work through trauma. Study sessions, eight hours in total, are designed with enough time for the effect of MDMA to come on and, eventually, subside. The eight-hour therapy sessions allow the participant to go through their process without pressure to rush; it takes time to do deep healing work. It can be powerful when the therapists communicate, "There's time for you, there's time now for your healing process."

All therapy visits are conducted by a co-therapy pair. With two therapists, the amount of care, attention, and interaction takes on a greater depth than is usually possible with just one. Each has a different perspective and contributes unique strengths. The participant will have a different response to each of the therapists, which adds richness to the therapeutic relationship. Both therapists are in service to the participant and their inner healing intelligence, and support each other in providing and improving this act of service. In addition to the benefit of relational support, two therapists are needed in order to sufficiently attend to the necessary protocols, such as taking vitals, monitoring hydration, administering psychological assessments, adjusting music, walking the participant to the bathroom, completing progress notes or source records, and conducting psychotherapy for the long eight-hour sessions, in which the participant is never left alone.

In some cases, the care from two therapists serves as a corrective experience to the abusive or neglectful ways the participant was treated in the past. For many people with traumas of abuse, attention from others was dangerous. The therapists act with integrity and take responsibility for upholding professional boundaries. By receiving ethical care, the participant gets an opportunity to experience nurturing and trustworthy relationships and to tend to their inner healing.

The results of the Multidisciplinary Association for Psychedelic Studies (MAPS)' first completed study of MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD (Mithoefer et al., 2011) highlight the impact of the therapy alone. After two eight-hour experimental sessions, 25% (2/8) of participants who received placebo had a greater than 30% drop in their PTSD symptoms (measured by the Clinician Administered PTSD Scale [CAPS-4]) and no longer met the diagnostic criteria for PTSD. While the sample size was small, this is a considerable change in response to the therapy modality without MDMA. By comparison, the MDMA experimental group had a much higher response: 83.3% (10/12) of participants who received MDMA had a greater than 30% drop in CAPS, and 10 no longer met diagnostic criteria for PTSD.

During preparatory sessions, the therapists discuss the structure of the sessions and outline specific ways in which they will be attentive to the participant. Directly stating the intention to support a participant provides a powerful experience for the participant, as the therapists set the tone for deep healing work. This affirms the container of safety, defining the growing conditions of the greenhouse. Below is an example of how the therapists might articulate some of the ways they will be supportive and ensure the participant's safety. This example does not include all of the required elements to be discussed during preparation, but it touches on many, and would be part of a longer conversation about safety, support, and what to expect during an experimental session.

> *We are here to support you and your process; this day is for you. We will be here with you. We encourage you to ask for what you need and will also do our best to anticipate your needs. There are no silly questions. We invite you to express yourself in any way that feels right, whether that's using your voice or moving your body, this can actually help the process unfold as things come up during the session. We are here to ensure your safety, we will be monitoring your vital signs and hydration. When you stand up or move we will protect you from falling or hurting yourself, such as helping you walk to the bathroom, or using a pillow to keep you from hitting the wall or the floor if you are moving your body. In the rare case of immediate medical concern, we will consult a physician. We already discussed with you some of the boundaries that protect you in this work, to reaffirm one of them, sexual contact isn't part of this work and we won't engage in that way. If you experience sexual energy you are welcome to talk about it and feel through it, if that seems helpful to your process, but not to act on those feelings during the session. We want you to know that we take your health and safety very seriously. Do you have any questions about what I've said so far?*
>
> *We want to do whatever we can to make this the most helpful to you, please let us know if there is ever anything we can do more or less of, you won't hurt our feelings. You don't have to take care of us. Each of us will take a short break for lunch, one of us will always be with you. We want to know about your experience and encourage you to share your internal process by talking with us when it feels right; but not to feel any pressure to talk to us before the time is right for you; we will also check in with you regularly during the session to see what's happening so that we can best support you. If at any point you feel stuck, overwhelmed, or confused, let us know, we will help, that is what we are here to do. As you work through aspects of trauma, difficult, scary, or seemingly*

overwhelming thoughts, feelings, or images may come up: we will be with you to support you in staying with them as much as you can in order to process and move through them. We are honored to be a part of your process.

Notice that the communication about safety emphasizes the ways the therapists will *actively* attend to the participant, and even intervene when necessary to prevent bodily harm. It's important for the participants to know that the therapists are not passive. The therapists are attentive and responsive, responsible for ensuring safety throughout the session so that the participant can allocate their resources towards healing instead of defense.

Once the parameters of safety are established, the therapists discuss with the participant the concept of the inner healing intelligence. The therapists encourage the participant to consider, in a way that makes sense to them, that they have strengths and resources that are valuable assets in this healing journey. Throughout the treatment the therapists prompt the participant to reach for their internal resources, validating the participant's strengths and capability while reinforcing that the therapists are presently supporting the process.

MDMA-assisted psychotherapy is inner-directed, meaning the therapeutic content and the direction of the session is informed primarily by the participant and their inner healing intelligence. The participant's relationship with their internal source of power will outlast the course of treatment and their relationship with the therapists. When a participant is (re)acquainted with the confidence that they can lead a healthful life, they get to reap the rewards of their hard work and know it was them who made it happen. In the same way, at some point a well-cared-for plant will outgrow its greenhouse shelter, and go out into the world with the health and strength to protect itself and sustain its own life.

Therapists who help their clients establish a deep connection with their inner guide give a tremendous gift, one that can last as the client applies their own wisdom to a myriad of life's challenges.

The compliment to *inner-directed* therapy, guided by the participant's internal wisdom, is *non-directive* therapy, which means that the therapists are not guiding the session in a particular direction or holding an agenda. This is counterbalanced with the active support the therapists give in ensuring the participant's safety and wellbeing. It can be challenging for a therapist to be non-directive. Typically, we want to "do" something to help, especially when it is our job to help. An overly active therapist could inadvertently bypass or overpower the person's own inner healing intelligence, robbing them of the experience to connect to their self-power. Therapists who help their clients establish a deep connection with their inner guide give a tremendous gift, one that can last as the client applies their own wisdom to a myriad of life's challenges.

In communicating about the inner healing intelligence, the therapists may say something like:

We are here to support you and step in to offer help when needed. You are resilient, motivated, and wise. We want to endorse your strengths. We trust your process and ask you to try to do the same. If you come to a place of confusion or overwhelm, please let us know, we are here with you. At that point, we encourage you to take a few breaths, slow down if possible, and see if you can get in touch with the part of you that is connected to insight and clarity. In this work, you may find that, more often than not, deep down and with a bit of support and patience, it will become clear what to do, or to allow to happen, and you will find many of the answers you seek. A large part of this work is connecting to that place of inner knowing, it's not easy and there's no one right way to do it. We are here to help you navigate that process.

A greenhouse doesn't intervene in the growth of a seed—it doesn't tell a seed what it should or shouldn't do. In fact, the greenhouse doesn't even know how a seed grows to a plant. It just provides the right circumstances. In a very similar way, MDMA-assisted psychotherapy creates a container for safety and support, so that the participant can connect with their innate ability to heal and grow, through developing a relationship with their inner healing intelligence and, from there, working through trauma.

It takes courage and resilience for a person to pursue trauma therapy. I am hopeful that there are increasingly more effective treatment options to make this difficult journey worth the effort. My hope in this modality is that people can get their lives back, enjoy satisfying relationships and work and a positive sense of self, and that they will always know their intrinsic wisdom and ability to heal.

Shannon Clare Carlin, M.A., *received her Master's Degree in Integral Counseling Psychology from the California Institute of Integral Studies in 2014, including a practicum working with youth on moderation management for drug and alcohol use. At MPBC Shannon serves as Associate Director of the Training & Supervision Department, overseeing administration and program development to educate professionals and researchers to provide MDMA-assisted psychotherapy for PTSD in approved settings. Shannon is also committed to psychedelic harm reduction, and continues to provide integration services through the Zendo Project. Shannon served as co-therapist on the MAPS-sponsored Phase 2 trial researching MDMA-assisted psychotherapy for anxiety associated with life-threatening illness, and will be a co-therapist at the Phase 3 site in Los Angeles, researching MDMA-assisted psychotherapy for severe PTSD. She can be reached at shannon@mapsbcorp.com.*

Creating an Ethical Framework for Psychedelic Therapy Research

DOMINIC SISTI, PH.D.

Dominic Sisti, Ph.D.

With MDMA-assisted psychotherapy receiving Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA), the MAPS Public Benefit Corporation (MPBC) is on the cusp of a major advance in how trauma-based disorders are treated in the U.S. and abroad. The potential to relieve human suffering on a grand scale is real, and so too are the ethical challenges. In fact, the study of psychedelic drugs has always been ethically fraught. Fortunately, the Multidisciplinary Association for Psychedelic Studies (MAPS) is sensitive to this fact, and has committed to developing an ethics program that will offer a space for ethical reflection, respectful debate, and informed decision-making regarding psychedelic research and therapy.

