MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Volume XXVI
Number 3

2016 Annual Report
BULLETIN

Winter 2016

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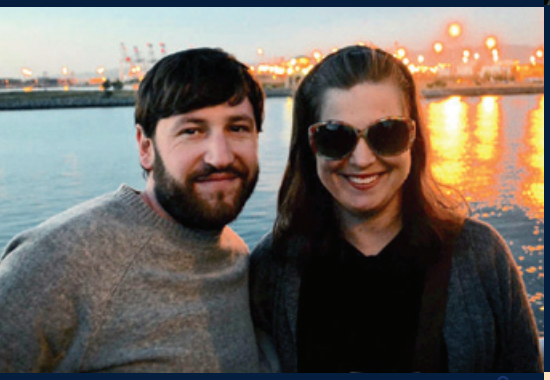

PSYCHEDELIC COMEDY BANQUET

Explore the lighter side of psychedelic science in an evening of fine dining and unique performances.

FEATURING:

Rick Doblin, PhD
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Amanda Feilding
David Nichols, PhD
Stanislov Grof, MD, PhD
Michael Mithoefer, MD
Annie Mithoefer, BSN
Ethan Nadelmann, JD, PhD
David Nutt, MD
Beatriz Labate, PhD
Android Jones
Alex Grey
Allyson Grey
... and many more!

THREE-DAY CONFERENCE

Discover the latest research into the benefits and risks of psychedelics and marijuana for psychotherapy, neuroscience, spirituality, creativity, and more.

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Enjoy a casual dinner, refreshments, and music in the company of friends and colleagues on a three-hour cruise on the San Francisco Bay.

Presented by MAPS BECKLEY FOUNDATION

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
ISSN 1080-8981

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MAPS Bulletin interior pages are printed on recycled paper.

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From the Desk of Rick Doblin, Ph.D.

As I write this, we're approaching the most important reality check in the Multidisciplinary Association for Psychedelic Studies (MAPS)' 30-year history: our End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA), taking place on November 29, 2016, at FDA headquarters in Silver Spring, Maryland. At this meeting, we will review the data gathered from our international series of Phase 2 pilot studies of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) in the U.S., Canada, Switzerland, and Israel. These studies have investigated the use of MDMA-assisted psychotherapy in 107 people suffering from chronic, treatment-resistant PTSD.

It is tremendously exciting to finally present our promising data to the FDA. We began Phase 2 clinical trials of MDMA-assisted psychotherapy for PTSD in Spain in 2000. The Spanish study was prematurely—and heartbreakingly—halted for political reasons by the Madrid Anti-Drug Authority after it received favorable media attention. We have come a long way since then.

The primary purpose of the November 29 meeting is to come to an agreement with the FDA on the design of our multi-site Phase 3 clinical trials, which the FDA requires prior to deciding whether to make MDMA-assisted psychotherapy a legally available treatment option. The meeting is also an opportunity to determine whether additional human or animal toxicity studies will be required prior to obtaining prescription approval. While our 90-minute meeting on November 29 may not resolve all of these issues, it will clarify what steps need to be taken to come to a full agreement. Once we have received feedback from the FDA, we will start discussions with the European Medicines Agency (EMA) as the first step to making MDMA-assisted psychotherapy legally accessible for PTSD in Europe.

I'm proud to report that in October 2016, just a week before we submitted our End of Phase 2 packet to the FDA, we had the opportunity to significantly improve our strategy. We had been working on our presentation for several months, wisely guided by three former officials from the FDA's Division of Psychiatry Products who have been providing consulting services to MAPS. As we prepared our submission and carefully reviewed our results, these consultants grew increasingly impressed with the data that we have gathered. With their advice in mind, before submitting our proposal, we modified our proposal in two ways.

First, we were advised submit a request to file a full application for Breakthrough Therapy Designation, the most important program that the FDA has for expediting the development of new medications that represent "breakthroughs" over existing treatments. We had initially decided not to submit the request. Previously, we had been advised that due to the large effect sizes we have seen in our Phase 2 studies, and the controversial (but increasingly less so) nature of MDMA research, our application would probably result in greater attention from senior FDA officials anyway, the main benefit of Breakthrough Therapy Designation. However, after our consultants closely reviewed our Phase 2 data, they suggested that it is compelling enough to make it worthwhile to ask the FDA for approval to apply for Breakthrough status. We submitted our request on October 18, and the FDA scheduled a teleconference with us in mid-December to discuss our request.

The second modification to our strategy suggested by our consultants is potentially even more consequential. Generally, the FDA requires two large multi-site Phase 3 studies to prove safety and efficacy. Given the serious and life-threatening nature of PTSD, and the enormous number of people for whom existing PTSD treatments are not fully helpful—for example, there are currently over 868,000 U.S. veterans receiving PTSD disability payments from the Department of Veterans Affairs at an estimated cost of $17 billion per year—we have proposed to the FDA that we conduct just one large multi-site Phase 3 study, with our meta-analysis of the 107 subjects in our Phase 2 studies serving as the second confirmatory study.

The support of our donors and the work of our staff over the last three decades have brought us to this historic point, with our End of Phase 2 meeting on the horizon.

While we're not sure how to estimate the chances that the FDA will accept our two modifications—for Breakthrough Therapy Designation and to conduct one rather than two Phase 3 trials—we're asking for the best outcome possible.

The support of our donors and the work of our staff over the last three decades have brought us to this historic point, with our End of Phase 2 meeting on the horizon. The road to approval for the prescription use of MDMA in psychotherapy is getting clearer, and our fundraising needs are growing along with our research. Together, MAPS donors and MAPS staff will integrate psychedelic-assisted psychotherapy into medicine, and introduce new approaches to healing, spirituality, compassion, and empathy into our culture.

Rick Doblin

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

Annual Financial Report

Fiscal Year 2015–16 (June 1, 2015–May 31, 2016)

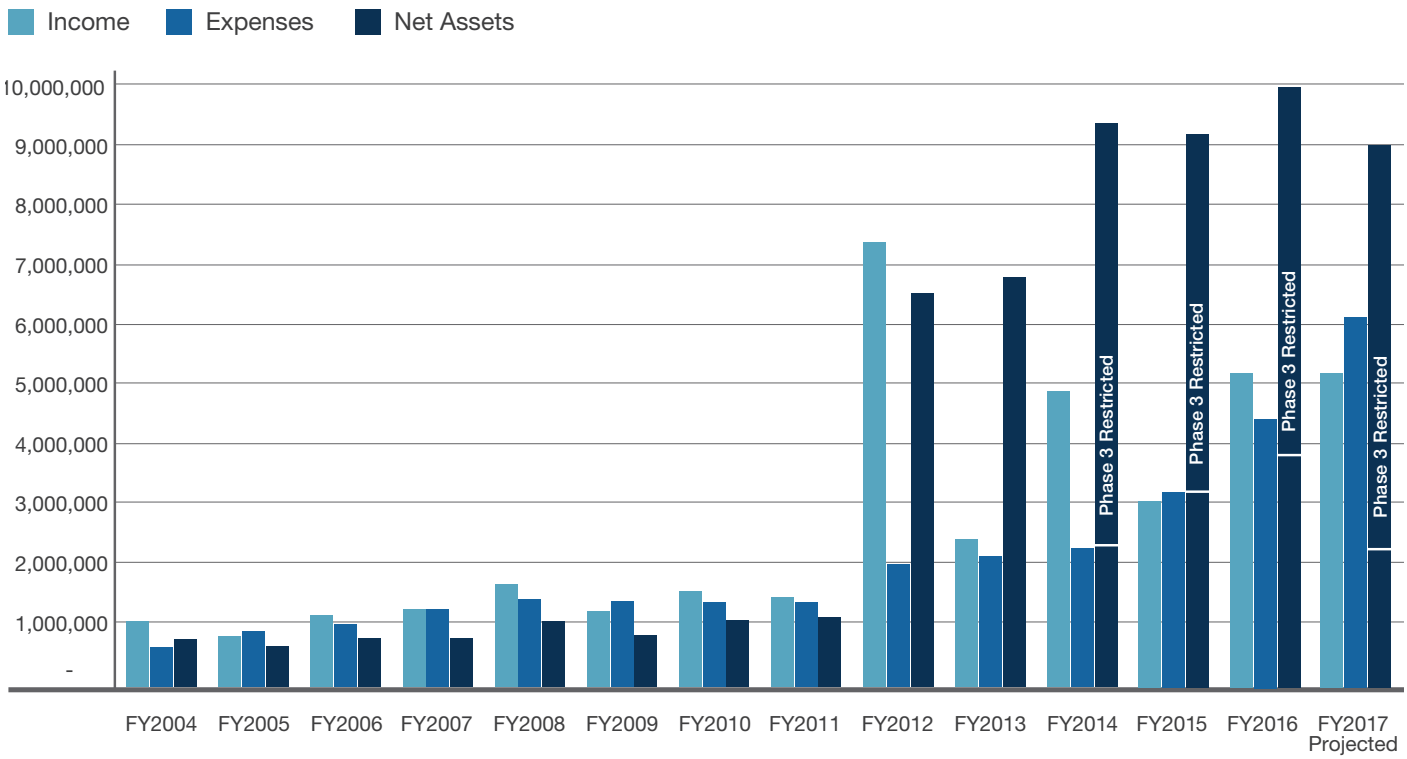
RICK DOBLIN, PH.D.

Each year, the Multidisciplinary Association of Psychedelic Studies (MAPS), a 501(c)(3) non-profit organization, presents its year-end consolidated financial report with substantial details about where our income comes from and how our expenses are allocated and prioritized. We do this as a commitment to transparency and an invitation for dialogue. This report describes our most recently completed Fiscal Year from June 1, 2015 to May 31, 2016 (FY16) and consolidates financial information from MAPS, MAPS Inc. (MAPS' Canadian research operation) and the MAPS Public Benefit Corporation (MPBC), a subsidiary that is 100% owned by MAPS. The MAPS Board of Directors created the MPBC in FY15 to conduct MAPS' clinical research and eventually to market MDMA as a prescription medicine. Additional information on MPBC can be found at **mapsbcorp.com** and in a MAPS bulletin article, "Introducing the MAPS Public Benefit Corporation" (Vol.25, #1, p. 4–5).

MAPS' FY16 Annual Report demonstrates our efforts to strategically leverage the resources that MAPS supporters have so generously empowered the staff to use to transform psychedelics and marijuana into FDA-approved prescription medicines. Medicalization of psychedelics and marijuana is an essential part of our larger mission to mainstream these substances into our culture for a wide range of beneficial uses.

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**. We also invite you to donate to MAPS 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.

Chart 1. MAPS FISCAL YEAR 2004–2017 INCOME, EXPENSES & ASSETS



OVERVIEW

MAPS' net revenue in Fiscal Year 2016 (June 1, 2015–May 31, 2016) totaled $5,186,379 from more than 2,500 donors, events, sales, and investments, with $4,687,600 in contributed revenue. Net revenue in FY16 was more than $2 million above the $3,055,686 that MAPS raised in the previous year. Expenses totaled $4,442,419, more than $1.1 million over the previous year's expenses of $3,256,007 as MAPS expands in preparation for Phase 3 MDMA/PTSD research. In FY16, MAPS increased its net assets by $743,960 to $9,906,814, still less than half of what we anticipate needing to spend on Phase 3 MDMA/PTSD research.

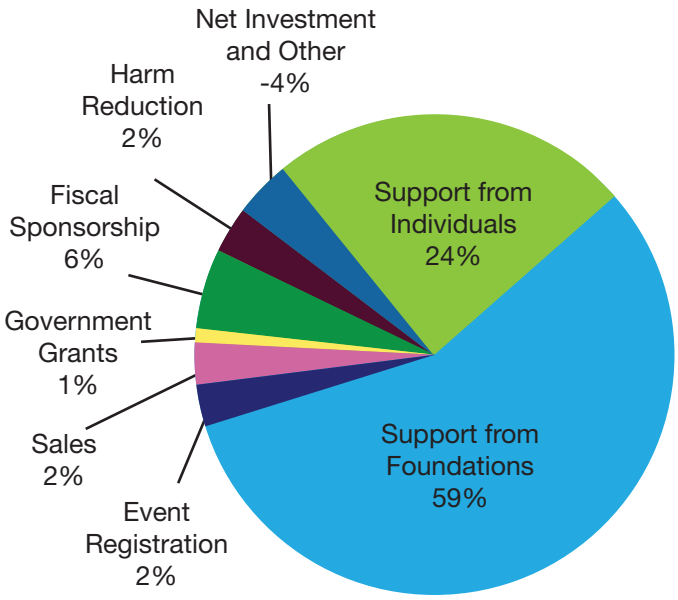
For historical information on overall annual income, expenses and net assets, see Chart 1. Charts 2 and 3 present detailed information on FY16, with Chart 4 projecting annual income, expenses and net assets for FY17. Chart 5 presents data on which of MAPS' assets are restricted to which specific projects and estimates these numbers for FY17. Chart 6 is a detailed discussion of MAPS' projected and actual expenses for FY16 on a project by project basis, with estimates for FY17. Charts 7–10 are about MAPS' MDMA Phase 2 and Phase 3 research expenses through FY21. Chart 11 reviews our marijuana/PTSD research cost projections.

Chart 2. STATEMENT OF ACTIVITIES

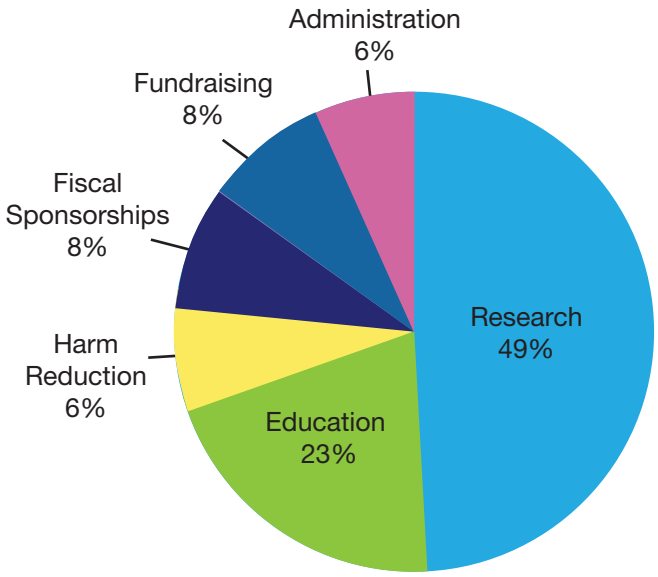
Fiscal Year 2015–16 (June 1, 2015–May 31, 2016)

Revenue	
Support from Individuals, Corporations, Bequests	1,342,459
Support from Foundations	3,345,141
Event Registration	145,230
Sales	109,218
Government Grants	34,610
Fiscal Sponsorship Income	359,821
Harm Reduction Income	124,435
Net Investment and Other Income	-207,114
Total Revenue and Support	**$ 5,253,800**
Cost of Goods Sold	67,421
Net Revenue	**$ 5,186,379**
Expenses	
Research	2,161,926
Education	1,014,262
Harm Reduction	287,397
Fiscal Sponsorships	351,889
Total Programs	3,815,474
Fundraising	349,390
Administration	277,555
Total Expenses	**$ 4,442,419**
Change in Net Assets	**$ 742,960**

FY2016 Net Revenue
$ 5,253,800



FY2016 Expenses
$ 4,442,419



REVENUE REVIEW FOR FISCAL YEAR 2015-16

The increase in revenue in FY16 can largely be attributed to two new generous donors giving $1 million and $1.5 million. Moshe Tov Kreps pledged $1 million, mostly for MAPS' research into MDMA-assisted psychotherapy for PTSD in Israel. The Tides Foundation pledged $500,000 a year for three years for operational expenses for a total of $1.5 million, with accounting rules requiring booking multi-year grants all in the first year rather than over the years during which the funds will actually be received. A total of $1.65 million of FY16 net revenue of $5,186,379 was in multi-year grants that will be received in future years.

Major support totaling $1,104,080 was received for MAPS' Phase 3 MDMA-assisted psychotherapy studies; this includes $500,000 for Phase 3 Israeli MDMA/PTSD research, $301,080 for ongoing Phase 3 Therapist Training in which over 60 therapists have already been trained to conduct MDMA-assisted psychotherapy, $150,000 for Phase 3 General Support which has been used to design the Phase 3 protocol and prepare submissions to FDA reporting on our Phase 2 data, select sites, and recruit staff, and $153,000 towards the purchase of a kilogram of GMP MDMA ($400,000 required) for Phase 3 research raised by MAPS and its partner MAPS Canada.

Additional support in the amount of $914,036 was donated for a range of projects. These projects include: $881,003 for the completion of Phase 2 MDMA-assisted psychotherapy projects, $24,249 to support MAPS' obtaining approval for our study of marijuana for treating PTSD in 76 US veterans (with the approved study itself funded by a $2.15M cost reimbursable grant from the CO Dept. of Public Health and Environment the income of which will be recognized monthly as received over the next three years), $5,000 for future work on the impact of Marijuana on opioid addiction, $2,454 for Ibogaine funding to complete reports on observational studies in New Zealand and Mexico, and $1,300 for Ayahuasca/PTSD research. In total, $1,993,699 was raised for MDMA-related research and $33,003 was raised for Marijuana related and other projects for a total of $2,018,116.

MAPS also raised an additional $503,084 for its educational initiatives. These include $124,435 for psychedelic harm reduction, $18,828 for conference and events, and $359,821 in Fiscal Sponsorships (see Chart 6, Note 1).

The balance of MAPS' funds raised in FY16, in the amount of $2,732,600, was designated for unrestricted use. Of this amount, $1.5 million is from the Tides Foundation grant of $500,000 a year for three years for operational expenses.

Due to fluctuations in the stock market, MAPS' FY16 net revenue was negatively impacted by $240,637 in unrealized losses in our portfolio at the San Francisco Foundation as of May 31, 2016. As of the date of the writing of this report almost five months into FY17, these losses have been recovered.

Chart 3. STATEMENT OF FINANCIAL POSITION

June 1, 2015–May 31, 2016

Assets	**May 31, 2015**	**May 31, 2016**
Cash and Equivalents	825,154	1,006,176
Pledges Receivable	2,283,583	2,194,352
Other Current Assets	6,655,589	6,989,869
Total Assets	**$ 9,764,326**	**$ 10,190,397**
Liabilities		
Accounts Payable & Accrued Expenses	100,420	283,583
Total Liabilities	**$ 100,420**	**$ 283,583**
Net Assets		
Unrestricted	2,648,739	2,891,675
Board Restricted[1]	6,049,715	6,049,715
Temporarily Restricted	965,451	965,424
Total Net Assets	**$ 9,663,906**	**$ 9,906,814**
Total Liabilities and Net Assets	**$ 9,764,326**	**$ 10,190,397**

1) These funds are restricted to Phase 3 drug development of MDMA-assisted psychotherapy for the treatment of PTSD.

Chart 4. STATEMENT OF ACTIVITIES (PROJECTED)

Fiscal Year 2016–17 (June 1, 2016–May 31, 2017)

Revenue	**(Projected July 2016 Board)**
Support from Individuals, Corporations, Bequests	1,405,038
Support from Foundations	1,962,000
Event Registration	625,000
Sales	115,000
Government Grants	1,008,125
Fiscal Sponsorship Income	100,000
Harm Reduction Income	28,000
Net Investment and Other Income	0
Total Revenue and Support	**$ 5,243,163**
Cost of Goods Sold	53,894
Net Revenue	**$ 5,189,269**
Expenses	
Research	3,902,704
Education	1,276,170
Harm Reduction	203,420
Fiscal Sponsorships	95,000
Total Programs	5,477,294
Fundraising	353,779
Administration	278,750
Total Expenses	**$ 6,109,823**
Change in Net Assets	**- $ 920,554**

SOURCES OF REVENUE IN FISCAL YEAR 2015-16

Following this report is a list of MAPS donors of $120 or more, who along with an additional 1,926 individuals and 11 organizations who donated up to $120, make our work possible. MAPS staff are profoundly grateful for our donors who empower us with resources and also their hopes and trust.

About 90% of net revenue was contributed by 2,547 individual donors and family foundations. In FY16, MAPS saw an 246% increase in the amount of major donations ($20,000+) and a 10% increase in mid-level donations ($1,000–$19,999), with the total number of donors at these levels also increasing from the previous fiscal year. However, grassroots donations (under $1,000) stayed about the same and the total number of grassroots donors decreased. In FY15, the Legalizing Psychedelic Therapy crowdfunding campaign brought in 1,000 donors alone. There was no campaign of this scale in FY16 which explains the decrease in number of grassroots donors in FY16 from the previous year. Overall, the number of donors decreased only slightly in FY16 by about 140, with a renewal rate of 27%. The low renewal rate can be attributed to MAPS crowdfunding campaigns which generally engage large numbers of first-time donors most of whom we have not been able to persuade to renew their support.

Grants revenue of $3.345 million was received from family foundations and donor advised funds. In all cases, we have a pre-existing relationship with the courageous and visionary donors. We anticipate eventually obtaining funding from large, more staff-driven, perpetual foundations once we've completed negotiations with FDA regarding the design of our Phase 3 MDMA/PTSD studies and can present complete budgets to these foundations which reflect the FDA-approved design of these studies.

In FY16 we celebrated our 30th Anniversary with a banquet and celebration in Oakland, CA. In conjunction with our 30th Anniversary, we launched our Global Psychedelic Dinners, a peer-to-peer campaign raising funds for our purchase of 1 kilogram of GMP MDMA. Over 82 MAPS supporters hosted fundraising dinners in 16 countries which raised over $45,059. A total of $153,000 was raised for GMP MDMA through the efforts of the 30th Anniversary and the Global Psychedelic Dinners. Those who wish to host a Global Psychedelic Dinner still have a chance to do so by visiting **psychedelicdinners.org**.

MAPS' long-term account for our assets, The Curing Fund, is managed by the San Francisco Foundation and is invested in the stock market. The Curing Fund began FY16 with a balance of $6,714,261 and experienced a loss of $243,334 (3.6%) as of May 31, 2016. This represents a substantial improvement from the estimated loss of $615,316 reported in February 2016. There were no new contributions made to the fund in

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

Fiscal Year 2015–16 and 2016–17 (at May 31)

	May 31, 2016			May 31, 2017		
MDMA Studies	**Temporarily Restricted**	**Board Restricted**	**Total Restricted**	**Temporarily Restricted**	**Board Restricted**	**Total Restricted**
Israel Phase III	500,000	-	500,000	431,694	-	431,694
Boulder MDMA	154,868	-	154,868	-	-	-
US MDMA/PTSD Veterans	3,404	-	3,404	-	-	-
US MDMA/PTSD Phase 3	-	6,049,715	6,049,715	246,598	6,049,715	6,296,313
Phase III Program General	58,346	-	-	-	-	-
Phase III Training	146,528	-	146,528	-	-	-
Phase III GMP Drug	81,022	-	-	-	-	-
MDA-1	-	-	-	61,264	-	61,264
MPVA-1 (CBCT Charleston/Canada)	6,063	-	6,063	-	-	-
US MDMA Qualitative	8,719	-	8,719	442	-	442
Total MDMA	**$ 958,950**	**$ 6,049,715**	**$ 6,869,298**	**$ 739,998**	**$ 6,049,715**	**$ 6,789,714**
Other Studies & Restrictions						
LSD/Psilocybin General	4,843	-	4,843	4,543	-	4,543
Ayahausca	658	-	-	-	-	-
Marijuana Opiate	-	-	-	15,000	-	15,000
Ketamine Book	1,000	-	1,000	-	-	-
Total Other Studies	**$ 6,501**	**$ 0**	**$ 6,501**	**$ 19,543**	**$ 0**	**$ 19,543**
Total Temporarily & Board Restricted Funds	**$ 965,451**	**$ 6,049,715**	**$ 7,015,167**	**$ 759,541**	**$ 6,049,715**	**$ 6,809,257**

FY16 as all major receipts had been used to support operating expenses. About $6.05 million of the Curing Fund funds have been board-restricted to Phase 3 MDMA/PTSD research.

