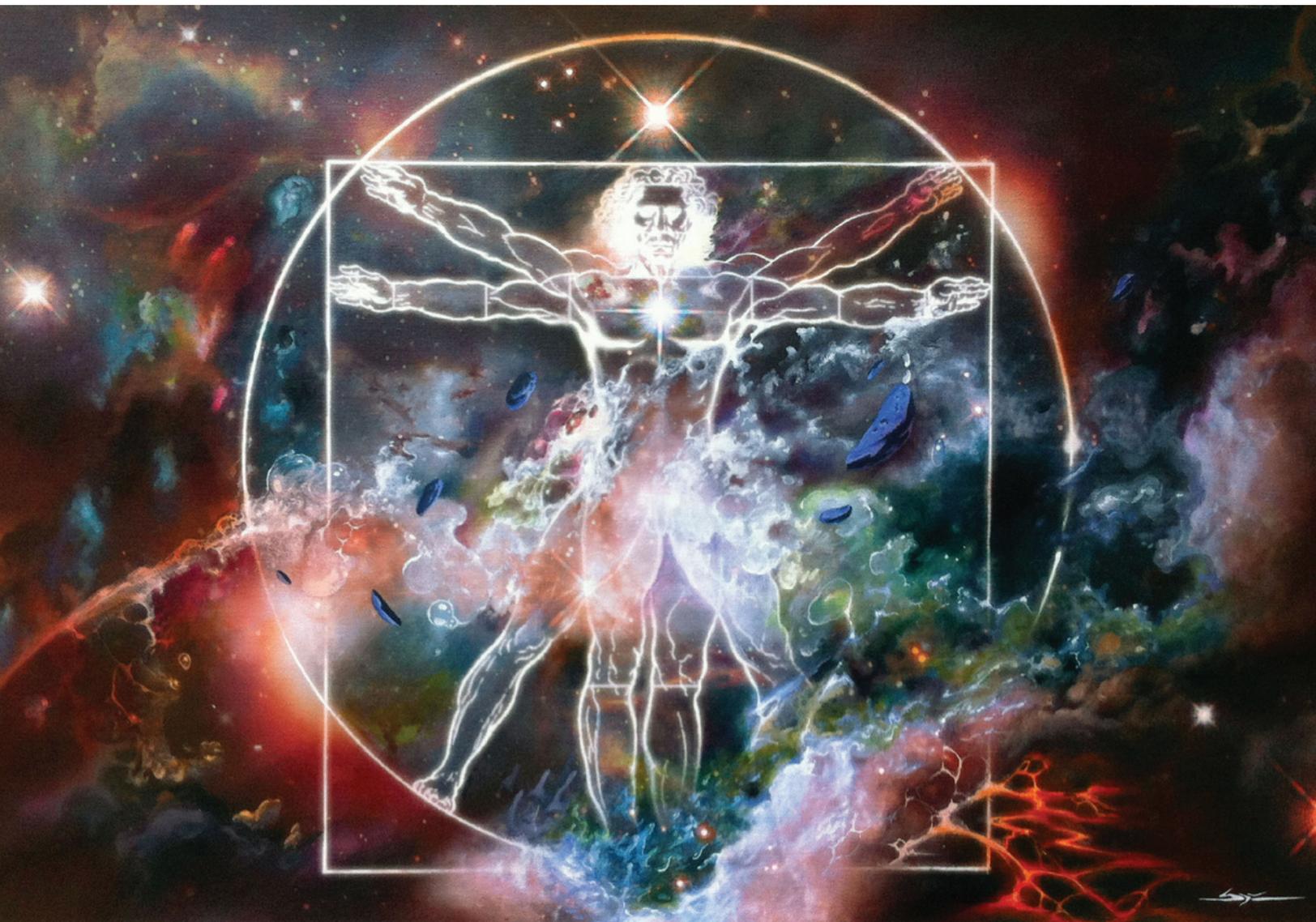


2013 Annual Report
BULLETIN



Winter 2013

Healing Trauma in Veterans with MDMA-Assisted Psychotherapy



“I went to Iraq in 2006 and 2007, and when I got back I was diagnosed with PTSD. During the MDMA-assisted therapy, one of the first things I said was ‘this is what I’ve been looking for.’ I reconnected with myself, I did a lot of internal work, and afterwards it was like a huge weight was lifted off my shoulders.”

—Sgt. (Ret.) Tony Macie, U.S. Army veteran and MDMA-assisted psychotherapy for PTSD study participant

Our ongoing study in U.S. military veterans, firefighters, and police officers is halfway complete, and early results are promising. MAPS’ government-approved research shows that MDMA-assisted psychotherapy can be an effective treatment for people who do not respond to traditional therapies for posttraumatic stress disorder (PTSD).

We need your help to complete this study and spread awareness about the need for more effective treatments for PTSD. According to the U.S. Veterans Administration, over 240,000 service members returning from Iraq and Afghanistan have been diagnosed with PTSD.

Contribute on  indiegogo (maps.org/healingtrauma) until December 31, 2013, and after January 1 at maps.org (maps.org/donate).



“I was one of the original subjects in the clinical trial. I was diagnosed with acute-complex PTSD. From my first session with MDMA-assisted psychotherapy, **I immediately had an obvious reduction in symptoms.** For 20 years, I wanted to be free, and I didn’t get any real healing until MDMA-assisted therapy.” —Rachel Hope



“I think the **MDMA psychotherapy is a personal approach, it’s a relationship.** The MDMA allows the veteran to establish a relationship with the therapist and that’s the most important thing.” —Tim Amoroso, Specialist (Ret.), U.S. Army veteran and combat PTSD survivor



“Let’s remember the fact that we have a veteran population that is hurting. **Let’s think outside the box and get them the help they need.** We as a culture and as a society can do a lot better when it comes to dealing with posttraumatic stress disorder.” —Scott Hudek, Senior Airman (Ret.), U.S. Air Force veteran and combat PTSD survivor



“If you know a veteran, ask them, **if they could be offered a cure for their PTSD, would they take it?** They would be able to be loved and give love again. That’s a very big thing for somebody that’s stuck in trauma and doesn’t remember what love feels like.” —HM2 (Ret.) Lucas Jushinski, U.S. Navy Veteran and combat PTSD survivor



“In our first study, participants had not been adequately helped by previous psychotherapy and medications for PTSD. The average duration of PTSD in that group was 19.5 years. **83% of the subjects who had not responded to other treatments responded to MDMA-assisted psychotherapy.** We see the MDMA as a catalyst to help people have a therapeutic experience that goes to the root of what underlies the symptoms.” —Michael Mithoefer, M.D., psychiatrist, MDMA-assisted psychotherapy researcher



“When it comes to the health and well-being of those who serve, we should leave our politics at the door and not be afraid to follow the data. **There’s now an evidence base for this MDMA therapy** and a plausible story about what may be going on in the brain to account for the effects.” —Brig. Gen. (Ret.) Loree Sutton, founding director of the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury



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.

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CONTENTS

- 2 From the Desk of Rick Doblin, Ph.D.
- 4 Annual Financial Report
Rick Doblin, Ph.D.
- 13 Research News
- 19 Building a Sustainable Non-Profit through MDMA Research
Rick Doblin, Ph.D.
- 25 Rating Adherence and Training Therapists in MDMA-Assisted Psychotherapy for PTSD Research
Evan Michael Sola
Yevgeniy (Zhenya) Gelfand, M.D.
- 28 How Does Clinical Psychedelic Research Support Human Rights?
Jennifer Near
- 30 Findings from a Collective Case Study of the MDMA/Ecstasy Experiences of Adults on the Autism Spectrum: Transcript from Psychedelic Science 2013
Alicia Danforth, Ph.D.
- 36 Will the Obama Administration Stop Standing in the Way of Marijuana Research for Veterans?
Sue Sisley, M.D.
Rick Doblin, Ph.D.
- 40 Cannabinoid Science Sheds New Light on the Darkness of PTSD
Martin Lee
- 43 Zendo Project 2013: Psychedelic Harm Reduction Update
Linnae Ponté
- 47 Working with Trauma: Psychedelic Harm Reduction and Transpersonal Psychotherapy
Sara Girón, M.A.
- 50 Repositioning Psychedelics in the Collective Consciousness
Lakshmi Narayan
- 54 MAPS: Who We Are
- 56 MAPS Membership



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From the Desk of Rick Doblin, Ph.D.



Rick Doblin, Ph.D.

AS WE APPROACH THE END of 2013 and look ahead to 2014, the Multidisciplinary Association for Psychedelic Studies (MAPS) has more opportunities than at any other time in our entire 27½ year history.

We currently have four Phase 2 pilot studies of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) underway—in Charleston, SC; Boulder, CO; Vancouver, Canada; and Beer Yaakov, Israel—and have obtained promising results from our two completed Phase 2 studies in Charleston, SC, and Solothurn, Switzerland. We are also in discussions with the U.S. Veterans Administration (VA) regarding a possible collaborative study of MDMA-assisted psychotherapy in subjects with war-related trauma.

While it's not clear if we can establish a collaboration at this time with the VA, we've never been this far before and it's starting to seem more like a question of "when" rather than "if." We're also simultaneously working on a grant application to the National Institute of Mental Health (NIMH) for our MDMA-assisted psychotherapy research for PTSD—it's a long shot, but success is not out of the question.

The path ahead of us is open to our End-of-Phase 2 meeting with the Food and Drug Administration (FDA) in about 2½ years, the outcome of which (we anticipate) will be an agreement on the design of our Phase 3 MDMA-assisted psychotherapy for PTSD studies. Fortunately, due to a generous bequest from Ashawna Hailey, we have already set aside \$5.3 million in restricted funds to be used toward the currently estimated cost of about \$16 million for two large-scale, multi-site, Phase 3 studies. These Phase 3 studies are required to demonstrate safety and efficacy prior to the approval of MDMA-assisted psychotherapy as a prescription treatment by the FDA, which we expect to take place in 2021.

For the first time ever, we're even able to envision MAPS as a sustainable non-profit with income from sales of prescription MDMA covering some or all of MAPS' future research and educational projects. The article "Building a Sustainable Non-Profit through MDMA Research" on page 19 discusses the assumptions on which we've based our projections, including income, expense, and net income estimates for 2022 through 2031.

In early 2014, we're going to be starting our study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum, to take place at Harbor-UCLA Medical Center/Los Angeles Biomedical Research Institute. We are also seriously considering whether to start developing a new study of the therapeutic use of MDMA-assisted therapy for anxiety, depression, and pain associated with advanced-stage illness.

We're also anticipating that by early 2014, a peer-reviewed journal will have accepted for publication our paper on the results of our Swiss study of LSD-assisted psychotherapy in subjects with anxiety related to advanced-stage illness. We've already resubmitted our revised paper after taking into consideration the initial reviewer comments. We are likely very close to publishing the results of the first LSD-assisted psychotherapy study in over 40 years. The promising results from this initial pilot study have created new opportunities for additional LSD research worldwide.

Even MAPS' efforts to start medical marijuana drug development research—which we began working towards 21 years ago in partnership with Donald Abrams, M.D., at the University of California, San Francisco, but which remains blocked by the National Institute on Drug Abuse (NIDA) monopoly on the supply of marijuana legal for FDA-regulated research—may start moving forward in 2014. The article "Will the Obama Ad-

ministration Stop Standing in the Way of Marijuana Research for Veterans?” on page 36 discusses the resubmission to the Public Health Service (PHS) of our now FDA and University of Arizona IRB-approved protocol to study marijuana in U.S. veterans with chronic, treatment-resistant PTSD. Our arguments for ending the obstructive PHS review process are also starting to gain traction among members of Congress.

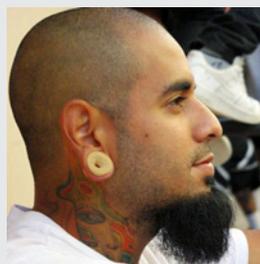
Even our 12-year struggle to start our own medical marijuana production facility in partnership with Prof. Lyle Craker of the University of Massachusetts-Amherst, which has been successfully blocked by the Drug Enforcement Administration (DEA), may become possible in the years to come. Once we’re able to import medical grade marijuana produced in Israel, Canada, or the Netherlands, probably in about two to three years, the NIDA monopoly will have effectively ended and DEA resistance to domestic production is likely to decrease.

The continued support from MAPS supporters has brought us to this place of great opportunity. As a result, we’re increasingly realistic rather than quixotic in our quest to mainstream the careful uses of psychedelics and marijuana, and the healing and spiritual growth that they can catalyze. We won’t take progress for granted, and are proceeding carefully. As I turn 60, I can see that by 70, the dream I had as an 18-year old has an excellent chance of being realized.

Rick Doblin

Rick Doblin, Ph.D.

MAPS Founder and Executive Director



Brian Scott Hampton

COVER ARTISTS

Front cover:
Cosmic Vitruvian
by Brian Scott Hampton
22” x 34”
mixed media on canvas

I was born in El Paso, Texas and raised in Owasso, Oklahoma. I’ve been artistic all my life but it wasn’t until my twenties that I woke up to my calling. Since 2008, learning to paint, traveling, and collaborating with other artists have all opened my mind. The journey has been long and winding, but one full of eye opening and ego dissolving realizations. After 2010, the archetypal role of “artist” was no longer the highest priority. I learned if I contribute my most genuine visions, I’m achieving a creator’s goal, no matter how it fits into the time period I live in. The idea of a right or wrong way to be an artist has all but gone from my head and this has changed my path drastically. My work became a reflection of the world of energy we exist in.

My joy comes from the bliss I feel along the journey. I hindered my own joy for many years by telling myself that my work had to turn out a specific way or it wouldn’t be worthy. Many creative individuals fall victim to this thinking, and the journey fizzles before it even begins. I want to share ways to avoid and conquer this issue. We the created need creative outlets and an open mind to navigate this reality. I feel a powerful calling to broadcast this message, and use my craft as a tool to do so.

For prints and additional artwork, visit stylarosa.com and theyrda.com.



Peter Bynum

Back cover:
No. 230
by Peter Bynum
40” x 40” x 5”
acrylic paint on tempered glass
(6 panels), LEDs, steel bracket

Working in a vast studio on the banks of the Hudson River 40 miles north of Manhattan, Peter Bynum creates vivid optical experiences that illuminate the nature of paint and the structural perfection of nature itself.

Bynum presses paint between 6 to 10 layers of glass, lighting the glass layers from behind. Museum curator Dede Young writes, “Peter Bynum has invented a new way of painting with light, and pushed the language of painting into a new place. It changes the conversation.”

His most recent museum exhibition was at New York’s Museum of Art & Design, where a monumental painting was featured in a survey of the most influential artists of the last half-century who work with glass. His most recent gallery exhibition was a solo show at JanKossen Contemporary in Basel, Switzerland. He is currently working on a series of large paintings for the 5th Avenue windows of the New York Public Library.

“The communion of paint, botany, biology and divinity is what interests me and drives the work forward. On a social and political level, the goal is to illuminate the life-force in action, create beauty, and present the natural world as a divine gift to be respected and exalted.” —Peter Bynum

For additional artwork and information, visit peterbynum.com.

Annual Financial Report

Fiscal Year 2012–13 (June 1, 2012–May 31, 2013)

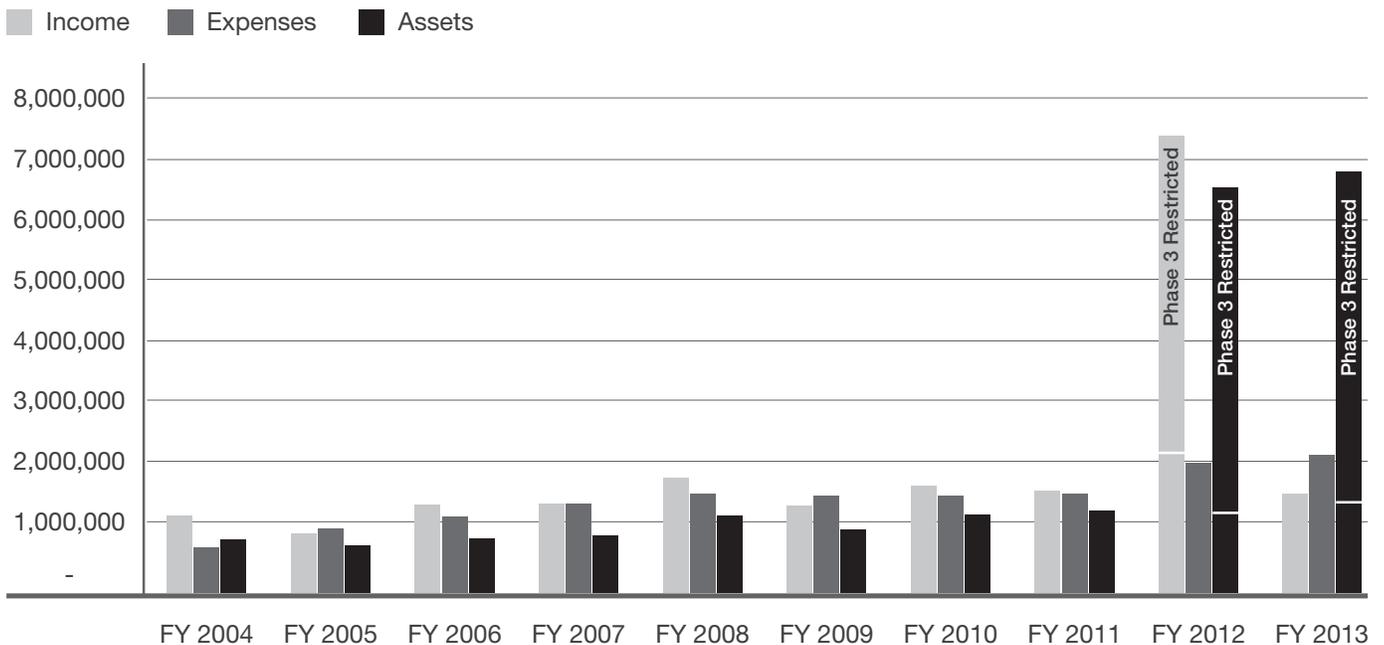
RICK DOBLIN, Ph.D.

THIS YEAR-END FINANCIAL REPORT from the Multidisciplinary Association for Psychedelic Studies (MAPS) is a key element of our commitment to transparency and clear communications about our finances. This report depicts our year-long focus on strategically and efficiently leveraging resources that our donors have so generously empowered us to use towards realizing our shared mission of transforming psychedelics and marijuana into FDA-approved prescription medications. The medicalization of psychedelics and marijuana is an essential part of our larger

mission to facilitate the mainstreaming of psychedelics into our culture for a wide range of beneficial uses with associated harm reduction practices.

As I write this report, we’ve just completed an independent audit of our financial information for the third year in a row. These audits are part of a concerted effort to raise funds from major foundations and government agencies, both of which require such audits. The audits are also helpful for individual donors and family foundations that feel more comfortable

Chart 1. MAPS FISCAL YEAR 2004–2013 INCOME, EXPENSES & ASSETS



knowing that MAPS' books are independently audited. In FY 2013–14, and in the years to come, we must expand our sources of funding so we can generate the resources needed to complete our Phase 2 studies of MDMA-assisted psychotherapy for PTSD, to initiate and fund the Phase 3 multi-site MDMA/PTSD studies, and to fund our other research and educational activities.

What follows is a comprehensive reporting and discussion of MAPS' financials for FY 2012–13 (June 1, 2012 to May 31, 2013). Should you have any questions about anything in this financial report, you are invited to inquire at askmaps@maps.org.

OVERVIEW

MAPS' income in Fiscal Year 2012–13 was \$2.4 million, expenses were \$2.14 million, increase in net assets was \$264,000, and total assets at year-end were \$6.9 million. Of these assets, \$5.5 million are in a Board Restricted Fund. This Fund was created last year, from a bequest received from the estate of Board member Ashawna Hailey. We restricted \$200,000 as funding of last resort for a study of MDMA for the treatment of social anxiety in adults on the autism spectrum, with the balance (\$5.3 million) restricted to our Phase 3 studies of MDMA-assisted psychotherapy for PTSD. We restricted most of Ashawna's bequest to Phase 3 MDMA/PTSD studies in order to leverage the bequest to help raise the additional \$11 million of the estimated \$16 million that will be required for Phase 3. With such a substantial percent of the Phase 3 budget already in hand, there is an increased likelihood that we will be able to motivate donors to fund the remaining costs since reaching the goal isn't so intimidating. In addition, reserving \$5.3 million of Ashawna's bequest for Phase 3 should make it easier for MAPS to raise the roughly \$2.5 million estimated to complete Phase 2 since we have increased our ability to fully fund Phase 3.

AN EXPRESSION OF OUR GRATITUDE

Gifts Over \$9,000 in Fiscal Year 2012–13
All gifts are for general expenses, except where noted.