I am a professional medical ethicist. For the past two years, I've been in conversation with the leadership and staff of MAPS and MPBC about the ethical challenges that are woven into the fabric of psychedelic research. Many of these challenges are commonly discussed in other biomedical research settings, and they include protecting the safety of vulnerable persons and ensuring participants are competent to provide truly informed consent.

However, psychedelic research still has several unique ethical challenges.

For example, it may be difficult to fully inform participants about the potentially profound changes that may accompany a psychedelic experience. In most other drug studies, the radical transformation of one's identity is generally not an issue—but with MDMA and other psychedelics, researchers and therapists must remain sensitive to and aware of the transformation of awareness experienced by participants in order to guide them on their therapeutic journey. This requires a sophisticated kind of ethical wisdom and virtue that is beyond simple rule-following or maintaining compliance with federal regulations.

When my colleague, bioethicist Jonathan Moreno, Ph.D., and I were asked to begin developing an ethical framework for MPBC, we started by thinking through how the goals and practices of MPBC already reflected the ethical values of human subjects research that have been articulated by bioethicists over the past half century. We turned to a canonical bioethics document, the Belmont Report, which was first published in 1979 and enumerates three principles of ethical research: Respect for Persons, Beneficence, and Justice. Each of these principles has concrete applications and serve as the foundation for modern research ethics regulations. From there, we developed a set of principles that integrates values from the open science movement and lessons related to reporting conflicts of interest (Table 1).

For example, the principle of Radical Transparency reflects MPBC's commitment to publishing all of its findings—both positive and negative—in the scientific literature and on the organization's website. Radical Transparency also commits MPBC to disclosing all of the financial relationships and support it receives.

MPBC also is committed to advancing the science of psychedelics through strategic partnerships with other research organizations. This potentially includes working cooperatively with for-profit firms, whether or not MAPS receives a direct benefit from that cooperation. Again, this principle reflects the fundamental aim of MAPS and MPBC: to bring these medicines to market for the sake of patients. There may be instances where a for-profit partner makes decisions that actually inhibit access to medicines; in such cases, an MPBC ethics committee will convene to discuss the matter and determine an appropriate course of action.

Similarly, MPBC will engage the community through educational programming and public discussions of its research. The principle of Democratic Deliberation conveys the importance of community engagement in psychedelic research, which remains a socially sensitive subject.

Finally, the MPBC ethics program will be evaluated annually. We are working on developing a new kind of scorecard to measure how well the organization is living up to its ethical commitments. This tool will be the first of its kind, and may serve as a template for other pharmaceutical benefit corporations.

It is clear that both MAPS and MPBC have a strong commitment to ethics across all of their operations. In the months and years to come, this commitment will catalyze the science of psychedelics, leading to new treatments for some of the most intractable mental health conditions.

Table 1. Overview of the draft MPBC ethical framework.

Principle	**Application**
Respect for Persons	Ensuring voluntariness, capacity, and informed consent, harm/benefit analysis that is justifiable for individual participant or their population.
Radical Transparency	Publishing research protocols, drug sourcing information, outcomes, ancillary data, and finances.
Collaboration & Open Science	Working in partnership with other research organizations, whether nonprofit or for profit, to advance the science of psychedelics.
Justice & Fairness	Committing to fair distribution of research benefits and burdens; commitment to diversity in recruitment of participants; benefit sharing and compassionate use.
Democratic Deliberation	Maintaining open dialogue with communities involved in research; regular educational programming for participants, advocates, and the broader community.

Dominic Sisti, Ph.D., *is director of the Scattergood Program for the Applied Ethics of Behavioral Health Care and assistant professor in the Department of Medical Ethics & Health Policy at the University of Pennsylvania. He holds secondary appointments in the Department of Psychiatry, where he directs the ethics curriculum in the residency program, and in the Department of Philosophy. Dr. Sisti's research examines the ethics of mental health care services and policies, including long-term psychiatric care for individuals with serious mental illness and ethical challenges in correctional mental health care. He also studies how mental disorders are defined and categorized with a focus on personality disorders. Dominic received his bachelor's degree in biology from Villanova University, a master of bioethics from the University of Pennsylvania, and his doctorate in philosophy from Michigan State University. Dr. Sisti teaches a graduate seminar on ethics in behavioral health care and, for the past six years, he has organized the ethics track for the American Psychiatric Association's Annual Meeting. He can be reached at sistid@upenn.edu.*

Bitcoin, Ketamine, And Pineapples: Why I Donated $5 Million in Bitcoin to MAPS

"PINE"

On March 9, 2018, the Multidisciplinary Association for Psychedelic Studies (MAPS) announced the successful completion of a $4 million matching grant from the Pineapple Fund for U.S. Food and Drug Administration (FDA) Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD). The Pineapple Fund was created by an anonymous cryptocurrency philanthropist known only as "Pine." Over a period of several months, the Pineapple Fund turned 5104 bitcoins into $55 million for charities.

The Pineapple Fund's match came just one month after their December 14, 2017, gift of 59.89 BTC to MAPS, initially valued at $1 million.

Over eight weeks, the matching campaign inspired $4 million in new gifts from over 550 individuals, which the Pineapple Fund has matched in Bitcoin, for a total of $8 million. 149 of these new gifts, totaling $1,093,330, were received in cryptocurrency.

On behalf of the millions of people and families who will benefit from legal MDMA-assisted psychotherapy for PTSD when it's approved, MAPS expresses its sincere gratitude to all of the individuals and foundations who contributed to the Pineapple Fund matching grant.

★

Everything in my life made sense after I learned about borderline personality disorder (BPD). For as long as I can remember, I've experienced a powerful cocktail of intense emotions, episodes where I feel out of control, and far more. Life with BPD is tough, as evident by our suicide rate being 50 times higher than the national average.

The first symptom I experienced was an extreme fear of abandonment. Many of us have a childhood history with abandonment. Perhaps one or both of our parents left us, or our early friendships and relationships were traumatically unstable.

When a close friend takes longer to reply than usual, I experience intense and physical anxiety. Did I say something wrong? Am I not good enough? Before they even have the chance to explain that they've simply had a busy day, I begin to worry that our friendship is completely over.

My emotions can often feel like a rollercoaster. I could feel euphoric one moment, and utterly depressed the next. Minor things that other people do can act as triggers that send me down a bottomless pit. Unlike depression or bipolar disorder, these mood swings are extremely short and last minutes or hours at most. And for those who I have opened up my emotions to, they sometimes feel like they're walking on eggshells.

However, even more perplexing is my unstable sense of identity. It's hard for me to ever feel satisfied with who I am, or to feel like I can love myself. I frequently change jobs, goals, friends, and more. I want something until I have it; then I hate it. These are just some of my symptoms. It's a complex condition, and everyone with BPD has their own story.

Every different anxiety I had on my mind seemed to organize themselves and categorize themselves. I started thinking about how to move on and how to stop regretting the past.

Is there anything positive about BPD? Somewhat. The intensity of our emotions is usually not welcome, but we can, in fact, feel and express love stronger than most people. By nature, we have to be resilient. Our emotional journeys make us more empathic and compassionate.

MAGICAL INTERNET MONEY

When I first heard about bitcoin in 2011, I was highly skeptical. I downloaded the software and promptly uninstalled it. It took a couple of months of procrastination until I saw the potential. Money issued and regulated through nothing more than code, transferable to anyone in the world without intermediaries and their costly fees; that is powerful.

Bitcoin was such a small community back then. Most of us went by pseudonyms, but that didn't stop us from uniting around the mission of bringing decentralized money to the world.

Over the years, what originally was play money, slowly became an enormous sum. I haven't really done much with my cryptocurrency for many years because I had little idea of how to spend this sum productively, and very little desire to do so, due to my BPD. The one thing I did have was plenty of optimism for the power of cryptocurrencies.

As life went on and the years went by, I gradually realized more and more how unhappy I was. I had just gotten out of a toxic relationship that made my BPD much worse, and then started needing Valium for panic attacks. I had little direction in life, and while I had amazing friends who stood by me, chronic emptiness was burning a hole through my body.

I've tried dialectical behavior therapy (DBT) and schema-therapy with multiple therapists. It worked to some extent, but it wasn't really effective. Part of it might be fluctuating motivation; another may just be how everyone's BPD is different. During my research, I came across one promising clinical trial: novel uses of ketamine to treat borderline personality disorder.

The pharmacology made sense; BPD is typically associated with dissociation. For me, during intense emotional experiences, I naturally dissociate. It's not a lot of fun. Ketamine is a dissociative, but it also features many more mechanisms of action that are actively researched. It's believed to promote neuronal regeneration. While that particular clinical trial was closed, I kept the idea in the back of my mind.