Our fiscal sponsorship program had gross revenue of $359,821, an average 5% administrative fee charged, and the balance disbursed to projects that are in alignment with MAPS' vision and mission.

Product sales and event registrations combined are each less than 5% of our revenue, but remain important aspects of our work as the income offsets the costs of events and products, which serve to draw new supporters, strengthen our relationships to current supporters, and promote our message.

EXPENSE REVIEW FOR FISCAL YEAR 2015-16

In Fiscal Year 2016, program costs totaled 85.9% of all expenses. Programs include Research expenses of $2,161,926 (48.7%), Education and Communication expenses of $1,653,548 which includes Harm Reduction of $287,397 and Fiscal Sponsorships of $351,889 (37.2%). Fundraising expenses were $349,390 (7.8%) and Administrative expenses were $277,555 (6.3%).

Our primary expenditure in FY16 was research into MDMA-assisted psychotherapy with expenses of slightly more than $2 million. MAPS spent $1,099,431 on completing Phase 2 research into MDMA-assisted psychotherapy for the treatment of PTSD and associated projects and $609,334 was spent in preparation for Phase 3 MDMA/PTSD research. We also continued our study looking at the safety and efficacy of using MDMA-assisted therapy for anxiety in adults on the autism spectrum ($106,310), and continued our study of MDMA-assisted psychotherapy for end-of-life anxiety ($197,978). Both studies are expected to be completed by the end of FY17. An additional ($12,783) was spent on the MDMA/PTSD Memory Reconsolidation mechanism of action study.

In FY16 we completed gathering primary outcome data from all subjects in our international series of Phase 2 MDMA/PTSD pilot studies and have gathered almost all of the 12-month follow-up data. In addition to our core MDMA/PTSD drug development research, we continued to prepare, fund and sponsor a series of studies in collaboration with researchers who work with the U.S. Department of Veterans Affairs' National Center for PTSD using MDMA combined with more traditional methods for treating PTSD including Cognitive-Behavioral Conjoint Therapy (CBCT) and Prolonged Exposure (PE). We received FDA and DEA approval for our Charleston CBCT study treating couples/dyads, where one member of the couple/dyad has PTSD and the other member is impacted. In FY16 MAPS spent $37,275 on these collaborative projects. These studies are possible thanks to the work of Dr. Richard Rockefeller who devoted his time and strategic wisdom in deepening MAPS' relationship with the Department of Defense and Department of Veterans Affairs (VA).

Marijuana research expenses totaled $129,714. Nearly all of this covered the costs to develop and obtain approval of the protocol, and set up study sites, for a pilot study in which marijuana will be tested to manage PTSD symptoms in 76 veterans with treatment-resistant PTSD. Half of the subjects will be treated at Johns Hopkins University and half will be treated in Phoenix, Arizona. In FY16 we received all regulatory approvals needed to begin the study, including FDA, DEA, Public Health Services (PHS), National Institute on Drug Abuse (NIDA), Johns Hopkins IRB, University of Pennsylvania IRB, and the Copernicus IRB. MAPS funds spent on regulatory approval were not reimbursable by our contract with the Colorado Department of Public Health which only became active after all of the approvals had been obtained. MAPS currently has about $80,000 in non-reimbursable expenses for our marijuana/PTSD study. We've thus leveraged about $80,000 of MAPS expenses into a $2.15 million grant.

Education expenses of $1,653,548 include events, publications, communications, psychedelic harm reduction, and fiscal sponsorships. Conferences, events, and initiatives had expenses of $491,653. The event with the largest expense was our 30th Anniversary Banquet and Celebration which cost $96,548 and raised more than $153,000 towards the purchase of MDMA for Phase III research. In FY16 MAPS produced nine events and provided sponsorship, speakers, tables, formal representatives, and/or promotional support for 35 outreach events. Expenses on general advocacy were $73,892, Americans for Safe Access (ASA) Medical Marijuana Education and outreach expenses were $107,074, and the successful work to end the NIDA Monopoly incurred expenses of $11,150.

Communications expenses of $522,610 include active engagement in public education through media contacts, website and social media presence, publishing three MAPS *Bulletins,* 12 Email Newsletters and several books. We maintained maps.org, mdmaptsd.org, mdmaautism.org mapscanada.org, psychedelicscience.org, psychedelicdinners.org, mapsbcorp.com, and zendoproject.org. MAPS experienced a 30% to 100% increase in exposure compared to the previous year in all our social media outlets (Facebook, Twitter, YouTube, Google+, LinkedIn, Pinterest, Tumblr, Instagram, and reddit). MAPS also received 394 unique media mentions from online and print publications. Media outlets include: *New York Times, NPR, Salon, U.S. News, San Francisco Chronicle, The Washington Post,* NBC Bay Area, *Popular Science, Aljazeera, The Wall Street Journal, Business Insider,* Fox 10, *VICE, Rolling Stone, The Huffington Post, The New Yorker, Los Angeles Times, Military.com, Military Times,* CBS News, *Marie Claire,* and many more.

Our Zendo Project psychedelic harm reduction program incurred costs of $287,000 with the largest expense of $84,778 being the building of a new cardboard Zendo structure to be used at Burning Man, 91% of which was funded by grants of $77,000. The Zendo Project provided services at 6 major festivals including: Burning Man (Black Rock City, NV), Envision (Costa Rica), AfrikaBurn (South Africa), Lightning in a Bottle (Bradley, CA), Symbiosis (Oakdale, CA), Youtopia (San Diego); and other events such as Bicycle Day (San Francisco, CA), The

Denver Cannabis Cup, and more. The Zendo Project also provided on-site harm reduction consultation services to the Electric Daisy Festival in Las Vegas, NV. Over the past two years (2015 to 2016), the Zendo Project has served over 1,516 people, and trained over 666 new volunteers. The Zendo project now has three structures in which to provide a safe and supportive environment at festivals. We're building awareness and support for the provision of psychedelic harm reduction services through event promoters at events and venues in the US and around the world. At the most recent Burning Man, in MAPS FY17, for the first time ever, the Burning Man organization (BMorg) included an insert about Zendo in the greeter package given to over 70,000 attendees, and permitted us to state that Zendo provides "psychedelic harm reduction", rather than the language we'd been required to use in previous years of "psychological support services". As a result of this greater visibility, Zendo served over 470 guests, three times more than in any previous year. Most astoundingly, the BMorg arranged for Sara Gael, Director of MAPS' Zendo Project, to speak about Zendo to about 60 federal police from the Bureau of Land Management (BLM), who ended up sympathetically supporting Zendo and psychedelic harm reduction at Burning Man.

MAPS continued its long-running Fiscal Sponsorship program in FY16 with donations totaling $359,821. This program supports projects that are in alignment with MAPS' mission and vision by offering donors a way to provide support for projects conducted by non-501(c)(3) organizations by passing funds through a 501(c)(3) nonprofit sponsor organization. MAPS monitors the project budget, takes a small fee, and sends the donor a receipt for their contribution.

Major contributions include donations of $200,161 for the Ayahuasca Foundation's research facility in Peru, $45,100 for the International Center for Ethnobotanical Education, Research & Service (ICEERS) which works towards the integration of iboga, Ayahuasca, and other traditional plants into Western society, $87,753 for the films *From Shock to Awe* ($43,101), *Huxley's Exit* ($30,213), *Divinorum* ($10,695), the multimedia project "Sublime Visions" ($3,744) dedicated to the therapists and visionaries

Chart 6. MAPS FY 2015–16 ACTUALS COMPARED TO FY 2015–16, FY 2016–17 PROJECTED DETAIL EXPENDITURES

Research	FY 2015–16 Actual	FY 2015–16 Projected	FY 2016–17 Projected
Ayahuasca			
Ayahuasca General	294	500	1,020
Ayahuasca PTSD	12	4,000	3,400
Ayahuasca Addiction	356	12	-
Total Ayahuasca	**$ 661**	**$ 4,512**	**$ 4,420**
Ibogaine			
General	-	-	-
IOA-3 Ibogaine (Mexico)	3,146	4,500	1,000
IOA-4 New Zealand	2,256	6,009	1,000
Total Ibogaine	**$ 5,402**	**$ 10,509**	**$ 2,000**
LSD/Psilocybin			
General	312	250	300
Total LSD/Psilocybin	**$ 312**	**$ 250**	**$ 300**
Marijuana			
General	459	500	2,150
MJP-1 Cannabis PTSD	129,255	221,400	1,008,125
Total Marijuana	**$ 129,714**	**$ 221,900**	**$ 1,010,275**
MDMA/PTSD Key Research Studies			
MP1: Charleston, Pilot	1,398	1,073	8,000
MP8: Charleston, Veterans	118,653	97,165	20,000
MP8-S1: MDMA PTSD-US Vets Substudy	12,105	10,813	-
MP1-E2: Charleston Relapse	817	1,002	-
MT1: Charleston, Therapist Training (Phase III)	77,197	135,022	153,276
MP4: Canada	79,674	100,903	41,009
MP9: Israel	114,790	144,718	85,108
MP10: UK	10,906	11,072	36,028
MP12: Boulder	193,052	194,573	33,124
MDMA Research Studies, other			
MAA1: Autism Anxiety, Los Angeles	106,310	150,526	70,210
MDA1: End-of-Life Anxiety, San Anselmo	197,978	267,842	188,736
MPVA1: PTSD, Cognitive-Behavioral Conjoint Therapy	36,011	50,068	148,254
MPVA2: CPT Cincinnati	384	384	-
MPVA3: PTSD, PET, Charleston	259	259	-
MPVA4: PTSD, Prolonged Exposure Therapy, Emory	621	15,000	163,975
MDMA Qualitative	5,256	10,000	8,277
Memory Reconsolidation Study	12,783	18,185	10,402
MDMA Research Support			
MDMA Therapist Adherence	22,155	20,125	26,000
MDMA Therapist Training Program (Phase II)	14,651	4,479	-
MDMA Lit Review & (Investigator Brochure)	46,124	40,012	10,000
Mithoefer Expert Advisory Time	47,006	40,000	-
MDMA Treatment Manual	1,483	2,000	-
MDMA Program General	201,232	153,993	-
End of Phase 2	69,462	60,421	60,000
MDMA Researchers Retreat	-	15,000	-
MDMA Supply (Phase II)	4,732	6,296	4,250
MDMA NIMH	-	-	2,500
MDMA PTSD-US Dept. Defense	-	2,000	-
Phase 3 GMP MDMA ($96,930 capitalized on Balance Sheet)	27,223	3,183	226,170
Phase 3 Program General	92,354	71,186	250,169
Phase 3 Therapist Training	154,552	134,825	252,600
Phase 3 Trial 1	423	-	880,375
Phase 3 Trial 2	-	-	35,000
Clinical Research General	376,246	218,049	172,246
Total MDMA	**$ 2,025,836**	**$ 1,980,174**	**$ 2,885,709**
Total Research	**$ 2,161,926**	**$ 2,217,345**	**$ 3,902,704**

Education	FY 2015–16 Actual	FY 2015–16 Projected	FY 2016–17 Projected
Conferences, Events & Initiatives			
Advocacy	73,892	52,462	84,572
APA Meeting	2,302	5,207	-
Psychedelic Science 2017	30,707	4,703	569,293
Breaking Convention	5,655	5,662	-
Cannabis Cup: LA, SF, Seattle	617	5,000	642
DPA	11,019	-	-
Giger SF	14,048	13,721	-
Dead and Company	36,399	36,690	2,500
Harm Reduction *(see note 2, p.10)*	202,618	150,529	203,420
Cardboard Zendo *(see note 2, p.10)*	84,778	84,691	-
Horizons	4,364	4,136	4,539
Open Conference (Amsterdam)	10,161	-	1,660
MAPS 30th Year Anniversary	96,548	30,000	76
Special Events	27,940	34,213	36,440
Stitching Open	1,071	-	1,114
Events Staff, Education Staff, General Expense	58,706	61,257	60,000
ASA Medical Marijuana Education and Outreach	107,074	-	-
End PHS Review and NIDA Monopoly	11,150	7,000	-
Total Conference, Events & Initiatives	**$ 779,050**	**$ 495,271**	**$ 964,256**
Communications			
Web & Multimedia	87,964	76,601	98,714
Media	9,803	8,679	9,803
Publishing	97,349	99,598	104,849
Newsletter	6,741	5,629	6,741
Social Media	26,103	26,979	36,853
Communications	59,628	77,793	70,378
Marketing	3,718	4,584	8,718
Communications General Expense	231,304	240,721	179,279
Total Communications	**$ 522,610**	**$ 540,584**	**$ 515,334**
Total Education	**$ 1,301,659**	**$ 1,035,854**	**$ 1,479,590**
Fiscal Sponsorships *(see note 1, p.10)*	351,889	276,986	95,000
Total Programs (Research, Education, Fiscal Sponsorships)	**$ 3,815,474**	**$ 3,530,185**	**$ 5,477,294**
Fundraising			
Events	11,494	32,781	11,494
Campaigns	60,516	46,564	63,541
Donor Meetings	21,661	6,733	22,744
Fundraising Staff and General Expense	255,719	232,304	256,000
Total Fundraising	**$ 349,390**	**$ 318,382**	**$ 353,779**
Operations			
Business Expenses	9,380	16,594	10,000
Audit & Tax	48,430	35,000	49,000
Accounting and Finance	52,405	55,000	52,000
Legal and Tax Advisory Services	3,865	62	4,000
Information Technology	5,066	12,500	5,000
Facilities and Equipment	7,123	14,334	7,000
Occupancy	5,251	10,251	5,500
Office Supplies, Utility, Phone, Post, Print, Misc	27,795	31,690	27,500
Staff Development	9,551	14,265	9,000
Travel	9,618	27,137	9,750
Operations Staff and Other Expense	99,071	104,071	100,000
Total Operations	**$ 277,555**	**$ 320,904**	**$ 278,750**
Total Expenses	**$ 4,442,419**	**$ 4,169,471**	**$ 6,109,823**
Programs Ratio (Education/Total Expense)	85.9%	84.7%	89.6%

working with psychedelics as contemporary therapeutic medicines, and donations of $20,231 for several other educational projects including the Bluelight Forum on psychedelic drugs ($13,170), Women's Alliance for Medical Marijuana (WAMM) and its educational work in the compassionate use of medical marijuana ($4,200), Global Ibogaine Therapy Alliance (GITA) and its work supporting the sacramental use of Iboga ($8,165), and Cosmic Sister and its work educating the public on the unique psychedelic experiences of women ($1,059).

Fundraising expenses were $349,390. Of that amount, $255,719 are primarily for staff, mail and delivery, donor research and database costs, with another $60,516 for campaigns including premiums for crowd funding and other efforts, and fundraising events and travel and lodging for individual donor visits. Fundraising accounts for 7.8% of MAPS' expenses.

Operational costs were $277,555. There are the unglamorous but necessary expenses of staffing, office rent, taxes, fees, accounting, information technology, equipment, supplies, and postage. Operations accounts for 6.3% of MAPS expenses.

PROJECTIONS FISCAL YEAR 2016-17

As an overview, in FY17 we plan on shifting our focus to multi-site Phase 3 studies required for FDA approval of prescription use of MDMA-assisted psychotherapy for PTSD. Based on our current timeline, we anticipate submitting our New Drug Application (NDA) to the FDA in 2021. In FY17, we're projecting total research expenses of $3.9 million (63.9%) and about $1.57 million for our communications and public education programs including the Zendo Project and fiscal sponsorship (25.8%), with $632,529 for fundraising and administration (10.3%).

Estimated spending ($6.10M) in FY17 is projected to be almost $2M more than in FY16. Of this amount, programmatic expenses—research ($3.9m) and education ($1.57m)—will account for 89.6% of total expenses. The increase primarily reflects the increased tempo of MAPS' anticipated early 2017 approval for its Phase III MDMA/PTSD research on which we'll spend about $2.1 million in FY17. There will be $602,828 in expenses for related Phase 2 MDMA/

PTSD projects, which includes completion of follow-ups, publishing results, and several secondary studies conducted with researchers affiliated with the Veterans Administration including the study of MDMA combined with Cognitive-Behavioral Conjoint Therapy (CBCT) and MDMA combined with Prolonged Exposure. Additional expenditures of $296,283 are projected on other MDMA research projects include MDMA-assisted psychotherapy in people suffering from anxiety as a result of life-threatening illness ($188,736), and MDMA-assisted psychotherapy in autistic adults with social anxiety ($70,210). Phase II marijuana research ($1,010,275) is almost entirely dedicated to MAPS' investigation into the impact of marijuana on the symptoms of PTSD in 76 US veterans ($1,008,125) with the balance of $2,150 for general marijuana-related expenses. The balance of research expenditures of $6,720 is split amongst MAPS projects on Ayahuasca, Ibogaine, and LSD.

In addition, MAPS Psychedelic Science 2017 conference is expected to cost an additional $569,000 during FY17 (with income anticipated of $625,000). MAPS will be co-hosting our Psychedelic Science 2017 conference in Oakland, California with the Beckley Foundation. PS2017 is a six-day global gathering, featuring three days of conference presentations and three days of workshops, a Sunset Cruise on the San Francisco Bay, the world's first Psychedelic Comedy Banquet, and more. This is a space for the scientific and psychedelic community to share and discover new research into the benefits and risks of MDMA, LSD, psilocybin, ayahuasca, ketamine, ibogaine, medical marijuana, and more. For more info, visit **psychedelicscience.org.**

We currently project income of $3.37 million from anticipated donors in FY17, about $369,500 less than in FY16. In FY16 we received a large number of new major donations and pledges, over $3 million of which were not initially anticipated. In FY17 we hope to obtain new major contributors but have not included any such donations in our FY17 income projections since these new relationships are still in the process of coming to fruition. Additional funding from the State of Colorado medical marijuana research grant ($1.08M), conference income ($625,000), sales income ($115,000), fiscal sponsorship income ($100,000), and harm reduction income ($28,000) will leave MAPS with a $920,554 deficit between projected income and expenses. This deficit will either be funded from additional donations from existing or new donors, or will be drawn down from MAPS' net assets, potentially leaving MAPS with $8.98 million at the end of FY17, still less than half of what we anticipate needing for Phase 3 MDMA/PTSD expenses.

Note 1:
FY16 FISCAL SPONSORSHIP DETAIL

	Total Raised	Total Disbursed
Ayahuasca Foundation (Peru)	200,161	190,566
Huxley's Exit	30,213	28,703
ICEERS	45,100	41,838
Cosmic Sister	1,059	982
Bluelight	13,170	7,303
GITA	8,165	7,852
Sublime Visions	3,744	3,325
WAMM	4,292	4,292
Divinorum	10,695	10,160
Prism	-	2,168
From Shock To Awe	43,101	40,658
Ethnobotanical Stewardship Council	120	216
Sub-Total	359,821	338,064
MAPS Fees	-	13,825
Total	**$ 359,821**	**$ 351,889**

Note 2:
FY16 HARM REDUCTION DETAIL

	Income	Expense
Burning Man 2014	-	3,627
Burning Man 2015	9,050	53,633
Burning Man 2016 (prep)	-	13,557
Cardboard Zendo	77,000	84,778
Harm Reduction General	23,485	116,241
Afrika Burn	3,500	3,510
Envision	4,400	3,570
Lightning in a Bottle	5,000	2,899
Once Upon a Festival	-	1,510
Symbiosis	2,000	1,559
Youtopia	-	2,512
Total	**$ 124,435**	**$ 287,397**

CONCLUSION

FY16 was a remarkably successful year. Expenses were about $1.2 million more than in any previous year in MAPS' 30-year history yet we still managed to inspire enough donations and multi-year pledges to end the year with a surplus of $743,960. Expenses in FY17 are projected to be about $1.6 million more than in FY16, with a deficit projected to be $920,554. Our challenge for FY17 is to raise sufficient amounts of new, unanticipated donations to more than breakeven, as we expand into Phase 3 MDMA/PTSD research which we are currently estimating will cost $25 million (see Chart 8).

As I write this annual report, I'm looking forward to our FDA End of Phase 2 meeting on November 29, 2016. As you read this annual report, it's likely to be after that meeting. I feel confident that if that meeting goes well and we are indeed on track to start Phase 3 research, that we will be able to motivate and inspire the new donors that will enable us to expand our research. The need is great for new treatments for PTSD, and our Phase 2 data on safety and efficacy is promising, especially considering that we have been enrolling chronic, treatment-resistant subjects who are the people most difficult to treat. As MAPS moves into its 31th year, , we present this financial report for your review, along with an appeal to existing MAPS donors for continued and expanded support and to new donors who are inspired to join with us in our mission of healing, spirituality, and cultural evolution.

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**.

Chart 7. MDMA/PTSD PHASE 2 RESEARCH PROJECTS

Projected expenses include direct costs and a 10% overhead allocation.