Peter Lewis	\$402,160
Joby Pritzker	\$200,000
David Bronner	\$130,000
Riverstyx, Cody Swift	\$90,000
<i>For qualitative studies in our MDMA/PTSD trials (\$15,000), for general MDMA/PTSD expenses (\$72,500) and for Canadian researcher travel to Psychedelic Science conference (\$2,500).</i>	
Adam Wiggins	\$60,000
Libra Foundation	\$52,500
<i>For MDMA/PTSD Veterans study in South Carolina (\$40,000), and office intern support (\$12,500)</i>	
Mental Insight Foundation	\$50,000
<i>For MDMA/PTSD Veterans study in South Carolina</i>	
Anonymous	\$40,000
Richard Rockefeller	\$37,500
<i>For MDMA/PTSD study using interns in Colorado</i>	
Larry Thomas bequest	\$26,352
John Gilmore	\$25,000
Anonymous	\$21,500
Carey & Claudia Turnbull	\$20,750
<i>For MDMA/PTSD study using interns in Colorado</i>	
Robert Barnhart	\$15,715
A. Miller	\$15,250
<i>For MDMA/PTSD study using interns in Colorado</i>	
Ian Brown	\$15,000
David Rockefeller Fund	\$15,000
<i>For MDMA/PTSD study using interns in Colorado</i>	
Arsenault Family Foundation	\$15,000
Joakim Arfvidsson	\$12,000
Josh Mailman Foundation	\$10,000
Lisa Blue	\$10,000
Vanja Palmers	\$9,050
<i>For MDMA/PTSD study using interns in Colorado</i>	

We began FY 2012–13 with a budget projecting that we would spend almost half a million dollars more than we knew we could raise from existing sources. Nevertheless, we decided that it was essential to go full speed ahead with our research and we were willing to draw down much of our unrestricted reserves. However, through a series of fortuitous events, we managed to end FY 2012–13 in the black and raised \$264,000 more than we spent.

Among the leading reasons for this remarkable outcome in FY 2012–13 are that: Peter Lewis donated \$402,000 to MAPS, almost double his gift of the prior fiscal year; Joby Pritzker donated \$200,000, twice what we had estimated; we earned over \$130,000 from the Psychedelic Science Conference when we'd

estimated a break-even; we obtained over \$100,000 from first time major donors; and we invested Ashawna's bequest with the San Francisco Foundation which increased our assets in value by about \$246,000. Finally, and the only unfortunate aspect to this financial surplus, is that a substantial amount of research expenses were delayed due to slower than anticipated approvals from regulatory agencies. These anticipated expenses will be incurred in future years. At the time I'm writing this report, we've obtained all the regulatory approvals we've been seeking for our international series of Phase 2 MDMA/PTSD pilot studies. We're projecting MDMA-related research direct expenditures for FY 2013–14 of about \$1.3 million, almost double our FY 2012–13 expenditures.

Chart 2. STATEMENT OF ACTIVITIES

Fiscal Year 2012–13 (June 1, 2012–May 31, 2013)

Revenue	
Support from Individuals	1,167,610
Support from Foundations	290,131
Event Income	541,804
Sales	73,649
Bequests	26,353
Donated Goods and Services	60,441
Fiscal Sponsorship Income	23,546
Net Investment and Other Income	246,558
Total Revenue and Support	\$ 2,430,092
Cost of Goods Sold	22,020
Net Revenue	\$ 2,408,072
Expenses	
Research	796,107
Education	752,531
Total Programs	1,548,638
Fundraising	162,263
Administration	433,105
Total Expenses	\$ 2,144,006
Change in Net Assets	\$ 264,066

Chart 3. STATEMENT OF FINANCIAL POSITION

Fiscal Year 2012–13 (at May 31, 2013)

Assets	
Cash and Equivalents	1,045,070
Pledges Receivable	1,407,037
Other Current Assets	4,443,921
Total Assets	\$ 6,896,028
Liabilities	
Accounts Payable & Accrued Expenses	89,600
Total Liabilities	\$ 89,600
Net Assets	
Unrestricted	1,139,142
Board Restricted ¹	5,513,346
Temporarily Restricted	153,940
Total Net Assets	\$ 6,806,428
Total Liabilities and Net Assets	\$ 6,896,028

1) \$5.3 million of this fund is restricted to Phase 3 drug development of MDMA-assisted psychotherapy for the treatment of PTSD; the balance is restricted to the MDMA Adult Autism study.

REVENUE SUMMARY

MAPS' total income for FY 2012–13 was \$2.4 million, of which \$1,544,535 (64%), was contributed support. MAPS received \$1,272,777, from 22 individuals and family foundations giving \$9,000 or more, and \$118,944 from 47 donors giving between \$1,000 and \$10,000. An additional \$92,373 was received from 1,145 individuals giving under \$1,000. These donations of less than \$1,000 are a crucial part of MAPS' success—they help us cover our operational expenses, are part of building the MAPS community, lead to word-of-mouth contacts with new donors, and are the way donors began to get to know MAPS by enabling them to evaluate our work before they make a larger gift. In addition, \$60,441, worth of auction items, professional time,

and event venues were donated to help MAPS' fundraising and clinical activities.

Sales of books, art, clothes and other items totaled \$73,649. Event Income of \$541,804 is from all our events this year, primarily from the Psychedelic Science Conference. For all events, income sources are: \$506,227 tickets; \$10,929 commission on art sales; \$4,775 vendor fees, and \$15,775 auction income. Total Psychedelic Science Conference revenue was \$589,298, from these sources, plus sponsorships and other miscellaneous income. Investment income includes \$246,558, net of fees, from our assets invested at the San Francisco Foundation. Our fiscal sponsorship revenue of \$23,546 is re-granted to the groups that raise the funds, minus a small administrative fee.

Chart 4. TEMPORARILY RESTRICTED, BOARD RESTRICTED, AND OTHER RESTRICTED FUND DETAIL

Fiscal Year 2012–13 at May 31, 2013

	Temporarily Restricted	Board Restricted
MDMA Studies		
US MDMA/PTSD Veterans	27,532	-
US MDMA/PTSD Interns	70,551	-
US MDMA/PTSD Phase 3	-	5,331,613
US MDMA Adult Autism	-	181,733
US MDMA Qualitative	15,000	-
Total MDMA	\$ 113,083	\$ 5,513,346
Marijuana Studies		
Vaporizer Study	10,364	-
Start Up Fund (UMass Amherst)	3,900	-
Total Marijuana	\$ 14,264	-
Other Studies		
New Zealand Ibogaine	6,226	-
LSD/Psilocybin General	19,367	-
Ketamine Research	1,000	-
Total Other Studies	\$ 26,593	-
Total Temporarily & Board Restricted Funds	\$ 153,940	\$ 5,513,346

EXPENSE SUMMARY

MAPS' expenses in Fiscal Year 2012–13, totaled \$2.14 million. 37% was spent on research; 35% on education, including the Psychedelic Science Conference; 20% was management and general operations; and 8% was spent on the cost of fundraising.

Research is MAPS primary activity. Our focus has been, and will continue to be, on our MDMA Research (\$796,107). Our four main studies for MDMA-assisted psychotherapy for the treatment of PTSD take place in Vancouver, Canada; Beer Yaakov, Israel; Boulder, Colorado; and Charleston, South Carolina. Over half our expenses for these studies are for personnel. These include MAPS internal staff: the clinical director, research associates, information specialists, data coordinators, and statistical analysis. Site staff includes the principal and co-investigators, independent raters, overnight physicians, attendants, and study coordinators. In our Veterans study (\$262,555 in FY 2012–13), staff and contractors fees are 64% of the expenses. Other significant expenses are for subject travel and lodging (18%), and facilities (13%). Most studies follow a similar pattern.

In addition to the direct study expenses, we had MDMA-study related program expenses including the staff costs of video data storage and streaming systems development, budgeting, contracting, and meetings (\$49,216), the costs of developing the treatment manual (\$10,260), the training of therapists (\$8,166), and blinded therapist adherence training (\$4,829). We also have the costs of MDMA-study related supervision of therapists, presentation of our data at conferences, and speaking to the media (\$68,859).

Our Clinical Research General costs (\$89,448) are primarily staff costs related to developing the infrastructure needed for our clinical trials, including work with communications and fundraising departments, staff professional development and conferences, and video streaming and statistical software. The clinical research general expenses are related to our various MDMA studies.

Expenses in FY 2012–13 for Ibogaine research were dedicated to finalizing our studies in Mexico (\$7,653), and New Zealand (\$2,914). FY 2012–13 LSD expenses (\$26,294) were used to complete the study. In FY 2013–14 we will publish our LSD end of life article in a peer-reviewed journal, and develop a protocol

Chart 5. MAPS FY 2012–13 ACTUALS COMPARED TO FY 2013–14 PROJECTED DETAIL EXPENDITURES

Research	FY 2012–13 Actual	FY 2013–14 Projected
Ibogaine		
IOA-3 Ibogaine (Mexico)	7,653	2,200
IOA-4 New Zealand	2,914	6,226
Total Ibogaine	10,567	8,226
LSD/Psilocybin		
General	724	100
LSD Creativity	-	10,000
LSD Swiss End of Life Study	25,570	9,500
Total LSD/Psilocybin	26,294	19,600
Marijuana		
General	1,361	200
MJ Production Facility/UMass Amherst	1,000	-
MJP-1 Cannabis PTSD	6,214	2,000
Israel MMJ/PTSD Study	1,485	200
Total Marijuana	10,060	2,400
MDMA		
MDMA Lit Review	7,831	2,375
MDMA PTSD-Australia	272	-
MDMA PTSD-Canada	13,604	202,194
MDMA PTSD-England	137	1,000
MDMA PTSD-Israel	90,294	188,458
MDMA PTSD-Jordan	420	-
MDMA PTSD-Swiss	4,218	250
MDMA PTSD-US Intern: Boulder	73,623	298,216
MDMA PTSD-US Pilot	11,651	4,000
MDMA PTSD-US Relapse Treatment	15,741	2,400
MDMA PTSD-US Vets: Charleston	262,555	328,238
MDMA PTSD-US Dept. Defense	14,768	-
MDMA Research General	49,216	50,000
MDMA Supply	3,987	5,000
MDMA Therapist Adherence & Training	4,829	6,000
MDMA Therapy Training Protocol	8,166	13,400
MDMA Treatment Manual	10,260	-
MDMA-US Autism	17,998	66,844
MDMA NIMH	798	3,000
MDMA Qualitative	-	3,100
End of Phase 2 Meeting	-	500
Mithoefer Supervisory/PR Time	68,859	20,000
Mithoefer Therapist Training Program	511	1,000
Clinical Research General	89,448	80,105
Total MDMA	749,186	1,276,080
Total Research	\$ 796,107	\$ 1,306,306

Education	FY 2012–13 Actual	FY 2013–14 Projected
Conferences & Events		
Psychedelic Science 2013	445,743	-
Bioneers	-	1,100
Breaking Convention	-	5,300
Cannabis Cup: LA, SF, Seattle	1,872	2,550
Club Health	-	150
Harm Reduction (Zendo Project)	28,727	20,161
Horizons	3,305	3,000
Institute for Noetic Science	-	550
Knowphest	504	-
Mental Health Conference	3,289	-
Reform Conference 2013 (DPA)	-	1,500
Science and Nonduality	-	150
Spirit, Plant, Medicine	-	600
Stitching Open	3,367	-
Toward a Science of Consciousness	-	1,200
Wisdom 2.0	1,078	-
Women’s Visionary Congress	123	125
Events Staff and General Expense	17,828	24,854
Total Conferences & Events	505,834	61,240
Communications		
Bulletins, Book Publishing, Prospectus	54,044	33,050
Email Newsletter	3,427	6,979
Internet/Webhosting	7,500	5,200
Media	7,447	2,600
Social Media	2,649	1,600
Web and Multimedia	14,841	19,800
Staff and General Expense	133,086	112,014
Total Communications	222,995	181,243
Total Education	\$ 728,829	\$ 242,483
Fiscal Sponsorships	\$ 23,702	\$ 103,439
Total Programs (Research, Education, Fiscal Sponsorships)	\$ 1,548,638	\$ 1,652,228
Fundraising		
Events	8,238	15,600
Fundraising Staff and General Expense	154,025	167,846
Total Fundraising	\$ 162,263	\$ 183,446
Operations		
Business Expenses	22,351	26,594
Audit, & Tax	22,665	18,000
Accounting, Bookkeeping, & Legal	52,474	63,500
Information Technology	29,893	54,610
Facilities and Equipment	5,004	9,600
Occupancy	39,642	42,088
Office Supplies, Phones, Postage, Printing	34,604	33,464
Staff Development	4,627	6,600
Travel	2,653	6,200
Operations Staff	219,192	166,891
Total Operations	\$ 433,105	\$ 427,547
Total Expenses	\$ 2,144,006	\$ 2,263,221

for LSD and creativity. Our Marijuana/PTSD study is still in the protocol approval process. FY 2012–13 funds (\$6,214) were used to obtain FDA and IRB approval, and FY2013–14 funds (\$2,000) will be used to continue our work to secure marijuana from the National Institute on Drug Abuse (NIDA). (See article on page 36.)

Education (\$728,829) expenses include events, and publications and communications programs. Events expense (\$505,834) includes the Psychedelic Science Conference, our largest non-clinical activity for the year, held in April 2013 (\$445,743 in FY 2012–13). Over 1,900 people attended the conference and associated events, which presented over 100 speakers from more than 30 countries. Our Zendo psychedelic harm reduction program (\$28,727) offered services at festivals in the Black Rock Desert, Nevada; at BOOM in Portugal; AfrikaBurn, South Africa; and Envision, Costa Rica; and produced a Harm Reduction manual, available for free on the MAPS website. In addition, MAPS staff attended more than 18 events that others produced, and provided speakers, exhibits, sales of books and MAPS bulletins, and free distribution of clinical protocols, and articles from peer reviewed journals.

Publications (\$222,995) included three editions of the Bulletin, the development and management of our comprehensive website on psychedelic research, the writing and distribution of 12 monthly e-newsletters, and the implementation of spirited public relations campaigns that share current research on psychedelics and marijuana with TV, print and online journalists internationally. MAPS also published two books, Claudio Naranjo’s *The Healing Journey*, and Torsten Passie’s *Healing with Entactogens*.

Our Fiscal Sponsorship program (\$23,702) provided fundraising assistance to organizations that are in close alignment with our mission and values, including: Bluelight, Yawanawa ayahuasca project, WAMM, and the Temple of Wholyness at Burning Man.

Fundraising costs are primarily for staff, direct mail, donor research and database costs, MAPS produced events, and travel and lodging for individual donor visits. Operations are the unglamorous but necessary unallocated expenses of staffing, occupancy, taxes, fees, accounting, information technology, equipment, supplies, and postage.

Chart 6. MAPS FY 2013–14 PROJECTED FINANCIALS

June 1, 2013–May 31, 2014

Revenue	FY13–14
Support from Individuals	1,563,527
Support from Foundations	299,747
Fiscal Sponsorships	108,884
Event Income	5,000
Sales	67,476
Investment and Other Income	224,887
Total Revenue	\$ 2,269,521
Cost of Goods Sold	6,300
Gross Revenue	\$ 2,263,221
Expenses	
Research	1,306,306
Education	242,483
Fiscal Sponsorships	103,439
Total Programs	1,652,228
Fundraising	183,446
Administration	427,547
Total Expenses	\$ 2,263,221
Statement of Net Assets	
Change in Net Assets	-
Temporarily Restricted Assets	40,351
Board Restricted Assets	5,513,346
Unrestricted Assets	1,252,731
Net Assets May 31, 2014	\$ 6,806,428

FISCAL YEAR 2013–14 SUMMARY

MAPS faces a major fundraising challenge in FY 2013–14 and beyond. Although our revenue has grown over the last few years, our clinical expenses may outpace our fundraising for the first time. We have all the regulatory approvals required for our MDMA/PTSD studies in Israel, Canada, and two in the US. We're predicting that we may more than double our MDMA/PTSD research expenses to an estimated \$1.3 million of direct expenses in FY 2013–14. At the start of FY 2013–14, we estimate that we need about \$750,000 in new revenue in order to breakeven. With the success of our research, our financial needs to develop MDMA-assisted psychotherapy into a prescription medicine in the treatment of PTSD will keep increasing.

Nevertheless, MAPS' fundraising goals for FY 2013–14 are attainable. The need for research into the healing potential of psychedelics is profound, we are building a track record of success, and interest in our work is growing.

MAPS' mission has always been ambitious. As you contemplate your charitable donations, we offer this detailed report on our income and expenses so you can see exactly where our money comes in and where it goes. You can also see our audited statements and IRS Form 990 at maps.org/about/fiscal. Please consider making a generous donation to MAPS and mentioning MAPS in your will. What was once forbidden, even for research, is now being studied and will, with your help, become an accepted and mainstream option for healing, inspiration, and spirituality.

TIME AND COST ESTIMATES FOR MDMA/PTSD PHASE 2 AND PHASE 3 STUDIES: FY 2013–2021

Chart 7 (page 11), shows the actuals and projected expenses for MAPS' ongoing MDMA/PTSD Phase 2 pilot studies, along with the associated projects needed to complete these studies. MAPS expects to spend an additional \$2.5 million to complete Phase 2. These studies lay the groundwork for a Federal Drug Administration (FDA) End-of-Phase 2 meeting in 2016. The purpose of this meeting is to come to agreement with the FDA on the design of MAPS' two required large-scale multi-site Phase 3 studies evaluating safety and efficacy prior to prescription approval. Chart 8 (page 12) shows our current estimates for these Phase 3 studies. These estimates for the pivotal Phase 3 studies are our best guesses and will become more definitive after the End-of-Phase 2 meeting, and agreement on the study designs. 🌀

Chart 7. MDMA/PTSD PHASE II RESEARCH PROJECTS

Key MDMA Research Projects	Actuals 2009–10	Actuals 2010–11	Actuals 2011–12	Actuals 2012–13	Projected 2013–14	Projected 2014–15	Projected 2015–16	Projected 2016–17
US MDMA/PTSD Pilot	110,000	19,241	7,239	11,651	4,400	-	-	-
US MDMA/PTSD Relapse	-	5,845	19,567	15,741	2,640	11,000	-	-
US MDMA/PTSD Veterans	35,806	147,600	202,867	262,555	361,062	184,329	32,712	26,313
US MDMA/PTSD Intern	-	-	20,885	73,623	328,038	109,375	24,418	16,691
Swiss MDMA/PTSD	33,500	30,666	25,544	4,218	275	-	-	-
Israel MDMA/PTSD	27,308	33,696	43,861	90,294	207,304	47,255	8,074	5,060
Canadian MDMA/PTSD	9,814	8,615	2,433	13,604	222,413	259,366	41,381	23,753
Jordanian MDMA/PTSD	31,456	21,458	1,831	420	-	-	-	-
MDMA Therapist Training (MT-1)	15,038	19,244	14,335	8,166	14,740	-	-	-
MDMA NIMH	-	-	-	798	3,300	-	-	-
MDMA Qualitative	-	-	-	-	3,410	3,410	5,830	3,850
Total Key MDMA/PTSD Research Projects	\$ 262,922	\$ 286,365	\$ 338,563	\$ 481,070	\$1,147,582	\$ 614,735	\$ 112,415	\$ 75,667
Associated MDMA Research Projects								
End-of-Phase-2 Meeting w/ FDA	-	-	-	-	550	11,000	17,600	-
England MDMA/PTSD	-	-	-	-	1,100	-	-	-
MDMA Literature Review	3,256	6,063	3,764	7,831	2,613	4,400	4,400	-
MDMA Therapist Adherence Criteria	-	-	-	4,829	6,600	5,500	5,500	-
MDMA Therapist Training	-	-	-	511	1,100	-	-	-
MDMA Treatment Manual	8,752	5,219	1,001	10,260	-	3,300	5,500	-
MDMA Researchers Retreats	27,067	2,092	-	-	-	-	-	-
Mithoefer Supervisory/PR Time	27,951	33,975	49,701	68,859	22,000	22,000	22,000	-
Site Differences in CAPS Scores	-	400	71	-	-	-	-	-
MDMA Supply	-	-	-	3,987	5,500	-	-	-
MDMA PTSD-US Dept. Defense	-	-	-	14,768	-	-	-	-
MDMA Research General	11,404	54,911	32,294	49,625	55,000	61,409	65,579	-
Clinical Research General	38,036	38,885	40,583	89,448	88,114	94,958	99,708	-
Total Associated Projects	\$ 116,466	\$ 141,545	\$ 127,414	\$ 250,119	\$ 182,577	\$ 202,567	\$ 220,287	-
Total MDMA Projects	\$ 379,388	\$ 427,910	\$ 465,976	\$ 731,189	\$1,330,159	\$ 817,302	\$ 332,702	\$ 75,667

FY 2009–2012 Actual Cost \$2,022,461 over past four years

FY 2013–2016 Projected Costs \$2,555,830 over next four years

Expenses include direct costs and a 10% overhead allocation.