A month later, while planning a trip to the US, I found a ketamine infusion clinic in Colorado. That clinic mainly dealt with depression and PTSD, but I emailed them and discussed my condition. I booked an appointment with minimal expectations.

INFUSIONS

After spending a week in New York with friends, I flew to Denver and went to the IV therapy center. After a consultation with the doctor, I was scheduled for my first ketamine infusion the very next day. Little did I know; this trip would be a defining moment of my life.

The actual infusion was pretty standard. A needle is used to pierce your skin, a cannula is inserted inside your vein, and a machine controls the rate of flow. It took minutes for me to feel the effect, and I dissociated more and more until my senses and emotions felt like they were contained and isolated. My body felt strange, with a great sense of disorientation.

In reality, my first ketamine infusion wasn't particularly useful. I remember sleeping very well that night, which was great given my then-insomnia, but other than that, I didn't feel any changes just yet. Ketamine infusion therapy is generally conducted in sets of 3 or 5. My second infusion, however, was incredibly significant.

Some time into my second infusion, I suddenly couldn't think of anything other than "I'm fucked up." I was in a foreign country, getting ketamine through my veins, because of my depressing BPD. This train of thought brought up tons of negative thoughts and fears, and caused me to fully realize my emptiness. It all hit me at once.

Traumatic experiences of my past flashed back. Every different anxiety I had on my mind seemed to organize themselves and categorize themselves. I started thinking about how to move on and how to stop regretting the past, and made commitments to myself that I wouldn't have been able to otherwise.

I've had the idea to donate a large portion of my bitcoins for a while, and it is through this journey of discovering myself that made me actually commit to it. Nothing about my quality of life or my financial comfort would change, however it was the easiest and most direct way I could make a mark on this world.

IMPACT

I definitely had a lasting impact from ketamine infusion therapy. For the days immediately after the infusions, I felt far more clear-headed than I normally felt. My anxieties were tuned down, and I had a rare glimmer of hope and optimism for the future. I was even starting to like myself a little bit more; these seem to be the typical antidepressant effects of ketamine.

BPD-wise, my emotional peaks and troughs became a little bit more normalized. The intrusive thoughts that had been frequent for me didn't go away completely, but they did reduce in frequency and severity. The main symptom that didn't improve, however, was black and white thinking.

Over the coming months, I've used the opportunity that the infusions provided me to get my life and emotional state on a stronger, lasting ground. While the effects gradually faded (perhaps not entirely), the impact is lasting to this day, thanks to the more positive and self-loving mindset that has remained. It's now much easier for me to manage my symptoms.

I knew that psychoactive compounds can allow for introspective journeys that are extremely difficult to reach otherwise, and the combination of the substance with therapy is what has the most impact.

In late 2017, I finally got started on my charity project. I love pineapples, so why not call it the Pineapple Fund? The project was very much an experiment in donating money to charities, entirely with crypto. I've always admired the legend of Satoshi Nakamoto, the creator of bitcoin who used a pseudonym and kept their identity private, so I took on the nickname of Pine.

When I discovered MAPS' work on MDMA-assisted psychotherapy research, I immediately saw parallels with my own experiences. I knew that psychoactive compounds can allow for introspective journeys that are extremely difficult to reach otherwise, and the combination of the substance with therapy is what has the most impact.

I'm proud that I'm able to help fund MAPS' work on Phase 3 trials through donating over $5 million in Bitcoin, and I hope it is only the beginning of things to come. The use of psychedelic and related substances for mental health shows extreme promise in reputable studies, and I see this as the beginning of a renaissance. Thank you for listening to my story.

Cryptocurrency and Psychedelics: Decentralizing Trust: An Interview with Matt McKibbin

JENNIFER BLEYER

Matt McKibbin

*To blockchain advocate Matt McKibbin, decentralization isn't just about monetary systems—it's about the Internet, the media, reputation management, and even how he lives as a global nomad without a fixed home. ("I'm decentralized!" he proudly proclaims.) The founder of DecentraNet, a blockchain advisory and investment firm (**decentranet.com**), McKibbin is also a psychedelics enthusiast who cofounded CryptoPsychedelic, a summit devoted to exploring the intersection of blockchain technology and psychedelic science which held its first-ever gathering last winter in Mexico (**cryptopsychedelic.com**). Matt has been a MAPS supporter since 2014.*

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How did you get involved with cryptocurrency?

I graduated from college with a degree in physics in 2008, right when everything crashed, and I started paying attention to what was going on in the world. When the government said it printed a trillion dollars and gave it to the banks, I was like, what does that mean? The orders of magnitude of that number are mind-boggling—and they just created it? I wanted to understand how our money system works. Then I went to grad school for environmental health and safety engineering, and ended up working at a nuclear facility getting rid of depleted uranium. On the job I had a lot of down-time to read policy material and do my own self-education. I started becoming more of a libertarian activist, especially from reading a lot of economic and monetary policy. I realizing that printing more money isn't the solution to bailing out the economy. In 2012, I moved to D.C., which was my first time living in a city. That was when I really learned a lot, arguing with policy people there. I was very scared about the state of the world financial system because a lot of people I spoke to didn't feel the problems had been fixed since the crash. That's when I discovered Bitcoin, which offered a new, open-source system to build on rather than this closed-source one. I realized I'd rather build on something new than try to fix the problems of the existing system.

What's the potential of the cryptocurrency movement, in your opinion?

By open-sourcing money, we are able to create monetary systems based on our own values. I would say our current money systems are not based on the people's values. They're based on oil money, and it's not a system that keeps everyone's incentives and cares in mind. The potential here is to create values-based systems for the whole world that are new and innovative and that no one person or government gets to dictate, rather than the top-down systems we have now.

What does this mean in practical terms for someone living in poverty in a developing nation?

Up until now, people living on a dollar a day haven't really had a choice of currency. Now they can have a choice to use a currency with no government controls, and day to day, somebody can't destroy the value of their life savings. With a public worldwide immutable accounting ledger, which is what a blockchain is, anyone with a cellphone and an Internet connection can be their own bank and transact with the world and actually do business. That's why a lot of the creators of the UN's Sustainable Development Goals are looking at blockchain systems to be able to implement them around the world.

What is the connection between the cryptocurrency and modern psychedelic movements?

When we founded cryptopsychedelic.com, that's something we wanted to explore. We knew there was a large overlap and wanted to articulate what it is. I'd say part of it is that some people who take psychedelics and experiment with sovereignty of mind (in therapy or elsewhere) are able to remove a lot of their cultural conditioning, and money is an element of that. Money is something people don't think a lot about, especially in the privileged western world. When a child asks her parent where money comes from, she's usually told that it comes from the government and that's it. Psychedelics allow you to examine things like money away from the cultural conditioning, and to want to create to new systems—monetary and otherwise.

Another connection is that until recently they've both been fringe, underground communities whose benefits many people don't necessarily understand. Both communities are also trying to figure out the best way to be integrated into society. Cryptocurrency provides a banking solution or value exchange system for people who don't want to use the traditional systems, but it's also about experimenting with different kinds of governance. Similarly, I know that within the psychedelic science community there's a strong sense of wanting to guide how we integrate psychedelics within society and to keep out bad actors. Similarly, with blockchain technology, there's an ability to build systems for community trust to scale beyond the people in your inner circle.

Can you elaborate on that idea of trust?

According to research, there's a certain known number of people that we can trust within our inner circle—about 150. Without that, we can't really scale trust systems without going through a central party, like Google or a bank. With blockchain technologies, you can scale past that number endlessly without having to offload the trust system to a central party. With psychedelics, I believe these blockchain technologies can be used to come up with reputation systems within the community of people who are going to be practicing within this new field. This is going to be very important to integrate as psychedelic therapy scales up globally.

Who are the people who are going to be practicing in this new legitimate field?

At first, they'll be therapists. You want your therapist to be very skilled, you want to know that they haven't had a lot of bad reports about their practices. You don't want them to have just taken an online course and say, "Hey, I'm a shaman now!" So as this becomes more popular and more people investigate using psychedelics with a trained therapist, I think blockchain technologies will allow us to create a global community of trusted agents.

So blockchain is not just about currency?

Not at all—it has impacts on law, on reputation and identity, on property registration. So with psychedelics, creating the reputation system of the practitioners may be an interesting application.

Have psychedelics personally affected your life outlook?