Key MDMA Research Projects	Actuals 2009–10	Actuals 2010–11	Actuals 2011–12	Actuals 2012–13	Actuals 2013–14	Actuals 2014–15	Actuals 2015–16	Projected 2016–17	Projected 2017–18
MP1: US MDMA/PTSD Pilot	110,000	19,241	7,239	11,651	11,669	3,010	1,398	8,000	-
MP1-E2: US MDMA/PTSD Relapse	-	5,845	19,567	15,741	6,665	5,264	817	-	-
MP8: US MDMA/PTSD Veterans	35,806	147,600	202,867	262,555	282,213	318,581	118,653	20,000	-
MP12: US MDMA/PTSD Boulder	-	-	20,885	73,623	178,665	241,559	193,052	33,124	-
MP2: Swiss MDMA/PTSD	33,500	30,666	25,544	4,218	280	-	-	-	-
MP9: Israel MDMA/PTSD	27,308	33,696	43,861	90,294	84,127	65,278	114,790	85,108	-
MP4: Canadian MDMA/PTSD	9,814	8,615	2,433	13,604	74,868	164,203	79,674	41,009	-
MP7: Jordanian MDMA/PTSD	31,456	21,458	1,831	420	-	-	-	-	-
MT1: MDMA Therapist Training	15,038	19,244	14,335	8,166	25,849	3,154	-	-	-
MDMA NIMH	-	-	-	798	-	-	-	-	-
MDMA Qualitative	-	-	-	-	326	699	5,256	8,277	-
Overhead *(10% Allocation for Projected)*	26,292	28,636	33,856	48,107	61,775	80,175	-	19,552	-
Total Key MDMA/PTSD Research Projects	**$ 289,214**	**$ 315,001**	**$ 372,419**	**$ 529,177**	**$ 726,437**	**$ 881,923**	**$ 513,639**	**$ 215,070**	**-**
Associated Research Studies									
MP10: England fMRI MDMA/PTSD	-	-	-	-	501	224	10,906	36,028	36,028
MP8-S1: MUSC fMRI MDMA/PTSD Veterans	-	-	-	-	8,876	150	12,105	-	-
MPVA1: PTSD CBCT, Charleston	-	-	-	-	1,358	20,320	36,011	148,254	8,000
MPVA2: PTSD, CPT, Cincinnati	-	-	-	-	231	1,473	384	-	-
MPVA3: PTSD, PET, Charleston	-	-	-	-	-	3,301	259	-	-
MPVA4: PTSD, PET, Emory	-	-	-	-	302	723	621	163,975	8,000
MDMA PTSD-US Dept. Defense	-	-	-	14,768	2,656	613	-	-	-
Associated Research Projects									
MDMA Literature Review	3,256	6,063	3,764	7,831	5,036	19,951	46,124	-	-
MDMA Therapist Adherence Criteria	-	-	-	4,829	5,980	32,344	22,155	-	-
MDMA Therapist Training Program	-	-	-	511	6,176	12,806	14,651	-	-
MDMA Treatment Manual	8,752	5,219	1,001	10,260	666	4,639	1,483	-	-
MDMA Researchers Retreats	27,067	2,092	-	-	-	-	-	-	-
MDMA Supply	-	-	-	3,987	6,060	96,930	4,732	4,250	-
Mithoefer Expert Advisory Time	27,951	33,975	49,701	68,859	30,868	3,858	47,006	-	-
Site Differences in CAPS Scores	-	400	71	-	-	-	-	-	-
MDMA Program General	11,404	54,911	32,294	49,625	74,619	171,967	201,232	-	-
Clinical Research General	38,036	38,885	40,583	89,448	176,769	249,360	188,123	-	-
Overhead *(10% Allocation for Projected)*	11,647	14,155	12,741	25,012	27,287	19,733	-	35,251	5,203
Total Associated MDMA/PTSD Projects	**$ 128,113**	**$ 155,700**	**$ 140,155**	**$ 275,131**	**$ 338,509**	**$ 638,392**	**$ 585,792**	**$ 387,758**	**$ 57,231**
Total Phase II MDMA/PTSD Projects	**$ 417,327**	**$ 470,701**	**$ 512,574**	**$ 804,308**	**$1,064,946**	**$1,520,315**	**$1,099,431**	**$ 602,828**	**$ 57,231**

FY 2009–2015 Actual Costs **$ 5,889,602 over past seven years**
FY 2016–2017 Projected Costs **$ 660,059 over next two years**

Chart 8. MDMA/PTSD PHASE 3 COST PROJECTIONS

Phase 3 MDMA/PTSD Research Projects	Actuals 2014–15	Actuals 2015–16	Projected 2016–17	Projected 2017–18	Projected 2018–19	Projected 2019–20	Projected 2020–21
End-of-Phase-2 Meeting w/ FDA	2,060	69,462	60,000	-	-	-	-
GMP MDMA Supply	205	27,223	131,170	-	-	-	-
MDMA Therapist Training-Protocol (MT-1)	-	77,197	153,276	128,512	75,000	-	-
MDMA Literature Review	-	-	10,000	10,000	10,000	10,000	10,000
MDMA Therapist Adherence Criteria	-	-	26,000	20,000	20,000	-	-
Phase 3 Therapist Training	52,549	154,552	252,600	212,240	78,660	-	-
Phase 3 Program General	-	92,354	250,169	260,176	270,583	281,406	292,662
Clinical Research General	30,114	188,123	172,246	179,136	186,301	193,753	201,503
Preclinical Toxicity Studies	-	-	-	334,000	333,000	333,000	-
Phase III Trial 1	-	423	880,375	5,317,959	2,771,232	526,485	-
Phase III Trial 2	-	-	35,000	652,377	5,733,566	1,306,956	287,766
NDA Process	-	-	-	-	-	-	354,060
Overhead *(10% Allocation for Projected)*	-	-	154,842	667,509	902,146	217,644	65,183
Total Phase III MDMA/PTSD Research	**$84,928**	**$609,334**	**$2,125,678**	**$7,781,908**	**$10,380,488**	**$2,869,245**	**$1,211,174**

Total Phase III Projected Costs $25,062,756 over next five years including overhead of $1.9M

Chart 9. MDMA/OTHER PROJECTS COST PROJECTIONS

MDMA/Other Research Projects	Actual 2013–14	Actual 2014–15	Actual 2015–16	Projected 2016–17	Projected 2017–18
MDA-1: MDMA End of Life Anxiety	8,387	128,911	197,978	188,736	86,235
MAA-1: MDMA Autism	44,343	142,842	106,310	70,210	-
Memory Reconsolidation Study	-	-	12,783	10,402	-
Overhead *(10% Allocation for Projected)*	5,273	27,175	-	26,935	8,624
Total MDMA/Other Research Projects	**$ 58,003**	**$ 298.928**	**$ 317,071**	**$ 296,283**	**$ 94,859**

Total MDMA/Other Research Projects $ 1,065,143 over five years

Chart 10. MDMA ANNUAL COST SUMMARY

Project Phase	Actuals 2014–15	Actuals 2015–16	Projected 2016–17	Projected 2017–18	Projected 2018–19	Projected 2019–20	Projected 2020–21
Phase II	1,520,315	1,099,431	602,828	57,231	-	-	-
Phase III	84,928	609,334	2,125,678	7,781,908	10,380,488	2,869,245	1,211,174
Total	**$ 1,605,243**	**$ 1,708,765**	**$ 2,728,506**	**$ 7,839,139**	**$ 10,380,488**	**$ 2,869,245**	**$ 1,211,174**
MDMA Other Projects	**$ 298,928**	**$ 317,071**	**$ 296,283**	**$ 94,859**	**-**	**-**	**-**
Total	**$ 1,904,171**	**$ 2,025,836**	**$ 3,024,788**	**$ 7,933,998**	**$ 10,380,488**	**$ 2,869,245**	**$ 1,211,174**

Chart 11. MARIJUANA/PTSD PHASE 2 COST PROJECTIONS

Phase 2 Marijuana/PTSD Research Projects	Actuals 2012–13	Actuals 2013–14	Actuals 2014–15	Actuals 2015–16	Projected 2016–17	Projected 2017–18	Projected 2018–19
MJP-1 Total Costs	6,213	9,490	45,044	129,714	1,008,125	839,895	274,744
Total Phase II Marijuana/PTSD Research	6,213	9,490	45,044	129,714	1,008,125	839,895	274,744
Total Phase II Projected Costs	2,313,225	-	-	-	-	-	-
Donations	5,748	4,287	38,009	24,249	1,396	-	-
Grant reimbursable funds	-	-	-	33,866	1,008,125	839,895	$274,744
Net Income/(Expense)	**-$ 465**	**-$ 5,203**	**-$ 7,035**	**-$ 71,599**	**$ 1,396**	**$ 0**	**$0**

Total Phase II Net Costs -$ 82,905

MAPS FISCAL YEAR 2015–2016 DONORS

These pledges and donations were made between June 1, 2015 and May 31, 2016. 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 make a difference.

$1,000,000 & ABOVE

Tides Foundation $1,500,000

Moshe Tov Kreps $1,000,000

$100,000–$999,999

Riverstyx Foundation $332,000

Dr. Bronner's $220,308

Scorpio Rising $200,000

Libra Foundation $200,000

Rockefeller Philanthropy Advisors $200,000

David Rockefeller $100,000

$50,000–$99,999

Adam Wiggins $60,000

Mental Insight Foundation $60,000

Jeremy Tarcher Bequest $50,000

Tim Butcher Bequest $50,000

$10,000–$49,999

Arjun Banker $10,000

Robert J. Barnhart $24,385

Ian Brown $11,000

Steve Chapman $18,000

Adam Denmark Cohen $10,000

Khaliya and Thomas Ermacora $10,000

John Gilmore $30,000

George Goldsmith & Katya Malievskaia $25,000

HeadCount $38,979.43

Philip Jensen $10,000

Jewish Community Foundation of LA $10,000

Bill Linton $10,000

Laura and Ed Littlefield $40,000

Mai Family Foundation $25,000

William N. Melton $10,000

Roger & Margot Milliken $10,000

Justin Rosenstein $10,000

René and Susan Ruiz $10,000

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Smart Family Foundation $20,000

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William H. Donner Foundation $15,000

Anonymous $40,000

Anonymous $10,000

Anonymous $10,000

$1,000–$9,999

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AmazonSmile Foundation $2,543.65

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John Balquist $1,400

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Brian Brown $1,250

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Ulrich Buddemeier $1,000

Sheila Burgel $2,500

Frederick Burks $1,275

California Institute of Integral Studies $3,000

Giancarlo Canavisio $2,000

Elizabeth Davis $1,000

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Candra Docherty $4,500

Charles T Dunn $1,200

Paul Eastham $3,000

Dean Edell $1,958.25

Bob Eisenberg $1,000

Evolver $1,580

Leander Fortmann $1,100

Mack Fuhrer $2,000

Robert & Margaret Gansser $1,000

Nicholas Greco $1,072

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Michelle & Ian Glass $1,000

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Gary Lippman $5,000

Ingrid & Anthony Lombardino $1,000

Jared Luxenberg $3,000

Donald Mack $2,000

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Magaly Mauer $2,000

Chris McKulka $1,125

Daniel McMurtrie $1,000

Constance & H. Roemer McPhee $2,000

Jeff Mease $1,000

Scott Meyer $1,035

John Christoper McCormick $2,500

Stephen Milstein $1,500

Michael Montagne $1,000

Dan Mottsman $3,300

Nathan Cummings Foundation $5,000

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If your name is not here and you would like it to be, or you have any questions or corrections, please let us know!

Contact: Aidan Boling, Operations Associate
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Join the Next Horizons Society and list your name as someone who has included MAPS in your planned gifts though a will, trust, retirement plan, life insurance policy and other options. Making a bequest is a simple, lasting way to help MAPS realize your vision, and carry that vision into the future.

To discuss your plans, please contact Jade at giving@maps.org or call 831.429.6362.

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Research News

Treating PTSD with MDMA-Assisted Psychotherapy

mdmaptsd.org

MAPS and MPBC staff and researchers will meet with the FDA on November 29, 2016.

Phase 3 Trials: FDA Grants Request for End of Phase 2 Meeting

On October 3, 2016, the U.S. Food and Drug Administration (FDA) granted our request for an End of Phase 2 Meeting, with the meeting scheduled for November 29, 2016. The goal of this meeting will be to come to an agreement on the design of our upcoming Phase 3 trials, the final stage of research required to make MDMA-assisted psychotherapy a legal prescription treatment for PTSD. Staff and researchers at MAPS and the MAPS Public Benefit Corporation (MPBC) will travel to the FDA's White Oak Campus in Silver Spring, Maryland, for a 90-minute meeting to review the promising data from our six completed Phase 2 studies, and to decide on an efficient and scientifically rigorous design for our Phase 3 trial—with 400 or more additional participants—which we anticipate starting in 2017.

Our submitted meeting materials include a 90-page summary of initial indications of safety and efficacy based on our Phase 2 results, plus what is now known about the toxicology, pharmacology, and abuse liability of MDMA from over 5,000 peer-reviewed scientific papers published on MDMA or Ecstasy. We also had multiple attachments consisting of our Chemistry, Manufacturing, and Control (CMC) proposal for MDMA production under current Good Manufacturing Practice (cGMP) standards for Phase 3 and post-approval formulation, toxicological study proposals, key elements of MDMA-assisted psychotherapy, and references.

"We will receive the FDA's questions on our End of Phase 2 submission package just two days before the meeting, giving our team very little time to prepare our responses for the meeting," says MPBC Executive Director Amy Emerson. "It's both challenging and exciting, since after the meeting we'll have clear direction on the design of our Phase 3 trials." As long as we receive the funding needed to complete the research, we anticipate FDA approval of MDMA-assisted psychotherapy as a treatment for PTSD as early as 2021.

U.S. Veterans Study Officially Completed

Study Completed
Location: Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D.
Co-Therapist: Annie Mithoefer, B.S.N.
Estimated study budget: $1,429,000
This study has been fully funded.

On October 27, 2016, MAPS Public Benefit Corporation (MPBC) staff met with investigators in Charleston, South Carolina for the formal closeout of our largest Phase 2 study of MDMA-assisted psychotherapy in 24 U.S. veterans, firefighters, and police officers with chronic, treatment-resistant PTSD. Conducted by Clinical Trial Leaders Rebecca Matthews and Alli Feduccia, Ph.D., the closeout included a thorough review of the study's documentation, database, files, and adherence to regulations. All treatment sessions and long-term follow-up interviews for this study have now been completed. Led by Principal Investigator Michael Mithoefer, M.D., and Co-therapist Annie Mithoefer, B.S.N., in Charleston, South Carolina, the data from this study are now being prepared for analysis and publication in a peer-reviewed scientific journal.

"For us, the end of each of our MDMA/PTSD studies has been a bitter-sweet moment," states Dr. Mithoefer. "It's sad saying goodbye to research participants after the privilege of getting to know them and supporting them in their deep healing journeys. It's a time for celebrating the remarkable results of these journeys, that in so many cases have relieved painful, debilitating symptoms and brought deep healing and fulfilling

reengagement in their lives without the daily burden of PTSD."

Goals for this study included (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy in people suffering from war-related trauma; (2) comparing the effectiveness of the treatment for people with war-related trauma versus for people with trauma related to sexual abuse, assault, and other causes; (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind; and (3) increasing awareness and support for our work by assisting a population with mainstream public recognition.

20th Participant Completes 12-Month Follow-Up Interview in Boulder Study *Ongoing study*

Location: Boulder, Colorado
Principal Investigator: Marcela Ot'alora, M.A., L.P.C.
Estimated study budget: $771,000
This study has been fully funded.

On October 17, 2016, the 20th participant completed their 12-month follow-up interview in our Phase 2 study of MDMA-assisted psychotherapy in subjects with chronic, treatment-resistant PTSD in Boulder, Colorado. All subjects have now completed active study participation. 23 subjects will be included in our final analysis, while all 29 subjects, including six who dropped out or were excluded for not meeting study criteria, will be included in our intent-to-treat analysis. Long-term follow-up data will provide additional information to guide the design of our upcoming Phase 3 trials. The final results are being prepared for publication, which is expected in 2017.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD from a variety of causes, (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind, (3) exploring whether using intern co-therapists can reduce costs while maintaining treatment effectiveness, and (4) training the next generation of psychedelic psychotherapists.

Fourth Participant Completes 12-Month Follow-Up Interview in Israeli Study *Ongoing study*

Location: Beer Yaakov, Israel
Clinical Investigator: Moshe Kotler, M.D.
Estimated study budget: $509,000
This study has been fully funded.

On October 21, 2016, the fourth of 10 participants completed their 12-month follow-up interview in our Israeli Phase 2 study of MDMA-assisted psychotherapy for PTSD. Led by Principal Investigator Moshe Kotler, M.D., this Phase 2 study has treated 10 subjects with chronic, treatment-resistant PTSD from any cause. Once the final evaluations are complete, we will gather data for inclusion in an international meta-analysis of the safety and efficacy of MDMA-assisted psychotherapy for the treatment of PTSD.

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

Final Participant Completes 12-Month Follow-Up Interview in Canadian Study *Ongoing study*

Location: Vancouver, British Columbia, Canada
Principal Investigators: Ingrid Pacey, M.D.
Estimated study budget: $470,000
Already raised: $48,000 + $69,000 raised by partners
Needed to complete this study: $353,000

On October 17, 2016, the sixth and final participant completed their 12-month follow-up interview in our Phase 2 pilot study of MDMA-assisted psychotherapy for PTSD in Vancouver, Canada. All participants have completed treatments and 12-month follow-up interviews. This small pilot study gave Canadian therapists experience delivering MDMA-assisted psychotherapy for PTSD, with data collected from three women and three men. The final results are being prepared for publication as a part of a global meta-analysis of MDMA-assisted psychotherapy results.

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

18th Participant Enrolled in Therapist Training Study; Boulder Study Site Initiated *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)
Estimated study budget: $429,000
Already raised: $160,000
Needed to complete this study: $269,000

On September 28, 2016, the 15th participant was enrolled at our study site in Charleston, South Carolina in our ongoing Phase 1 study of the psychological effects of MDMA when used in a therapeutic setting by healthy volunteers. The Charleston site is led by Principal Investigator Michael Mithoefer, M.D. On October 23, the third participant was enrolled at the recently initiated Boulder, Colorado study site. Marcela Ot'alora, M.A., L.P.C., is serving as Principal Investigator of the Boulder site. Enrollment in this study is limited by invitation only to therapists in training to work on MAPS-sponsored clinical trials of MDMA-assisted psychotherapy for PTSD. This study has currently enrolled 18 out of 100 participants across both study sites.

Thirty trainees gathered in Los Angeles, Calif, from September 19–25, 2016, for Part B of the MDMA Therapy Training Program.

MDMA Therapy Training Program: Group Trainings Take Place in Los Angeles and New York *Training Program*

Location: Charleston, South Carolina, and Boulder, Colorado
Principal Investigator: Michael Mithoefer, M.D.
Co-Therapist: Annie Mithoefer, B.S.N.
Estimated study budget: $429,000
Already raised: $160,000
Needed to complete this study: $269,000

From September 19-25, 2016, 30 trainees gathered in Los Angeles, Calif., to participate in Part B of the MDMA Therapy Training Program, and 25 additional trainees participated in the same training from October 16-22, 2016, in Stony Point, New York. The MAPS MDMA Therapy Training Program has enrolled 121 people since December 2014.

The five-part program is preparing therapy teams for upcoming MAPS-sponsored Phase 3 trials of MDMA-assisted psychotherapy for PTSD. All Phase 3 researchers will also complete Parts C-E of the training program, which include an external workshop, a second week-long training, a final evaluation, and clinical supervision.

Part B of the program is a week-long training led by MAPS-sponsored researchers Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., and Marcela Ot'alora, M.A., L.P.C. Trainees learned the techniques of MDMA-assisted psychotherapy as outlined in the Treatment Manual, watched videos of therapy sessions from Phase 2 trials, and dialogued with other therapists in training about the therapeutic approach. The MDMA Therapy Training Program plans to train approximately 300 therapists before 2021, when we anticipate completing Phase 3 clinical trials of MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD.

Conjoint Therapy: First Pair of Participants Receive Treatment *Ongoing study*

Location: Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D.,
Sub-Investigator: Candice Monson, Ph.D.
Estimated study budget: $235,000
Already raised: $165,000
Needed to complete this study: $70,000

On August 5, 2016, the first pair of participants was enrolled in our new study of MDMA combined with Cognitive Behavioral Conjoint Therapy (CBCT) for PTSD in Charleston, South Carolina. These participants received their first and second experimental treatment sessions on August 6 and August 23. Final outcome measures for this pair (dyad) were collected during the one-month follow-up interview on October 9, 2016.

Led by Principal Investigator Michael Mithoefer, M.D., and Sub-Investigator Candice Monson, Ph.D., this is a pilot Phase 1/Phase 2 open-label study exploring CBCT integrated with MDMA-assisted psychotherapy for the treatment of chronic posttraumatic stress disorder (PTSD). Dr. Monson is a leading expert on individual and conjoint cognitive therapies to treat PTSD, and was introduced to MAPS by the U.S Department of Veterans Affairs National Center for PTSD.

The study will enroll 10 dyads, with one participant diagnosed with PTSD and one concerned significant other who does not have PTSD but does experience psychosocial distress. The primary goal of this study is to develop a combined method of MDMA with CBCT for PTSD. MDMA will be administered to both participants to help facilitate communication and connection between participants and therapists. We are now screening additional local participants for this study.

MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

Final Participant Treated *Ongoing study*
Location: Los Angeles, California
Principal Investigators: Charles Grob, M.D., and Alicia Danforth, Ph.D.
Estimated study budget: $400,000
Already raised: $13,000 + $15,000 raised by partners
Needed to complete this study: $372,000

On October 29, 2016, the 12th and final participant received their last blinded experimental session in our ongoing study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum. Sponsored by MAPS, this is a collaborative study between MAPS and the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, with blood plasma biomarker analysis conducted by researchers at Stanford University. MAPS-sponsored researcher Alicia Danforth, Ph.D., presented preliminary results on October 8, 2016, at Horizons: Perspectives on Psychedelics in New York City.

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

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

12th Participant Treated in Marin Study
Ongoing study
Location: Marin, California
Principal Investigator: Phil Wolfson, M.D.
Estimated study budget: $627,000
Already raised: $248,000
Needed to complete this study: $379,000

On October 24, 2016, the 12th participant was treated in our ongoing study of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness in Marin, Calif. Led by Principal Investigator Phil Wolfson, M.D., with Co-therapist Julane Andries, L.M.F.T., this study is gathering preliminary data about the safety and efficacy of MDMA-assisted psychotherapy for anxiety in 18 subjects diagnosed with a life-threatening illness. We are currently screening additional participants for this study.

We are continuing to make progress on an additional fMRI brain imaging study of the physiological correlates of MDMA-assisted psychotherapy in participants from this study. The brain imaging sub-study is a collaboration between the MAPS-sponsored study and Michael Silver, Ph.D., at the Helen Wills Neuroscience Institute at the University of California, Berkeley.

"Our study is progressing with wonderful experiences and gratifying changes in awareness, reductions of fear, self-worth, and relationships," reports Dr. Wolfson. "As our subjects have life-threatening illnesses, there is the unfortunate possibility of relapse or recurrence. With great sadness, we report the loss of one of our subjects to recurrent cancer. We are privileged to do this work in all its seriousness and great beauty."

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

MDMA Research Review Published in *Cell*

On July 14, 2016, the peer-reviewed scientific journal Cell published a new review of current research into the use of MDMA as an adjunct to psychotherapy for a range of neuropsychiatric disorders. Written by Boris Heifets, M.D., Ph.D., and Robert Malenka, M.D., Ph.D., of Stanford University, the article summarizes current knowledge about MDMA's mechanism of action, highlighting its ability to catalyze prosocial, empathogenic effects which may help treat symptoms of medical conditions such as major depressive disorder, social anxiety in autistic adults, posttraumatic stress disorder (PTSD), and schizophrenia. "Elucidating MDMA's mechanisms of actions in the context of treatment trials will pave the way for developing new therapeutic agents that target previously unidentified brain mechanisms," state the authors. "The world's populations need more compassion and empathy for one another. The study of MDMA provides one small but potentially important step toward reaching that goal."

Medical Marijuana Research

DEA Announces Intent to Eliminate Federal Monopoly on Marijuana for Research

On August 11, 2016, the U.S. Drug Enforcement Administration (DEA) announced their intention to grant licenses to additional marijuana growers for research, thereby ending the DEA-imposed 48-year monopoly on federally legal marijuana for research. Since 1968, the University of Mississippi, under contract to the National Institute on Drug Abuse (NIDA), has maintained the only facility in the United States with federal permission to grow marijuana for research.

MAPS has been working to eliminate this marijuana research blockade for over 15 years. NIDA's marijuana can be used for research but not sold as a prescription medicine, making it unacceptable for use in future Phase 3 studies. With

support from MAPS, Lyle Craker, Ph.D., of the University of Massachusetts-Amherst will submit his new application for a DEA license to grow marijuana for research later this year.

"There has been no production monopoly on any other Schedule I substance, like MDMA or LSD—only the cannabis plant," says MAPS Founder and Executive Director Rick Doblin, Ph.D. "Licensing non-government cannabis producers, and thereby creating a path to FDA approval, will finally facilitate the removal of marijuana from Schedule I."

Marijuana for PTSD: NIDA Provides Marijuana for Phoenix Site; Participant Screening Begins

Study in development
Location: Baltimore, Md., and Phoenix, Ariz.
Coordinating Principal Investigator:
Marcel Bonn-Miller, Ph.D. (University of Pennsylvania)
Co-Investigators/Site Principal Investigators:
Sue Sisley, M.D. (private practice) and
Ryan Vandrey, Ph.D. (Johns Hopkins University)
Co-Investigator: Paula Riggs, M.D. (University of Colorado)
Estimated study budget: $2,156,000
Already raised: $2,156,000 grant awarded by the State of Colorado. This study has been fully funded.

On August 10, 2016, the National Institute on Drug Abuse (NIDA) approved the Scottsdale Research Institute's official request to order 6.3kg of marijuana to be used by the Phoenix, Ariz., study site in our upcoming study of medical marijuana for posttraumatic stress disorder (PTSD) in 76 U.S. veterans. Multiple marijuana strains were requested, featuring varying levels of THC and CBD per strain, including high THC/low THC, high CBD/low CBD, balanced THC/CBD, and placebo.