Chart 8. MDMA/PTSD PHASE III COST PROJECTIONS

Phase III MDMA/PTSD Research Projects	Projected 2014–15	Projected 2015–16	Projected 2016–17	Projected 2017–18	Projected 2018–19	Projected 2019–20	Projected 2020–21
MDMA Supply	220,000	220,000	-	-	-	-	-
MDMA Therapist Training-Protocol (MT-1)	34,381	130,360	139,685	75,516	-	-	-
MDMA Literature Review	-	-	4,400	4,400	4,400	4,400	4,400
MDMA Therapist Adherence Criteria	-	-	5,500	20,000	20,000	20,000	-
MDMA Therapist Training	9,000	22,000	22,000	11,000	-	-	-
MDMA Research General	-	-	71,958	75,558	79,334	83,301	87,466
Clinical Research General	-	-	104,692	109,926	115,422	121,194	127,253
Phase III Trial 1	-	10,000	2,000,000	2,000,000	2,000,000	1,000,000	
Phase III Trial 2	-	10,000	5,000	2,000,000	2,000,000	2,000,000	1,000,000
NDA Process	-	-	-	-	-	-	30,000
Total Phase III MDMA/PTSD Research	\$ 263,381	\$ 392,360	\$ 2,353,235	\$ 4,296,400	\$ 4,219,156	\$ 3,228,895	\$ 1,249,119

Total Phase III Projected Costs \$16,002,546 over seven years

“My hope in working with trauma is that through enhanced awareness, we can remember what was forgotten in the darkness of despair...that there is potential for growth in every situation.”

—Marcela Ot’alora, LPC, MDMA-assisted psychotherapy researcher, Boulder, CO

“All of my neurons and potential were wide awake and I could see things more as they were. I felt empowered to say, ‘I don’t have to be afraid anymore. No one is out to get me.’ I could actually sort of rewire myself.”

—Rachel Hope, MDMA-assisted psychotherapy for PTSD study participant

Research News

Treating PTSD with MDMA-Assisted Psychotherapy

mdmaptsd.org

14th Subject Treated in Ongoing Veterans Study; Agencies Approve Amended Protocol

Ongoing study

Location: Charleston, South Carolina

Principal Investigator: Michael Mithoefer, M.D., with co-therapist Annie Mithoefer, B.S.N.

Estimated study budget: \$1,395,000

Already raised: \$881,000

Needed to complete this study: \$513,000

On November 8, 2013, the 14th subject began treatment in our ongoing study of MDMA-assisted psychotherapy for 24 U.S. veterans, firefighters, and police officers with service-related PTSD. On October 3, the U.S. Drug Enforcement Administration approved the amended study protocol. The change includes an addition of a 100 mg dose condition (along with 30 mg, 75 mg, and 125 mg). The randomized, triple-blind protocol amendment received approval from the Food and Drug Administration on October 6 after passing the 30-day review period without comment, with approval from the Institutional Review



Principal Investigator Michael Mithoefer, M.D., and co-therapist Annie Mithoefer, B.S.N., led a workshop on MDMA-assisted psychotherapy at Psychedelic Science 2013.

Board on August 28. There are currently over 450 people on the waiting list for this study for 11 more openings, sadly demonstrating the large number of treatment-resistant veterans and first responders with PTSD.

Goals for this study include (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.

Second and Third Subjects Treated in New Boulder Study; IRB Approves Amended Protocol

Ongoing study

Location: Boulder, Colorado

Clinical Investigator: Marcela Ot'alora, M.A., L.P.C.

Estimated study budget: \$582,000

Already raised: \$193,000

Needed to complete this study: \$389,000

On October 4 and 9, 2013, the second and third subjects began treatment in our ongoing study of MDMA-assisted psychotherapy for PTSD in Boulder, Colorado. Both subjects are women suffering from chronic, treatment-resistant PTSD

as a result of sexual abuse. On August 13, the Institutional Review Board approved an amended protocol, which includes changes to the dosing schedule (adding a 100 mg dose condition) and the addition of two



Encapsulated MDMA for the study in Boulder, Colorado.

safety measures. Led by Clinical Investigator Marcela Ot'alora, this study is exploring the safety and effectiveness of MDMA-assisted psychotherapy when one member of the male/female co-therapist team is an experienced therapist and the other is an intern being trained in therapy, social work, or nursing. The study will enroll 12 subjects with PTSD due to sexual assault, military combat, or other causes. Recent flooding in Boulder delayed experimental treatment sessions by about a month, and caused damage to our treatment room that has now been repaired.

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.

Third Subject Enrolled; First Two Subjects Complete 2-Month Follow-Up in Israeli Study

Ongoing study

Location: Beer Yaakov, Israel

Clinical Investigator: Moshe Kotler, M.D.

Estimated study budget: \$463,000

Already raised: \$39,000

Needed to complete this study: \$423,000

On October 30, 2013, the third subject was enrolled in our ongoing Israeli study of MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD. Two-month follow-up evaluations were conducted for the first two subjects on September 17 and October 3. This third subject will enable our third (of three) co-therapist team to start treating subjects.

This study will enroll 10 subjects, some of whom will be soldiers with war-related PTSD referred by the Israeli Defense Forces. Led by Clinical Investigator Moshe Kotler, M.D., this study is taking place at Beer Yaakov Mental Hospital. Adherence ratings for the first two subjects' treatment sessions were completed on July 31.



The setting for MDMA-assisted psychotherapy at Beer Yaakov Mental Hospital, Israel.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD mostly related to war and terrorism, (2) comparing different doses of

MDMA for therapeutic effectiveness and ability to create a successful double-blind, (3) working in direct association with the Israeli Ministry of Health, and (4) exploring the use of MDMA-assisted psychotherapy in other cultural contexts.

Canadian Study: Health Canada Approves Protocol Amendments

Study pending initiation

Location: Vancouver, British Columbia, Canada

Principal Investigators: Ingrid Pacey, M.D. and Andrew Feldmar, Ph.D.

Estimated study budget: \$592,000

Already raised: \$16,000

Needed to complete this study: \$576,000

On September 6, 2013, Health Canada approved an amended protocol for our upcoming Canadian study of MDMA-assisted psychotherapy for PTSD. The amendments include several changes to the study design to complement our other ongoing studies around the world, including changes to dose levels (adding a 100 mg dose condition), the schedule of subject visits, and the timing of treatment outcome assessments. Aligning our study protocols across sites enables us to compare data and make a stronger case for future Phase 3 studies. On August

20, the amended protocol was submitted to the U.S. Food and Drug Administration, and the initiation visit was conducted from August 22–24. After working for over five and a half years, we can now start screening subjects once the study site is set up.



Encapsulated MDMA in safe storage for the Canadian study.

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.

All Treatments Completed in Relapse Study

Ongoing study

Location: Charleston, South Carolina

Principal Investigator: Michael Mithoefer, M.D.

Needed to complete this study: \$55,000 still needed

All treatments have been completed in our relapse study of MDMA-assisted psychotherapy for three subjects whose PTSD symptoms returned after participating in our now-completed U.S. flagship study, which was completed in July 2010. Treatment in the relapse study consisted of a single open-label full dose session of MDMA-assisted psychotherapy, accompanied by non-drug preparation and integrative psychotherapy sessions. On April 27, 2012, the first subject completed their one-year follow-up interview, which revealed that the subject's score on the Clinician-Administered PTSD Scale was below the diagnostic cutoff for PTSD. The last follow-up interview is scheduled for May 2014.

The goal of this study is to determine whether a single additional MDMA-assisted psychotherapy session can restore subjects who relapsed following successful prior treatment with MDMA-assisted psychotherapy.

Researcher Claims Swiss Study Showed Large Treatment Effect, Not Small

Study completed

Location: Solothurn, Switzerland

Clinical Investigator: Peter Oehen, M.D.

This study is complete and has been fully funded.

On August 27, 2013, the *Journal of Psychopharmacology* published a Letter to the Editor from a researcher not affiliated with MAPS or with our completed Swiss pilot of MDMA-assisted psychotherapy for 12 subjects with chronic, treatment resistant PTSD. The letter, by Henri Chabrol of the University of Tou-

louse, France, pointed out that the study had a large effect size not previously reported in the January 2013 publication of the results in the same journal. The study paper describes clinically significant decreases in PTSD symptoms following MDMA-assisted psychotherapy that approached statistical significance (0.06), remarkable in such a small pilot study. In the unsolicited yet most welcome letter, Chabrol explains why our traditional statistical method should have been supplemented by an effect size calculation, and in fact subjects showed “on average, a substantial improvement in PTSD symptoms over the course of MDMA-assisted psychotherapy.” The journal also published a reply from study Principal Investigator Peter Oehen, M.D. The original paper was co-authored by Dr. Oehen along with Ulrich Schneider, M.D., former president of the International Society for Traumatic Stress Studies, the world’s largest organization for PTSD treatment providers and researchers. Receiving this unsolicited positive feedback on our results from an independent expert highlights both the importance of international collaboration in psychedelic research and the sincere caution with which we report our results.

Goals for this study included (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD in a different cultural context, and (2) pioneering the use of low dose MDMA as an active placebo.

Australian Study: Researchers Continue Working to Start Study *Study awaiting approval*
Location: Australia

In April 2013, Steve McDonald and Martin Williams of Psychedelic Research in Science and Medicine (PRISM) flew from Australia to attend Psychedelic Science 2013 in Oakland, California, where they discussed strategy with the MAPS clinical

team and other international researchers on how to work towards creating an approvable study in Australia. In July 2012, the Ethics Committee rejected our protocol for an Australian study of MDMA-assisted psychotherapy for PTSD. We are continuing to explore options for initiating this research in Australia.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD in a different cultural context, and (2) initiating the first clinical psychedelic research in Australia.

Therapists Receive MDMA-Assisted Psychotherapy in Training Protocol *Ongoing study*

Location: Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D., with co-therapist Annie Mithoefer, B.S.N.
Estimated study budget: \$460,000
Already raised: \$8,000
Needed to complete this study: \$452,000

In this randomized, double-blind, placebo-controlled crossover study, researchers administer a single MDMA-assisted psychotherapy session to healthy volunteers as part of training to be therapists in a MAPS-sponsored study of MDMA-assisted psychotherapy for PTSD. As of November 2013, three subjects have completed this study, all therapists in our ongoing Israeli study of MDMA-assisted psychotherapy for PTSD. This study is limited to therapists already involved in MAPS’ clinical research program, and was approved by the FDA in October 2009.

Goals for this study include (1) providing therapists with direct experience of MDMA when taken in a therapeutic context to enhance their ability to conduct effective MDMA-assisted psychotherapy, and (2) collecting additional data on the safety of MDMA-assisted psychotherapy in healthy volunteers taking MDMA in a therapeutic context.

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MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

Protocol Changes Approved by IRB and State Advisory Panel *Study awaiting approval*

Location: Los Angeles, California

Principal Investigators: Charles Grob, M.D., and Alicia Danforth, Ph.D.

Estimated study budget: \$302,000

Already raised: \$1,000

Needed to complete this study: \$301,000

On October 16, 2013, the Institutional Review Board (IRB) approved the amended protocol for our planned study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum, to be led by Principal Investigator Charles Grob, M.D., and Alicia Danforth, Ph.D., at Harbor-UCLA Medical Center/Los Angeles Biomedical Research Institute. On September 30, the Research Advisory Panel of California (RAPC) approved the amended protocol. The RAPC review is an additional layer of approval required only in California for research with Schedule I drugs. The study will begin screening and enrolling subjects after the research pharmacy and principal investigator receive their Schedule I licenses from the Drug Enforcement Administration, for which applications were respectively submitted on October 2 and October 9. Dr. Grob has already received his DEA Schedule I license and the pharmacy license is in process. We anticipate that we will be able to begin screening subjects in early 2014.

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.

LSD-Assisted Therapy for Anxiety

Final Report Submitted from Swiss Study; Paper Resubmitted for Publication *Study completed*

Location: Solothurn, Switzerland

Principal Investigator: Peter Gasser, M.D.

This study is complete and has been fully funded.



The last LSD capsule from the Swiss study.

On September 17, 2013 the Final Report for our completed study of LSD-assisted psychotherapy for anxiety associated with life-threatening illness was submitted to Swissmedic. The

report includes information about the study protocol, how the study was conducted, and all data in both raw and analyzed formats. This report is required under International Council on Harmonization/Good Clinical Practice (ICH/GCP) as well as FDA regulations. Led by Principal Investigator Peter Gasser, M.D., the first subject was enrolled on April 23, 2008, and the last long-term follow-up interview was conducted on August 8, 2012. On November 14, 2013, the paper describing the results was resubmitted for publication in the *Journal of Nervous and Mental Disease* with responses to reviewer comments.

Goals for this study were (1) gathering evidence for the safety and effectiveness of LSD-assisted psychotherapy for subjects with anxiety related to advanced-stage illness, and (2) completing the first study of LSD humans in over 40 years.

Ibogaine Therapy for Addiction Treatment

Tenth Subject Enrolled in New Zealand Ibogaine Study; Treatment Death Pauses Enrollment and Raises Safety Concerns *Ongoing study*

Location: New Zealand

Principal Investigator: Geoff Noller, Ph.D.

Donations are needed to support ibogaine research.

On September 20, 2013, the 10th participant was enrolled in our ongoing observational study of ibogaine-assisted treatment for opioid dependence in New Zealand. In this study, Principal Investigator Geoff Noller, Ph.D., is collecting follow-up data from subjects undergoing treatment at an independent ibogaine center in New Zealand. Dr. Noller was previously collecting data from two treatment centers, but one of these centers has now closed due to a recent death in treatment at a time when the patient was not under medical supervision. The death has raised significant concerns in the New Zealand ibogaine treatment community, and emphasizes the importance of establishing clear treatment protocols, which were not followed at the facility where the death took place. Treatments were halted at both facilities after the death but have resumed at the facility with a continued record of no significant health issues and where patients are continually monitored. Dr. Noller reported that he felt "very confident" in the remaining provider's practice and anticipates that the study is likely to be completed in Spring 2015.

Goals for this study include (1) gathering preliminary evidence about the safety and potential benefits of ibogaine-assisted therapy for opiate addiction, (2) supplementing the data from our completed observational ibogaine study in Mexico, and (3) initiating and encouraging psychedelic research in New Zealand.

Medical Marijuana

Marijuana for Veterans with PTSD Study Protocol Resubmitted to HHS *Study pending*

Location: Phoenix, Arizona

Clinical Investigator: Sue Sisley, M.D.

Estimated protocol design and approval budget: \$ 20,000

Already raised: \$10,000

Needed to complete protocol design and approval: \$10,000

Study budget to be determined after protocol approval.

On October 24, 2013, MAPS resubmitted to the U.S. Department of Health and Human Services the protocol for our Food and Drug Administration (FDA) and Institutional Review Board (IRB)-approved study of marijuana to treat symptoms of PTSD in 50 U.S. veterans with chronic, treatment-resistant PTSD. Currently, the National Institute on Drug Abuse holds a monopoly on the supply of marijuana for research in the U.S. Under current federal policies, reviewers from the Public Health Service (PHS, a division of the Department of Health and Human Services/HHS) must approve all privately funded research seeking to use NIDA marijuana. The FDA approved the protocol in April 2011, but HHS reviewers unanimously rejected the protocol in September 2011, preventing the study from going forward. At the time of the HHS rejection, the study had not yet been approved by an IRB.

In October 2012, the IRB at the University of Arizona approved the study protocol. The IRB accepted all of the core elements of our design, added several safety measures and proce-

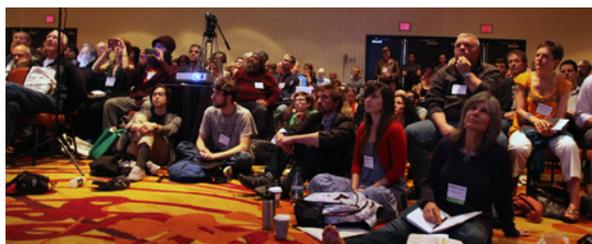
dures, and rejected HHS' critiques of the protocol design. We are requesting that HHS agree to sell MAPS the marijuana needed for the study, as well as to abandon the PHS review process entirely, which exists



Clinical Investigator Sue Sisley, M.D., in discussion after her presentation at Psychedelic Science 2013.

only for marijuana and not for research with any other drug. MAPS is also working with other groups on a Congressional Sign-On letter to HHS Secretary Kathleen Sebelius urging her to eliminate the PHS review and require NIDA to sell marijuana to sponsors of all protocols that obtain approval from FDA, IRB, DEA, and relevant state authorities [full story on page 36].

Goals for this study include ending the obstruction of medical marijuana drug development research by the National Institute on Drug Abuse (NIDA). If successful, our goals will also include (1) collecting evidence for the safety and effectiveness of marijuana for symptoms of PTSD in U.S. veterans; (2) starting the research needed to make whole-plant marijuana a legal, FDA-approved prescription medicine; (3) comparing the safety and effectiveness of smoking vs. vaporization as medical marijuana delivery systems; and (4) comparing the effectiveness of strains of marijuana with different ratios of THC and CBD for symptoms of PTSD.



Psychedelic Science 2013 videos are available online! Visit maps.org/videos.

At Psychedelic Science 2013, over 100 of the world's leading researchers and more than 1,900 international attendees gathered to share recent findings on the benefits and risks of LSD, psilocybin, MDMA, ayahuasca, ibogaine, 2C-B, ketamine, marijuana, and more, over three days of conference presentations, and two days of pre- and post-conference workshops.

Ayahuasca Treatment for Addiction

Results Published from Canadian Observational Study *Study completed*

Location: British Columbia, Canada

Principal Investigator: Gerald Thomas, Ph.D.

This study has been completed and is fully funded.

In June 2013, the results of a recently completed MAPS-sponsored observational study of ayahuasca-assisted therapy for addiction were published in *Current Drug Abuse Reviews*. This was the first study of its kind in North America and involved 12 members of a rural First Nations community, several of whom had been through multiple unsuccessful treatments for their problematic substance use. Combining Western psychotherapeutic techniques with South American shamanic healing

practices, this study gathered preliminary evidence about the safety and effectiveness of ayahuasca-assisted therapy. The results, which were presented at Psychedelic Science 2013, suggest that participants may have experienced positive psychological and behavioral changes in response to this therapeutic approach. Proper clinical studies are recommended to more adequately test the efficacy of this novel form of treatment. Health Canada indicated openness to approving research protocols utilizing standardized, freeze-dried, encapsulated ayahuasca; but the South American shamans who administered the ayahuasca indicated that they were only willing to work with ayahuasca prepared in the traditional manner as a tea.

Goals for this study included (1) gathering preliminary evidence about the safety and potential benefits of ayahuasca-assisted therapy for problematic substance use and quality of life, and (2) initiating and encouraging psychedelic research in Canada.

MAPS in the Media



Timothy Leary's Transformation From Scientist to Psychedelic Celebrity

by Greg Miller

October 1, 2013



Sanjay Gupta: Only 6 Percent Of Marijuana Research Considers Medical Benefits

by Shaunacy Ferro

August 12, 2013



Molly is the New Club Drug, But What's In It?

by Frank Owen and Lera Gavin

October 20, 2013



MDMA Still Irrationally Restricted, Despite Medical Benefits

by Brendan Ferreri-Hanberry

August 7, 2013



Marijuana Is Helping Our Vets Cope With War

by Josh Zepps

November 11, 2013



Electronic Dance Music's Love Affair With Ecstasy: A History

by P. Nash Jenkins

September 20, 2013



Making Psychedelic Trips Safe—Even at Burning Man

by April Short

August 9, 2013



Do Party Drugs Have a Place in the Medical Office?

by Heidi Anne Duerr, MPH

October 2, 2013

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Rick Doblin, Ph.D.

Building a Sustainable Non-Profit through MDMA Research

RICK DOBLIN, Ph.D.

MAPS' SUSTAINABILITY PLAN (MSP) IS intended to communicate to MAPS' donors that their support helps to develop MDMA-assisted psychotherapy into a legal prescription treatment for PTSD, while also empowering MAPS to fulfill our rare opportunity to become a sustainable non-profit.

Unlike most non-profit organizations, MAPS' mission to develop psychedelics and marijuana into FDA-approved prescription medicines is explicitly intended to result in the sale of products, initially MDMA for PTSD and for other "off-label" uses. Through such sales, MAPS could generate funds for further research, relying to a substantial extent on earned mission-related income to sponsor research into the risks and benefits of other potential medicines such as LSD and the marijuana plant. We've used conservative assumptions in the MSP since it is intended not as a precise estimate but rather as an initial reality check on the concept.

We're seeking venture philanthropists, not venture capitalists. From a social perspective, it seems healthier for MDMA to be distributed by a not-for-profit that can take into account factors other than just maximizing income: factors like the quality of therapists, the effectiveness and efficiency of the treatments, the careful integration of MDMA and psychedelic psychotherapy into our society in a manner that avoids backlash, and the maximization of the social utility of MDMA that comes from reasonable pricing.

Making our sustainability plan public is part of our overall prioritization of transparency. If any other company, non-profit or for-profit, decides on the basis of our income projections that they want to start developing MDMA-assisted psychotherapy into a legal prescription treatment to be first to market before MAPS, we welcome them to the field. An essential part of MAPS' mission is to open the door for the full cornucopia of prescription psychedelic medicines. The more research underway, the sooner that part of our mission will be realized and the closer we will be to the full mainstreaming of psychedelic experiences in our culture and laws.

INTRODUCTION

The MAPS Sustainability Plan (MSP) illustrates how MAPS intends to build a sustainable long-term income stream from prescription sales of MDMA to support MAPS' mission. These income projections are not intended to be used to seek investors in MDMA/PTSD research. Rather, they are intended to further motivate donors to support the development of MDMA-assisted psychotherapy for PTSD into a legal prescription treatment, thereby generating income to further fund MAPS research into MDMA, other psychedelics, and medical marijuana.