Most certainly—they're one of the biggest things that have affected me. Years ago, I was anxious about the world financial system to the point that it was detrimental to my life. I was one of those people who thought we should be buying land in Latin America and getting out of here because I didn't know how long this system was going to last. Then, in 2014, I did an ayahuasca ceremony, and that completely healed the anxiety and pain I'd been inflicting on myself by living in such a state of fear. And it also led me to focus on solutions like blockchain, versus being scared and fearful. Also, MDMA specifically has helped me relate and empathize and communicate with other humans much better than I could prior to ever using it. I think a lot of cryptocurrency people have been affected by psychedelics in their thinking and healing, and the evidence of that is that the Multidisciplinary Association for Psychedelic Studies (MAPS) has been given millions of dollars in cryptocurrency donations.

How did you get involved with MAPS?

A few years ago, before I'd ever tried any psychedelic drug, someone offered me MDMA. I was an industrial safety hygienist with a lot of practice looking up toxicology and epidemiological studies to make sure people weren't being exposed to hazardous materials. So when someone said, hey do you want to try some of this, I knew I wanted to do research first. When I dove into it, I saw that the old medical research was really suspect—stuff about it putting a hole in the brain that I realized wasn't true. So what was true? What's actually going on here? I dug deeper and found MAPS and some of the research they were doing. I remember saying back then, in 2014, we need to scale out a system of therapy centers immediately! Why isn't this happening? In preliminary trials, MDMA-assisted psychotherapy has eliminated PTSD in two-thirds of people going through it—how is this not an immediate thing? Ever since then, I've been very adamant about supporting MAPS' work, and I hope lots more will join me.

Jennifer Bleyer *is a journalist based in New York who has written about psychedelic science for* Psychology Today, Tablet, *and* NYU Magazine.

Matt McKibbin *is the founder of Decentranet. He has been a blockchain evangelist since 2013 when he coordinated the DC Blockchain Meetup and was heavily involved in the BitAngels investment group. Matt is the former Co-Founder and Chief Decentralization Officer at d10e, the world's leading conference on decentralized technologies, philosophies and social organization. He serves as an advisor to Dispatch Labs, ImpactPPA, Humaniq, Securrency, and Loci and has been involved in several early-stage blockchain startups, including Ubiquity and Trive.news. Matt is a prolific and sought-after speaker as an expert on decentralization at leading conferences worldwide. He has been featured in dozens of media publications, including Bloomberg, Nasdaq, TechCrunch, CoinDesk, CoinTelegraph, Bitcoin Magazine, and more. Matt received his Bachelor's of Arts in Physics from West Virginia University.*

Sara Gael, M.A., and Ryan Beauregard

The Zendo Project: Six Years of Psychedelic Peer Support

SARA GAEL, M.A., & RYAN BEAUREGARD

The Zendo Project provides a supportive environment and specialized care designed to transform challenging psychedelic experiences into valuable learning opportunities. We work to reduce the number of unnecessary psychiatric hospitalizations and arrests and create a harm reduction model for a post-prohibition world.

Since 2012, the Zendo Project has assisted over 4,200 guests, trained over 3,000 volunteers, and provided outreach and education to thousands more in the principles of psychedelic peer support. Zendo Project media reach has steadily increased, and expanded significantly over the last year, with Zendo Project staff regularly featured on podcasts and news articles.

The Zendo Project has become an industry leader and model program in the field of psychedelic harm reduction. As evidenced by an increased number of grassroots peer support organizations that utilize our training materials, people look to the Zendo Project as a model to emulate in their own communities and at local events. In 2018, we have seen an exponential increase in demands for harm reduction services from festival producers, the festival community, and the public.

ZENDO PROJECT
zendoproject.org

TRAINING AND OUTREACH

In response to increased international demand and in service of our mission, we have increased our focus on education and outreach in 2018. Our primary goals in this area have been expanding public knowledge of psychedelic harm reduction and creating industry standards for the practice of psychedelic peer counseling.

We are increasingly focused on providing education to other emergency service professionals including law enforcement, medical personnel, and security staff, as well as festival production teams hoping to gain knowledge in harm reduction and psychedelic peer counseling.

In 2018, the Zendo Project facilitated nine Peer Support Trainings. Three of these trainings were at music festivals, and six took place in major cities throughout the US: Portland, Seattle, Washington, D.C., New York, Pittsburgh, and Santa Fe. We also partnered with two universities as training hosts: Humboldt State University and the University of Colorado Boulder.

EXPANDING OUR IMPACT

In 2018, our team provided services at Envision Festival (Costa Rica), Lightning in a Bottle (California), Burning Man (Nevada), and a handful of other events. Our team of both staff and volunteers has grown significantly over the past few years, and we've seen that our approach has created a replicable model that is scalable. With an experienced a group of supervisors and leads, we see how the systems we have created for handling the flow of guests can run smoothly and sustainably.

This year at Burning Man, we were placed directly next to the official Black Rock Rangers headquarters and Sanctuary, and for the first time since 2013, directly on the Esplanade—the

The Zendo Project trained 280 volunteers during Burning Man 2018.

Main Street of Burning Man. The feedback we received from both guests and volunteers was overwhelmingly positive, and the consensus was that 2018 was the smoothest year to-date in regard to operations.

Our 2018 fundraiser was also our most successful to date, raising over $127,000 from 412 donors. We are deeply grateful to everyone who donated and shared the campaign for contributing to the Zendo Project's development, expansion, and continued impact. With the funds raised, we are purchasing upgraded infrastructure, as well as expanding our training program and outreach initiatives to more events. The Zendo Project is completely made possible by our community of donors who believe in the importance of this work.

THE FUTURE OF THE ZENDO PROJECT

With the ongoing mainstreaming of psychedelics, most recently exemplified by the popularity of Michael Pollan's new #1 New York Times bestselling book *How to Change Your Mind,* people are becoming more aware of the beneficial potential of psychedelics and are more curious than ever about them. That's why it is increasingly important to provide the public with information necessary to mitigate the psychological risks associated with all drug use, including psychedelics.

As we head into 2019, the Zendo Project will continue to develop and expand our training program, increasing our reach, depth, and accessibility. We are in the beginning stages of developing an international outreach initiative tour to connect communities, organizations, and individuals around the world with resources for psychedelic peer support. While we have a lot of work ahead of us, our global community is making this vision a reality, and helping bring our passion and perspective about this work to the international stage. Please contact us directly at **zendo@maps.org** if you have access to lodging, venues, or communities that can help support our staff on our upcoming world tour.

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

Ryan Beauregard *received his B.A. in Psychology from Claremont McKenna College, and spent 10 years mentoring at-risk teens and families through wilderness survival skills and nature connection. His passion for community connection, the environment, and intrapersonal healing continued with his involvement in permaculture, natural building, and ancestral grief rituals. As a volunteer with the Zendo Project since 2013, Ryan has had the opportunity to connect and expand the scope of psychedelic harm reduction in communities and festivals all over the globe. As the Zendo Project Manager, he integrates his skills in psychology, design and and community engagement. He can be reached at ryan@maps.org.*

Overview of the Heffter Research Institute

DAVID E. NICHOLS, PH.D.

David E. Nichols, Ph.D.

HEFFTER
RESEARCH INSTITUTE

The story of the Heffter Research Institute (**heffter.org**) is a tale of what it takes to fight for the things you believe are really important—even when the "establishment" is trying to prove exactly the opposite.

It was 1993, in the aftermath of three decades of negative news that managed to forge a totally negative image of hallucinogens and related compounds (also called psychedelics). The result was the outlawing of those substances, which put a stop to several clinical studies that had been ongoing in the US, and prevented the initiation of any new clinical work. The exaggerated media hype of the 1960s had negatively colored popular opinion, as well as attitudes at national funding institutes, such as the National Institutes of Health (NIH), National Institute of Mental Health (NIMH), and the National Institute on Drug Abuse (NIDA). Therefore, taking the position that psychedelics might have useful medical value was still very controversial in 1993.

Despite the adverse climate, a small but enthusiastic group of scientists[1] remained convinced of the importance of psychedelics, believing they had great, unexplored potential that would require independently funded scientific research to discover their best uses in medical treatment. The early clinical studies had provided interesting anecdotal reports and promising outcomes, even though their methodology had been relatively rudimentary, and their results were widely questioned. We believed that the fact that we all were respected scientists in our particular fields of endeavor meant that what we said and did might carry some weight among establishment scientists and clinicians. Fortunately, that has proved to be the case.

The Heffter Research Institute was incorporated in New Mexico in 1993 as a non-profit, 501(c)(3) scientific organization to "promote research of the highest scientific quality with the classic hallucinogens and related compounds (sometimes called psychedelics) in order to contribute to a greater understanding of the mind, leading to the improvement of the human condition, and to alleviate suffering." We have remained faithful to our mission. Since its inception, Heffter has been helping to design, review, and fund the leading studies on psilocybin-assisted therapy at prominent research institutions in the US and Europe. Our research has explored psilocybin for the treatment of cancer-related distress, addiction, for understanding the relationship between the psychedelic experience and spirituality, and for basic science research into the physiology of brain activity, cognition, and behavior. (I might note that my Purdue University laboratory was able to make a key improvement to the synthesis of psilocybin, so that it would be more available to investigators.)