On August 25, 2016, Site Principal Investigator Sue Sisley, M.D., received the first shipment of marijuana from the National Institute on Drug Abuse (NIDA), at the Phoenix, Ariz., site. The marijuana arrived in dried bulk form, and sent to a secondary DEA-licensed laboratory for potency, mold and yeast testing. Researchers at the Phoenix, Ariz., site began screening participants for enrollment on October 3.

The randomized, blinded, placebo-controlled study will test the safety and efficacy of botanical marijuana in 76 U.S. military veterans with treatment-resistant PTSD. The study is funded by a $2.156 million grant from the Colorado Department of Public Health and Environment (CDPHE) to MAPS, which is sponsoring the study. MAPS' study protocol will be replicated using vaporization by the Canadian medical marijuana producer Tilray, and by the University of Sydney using Tilray extracts in orally administered capsules.

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

The first shipment of marijuana from the National Institute on Drug Abuse (NIDA) arrived at the Phoenix, Ariz. site of our upcoming trial of smoked marijuana for symptoms of PTSD in U.S. veterans.

Ayahausca Research

Data Collection Survey Underway *Ongoing study*

Principal Investigator: Jessica Nielson, Ph.D.

As of November 9, 2016, we have received 175 completed responses for our new anonymous questionnaire about the potential risks and benefits associated with taking ayahuasca as a therapy for posttraumatic stress disorder (PTSD). The data collection is being sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS). Jessica Nielson, Ph.D., is the Principal Investigator for this study.

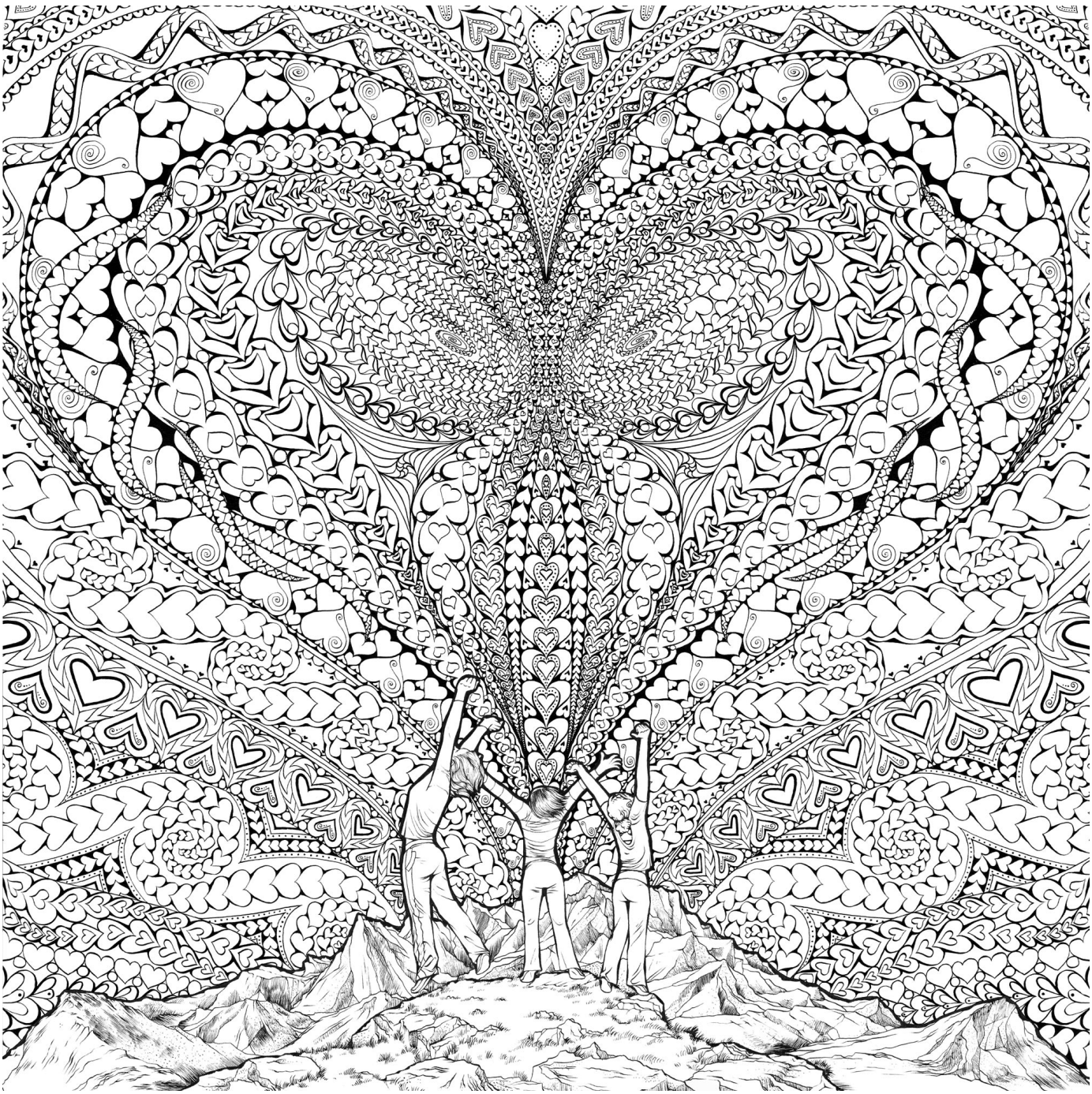
"Initial results show a wide range of responses to ayahuasca from people either with or without a current diagnosis of PTSD," explains Nielson. "An important feature to whether it was healing or harmful suggests the need for experienced facilitators and personal helpers during difficult moments, adherence to dietary and drug interaction recommendations, and some form of post-ceremony integration to help with processing their experiences." To participate, take the survey at **surveymonkey.com/r/AyaPTSD**.

Ibogaine-Assisted Therapy for Drug Addiction

Data Prepared for Publication in Scientific Journals *Ongoing study*

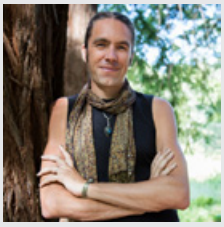
Locations: Mexico and New Zealand
Principal Investigators: Thomas Kingsley Brown, Ph.D. (Mexico), and Geoff Noller, Ph.D. (New Zealand)
Donations are needed to support ibogaine research.

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



Art by Jessica Legon. Facebook: @Jessicalllustrates Twitter: @jesselegon Instagram: @jessicaillustrates

COVER ARTIST: MICHAEL DIVINE



Michael Divine

Front and back cover:
***The Crucible,* acrylic on canvas, 72 x 30 in**

The Crucible was commissioned by a married couple who are collectors of my work. They asked me to create a painting of Love. This is what I came up with.

A crucible is a container within which we add various metals at extremely high heat, blending them to create a new form. Love, I think, is the great crucible. It is transformation, growth, light and dark, all at once. It is one of the great undefinable concepts that all humans experience in some form or another in their lifetimes. There, in that space of love, we lose ourselves and can find ourselves made anew.

For me, the narrative flow of the image progresses upwards from the bottom, where two figures sit in a clearing. These two people are sort of in that first sphere of meeting. Here the first crystallization of love unfolds—opening, reflecting, and refracting.

Then, as we move outside of that sphere, we encounter a variety of other identities, faces, aspects of ourselves and aspects of the other. I think this happens in relationships: we meet each other and present our best face. It's lovely and enticing. Eventually we meet the rest of the person—their whole spectrum. We find doubts, fears, and unknowns. Sometimes, we turn away because we are that person, too. Part of the challenge a truly loving relationship poses is how to embrace the other and ourselves in our entirety. Rather than letting those revelations divide, we can create something stronger, more whole, more beautiful.

Out of the middle of that dance grows a flower, of sorts. There is a flourishing—an unfolding, rippling sensation and here we experience the fruit of our labors. We reach these crystallized archways which I think of as crowns—the royal WE in each individual. Between those crowns, are two intimately bowing spirals. As they move upwards through the painting they seem to compete with each other, now higher, now lower, but here in this space, they see eye to eye, reflections bowing to one another.

From there… from there: we are two great jewels dancing all of the colors of the rainbow flowing from one into the other and back again—the jewel mind of our hearts, breathing, expanding and contracting, passing light between one node and another, onwards and upwards, ad infinitum.

Love: it is the crucible within which we dissolve, where self dissolves with self, one with the other, and that which remains…

That which remains is best described as Love.

*

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**

MAPS in the Media

Obama Administration Set to Remove Barrier to Marijuana Research
by Catherine Saint Louis and Matt Apuzzo on August 10, 2016. *The New York Times* reports on the U.S. Drug Enforcement Administration (DEA)'s decision to end the federal monopoly on marijuana for research. "It's clear that this was a significant hurdle in limiting the quantity of clinical research taking place in the U.S.," said Paul Armentano, the deputy director of the National Organization for the Reform of Marijuana Laws.

DEA Keeps Marijuana on List of Dangerous Drugs, Frustrating Advocates
by Catherine Saint Louis on August 11, 2016. *The New York Times* reports on the U.S. Drug Enforcement Administration (DEA)'s decision against removing marijuana from the list of Schedule I substances due to a lack of medical research. MAPS Founder Rick Doblin, Ph.D., details how conducting marijuana research can lead to federal approval of medical marijuana, stating, "If you make it through the F.D.A.," explains Doblin, "insurance companies will cover it."

"My Therapist Gave Me a Pill": Can MDMA Help Cure Trauma?
by Olivia Solon September 16, 2016. *The Guardian* interviews study participants Alice and CJ about how MDMA-assisted psychotherapy helped them overcome chronic, treatment-resistant posttraumatic stress disorder (PTSD). The article covers MAPS' upcoming Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD, includes a brief history of the politics surrounding MDMA, and features additional interviews with researchers Ben Sessa, M.D., Michael Mithoefer, M.D., and MAPS Founder Rick Doblin, Ph.D. "The MDMA just pulls things out of you," says Alice. "It supports you. You can start looking at all your experiences and how they are affecting you."

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

The federal marijuana plant at the University of Mississippi in Oxford in 2014. Image: Lance Murphey for The New York Times

Why the US Decision to Expand Marijuana Supply for Research Matters
by Ramin Skibba
August 12, 2016

Can Marijuana Improve PTSD Symptoms for Veterans?
by Matthew M. Burke
September 5, 2016

Can MDMA Help Relieve Social Anxiety Epidemic Among Autistic People?
by April Dembosky
October 24, 2016

LSD Now: How the Psychedelic Renaissance Changed Acid
by Jesse Jarnow
October 6, 2016

Legitimising MDMA, 'The Love Drug', For Couples Therapy
by Rosalind Stone
September 20, 2016

Why Banning the Opiate-Like Plant Kratom Might Do More Harm Than Good
by Alessandra Potenza
September 22, 2016

Treating PTSD with MDMA-Assisted Psychotherapy:

Product Development Status and Proposed Design for Phase 3 Clinical Trials

Amy Emerson

AUTHOR: AMY EMERSON

CONTRIBUTING AUTHORS: BERRA YAZAR KLOSINSKI PH.D., ALLISON FEDUCCIA PH.D., ILSA JEROME PH.D., RICK DOBLIN, PH.D.

SUPPORTING WORK FROM: COLIN HENNIGAN, REBECCA MATTHEWS, ALLISON WILENS, BEN SHECHET

INTRODUCTION

The following is an edited excerpt from the recent Multidisciplinary Association for Psychedelic Studies (MAPS) and MAPS Public Benefit Corporation (MPBC) regulatory submissions in support of a Type B Formal End of Phase 2 Meeting with the Division of Psychiatry Products at the U.S. Food and Drug Administration (FDA) for MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD). The submission presents evidence that PTSD is a serious and debilitating disorder leading to increased mortality and morbidity, and that PTSD patients who are insufficiently treated continue to suffer from an unmet medical need. A summary of initial indications of safety and efficacy based on Phase 2 clinical trial results, as well as what is known about the toxicology, pharmacology, and abuse liability of MDMA, is presented as well as plans for the Phase 3 clinical program.

BACKGROUND

PTSD is a stress-related psychiatric condition that can occur following traumatic events such as war, natural disasters, sexual abuse, violence, terrorism, and accidents. According to the *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5),* there are four main symptom categories for PTSD: arousal and reactivity, avoidance of triggers, negative thoughts and feelings, and intrusive thoughts and nightmares. These symptoms can be severe and long-lasting. PTSD negatively impacts a person's daily life, often resulting in fractured relationships, depression, inability to maintain employment, diminished cognitive and psychosocial functioning, substance abuse, high-cost healthcare utilization ($34.9 billion in inflation-adjusted charges for hospitalizations in the U.S. from 2002-2011, Haviland et al., 2016), and increased risk of suicide. Currently available medications for PTSD effectively treat only a fraction of patients. Approximately 7% of the U.S. population (Kessler et al., 2005), and up to 17% of military veterans (Hoge et al., 2004), will have PTSD sometime in their life. In 2012, there were 572,612 veterans on disability for PTSD (VA Annual Benefits Report, 2013). As of June 2016, more than 868,000 veterans with PTSD were receiving disability compensation, with an estimated cost of $17 billion per year (Solon, 2016). In the general population, 27% of suicides are associated with PTSD (Tarrier, 2004). In a nationally representative sample, PTSD was the only anxiety disorder found to be associated with suicidal ideation or attempts (Sareen et al., 2005).

3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy is a novel treatment package that combines psychotherapeutic techniques with MDMA as a pharmacological adjunct to enhance certain aspects of psychotherapy. MDMA is a psychedelic compound in the Entactogen class. MDMA inhibits reuptake of monoamines, with greatest effects on serotonin and norepinephrine, and to a lesser extent in humans, dopamine. MDMA binds to the serotonin reuptake transporter, similar to the approved PTSD medications, which are both selective serotonin reuptake inhibitors (SSRIs). Unlike SSRIs, MDMA is a potent releaser of monoamines (Rothman & Baumann, 2002), and at higher doses evokes sustained glutamate release in the hippocampus (Anneken & Gudelsky, 2012). These combined effects may facilitate fear extinction learning, by triggering neuroplasticity via Brain Derived Neurotrophic Factor (BDNF) expression, and assist with the recoding of traumatic memories (Young et al., 2015), thus treating the core psychopathology of PTSD (see Table 1).

MDMA produces anxiolytic and prosocial effects (Bedi et al., 2010), which counteract avoidance and hyperarousal in therapy. PTSD increases activity in the amygdala, causing heightened encoding of fearful memories and decreasing blood flow to the prefrontal cortex. In contrast, MDMA acutely decreases activity in the amygdala and hippocampus, and increases blood flow to the prefrontal cortex (Carhart-Harris et al., 2015). MDMA also increases serum levels of the affiliative neurohormones oxytocin and arginine vasopressin, which likely helps to increase trust and reduce reactivity to threatening cues such as traumatic memories (Kirkpatrick et al., 2014). The combined neurobiological effects

of MDMA can increase compassion for self and others, and diminish psychological defenses and fear of emotional injury, while enhancing communication and capacity for introspection. The subjective effects of MDMA may therefore create a desirable psychological state that enhances the therapeutic process.

The two currently available PTSD medications—the SSRIs sertraline (Zoloft) and paroxetine (Paxil)—have small to medium effect sizes (0.31-0.37 and 0.45-0.56, respectively) and require daily dosing for 12 weeks, as compared to MDMA-assisted psychotherapy (effect size 0.9) which requires single-dose administrations. Sertraline and paroxetine demonstrated superiority on the Clinician-Administered PTSD Scale (CAPS-4) over placebo in two 12-week pivotal trials, with dropout rates trending higher in SSRI groups. The differential effects for these medications over placebo were small when compared with MDMA, as shown by CAPS-4 reductions in Table 2.

Despite treatment with SSRIs, many patients still meet diagnostic criteria for PTSD, as seen in the large numbers of veterans remaining on disability. Maintenance treatment is common, but symptoms often return upon discontinuation, which is more likely when adverse effects of maintenance SSRI treatment—such as sexual dysfunction, weight gain, and sleep disturbance—are more severe. Given the chronic nature of PTSD, high dropouts from treatment, and limited recovery using current medications, PTSD patients suffer from serious unmet medical need.

STATUS OF PRODUCT DEVELOPMENT

In 2000, based on past reports of MDMA use, nonclinical studies, and results from investigator-initiated trials, MAPS launched an international Phase 2 Clinical Development Program to obtain U.S. Food and Drug Administration (FDA) approval for the use of MDMA-assisted psychotherapy for patients with chronic and moderate or severe PTSD (scores of 50 or greater on the CAPS-4). Outcomes from six completed Phase 2 studies have been promising, and have generated a range of methodological information for the design of Phase 3 studies. MAPS-sponsored studies are now implemented through its wholly owned subsidiary, the MAPS Public Benefit Corporation (MPBC).

In Phase 2 studies, MDMA was administered in two or three single-dose sessions spaced three to five weeks apart. The onset of effects occurs about ½ to one hour after MDMA administration, with peak effects occurring 1¼ to two hours after the initial dose. The effects of the initial dose last three to six hours, which is extended to five to eight hours with a supplemental half-dose. In humans, orally administered MDMA has a half-life of seven to nine hours. Unlike currently approved medications for PTSD, MDMA has a rapid onset, and does not require daily dosing or steady blood plasma levels to be effective.

Our Phase 2 studies followed a randomized, double-blind, comparator or placebo-controlled, single-site design with the CAPS-4 as the primary efficacy measure. The basic design includ-

Table 1: How MDMA May Facilitate Fear Extinction Learning in Psychotherapy

Activity	Effects	Application in PTSD Psychotherapy
SEROTONIN Release Downstream Post-synaptic 5-HT1A 5-HT1B	↓ depressed mood ↓ anxiety ↓ fear recognition (amygdala) ↓ aggression and defensiveness ↑ self-confidence	• Facilitates experience of positive mood and reduced anxiety • Increases engagement and ability to focus on trauma without overwhelm
5-HT2A	↑ alterations in the perceptions of meaning	• Provides opportunity to see old problems in a new light
NOREPINEPHRINE Release DOPAMINE Minor ↑ secondary to Serotonin	↑ arousal ↑ alertness ↑ conscious of external stimuli	• Increases motivation to engage in therapy • Improved recall of state-dependent memories • Works with other activity to create optimal arousal zone
ALPHA-2 ADRENO-CEPTORS ↑ activity	↑ relaxation ↑ calmness	• Reduces hypervigilance associated with PTSD • Works with other activity to create optimal arousal zone
HORMONAL EFFECTS Release of oxytocin, vasopressin, prolactin and cortisol	↑ attachment ↑ feelings of trust ↑ empathy ↓ perception of social rejection	• Improves capacity to reflect on traumatic memories • Improves therapeutic alliance • Improves discussion of social/emotional relationships
BDNF Upregulation	↑ neuroplasticity ↑ fear extinction learning	• Allows reflection on traumatic memories during psychotherapy without being overwhelmed • Facilitates memory reconsolidation
REGIONAL BRAIN CHANGES ↑ PFC activation ↓ amygdala activation ↓ cerebral blood- right amygdala and hippocampus	↑ detection of happy faces ↓ detection of fearful faces ↓ subjective fear response on recall of negative memories	• Enhances levels of shared empathy and pro-social functioning • Increases reflection on painful memories of trauma during psychotherapy

Source: (Sessa, 2016; Young et al., 2015)

Table 2. ITT LOCF Placebo/Comparator-Subtracted Mean CAPS Reduction

	Zoloft 12 weeks CAPS % dropout, N Rand	Paxil 12 weeks CAPS % dropout, N Rand	MDMA pooled 12-20 weeks CAPS % dropout, N Rand
Study 1	-6.8 29.3% from N=208	-10.8 41.7% from N=307	-26.2 7.6% from N=105
Study 2	-9.8 22.5% from N=169	-14.3 to -12.2 35.6% from N=551	N/A

ed three weekly preparatory psychotherapy sessions, followed by three treatment modules, each consisting of one eight-hour experimental session assisted with MDMA or comparator/placebo, plus three weekly 90-minute non-drug integrative psychotherapy sessions. Each treatment module was repeated two or three times, with experimental sessions scheduled approximately one month apart. Independent Raters (not present during treatment and blinded to condition assignment) administered the CAPS-4 at baseline and at the primary endpoint three to eight weeks after blinded treatment. Secondary endpoints included CAPS-4 assessments at three to eight weeks, and at least 12 months after the last active dose experimental session. Participants who completed at least one blinded experimental session and completed at least one follow-up CAPS-4 were included in the ITT analysis.

In 2016, we completed an ITT analysis of primary efficacy and safety data from our six Phase 2 clinical trials in the U.S., Switzerland, Israel, and Canada consisting of 105 blinded subjects with chronic PTSD. Two Phase 2 studies have been published, one in the U.S. with a long-term follow-up conducted an average of 3.8 years after the final MDMA-assisted psychotherapy session (Mithoefer et al., 2011; Mithoefer et al., 2013), and one in Switzerland (Oehen et al. 2013). Our first completed Phase 2 study was followed by a small open label extension study examining the treatment of relapse in three subjects with a single MDMA-assisted psychotherapy treatment and a 12-month follow-up. Three additional studies have completed treatments, and two international studies in Israel and Canada were terminated early for logistical reasons with partial datasets. These studies tested a range of designs, such as a placebo control (U.S. and Canada), low dose MDMA comparator control (U.S. and Israel), and three-arm dose response (U.S.).

The analysis of Phase 2 data shows that regardless of the original cause, PTSD is treatable with two to three sessions of MDMA-assisted psychotherapy. Mean baseline CAPS scores (84.7) indicated extreme chronic PTSD with an average duration of 17.8 years. At the primary endpoint across Phase 2 studies, an initial dose of 75-125 mg MDMA was statistically superior to an initial dose of 0-40 mg MDMA, demonstrating dose response. The dropout rate across Phase 2 studies was 7.6%, and MDMA was well tolerated. By long-term follow-up (at least 12 months following the final experimental session) the overall remission rate was 66.2%, with an average drop of 47.7 points on the CAPS.

MDMA transiently increases heart rate, blood pressure, and body temperature depending on dose, though none of these effects are problematic for physically healthy individuals. Most people do not experience elevations in cardiovascular measures exceeding those occurring after moderate exercise. These favorable efficacy and safety outcomes support expanding the research to include a larger sample of participants in Phase 3 clinical trials.

PROPOSED DESIGN OF THE PHASE 3 CLINICAL TRIALS

Our proposed Phase 3 trial is a confirmatory placebo-controlled, double-blind, randomized study, with primary outcomes assessed by a centralized Independent Rater pool, in 230 participants with severe PTSD. The Phase 3 trial will assess the efficacy, safety, and tolerability of a flexible dose of 80 or 120mg MDMA (plus supplemental half dose of 40 or 60mg unless contraindicated). One group will receive MDMA, and the other group will receive inactive placebo. The treatment package of MDMA-assisted psychotherapy includes three monthly experimental treatment sessions with manualized psychotherapy (maps.org/treatmentmanual), preceded by preparatory sessions and interspersed with 12 weeks of integrative psychotherapeutic sessions.

The study's primary objective will be to evaluate changes in participants' CAPS-5 scores between baseline and two-month follow-up, after the third experimental session. Phase 3 will also include a follow-up extension study to collect efficacy and safety data 12 months after treatment. This will be followed by an open-label extension study, to allow those participants who received placebo to receive the full experimental treatment. Data on drug response, safety, tolerability, and administration will also be collected. We will also request permission from the FDA for a single expanded access study to collect additional safety data in the PTSD population. Expanded access will make MDMA-assisted psychotherapy available to patients with PTSD who cannot participate in the Phase 3 trial due to closed enrollment or geographic accessibility.