Major milestones to reach the start of the MSP include:

1. Completion by 2016 of Phase II studies of MDMA-assisted psychotherapy in subjects with chronic, treatment-resistant PTSD.
2. \$18.6 million raised for Phase II and III studies for MDMA-assisted psychotherapy in subjects with chronic, treatment-resistant PTSD—of which over \$5.3 million has already been raised.
3. Completion by early 2021 of Phase III studies of MDMA-assisted psychotherapy in subjects with chronic, treatment-resistant PTSD.
4. FDA approval in late 2021 for the prescription use of MDMA-assisted psychotherapy in treating PTSD and start of 5 year period of marketing and data exclusivity during which time our data cannot be used by any other entity as the basis for selling MDMA on a generic basis.
5. Government and/or private sector insurance provides reimbursement for the expense of the treatment.

OVERALL RESULTS

Key variables include annual number of prescribers, annual number of patients treated, sales price of MDMA, and production costs of MDMA. The MSP is based on conservative estimates and is projected to generate net income of \$9.2M per annum at the end of the five year data exclusivity period. Due to the one year or more processing time required by FDA to approve a generic medication, it is likely that the MSP will generate additional net income of \$11.2M at the end of the sixth year of operation. In total, the cumulative net income from the project is projected to be \$23.4M over five years and \$34.7M over six years. At the end of that time, new competitive factors are likely to emerge in the form of generic competition. Starting in year 7, competitive pressures are projected to reduce pricing by 50% going forward. The following table summarizes the projected proceeds from the MSP over a 10-year period.

REVENUE DRIVERS

MARKET SIZE

PTSD Patients: The National Comorbidity Survey Replication (NCS-R), conducted between 2001–2003, estimated that current past year PTSD prevalence from all causes was 3.5% among adults over 18, who comprise 76.5% of the population in 2012 according to the US Census. Assuming a population of 300 million, there are 7.91 million people every year with

PTSD to some degree. If MAPS were to solely focus on PTSD caused by Combat and Cancer treatment, by way of illustration but which we are not going to do, after 5 years we would serve 27,000 or 3.5% of the total Combat and Cancer-related PTSD market. The table below shows the current PTSD market data for these segments and the anticipated growth of MDMA-assisted psychotherapy treatment expected over a 10 year period. This part of the MSP is using conservative estimates for therapists trained and patients treated. There will also be prescription sales to treat patients with PTSD from other causes and off-label prescription to other patient groups which we are not estimating.

Therapists: The primary constraint on serving a larger proportion of the market is MAPS’ ability to train qualified psychiatrists and psychotherapists in administration of the protocol. There are an estimated 50,000 psychiatrists and 93,000 psychotherapists, (total 143,000) currently practicing in the United States alone. The VA has already trained over 6,000 of its therapists in evidence-based psychotherapies for PTSD. MAPS is projecting that it will train 300 net new therapy providers each year accounting for a 5% attrition rate. This will result in a total of 1,500 therapy providers at the end of 5 years or 3,000 trained MDMA therapists at the end of 10 years. The following table shows the estimated number of practicing therapists and the percentage of primary trained therapists in MDMA-assisted

Net Profit (\$1,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Income	4,283	6,428	9,723	13,019	16,314	19,676	12,306	13,982	15,657	17,332
Expenses	3,148	4,129	5,097	6,510	7,021	8,383	9,227	10,227	10,493	11,394
Net Profit	1,134	2,299	4,627	6,508	9,293	11,293	3,079	3,755	5,164	5,938
Cumulative Net Profit	1,134	3,433	8,060	14,568	23,861	35,154	38,234	41,988	47,152	53,090

PTSD Market Data (in ,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Est. PTSD Market Size (non Combat/Cancer)	7,096	7,160	7,169	7,176	7,183	7,190	7,196	7,202	7,207	7,211
PTSD (Combat)	260	247	235	223	212	201	191	182	172	164
PTSD (Cancer)	554	558	562	566	570	574	578	582	586	590
Total Market Size	7,910	7,965	7,965	7,965	7,965	7,965	7,965	7,965	7,965	7,965
Total Patients Treated	5.40	10.80	16.20	21.60	27.00	32.40	37.80	43.20	48.60	54.00
% of Market	0.1%	0.1%	0.2%	0.3%	0.3%	0.4%	0.5%	0.5%	0.6%	0.7%

psychotherapy over a 10 year horizon. In addition to the primary therapists, we also estimate that we'll train 75 co-therapists per year in MDMA-assisted psychotherapy. These co-therapists assist the primary therapists in treatment but do not themselves offer MDMA-assisted psychotherapy on a stand-alone basis. Other co-therapists will be selected and trained by the primary therapists and could include nurses, social workers, students and interns. Some of these other co-therapists themselves will eventually become trained by MAPS in order to become primary therapists with approval to prescribe.

These estimates of numbers of therapists able to prescribe MDMA post-approval do not include any therapists trained to prescribe as a result of possible FDA approval of Expanded Access. FDA's program of Expanded Access is for drugs that treat serious and life-threatening illnesses in patients who are treatment-resistant to currently available therapies, criteria that MDMA-assisted psychotherapy for subjects with chronic, treatment-resistant PTSD can reasonably meet. Should it be granted, patients can pay the costs of receiving treatment outside of our Phase 3 studies but MAPS cannot make a profit and cannot slow down our Phase 3 studies. We will be applying for Expanded Access at our End-of-Phase 2 meeting sometime in 2016. If Expanded Access is granted, we'd be able to start training therapists to provide therapy at cost for 5 years while simultaneously conducting our Phase 3 studies. Once FDA approval is granted for prescription use, we'd be starting with a

group of therapists with the training to prescribe MDMA that is well over 300 people, the estimate we're using in this MSP of the number of therapists that can treat patients in the first year that MDMA is an approved prescription medicine.

Revenue Sources: The MSP assumes two revenue sources—the sale of MDMA to licensed practitioners and training in the administration of MDMA therapy. Both revenue streams are highly dependent on the number of trained practitioners providing MDMA-assisted psychotherapy. The primary source of revenue is the recurring sale of MDMA to licensed practitioners. Training is assumed to be a one-time source of revenue from therapists at this time—yet as time passes and new techniques are developed additional types of trainings may be added. Estimated revenues for both sources are displayed in the table below. A third revenue source will come from MAPS owning and operating a network of treatment clinics to set the standard of care in the field. We've not yet modeled this revenue source due to the complexity of the analysis but will do so before the end of 2014.

MDMA Sales: As noted, the primary source of income is the sale of MDMA by MAPS to therapy providers. The incremental quantity of MDMA sold is related to the average dose per session, average number of MDMA-assisted therapy sessions per patient treated, and of course the actual price of the drug itself.

Practicing Therapists	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
US Based Psychiatrists & Psychotherapists	143,000	143,000	143,000	143,000	143,000	143,000	143,000	143,000	143,000	143,000
MDMA Trained Psychiatrists & Psychotherapists	300	600	900	1,200	1,500	1,800	2,100	2,400	2,700	3,000
% of Practicing Psychiatrists & Psychotherapists	0.2%	0.4%	0.6%	0.8%	1.0%	1.3%	1.5%	1.7%	1.9%	2.1%
MDMA Trained Co-Therapists	75	150	225	300	375	450	525	600	675	750

Revenues	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Drug Sales	2,970	4,995	8,235	11,475	14,715	18,023	10,598	12,218	13,838	15,458
Training	1,313	1,433	1,488	1,544	1,599	1,654	1,709	1,764	1,819	1,874
Total Sales	4,283	6,428	9,723	13,019	16,314	19,676	12,306	13,982	15,657	17,332

For an individual patient, the MDMA-assisted therapeutic protocol assumes that each session will have an initial dose of 125 mg as well as a supplemental dose of 62.5 mg administered 1 ½ to 2 ½ hours after the initial dose. The protocol further assumes that patients will, on average, have 3 MDMA-assisted therapeutic sessions in total. Finally, the price of the MDMA per session is currently estimated to be \$150 per session (initial dose plus supplemental dose). A review of historical drug pricing indicates that MAPS is likely to have significant upward flexibility in its pricing strategy should it choose to exercise that option since the cost of MDMA is only a small fraction of the cost of the therapists.

The total amount of MDMA sold will be dependent on the total number of therapy providers offering treatment as well as the number of patients they can see over the course of any given year. As previously mentioned, it is assumed that the number of therapy providers will grow to a total of 1,500 over 5 years. It is also assumed that we'll train 75 co-therapists per year who will pair with other trained therapists. The remaining 225 therapy providers trained per year without a co-therapist who has also been trained by MAPS will each select an intern/student as a co-therapist who has not yet gone through the training. Some of these intern/students will eventually become trained by MAPS to be lead therapists, such that there would be 1500 co-therapist teams at 5 years and 3000 teams at 10 years. This is another conservative assumption since many therapists may choose to work alone rather than in pairs, though our model is a male/female co-therapist team.

Each co-therapist team will treat an average of 18 patients per year or 6 patients at any given time. With each patient receiving three MDMA-assisted therapeutic sessions per treatment plan, MAPS total revenue per therapist team per year will

average \$8,100 at an average price of \$150/session. At the end of five years, it is estimated that MDMA sales will total \$14.7M/annum. At the end of 6 years, that will amount to \$18 million. We estimate that the data exclusivity will in practice last 6 years since generic manufacturers cannot file for approval for generic sales until the five year data exclusivity period is over and FDA review and processing time is about 12–18 months.

Therapist Training & Credentialing: As part of the treatment process, therapists are required to undergo a 10 day intensive training program which will culminate with a MAPS MDMA-assisted psychotherapy credential required for prescribing authority. The price of this training is anticipated to be \$3,500 and MAPS estimates that it will train approximately 300 new primary therapists per year and 75 co-therapists as well as replace exiting therapists (estimated at 5% churn/annum). The total revenue derived from therapist trainings is estimated to be roughly \$1.3M in the first year rising to \$1.52M in the fifth year. The increase in revenue is driven by the rate of churn—i.e. therapist attrition rate. As a proportion of total revenue, trainings represent just under 8% of total revenue by the 5th year of operations. The table below shows training-derived revenue over the forecast period.

Therapist Income (Non-MAPS Revenue): Based on a treatment protocol of no more than 6 patients at any given time, the 15 week protocol requires therapists to put in an average work week of just less than 15 hours per week. The amount of time required varies depending on the stage that the patient group is at and can run as high as 21 hours/week. For reference purposes, an actual MDMA-assisted therapeutic protocol has a duration of 39 hours and includes 3 eight hour MDMA

Therapist Training Revenue (\$,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Therapist Training Revenue	1,313	1,365	1,418	1,470	1,523	1,575	1,628	1,680	1,733	1,785

Expenses	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Drug Costs	1,075	1,541	2,165	3,015	3,295	4,032	4,737	5,457	5,267	5,879
Training Costs	518	645	669	694	718	743	767	791	816	840
Marketing	150	300	450	600	750	900	1,050	1,200	1,350	1,500
Admin	1,405	1,643	1,812	2,202	2,258	2,709	2,673	2,779	3,060	3,176
Total Expenses	3,148	4,129	5,097	6,510	7,021	8,383	9,227	10,227	10,493	11,394

-assisted psychotherapy sessions three to five weeks apart along with about 12 non-drug psychotherapy sessions for preparation and integration, each lasting between 60-90 minutes. With an assumed average reimbursement rate of \$200/hour/therapy team, total therapist revenue is estimated at \$7,800/patient. This creates an average income stream of \$140,000/therapist team per year. MAPS believes this will be highly competitive from a remuneration perspective.

It is also anticipated that government and private insurance providers will react favorably to this treatment protocol as it represents a significant cost reduction compared with PTSD disability payments. For example, the average annual cost to the VA for a veteran receiving disability payments for PTSD is \$20,000 per year. In 2012, there were an estimated 275,000 vets receiving disability payments for a total of \$5.5 billion per year in PTSD disability payments, with this number increasing every year.

EXPENSE DRIVERS

The MSP plan expenses are loosely divided into four groups: Drug Costs, Training Costs, Marketing Costs, and Administrative Costs. Total annual expenses are projected to grow to \$6.5M at the end of 5 years. The cost of manufacturing, encapsulating, and distributing the MDMA to licensed therapists is the largest cost center (\$3.3M). Administrative costs (\$2.3M) are the second largest cost center. The need for highly trained personnel to oversee and grow the operation from day one comprises the bulk of these costs. After that, Training (\$.7M) and Marketing (\$.2M) make up the balance of the expenditures.

Drug Costs: Drug costs consist of GMP certified manufacture of MDMA, encapsulation, and distribution costs. The total cost per kilogram in the first year of operations is estimated at \$289,601 or \$54.30 per dose. These costs are subject to economies of scale even in the first year as the estimated end to end cost for a single kilogram is actually \$340,000 or \$63.75/dose.

MDMA Costs	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Kilograms Sold	3.71	4.07	8.12	12.17	16.22	20.27	24.32	28.37	32.42	36.47
Production Cost (per kg)	178,500	151,725	128,966	128,966	109,621	109,621	109,621	109,621	93,178	93,178
Encapsulation Cost (per kg)	106,250	90,313	76,766	76,766	65,251	65,251	65,251	65,251	55,463	55,463
Shipping	4,851	4,803	4,614	4,432	4,257	4,090	3,928	3,774	3,625	3,482
Total Cost (per kg)	289,601	246,840	210,346	210,164	179,129	178,962	178,800	178,646	152,266	152,123
Cost/Dose	54.30	46.28	39.44	39.41	33.59	33.56	33.53	33.50	28.55	28.52

Admin Costs (\$,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Total Payroll & Benefits	1,108	1,313	1,380	1,645	1,706	1,971	2,105	2,167	2,391	2,459
Communications (Phones, Internet)	32	48	73	98	122	148	92	105	117	130
Occupancy	53	63	70	84	88	102	109	112	123	130
Office Equipment & Supplies	81	38	53	83	77	83	79	77	81	79
Travel & Entertainment	54	80	122	163	204	246	154	175	196	217
Other Admin	16	24	36	49	61	74	46	52	59	65
Total Admin Costs	1,344	1,566	1,733	2,121	2,258	2,622	2,585	2,688	2,966	3,079

Training Costs (\$,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Trainers	362	466	484	501	519	536	554	571	589	606
Training Space	63	81	84	88	91	94	97	100	103	106
Materials	94	98	101	105	109	113	116	120	124	128
Total Training Costs	518	645	669	694	718	743	767	791	816	840

Marketing Costs (\$,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Marketing	150	300	450	600	750	900	1,050	1,200	1,350	1,500

This cost is based on an actual bid obtained by MAPS from a Canadian manufacturer. We’re currently negotiating with a German company for roughly half the price, but we have not yet signed a contract. By the 5th year the cost per kilogram is expected to be reduced to \$179,129 per kilogram or \$33.59 per dose. The table on page 23 illustrates MAPS’ estimated manufacturing and distribution costs on a per kilogram basis as well as the resultant cost per dose. Costs are assumed to decline as volume increases during the initial years with a flattening of costs starting in 2026 as volume growth percentage slows.

Administrative Costs: Administrative costs primarily consist of salaries and benefits (75% of total administrative costs by 2025). The balance of the costs is distributed across general overhead—office expenses, travel, communications, supplies and equipment, etc... The table on page 23 illustrates the projected administrative cost structure over the 10 year projected horizon. Certain costs, such as Communications and Travel and Entertainment, are capped after reaching a certain level as the growth of these costs is not assumed to be proportional to revenue growth after a certain period.

Training Costs: Training expenses include the cost of trainers (\$12,000/training), the training venue (\$2,500/venue) which is held at a clinical site, and materials (\$250/therapist). The trainings are 80 hours in length over a period of 10 days. Trainings are held quarterly and on a regional basis. Each cohort has a maximum size of 12 therapists and is led by a MAPS-certified MDMA therapist trainer. Each therapist is provided with course materials covering the training and current clinical research literature on MDMA/PTSD therapy. Each therapist who successfully completes the training will also receive \$500 in initial marketing support—see the marketing budget above.

Marketing Costs: Marketing costs are driven by the number of new therapists added each year. The intent of marketing expenses is to provide basic support to enable new therapists to advertise their availability to provide services to the community. Marketing expenses are estimated at \$500/new therapist trained and include the provision of marketing materials detailing the therapy and its prospective benefits.

CLOSING THOUGHTS

The completion of Phase II studies and the implementation of Phase III studies over the next few years will help refine the assumptions presented above and provide additional data which may lead to further improvements in the therapeutic model currently being used in MAPS’ clinical trials. The model attempts to make allowances for potential improvements by using highly conservative pricing (sale of MDMA), production (cost of MDMA production and distribution), and therapist adoption rate assumptions. In addition, the model assumes that the eventual loss of exclusivity will have an immediate and dramatic effect on the MSP’s revenue stream from the seventh year forward. Overall, the MAPS staff believes that the assumptions are a conservative estimate of the potential that lies ahead for MDMA-assisted psychotherapy.

Nonetheless, we would be remiss in not seeking out the input and comment of others who are also well versed in the details of various aspects of the proposed plan. To that end, MAPS would like to solicit comments and suggestions at sustainability@maps.org. It is our hope that the thoughtful contributions of others will help hasten the day when MDMA-assisted psychotherapy becomes a reality and that the damage done by PTSD can be treated more successfully and at a lower long-term cost than is currently the case. 🌱

Rating Adherence and Training Therapists in MDMA-Assisted Psychotherapy for PTSD Research

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FOR MDMA-ASSISTED PSYCHOTHERAPY TO reemerge as a legal treatment for PTSD and potentially other psychiatric disorders, the method we use to demonstrate our results has to be sound, scientific, reproducible, polished, and refined. It must have certain checks and balances, with the therapists conducting the experimental sessions needing to demonstrate adherence to the protocol and treatment method (and, of course, a high level of proficiency) even though they are utilizing a relatively non-directive approach. This is where we, the Adherence Raters, come in.

MDMA-assisted psychotherapy is an organic, ever-evolving treatment, and the work and observations done by the Adherence Raters help the process along. It's a meticulous and sometimes grueling process, but it has important implications for the research.

THERAPEUTIC QUALITY CONTROL

Performing adherence ratings helps ensure that the therapists demonstrate competency and adhere to the *Manual for MDMA-Assisted Psychotherapy in the Treatment of Posttraumatic Stress Disorder* [available at maps.org/treatmentmanual], which makes sure that the treatment was applied as it was intended and that it improves the quality of the data, strengthening the validity of the study. Through a kind of therapeutic quality control, we provide useful feedback to the therapists with the intention to improve the quality of treatment for the participants and aid in the training of new generations of psychedelic psychotherapists. Also, since there are multiple studies going on around the world, establishing adherence may aid in pooling all of the data together into a meta-analysis. Adherence Raters even help find ways of improving the rating process itself.

As Adherence Raters for ongoing studies, our job consists of watching videos of study sessions and monitoring how well the therapists follow the study protocol. At the same time, we rate how effectively they work as a therapeutic team with the participants. We pay special attention to how well the therapists communicate with study subjects, the strength of the rapport between the therapists and subjects, and the strength of the therapeutic alliance. We also monitor how well the therapists allow the subjects to feel safety and complete support during the process, while themselves maintaining a strong empathic presence; that they are well timed and complete at acquiring all the relevant information; and that they are attending to any questions or needs the subjects may have.

The therapists need to demonstrate these qualities while utilizing a very non-directive approach at the same time. In addition, while watching the study sessions, Adherence Raters review several checklists, making sure the therapists address all of pertinent points of the protocol. Importantly, we also have to show that we have “inter-rater reliability:” that is, we have to make sure that we are consistent amongst each other, that between us we are using the same “yardstick” to measure therapist adherence.

BEGINNER’S MIND

The *Therapist Adherence and Competence Rating Manual* [available at maps.org/treatmentmanual] has been considered a living document since its inception in the Spring of 2010, built in the general spirit of assuring quality and safety in the standard of care provided to participants in MAPS-sponsored studies. That year, Michael Mithoefer, M.D., and his wife and co-therapist Annie Mithoefer, B.S.N., led an intensive MDMA-assisted psychotherapy training in Charleston, South Carolina, for the research team for the (later rejected) Jordanian study as well as those who became the original four members of the Adherence Team (Ray Worthy, Blu Cohen, Zhenya Gelfand, and Evan Sola). After that first training, the Mithoefers began some initial attempts to organize their thoughts regarding what MDMA-assisted psychotherapy should look like. These meetings became the first Adherence Rater trainings.

The initial outline of Adherence Items echoed major ideas set forth in the *Treatment Manual*, with theoretical scaffolding largely generated from the work of Stan Grof. Already inherent in this document when the original team of raters coalesced was the notion of an “inner healing intelligence,” and the importance of a non-directive approach to engaging participants. The core of this work, from the beginning, seemed to be about allowing the “inner healer” to do its work by setting up a safe environment, and then simply staying out of the way. The idea is that the drug will catalyze the emergence of this inner intelligence, and the role of the therapists is to actively watch and listen, ready to engage the participant when needed, otherwise poised in reverie. This philosophical base, as well as the protection of a therapeutic approach that can allow participants to maximize their sense of safety and support before entering into narratives and states of awareness that might feel unsafe, has remained the common denominator between the many (often shifting) Adherence Items.