The psychedelic research renaissance we are witnessing today must be at least partly attributed to Heffter Institute activities. The climate is now considerably different from what it was in 1993. As one example from that time, we spent countless hours debating whether to refer to our mission as focused on "hallucinogens" or "psychedelics." In the scientific literature of the time, it was usual and accepted practice to refer to LSD, mescaline, and psilocybin as hallucinogenic substances. Nevertheless, the term is not an apt one for what these substances actually do; they only very rarely produce true hallucinations, which are experiences that cannot be distinguished from reality.

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[1]Original board members of the Heffter Research Institute included Mark Geyer, Ph.D., George Greer, M.D., Charles Grob, M.D., Dennis McKenna, Ph.D., and David Nichols, Ph.D. Current members of the board include Robert Barnhart, Betsy Gordon, Roland Griffiths, Ph.D., Bill Linton, Cody Swift, Carey Turnbull, Claudia Turnbull, Franz Vollenweider, M.D., and our business manager Lynette Herring.

Many folks counseled us not to refer to these compounds as psychedelics; it was still too controversial, and might damage our cause. Yet, we went against that advice because psychedelic was a name that more accurately described the class of compounds and what they do. I might note that a major scientific review of the field that I wrote in 2004 was titled "Hallucinogens," yet a more recent review published in 2016 in a mainstream scientific journal was titled, "Psychedelics." When I submitted the manuscript for the latter to the journal for peer review, I still was not sure that the reviewers would allow me to refer to these substances as psychedelics. Now, however, the name psychedelics has become widely accepted, not only with the public, but also in most of the scientific and medical community.

So, here we are, 25 years after our founding, and still active. The Heffter Institute does not have huge name recognition because we are a virtual institute that primarily reviews and funds research, having no full-time employees, no actual facilities, minimal overhead costs, and no public relations or outreach staff. Other than our essentially cost-free twice-yearly newsletter, we have not spent significant resources on getting our story out. That approach has allowed us to put most of the precious funds we are able to raise directly into scientific research investigations. That has been a two-edged sword, however, because it also has kept recognition of our work largely out of the public eye, and that includes potential philanthropists that could embrace our cause. By the way, we thank MAPS for this opportunity to tell our story!

Even if you have not heard of Heffter, we did receive widespread media coverage after the 2016 publications of research reports of Heffter-supported studies of psilocybin-assisted therapy in cancer patients at Johns Hopkins University and New York University. Although continuing blogs on Facebook and elsewhere about the use of "mushrooms to treat depression," rarely include the fact that most of those studies were supported by the Heffter Institute, you have heard about our work, whether or not you knew it.

Heffter has supported, or is supporting, clinical studies of the potential medical value of psychedelics, primarily psilocybin, at the University of Arizona, Harbor-UCLA, the University of New Mexico, Johns Hopkins University, the University of Wisconsin, New York University, the University of Alabama, Yale University, UCSF, and the University of Zürich Hospital. We supported the seminal studies on the use of psilocybin-assisted therapy for the treatment of depression and anxiety in cancer patients, and supported a pilot study of the same therapy for treating alcoholism and nicotine addiction. The results from these latter two studies were so encouraging we have expanded them to larger patient populations, which are currently ongoing. A small study of psilocybin-assisted therapy also has been underway at the University of Alabama for treatment of cocaine addiction, and we have just approved a small safety study of psilocybin-assisted therapy for opioid addiction.

What do we hope to accomplish by supporting studies into so many different indications? Readers may not be aware that the FDA only allows new drug applications for a single indication; currently MDMA for PTSD, and psilocybin for depression. Moving drug development along to gain eventual FDA approval for prescription use requires many tens of millions of dollars, and MAPS members will already have seen the cost estimates to do that for MDMA. Similar costs are expected for the development of psilocybin therapy, a task that has been undertaken in the U.S. by the Usona Institute. Obviously, there are not enough philanthropists out there to fund development of psilocybin for all of the other possible indications we are studying. Therefore, our goal is, first of all, to explore the landscape of what is *possible* with psilocybin therapy. If psilocybin is ultimately approved by the FDA for treating depression, there have been some doubts that "off-label" (non-FDA-approved) use for any other indication will be allowed. Those waters are untested, however, because there has *never* been any other drug class where its use may be appropriate for so many different indications: depression, anxiety, addictions of various types, and perhaps obsessive-compulsive and eating disorders, among others. If our trials are large enough to be confident that psilocybin therapy is efficacious for this host of disorders, we believe it is likely that at some point in the future properly trained clinicians will be able to use psilocybin therapy for indications not initially approved by the FDA, such as addictions. That is a debate for another time, but in the meantime, if our studies give positive results, at least we will have opened the door of possibilities for the range of psychiatric disorders that may yield to treatment with a psychedelic drug.

…if our studies give positive results, at least we will have opened the door of possibilities for the range of psychiatric disorders that may yield to treatment with a psychedelic drug.

In my opinion, we are on the verge of a great revolution in the treatment of mental illnesses. Or, in the immortal words of Bob Dylan, "The times they are a changin'."

David Nichols, Ph.D., *is Co-Founder and President of the Heffter Research Institute. He was a Distinguished Professor of Medicinal Chemistry and the Robert C. and Charlotte P. Anderson Chair in Pharmacology at the Purdue University College of Pharmacy and adjunct Professor of Pharmacology at the Indiana University School of Medicine. He is currently an Adjunct Professor at the University of North Carolina, Chapel Hill. His research has investigated the relationship between molecular structure and the action of psychedelic agents and other substances that modify behavioral states. He is recognized as one of the foremost experts on the medicinal chemistry of hallucinogens. He can be reached at dave@heffter.org.*

Ekaterina Malievskaia, M.D., M.Sc.

Navigating Mental Health: COMPASS Pathways' Psilocybin Research Program

EKATERINA MALIEVSKAIA, M.D., M.SC.
CHIEF MEDICAL OFFICER & CO-FOUNDER

COMPASSION
Navigating Mental Health Pathways

I first came to psychedelic research from a very personal experience with the limitations of psychiatry. I am a physician. George Goldsmith, my partner in life and business, has worked on complex regulatory and ethical issues of public-private collaboration. But despite our backgrounds, nothing prepared us for the devastation caused by the failure of the mental health care system when my son became ill. Even when the best doctors in the best institutions gave up on us, I kept looking for solutions. As we shared our story with friends and strangers, we realized that all of us are affected by the mental health crisis. And in the depth of our despair, we were still aware of how fortunate we were: we had resources and connections, and we could understand and assess the risks and benefits of emergent evidence for novel approahes. We resolved to make a difference for families who are in dire need of better treatments.

THE EARLY DAYS

George and I were impressed by the vision and scientific rigor of the researchers at the Multidisciplinary Association for Psychedelic Studies (MAPS) and the Heffter Research Institute. Immediately after our first Heffter Board meeting in 2014, we offered not only financial support to the field, but help with regulatory strategy so that patients could benefit sooner. Despite significant challenges, we remain true to these commitments four years later.

In 2015, we created a US/UK non-profit, COMPASS Pathways (compasspathways.com) to support a pragmatic research project into psilocybin for psychological distress in hospice on the Isle of Man. Margaret Simpson, the visionary CEO of the hospice center, secured the support of the government, and together we received permission to train the first group of psychedelic therapists with psilocybin. There was only one obstacle: while Usona Institute had already started the GMP psilocybin synthesis with Shasun/Sterling contract manufacturer in 2015, they were not able to suply it for our project on the Isle of Man. Unclear of the barriers and timelines, some of COMPASS' trustees recommended that we manufacture psilocybin ourselves. Given our mission, and uncertainty about the availability of psilocybin made under current Good Manufacturing Practices (cGMP), we followed their recommendation.

We anticipated that if we followed the published process of synthesis, the cost of manufacturing would be in the range of £350,000 to £750,000 ($460,000 to nearly $1 million). We set out to create our supply for research in Europe. However, while we shifted our focus to the manufacturing of GMP psilocybin, the hospice CEO retired, the political leadership of the Isle of Man changed, and the opportunity passed.

The process of synthesis and formulation turned out to be much more complex and expensive than anticipated. We funded this work out of our personal funds, and the ever-rising cost was simply outside of our reach. That led us to establish a drug manufacturing company eligible for tax credits under a UK government program that helps underwrite the cost of medicine research and development. That option, as well as other government incentives, are not available for non-profits.