THE FUTURE OF MDMA IN PSYCHOTHERAPY

Based on the data from MAPS' Phase 2 clinical trials, the risk/benefit profile for MDMA-assisted psychotherapy is favorable for participants with PTSD. Across the Phase 2 trials, 75-125 mg MDMA was statistically superior to 0-40 mg MDMA, and there was a large difference in the size of the effects between the two groups. The overall rates of adverse events and negative reactions across Phase 2 trials were also low. The Phase 3 study proposed by MAPS is intended to gather further information about abuse liability, safety, and efficacy, with the goal to obtain an approved New Drug Application (NDA) for MDMA-assisted psychotherapy in the treatment of PTSD in a controlled clinical setting.

It is anticipated that MDMA, with its unique pharmacological mechanisms and administration in conjunction with psychotherapy, can improve upon existing first-line PTSD treatments in terms of side effect profiles, efficacy, and durability of remission. MAPS will seek marketing approval for MDMA-assisted psychotherapy for PTSD in adults, based on evidence from Phase 2 trials and a confirmatory Phase 3 clinical trial, subject to feedback from the FDA on our proposed development plan.

If the FDA determines that the data supports a favorable NDA, MAPS proposes to collaborate with the FDA in the development of a Risk Evaluation and Mitigation Strategy (REMS) potentially consisting of:

- A sponsor-developed training or certification program for providers demonstrating proficiency in manualized MDMA-assisted psychotherapy
- Restricted distribution from a limited number of pharmacies
- Administration only in a clinical inpatient setting under continuous observation
- Continued restrictions on treatment of patients with renal and hepatic impairment until satisfactory completion of additional safety studies after approval
- Continued requirements of pregnancy testing and effective birth control during treatment
- Driving restrictions after receiving MDMA-assisted psychotherapy.

MAPS proposes a model of care in which treatment can be provided by certified practitioners at clinics with the following minimum capabilities:

- A physician holding a license of the appropriate schedule for MDMA;
- Physicians, nurses, counselors, or therapists from various specialties who are licensed according to state and local requirements to deliver psychotherapy, and who are certified by the sponsor to deliver MDMA-assisted psychotherapy upon satisfactory completion of training;
- Trained personnel under direct supervision of licensed psychotherapists to assist with delivery of the treatment package;
- Suitable facilities for treatments in a residential setting to limit risk of abuse, misuse, diversion, and accidental pediatric exposure.

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Amy Emerson *is Executive Director and Director of Clinical Research of the MAPS Public Benefit Corporation (MPBC). Amy earned her B.S. in genetics and cell biology from Washington State University in 1992 and has managed MAPS' clinical research programs since 2009. She can be reached at amy@mapsbcorp.com.*

Ilsa Jerome, Ph.D.

In Pursuit of GMP MDMA

ILSA JEROME, PH.D.

In 2017, when MAPS begins conducting our Phase 3 clinical trials on MDMA-assisted psychotherapy as a treatment for posttraumatic stress disorder (PTSD), we will need 500 grams or more of methylenedioxymethamphetamine (MDMA). This material must be manufactured under very specific conditions, called Good Manufacturing Practices (GMP). These practices refer to the conditions found in the laboratory where the drug is made, the documentation of the chemicals involved in the synthesis, the manufacturing process, and specific analyses of stability and purity. GMP-certified MDMA is not only required for Phase 3 studies in the U.S., but also for trials in the European Union.

The MDMA that was used in MAPS' U.S. Phase 2 studies was manufactured by David Nichols at Purdue University in 1985. The MDMA used in our Swiss and Canadian Phase 2 trials was manufactured in Switzerland in 1998 by pharmaceutical supplier Lipomed AG. Both original batches are highly pure and stable, but neither was made under GMP. As a result, despite having access to pure and stable MDMA, MAPS had to locate a company willing and able to manufacture GMP MDMA for our Phase 3 studies, which meant that the company also had to possess or obtain a Schedule I license from the U.S. Drug Enforcement Administration (DEA). At first, we had some hope that we could obtain retroactive GMP certification for the MDMA we already had, however we soon learned that regulators would require us to make a new batch of MDMA from scratch.

I was excited to assist with this project in part due to the impact that a shortage of GMP MDMA was having on human trials. The absence of GMP MDMA available for research makes the work more difficult and expensive, and discourages scientists from pursuing interesting questions. By manufacturing affordable GMP MDMA and making it available to researchers, we can spur more research into the therapeutic efficacy and mechanisms of action of MDMA.

THE SEARCH

In order to find the right manufacturer, we first had to locate companies that had GMP facilities and Schedule 1 licenses, or at least one of those features. The search was a team effort, with several researchers and colleagues contributing the names or contact information for candidate firms or offering advice about what to look for in a candidate firm.

I was able to establish through searching company websites that over half of our first set of candidates lacked one or both of the essential features we needed, while others had at least one GMP facility or a Schedule 1 license. These companies were found around the world, but most had a U.S. or North American office.

A few firms initially expressed interest but later declined to take on the project. After gathering advice from colleagues with experience in drug development, we started asking representatives more specific questions. We asked about the company's prior experience taking a drug through the U.S. Food and Drug Administration (FDA) drug approval process, their experience working with similar molecules, and what processes were in place for documenting the processes and resolving issues. The process was slower than I might have imagined.

When candidate firms were interested in the contract, they sent a proposal to us with information on time scale and pricing for their product. Collecting and comparing these various proposals was a significant organizational challenge which we were able to solve. We met with representatives from candidate companies at several points in the search, varying from a simple telephone conversation to a teleconference with half a dozen people in three different time zones. We even had a few in-person meetings with representatives from two of the strong candidates, including Shasun, a UK-based pharmaceutical manufacturing company with GMP facilities.

FINDING A FIRM

We chose Shasun—now Sterling Pharmaceutical Services LLC (SPS)—because they offered a reasonable price and an organized proposal, had previous experience with the FDA, and already had plans for shipping and storage. The Shasun/SPS representatives we met also seemed interested and very engaged in the project, meeting with me and MAPS Executive Director Rick Doblin in person, and responding quickly to our questions. They even had prior experience with similar molecules, and had taken drugs through the FDA approval process. Unfortunately, they were not able encapsulate or package the MDMA after manufacturing, so we are now in the process of locating

one or more firms willing to complete these final steps. I was personally excited, too, since SPS' final proposal had selected as a precursor a compound used in flavoring and perfumery, and I have a personal interest in fragrance chemistry.

Since we signed the contract with SPS, we have received regular communications from members of their team in the UK. After resolving a small issue obtaining a license from the British Home Office to manufacturer a controlled substance, SPS began taking the first steps in formulating a production route. They send us biweekly reports of each step in the process, including any snags or difficulties they encounter. At one point, we received images of test results from the material. We are fortunate to have the expertise of David Nichols and a Swiss pharmacologist in this process, whom we include in our correspondence with SPS.

Kevin Cook, CEO of Sterling Pharmaceutical Services LLC Photograph: Christopher Thomond for The Guardian.

Shasun/SPS CEO Kevin Cook generously agreed to speak with *The Guardian (UK)* for a September 2016 feature article entitled "My Therapist Gave Me a Pill: Can MDMA Help Cure Trauma?" The article reported that about 20 of the company's 325 UK staff are involved in the MDMA production process. "We can handle products here where there is a high risk of diversion—products that can be used for recreational as well as medical benefit," Cook told *The Guardian*. For Shasun, MDMA fits right into their existing work. "We just treat it like any other project," said Shasun chemist Robert Smith, Ph.D.

We have now moved from route finding and small test batches of MDMA to larger-scale manufacturing. Ultimately, SPS will produce one kilogram of MDMA for MAPS later this year. After production, SPS will perform further tests and analyses, including a long-running stability test. MAPS will need about 500 grams of MDMA for use in our Phase 3 research studies. The remainder of the material will be used in Expanded Access trials, and distributed by MAPS to other researchers around the world.

LESSONS LEARNED

Finding a GMP manufacturer, and now searching for a firm to package the drug, has taught me much about the pharmaceutical chemistry industry. I was surprised at how specific a niche a company might occupy. Some companies only produce the active pharmaceutical ingredient (API) without encapsulating or tableting it, while other companies primarily encapsulate or package, and others work on biological materials only.

I also learned that what we had considered to be a large batch of MDMA is actually considered small in the realm of drug manufacturing. Representatives from several firms told us that they could just as easily make a kilogram of MDMA as they could 100g or 500g, so the price would be almost the same. Since that was the case, trying to determine exactly how much MDMA we would need for Phase 3 trials was not necessary. If the price is similar and we can further more research by bringing more GMP MDMA into the world, then why not order a kilogram?

I had expected that manufacturing a chemical that is over 100 years old to be a simple process, like making widgets. I thought that there was a set of directions that all pharmacologists and chemists would know that would produce MDMA. However, from our discussions and exchanges during the search, we learned that building a chemical is more akin to cooking or artwork: finding a cost-effective, high-yield route to making a future medicine is a creative process of discovery, not to be found in a single set of directions.

NEED FOR FUNDING

The manufacture of GMP drugs is not cheap. The total cost of one kilogram of MDMA from SPS is approximately $400,000, not including the cost of encapsulating and packaging our finished product. To give further perspective, the MDMA for a single treatment session costs $75, while the MDMA for three sessions (one course) costs $250. We recently raised about $150,000 for GMP MDMA from our 30th Anniversary and our Global Psychedelic Dinners last spring, but the remaining funds needed to purchase this MDMA are still significant. Before 2016 comes to a close, I hope you will support this crucial step in making MDMA a prescription medicine.

To learn more and help us purchase 1 kg of GMP MDMA, please visit **maps.org/gmp**.

Ilsa Jerome, Ph.D., *is a Research and Information Specialist for MAPS Public Benefit Corporation. She earned her Ph.D. in Psychology from the University of Maryland-College Park. At MAPS and MPBC, she has played a role in study development, including capturing information about the study drug, measures, and data analysis. She also oversees submission of research documents to regulatory agencies. She follows literature related to MAPS and MPBC's study drugs and gains further knowledge through discussion with other researchers. She has helped to create and maintain documents related to MAPS-supported studies, and plays a role in maintaining and updating the MAPS Psychedelic Bibliography. She has written informational documents on psilocybin, LSD, and MDMA. She can be reached at ilsa@mapsbcorp.com.*

The Walls Come Tumbling Down:

My First MDMA-Assisted Psychotherapy Session

ANDY GOLD

Andy Gold

I WENT FOR MY FIRST MDMA-assisted psychotherapy session on November 30, 2015, the Monday after Thanksgiving. Was it really a coincidence that the colonoscopy which found a malignant tumor in my colon some years earlier had also taken place on the Monday after Thanksgiving? I think not. Full circle, indeed.

I arrived at the site in Marin County, Calif., where the session was to take place, at 9:30 in the morning. One of the study requirements is that you do the sessions while fasting. Someone also has to bring you to the site and pick you up. My adult son dropped me off and took a couple of minutes to meet Dr. Phil Wolfson and Julane Andries (the study co-therapists) and see their place. I think he was suitably impressed by the location, and comfortable with the idea of his father tripping in that environment, under the care of those people. He seemed supportive, if perhaps a bit mystified at the thought of his dad taking part in a drug trial for MDMA. I made it clear to him that this was not a rave.

After passing a urine test (good thing I studied for it) I was placed on a couch under a shaggy blanket that looked like it had been stolen from the set of an Austin Powers movie. I don't remember the exact order of operations, but over the next 15 or 20 minutes I picked a card from an animal deck (the first one I picked was blank, and the second was a goose), Phil shook a rattle and called in the spirits for their assistance, somebody played bells and/or a gong, they asked me if I had an intention for the session (I hadn't yet thought about it), and I took a pill, which was either MDMA or placebo. I felt hyperaware, with all of my cynical controls set to full power. As New York-bred Phil called in the spirits from the compass points, I imagined he was bringing them in from the Bronx to the north, Brooklyn to the east, Staten Island to the south, and Hoboken to the west. I was trying to keep my expectations to a minimum—in fact, I really had no specific expectations—and while part of me was curious or excited about what was about to unfold, part of me was thinking, "Have I totally lost my mind? What on earth am I doing here?"

I wouldn't say that I went in knowingly anxious and defensive, but I'd never done the drug before and didn't know what the physical, emotional, or psychological effects might be. Also, I had a rather negative experience the last time I took a psychedelic drug—about 40 years previously—and I'm pretty wary of all kinds of mind-altering substances. I tend to like my mind just the way it is, and I was reluctant to hand over the keys to another driver. As a result, all of my warning systems were on red alert.

I lay under the blanket and we talked. I don't remember what we talked about, but after a little while they asked if I felt anything. At that point all I felt was hungry. I remember thinking, "What am I going to do here all day if this turns out to be placebo?" More time went by—I suspect 30 or 40 minutes—but I still did not feel the drug taking effect, and enough time had passed that it seemed as if it should have.

Apparently every defense mechanism in my being—walls, trenches, moats, barbed wire fences, magnetic force fields, radar installations, anti-aircraft batteries, as well as psychic barriers—was doing its best to fend off, or at least be the first to spot, the drug's first incursion into my perceptual sphere. The reconnaissance planes and drones circled overhead to keep a lookout. The drawbridge was up, the entrance gates were locked, the bomb shelter was stocked with supplies, and the royal family (me, myself, and I) had withdrawn to the inner sanctum.

Still, the drug found its way inside. I have no specific memory of it happening, no "Ah ha!" moment or sudden recognition that I was "under the influence." Instead, I just kind of slipped out of the normal space/time continuum and landed in some other perceptual zone. I wasn't asleep, but I wasn't exactly awake either. I recall a sort of buzzing energy force around me, a feeling like being underwater and carried along by a stream without needing to hold my breath. The feeling was not unpleasant or scary, nor was it euphoric. It just was. I never felt at risk or insecure in any way. The anxiety and trepidations were gone, and I felt fully conscious. I did not try to resist it or fight it, which I'm convinced would have been futile.

I felt like I knew the passwords for all of my mental programs, and had a master key to unlock all the doors that blocked the entry to my inner self.

I remember opening my eyes once or twice, and seeing Phil or Julane. I vaguely recall one of them walking out of the room for a bit, and I remember seeing Phil reading a book, but it was in a kind of stop-action, like the room was lit by a strobe light (it wasn't). I observed them speaking quietly to each other, and I assumed they were talking about me. Maybe they were laughing about how far gone I was, or congratulating themselves on knocking the psychic stuffing out of this unsuspecting middle-aged lawyer.

I was conscious of their presence, and relieved that someone was keeping an eye on me. At one point Phil asked if I could talk, and at first I said no, but sometime later I decided that I needed to try to communicate something, to send up a flare to signify that I was still functioning, if not yet quite functional. With great effort I formulated in my mind the one sentence that I thought best captured my present state. I gathered my strength, made sure that I had enough breath to speak, and proclaimed as precisely as possible, "You have managed to render me inarticulate." That was all I could manage.

Then I fell back into the stream. It was like a fish jumping out of the water for an instant to see where its next evolutionary step was going to take it, and then returning to its natural habitat. I could have just as easily been crowd-surfing at a rock concert, passed along by the unseen hands of hundreds of strangers, or beamed up to the Starship Enterprise.

At one point Julane put headphones on me, and I remember some kind of New Age music playing. I don't know if the music was there to guide me, or just to keep me marginally connected to reality. I would have been happy to listen to Balinese gamelan, or Beethoven string quartets, or John Coltrane ballads, but that's not what this was. There are some kinds of gentle, calming background music that I can appreciate and sink into, like Japanese shakuhachi or Tibetan bells, maybe even Gregorian chants, but I find some allegedly spiritual or healing music insipid, and it actually gets on my nerves. I have often said that hearing is my strongest and most evolved sense, which is no surprise given that my ears grew to their full adult size by the time I was about eight years old.

Involuntarily, I whipped the headphones off and tossed them away. It was pure reflex. I wasn't violent about it, and I had no evil intent, but whatever was coming through them had become an irritant rather than an aid. I think Phil and Julane were surprised to see the headphones flying through the air. Luckily they (the headphones, as well as Phil and Julane) were unharmed, but in subsequent sessions they did not try to put headphones on me again.

Eventually I must have started to show signs of life, prompting Phil to ask me how long I thought I'd been laying there. I guessed an hour and a half; he told me it had been more like three and half hours. I gradually floated back to the surface, and regained some semblance of normal consciousness and communication skills. At the moment I cannot even recall what we talked about in the ensuing hours. I have far greater recollection of the substance of my second and third MDMA sessions; I think the first session served mainly to begin to break down my many barriers and soften me up for the subsequent sessions.

The physiological effects of the drug (based on when my blood pressure returned to base line) lasted about six hours. Around three hours in I was given a "booster" of half the initial dose to maintain the peak. The therapy was "non-directive," meaning that although the therapists nudged me occasionally to explore certain things, mostly they helped me explore wherever I wanted to go. I remember feelings and sensations more than the substance of our conversation. The drug does have a stimulant effect, so I was hyperaware throughout the session, and completely exhausted when the drug wore off. The only physical after-effect was that my jaw was sore from clenching my teeth.

For several days after my first session, I felt like my gyroscope had been knocked off balance, my magnetic poles

reversed, as if the earth had slipped off its axis. I've tried out a series of metaphors in an effort to explain it: a tsunami rolling over me, a wind blowing through my head, a fire scorching my brain, an explosion knocking down the walls and blowing open the doors and windows, a volcano erupting and flattening the immediate countryside. Whatever happened was powerful, and I felt as if I suddenly had access to parts of myself that I had never encountered before.

It's not as if I'd never looked inside myself before—I can actually be pretty introspective. But this was different. I couldn't just see inside myself, I could go inside myself. I felt like I knew the passwords for all of my mental programs, and had a master key to unlock all the doors that blocked the entry to my inner self. I could wave my hand like Obi-wan Kenobi and waltz past the guards into the secret chambers of my head and heart. I was the NSA of my own mind. I could rewind all the old tapes and play back everything I'd ever said, and see everyone I'd ever known, everywhere I'd ever been, and everything I'd ever done. More amazingly, I could see it all without harshly judging any of it. I was a deeply involved, but fundamentally dispassionate, observer. I was like a UN peacekeeping force patrolling the formerly contested borders of my brain.

In addition to this sense of unprecedented access to "me," I have to say there was also some collateral impact. It felt like large parts of my infrastructure and many of my operating systems had been affected, like my brain was undergoing renovation and I was waiting for the construction crew to install the new one. Yet while it took time to rebuild the infrastructure of my everyday functioning self, it also gave me an opportunity to upgrade some aging systems. You can't really get to the sewer lines unless you tear up the roads, I thought, so as long as everything is in shambles, let's see what we can improve.

I felt a bit physically and mentally unstable for a few days, a little spaced-out or forgetful. I had trouble finding the right words, and routinely failed little memory tests I gave myself (names of musicians, actors, restaurants, that sort of thing). I was very cautious driving, and even walking around or cooking. I was frankly a little worried that I had been permanently knocked off-kilter. Maybe the dose was more than I could handle, I thought, or maybe I was rendered emotionally fragile because the drug had shattered the cage in which I had been living and (I feared) left me permanently unfit for humankind. I am happy to report that those side effects dissipated gradually after the first session, and more quickly after the two subsequent sessions. I am now restored to full operating power, and just as irreverent as I was going in to the treatments.

I also felt as if I had taken a truth serum, and lost the power to be anything other than constantly (perhaps even brutally) honest and forthcoming. For the first few days after the session, I felt like every time I opened my mouth my deepest thoughts or feelings would come pouring out, regardless of whether they were appropriate for the occasion. I don't think I deeply offended anyone, or overwhelmed them with my forthrightness, but I don't really know. Even in an unenhanced state I can come on a little strong sometimes, but I can usually adjust the intensity of my emotional output and intellectual inquisitiveness. Now the fire hydrant was stuck open, and I didn't have a wrench to close it. I was a babbling brook that couldn't stop babbling.

I do believe there's a risk there. I'm not sure you can actually go through life in the modern world as a non-stop, unvarnished truth teller. Can one be too open? Is it possible to be too vulnerable? How does one see and feel deeply, and be open and honest in their dealings with the world, without being taken advantage of? What is the difference between being open and vulnerable, and being over-sensitive and weak? Can a person survive in a hierarchical, structured workplace with no emotional filter? Or in my case, can one actually function as a litigator—my profession for the last 30 years—in this condition? To put it mildly, the adversarial process does not generally reward emotional openness and unvarnished honesty. Will all of us who have gone through this intensive therapy have to be sent somewhere where we will be protected from the evils of an insensitive world?

Maybe these are just the musings of an excessively self-reflective person coming out of intensive MDMA-assisted psychotherapy with too much time on his hands. Or maybe this is something that should be kept in mind for future uses of the drug. I am curious to learn more about how others have come out of this experience and reintegrated into their day-to-day worlds. I am probably not the best subject for this part of the experiment as I no longer have small children, nor work full-time, nor regularly encounter many of the stresses that might dampen the openhearted MDMA glow. I'm personally thrilled that I'm now experiencing my world in a deeper and richer way, and I hope to continue to feel that way. I just wonder how to maintain, and to carry forward that feeling into a world filled with contradictions, challenges, and dangers. Time will tell….

Andy Gold *is a lawyer in Oakland, California. In December 2004 he was diagnosed with Stage 3 colon cancer. After surgery and 6 months of chemotherapy he was told (mistakenly, as it turned out) that the cancer had apparently metastasized and that he would need additional surgery and experimental treatments. While coping with a potentially fatal illness, he was also handling the biggest case of his career, including managing a team of 25 lawyers and paralegals, all without telling his staff, his client, opposing counsel or the court that he was being treated for cancer. As a result, he was unable to contemporaneously process the psychological impact of the cancer. Years later, still struggling to deal with the long unaddressed multiple traumas of the cancer, the misdiagnosed metastases and the stress of hiding the illness while pushing himself to (and beyond) his physical, mental, and emotional limits, he sought help. At the recommendation (and urging) of a psychiatrist, he ended up as a subject in a MAPS sponsored study of MDMA-assisted psychotherapy for people suffering anxiety from life threatening illnesses. This is the story of his first MDMA session. He can be reached at agold@sonic.net.*

Charlotte Jackson, M.A., R.C.C.

Integrity, Mentorship, and Self-Care:

Highlights from Training for Therapists Involved in Phase 3 Clinical Trials of MDMA-Assisted Psychotherapy for PTSD

CHARLOTTE JACKSON, M.A., R.C.C.

"Crushing truths perish from being acknowledged."
—Albert Camus

In April 2016, I was one of a group of therapists, researchers, and others who convened in Fort Collins, Colorado, for our first in-person training for individuals who will be working on Phase 3 trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS). I am a Registered Clinical Counsellor in Vancouver, Canada, working in the field of mental health and substance use, and I was fortunate to be among those invited to participate from across Canada and the U.S.

The course was led by Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., and Marcela Ot'alora, L.P.C., who are also the Principal Investigators for MAPS' Phase 2 trial sites in South Carolina and Colorado. They brought a wealth of knowledge and great generosity in the sharing of their work, which set the tone for an inclusive and productive week.

THE TRAINING

The training consisted of viewing videos of MDMA-assisted psychotherapy sessions from Phase 2 PTSD trials, with lively discussions about what we were seeing, questions about the therapists' interventions, and the sharing of our own therapist backgrounds. Some of the recorded sessions were intense; I was periodically distressed by what I saw and others reported the same. I found myself wanting to lash out at those who had perpetrated the traumas, but there were no enemies present, just my own old grievances that were surprisingly activated by watching the videos. Trauma has this effect, moving scattershot amongst those that it touches. This proved to be an *in vivo* inoculation for the work ahead.