The *Adherence Manual* further emphasizes the importance of bringing the insights that are revealed in experimental sessions into the everyday lives of participants. The important work of revisiting the path that had been cleared by MDMA-assisted psychotherapy, later experienced from an ordinary state of consciousness, is what therapists call *integration*. Integration

is a concept referenced often in the entheogenic (psychedelic) community, but usually with little elaboration on what exactly it entails; thus the Adherence Team has been faced with the challenge of bringing form to something that is amorphous, and yet hugely important. We have tried to provide a standard that is comprehensive and available for others in the field, as well as for curious explorers in the lay community. The importance of integration sessions is clear in the therapeutic protocol: for every one experimental session, participants receive three integration sessions. Other work focusing on mind-body integration is suggested for use in between MDMA-assisted psychotherapy sessions, including ongoing, long-term psychotherapy with an alternate therapist.

As Adherence Raters, we consciously strive to maintain the attitude known as “beginner’s mind.” We hope to bring this attitude of openness both to the therapeutic approach for which we provide feedback and to our regular amendments to the *Adherence Manual*. In introductory and experimental sessions, Dr. Mithoefer has often helped facilitate this attitude by reminding participants of the importance of allowing a process that shifts, and exemplifying an attitude of availability to whatever emerges, including feelings of being stuck and discomfort. This approach is an integral part of MDMA-assisted psychotherapy that has inspired the Adherence Team to stay open to what we notice and are inspired by in the therapy. We keep our eyes and ears open to what heals; and to what opens dialogue, intimacy, and catharsis.

We keep our eyes and ears open to what heals; and to what opens dialogue, intimacy, and catharsis.

TRAINING A NEW GENERATION OF RESEARCHERS AND THERAPISTS

The importance of training the next generation of Adherence Raters with this attitude is apparent in how many revisions we made to the Adherence Items after each of our recent trainings in Boulder and San Francisco. Each new group trained brings a slightly new perspective on how we might improve or reconceptualize our work. Adherence Raters are trained to become critical of the therapy MAPS-sponsored researchers provide, and not simply to follow an already established protocol.

The training of the next wave of raters is a major priority for Adherence Raters, since we will require many new teams in order to meet the rating needs of Phase 3 MDMA-assisted psychotherapy for PTSD studies. Phase 3 will be conducted in multisite fashion—many sites consisting of multiple studies with different therapist configurations. Hopefully, this gives a sense of the need for a multitude of trainees, as well as a sense of the expansion of this research, and the growing number of participants in the experimental therapy.

Due to the level of success and impact MAPS’ MDMA-assisted psychotherapy has had in previous studies and on the broader culture, we decided it was important to maintain a high level of training. We require a standard for Adherence Rater

trainees to have professional experience in the mental health field. We also require them to have direct experience resolving ethical dilemmas, a clear understanding of the imperative of self-care, and relationships with other professionals demonstrating ongoing consultation and supervision. This movement to meet Phase 3 research needs has brought on a need for new positions within the Adherence Rater Group, mainly dedicated to conceptualizing Adherence Rater training within the context of the *Treatment Manual*.

Since Adherence Raters become the standard for inter-rater reliability, and thus the backbone for understanding the results of the study, the original Adherence team members have taken on new positions to help ensure a smooth transition, including the management and training of new raters. Another level of general oversight of adherence issues, especially as they relate to reliability and validity, will be provided by Ingmar Gorman, who recently joined the Adherence Rater team, with experience in the field coming from his work at the New School for Social Research, as well as his current work on the role of the therapeutic alliance in MDMA-assisted psychotherapy. Other original members have moved on, being groomed for inclusion as therapists in upcoming studies. Ultimately, the position of Adherence Rater is a major stepping-stone in becoming a therapist in MAPS-sponsored research.

Adherence Raters become the backbone for understanding the results of the study.

Q: WHY DO YOU WORK AS AN ADHERENCE RATER IN MAPS' MDMA-ASSISTED PSYCHOTHERAPY RESEARCH?

ZHENYA: There are several reasons why I personally work on adherence for MDMA-assisted psychotherapy. Primarily, I believe in the cause of psychedelic research to the very core, and I feel honored and privileged to have the opportunity to contribute to its reemergence. I am also hoping to someday be part of a therapy team working with psychedelic-assisted psychotherapy both in a research setting and—hopefully—in my psychiatric and wellness practice. Being part of the Adherence Rater team serves as a gateway into this promising and fascinating field and adds immensely to my experience and understanding. Hopefully, that can someday manifest into my aspiration of practicing psychedelic psychotherapy and bringing healing and wellness into the lives of my clients in a way that conventional medicine simply cannot.

EVAN: Since the first session video I watched in 2010, I was struck by the deep listening of both participants and therapists that reflected the level of healing experienced, beyond what could be explained by the medicine alone. I was blown away by the stories, the raw and genuine emotive force of a life-shattering narrative now being held delicately in the hands of two bodhisattva-like therapists: wounded individuals and the

illuminated space between them all greatly enhanced by the medicine. I remember audibly sobbing the night after watching those first sessions.

While serving as Night Attendant for the study, on the nights when I wasn't sitting with participants until dawn, I woke up from sleep grasping, with what might have been my unconscious mind, the importance of the work being done. Again, a bursting forth of tears, accompanied by images and memories of my own hurt places. My dreams were piecing together something difficult to hold in my waking life. The release I felt in my chest was, I believe, permitted by what I had observed (and felt!) while watching the cathartic surrenders of participants in those difficult hours of experimental sessions.

Since the work first drew me in, I had to learn when to shut the laptop and go for a walk, run, do yoga, talk, etc. I learned how important social support was to counteract the isolation felt by those holding in emotional turmoil. The participants and therapists were teaching me something about emotional development and mature responsibility in caring for the wounded and impressionable parts of the psyche. The work has delivered inspiration for me in so many personal ways that I made it the focus of my dissertation, "Phenomenology of surrender: The complex mission of the combat veteran in MDMA/PTSD psychotherapy." 🌀

Evan Sola, M.A. is a Psy.D. candidate at the California Institute of Integral Studies (CIIS) in San Francisco. He has worked with MAPS on MDMA-assisted psychotherapy research for PTSD since 2010 as Night Attendant, Lead Adherence Rater, and currently as Senior Adherence Rater Manager. He can be reached at solae1@citadel.edu.

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How Does Clinical Psychedelic Research Support Human Rights?

JENNIFER NEAR



Jennifer Near

AT THE LIBRA FOUNDATION, WE believe that all people are born with equal and inalienable rights and fundamental freedoms, that they have a right to live in a healthy environment, and in a just and equitable society that values dignity, equality and participation. One of the greatest barriers to ensuring these rights and freedoms of all peoples, particularly in low-income communities and communities of color, are the punitive policies that have stemmed from the United States' "war on drugs" and prohibition. Therefore, The Foundation works to advance human rights through supporting targeted reforms in the U.S. criminal justice system, and changes in domestic and international drug policies.

In accordance with The Libra Foundation's human rights mission, vision and values, changes in drug policy are based on the recognition of the harms caused by prohibitionist policies and criminalized solutions to problems that are fundamentally social and economic. To strengthen human rights, Libra funds leading organizations working on legalization, decriminalization, clinical trials for re-classification of illegal drugs, patient rights, harm reduction, and models for diversion. The Foundation also works to promote greater awareness of drug policy issues among social justice advocates working on economic and racial justice, criminal justice, prison and sentencing reform, civil liberties, and immigration. This awareness regarding the connection between current drug policies and human rights, encourages these organizations to include strategies in their work that help reduce the harms and impacts of the drug war on their constituents.

The "war on drugs" has infiltrated the United States legal and medical systems and has been destructive to the fulfillment of human rights and to the provision of health care. The criminalization of drugs has framed the public's perception of drugs as "dangerous" illegal substances, and identifies the people who use them as criminals that should be "treated" in our prisons, not in our health care system. It also blurs the distinction between individuals who have substance abuse problems, and those using illegal substances for medicinal use. From the Foundation's perspective, access to treatment options, be it psychedelics or medical marijuana, is a human right. Ill-informed policies with a political agenda should not be the basis for medical treatment in our country.

The Foundation's support for MAPS' work on Federal Drug Administration (FDA) approved trials for re-classification of illegal drugs is a critical component of our drug policy priority area. MAPS' research successfully demonstrates the benefits for the therapeutic uses of psychedelics; persuasively educates the public by providing accurate information; creates support for the medicinal value of certain "illegal" substances; and challenges fears that are the premise of the public's support for punitive, prohibition-based drug policies. As MAPS' Phase 2 studies continue to make significant advance-

ments, they bring the drug policy reform conversation to new platforms, and shift the current paradigms on what should or should not be classified as an illegal or prescribed substance.

There is much work to be done to move away from the draconian approach of the drug war to a human rights approach. Clinical trials are an important way to demonstrate that current drug policies are not fact based. As MAPS removes the stigma and judgment from psychedelics while demonstrating their medicinal value, they re-humanize the individuals that take these substances. This is a critical cultural shift to achieving the human rights of all citizens in our country and to developing harm reduction and reason based approaches to drug policy. Betsy Brill, the Executive Director of The Libra Foundation, acknowledges that the Foundation's grant to MAPS is critical to the goals of the Foundation. Ms. Brill writes:

“Access to the appropriate and effective medical treatment is a human right, this should not be denied as a result of political interests to criminalize certain drugs. At the same time, the current drug classifications disproportionately violate the human rights of minority and low-income populations. MAPS' work seeking FDA approval bridges these two critical issues that have come out of the U.S. Drug War.”

Although there are powerful political and corporate interests that have a vested interest in the criminal justice system, there is growing public interest in de-criminalization. MAPS and other drug policy reformers are successfully providing scientific evidence that exposes the fallacies of fear-based policies. During this momentous time, it is critical that The Foundation and other funders continue to challenge punitive policies that marginalize the individual, and embrace harm reduction strategies that treat drug users as humans with inalienable rights, and who are able to choose their medical treatment with the counsel of medical professionals. Finally, the field must continue work to support organizations, like MAPS, that are increasing the public's support for a new era of drug policies and that pave the way for making all of these reforms possible. ●



The universal human rights logo.

Jennifer Near is a Senior Program Officer at The Libra Foundation. The Libra Foundation's mission is to advance human rights domestically and abroad, with a priority focus on women's rights, environmental sustainability, social justice and drug policy reform. The Foundation's Drug Policy Priority Theory of Change, states that a realistic end to the "war on drugs" be based on the recognition of the harms caused by prohibitionist policies and militarized solutions to fundamentally social and economic problems, and on the implementation of health-based approaches to substance abuse problems.

Findings from a Collective Case Study of the MDMA/Ecstasy Experiences of Adults on the Autism Spectrum: Transcript from Psychedelic Science 2013

ALICIA DANFORTH, Ph.D.



Alicia Danforth, Ph.D.

*METAPHORS AND SYMBOLS FROM *The Wizard of Oz* were guiding tools for me on many levels when I was analyzing interview transcripts and identifying emergent themes for my dissertation. In the slides for this presentation, I supported the literal, verbal content with images from the film, in support of visual and figurative thinkers. Here are some of the Oz-inspired concepts that helped me make sense of what the research participants shared with me:*

The black-and-white to color transition in the film reminded me of the impression lots of folks have of their pre- and post-MDMA perceptions of the world. Even more so, I felt that the juxtaposition of Kansas and Oz was relevant as a before-and-after comparison.

I don't think it's a coincidence that Dorothy and her companions have a mind-altering experience in a poppy field just before arriving at the gates of the Emerald City. Sure, they are sedated instead of energized, but the consciousness shift precedes access to a dreamlike, transformative world.

The America song, "Tin Man," by Dewey Bunnell inspired me: "No, Oz never did give nothing to the Tin Man that he didn't, didn't already have." Those lyrics were a reminder that, despite stereotypes about ASD, the study participants did not lack empathy, feelings, heart, soul, compassion, caring, or other higher human attributes. They struggled with perception and processing, similarly to how the Tin Man was frozen until he got support from companions.

The balloon that leaves the Emerald City has the words "Omaha State Fair" printed on it, which reminded me of the return from non-ordinary states of consciousness to default reality, a transition that can be like returning from Oz to Kansas. So, the question remains when one is back in Kansas: What to do with exposure to the wonders of Oz? You've seen "a horse of a different color"—now what?

TRANSCRIPT FROM PSYCHEDELIC SCIENCE 2013

Good afternoon.

I'm going to begin this talk by addressing any members of this audience who might be on the autism spectrum. I want to let you know that what I am about to do is to support any members of this audience who are not autistic but are challenged with experiencing empathy for the conditions of others. That comment was only mildly sarcastic.

For those of you who are neurotypical, non-autistic, typically developing, I want to invite you for a moment to imagine the following. Imagine that you are as intelligent as you are today, you have valuable marketable skills, you engage with life through your deep and passionate interests, however your personal processing system prevents you from correctly interpreting social cues of the dominant culture in which you are expected to function every day.

You want a relationship, but you don't have any idea how to flirt. You want employment, but you have difficulty securing and maintaining employment. Sometimes you have emotional meltdowns that look like temper tantrums, but they are absolutely out of your control. Eye contact is distressing for you. You cannot interpret facial expressions or body gestures. Figurative language, such as metaphors and sarcasm, is just lost on you. You don't know how to dance. You are more like Mr. Spock from Star Trek, in a world that expects and sometimes demands that you behave like Captain Kirk, and you have no idea how to do that nor do you particularly want to.

You are more like Mr. Spock from Star Trek, in a world that expects and sometimes demands that you behave like Captain Kirk, and you have no idea how to do that nor do you particularly want to.

One day or evening you have an opportunity to take MDMA. What might that experience be like for you? That was the primary research question that informed my dissertation research. The emphasis in this talk today will be on my qualitative findings; the quantitative data will be presented elsewhere in future presentations.

Here's a closer look at the research project: It's primarily qualitative with an embedded quantitative component, that's represented by the smaller circle at the bottom. It's exploratory, not explanatory. The purpose is pragmatic, to inform future clinical investigations. It's data-driven, based on the comments and survey results of individuals on the spectrum. It's inductive, intended to cast a broad net, to capture all sorts of specific instances, different data points that are then used as part of the scientific method to inform hypotheses for later research. It's also intended to be atheoretical. I did use an actual method; this isn't a matter of cherry-picking data to serve my purposes. I used *applied thematic analysis*.

Three of the most important points I'll make today are that [1] this research is not about treating or curing autism, [2] it's not about children or teens, and [3] it's not about individuals who lack empathy. I am a biased researcher. I am a psychedelics researcher. I study psychedelics and empathogens. I am not an autism researcher, nor do I intend to speak on behalf of autistic individuals. That's a brief list [referring to presentation slide] of some of the processes I implemented to offset my bias, so that I could stay true to what they told me and represent that data to you accurately, minimizing the influence of my bias. This research was made possible by support from the Betsy Gordon

Foundation and the James Fadiman Dissertation Support Fund.

For the smaller, quantitative portion of this research, 150 online surveys were collected, four assessments were used, 100 MDMA-experienced individuals participated, and 50 who were MDMA-naïve served as a comparison group. Those are the instruments I used [The Autism Spectrum Quotient (AQ), The Empathy Quotient (EQ), The Interpersonal Reactivity Index (IRI), and the Cambridge Friendship Questionnaire (FQ)]. I won't say a lot about them today but I'll come back to one of them a little bit later. Thirteen countries contributed data to the final data analysis.

The data are still being analyzed, and I'm going to defend this thesis next month, so some things might change. One important thing I'd like you all to know [is] that as of May 2013, the definition of autism in the DSM-V [Diagnostic and Statistical Manual of Mental Disorders, 5th Edition] is going to change in a very significant way: There will be no more categories that

distinguish one level of autism from another. It will all be "Autism Spectrum Disorder."

Relevant to this study, Criterion A states that autism is a condition in which there are persistent problems in social communication and social interaction across context. Most participants in this research would meet the criteria for Asperger's Syndrome.

There were early studies working with minors with autism, with LSD, UML, and psilocybin. A very significant finding from that early research is that none of the mute children suddenly acquired language or were instantly not autistic anymore. This was our first indication that psychedelics do not treat or cure autism.

A note about the AQ score (one of the assessments): It's the Autism Spectrum Quotient, and it's not a diagnostic measure, but it is an indication of the likelihood that an individual may be on the spectrum. Using independent samples T-tests, I was able to determine that there was a statistically significant difference between the MDMA users and the non-MDMA users. But that only gives us a correlation; it doesn't say anything about cause. It doesn't indicate that MDMA somehow made some individuals less autistic, but it does tell us something about a trend we might see in a future study, if we could acquire baseline data.

One interesting finding: 41% of participants for this study used MDMA 11–20 times. No one reported using it 21–50 times, and using it over 50 times was an exclusion limit for this study, but it was an indication to me that most of the people who participated in this study showed some common sense about how often they used MDMA/Ecstasy. Sixty-nine percent of the participants in this study reported that they were highly confident that the substance that they took contained MDMA.

Only one individual said that he was not confident at all.

Here is a brief look at some examples of key findings: Seventy-two percent of survey respondents reported feeling “more comfort in social settings” as a result of using MDMA/Ecstasy, and for 12% of them, that change persisted over two years. Seventy-eight percent of them reported “feeling at ease in my own body.” For 15% of them, it lasted more than two years. Seventy-seven percent reported that it was “easier than usual to talk to others,” with effects lasting up to a year or more for 18%.

One interesting exception to the other participants was one individual who submitted a survey on June 10, 2012, and filled out all of his data as an MDMA-naive participant, then came back after having used MDMA/Ecstasy for the first time a couple of weeks later. On all of the outcome measures, his scores showed a trend toward increased social adaptability and prosocial behaviors.

When I first began this research I knew very little about autism. Early on I came across an image of a pin on the internet. It said, “You don’t get to talk about autism if you won’t listen to autistics.” I printed it out on a big piece of paper and posted it by my computer as a guidepost to follow when I began the interviewing process.

I spoke with 22 males and two females. The mean age was about 30 years old and the mean AQ score was 37.6. The mean score for “typically developing” individuals is about 16. In addition I interviewed two third-party observers, a best friend and a girlfriend of two of the participants, to see if they observed any change before and after MDMA/Ecstasy use.

This slide [of images of snowflakes] just serves as a reminder that autism is a spectrum. I can’t disclose the identity of my participants, so these snowflakes will stand in as representative of the people with whom I spoke. All of the individuals who I spoke with were as individual and unique from one another as these snowflakes.

I asked everyone essentially three open-ended questions:

[1] Describe your experience of taking MDMA/Ecstasy, [2] What led you to try it?, and [3] describe what if anything changed for you after your experience. As a result, three meta-themes emerged.

The first of those was “Change.” What I’m going to do now is read to you excerpts from the actual interview transcripts to give you an idea of how the individuals expressed their experience. To give you a sense of how people expressed the changes that they experienced, first I’ll mention that everyone in the study assigned themselves his or her own pseudonym, and sometimes they made kind of whimsical choices. I’m going to present this data using literal words and terms as well as symbols, images,

and more visual ways of describing what was conveyed to me.

A first comment under the broad heading of **change** in general came from Meri, a 24-year-old male. *“It feels nice to be able to change as a person; it was not something that I was expecting very much; for most of my life, I did not change.”*

The first subtheme [to emerge from the interviews] is **courage**. Pertaining to courage, Haus, a 21-year-old male, said, *“I guess it broke down barriers, is how I would describe it. Yeah, it felt like up until that point, I just sort of always lived in a shell, like in a bubble. The way I isolated from people, and, yeah, I just sort of tore that down, I said, ‘There’s no need for there to be a barrier.’”*

On **communication**, George, who is 24, said, *“I wanted to talk to people, but not in the way I usually do, i.e., lecture them. I listened to other people and cared deeply about what they were saying. I was actually enjoying making eye contact. Suddenly, there was no discomfort at all. Not only no discomfort, but suddenly, it was like I could see the person behind the eyes, and I wanted to sort of know who it was. And I was sort of just looking in there*

to look for a slight reaction, slight sort of changes just to see how he was reacting to me.”

Regarding **social conversation**, Begrimed, a 25-year-old male, said, *“MDMA didn’t make me unafraid of it, unafraid of conversation. It made me want to actually converse and make friends and*

all that. It was...it was something else.”

On **connection**, Sylvan, a 24-year-old male: “There were actually certain friends I had made months previous to that that I really wanted to get to know better, but due to my social anxiety, I was really just, well I was intimidated by them. I really looked up to them and thought they would never really want to be my friends, so I kind of stopped talking to them out of shyness. But for a while I really wanted to make a connection with them. It felt really important. So the day after that experience, I was still feeling so open and so changed that I made an effort just to get past my shyness, and make a call to them and I actually ended up seeing them that day and it was really kind of great. It was a great connection, and I told them about my experience, and since then we’ve been pretty much best friends. And we do all of these things together, and it’s been one of the best places I’ve ever been in my life, to reconnect, and I really feel that that was because I was so changed by that experience.”