In 2016, Heffter researchers asked us to write a regulatory commentary on the upcoming publication of two landmark studies of psilocybin for cancer-related distress. Our advisor, the former head of the UK regulator, the Medicines and Healthcare products Regulatory Agency, Professor Sir Alasdair Breckenridge, agreed to do this. Heffter researchers also agreed for us to share the studies with the European Medicine Agency's Scientific Advice Working Party in October 2016, a few weeks prior to the studies' publication. The meeting with the EMA team was pragmatic, collaborative, and sobering. The regulators acknowledged the early evidence of efficacy, but encouraged us to focus on the indication of major depression instead. We shared the details of these discussions with both Heffter and Usona to help inform their regulatory strategy and further study designs.

We took a sabbatical to consider our options. It was clear there were no political barriers to developing psilocybin as a medicine should the science meet regulatory standards. If we wanted to explore the therapeutic potential of psilocybin for depression, we were expected to take the traditional clinical development path, just like any other Investigational Medicinal Product (IMP). This meant we needed to go back to basics, starting with preclinical and simple dose-finding studies. It also meant the overall cost of development of psilocybin for the indication of depression would be over £100 million ($130 million).

We knew we would not be able to raise the necessary funds through donations since the clinical research was still in an early stage, and the indication of depression is among the most challenging ones. If we were to spend over £100 million on drug

development, we wanted the solutions to be affordable, scalable and sustainable. In February 2017, we made the decision to transition to a for-profit life sciences company. The non-profit was only funded by us personally and had no outstanding obligations to others, so this process was legally and logistically straightforward.

MANUFACTURING AND PATENTING

While psilocybin is a naturally occurring molecule, psilocybin as an Investigational Medicinal Product or IMP is a regulatory entity that includes a detailed description of a GMP-compliant, scalable and reproducible manufacturing process; associated preclinical data; and ongoing safety data collected in clinical trials. The IMP can be thought of as a product's fingerprint, so that regulators can recognize the safety and efficacy evidence gathered in the clinical trials as it relates to this unique product. The creation of an IMP is an extremely complex and expensive process that requires sustainable funding and a serious multidisciplinary team effort. Based on our experience and the regulatory input from EMA, we now estimate that the development process will continue through marketing authorization and cost over £3 million (nearly $4 million).

In the process of synthesis, formulation and creation of preclinical data, we reached out to the researchers at Heffter and Usona with offers to share experience and ever rising cost, the last conversation being at PS17 in Oakland. Shortly after, the initial phases of the synthesis and formulation were completed, and psilocybin became the Investigational Medicinal Product. From that point on, for the reasons of data consistency, there was no regulatory mechanism of "sharing" it other than through standard licensing agreements for the use of IMP. This is the way clinical research regulation works around the world.

As the previously published synthesis processes did not scale to meet regulatory standards, we had to invent our own process. As he would have done for anyone who would have asked for his help, David Nichols advised our manufacturing team. With his support our team has solved over 60 distinct technical problems in the synthesis and formulation process. Some of these inventions became the basis for our manufacturing patents. In general, patents provide an opportunity for an organization willing not only to take a significant financial risk to recoup the expenses, but more importantly, to ensure integrity of the data collected before and after the approval.

Our patents do not preclude others from creating a range of different solutions for the synthesis and formulation of psilocybin; nor do they preclude the use of naturally occurring mushrooms, extracts, or any other products created by alternative synthesis and formulation routes. Equally, our patents do not prevent other clinicians from using our product or any psilocybin-containing products in conjunction with the types of therapy or psychological support they judge to be helpful, as long as it does not jeopardize patient safety. Lastly, neither our patents, regulatory strategy, nor pricing strategy have an impact on the practices of the underground community of practitioners in nonclinical settings.

Our exclusive contract with the drug manufacturer does not prevent others from choosing among many different competing manufacturers though the standard Request for Proposal (RFP) process. We selected Onyx when Usona was already working with their own manufacturer for over a year, so there is no way we could have blocked Usona from accomplishing the GMP synthesis. The advances of science may now offer new creative solutions for the synthesis and formulation of psilocybin with new partners for those who are willing and able to spend the time, effort, and funds to create an alternative psilocybin-based IMP.

While we have created the supply of psilocybin for our own research, we have made the unusual decision to share it with qualified independent researchers. We provide it free of charge in exchange for being able to use their safety data. The researchers however are responsible for the packaging and shipping costs. Packaging costs can be significant in clinical trials due to the need for thorough documentation and controls. The shipping costs are outside of our control.

Providing GMP psilocybin to qualified researchers was not a commercial decision, but yet another way to accelerate the generation of clinically relevant evidence that may ultimately improve patient outcomes.

This process has proven to be challenging at times. As we have learned, university legal departments and technology transfer offices are vigilant about the potential Intellectual Property (IP) that might be created in the process of investigator-initiated studies. This IP, despite the best intentions of the researchers, does not belong to the scientists, who have limited say in how it is used by their institutions. In the event of IP creation, Technology Transfer Offices have a legal obligation to license it out to the 'highest bidder' with the most aggressive and scalable business model that will generate the most return for the academic institution. Even though such IP would be created by independent researchers with our IMP, in order to use the invention, we still have to compete with other commercial entities who might have different ethics or commercial goals.

This is an important consideration for the signatories of the Statement on Open Science for Psychedelic Medicines and Practices who work for academic institutions, as they need to align with their institutions on terms of IP licensing. The core principle of the statement is that knowledge created by signatories is open to all— that is, the knowledge is to be given away unconditionally by relinquishing researchers' rights to protect it or to control who gets to use it after it becomes public.

We believe our patent strategy offers some protection against uses that may not be fully aligned with our mission to create access to innovative treatments for as many people as possible at an affordable cost to patients and health care systems.

OUR FOCUS: IMPROVING OUTCOMES FOR THE MAXIMUM NUMBER OF PEOPLE

Many people have asked us about our business model. Given that we are in the early stages of the development, the model is still evolving and will largely depend on the conditions of the regulatory approvals. In general, U.S. law focuses on private companies

maximizing value for shareholders only. UK corporate law is different: it requires us to create value for both shareholders and stakeholders. As a UK-based company, every COMPASS Pathways Board meeting starts with a reminder of this commitment.

Businesses might have different strategies to create value for shareholders. Charging high prices and stifling competition is one of them, but it is not the approach we take. Instead, our goal is to provide broad access to all in need regardless of their ability to pay, creating greater value for health systems and translating to lower health insurance premiums and decreased health care cost. This is the approach our shareholders invested in and continue to support.

The high cost of clinical trials and drug development aside, the cost of manufacturing GMP psilocybin itself post-regulatory approval is likely to be relatively low. The future cost of psilocybin therapy will be determined at the point of care delivery by the treatment models, the services provided by the treatment centers, but mainly by the fees of individual providers. The creation of reimbursable models of care then becomes essential if we are to ensure that everyone who would benefit from psilocybin therapy can access it regardless of their ability to pay. It might be that "a thousand flowers will bloom" – and eventually the best models will prevail simply through quality and price competition, or that treatments will be rolled out in a more regulated way. This will require constant feedback and frequent course correction, as we continue to learn from our collective experience.

One way to decrease this uncertainty and ensure the accessibility of the treatment is by engaging in frequent in-depth conversations with the regulators and payers early in the process, just as we suggested after our first Heffter Board meeting in 2014. This remains our main strategy today.

To date, we have had conversations with regulators in 12 different countries in Europe and North America. We have assembled hundreds of pages of detailed feedback on the clinical development of psilocybin for depression and other indications, and on regulators' general views of the challenges and opportunities for the clinical development of psilocybin. We share these insights regularly with MAPS. We also offered to share our plans and experience with Usona and Heffter. However, we understand that the psychedelic community is facing many challenges as it grows and some might not consider these perspectives a priority at this time.

We realize now that we could have taken more time to communicate with researchers who supported us during our early non-profit stage. At that time, we simply assumed that we were all motivated by the urgent need to create safe, effective, and sustainable options for patients. In our drive to get things done, we may have unintentionally hurt some people by not communicating clearly enough about our intentions and decision process that led us to move from non-profit to profit and from a focus on existential distress in cancer patients to treatment-resistant depression. We sincerely regret this and intend to do a better job in the future. Today, many researchers have continued working with us, while others have chosen not to, citing their discomfort with a for-profit approach. We respect their choice.

In the meantime, my son has recovered and now lives a happy and productive life. This was inconceivable just three years ago. Our story is not simply the story of a miracle cure, but the story of access to innovation, particularly for those who cannot afford it. We will have walked this challenging path so other families do not have to do so.

We appreciate that not everyone agrees with our model. We believe different models of care and organizational structure can co-exist, and we embrace healthy competition through creating alternative solutions. We also understand that in the diverse psychedelic community, there is a range of views on how to move forward. We appreciate the dedication, skills, and achievements of those who have chosen to work on legalization efforts, and we do not think our models are contradictory. In fact, arguments for decriminalization can be enhanced by the evidence generated in large-scale clinical trials conducted according to the highest regulatory standards. Regardless of the results of the trials, the individual patient experiences and extensive safety data collected and published in the process can be of significant value in helping change public and legislative opinions.