The videos were rounded out by introductions to the Internal Family Systems (IFS) approach to therapy and Holotropic Breathwork™, modalities that inform MAPS' approach to MDMA-assisted psychotherapy for PTSD. IFS is a model of psychotherapy, developed by Richard C. Schwartz, that posits that our minds are comprised of sub-personalities, or parts. According to IFS, under conditions of duress these sub-personalities keep traumatic memories compartmentalized, sometimes outside of conscious memory. This compartmentalization is helpful for survival of the organism while the trauma is happening, but later on it can also interfere with our ability to comprehend events and our ability to take responsibility for healing them—leading to the feeling that when we *feel* bad, it must be because we *are* bad. Due to the compartmentalization, we fail to see the larger picture and the impossible positions we have experienced. One of the goals of IFS is to encourage these separate parts to communicate and work together. I have used IFS concepts in my own work with clients, and have found it helpful in de-pathologizing their internal experience of distress.

Holotropic Breathwork™ (HB) was developed by Stanislav Grof, M.D., Ph.D., and Christina Grof, Ph.D., out of their desire to continue working with the healing potential of non-ordinary states of consciousness after therapy with psychedelic substances became illegal. HB works from the premise that we all have an "inner healing intelligence" which, when given the right conditions, will naturally evoke the emotional material needed for healing. I spent two weeks in an immersive HB retreat in February, and I can attest to the power of the set and setting created. Through the use of specific breathing rhythms and evocative music, I was able to access non-verbal experiences that transcended my logical mind. I felt into deep wells of sadness and grief of which I was not previously aware—apparently, I (like many people) have been a very effective suppresser of emotional distress. In that experience, I got a small taste of what psychoanalyst D.W. Winnicott called *primal agony*. When pockets of grief are allowed to come into consciousness, it becomes possible to integrate them, providing a measure of control over how we feel about events that gave rise to that grief.

WHY MDMA?

Unresolved trauma has a way of manifesting in the present. Without making trauma present and digestible, its symptoms emerge, unbidden, in myriad forms: flashbacks, nightmares, triggers, fear,

and circumscribed lives. Individual potential is thus curtailed. Without the ability to bring traumatic memories into the light where they can be integrated, symptoms will continue to recur.

MDMA decreases activation in the amygdala, or fear center, and releases the bonding hormone oxytocin. These properties allow people to feel safe and connected, perhaps for the first time in their lives. MDMA's stimulant effect provides the stamina required to stay with difficult emotional material for longer periods of time. In combination, these effects create the conditions for traumatic memories to emerge and be spoken.

Harvard psychiatrist Judith Lewis Herman, M.D., posits that there are three necessary phases in successful PTSD treatment: (1) developing a safe relationship; (2) remembering and processing the trauma; and (3) reconnecting with others after the process. MDMA-assisted psychotherapy seems to allow for the establishment of sufficient safety within the experimental (active dose) session, which without the MDMA could take months or years, or in some cases may never develop. Further, this safety creates the container within which exiled memories and experiences can be brought to the surface for processing. The treatment process includes follow-up sessions and check-ins, allowing for further integration and reconnection.

SELF-CARE FOR THERAPISTS

As with any work involving trauma processing, providing MDMA-assisted psychotherapy requires a commitment to self-care and integrity on the part of the therapist. During the training week, we discussed the importance of attending to ourselves. Sitting with subjects who are metabolizing trauma requires presence and transparency. In order to effectively support another in giving voice to the unspeakable, the therapists' instrument—which is the self—needs to be as robust and intact as possible. As Laura Huxley, psychotherapist and widow of Aldous Huxley observed:

> *A person in a psychedelic state can perceive much more in other human beings than he can when he is in his everyday mind. Anyone who is a companion must give up any attempt at self-hiding. Not only is it useless, but it creates a fatiguing and distracting tension for both.*

In therapy, pretending or performing by the therapist will be perceived for what they are: disingenuous and therefore not safe. It is incumbent on therapists, then, to attend to our own lives with integrity so as not to cloud or detract from the process. This includes our physical selves. Attending to our physical bodies before, during, and after sessions is essential. I see preparing for this study akin to training for a marathon: I need regular exercise, stretching, meditation, good nutrition, and sleep. During our week together, our group spent our non-training time participating in yoga, early morning hikes, meditation, drumming, singing, laughing, socializing, and dancing. The expressed spirit of the training was to nurture non-competitive relationships, which the extracurricular activities helped develop and deepen.

My highlights of the training included witnessing, in the session videos, Michael, Annie, and Marcela providing loving corrective experiences to subjects who were receptive and available to their wisdom and care. Another highlight was our final dance party on Saturday night, where we discharged the tensions of the training week and proved that therapists can DJ an inspired set. Both the videos and the celebration were a great privilege to experience.

NEXT STEPS

Fifty years ago, in *This Timeless Moment,* Laura Huxley asked questions about the necessary checks and balances required for the safe and ethical administration of psychedelic therapy: "How should the psychedelics be administered? Under which circumstances, with what kind of preparation and follow up? These are questions that must be answered empirically, by large scale experiments." Now, 50 years later, we are at the point where these large-scale experiments are at hand, and we will soon have the empirical data required to answer these questions. In early 2017, my cohort will meet with the other therapist groups in training for Phase 3 trials for a final in-person training before Phase 3 trials begin recruiting participants.

This is an exciting time, and one that calls for some sober reflection. Many have come before us and have made this research possible. I want to express gratitude to our teachers, Michael and Annie Mithoefer and Marcela Ot'alora, and of course to Rick Doblin and MAPS who have built this foundation, allowing us to gather data with the express goal of making this a legal prescription treatment and thereby offering relief to individuals and families who have not found healing through currently available treatments. I have worked with many individuals in my own practice, and have felt helpless when I cannot offer more concrete relief to their suffering. MDMA-assisted psychotherapy may offer a potential for healing that many have not been able to access through talk therapy alone. I will continue working with MDMA in therapy outside of research contexts when it can be legally prescribed.

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Charlotte Jackson *is a Registered Clinical Counsellor working in Mental Health and Substance Use for over 15 years in Vancouver, BC. She works from a harm reduction, strengths based, trauma informed perspective, as well as from an anti-oppression framework. She works with individuals and couples addressing trauma, anxiety, depression and life transitions. Charlotte is currently in training with the Multidisciplinary Association of Psychedelic Studies (MAPS) to be a therapist in the Phase III study using MDMA-assisted psychotherapy for individuals with treatment resistant PTSD. Her mentor is Andrew Feldmar, social phenomenologist and radical psychotherapist. Charlotte believes in each individual's innate capacity to move towards wholeness and healing given the right conditions. She can be reached at mail@charlottejackson.ca.*

Adherence Rating in MDMA-Assisted Psychotherapy for PTSD Research

JUSTIN FORMAN, PH.D.

Justin Forman, Ph.D.

HISTORY AND TREATMENT OF PTSD

Symptoms of posttraumatic stress disorder (PTSD) have been articulated in mythologies, religions, histories, and literary works for centuries (Friedman 2015). These narratives document the experiences of individuals and communities that have been impacted, and their struggles to find meaning and healing. Over the last several hundred years, this group of symptoms has been given various names and attributed to various causes. However, it wasn't until 1980 that PTSD was first introduced as a discrete psychiatric diagnosis in the *Diagnostic and Statistical Manual of Mental Disorders, Version 3 (DSM-III).* Since that time, numerous studies have helped to further refine our understanding of pre-disposing factors, causes, symptomology, and effective methods of treatment.

One of the primary tasks of trauma therapy is to help clients to achieve a sense of safety and stabilization before any processing can occur. Friedman (2016) has reviewed recent findings focused on the neurobiological aspects of trauma, and deepened our understanding of how to regulate somatic and sensory systems while working with traumatic material. Current approaches include diaphragmatic breathing, guided visualizations, focused expression of affect, and sensory grounding. Another important aspect of developing safety is the therapist's capacity to build rapport, connect empathically, and maintain a non-judgmental attitude with respect to the client's experience. This helps to build a therapeutic container that can then allow for processing and integration of traumatic experiences. Although these methods have been shown to be effective, they can take time to implement and develop. In some cases, there is a back-and-forth movement between containment and processing periods, which can lead to longer therapies and frustration for both clients and therapists.

In the *Treatment Manual for MDMA-Assisted Psychotherapy for PTSD* (**maps.org/treatmentmanual**), the authors draw upon previous research with MDMA and suggest that one of the effects of the medicine is to provide a kind of experiential container in which the body is more regulated. From this place, participants appear more capable of tolerating and expressing difficult emotional experiences associated with the trauma, thus stepping out of the flooding and numbing cycle. MDMA has also been associated with increased empathic connection, which may allow for deeper exploration of relationships, healing of attachment wounds, and feelings of interpersonal safety. These particular benefits of MDMA allow for the possibility of a sufficient container to be built more quickly and begin a more tolerable healing sequence for the participant. The therapists are then able to join the participant in their healing more as guides rather than directors, helping them to stay open and curious with whatever is arising. The synthesis of this therapeutic approach and the pharmacological attributes of MDMA appears to result in a powerful and rapid approach to working with PTSD.

THE ROLE OF PROTOCOL ADHERENCE IN THE VALIDITY OF CLINICAL TRIALS

In order for MDMA to be approved by the U.S. Food and Drug Administration (FDA) as an adjunct to psychotherapy for PTSD, and thus made more broadly accessible, clinical trials must demonstrate treatment efficacy, and these results must be both valid

and reliable. Adherence raters have the task of verifying that the procedures and approach outlined in the *Treatment Manual a*re being applied accurately and consistently. This process enhances internal validity, a measure of the level of confidence that the differences measured between groups are due to the independent variables and not to random variation. In MDMA-assisted psychotherapy for PTSD research, adherence to the protocol is measured across two separate domains: One relates to specific tasks and therapeutic objectives such as psycho-education, safety precautions, and gathering relevant history; while the second domain relates to competence of the therapists in various areas including non-directive stance, empathic connection, and communication. Study therapists receive ratings as a form of feedback that allows for refinement of techniques within the study.

TRAINING AND IMPLEMENTATION

In a prior MAPS *Bulletin* article, Sola and Gelfand (2013), wrote about the first adherence rating team and the importance of being able to carefully articulate relevant skills so that adherence rigor could be maintained in the next generations of raters. There were several valuable aspects of the training process that continue to inform my work both as a rater and as a therapist. One of the first tasks was developing familiarity with the theories behind MDMA-assisted psychotherapy for PTSD treatment, including concepts such as *inner healing intelligence, non-directive stance,* and *beginner's mind*. These terms are not inherently complicated, but they reflect a kind of disciplined awareness and inquiry that is in some ways similar to meditation practice. In order to be able to rate the therapy, we had to develop our own experiential capacity to engage in it. We practiced these skills through hours of individual practice ratings followed by group discussion.

In the trainings, we also learned to rate less discreet variables, such as *empathic attunement*. This required being able to recognize and interpret more subtle interactions between therapists and participants. Being able to witness these kinds of interactions not only enhanced my ability as a rater, but also as a therapist. Seeing the effect of a validating comment like "It makes sense to me that you would feel that way," has helped to shape my own practices in the office. Another feature of this training experience is developing the capacity to stay focused and centered. Although we are watching videos instead of actually being in the room, the experience can be very intense and may sometimes evoke a parallel process in us. It is imperative for us to be able to develop the capacity to maintain awareness of both empathic connection and our own grounded being, so that we don't inadvertently communicate to our clients that their trauma is too big or too scary to hold.

THERAPEUTIC CONTAINMENT

Even with this "dual awareness," it is still necessary to take breaks, especially when rating an entire experimental session. However, even with breaks it can still be mentally and emotionally challenging. During an experimental session, therapists are present for the duration of the active time of the drug, which can be up to six hours with only short breaks. So how do the therapists stay regulated? There may be several protective factors that allow therapists to stay engaged in trauma process for so long. One of these could be related to an understanding of the potential of the MDMA to keep emotions and somatic processes within a tolerable range. This may help to maintain a positive expectation of healing. Another factor could be related to having a therapist team rather than a single therapist, which creates an environment where the therapists can draw on each other for resourcing if needed.

One might think of the healing process as weaving together disparate threads of sensory experience in an associational process. The meaning or significance may not be appreciated until later, when the pattern of the weave begins to emerge.

One of the rating items during the experimental session regards our belief of which dose the participant received. In the absence of other data to confirm my guess, I am left to consider my observations of participant expressions and therapist responses. Generally, participants seem to experience some shift at the lower dose, but it does not seem to be enough to create a sufficient sense of containment for deeper work to happen. Participants may be more frustrated, engage in self-critique, or have difficulty trusting the inner healing intelligence. Therapists may become more directive, draw more heavily on specific tools and techniques, and experience more difficulty staying empathically attuned. It would seem that this is an area where MDMA, in the right dose, is particularly effective and sets the stage for the rest of the healing process to occur.

INNER HEALING INTELLIGENCE

The *Treatment Manual* designed by Mithoefer and colleagues describes the concept of the *inner healing intelligence*. Briefly, this is the idea that each of us has within the necessary ingredients for our own healing; we simply need to have the right circumstances. The *Treatment Manual* compares this to a physical injury; we may go to a doctor for stitches but the body does the real healing. One of the ways of to support the process is to treat anything that arises as being relevant to the participant's healing. This may occur in a variety of ways: somatic sensations, affects, memories, images, perceptions, or interactions with the therapists. One might think of the healing process as weaving together disparate threads of sensory experience in an associational process. The meaning or significance may not be appreciated until later, when the pattern of the weave begins to emerge. Having seen this process many times now, I have more trust that

healing is happening even when I can't quite see the whole pattern. The goal then becomes to support the participant in staying present to emerging experience and trusting the process.

One of the ways this is achieved is through using a non-directive approach. The *Treatment Manual* suggests that by following the participant's lead, the therapist can then join the participant as a companion to offer suggestions and emotional support throughout the journey. One of the primary benefits of this stance is that it does not engender reliance on the therapists or the medicine. Instead, participants become active participants in their own healing. This is a crucial part of resolving experiences of powerlessness, hopelessness, and brokenness that so often accompany trauma.

Trusting the inner healing intelligence may be one of the harder tasks for both clinicians and participants. From the participant standpoint this is likely a completely new concept, and may take time and experience to undo past therapy, or to trust that their bodies and minds can engage in a healing process instead being constantly hijacked by symptoms. This level of trust may also be difficult for clinicians after having been inundated with more directive therapeutic techniques and theories. There may be an experience factor that helps clinicians relax and sink into an embodied faith in the process. It also seems that the capacity of the clinician to achieve that level of trust facilitates the deepening of the participant's level of trust as well.

MULTIPLICITY

The *Treatment Manual* describes the importance the importance of validating and exploring experiences of *multiplicity* if they arise. Many psychological schools have rejected a unitary theory of the psyche, instead seeing it as composed of multiple parts, sub-personalities, or subjectivities with different frames for understanding and engaging with the world. On one level, these different self-images represent the psyche's way of adapting in order to contain experience that is overwhelming. In many cases, these adaptations were—at one point in the participant's life—necessary for psychological survival. These subjectivities can become guardians of experiential memory, holding it until it can be safely processed. It is vital for both the participants and the therapists to stay engaged and curious about these subjectivities, as they often hold keys to healing.

This is where the practice of going within with music can be particularly effective. In this way participants have the opportunity to dialogue with various parts of the self: the ones that carried the experience of trauma, the warriors/protectors, the nurturers, etc. Several of the soldiers in the study accessed powerful insights and healing through coming into balance with the part of them that is a warrior. Working with multiplicity also provides room for spiritual and archetypal realms of experience that have an impact on the healing work. Guides, allies, saints, or spirits, can show up in various ways: bringing experiences of compassion, reconnecting to religious or spiritual practices, or pointing the way towards some new understanding or experience. This is a very important aspect of healing, since the connection to the multiplicity within may pave the way to connection with the outer community, beginning the process of reintegration.

PERSONAL NOTE

Working as an adherence rater for MAPS has been a profound experience for me personally and professionally. I was unprepared for the strength of the work, for the depth of my reaction, the compassion of the researchers, and the vulnerability of the participants as they share their stories. Watching each session, I had the opportunity to see them urge themselves forward, to watch themselves find a sense of safety, and to observe bodies begin to release trauma, bit by bit. I also contacted places within me that were in need of healing and support, and learned to engage in my own self-care. While the tasks of an adherence rater are straightforward, it is a participatory experience that can lead to personal transformation. For this I am grateful and humbled by each reminder of the resilience of the human spirit.

I am also grateful to be a part of the team that is working to create a new approach for working with trauma and helping people heal. But most importantly, I thank those who have participated in this research. Thank you for having the courage and vulnerability to share your healing stories with us. I feel blessed to have witnessed your work.

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Justin Forman, Ph.D. *is a licensed psychologist working in private practice in Santa Rosa, California. He is also a faculty member at Meridian University, teaching courses on Imaginal psychology and research methods. He has worked as an adherence rater with MAPS since 2013. He can be reached at justinforman@meridianuniversity.edu.*

Psychedelic Science and Neurodiversity:

Twelve Autistic Adults Treated in MDMA-Assisted Therapy for Social Anxiety Trial

ALICIA DANFORTH, PH.D.

Alicia Danforth, Ph.D.

By the time this update is published, investigators will have completed the blinded treatment phase of the first pilot study of MDMA-assisted therapy for social anxiety in autistic adults, sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS). We enrolled and treated 12 participants, with 11 completing all treatments per the study protocol (one participant had to drop out after the first treatment session for a reason unrelated to safety). The last subject treated will remain in follow-up until April 2017, and might be eligible for two open-label MDMA-assisted therapy sessions a month apart if we learn that they received placebo. Currently, the investigators—Charles Grob, M.D. and I—are still blinded to the results from the primary outcome measure, the Liebowitz Social Anxiety Scale (LSAS). We are looking forward to sharing our findings at the Psychedelic Science 2017 conference in Oakland, Calif., this April.

RECRUITMENT DELAYS

If you have been following our periodic progress updates in the MAPS Email Newsletter, you might be wondering why the study took longer than expected. As has been the case with nearly all clinical trials of psychedelic-assisted therapies so far, we encountered challenges with recruitment. Although inquiries have continued to come in from across the country at a steady pace, finding individuals who meet all of the study requirements proved difficult throughout the spring and summer of 2016.

Several key factors contributed to our enrollment challenges. First, with safety as our top priority, MAPS and the investigators set a high bar for screening, with strict inclusion and exclusion criteria. Anxiety and depression are common in autistic adults, so many potential participants were ruled out when we could not advise tapering off their standard psychiatric medications.

Another obstacle to enrollment was making initial contact with the individuals we wanted to reach. Our population—adults on the autism spectrum who have completed two years of college or the equivalent—does not qualify for services available to students and younger adults, and typically has lower levels of disability than would be required for them to access the scarce public services available for adults. They also often do not have the resources to afford private services. As a result, we could not rely on local clinicians, service providers, or regional centers for leads. Many of the adults we sought for the trial were also often unemployed, living in social isolation and less likely to receive information about the study from others. MAPS generated consistent leads through their monthly newsletter and social media, but the majority of inquiries came from outside of the Los Angeles area, or from individuals who had prior experience using MDMA, did not want to stop using medical cannabis to treat their anxiety, or did not have adequate resources (such as reliable transportation) to meet the study requirements.

DEMONSTRATED SAFETY AND FEASIBILITY

Despite the recruitment delays, this study met its primary goal, demonstrating both safety and feasibility. We established feasibility by successfully treating 12 individuals, and the safety data have been encouraging thus far and support future studies of MDMA-assisted therapy. MAPS, as the sponsor for this pilot study, completed an interim analysis for safety at the halfway point, finding no evidence of harm to participants.

There have also been no serious adverse events reported for the duration of the study.

Because we were working with a population with a high incidence of sensory hyperarousal and atypical responses to psychoactive medications, we structured the protocol as a dose-finding study as an extra measure of caution. By using a dose range of 75-125mg MDMA, we wanted to minimize the risk of overstimulation while still providing potentially therapeutic doses. All participants tolerated the lower doses well, and opted to escalate to higher doses for their second session.

POST-SESSION LOW MOOD REPORTED INFREQUENTLY

One question that comes up frequently about clinical MDMA-assisted therapy research is whether participants experience low mood after treatment. We anticipated reports of what is commonly referred to in non-clinical settings as the "blue Mondays" or the "crash" after taking "Ecstasy" or "molly" (which often contain no MDMA at all and cannot be pharmacologically compared with pure MDMA). Therefore, daily phone calls for seven days post-treatment were included in the protocol. Mood and general wellbeing were monitored closely, and all spontaneously reported reactions were recorded and rated as either mild, moderate, or severe. Although some participants processed challenging emotions during the treatment, no participants reported severe low mood during treatment sessions or during the seven-day period following treatment with either placebo or MDMA. Moderate and mild low mood reactions were reported infrequently and resolved quickly (see chart).

CREATING AN AUTISM-FRIENDLY SETTING

Working with neurodivergent individuals on the autism spectrum made it necessary for us to create an autism-friendly treatment space that would be flexible enough to support a wide variety of sensory preferences and sensory integration challenges. Below are a few setting tips for future research teams:

- Spend time in the treatment room at different times of day, and evaluate the setting based on how it affects each of the five senses. Also, when working with autistic individuals, remember that attention to proprioception is important, so having items such as bolsters or weighted blankets might be indicated.
- Pay careful attention to lighting. If possible, avoid fluorescent lights and add elements of soft, diffused light instead. Be extra aware of how to control natural light coming in through window blinds at different times of the day.
- Go above and beyond ordinary measures to minimize noise. For some populations, even the soft whirring of a fan can be a distraction or uncomfortable. Be aware of the potential impact of intermittent external sounds such as heating and air-conditioning equipment, plumbing, and traffic. We had to prepare our participants in advance for the possibility of medevac helicopters landing at the nearby emergency room.

	Treatment Day	Post Day 1	Post Day 2	Post Day 3	Post Day 4	Post Day 5	Post Day 6	Post Day 7
* Subjects Reporting Mild Intensity Low Mood								
Session 1 (n=12)			3					
Session 2 (n=11)	1		1				1	
* Subjects Reporting Moderate Intensity Low Mood								
Session 1 (n=12)	1		2		1		1	1
Session 2 (n=11)								

** Includes combined reports for blinded placebo and MDMA sessions*

During treatment sessions, study participants are invited to explore a variety of ways to express emotions. Pulling cards from the Mixed Emotions™ therapy cards deck can be effective when putting words to feelings is difficult.

- Select a location with a private restroom adjacent to the treatment room. Socially anxious individuals often appreciate the option of stepping into the temporary seclusion of a restroom to regain composure. In other MAPS-sponsored studies, 27% of participants who receive 100-125mg MDMA in clinical settings have reported nausea. Only one subject reported momentary, mild nausea in this study, but we were glad that a restroom was a few steps away just in case.
- Design the treatment room with an adjustable furniture configuration with extra room for stretching and movement. Facilitators should be able to easily adjust their sitting distance from the participants as needed.
- The focus of autism services has been on children for so long that adults often encounter spaces that resemble pediatrician offices when seeking professional support. We received feedback that our study participants appreciated a space designed for adults.
- If your budget allows, invest in a motorized, overstuffed recliner chair that the participant can control. This simple element can go a long way toward reinforcing the participant's sense of agency in the process, as well as their comfort.
- Many autistic individuals use repetitive motions or stimming to self-soothe. One of our participants recommended a website (stimtastic.co) that provides a wide assortment of stim toys and fidget objects that can also be an effective way to address the stimulating effects of MDMA.
- If providing meals or snacks, always confirm food and beverage preferences in advance. Be prepared to inquire in more detail than usual about likes and dislikes.
- Using elements of nature as the primary decorating theme was universally well-received from our neuro-, gender-, age-, ethnically, and spiritually diverse participant group. Relying on design elements from nature also helped to minimize potential expectancy bias that may result from the presence of images and objects from specific cultural and religious traditions.
- Autistic adults frequently require additional time to compose spoken statements and appreciate alternative methods for communication. Be prepared to expand the time required for office visits to accommodate a slower than typical pace of verbal as well as non-verbal conversation, when appropriate.