One important note: You hear a lot of talk about empathy and autism. I just want everyone to remember how complex the various domains of empathy are; we need to be very careful what we mean when we say empathy. The individuals with whom I spoke did not lack empathy in terms of concern for others. However, often they were challenged in interpreting the cues that would help them understand the condition of someone else.

Sometimes the connections that were made were on a deeper and more profound level of **communion**. Michelangelo felt as if “the mystery of other people had been dissolved a bit.” Fuzzy, 23, said, “I felt more emotionally connected to my friend, and I could understand his situation better.” Jules, 32, said, “I found people much more interesting to be around. I wanted to connect with people. I want to be around people, I want to hang out and commune with like, some aspect of community.”

Tony, age 36, was a classic non-responder. He took MDMA several times and he only experienced the amphetamine-like effects; he didn’t experience the empathogenic effects. It’s a good reminder to remember that some people have that experience. This is what he had to say: “I’m a little bit skeptical of some people’s impressions of Ecstasy, because Ecstasy is also an amphetamine, and while it increases your sense of empathy, it probably increases your delusions of empathy at the same time,” and he laughed, and I think

he’s right.

One unexpected finding that caught me off guard: When we talk about ecstasy, most often we hear about the empathic heart opening, the love drug, the feel-good drug. The majority of participants in this study emphasized mental clarity, a sort of straightening out, a clearness in their thinking that was new and novel for them, more than we’re accustomed to hearing from neurotypical reports.

Examples [of this kind of report] include Morton. He was 49. “It gave me a complete clarity about things that I didn’t have prior to that. And the reason that I didn’t have clarity prior to that was because I was always worried and anxious.”

Fuzzy, 23: “I have a tendency to just get stuck in thought loops about things, usually things that I don’t want to be thinking about, and this kind of seemed to just not make that happen while I was on it. It didn’t seem to happen at all.”

Begrimed, age 25: “For the first time, it was very, [sigh], like, like I finally got it. Like, you know how, I guess, autistic people, they don’t really know those unwritten social rules and all that? You know, the nuances in conversation and stuff like that? Like, I got it. Like, it was just like, bing!” And George said, “my thoughts were flowing lucidly.”

Fifty-eight percent of participants in this study reported experiencing what they described as *epiphany*: significant new insights, or revelation.

There were undesirable effects and outcomes. I want to acknowledge that very forthrightly.

No one had any severe persisting outcomes. I didn’t hear any horror stories that came after the fact, but here are some examples: distress, disappointment, being overwhelmed, overdisclosure or the fear that one might overdisclose to others by talking too much, and some people had a bumpy come down, but none that lasted more than a few days.

An example from Tony, the non-responder: “I just kind of wanted the general happiness feeling of it because I don’t naturally feel much of that at all.

My general sensation is neutral to cold, I would say, and so I was hoping it would have some effect there, and I got, you know, I got pretty upset that it didn’t, that it, nothing, it’s like, am I ever going to have that?”

Sylvan, 24, said, “It was a bit hard to find a kind of ground in myself for a while, because all these kind of new thoughts and new kinds

Siobhan: “I don’t think MDMA changes your nature at all. I think it just brings it out to the forefront.”



of new feelings were flooding into me, and it was disorienting for a while. It was, I was just stuck to my bed, not knowing what to do, you know?"

Descartes, age 30: *"I find it a bit too overwhelming, and too different from the autistic wiring. If I had to pick any substance as the preferred substance for treating autistic symptoms, I'd suggest methylene or methedrone. The impact on empathy and overall intuition is similar to the impact of MDMA, but the serotonin release is a lot milder, which allows a lot more introspection and analysis."*

The second meta-theme was one of **transformation**, a positive change that persisted long after the actual MDMA experience. Some brief examples of what that sounded like:

BioDrinx, age 33: *"The person I went with noticed the old me is definitely way gone, and much more confident and happy."*

Sylvan, 24: *"I'm actually a totally different person since, well, I would say, yeah, since I did it...It was one of the best places I've ever been in my life. I was so changed by that experience."*

David: *"Comparing how I was and what I am now, there's a big difference."*

Jules, age 32: *"It's definitely helped. My life would be very different if I had not had this experience."*

Meri: *"For most of my life I was a very consistently depressed person and very much a hateful person, and I'm fairly certain that MDMA made me a very loving person."*

So what are we to make of these comments about profound transformation? Another theme that came through loud and clear was **"I am still me."** Like Dorothy when she returned to Kansas, she had her profound experience in Oz, but then you come back to your ordinary life and you are still you. Here is what that sounded like:

Sylvan: *"I was completely myself, except inverted, just very social for once."*

Siobhan: *"I don't think MDMA changes your nature at all. I think it just brings it out to the forefront."*

Begrimed: *"It just felt like there was more added to what was already there."*

David: *"Even after taking the MDMA and all that, it's not that it made me normal or anything, but it made me much more aware."*

How long did these benefits last? It varied from indi-

vidual to individual. But there were many comments that kind of quantified how long the changes lasted. Here are some examples:

Meri: *"I can sort of recall that one moment, that memory, and it's fresh in my mind, and it's a very necessary thing in my life now...With the MDMA moments, I remember them very vividly, and they fill me with a very great joy."*

George: *"I was always, sort of, you know, slightly critical of myself. You know, 'You can't keep a conversation with other people because you just can't. Don't even bother trying.' Whereas now, I've got this memory*

of, well hang on a minute, one night there a week ago I went out and I talked to a bunch of strangers and they enjoyed my company, and I enjoyed their company, you know, this is one step really, isn't it? At the moment, it's really helping that."

David: *"By giving me that perspective, I can bring a lot of that back when I, you know, to my normal day-to-day life."*

I'm going to read for you a portion of a case history about George's experience on the train. By including a photo of an adorable small child, I'm really not trying to manipulate your emotions or make you feel a certain way. I'm trying to give you a sense of George's embodied experience.

At sunrise on the morning after he took MDMA/Ecstasy at a dance club for the first time with little idea of what to expect, George boarded a commuter train for the journey home. He was still feeling exhausted yet stimulated from his night out when a man with a child in his arms sat down beside him. The child started grabbing at George's water bottle. He explained why such a situation normally would "scare the hell out of him," to quote him.

He said, *"I have no idea how to engage children. They sort of look at me in the eye, and I have no idea what to do or say back at them. They look at me in the eye, and they don't get the reaction they normally get from other people. And you can sort of see it in their faces. They just go,*

'I don't trust you,' and move away from you. I'll have none of that."

However, in his post-MDMA experience afterglow state, George was able to interact with the child in an empathic and engaged way. *"And it was really interesting to me, because when this kid looked at me, I was directly looking back, in the eye. I was intrigued*

Michelangelo: "I feel like I understand people just a little bit better, and that pushed me into the area of confidence that I needed to be in, and that stayed with me ever since."



by it and interested by it and I was sort of happy for the child.”

George contrasted this sense of communion with how he usually perceived children. “Ordinarily, I would just not see the appeal of it at all. I would see nothing nice in it. All my mind would be telling me is ‘great, here’s another human being in the world, that’s overpopulated as it is, and we’re here doting over, you know, it’s just a child. It’s going to grow up to be an investment banker or something.’ You know, this is the thing people don’t see. All they see is the big eyes of the child, and it’s just the most amazing thing in the world, to them. And to me, it’s just totally abstract. It’s arbitrary. It’s totally meaningless for me.”

In addition to achieving some sense of communion with a child, George also became aware that he was participating in a unitive experience with others who were enjoying the child’s antics on the train.

“But as I sat there, I looked at everyone else, looking after the child, and suddenly, as a result of the effects of the ecstasy, I could understand, I could see peeping out, I could look at the child and I could just see the sort of curious, innocent wonder of the child. And suddenly it wasn’t a sort of a stupid, arbitrary thing. Suddenly I could understand it. Suddenly I was one of those people actually looking after the child, going, ‘How cute!’ I just found out. And that was just so totally uncharacteristic of me, like, I mean, if you ask anybody that[sic] knows me, and told them that I’d done that, they wouldn’t believe you.”

The final and probably most significant meta-theme was all about **healing**. I’ll zip through to show you the categories without reading the quotes. Many of the themes supported the potential of MDMA-assisted psychotherapy for individual and couples therapy. Here are a few examples of areas in which it may be helpful [referring a slide that lists Affect Awareness, Therapeutic Rapport, Alexithymia, Improved Mood, Problem Solving, Optimism, Insight, and Social Adaptability].

Three participants spontaneously reported that they had PTSD (Posttraumatic Stress Disorder) that was helped by their MDMA/Ecstasy experience. Fifty-eight percent of participants

in this study commented about how MDMA/Ecstasy affected their social anxiety.

BioDrinx: “Socially, all the anxiety I had, completely gone.”

Sylvan: “I’ve credited that one experience to nearly wiping out my social anxiety, which at that point had been strong.”

Morton: “I used to experience terrible anxiety before I took Ecstasy, and this disappeared completely while I was actually high on the drug, and I was able to communicate much more openly.”

Doc Star: “I just felt comfortable talking about everything, and so it was kind of a relief of the anxiety of holding things back.”

David: “It reduces social anxiety for me, I guess. I feel like I can step onto a dance floor and have a lot of fun.”

Isabeau: “It’s a little easier just being around the whole press of people, without still feeling like, oh my God, there’s all these people, and they’re all around me, and I don’t know how any of them think.”

Michelangelo: “I feel like I understand people just a little bit better, and that pushed me into the area of confidence that I needed to be in, and that stayed with me ever since.”

To conclude, I’ll just state, that it’s my hope for the future that that proportion we saw in the beginning, with a big Qual[itative], with a small embedded Quant[itative] will reverse,

that we’ll start seeing double-blinded, randomized, placebo-controlled studies applying the scientific method, but that we won’t lose that piece of the qualitative that informs us about the population with whom we’re co-researching. So that’s my hope for the future, and thank you. 🎧

The full video of this presentation is available at psychedelicsscience.org.

Special thanks to our volunteer transcription and translation team at Amara.



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Will the Obama Administration Stop Standing in the Way of Marijuana Research for Veterans?

SUE SISLEY, M.D.

RICK DOBLIN, Ph.D.



Sue Sisley, M.D.



Rick Doblin, Ph.D.

ON OCTOBER 24, 2013, THE Multidisciplinary Association for Psychedelic Studies (MAPS) and Principal Investigator Dr. Sue Sisley of the University of Arizona College of Medicine-Phoenix, resubmitted to the Public Health Service (PHS) our protocol to study the use of marijuana in treating 50 U.S. veterans with chronic, treatment-resistant posttraumatic stress disorder (PTSD).

A Guidance from the Department of Health and Human Services (HHS), issued May 1999, requires PHS protocol review and approval for privately funded studies seeking to obtain permission to purchase a supply of marijuana from the National Institute on Drug Abuse (NIDA). Unfortunately, NIDA holds a DEA-protected monopoly on marijuana legal for use in Food and Drug Administration (FDA)-regulated research.

MAPS began trying to conduct FDA-approved medical marijuana research in 1992, working with Dr. Donald Abrams to design a study of marijuana to promote appetite and weight gain in HIV-positive patients suffering from AIDS wasting syndrome. While we obtained approvals from the FDA, the University of California, San Francisco Institutional Review Board (IRB) and the Research Advisory Panel of California (RAP-C), NIDA refused to provide us with the marijuana.

In 1999, MAPS worked with Dr. Ethan Russo to obtain FDA and IRB permission for a study of marijuana in treating people suffering from migraines. Yet again, NIDA rejected the protocol and refused to sell MAPS the marijuana we needed, preventing the study from taking place. Between June 2003 and August 2009, MAPS unsuccessfully attempted to purchase 10 grams of marijuana from NIDA for research with vaporized marijuana. Due to excessive delays and frustration, in August 2009 the laboratory we were working with on the project withdrew its efforts.

MAPS and Dr. Sisley began working together in 2010 on our current protocol exploring marijuana for symptoms of PTSD in U.S. veterans. What follows is the initial portion of our October 24, 2013, resubmission to PHS of that protocol. We review the history of the protocol review process and request that HHS revise the 1999 Guidance and end the PHS protocol review, which exists only for studies with marijuana and is biased against studies designed to develop the marijuana plant into an FDA-approved prescription medicine.

In the letter, we request that privately funded medical marijuana protocols be reviewed the same way that protocols using MDMA, psilocybin, LSD, and any other Schedule I drug are reviewed, requiring approval from FDA, IRB, DEA, and state authorities, but not PHS review. We're currently in the early stages of seeking Congressional support for our request to HHS to eliminate the PHS protocol review process.

Our responses to the specific protocol critiques of the PHS reviewers can be found at maps.org/research/mmj/marijuana_for_ptsd_study. 🌿

October 23, 2013

Sarah A. Wattenberg MSW
Sr. Advisor on Substance Abuse Policy and Marijuana Research Review Committee Chairperson
Office of the Assistant Secretary of Health
U.S. Dept. of Health and Human Services

Ms. Sarah Wattenberg,

Hello again and best wishes from Rick Doblin, Ph.D., Executive Director of MAPS, a non-profit research and educational organization. I'm writing you now in a belated response to your September 21, 2011, letter reporting that all five Public Health Service (PHS) reviewers had recommended against approving the privately-funded, MAPS-sponsored, Food and Drug Administration (FDA)-approved drug development pilot study, "Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Five Different Potencies of Smoked or Vaporized Marijuana in 50 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)". I had submitted the protocol to you for review four months and three weeks previously on April 28, 2011.

In your letter, you concluded, "If you plan to submit a revised protocol, please forward it to my office for review." Attached is our revised protocol and informed consent form for review. You also highlighted in your letter four specific issues regarding the protocol, to which I'll respond further below. I'll also respond to the critiques of the 5 PHS reviewers in a separate document that elaborates on the rationale for our protocol design decisions, as requested by the reviewers.

When I submitted our initial protocol to you, it had been approved by FDA but had not yet been submitted to an IRB. In July 2012, after all five PHS reviewers rejected the protocol, Dr. Sue Sisley, Principle Investigator, submitted the unchanged protocol to the University of Arizona Institutional Review Board (IRB). We also included in our IRB submission your cover letter, the comments of all five PHS reviewers, our document responding to the issues raised by the reviewers, an informed consent form and related documents. The IRB reviewed all the information and accepted all the core elements of our protocol design as originally approved by FDA, despite the critiques of the PHS reviewers.

However, the IRB did raise several new issues requiring additional safety measures and procedures. We then revised the protocol and, resubmitted it to the IRB on October 14, 2012. On October 23, 2012, the IRB issued its final approval of the protocol and informed consent form. Attached is a comprehensive eight page list of the changes from the initial protocol to the IRB-approved version we are now submitting. Below is a summary of the major changes.

New Safety Measures in Revised and IRB-Approved Protocol

The protocol now includes an assessment of anxiety as well as assessments of PTSD symptoms and depression. New safety procedures include increased monitoring for psychiatric symptoms through daily telephone contact by research staff with the subjects during the first week of marijuana self-administration and mid-week for the second, third and fourth weeks, and through research staff gathering information on a regular basis from a personal contact selected by each subject who will independently verify marijuana self-administration and report any signs of behavioral change.

A Plea for HHS to Defer Review of MAPS' Marijuana/PTSD protocol to FDA, IRB, DEA

Prior to our responding below to the specific protocol design issues you raised in your Sept. 21, 2011 letter, what follows first is the rationale for our request that HHS eliminate the PHS review process for privately-funded medical marijuana drug development studies. We request that HHS defer the review of MAPS' marijuana/PTSD protocol to FDA, IRB, and DEA, where Congress placed that responsibility and which is the review process for privately-funded research with all other Schedule 1 drugs.

The protocol that MAPS is now submitting to you is a much delayed and much needed attempt to gather pilot data in 50 US veterans with chronic, treatment-resistant PTSD at a time when about 22 veterans and 1 active duty soldier commit suicide every day.

Challenges to NIDA'S Monopoly on the Supply of Marijuana for Privately-Funded Research

Starting in 2001, MAPS began sponsoring the efforts of Prof. Lyle Craker, UMass Amherst, Medicinal Plant Program, Department of Plant, Soil and Insect Sciences, to obtain a DEA license to produce a supply of medical marijuana under contract to MAPS to be used exclusively in federally-regulated research. In February 2007, after extensive legal hearings before DEA Administrative Law Judge (ALJ) Mary Ellen Bittner, Prof. Craker won his lawsuit against the DEA for refusing to issue him a license. DEA ALJ Bittner recommended to the DEA Administrator that it would be in the public interest for DEA to license Prof. Craker to grow medical marijuana for MAPS' privately-funded, federally-regulated research.

After not responding to the ALJ recommendation for almost two years, DEA Administrator Michelle Leonhart finally rejected ALJ Bittner's recommendation on January 14, 2009, six days before the inauguration of President Barack Obama. Prof. Craker subsequently sued DEA in the US First Circuit Court of Appeals. On April 5, 2013, after more than four additional years, the US First Circuit Court of Appeals accepted DEA's rationale for rejecting the February 2007 recommendation of DEA ALJ Bittner, bringing to a conclusion our 12 years struggle. Out of necessity, MAPS and Dr. Sisley are now returning to the PHS to request approval to purchase NIDA marijuana at cost for our FDA and IRB-approved study.

PHS Review Biased Against Privately-Funded Medical Marijuana Drug Development Research

According to the May 21, 1999, Announcement of the Department of Health and Human Services' Guidance on Procedures for the Provision of Marijuana for Medical Research, PHS protocol approval is currently required by the Department of Health and Human Services (HHS) before sponsors of privately-funded medical marijuana research can purchase at cost any of NIDA's research grade marijuana, for which it has a Drug Enforcement Administration (DEA)-protected monopoly. Without PHS protocol approval, privately-funded medical marijuana drug development protocols cannot proceed.

In contrast, all other Schedule 1 drugs such as LSD, MDMA, psilocybin, mescaline, and DMT, are available from multiple DEA-licensed producers. Privately-funded drug development protocols studying the risks and benefits of all Schedule 1 drugs other than marijuana require approval from FDA, an Institutional Review Board (IRB), and DEA, but not the PHS. At present, PHS review and approval is required only for privately-funded medical marijuana drug development protocols, exists only because of NIDA's unique monopoly on DEA-licensed marijuana, protects no government funding, and asserts authority over drug development research that Congress created the FDA to review.

Fundamentally problematic, the current HHS Guidance explicitly rejects providing marijuana at cost to privately-funded medical marijuana drug development protocols seeking to obtain FDA approval for the prescription use of smoked marijuana in plant form. The protocol MAPS is submitting to you now for PHS review is seeking to conduct research with the exact aim that the HHS Guidance rejects as outside the boundaries of acceptable research, but which FDA and the UArizona IRB have approved.

Section II of the Guidance, "Availability of Marijuana For Research Purposes", states, "The goal of this program must be to determine whether cannabinoid components of marijuana administered through an alternative delivery system can meet the standards enumerated under the Federal Food, Drug, and Cosmetic Act for commercial marketing of a medical product (see e.g., 21 U.S.C. 355). As the IOM report stated, "Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, nonsmoked cannabinoid delivery systems."

As long as HHS's May 21, 1999, Guidance on Procedures for the Provision of Marijuana for Medical Research remains in force and are followed by PHS reviewers, the rejection of MAPS' revised protocol, now approved by both FDA and the UArizona IRB, seems inevitable. When the DEA-protected NIDA monopoly and the PHS review process operating under the HHS Guidance combine to block all efforts to develop the marijuana plant itself into an FDA-approved prescription medicine, science is preempted by politics. It's therefore only to be expected that when the science is blocked, advocates of the medical uses of marijuana will turn to politics to provide access for physicians and their patients to medical marijuana.

There are currently 20 medical marijuana states and the District of Columbia. Of these states, PTSD is an explicit qualifying condition for a medical marijuana recommendation in 5: New Mexico, Maine, Oregon, Connecticut, Delaware,

and its use for PTSD is permitted in California., all without a single controlled study of the use of marijuana for PTSD. It's long past time to facilitate privately-funded, federally-regulated research into the use of marijuana in veterans with chronic, treatment-resistant PTSD, for which there are many positive anecdotal reports.

PHS Review is Inappropriate for Privately-Funded, FDA-regulated Research

Even if the HHS Guidance didn't explicitly reject providing NIDA marijuana at cost to privately-funded protocols seeking to develop the marijuana plant into an FDA-approved prescription medicine in smoked form, there is a fundamental mismatch when PHS reviewers evaluate a privately-funded drug development protocol design through the lens of basic science grant application standards.

PHS protocol reviewers have extensive and valuable experience reviewing grant applications submitted by academic researchers seeking National Institutes of Health (NIH) funding for basic science studies. NIH-funded basic science research is primarily about understanding mechanisms of action to gain insight into the processes and building blocks of life. In contrast, privately-funded drug development protocols are focused on proving safety and efficacy to FDA standards. FDA does not require an understanding of mechanisms of action for approval for prescription use.