The "elders" of psychedelic research have triumphed at what they set out to do. The world is paying attention, patients and clinicians are hopeful, leading research institutions are hosting conferences and developing research ideas, and institutional and private funders are willing and able to support further development. Scientists and clinicians now have a real chance to offer hope and help for millions of people suffering from psychological distress, regardless of their spiritual practices or ideological convictions.

The field of psychedelic research is entering a new chapter. This is both exciting and highly uncertain, as this work has never been done at scale and in full public view. Working in this historically sensitized and highly regulated space takes a wide range of skills, experience, sustainable funding, team work and collaborations across disciplines. With care and respect for differences of opinions, we know it is possible to have a constructive and thoughtful dialogue, and to collaborate in the interests of patients. We at COMPASS Pathways are committed to doing our part. We look forward to sharing lessons of successes and challenges with many of you in the future.

Ekaterina Malievskaia M.D., M.Sc., *received her medical degree from St Petersburg Medical Academy in St Petersburg, Russia. After her Internal Medicine residency training, she completed an Environmental Medicine Fellowship at Mount Sinai School of Medicine and received her M.Sc. in Public Health from New York University Medical School. She worked in private practice, academic medicine and public health for more than 15 years in the greater New York area. She was a Clinical Instructor of Medicine at Mount Sinai School of Medicine, as well as a Research Professor at City University of New York. After moving to London in 2011, Ekaterina worked in global health and medical philanthropy, focusing on improving outcomes in maternal and child health. She founded COMPASS Pathways with her husband George Goldsmith in 2016.*

Paula Graciela Kahn

United to Cure Planetary PTSD: Advancing the Movement in 2019

PAULA GRACIELA KAHN

For the new year, I invite the MAPS community to join me in practicing accountability and healing justice. Let's turn up our presence in listening to the testimonies of those most impacted by the war on drugs, state violence, armed conflict, forced migration, immigrant detention, mass incarceration, the extractive industries, lack of access to healthcare, and poverty. May we listen with empathy and identify the calls to action for us to play a role of support and service to humanity.

When I attended last February's Plantas Sagradas en las Americas conference in Ajijic, near Guadalajara, Mexico, I heard two members of indigenous communities clearly state what their visions and needs were: to preserve and protect cultural knowledge and populations of endangered, sacred, psychoactive plants, teonanacatl (psilocybin mushroom) and hikuri (peyote). Some members of the audience missed those calls to action, choosing instead to focus on the inevitability of Western psychedelic tourism, or to justify and seek validation for their own spiritually-driven consumption, attempting to distinguish it from the greater trends of plunder and extraction. Some attendees' inability to listen to and center indigenous people's struggles and requests was deeply concerning.

After each of these presentations, I reached out to the presenters and said, "I see your vision as well. I will support you in fundraising through my networks in California. I work with immigrant communities and activists." We all agreed that humanity desperately needs access to plant medicines. We also came to the conclusion that humanity's access depends on our will power to center indigenous voices and enforce their rights.

A month later, we co-founded *Cosmovisiones Ancestrales* (Ancestral Cosmovisions, **cosmovisiones.org**). We inherited our cosmovisions, or ecological awarenesses, from our ancestors, and we work towards symbiosis to be responsible and loving ancestors. Our roles in healing justice align with the fulfillment of the 7 Generations, 7 Fires, and Eagle and Condor prophecies delivered by the Kanien'kehake, Anishinaabe, and Inca peoples; our motto aligns with MAPS' own quest: "United to cure planetary post-traumatic stress disorder."

What is planetary post-traumatic stress disorder? I observe planetary PTSD as the manifestation of the intergenerational and collective trauma we have inherited from ongoing colonialism, slavery, globalized warfare, patriarchy, and homophobia. When we study treatment-resistant depression, acute anxiety, and/or PTSD, we must recognize that sometimes these human conditions are symptomatic of the internalization and normalization of the violent cultures we have absorbed through generations of epigenetically-transmitted trauma. When we refer to healing justice, we speak of the process of reckoning with our collective inheritance, bearing witness to testimonies of the most oppressed in society, and aligning ourselves with historically targeted communities to repair harms of colonialism and slavery.

At Cosmovisiones Ancestrales, we recognize that our liberation from planetary PTSD must be crafted through reciprocity; extractive and for-profit behaviors that exclude the most marginalized populations will inevitably prove to be unsustainable and harmful to our planet—one needs to look no further for proof than the evidence for climate change itself. We operate by building bridges amongst members of different global communities through processes of trust building, consultation, asking for consent, respecting boundaries, and forming socially responsible relationships. We center the experiences and needs of indigenous communities defending their land from extractive industries and governments.

In 2019, how will we ensure that psychedelic-assisted or sacred-plant assisted therapy is available to people in ongoing, multi-generational humanitarian and ecological crises?

Those of us who are positioned at greater distance from immediate threats of violence must leverage our privilege to ensure that we play a role in de-escalating violence and awakening from any complicity in violence. We each have a unique role to play in whistleblowing bystander behavior to prevent genocide and mass atrocities from continuing the perpetuation of planetary PTSD. While MAPS advances MDMA through Phase 3 clinical trials, Cosmovisiones Ancestrales reminds our networks that this historically significant progress should include a pro-

(L to R) Cosmovisiones Ancestrales co-founder Inti García coordinates community education in his home to preserve Mazatec knowledge and culture amongst Huautla's youth.; Inti in front of the archive his father Renato García Dorantes initiated. Inti stewards vital information on Mazatec culture and Maria Sabina's life; Inti shows details of his father's archive on Mazatec culture. He emphasizes the value of preserving Mazatec culture to sustain a capacity for resilience and reclamation; founding members of Cosmovisiones Ancestrales view videos on mushroom cultivation techniques.

cess of trust-building amongst diverse populations around the world to repair the harms of the colonization and prohibition of psychoactives—medicines that long were a form of preventative healthcare. We caution that this process runs the risk of becoming diluted or weakened if marginalized populations are not initially included or invited to actively participate in drafting the frameworks for psychedelic- or plant-assisted therapies.

Why? Because individually focused psychedelic therapy runs the risk of only treating the micro-symptoms of a larger unaddressed cause: centuries of globalized genocidal culture. Because clinical trials for MDMA-assisted therapy are first taking place in the global north-in nations that are economically advantaged due to the inheritance of colonialism, slavery, and harmful foreign policy, it would be most just for mission-driven organizations to build strategic partnerships with initiatives led by indigenous healers and allies in formerly and currently-colonized territories. These alliances can work to preserve plant medicine and collaboratively coordinate effective approaches to planetary healing. This would ensure multiple options for treatment and would expand accessibility for mass consumption amongst populations with acute PTSD as soon as possible. It is unethical to advance psychedelic therapy if we do not collectively take ownership for repairing the harms of the colonization of psychoactive plant medicines used in indigenous communities throughout history.

At Cosmovisiones Ancestrales, we address planetary PTSD by institutionalizing violence prevention into our framework. We offer trainings in consent and anti-oppression to heal the race—and gender-based violence that we recognize to be entangled with environmental plunder and armed conflict. We recognize that this is a process of unlearning the spectrum of conscious, unconscious, subtle, and overt behaviors some of us have internalized through socialization. We call upon the psychedelic science and drug policy communities to listen to the constructive feedback of 2018.

In the era of #MeToo and #TimesUp, it is evident that our institutions and communities must formalize a protocol to build consent culture and tools to competently respond to reports of assault through restorative justice models. We must evolve our movement to listen to survivors of violence. We jeopardize the legitimacy of our institutions to heal planetary PTSD if we don't institutionalize violence prevention. For psychedelic-assisted therapy to authentically impact humanity, it must be built on a sturdy foundation that values sustaining truly safe spaces.

Building safer spaces in psychedelic science and drug policy institutions through enacting consent culture is in ethical alignment with the direction we must advance in trust-building processes with indigenous communities. Considering that the psychedelics and plant medicine movement would be non-existent without the knowledge of indigenous communities and ecosystems around the world, it would be just for the movement to center and uplift the UN Declaration on the Rights of Indigenous people, especially Article 19 on free, prior, and informed consent of indigenous peoples.

(L to R) A mural in Huautla's town center depicts Mazatec cosmovisión—the ecological relationships between youth, psilocybe mexicana, and life-force (heart); founding members of Cosmovisiones Ancestrales visit Maria Sabina's tomb to pay their respects, express gratitude for her healing work, to bless her, and ask for direction. Images from July 2018, Huautla de Jimenez, Oaxaca.