An analysis of how to establish and maintain elements in support of an effective set for facilitators and study participants will be addressed in future publications.

NEXT STEPS

Based on subjective reports during treatment and at six-month follow-up visits, as well as initial preliminary analysis of secondary measures, we anticipate that outcomes from the final data analysis will support larger, future studies of MDMA-assisted therapy for social anxiety. One of the most challenging aspects of the screening process was hearing so many reports from autistic adults who had already endured years of misdiagnosis and treatments with multiple, costly pharmaceutical interventions which were either minimally effective or not effective at all. Due to the scarcity of proven effective drug or non-drug treatment options for social anxiety, our hope is that future research teams will be inspired to explore the potential of MDMA-assisted therapy to reduce the fear and avoidance of social opportunities which can improve our quality of life as human beings.

Alicia Danforth, Ph.D., *is the co-investigator for a current MAPS-sponsored phase 2 pilot study looking at the effect of MDMA-assisted therapy on social anxiety in autistic adults. She began her work in clinical research with psychedelic medicines with Dr. Charles Grob at the Los Angeles Biomedical Research Institute, Harbor-UCLA Medical Center in 2004. In 2013, Danforth graduated from the Institute of Transpersonal Psychology (ITP) with a Ph.D. in clinical psychology, with a specialization in Transpersonal Research and Education.*

Sue Sisley, M.D.

Clinical Trial Update: Marijuana for PTSD in U.S. Veterans

SUE SISLEY, M.D.

After nearly seven years navigating barriers to cannabis research, the Multidisciplinary Association for Psychedelic Studies (MAPS)-sponsored clinical trial of cannabis for veterans with treatment-resistant posttraumatic stress disorder is nearly underway. We have already received over 400 requests from U.S. military veterans to volunteer at the Arizona site to be screened for the study. We have begun phone screenings and hope to enroll our first patient in November.

At least 76 veterans will be enrolled in total, and we expect that 38 will be recruited at each of two study sites. I will serve as Site Principal Investigator (PI) at the Scottsdale Research Institute in Phoenix, and my colleague Ryan Vandrey, Ph.D., will be the Site PI at Johns Hopkins University in Baltimore. Marcel Bonn-Miller, Ph.D., of the University of Pennsylvania is leading the study as the Coordinating PI. Additionally, Paula Riggs, M.D., an addiction specialist at the University of Colorado's Anschutz Medical Campus, will oversee data integrity for the study.

The study is being funded by a $2.156 million grant from the Colorado Department of Public Health and Environment, awarded to MAPS by the State of Colorado's Medical Marijuana Scientific Advisory Council in December 2014. Funds for the grant came from fees collected on state medical marijuana licenses. The grant is the first government funding that MAPS has received.

This pilot study will gather preliminary evidence of the safety and efficacy of four potencies of smoked marijuana to manage chronic, treatment-resistant posttraumatic stress disorder (PTSD) among 76 veterans. The objectives of this study are to evaluate whether i) smoking whole plant marijuana attenuates PTSD symptoms, ii) to compare the efficacy of varying ratios of THC and CBD to placebo using standard clinical measures, and to iii) collect safety data. If the trial is successful, MAPS intends to develop future studies and seek use of smoked botanical marijuana as a federally approved prescription drug.

We will be exploring the effectiveness of four varieties of marijuana on PTSD symptoms in this trial: (1) High THC/Low CBD, (2) High CBD/Low THC, (3) High THC/High CBD, and placebo. The precise ratios and potencies will be determined after we complete a final round of quality assurance testing on the marijuana we received from the National Institute on Drug Abuse (NIDA).

We have organized a stellar team to conduct this research, including the addition of former MAPS Clinical Research Associate Ben Shechet as our new Study Coordinator. We aim to collect impeccable data that will meet the highest possible standards for publication in peer-reviewed journals. We anticipate being able to submit results for publication in approximately three years. In the meantime, we will strive to guarantee that the study's methods and conduct represent a pillar of scientific integrity.

We are most grateful to the many veteran service organizations who have helped us reach this point. Veterans from around the U.S. have stood side-by-side with us as we have overcome all of the obstacles that have presented themselves along the way. We had to secure many regulatory approvals for this trial, including the Public Health Service (PHS), Food and Drug Administration (FDA), local and federal Drug Enforcement Administration (DEA) offices, three Institutional Review Boards (IRBs), the NIDA, and a number of additional security measures. We began developing the protocol in 2010; it has taken nearly seven years to obtain all of these approvals, to allow us to place the order of the study drug with NIDA.

After such a long wait, it was very exciting to receive our supply of marijuana for the study this past August. We are conducting multiple rounds of external quality assurance testing to characterize the product provided by the NIDA. We are hopeful that this process will be done in time to begin enrollment this November.

We thank you for your support and determination in helping us to see this groundbreaking study through its development process. We look forward to seeing and sharing the results with you when they become available.

Sue Sisley, M.D., *is an Arizona-based physician practicing Internal Medicine and Psychiatry. She works as Medical Director for medical cannabis license holders in 11 different US states/territories, enabling her to collect data on patient's response to state-level, lab-tested cannabis. Sue serves as Site Principal Investigator for the only FDA-approved randomized controlled trial in the world examining safety/efficacy of whole plant marijuana in combat veterans with treatment-resistant post traumatic stress disorder PTSD. She is on faculty at Colorado State University, and has been a Member of Nevada ILAC Medical Cannabis Commission for the past 2 years.*

Hand in Hand: How Psychedelic Harm Reduction Is Making a Difference Now

SHANNON CLARE PETITT, M.A., M.F.T.I.
ZENDO PROJECT COMMUNITY ENGAGEMENT COORDINATOR
MAPS MDMA THERAPY TRAINING PROGRAM COORDINATOR

Shannon Clare Petitt, M.A., M.F.T.I.

The Multidisciplinary Association for Psychedelic Studies (MAPS) continues to make huge strides towards the goal of establishing psychedelics as legal medicines. In advancing the cause of psychedelic therapy, the organization has also become a repository for experience and techniques essential for assisting people journeying through difficult psychedelic experiences. Psychedelic harm reduction is the practice of creating safe spaces in environments where the use of psychedelics is common, especially music and art festivals around the world. MAPS has committed to this mission by establishing the Zendo Project (zendoproject.org). MAPS MDMA Therapy Training and Zendo Project Community Engagement Coordinator Shannon Clare Petitt is one of the many people on the front lines of both the clinical and festival environments. Here, she discusses how MAPS' work in these two areas strengthen and complement each other.

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It's an exciting time in the field of psychedelic science, with MAPS' upcoming Phase 3 studies of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) bringing the hope of legally available psychedelic psychotherapy closer to reality. The tedious work we've completed over the last 30 years is paving the way for millions of people to gain access to new and effective treatment options. The research we're doing now will shape not only future medical practice, but also the foundations of knowledge from which people judge, understand, and use psychedelic substances.

I've had the honor of being a co-therapist on the MAPS-sponsored Phase 2 trial of MDMA-assisted psychotherapy to treat anxiety associated with life-threatening illness. For me, this work is a profound joy: facilitating a psychedelic journey in a safe and supportive setting, as each person works through painful histories that have hindered their life. There's also an ache in the work, while participants make lasting change in a matter of weeks, the overall process of research and drug development is slow. Phase 2 studies typically enroll less than 24 people, though our upcoming Phase 3 PTSD trials will treat about 400. Waitlists for each study are hundreds of names long, and the multitude of emails and phone calls we receive asking for help are a constant reminder of how many are still suffering and waiting for a breakthrough. This strongly motivates our work—we feel the urgency of making these treatments legally accessible to those who need them.

So we must ask: With clinical research being a lengthy process and legal psychedelic therapy still several years away, what actions can we take to make a positive impact in people's lives right now?

According to the 2015 National Survey on Drug Use and Health, 15.3% of people age 12 and older have used a psychedelic drug at some point in their lifetime; for MDMA it's 6.8%, and for marijuana 44%. People of all ages use psychedelics: at home, in nature, alone, in groups, at college, at parties, with friends, with family, in ceremonies, for fun, for healing. Many (if not most) of those having direct experiences with drugs are plagued by judgment, fear, misinformation, and a lack of unbiased research. There is a huge need for honest dialogue about drug use, and about psychedelics in particular. MAPS is a global hub of information about the risks and benefits of psychedelics and marijuana, helping people understand the risks and potential benefits of psychedelics and allowing people to make informed decisions about their drug choices.

One of two Zendo locations at Burning Man in 2016. Photo credit: Tomek Walas

Every day people make choices about putting these substances in their body: how much, how often, what they do during and afterwards, and how they make sense of it all. Psychedelic experiences can include being suddenly and intensely aware of emotions, positive and pleasurable as well as sad and painful. These effects are part of what make MDMA and psychedelics such promising therapeutic tools. In a safe container with trained professionals, and extensive preparation and aftercare, such experiences can be used to resolve past traumas, help people face their fears, develop trust and more authentic relationships, and gain access to feelings that were previously blocked.

These intense experiences can be risky, especially for those who don't know they have suppressed feelings and who went to a music festival to have fun. Even on our best days—at home, at work, completely sober—it can be hard to know what to do with overwhelming feelings, how to communicate needs and boundaries, or how to best to express ourselves. The psychedelic experience magnifies what is under the surface; as Stanislav Grof has written they are a "catalyst or amplifier of mental processes." We go from being barely aware of the subconscious in everyday life to hyper-aware in a psychedelic experience. This profound shift in consciousness can be frightening, empowering, or both.

How can we help psychedelic users make sense of these transformative experiences? Due to the historical stigma surrounding psychedelics, there are often not many places people can go to get support for these experiences. People are so afraid of getting into trouble or being criticized that they may not seek help when they need it, especially while in an altered mental state. One of the most constructive services we can offer is a place people can be themselves without fear of judgement.

MAPS and other organizations are making growing commitments to public education and psychedelic harm reduction. Since 2003, MAPS has supported harm reduction efforts at music festivals both formally and informally. In 2012, MAPS created the Zendo Project in order to provide public education and peer counseling at music festivals and other events. In the past four years, the Zendo Project has provided safety and care to 1,986 guests, and hundreds of passionate volunteers have received training in psychedelic support.

When a guest arrives at the Zendo Project, we greet them and learn about what they are experiencing. If our supervisors determine that they are in need of assistance, a trained volunteer offers them a place to rest, water, and a compassionate ear. Some guests respond with disbelief or even paranoia that we could be so welcoming of strangers, but usually after a few minutes building rapport they realize that the Zendo Project is designed precisely to provide this kind of care. Many people are amazed, and some feel undeserving. We assure them that is our privilege, and our mission, to be with them in whatever experience they are having.

Most importantly, at the Zendo Project we want people to be sheltered from the elements, hydrated, comfortable around others when they are in such a vulnerable state, and safe with themselves if they are engaging in dangerous behavior or having thoughts of ending their life. Having a safe space to receive support can help people acquire the internal tools needed to deal with psychological difficulties, build resilience, learn new emotional skills, increase self-awareness, face deeply-rooted issues, and gain overall confidence and trust.

One of the principles of psychedelic harm reduction is "Sitting, Not Guiding", which means that the trained volunteer "Sitter" respects the autonomy of the guest, allowing them to determine what is right and real for them. It's important as care-

givers, when someone is in a highly impressionable state, to be attentive to our own beliefs, wishes, and worries, to allow each guest the privilege of their own experience.

Another principle we embrace is "Difficult is Not the Same as Bad", which means that we often learn the most and grow from challenging experiences. Sometimes it can be hard to have this perspective while we're in painful or uncomfortable situations, but realizing that it will pass and that there may be something of value in it can help us build resilience. Psychedelic substances are magnifying lenses into our own psyche, often bringing up psychological or emotional content needing to be processed. It's not always fun, but it can be—and it can certainly be rewarding in the long term.

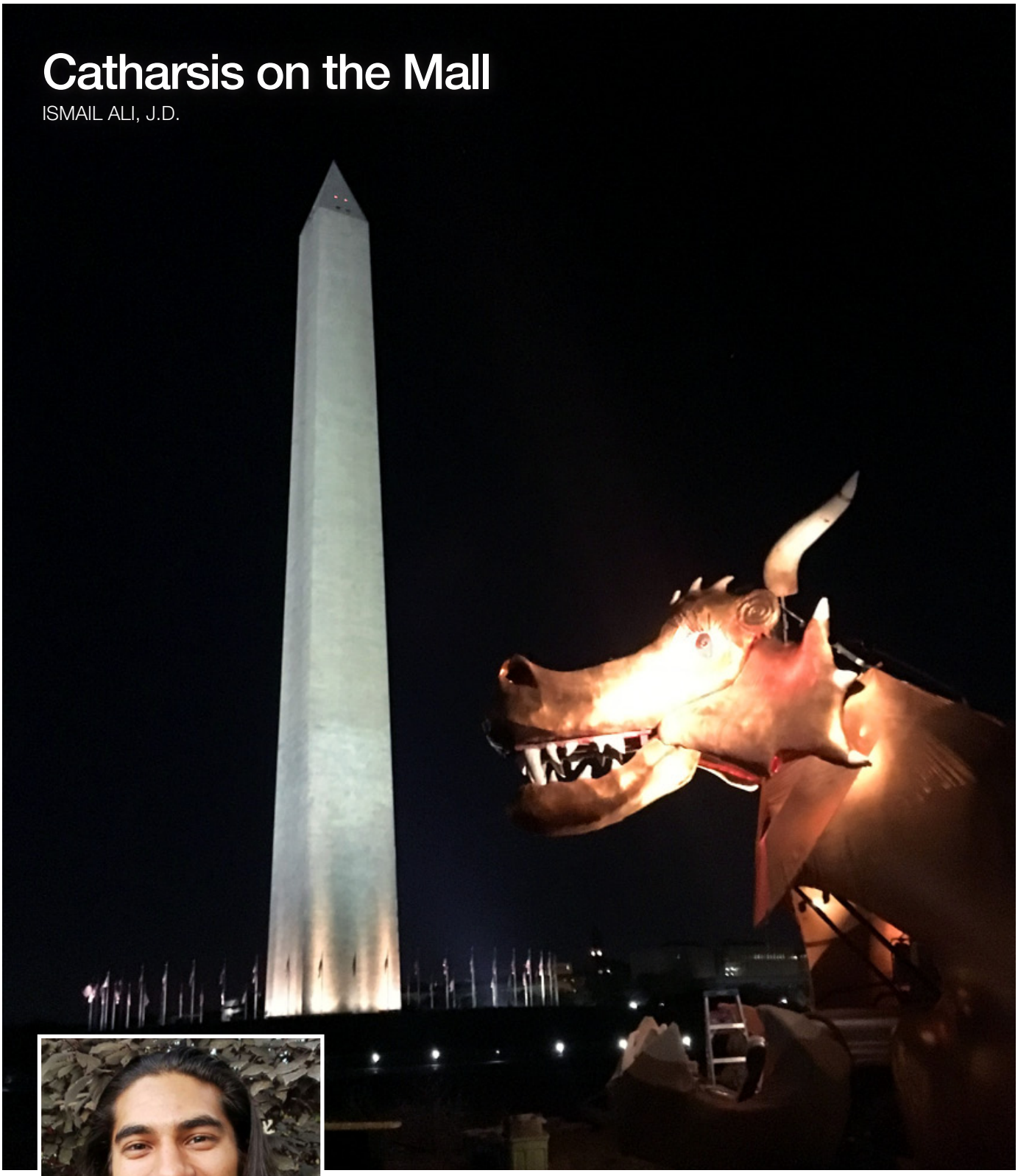
As we know from clinical trials, many of the benefits of psychedelic therapy come in the days and weeks after the sessions. This process of reflecting on the lessons and revelations, digesting them, and applying them to daily life is known as integration. Since 2015, the Zendo Project has offered Integration Circles at music festivals, both for our guests from the previous night as well as for other festival attendees as they prepare to return home to family and work. MAPS has also developed an online resource, the Psychedelic Integration List (**maps.org/resources**), which includes therapists, psychiatrists, coaches, and bodyworkers who understand non-ordinary states of consciousness and are willing to help their clients integrate after such experiences. We have a long way to go before the majority of mental health and medical professionals are prepared to help people who have had psychedelic experiences, but integration providers are working to build a network, document best practices, and create curriculums for disseminating this knowledge and making it widely available.

It would be inadequate to research the potential benefits and educate the public about the use of psychedelic drugs without acknowledging that many people already use them without sufficient safety and support. While MAPS continues to develop psychedelics into legal treatments for mental health, our work to reduce the risks that face psychedelic users outside the research setting contributes to public safety, and models a world in which psychedelics and other drugs are treated as matters of personal choice and public health.

Shannon Clare Petitt, M.A., M.F.T.I. *received her Master's in Integral Counseling Psychology from the California Institute of Integral Studies in 2014, with a practicum working with youth on moderation management for drug and alcohol use. Her passions include working with addiction, trauma, relationship, the body, and nature. At the Multidisciplinary Association for Psychedelic Studies she serves as the Therapist Training Program Coordinator. She also leads Community Engagement for the Zendo Project, bringing harm reduction services to events and expanding efforts for awareness and integration of psychedelic experiences. Shannon is a co-therapist in a MAPS-sponsored Phase 2 trial researching MDMA-assisted psychotherapy for anxiety associated with life-threatening illness. She can be reached at shannon@maps.org.*

Catharsis on the Mall

ISMAIL ALI, J.D.



Burning Man art car Abraxas, the golden dragon, visits Washington DC for Catharsis 2016.

Ismail Ali, J.D.

PARTY, SANCTUARY, VIGIL

In November 2015, the Drug Policy Alliance organized its biannual International Drug Policy Reform conference in Washington, DC. In some ways, the conference felt like Burning Man, with day after day of intentional serendipity, authentic connections, and interpersonal magic. Unlike Burning Man, however, this gathering was entirely focused on one goal: ending the failed war on drugs. Each day was filled with

content about human rights and drug policy; psychedelic science, sacrament, and therapy; and creative alternatives to punishment like harm reduction. However, the auspicious bustle of the event did not stay within the confines of the hotel (which, to the disappointment of the many cannabis users in attendance, was actually in Virginia, not in the capitol, which had already decriminalized the plant). A few miles away, just yards from the Washington Monument on the National Mall, another Happening was happening.

MAPS, represented by Policy and Advocacy Manager Natalie Ginsberg, joined Dr. Bronner's, the DC Cannabis campaign, and a team of DC-based social justice advocates and Burners, to organize an event called Catharsis. One of the organizers, writing for Burning Man about the event, called Catharsis "[equal] parts vigil, symposium, occupation, fire conclave, effigy burn, and party-until-dawn-under-the-stars… the first of its kind." Throughout the weekend of the Reform conference, Catharsis amplified the connections between the drug policy reform movement and the restorative, generative, and transformative culture that so many of us identify with. For three days, the alcohol-free space buzzed with activities, including a temple effigy, art installations, an open mic, a Zendo Project harm reduction space, outreach tables, a symposium of drug policy reformers, a vigil for lives lost in the war on drugs, a storytelling hosted by Psymposia, a ceremonial burn, and a dance party until sunrise. Activists and reformers discussed international and domestic consequences of the war on drugs. People directly affected, like mothers who lost their children in the 2014 mass kidnapping at Ayotzinapa, spoke of their experience. Others shared stories of how their experiences with psychedelics unlocked transformative channels of healing and joy within themselves, even in the midst of a perpetually challenging reality.

Witnessing the many variations of the impact of the war on drugs on different communities and in different places brought a unified awareness and empathy to the surface that many attendees, myself included, had never experienced before. Throughout the weekend, Catharsis became a container for people to share their truths with one another, filled with a richly spiritual fertilizer within which compassion, love, and resilience took root. We, the participants and co-creators of the experience, filled the container with connection after connection. People wrote messages on the Temple to loved ones who had been lost to addiction, police violence, or illness; they shared cruel stories of state-sponsored human oppression; they left mementos.

Late the last night, the Temple, which had been designed to look like a jail cell that had been lit on fire, was incinerated. As the Temple went up in flames, many of us reflected on the reality of the oppressive status quo, unifying in a shared spirit and commitment to continue to fight it. Together we chanted "No more drug war!" first quietly, and then louder and louder until the prayer rippled across the Mall. We danced into the next morning (at which point MAPS founder Rick Doblin ordered bagels and lox for the remaining "movers and shakers").

That weekend, and that night in particular, felt to me like a rite of passage. I spent four days learning everything I could about the incredible world of drug policy reform. I met dozens of inspiring, passionate, and fundamentally good people, and to top it all off, I got to dance at sunrise with Rick Doblin. Most importantly, everything I had ever studied, thought about, and believed in was together in one place. I watched hundreds of people from all over the world, from hundreds of possible paths in life, dancing, connecting, and healing.

The war on drugs costs money, is logically inconsistent, and constricts our minds. Above all, however, it claims lives. We must fight back, and at Catharsis I saw in action how fighting back can include the simple act of healing ourselves. Indeed, that weekend I realized that for those who of us have been victimized by the war on drugs (paraphrased from the words of Audre Lorde), caring for ourselves is truly an act of political resistance.

AT THE UNITED NATIONS

Six months after the Temple burned at Catharsis, we carried this spirit of resilience to New York City, where the United Nations General Assembly Special Session on drugs (UNGASS) provided yet another opportunity for a committed network of drug policy advocates to convene with a purpose. Natalie Ginsberg and I, with help from Italy's Nonviolent Radical Party, had the opportunity to join these advocates in representing the positions of global civil society organizations. Although I was still in my last month of school as a student at Berkeley Law, there was no doubt in my mind that I needed to go. It was my first official event as a member of the MAPS team, with newly-printed business cards stating my role as Policy Fellow.

Over the course of the week, Natalie and I joined representatives from dozens of countries and international NGOs for formal meetings, brainstorming sessions, and networking events. We sat in on meetings organized by coalitions of organizations and member states, the Civil Society Task Force, the General Assembly, and others. We learned how different bodies interpret the right to health and the right to essential medicine, and how drug policy reformers around the world are influencing their countries. We were met with enthusiasm when we briefly spoke to Colombia's Minister of Health about the possibility of starting trials for MDMA-assisted-psychotherapy in Colombia. The Czech "drug czar" also sought our assistance in moving psychedelic advocacy forward in the Czech Republic. We also networked with an even broader collection of advocates than I had seen at the Reform conference, from even more communities affected by the war on drugs, and strengthened our connections with advocates in Latin America, Europe, Africa, Oceania, and Asia.

UNGASS brought a pragmatic realism to this work that I had not yet experienced. Even within the limited frame of UN action, UNGASS is far from the final conversation. The Special Session was called in preparation for the full General Assembly meeting on drugs, which is scheduled for 2019. At UNGASS, I realized that working with reactionary governments and their political baggage, as well as the snail-pace progress of global

policy change, will undoubtedly continue to challenge us as activists and advocates. Making these essential changes will only be possible if we continue to fortify ourselves as a community.

PRINCE, AND OTHER VICTIMS

On April 21, which fell during the week of UNGASS, Prince died. That Thursday night, an international group of committed civil society representatives—myself included—made one last stop after a busy, chaotic, and sometimes challenging week, hoping that an afterparty to the event would re-fortify our hearts. The DJ in the main room of Brooklyn's House of Yes was committed to the artist's legacy, playing nothing but his music throughout the evening. At the time, the cause of Prince's death was unknown. As with the tragic, early demise of any celebrity, overdose was always a possibility, but I remember wanting to believe that this death was different. That night we undoubtedly danced to party, taking advantage of the support and sanctuary that our community had created after an exhausting week of activism and advocacy. Although we did not know it at the time, we were also participating in another drug war vigil.