PHS reviewers of grant applications are stewards of public funds while privately-funded drug development studies are investing and risking private money, not public money. PHS reviewers of grant applications can appropriately require additional measures and tests to better understand mechanisms, or can require larger studies to reduce uncertainty, the cost of which will be paid by the NIH grant should the application be accepted. Such protocol critiques are justified for basic science purposes but are not required by FDA or IRB and are inappropriate for privately-funded studies. Costs from additional research into mechanisms required by PHS reviewers must be paid by the private sponsors of the research, imposing in essence an arbitrary tax on privately-funded research into marijuana's potential medical uses.

Request to Waive PHS Review and Accept Approval by FDA, IRB, DEA, State Authorities

Fortunately, there is a way forward. The HHS Guidance states that "HHS will re-evaluate these procedures periodically..." As far as I can tell, the HHS Guidance document has not been reevaluated since it was written more than 14 years ago. The current NIH grant review process does a good job providing marijuana from NIDA's monopoly for NIH-funded basic science studies while ensuring that taxpayer funds are expended wisely. In contrast, the PHS review process is a success only at obstructing privately-funded medical marijuana drug development studies, an outcome contrary to the public interest. Approval from FDA, IRB, DEA and state authorities without the marijuana-only PHS review should be sufficient for NIDA to accept a request from privately-funded sponsors to purchase its marijuana at cost, especially since that process is sufficient for privately-funded research with MDMA, psilocybin, LSD, DMT, etc.

I'm writing to request that you consider the approvals of this protocol from FDA and the University of Arizona IRB, subject to licensing by DEA and state authorities, as sufficient for this study to proceed, as they would be for research with any other Schedule 1 drug. After licensing by DEA and state authorities, NIDA could then provide the required marijuana at cost.

New Promising but Uncontrolled Research into the Use of Marijuana for PTSD

In addition to our protocol, I am submitting two papers that report on uncontrolled studies of the use of marijuana in subjects with PTSD. The paper discussing the results of a study conducted by New Mexico psychiatrist Dr. George Greer in 80 PTSD patients applying for enrollment in the New Mexico Medical Cannabis Program has recently been accepted for publication in a peer-reviewed journal indexed on Medline. The other paper, reporting on a study conducted by the Israeli Ministry of Health in 29 Israeli Defense Force soldiers, is currently under review by a peer-reviewed journal indexed on Medline. Both report promising findings and call for controlled studies, none of which have yet been conducted.

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

Sue Sisley, M.D., University of Arizona College of Medicine-Phoenix

Cannabinoid Science Sheds New Light on the Darkness of PTSD

MARTIN LEE



Martin Lee

A RECENT ARTICLE IN THE journal *Neuroendocrinology* highlights the crucial role of the endocannabinoid system in protecting against posttraumatic stress disorder (PTSD), a debilitating chronic condition involving horrific memories that cannot be erased.

In an effort to understand the neurobiological mechanisms that underlie the onset and development of PTSD, a team of U.S. and Canadian scientists analyzed 46 subjects who were near the World Trade Center in New York City during the September 11 terrorist attacks. Twenty-four of these subjects suffered from PTSD following the attacks; 22 did not.

The researchers found that people with PTSD had lower serum levels of anandamide, an endogenous cannabinoid compound, compared to those who did not show signs of PTSD after 9/11. Innate to all mammals, anandamide (our inner cannabis, so to speak) triggers the same brain receptors that are activated by THC (tetrahydrocannabinol: The High Causer) and other components of the marijuana plant.

Concentrated in the brain and central nervous system, the cannabinoid receptor known as CB-1 mediates a broad range of physiological functions, including emotional learning, stress adaptation, and fear extinction. Scientists have determined that normal CB-1 receptor signaling deactivates traumatic memories and endows us with the gift of forgetting.

But skewed CB-1 signaling, due to endocannabinoid deficits (low serum levels of anandamide), results in impaired fear extinction, aversive memory consolidation, and chronic anxiety, the hallmarks of PTSD.

PTSD is one of many enigmatic conditions that may arise because of a dysfunctional endocannabinoid system. A 2009 report by Virginia Commonwealth University scientists discerned a link between the dysregulation of the endocannabinoid system and the development of epilepsy. Researchers at the University of Rome in Italy have documented low levels of anandamide in the cerebrospinal fluid in patients with untreated newly diagnosed temporal lobe epilepsy.

Dr. Ethan Russo postulates that clinical endocannabinoid deficiency underlies migraines, fibromyalgia, irritable bowel disease, and a cluster of related degenerative conditions—which may respond favorably to cannabinoid therapies.

Individuals have different congenital endocannabinoid levels and sensitivities that factor into how one responds to stress and trauma. Alcoholism induces endocannabinoid deficits. So does lack of exercise and a diet laden with corn syrup and artificial sweeteners.

Additional research has established that clinical depression is an endocannabinoid deficiency disease. Canadian scientist and Rockefeller University post-doc Matthew Hill analyzed the serum endocannabinoid content in depressed women and found that it was “significantly reduced” compared with controls.

Animal studies show that chronic stress is associated with decreased endocannabinoid levels. Cannabinoid receptor signaling has been identified as a key modulator of adaptation to stress.

In healthy individuals, acute stress triggers a spike in endocannabinoid levels. Scientists view this as a protective response—the fleeting uptick of anandamide eases stress and facilitates homeostasis (a return to baseline) by dialing down the production of stress hormones through a process known as “pre-synaptic inhibition.”

But chronic stress has a different effect than acute stress. Chronic stress depletes endocannabinoid tone and sets the stage for all manner of illness. Chronically elevated stress levels boost anxiety and significantly hasten the progression of Alzheimer’s dementia. Emotional stress has been shown to accelerate the spread of cancer. Stress also alters how we assimilate fats.

In 2012, a team of Brazilian scientists found that chronic stress decreases CB-1 receptor binding and expression in the hippocampus, an area of the brain that plays a major role in short and long-term memory consolidation. This has major implications for treating PTSD.

Chronic stress impairs endocannabinoid signaling and impedes fear extinction, according to NYU Medical Center professor Alexander Neumeister. In a recent scientific paper Neumeister argued for PTSD treatments that target the endocannabinoid system.

PTSD is one of many enigmatic conditions that may arise because of a dysfunctional endocannabinoid system.

Neumeister notes that “chronic stress produces an upregulation” of a crucial metabolic enzyme—fatty acid amide hydrolase, otherwise known as FAAH—which decisively influences endocannabinoid signaling.

Various enzymes are involved in the biosynthesis and creation of anandamide; other enzymes break down endogenous cannabinoid compounds. The FAAH enzyme figures prominently in the metabolic breakdown of anandamide and several other fatty acid messenger molecules. FAAH degrades these endogenous compounds; this is part of the normal, fleeting life cycle of anandamide and its fatty acid cousins.

Polymorphisms or unusual amino acid sequence repeats in the genes that encode FAAH are associated with a propensity for drug addiction and predisposition toward various afflictions. But it is the aberrant up-regulation and/or down-regulation of genes—more so than the genes themselves—that drives disease vectors. Stress messes with gene expression.

Chronic stress upregulates FAAH, and more FAAH results in lower endocannabinoid levels. Conversely, less FAAH means more anandamide, and more anandamide means elevated cannabinoid receptor signaling.

Cannabidiol—CBD—is a nonpsychoactive component of marijuana and hemp that enhances endocannabinoid tone by inhibiting the FAAH enzyme. And this is just one of the ways that CBD shows promise as a treatment for PTSD.

Brazilian scientists report that CBD reduces anxiety in animal models by binding directly to the 5HT1A serotonin receptor; activating this receptor confers an anxiolytic and anti-depressant effect. Preclinical research in Brazil indicates that “CBD has beneficial potential for PTSD treatment and the 5-HT1A

receptors could be a therapeutic target in this disorder.”

CBD and other therapeutic interventions that enhance cannabinoid receptor signaling could become breakthrough treatments for PTSD. CB-1 receptor transmission, in particular, has emerged as a target of novel cannabinoid-based remedies for anxiety and other mood disorders tied to stressful life events.

Smoking marijuana is one method of augmenting CB-1 receptor transmission. Numerous combat veterans and other PTSD patients claim that nothing can calm the storm that rages in their heads like a few puffs of pot. A 2011 observational study by Israeli scientists found that smoked cannabis, which directly activates the CB-1 receptor, improved symptoms of PTSD.

The National Institute on Drug Abuse continues to block FDA-approved research proposed by MAPS, which seeks to study the effects of smoked and vaporized cannabis—including a CBD-rich variety—on military veterans with PTSD.

Some scientists aren't high on marijuana as a PTSD treatment option. NYU's Neumeister contends that despite “their potential therapeutic value, direct-acting cannabinoid receptor compounds [such as THC] have very limited medical applications, mainly because of their undesirable psychotropic side effects and ability to cause addiction.”

This assertion reflects politically correct assumptions rather than scientific fact. The operative premise—that the marijuana high is an adverse side effect—doesn't pass the unbiased smell test. Cannabis doesn't cause addiction any more than food causes a person to become a compulsive eater.

Dismissing smoked cannabis as “an appealing short-term ‘solution’ that will more likely create longer term problems,” Neumeister favors “blocking endocannabinoid deactivation” by inhibiting FAAH, which “may lead to a more circumscribed and beneficial spectrum of biological responses than those produced by direct CB-1 receptor activation.”

That is (some of) what CBD does: it inhibits FAAH. Big Pharma, meanwhile, has its sights set on developing and patenting synthetic FAAH-inhibitors to treat PTSD, depression, and other pathological conditions—the very same conditions for which whole plant cannabis provides politically incorrect relief.

Cannabis is often the remedy of choice for people coping with PTSD and other stress-induced maladies. Some are already using CBD-rich extracts and flowers. Many others self-medicate with THC-dominant strains to ease posttraumatic stress. PTSD sufferers can't afford to wait for whatever benefits synthetic FAAH-inhibitors may offer in the years ahead. They need help now. 🍀

CBD and other therapeutic interventions that enhance cannabinoid receptor signaling could become breakthrough treatments for PTSD.

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Martin A. Lee is the author of several books including Acid Dreams and most recently Smoke Signals: A Social History of Marijuana: Medical, Recreational, and Scientific. He is a co-founder of the media watch group Fairness and Accuracy in Reporting (FAIR) and director of Project CBD, an educational service focusing on cannabis science and therapeutics. For more information, visit projectCBD.org or to make a tax-deductible contribution to support Project CBD's efforts, visit maps.org/projectCBD. Martin can be reached at aciddreamer@gmail.com.

Zendo Project 2013: Psychedelic Harm Reduction Update

LINNAE PONTÉ



Linnae Ponté



WHILE PSYCHEDELICS AREN'T REQUIRED FOR a good time at festivals, for many they are part of the celebration of free expression and self-exploration. Of course, pushing boundaries of any sort can be overwhelming, which is why we offer psychedelic harm reduction for those in need. Since 2001, the Multidisciplinary Association for Psychedelic Studies (MAPS) has brought together a diverse team of therapists, doctors, researchers, and experienced peers to create a safe space and provide compassionate care at large transformational gatherings.

MAPS' first efforts helped establish today's world model for psychedelic harm reduction at BOOM festival in Portugal and provided volunteer recruitment and training in Sanctuary at Burning Man from 2003–2007. The second iteration of MAPS' harm reduction program, the Zendo Project, began in the summer of 2012, in our own village in Black Rock City with 60 volunteers. After this initial success, we quickly expanded our services to a circuit of international events.

The mission of the Zendo Project is to provide a supportive space to help guests obtain some benefits from difficult psychedelic experiences, reduce the number of psychedelic drug-related arrests and hospitalizations, and train volunteers to provide compassionate care. More generally, we strive to reduce the public's fear of psychedelics and encourage honest and responsible conversations about their use. Our work has shown that it is possible to reduce the risks associated with the non-medical use of psychedelics at the community level, and that there is an enormous amount of volunteer interest in doing so. Since our debut in 2012, Zendo volunteers have provided training and support at Envision (Costa Rica), Bicycle Day (San Francisco), AfrikaBurn (Tankwa, South Africa), Black Rock City (Nevada), and a handful of smaller events in California and Colorado (see below).

ENVISION FESTIVAL 2013 (UVITA, COSTA RICA)

In February 2013, Zendo volunteers provided harm reduction services at Envision Festival in Uvita, a tropical hamlet on the Pacific edge of Costa Rica. Linnae Ponté and Sara Girón led a public training for volunteers, followed by a smaller private meeting with medical staff to discuss methods and techniques, and to develop triage protocols. With Zendo and medical spaces situated directly beside one another, the collaboration proved to be enormously helpful for both teams.

Twenty volunteers provided compassionate care throughout the event amidst the green jungle venue complete with swaying palms and a nearby waterfall that embodies the nation's catchphrase "pura vida!" One guest was almost arrested after being unwittingly dosed with LSD before security found him agitated and confused. Reflective of our ideal scenario, after volunteers worked with him, the guest returned the following

day to receive integration support and provide volunteers with feedback about his experience. It's not uncommon for guests who return to inquire about becoming a volunteer. Many of our existing team members are themselves working to give back to the community after receiving help during their own difficult experiences. In addition to many lessons learned this year, Envision taught us the value of reliable infrastructure as well as



Linnæ Ponté leads Zendo volunteer training at the Envision Festival.



*A group of AfrikaBurners watching the sunrise on the Sand Clan.
Photo credit: Mike Suss*



Linnæ Ponté and Zendo build volunteers begin construction in the Black Rock Desert.

the importance of having bilingual volunteers from different cultural contexts at festivals where many attendees do not speak English as their primary language.

70TH ANNIVERSARY BICYCLE DAY PARTY (SAN FRANCISCO, CA)

In commemoration of the 70th anniversary of the discovery of LSD, over a thousand attendees celebrated at a large multi-stage venue in San Francisco. Psychedelic Science 2013 conference attendees took a cruise boat from Oakland's Jack London Square to San Francisco to join the party, which was independently hosted by Alex and Allyson Grey. Volunteers provided care in a small, secluded space on the bottom floor of the venue, keeping one guest from being hospitalized or arrested and assisting many others.

There was a great need for harm reduction at the overcrowded event, where finding a place to sit and regroup might have seemed like an insurmountable feat. Our team learned the importance of working directly with security staff to plan for post-event support since some guests were still in need of help after the night was over, an issue we never had to deal with at festivals. The event offered a valuable opportunity for international conference attendees to gain harm reduction experience to bring back to their local festivals. It also gave DanceSafe and Zendo volunteers a chance to work together and share ideas for future collaborations.

AFRIKABURN 2013 (TANKWA, SOUTH AFRICA)

After attending the Zendo Project training at Burning Man in 2012, MAPS supporter and AfrikaBurn cofounder Mike Suss proposed bringing psychedelic harm reduction to the largest regional Burning Man event. Located in the Tankwa Karoo of Northern Cape Province, the barren desert that stretches for miles offers a perfect canvas for colorful art installations and costume. In its seventh year, AfrikaBurn 2013 brought together 7,500 international attendees for the weeklong festival that upholds Black Rock City's core principles of radical self-reliance, expression, inclusion, de-commodification, and gifting.

Volunteers provided a supportive space, compassionate care, and drug education while interfacing with medical staff, directors, and Rangers. Bringing together volunteers with different levels of experience created an environment analogous to a teaching hospital, where volunteers shared and compared techniques from their respective backgrounds. This was a strong example of how MAPS' harm reduction program provides a context for helping train the next generation of psychedelic therapists.

Working alongside the medical team and Rangers was crucial to our successful efforts at AfrikaBurn. Zendo volunteers

were dispatched to provide support in the field on several occasions, relieving medical staff from spending time with attendees who were only in need of psychological care. After seeing the value of psychedelic harm reduction in the field, medical personnel requested training for their staff. At AfrikaBurn 2014, medical and Zendo volunteers will work closely to further develop what may become the second leading model of psychedelic harm reduction (after Boom Festival in Portugal, where drugs are decriminalized and volunteers provide care as well as on-site thin layer chromatography adulterant screening).

BURNING MAN 2013 (BLACK ROCK CITY, NEVADA)

After 60 Zendo volunteers assisted 108 guests at Burning Man in 2012, we returned to Black Rock City in 2013 motivated for the project's second iteration. The Zendo was located within

Fractal Planet, a 500-person music and art camp that received an award from the Burning Man organization for outstanding village. The main stage at Fractal Planet drew a large crowd—

around 10,000 on some nights—as did the art gallery, speaker's dome, and numerous art installations near the stage.

One hundred forty individuals participated in the four-hour Zendo training, including 26 medical professionals (physicians, nurses, EMTs) and 22 mental health professionals (psychotherapists, psychologists). Other attendees included students training to be therapists and social workers, experienced harm reduction volunteers from other events such as Shambhala, BOOM, and AfrikaBurn, and a handful of Burning Man Rangers and Emergency Services staff who were off-duty and out of uniform. Trainers included coordinator Linnae Ponté, co-coordinator and therapist Sara Girón, psychedelic researcher George Greer, M.D., Holotropic Breathwork expert Sheelo Bohm, Burning Man Mental Health team member Richard Gottlieb, and MAPS Executive Director Rick Doblin, Ph.D.

Throughout the week, we had over 150 guests in the Zendo, 124 of which had taken psychedelics prior to their arrival. Similar to 2012, the substances guests most often reported having taken before seeking help at the Zendo in 2013 were LSD (32) and psilocybin (21). Many guests come to integrate a previous psychedelic experience, in order to deepen and take away meaningful lessons. Others stop by in search of non-substance-related psychological support including relationship counseling or to seek out information about psychedelics. Finally, some pay their visit just for water and rest—and at a non-stop party in the middle of the desert—that's a very important service.

After an outstandingly successful Indiegogo fundraising campaign that raised \$17,786 for the Zendo Project, we brought a custom-built solar-powered cooling system for the Zendo space and 10 sets of two-way radios to facilitate cross-playa communication. Additionally, David Bronner, President of

Bringing together volunteers with different levels of experience created an environment analogous to a teaching hospital.

Dr. Bronner's Soaps and member of MAPS' Board of Directors, donated an art car called Rainbow Bridge to shuttle guests and volunteers from the field to the Zendo, and between the Zendo and the Full Circle Tea House, a sister harm reduction space founded by Annie Oak of the Women's Visionary Congress.

POLITICAL DYNAMICS FOR HARM REDUCTION ARE SHIFTING

Two drug-related deaths at Electric Zoo, an event in New York held over Labor Day weekend 2013, further highlighted the need for festival organizers to prioritize attendees' health and safety by providing access to drug education and safe spaces to rest and hydrate.

The European organizers of TomorrowWorld, an electronic dance music (EDM) festival taking place from September 27–29, 2013 in Chattahoochee Hills, Georgia, took a progressive approach toward their three-day, 50,000 person-per-day event, as has become typical in Europe, where harm reduction is often required at festivals. In addition to the regular medical services, TomorrowWorld organizers paid for 20 DanceSafe volunteers' travel, accommodations, admission, and commissary. While adulterant screening was not permitted, DanceSafe staffed a festival-provided air-conditioned chill space beside the main medical station. Volunteers reported that many attendees expressed that "there should be something like this at every event."

TomorrowWorld offered a very public presentation of harm reduction with articles about it in *The New York Times* and *Rolling Stone*. Significantly, TomorrowWorld did not receive any negative backlash from media or law enforcement, with the organizers announcing "no deaths, no fights, no arrests, and

only 17 medical transports throughout the weekend." We thank the organizers of TomorrowWorld for taking this huge step in prioritizing their attendees' health and safety. By creating working models of psychedelic harm reduction, we are reducing the number of Drug War casualties and demonstrating our vision for a post-prohibition future.

PSYCHEDELIC HARM REDUCTION SPEAKS LOUDLY TO THE POWER OF COLLABORATION

While festival culture reflects our need for connection and community, the Zendo Project is an exercise in self-reliance at the level of the psychedelic community. As we show that we can help one another, we also reduce public fears surrounding psychedelics, a crucial step in reintegrating these tools and the experiences they can engender back into society.

The success of the Zendo Project can be attributed to the efforts of hundreds of individuals that make up this broad international, multigenerational, and multicultural community. A perfect example of the principle of "radical participation," we thank everyone who volunteered their time to work in the Zendo, as well as those who donated time, money, and resources to enable MAPS to organize the project. Over the next year, Zendo volunteers will travel to the same circuit of events as well as a handful of local events in California.

To find out about volunteering for the Zendo Project in 2014, I invite you to write to us at zendo@maps.org.

Linnae Ponté is Executive and Clinical Research Assistant and Harm Reduction Coordinator at MAPS. She can be reached at linnae@maps.org.

ZENDO PROJECT 2013 GUEST FEEDBACK

"I just needed a quiet, safe space away from lots of people and your volunteers were very compassionate."

"Thank you deeply to my sitter who listened and saw me at my most ugly and sad on the playa. Thank you also for providing this space. I only wish I had known about it earlier."

"I took two hits of acid and felt sick. I did not expect to be here or receive this service but I am so glad it was here... glad that someone made sure I am okay."

"We searched through loud dance party after loud dance party, we finally landed (by chance) in the sweet sanctuary of the Zendo. The amazing staff was kind, loving, compassionate, and just kickass in general. You guys are doing an incredible thing here. Keep up the fantastic work."