I observe many people with socio-economic privilege commodifying and profiting from plant medicines without transforming the relations of power between themselves and members of indigenous communities. In fact, through building partnerships with members of indigenous communities, I've learned about the harms caused by psychedelic tourism, such as the exploitation of the Mazatec mushroom priestess, Maria Sabina. During a recent visit to Huautla de Jimenez, I witnessed the consequences of 65 years of psychedelic tourism, including the endangerment of various species of teonanacatl (psilocybin mushrooms) due to climate change and severe extraction both by locals and foreigners. Poverty, survival sex work, and substance dependency destabilize Huautla de Jimenez and surrounding communities. Cartel violence and the extractive industries are also an ongoing threat, not just in Oaxaca but in all of Mesoamerica.

As a mixed GuateMayan-Jewish migration, genocide, and trauma scholar, witnessing the open-air prison my mother's homelands have become, I ask psychedelic science institutions and companies: What role are you playing in protecting the rights of indigenous peoples? It is important that we reflect on whether our approach to curing planetary PTSD undermines or enforces the rights of indigenous peoples. Commodification of life-saving, sacred, psychedelic medicine is a conversation that must include diverse perspectives from indigenous communities from around the world.

What message does the psychedelic science community send to indigenous and migrant communities of the world when there is not enough accountability? If our affiliations and endorsements of funders or companies are linked to the suffering of indigenous and immigrant populations, we betray the survival and trust of the indigenous communities and territories the psychedelic movement would not exist without. In 2019, let's practice Article 19th of the UNDRIP by adopting a norm of consulting and cooperating with indigenous, immigrant, and historically-oppressed peoples to prevent cycles of violence. Without the consent of those most immediately threatened by violence, we are not fully advancing our vision for curing PTSD.

Paula Graciela Kahn *is a migrant justice community organizer, consent & anti-oppression educator, conflict-mediator, and a performance artist. Paula loves building bridges between individuals, groups, and movements. Inspired by the raver principles Peace Love Unity Respect (PLUR), psychoactives, and the liberating power of music & dance, Paula is inspired to innovate demobilization, disarmament, and reintegration processes in contexts of armed conflict. Paula wishes to explore the role of entheogens in processes of historical memory, accountability, reparations, reconciliation, and transformative justice. She initiated Cosmovisiones Ancestrales in honor of her parents, envisioning popular access to preventative healthcare and holistic healing from PTSD and intergenerational trauma. Paula loves gothic music, reggaethon, and the supernatural. She can be reached at pau.graciela@gmail.com.*

MAPS: Who We Are

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Executive

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

Merete Christiansen, Executive Manager & Assistant to Rick Doblin, Ph.D.

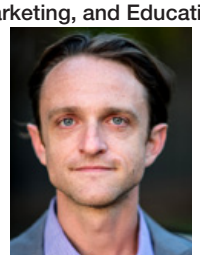
Clinical Research

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

Berra Yazar-Klosinski, Ph.D., Director of Research Development & Regulatory Affairs

Communications, Marketing, and Education

Brian Brown, Associate Director of Operations & Events



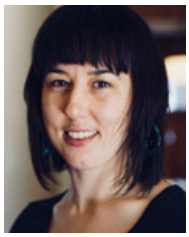
Brad Burge, Director of Strategic Communications

Sarah Jordan, Publications Associate

Bia Labate, Ph.D., Public Education & Culture Specialist

Amy Mastrine, Web & Email Marketing Associate

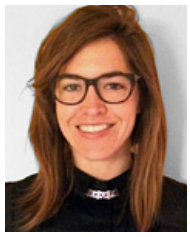
Bryce Montgomery, Associate Director of Communications & Marketing



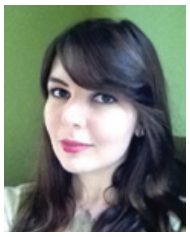
Renee Rosky, Multimedia Marketing Associate

Development

Erik Brown, Senior Development Manager



Liana Sananda Gillooly, Development Officer



Tess Shelley, Development Specialist

Jade Netanya Ullmann, Development Officer & Connector

Harm Reduction (Zendo Project)

Ryan Beauregard, Zendo Project Manger

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

Chelsea Rose, M.A., MFTI, Event Operations Coordinator, Zendo Project

Operations

Aidan Boling, Operations Associate

Kynthia Brunette, Event Volunteer Manager & CRM Systems Specialist

Rudy Maldonado, Sales & Outreach Assistant

Jenni Vierra, Sales & Outreach Coordinator

Policy and Advocacy

Ismail L. Ali, JD Policy & Advocacy Counsel

Natalie Lyla Ginsberg, Policy & Advocacy Director

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 establishing a network of treatment centers.
- Supporting scientific research into spirituality, creativity, and neuroscience.
- Educating the public honestly about the risks and benefits of psychedelics and marijuana.

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

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

MAPS Public Benefit Corporation

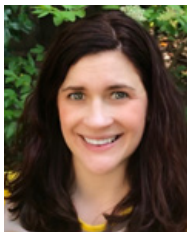
MAPS Public Benefit Corporation


Amy Emerson, Executive Director & Head of Clinical Development & Regulatory Affairs


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


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


Ritika Aggarwal, Executive Support & Operations Coordinator


Meghan Brown, Clinical Research Associate


Maryann Böger, Clinical Systems & Quality Manager


Shannon Clare Carlin, M.A., MFTI, Associate Director of Training & Supervision


Allison Feduccia, Ph.D., Clinical Data Scientist


Gabby Fortier, Clinical Research Associate


Zac Goldberg, Clinical Study Assistant


Connor Harada, Regulatory Data Specialist


Charlotte Harrison, Senior Clinical Research Associate


Libby Heimler, Clinical Research Associate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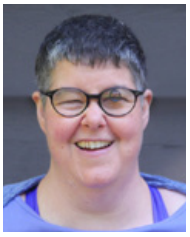
Ilsa Jerome, Ph.D., Research and Information Specialist


Joselyn Lindgren, Clinical Research Associate


Pierre Llorach, Clinical Intern


Rebecca Matthews, Associate Director of Clinical Operations


John Poncini, Video & Informatics Systems Associate


Niki Sauer, Adherence Program Coordinator


Sarah Scheld, M.A., MDMA Therapy Training Program Assistant


Chris Shelley, Ph.D., Training Systems Support Specialist


Brieta Ventimiglia, Clinical Research Associate

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

MPBC's primary work is completing Phase 3 clinical trials required to develop MDMA-assisted psychotherapy into an approved treatment for PTSD. MAPS continues to conduct education and harm reduction projects, to raise funds for MPBC projects, and serve as parent organization and sole funder of MPBC. MPBC was incorporated on December 19, 2014.

Multidisciplinary Association for
Psychedelic Studies, Inc. (MAPS)
PO Box 8423
Santa Cruz, CA 95061 USA
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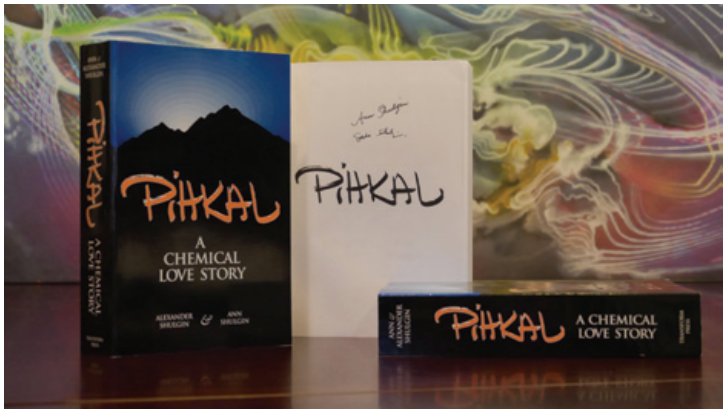

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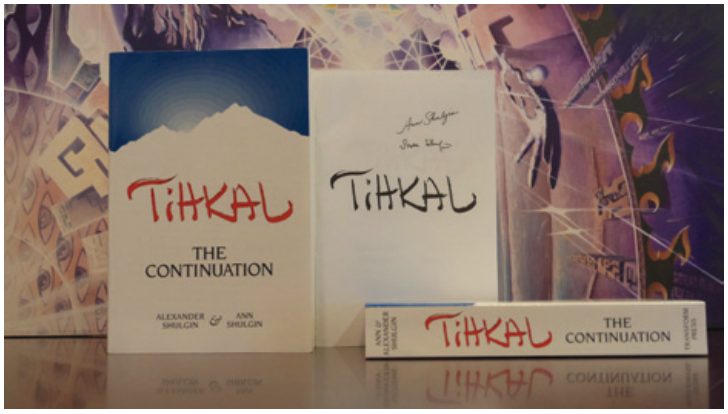

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Front cover: *Only Love Can (Reign Over Me) detail*; Back cover: *Only Love Can (Reign Over Me)* by Michael Divine
Artist information on page 2.