A few months later, the news came out that Prince had died of an accidental fentanyl overdose. This is the same fate that, in the last few years, has quietly met thousands of other people who use drugs. The synthetic opioid, which is 50–100 times stronger than morphine, has emerged in large part because illicit drug suppliers have begun to cut their heroin with fentanyl, which is cheaper, stronger, and easier to transport than heroin. Notably, Insys Therapeutics, a pharmaceutical company that manufactures fentanyl (and a brand new, synthetic THC) funded the successful anti-cannabis campaign in Arizona. Meanwhile opiate and other addictions are back in our mainstream national consciousness as overdoses in the United States rapidly increase, and there is little hope that traditionally accepted and presently accessible treatments will be any more effective than they have been in the past.

However, more innovative solutions may be on the horizon. In states like Vermont and New York, advocates have brought ibogaine research in the United States to the realm of legislative debate. Although ibogaine may not be a panacea for addiction, investigations into its effectiveness as an addiction interrupter hold promise. Now is a good time for US drug policy advocates to focus on obtaining support and permission for more research. Indeed, my work as Policy Fellow will include filling some of the gaps that still exist in the realm of ibogaine advocacy, and I will spend a significant amount of my time working with already-dedicated ibogaine advocates to push the discussion forward. Of course, access to ibogaine treatment is only one piece of the collective healing that must occur in the global drug-using community.

Early in November 2016—immediately following a traumatic election cycle, and appropriately over Veteran's Day weekend—the party, sanctuary, and vigil that is Catharsis was once again held in the shadow of the Washington Monument. Through more art, more activism, and more energy, its message

Monks visiting from Tibet stop to read and write reflections on the Temple of Rebirth at Catharsis 2016.

promoting community-wide healing from collective trauma once again resonated on the Mall. Thousands of people attended over the course of the weekend, many of whom expressed support and fascination both for the event as a whole and for MAPS itself. The event ended with a March for PTSD research, led by the giant golden dragon Abraxas, to draw attention to the urgent need for more government funding to find effective treatments—like MDMA—for trauma-related disorders and behaviors.

Prince will not be the last victim we dance for, and his death alone will not catalyze every change we hope to see. However, perhaps his passing carries with it a more urgent message, one that our society is finally ready to hear.

Ismail Ali, J.D., *earned his J.D. at the University of California, Berkeley School of Law in 2016, after receiving his Bachelor's in Philosophy from California State University, Fresno, in 2012. As a law student, among leading and participating in other extracurricular activities which focused primarily on human rights, civil liberties, and racial justice, he also worked for the ACLU of Northern California's Criminal Justice and Drug Policy Project. In addition, Ismail served as co-lead of Berkeley Law's chapter of Students for Sensible Drug Policy, where he coordinated events that helped educate the law school community about entheogens, challenge the stigma associated with psychedelic drug use, and critique the racial dynamics of the emerging cannabis industry in California. To support his work at MAPS, Ismail received Berkeley Law's Public Interest Fellowship, a fellowship which provides funding for qualified Berkeley Law graduates who pursue legal work in the public interest. Ismail believes that psychedelic consciousness is a crucial piece of challenging oppression in all of its forms, and that legal access to psychedelics is an essential part of a progressive drug policy paradigm. He can be reached at ismail@maps.org.*

Giancarlo Canavesio

Storyteller: An Interview with Filmmaker Giancarlo Canavesio

JENNIFER BLEYER

Giancarlo Canavesio *helped inform tens of thousands of people about the therapeutic effects of psychedelics through the 2013 documentary film* Neurons to Nirvana: Understanding Psychedelic Medicine, *which he co-produced. The film was just one part of the prolific producer's efforts to use film as a medium that can advance human consciousness and global healing. A longtime supporter of MAPS, he has generously hosted a fundraising dinner at his New York loft for the past three years, coinciding with the annual conference, Horizons: Perspectives on Psychedelics. He also accompanied MAPS representatives to Desert Trip in Palm Springs, California last fall. Interview by Jennifer Bleyer, senior editor at Psychology Today.*

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What did you like most about Desert Trip?

I grew up in Italy, which has a very different musical culture than the U.S., and I wasn't really familiar with these performers, so I enjoyed getting to know them better. My favorite was Neil Young. Also, the whole experience of being in the desert was great. At first I thought the idea of so many people spending so much to be in the desert was strange, but the desert really grows on you. We went for sunrise in Joshua Tree and it was just magic.

What part do you think music plays in changing culture and bringing about healing?

It has played a major part for millennia. Like my friend Alexandre Tannous says: "Sound is a dimension. If we focus on the harmonic overtones and the complexity of the overtones, we can merge into that dimension. That harmonic series, which includes all the overtones, is sometimes referred to as 'the living God,' or the 'stairway to heaven' in the esoteric philosophies."

How is it being a filmmaker who's open about psychedelics?

Being "out" has been easy because I don't feel any shame or taboo. There's so much scientific confirmation about how these compounds, in the right setting, can help with depression, anxiety, addiction and other problems. It's not even preliminary research at this point. On the other hand, making documentaries about this subject has been very challenging as a business.

What's next for you as a filmmaker who's committed to telling stories related to psychedelics?

This winter I'll be codistributing a documentary called *The Last Shaman,* directed by my friend Raz Degan, an actor and cinematographer who really understands about narrative arc. The film is about a Harvard student who cures himself of suicidal depression with the Peruvian tribe Shipibo's plants diet. It's very challenging for him to find the right shaman, and the audience really feels for him. I think *The Last Shaman* has all the ingredients for mainstream attention, because unlike other documentaries, it's not just talking heads and news reports. It has a protagonist, conflict, and resolution. The only way for psychedelic healing films to cross over into the mainstream is if there's a good story.

What was your first involvement with MAPS?

I've had an ayahuasca practice for ten years. I went to a MAPS conference in Oakland back in the beginning of my practice and my mind was blown by the research the organization was doing. I immediately knew I wanted to make a film about psychedelic healing. When I heard that Oliver Hockenhull was already doing this, I offered to help him, and ended up producing and releasing *Neurons to Nirvana: Understanding Psychedelic Medicines.*

What inspired you and your wife, Stephanie, to host the annual MAPS fundraising party in New York this fall?

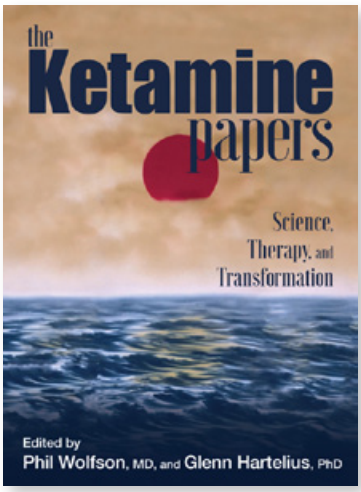
We appreciate the wide scope of MAPS' mission and of course Rick Doblin's resilience and stamina. This year was the third year we hosted the party, and I've also hosted some smaller networking dinners. One thing I usually tell people who come to the MAPS fundraiser is that we know New Yorkers are solicitied for so many causes to help so many people. If you add the amount of human suffering that psychedelics can alleviate—people affected by alcohol and tobacco addition, depression, anxiety, and so on—we're talking about a lot of people. Then if you look at mystical states as an antidote to fundamentalism, it's immeasurable. One dollar to MAPS could ultimately help billions of people.

Ketamine: A Transformational Catalyst

Review of *The Ketamine Papers: Science, Therapy, and Transformation* edited by Phil Wolfson, M.D., and Glenn Hartelius, Ph.D.

MICHAEL ZIEGLER

Michael Ziegler



maps.org/ketamine

Phil Wolfson, M.D., and Glenn Hartelius, Ph.D., have edited a new book entitled, *The Ketamine Papers: Science, Therapy, and Transformation,* published by the Multidisciplinary Association for Psychedelic Studies (MAPS). Ketamine is a Schedule 3 prescription drug that has been safely used in anesthesia for decades. Many years ago, it was discovered that as anesthesia wore off, patients were having unique and often disturbing psychedelic effects for which they were unprepared. These effects were dubbed an "emergent syndrome." This propensity of ketamine to occasion psychedelic experiences was pursued and used in psychedelic psychotherapy following the lead of the Mexican psychiatrist Salvador Roquet. In one of the many illuminating chapters of *The Ketamine Papers,* Richard Yensen recounts his direct experience with Roquet's methods and describes their evolution in psychedelic practice.

With the familiarity that arises from widespread applications, anecdotal information indicated that ketamine produces relief from depression. This was pursued in the late 1990s and thereafter by researchers at the National Institute of Mental Health, who made every effort by reducing dosage to exclude the psychedelic effects but still produce an antidepressant response.

Wolfson and others have come to understand from their practice that while psychedelic effects may not be necessary for the antidepressant response, if you eliminate them entirely then you lose the therapeutic effect. At a minimum, a state of dissociation, or what Wolfson describes as a "trance," appears to be both necessary and desirable. It is necessary to use a sufficient dose of ketamine that occasions a full immersion experience in order to benefit from its available therapeutic effects.

Pharmaceutical approaches to treat depression have met with limited success over the preceding decades. Ketamine's addition to the psychiatric toolbox has therefore been hailed as an important breakthrough. The current generation of doctors and psychotherapists have pioneered new uses for ketamine which can provide opportunities for drug treatment and psychotherapeutic work. These uses are considered to be "off label." That is to say, the drug is being used for applications that were not specifically indicated for the molecule as an anesthetic agent, for which it was originally given Food and Drug Administration (FDA) approval. At sub-anesthetic dosages, that produce at least a trance effect on recipients, ketamine has been increasingly revealed to be effective in the treatment of severe and unresponsive depression, suicidality, PTSD, and other psychiatric diagnoses, as well as for treating addiction and drug dependencies (specifically alcoholism and opioid dependency).

Some of ketamine's more profound effects, which are generally occasioned at higher but sub-anesthetic doses, include the simulation of a near-death experience, the complete dissolution of the identity of the participant, and visionary states that can occur with other psychedelic molecules. Given the potentially profound and singular nature of the ketamine psychedelic experience, the meaning-making that can be de-

rived from such experiences can effect a radical transformation of an individual's worldview.

The contributors to this book weigh in on their fruitful personal experiences regarding how to use the material (dose and delivery system), and their clinical strategies for ketamine psychotherapeutics. *The Ketamine Papers* provides an exposition of how this unique molecule can specifically be used in clinical settings to ameliorate difficult states of mind, by relaxing and enabling recipients to be more receptive to compassion and understanding for themselves and others. The book provides a clear exposition of the different protocols utilized for ketamine. Physicians and lay persons looking for an understanding of this new and controversial set of methodologies will benefit from a careful read of the collected papers in this book.

Ketamine's potential lies in its ability to catalyze individual transformation. The primary effect of ketamine seems to be its ability in recipients to shift their awareness from one fixated mindstate or perspective to a new one. Hopefully and usually, this kind of paradigm shift leads to a more enlightened view of their human condition. With adequate attention given to set and setting in its application, this can lead to better personal behavior. A radical shift of awareness can break the cycle of depression. A paradigm shift of awareness can also bring a person into a new relationship with their addictions. Users have reported that ketamine can also occasion profound non-dual and transpersonal experiences that provide them with a deeper understanding of their place in the world. Our evolving relationship with consciousness as revealed with this unique molecule may move us towards greater sensitivity, awareness, and compassion for ourselves and our fellow travelers on the planet.

Our evolving relationship with consciousness as revealed with this unique molecule may move us towards greater sensitivity, awareness, and compassion for ourselves and our fellow travelers on the planet.

Transformation can be either personal or political. The journey of transformation implies that we are capable of moving from one state to another. Sometimes with this perceptual shift comes the ability to stay in that new awareness. We are able to overcome the constraints of past inertia, habit and the "rubber band effect" (which describes how after an expansion we tend to go back to where we started). Political transformation of unjust systems, or personal transformations out of depression or addiction, may be aided by particularly potent catalysts. Ketamine may be a unique molecule that provides individuals with an experience which so powerfully shifts their awareness that it can, with the proper support, provide a tool for individual transformation.

Although there has been much publicity recently about the possible beneficial transformative powers of currently illegal psychedelic drugs such as MDMA, DMT, LSD, and psilocybin, today ketamine is the only psychedelic drug that can currently be legally administered and prescribed by physicians. All of the other psychedelic drugs are confined to Schedule 1, and thus their use outside of research is prohibited and criminalized. Recently a small number of these Schedule 1 molecules have been studied in tightly controlled research settings. Psilocybin and MDMA (the latter research being sponsored by MAPS) are the first of these medicines to be put through a rigorous screening process by the FDA after decades of suppression. All the while, many tens of millions of people worldwide use psychoactive substances to explore their awareness, in spite of the risk that their actions could land them in jail. What makes the ketamine molecule unique is that it is the only potentially transformative catalytic (psychedelic) now available for use by the medical community.

Ketamine is also unique among psychedelic materials because it is relatively short-acting. A ketamine experience generally lasts 25 minutes to an hour, with another hour or more needed for recovery to baseline. Intravenous sessions run 45 minutes to an hour, and occasion the trance experience. Ketamine-Assisted Psychotherapy (KAP) sessions tend to run three hours, which covers the arc of an initiation or induction, the direct experience of the medicine, and recovery and integration.

Wolfson describes how ketamine works as follows: "A ketamine psychedelic experience tends to offer up the possibility for transformation of the self by isolating the mind to some extent from external sensations, altering body consciousness towards an experience of being energy without form, and by amplifying the contents of mind in unpredictable ways—all of this generating the potentiality for changes in consciousness that may be beneficial and persistent."

Ketamine research has shown that the substance creates a high degree of neuroplasticity in rats. This may explain the so-called "cumulative effect" in humans that produces transformative results from multiple sessions in a relatively short time frame, often just two weeks. One attribute of neuroplasticity is the physical remodeling of the brain by dendritic shifts. It may be that the ability to occasion a shift in consciousness while under ketamine's influence and its aftermath contributes to optimistic neuroplasticity among the challenging mind states such as depression, PTSD, and addiction. Ketamine seems to allow these uncomfortable diseases to be felt in their origins and subsequently relaxed and re-contextualized. As recipients of ketamine move forward, what was previously experienced as a "hell realm" may be released as another variant in the flow of mind states that spontaneously and constantly arise and pass away. There arises the visceral experience that these impacted mind states can be loosened and not felt as inevitable and intrinsic parts of the self. Instead, they can be experienced as transitory and impermanent.

Many of the book's contributors describe how an individual's experience of the ketamine mindstate can provide a doorway to another mode of seeing and being. Patients have reported that with a single session of ketamine, persistent and previously untreatable depressions and suicidal intentions have gone away. In some cases the transformative capacity of the ketamine experience needs to be contextualized and grounded within a longer-term guided psychospiritual healing process. In other practices, low dose applications of ketamine used repeatedly over time have been shown to be effective for treatment-resistant depression and other emotional difficulties by means of a straight forward application of the molecule itself, in medical settings, without a psychotherapeutic component. *The Ketamine Papers* expands on all of these applications.

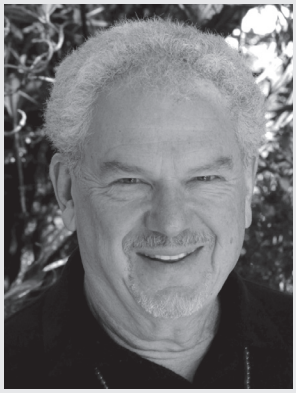
For a transformative catalyst to have widespread clinical applications, it must also be economically viable. The cost for the molecule and its delivery has to reasonable, especially in this case, as at this stage ketamine therapy is not covered by insurance. The cost of all attending doctors, psychotherapists, nurses, and other caregivers has to be within the economic reach of those who are seeking treatment. In the cases of MDMA and psilocybin, these molecules require from four to eight hours of dedicated care. We must consider the delivery cost for any medicine if it is to find widespread prescription use. All the ketamine delivery options can be delivered at a reasonable cost. As the market for this new psychiatric medicine widens we would expect to see delivery costs fall. Ketamine itself is an inexpensive generic medicine, costing only a few dollars for a dose.

It appears that we are entering a new era in which our understanding of the relationship between neurochemistry, mind-states, and behavior is rapidly expanding. The careful observations of the clinical community have revealed that there are existing psychoactive molecules that possess underappreciated primary effects which can aid in transformation and relieve suffering. We are just at the beginning of a journey towards deeper understanding of the class of pharmaceuticals which Ralph Metzner has called "allies for our awakening." The editors and contributors to *The Ketamine Papers* are to be applauded for their trailblazing efforts in bringing us a renewed vision of the ketamine molecule as an important ally for the therapeutic community, one which can provide relief for impacted mind-states, offer deep meaning-making possibilities, and serve as a catalyst for growth and transformation of consciousness.

Michael Ziegler *teaches in the The Psychedelic-Assisted Therapies and Research Certificate Program at the California Institute of Integral Studies. He is a founder of the Chaplaincy Institute and has served on the faculty of Naropa University and Wisdom University. He can be reached at mhziegler@yahoo.com.*

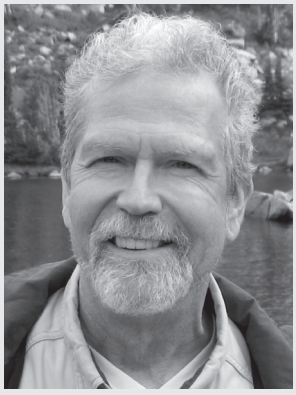
The Ketamine Papers: Science, Therapy, and Transformation

About the Editors



Phil Wolfson, M.D.

Phil Wolfson, M.D., is Principal Investigator for a Phase 2, FDA approved 18-person study of MDMA-Assisted Psychotherapy for individuals with significant anxiety due to life threatening illnesses. His clinical practice with ketamine has informed his role in the development of Ketamine Assisted Psychotherapy. Phil is a sixties activist, psychiatrist/psychotherapist, writer, practicing Buddhist and psychonaut who has lived in the Bay Area for 38 years. He is the author of *Noe: A Father-Son Song of Love, Life, Illness, and Death* (2011, North Atlantic Books). In the 1980s, he participated in clinical research with MDMA (ecstasy). He has been awarded five patents for unique herbal medicines. He is a journalist and author of numerous articles on politics, transformation, psychedelics, consciousness and spirit, and was a founding member of the Heffter Research Institute. Phil has taught in the graduate psychology programs at JFK University, CIIS and the UCSF School of Medicine Department of Psychiatry.



Glenn Hartelius, Ph.D.

Glenn Hartelius, Ph.D. is Founding Director of the Ph.D. in Integral and Transpersonal Psychology at the California Institute of Integral Studies (CIIS) in San Francisco, where he serves as Associate Professor. He is also leading an initiative to develop a new research facility at CIIS for research in whole person neuroscience. Glenn is main editor for the *International Journal of Transpersonal Studies,* a peer-reviewed academic journal. He is co-editor of *The Wiley-Blackwell Handbook of Transpersonal Psychology,* and Secretary of the International Transpersonal Association. His research on the definition and scope of transpersonal psychology has helped to define the field. He is developing a model of attention and how to manage it in lived experience that is designed to simplify complex skills such as meditation, sustained focus, and leadership presence. He has also taught at the Institute of Transpersonal Psychology, Naropa University, Saybrook University, and Middlesex University in the UK.

MAPS: Who We Are

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Executive

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

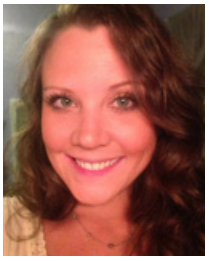
Merete Christiansen, Executive Associate and Assistant to Rick Doblin, Ph.D.

Communications and Marketing

Brian Brown, Communications and Marketing Manager

Brad Burge, Director of Communications and Marketing

Sarah Jordan, Publications Associate



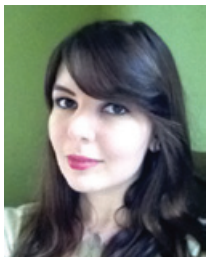
Cara LaChance, Social Media and Multimedia Associate

Amy Mastrine, Web Assistant

Bryce Montgomery, Content Manager

Development

Erik Brown, Development Manager



Tess Goodwin, Accounting and Development Consultant

Jade Netanya Ullmann, Development Officer and Connector

Harm Reduction (Zendo Project)

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

Shannon Clare Petitt, M.A., MFTI, Therapist Training Program Coordinator and Zendo Project Community Engagement Coordinator

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

Operations

Aidan Boling, Operations Associate

Kynthia Brunette, Event Volunteer Manager and CRM Systems Specialist

Jenni Vierra, Administrative Associate

Policy and Clinical Research

Ismail Ali, Policy Fellow

Natalie Lyla Ginsberg, Policy and Advocacy Manager

Berra Yazar-Klosinski, Ph.D., Clinical Research Scientist

MAPS Public Benefit Corporation

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 2 studies of MDMA-assisted psychotherapy for PTSD, and preparing for the 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.

MAPS Public Benefit Corporation

Amy Emerson, Executive Director and Director of Clinical Research

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

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Charlotte Harrison, Senior Clinical Research Associate

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Rebecca Matthews, Clinical Trial Leader

Sarah Sadler, Study Coordinator

Ben Shechet, Study Coordinator

Allison Wilens, Clinical Study Associate

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

MAPS furthers its mission by:

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

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

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

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Multidisciplinary Association for
Psychedelic Studies, Inc. (MAPS)
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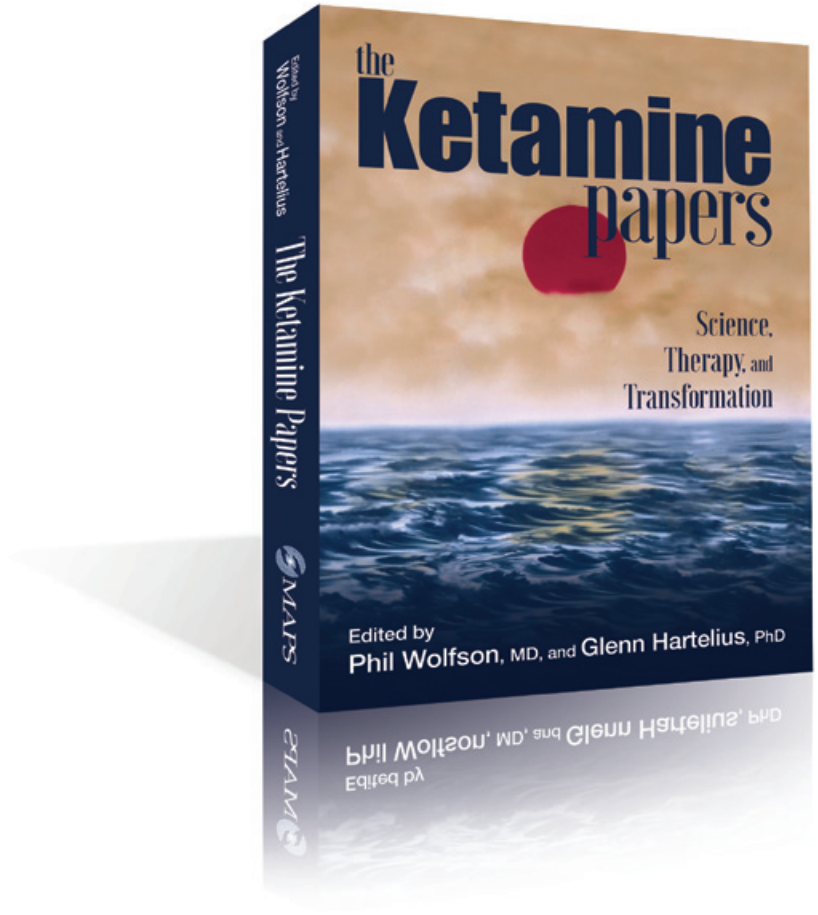

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