THE ZENDO PROJECT MISSION STATEMENT

It is our mission to:

- Provide a supportive space for individuals undergoing difficult psychedelic experiences or other psychological emergencies in order to help turn those experiences into opportunities for learning and personal growth, and to reduce the number of drug-related psychiatric hospitalizations.
- Create an environment where volunteers can work alongside one another to improve their harm reduction skills and receive training and feedback.
- Demonstrate that safe, productive psychedelic experiences are possible without the need for law enforcement-based policies.

zendoproject.org

Working with Trauma: Psychedelic Harm Reduction and Transpersonal Psychotherapy

SARA GIRÓN, M.A.



Sara Girón, M.A.

AS A TRANSPERSONAL PSYCHOTHERAPIST ENGAGED in the study of altered states, I became involved with The Zendo Project seeking to support others in shifting potentially traumatic situations into opportunities for healing, growth, and transformation. From a therapeutic standpoint, the safe environment created in the Zendo is not unlike the one created in the therapeutic alliance. Effective psychedelic harm reduction can mitigate the potential risks associated with substance use as well as support the healing process often catalyzed by the psychedelic experience.

Over the past year, I helped coordinate the Zendo Project in Black Rock City, Envision Festival in Costa Rica, and the Bicycle Day event in San Francisco. The festival setting is one of extremes where even without the use of a substance individuals are pushing the boundaries of their own consciousness. Like psychedelics, transformational festivals invite us to question everything we know about the universe and ourselves. This inherently disorienting environment provides a distinct container: one that at times can be supportive of healing experiences and at other times can be overwhelming.

Difficult psychedelic experiences have often been referred to as “bad trips.” The mindset evident in this term helps shed light on the outdated and often harmful methods by which these experiences are often addressed, including hospitalization and the involvement of law enforcement. This approach to handling someone having a difficult psychedelic experience is common at events and often worsens or escalates a situation. They are methods that attempt to end or interrupt the individual’s experience and can send a message to the individual that something is wrong with them or that they are not safe. The absence of a feeling of safety is a root cause of trauma and is not the ideal approach for someone who is already feeling overwhelmed or frightened.

OPPORTUNITIES FOR GROWTH

From the perspective of transpersonal psychotherapy, every difficult experience we have serves to further our learning and expansion. The internal and external support system of an individual determines how they relate to their experience and the extent to which they learn from it, integrate it, or become traumatized by it. Likewise, in the Zendo, we hold the view that a difficult experience does not necessarily mean a bad one. We provide support to the individual and empower them to shift their experience rather than end it. We accomplish this by providing positive regard, grounded presence, unconditional respect, deep listening, reassurance, and reflection. Uncomfortable emotions and physical sensations, fear, and disorientation are all common during a mind-altering psychedelic journey. People who ingest a psychedelic can expect to be pushed past their comfort zone, experience internal conflict, and learn and grow from these experiences. Altered states of consciousness reveal to us the extremes of suffering and bliss, pain, and ecstasy inherent in human existence.

A common experience of Zendo guests is that they are overwhelmed by their experience and not feeling the safety necessary to surrender to it. The conditions for this safety, or support system, are known as set and setting. Set refers to an individual's internal state and includes emotional state and mood, pre-existing mental conditions, stress, comfort, and developmental stage. Setting refers to individual's external conditions including where the person is, with whom they are with, dosage, and drug interactions. Set and setting are not mutually exclusive and affect and inform one another. When attention is given to set and setting, a safe container can be created, within which the individual can surrender to the experience, even when discomfort or fear arises.

In psychotherapy, the process of turning toward difficult emotions can create powerful opportunities to heal trauma. Pain is the gateway through which we access the parts of ourselves that need to be healed. The therapist can help the client use pain as a portal to healing by inviting the client to turn toward their experience within a safe environment provided by the therapist. During a controlled research study, this same process

is used together with the aid of a psychedelic drug. Therapists place significant importance on the creation of a safe and comfortable environment for the client, which allows the subject to feel deep emotions without being overwhelmed to the point of dissociation or hyper-arousal. Improving how we address

our emotions relating to our life experiences and trauma is at the core of psychotherapy, and is also crucial to helping someone process a difficult psychedelic experience.

In psychotherapy, the process of turning toward difficult emotions can create powerful opportunities to heal trauma.

CREATING A SAFE SPACE

Psychedelics can either help to heal trauma or cause it, depending on whether one feels safe enough to release resistance to the catalyzing effects of the substance. Without this sense of safety, the psychedelic may still illuminate the trauma but the individual will not be able to release their resistance to processing it. This resistance works against the natural healing process catalyzed by the psychedelic. It is important to note that it is this resistance to the experience, and not the experience itself, that causes someone to get stuck in a negatively focused difficult situation. What we resist persists: Resisting an experience creates fear and emotional discord as we attempt to hide from our pain.



Sara Girón and Zendo volunteer/unicorn Rion Beauregard outside of the volunteer yurt. Photo credit: Nicole Sylvestre



Sara Girón speaking to a group of Zendo volunteers.

If a safe container is not in place prior to ingesting a psychedelic, it is still possible to create it afterward. Effective harm reduction projects serve two main functions. The first is to reduce the potential harm caused by ingesting a psychedelic without a safe container; this means mitigating the potential trauma that can result from being overwhelmed by the psychedelic experience. The second is to provide an environment that supports the innate healing process present in each individual and catalyzed by the psychedelic experience.

HEALING TRAUMA

We have all experienced trauma to varying degrees. Trauma can be defined as any event that overwhelms the central nervous system and can be experienced as physical, mental, emotional, or spiritual. From a transpersonal perspective, traumatic experiences left unprocessed become “stuck” in the mind and body of an individual, often resulting in mental and physical illness. In this model, preventing and addressing trauma through harm reduction can have long-lasting beneficial effects on the health and happiness of the people receiving those services.

Psychedelics are catalysts with the potential to assist the innate healing process by helping the individual access and process trauma that has been repressed and relegated to their subconscious. By increasing awareness of energetic, emotional, and

mental processes, they can help disarm the defense mechanisms of our conscious mind. They can also help the individual see the larger context and meaning of their traumatic experiences, leading to understanding and integration.

When it comes to effectively preventing and working with trauma, psychotherapy and psychedelic harm reduction deeply inform one another. The Zendo volunteer team is comprised of many individuals with backgrounds and career aspirations in the mental health field, bringing together people with diverse experiences to apply their knowledge to helping people having difficult experiences. Psychedelic researchers, therapists, and students can benefit from the unique knowledge gained by the *in situ* experiences of The Zendo Project and similar harm reduction programs. I encourage all those interested in getting more involved in the Zendo Project to contact us at zendo@maps.org.

Sara Girón, M.A. is a transpersonal psychotherapist in Boulder, Colorado and co-coordinator for the Zendo Project. She can be reached at sggiron@gmail.com.



A safe place to rest inside the Zendo at Burning Man 2013.



The Zendo provides a comfortable setting.



Lakshmi Narayan

Repositioning Psychedelics in the Collective Consciousness

LAKSHMI NARAYAN

“I ONCE HEARD OF A behavioral study conducted at a university, years ago, long before I became interested in altered states of consciousness, that involved a group of chimpanzees who were placed in a room with a metal ladder, and in the middle of the room, dangling above the ladder, was a bunch of bananas, and of course, the researchers had electrified the ladder, and as expected, one of the chimps started up the ladder for a meal, and as you would imagine, one of the researchers engaged a switch and sent the chimp screaming down the ladder, electrified and terrified and empty-handed. Upon hearing the chimp’s distress, all the other chimps in the room began screaming and jumping with alarm. The mayhem eventually subsided and slowly, another chimp approached the ladder, and the chimp that got shocked, started screaming, and all the chimps joined in, and so no chimps would now approach the ladder.

“Then the researchers removed the chimp that was shocked and brought a new chimp in, that had no idea of what was happening in the room, and of course, the new chimp headed directly for the bananas dangling at the top of the ladder, and all the chimps that had witnessed the initial shocking, began screaming and jumping up and down, which stopped the new chimp, who now started screaming and jumping with the other chimps. This



happened over and over again until finally none of the chimps in the room had seen the original event and none knew what they were actually screaming about.”
 —Excerpted from the blog “Jacobs Ladder” in **thepolemicsofjack.com** by Jack Cross.

So here we are, the human race: war torn, economically bankrupt, mentally ill, over-medicated, over-crowded, fast losing our natural resources and constitutional liberties. And all because we won’t climb that ladder and have forgotten why we should.



THE BIG LIE TECHNIQUE

The idea behind the Big Lie Technique is that if you repeat something often enough it becomes accepted as true. It was articulated by Adolf Hitler in his autobiography *Mein Kampf*.

“...in the big lie there is always a certain force of credibility; because the broad masses of a nation are always more easily corrupted in the deeper strata of their emotional nature than consciously or voluntarily; and thus in the primitive simplicity of their minds they more readily fall victims to the big lie than the small lie...For the grossly impudent lie always leaves traces behind it, even after it has been nailed down, a fact which is known to all expert liars in this world and to all who conspire together in the art of lying.”—Adolf Hitler, Mein Kampf, vol. I, ch. X

WHAT’S THE BIG LIE ABOUT PSYCHEDELICS AND HOW HAS IT BEEN PERPETUATED IN OUR CULTURE?

The lie began in the Garden of Eden, with the tale of the forbidden fruit hanging from the Tree of Knowledge, and the consequences should we eat of it. With this single twisted tale, we gained the iconography that has made its way into our modern symbol for medical healing and emergency as the caduceus. The First Law makes it dangerous for us to partake of knowledge, makes the feminine “evil,” and accentuates the polarization of our human psyche.

It’s no accident that the caduceus is our universal symbol for healing and emergencies, both in the East and the West, as it symbolizes the ultimate healing—parity between male and female, and reversal of the mythic conditions leading to the Fall of Man.

The Western image for healing is two snakes intertwined around a pole, who kiss and grow wings at the top; in other words, they ascend and unite, becoming a creature of a higher order, from something that crawls to something that flies, from two to one. The snakes represent the male and female, or yin and yang, entwined like the double helix; no matter which way you slice it, it’s in the blueprint.



In the East, the caduceus represents the life force energy “rising” up the pole/spine of the neuron/tree to reach union in the pineal gland. Its called “Kundalini,” or Coiled Serpent, also known as the evolutionary energy of Man. It waits to be awakened at the base of the spine, perhaps by meditation, or perhaps by a chemical trigger. When activated, it moves up the spinal meridians, enlightening the way.

YOUR BRAIN ON DRUGS

The Big Lie about psychedelics has continued to perpetuate in many ways through the centuries, suppressing many wisdom paths along the way: the decimation of the Druidic cultures,

witch hunts in the Middle Ages, the demonization of the shaman by the Christian missionaries and Spanish *conquistadores*. The lie has certainly been repeated often enough.

In 1985, a group of powerful advertising agencies in the US created the Partnership for a Drug-Free America and ran a series of ad campaigns to “unsell drugs.” They targeted crack cocaine, marijuana, heroin, Ecstasy, and others. Best known among these is the “This Is Your Brain on Drugs” campaign which still reverberates today in the expression “being fried.”



No doubt well-intentioned, the Partnership for a Drug Free America lumped psychedelics with toxic and more addictive substances. For over 11 years they bombarded us with messages which, while they have not succeeded in making us drug-free, have succeeded in making us very confused about the nature of the substances we call “Psychedelics” (seeing into the soul) or, for some, “Entheogens” (generating God within).

2,000 YEARS OF AN EMPTY CHALICE, AND WE’RE A PRISON PLANET

When the path to Original Knowledge becomes recast as Original Sin, we have a culture that has been upside down for millennia. Long imprisoned by our ideas of what’s forbidden and what’s right and wrong, we’re stuck in context. Our relationship with our consciousness, with our spiritual nature, comes out of hearsay, books, over-translated long-dead religions, the tasteless wafer of sacraments that do not alter, empty rituals, idle worship, and questionable authorities.

Psychedelics are “mind-manifesting:” they can manifest the One Mind, or they can manifest the fragmented psyche. It all depends on the set and setting.

“Set and setting” is a term that was coined by Timothy Leary to describe the conditions which predicate a good psychedelic experience. While the set and setting can be controlled in one’s immediate physical environment for the duration of a

journey, the prevalent “global” set and setting that hangs over psychedelics in general is the shadow of ignorance and fear, which can only be transformed, not controlled. The price we currently pay for altering our consciousness is loss of freedom—making criminals of those who partake in self-healing and self-knowledge, and changing the nature of the experience itself in ways that *we cannot know or foresee*.

Psychedelics can help reframe reality by allowing a person trapped in a horrifying experience from their past to become aware of and release the memory, to experience the Self differently. The healing is of the body, mind, and spirit. But before psychedelics can reframe the global Self, we need to reframe how psychedelics are perceived in the public mind and portrayed in the media.

MEDIA CONDITIONS CULTURE

Both in their structure and their content, media and the psyche are inseparable. We are influenced by the cultural milieu we live in, despite ourselves. As Marshall McLuhan famously wrote: “The medium is the message.” What he meant is that the very form of the medium changes human experience, regardless of content. McLuhan felt that the content had little effect on the message, but in my view and experience, both medium and message are important: they are the yin and yang of how media work. Both *together* condition culture.

Until the advent of social media, media conditioning was a one-way street, from the big TV networks of information and the press to the “public.” You needed a hefty marketing budget and expensive technical skills and equipment to broadcast anything on media. In 2013, however, the landscape is dramatically different. We have email, Facebook, Twitter, YouTube, blogs, photo sharing, infographics, group text messages, image editing, mobile phone cameras, all kinds of easily accessible and mostly free ways to broadcast your message, whether you’re a corporation or an individual.

THE COLLECTIVE CONSCIOUSNESS TO THE RESCUE

Let’s suppose for a moment that psychedelics are, apart from being a medicine for healing PTSD, addiction, and other “conditions,” also agents of evolution, and that the lack of an

ongoing relationship with mind-expanding medicines has created a species on the brink of self-annihilation. Could it then be true, that if we, as a species, improve our relationship with psychedelics, we would

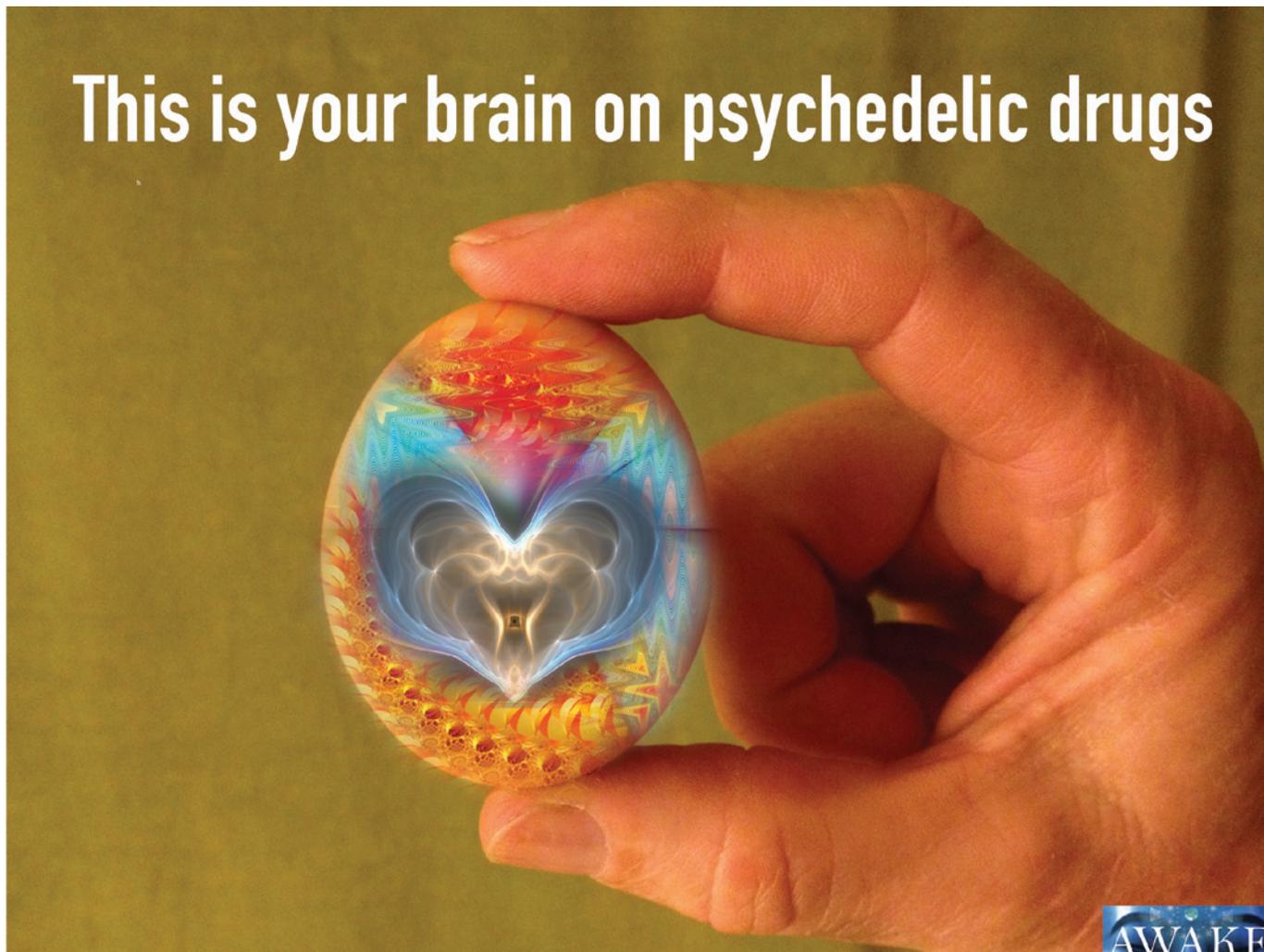
Could it then be true, that if we, as a species, improve our relationship with psychedelics, we would experience a flowering of culture, a kind of renaissance of human consciousness?

experience a flowering of culture, a kind of renaissance of human consciousness? If this is true, then psychedelics might well be the most effective and easily accessible tinder we have for expanding our compassion, our intelligence, our creativity, our

relationship with our body, our psyche, our mind, our planet, our cosmos, and our profundity.

It seems to me that this is a job for the collective conscious. An easy way to do this is for anyone who feels so inspired to intentionally blog, post timeline messages and YouTube videos sharing and re-sharing their real, lived experience with psychedelics. New ideas take time, as well as consistency and repetition, to take hold in the collective unconscious. But the

more positive messages there are out there, the more we shift cultural perception. So sign on to social media and post about what psychedelics are, how they have helped you, harm reduction tips, quotes from your favorite authors, visionary artwork that inspires you, and create your own timeline images. With the multitude of communication tools at our disposal, we can all become media wizards. What's TRUE about psychedelics? Share it on your timeline and help regenerate culture. 🌀



*Lakshmi Narayan is a graphic designer and the CEO of **AwakeMedia.com**, a Santa Cruz based design firm, working on projects that raise consciousness, be it political, social, environmental or spiritual. Awake Media creates brands, web sites, mobile apps, videos, print media, and events. Lakshmi can be reached at narayan@awake.net.*

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One out of three people
suffering from posttraumatic
stress disorder (PTSD) do not
respond adequately to treatment.

**Can MDMA-assisted
psychotherapy help?**

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MAPS: Who We Are

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 governments, pharmaceutical companies, or major foundations. That means that the future of psychedelic and marijuana research is in the hands of individual donors. Please consider making a donation today.

maps.org/donate



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Rick Doblin, PhD, Founder and Executive Director, earned his PhD in Public Policy from the Kennedy School of Government at Harvard University. Doblin was also in Stan and Christina Grof's first training group to receive certification as a Holotropic Breathwork practitioner.



Michael Mithoefer, MD, Clinical Investigator/Medical Monitor, is a psychiatrist practicing in Charleston, SC, where he divides his time between clinical research and outpatient clinical practice specializing in treating posttraumatic stress disorder (PTSD) with an emphasis on experiential methods of psychotherapy. He is a certified Holotropic Breathwork Facilitator and trained in EMDR and Internal Family Systems Therapy.



Annie Mithoefer, BSN, MDMA/PTSD Study Co-Investigator, is a Registered Nurse who lives in Charleston, SC where she divides her time between clinical research and outpatient clinical practice specializing in treating posttraumatic stress disorder (PTSD) with an emphasis on experiential methods of psychotherapy. She is a certified Grof Holotropic Breathwork Practitioner and is trained in Hakomi Therapy.



Brad Burge, Director of Communications and Marketing, earned his B.A. in Communication and Psychology from Stanford University in 2005 and his M.A. in Communication from the University of California, San Diego in 2009. His graduate work focused on the political, scientific, and cultural changes required to make illicit drugs into legitimate medicines.



Amy Emerson, Director of Clinical Research, earned her B.S. in genetics and cell biology from Washington State University. She has worked in clinical development and research for the last 15 years in the fields of immunology, oncology, and in vaccine development. Amy has worked with MAPS since 2003 facilitating the development of the MDMA clinical program.



Virginia Wright, Director of Marketing and Development, brings a wealth of fundraising experience to MAPS. Her firm Wright & Associates has provided strategic thinking, marketing, and fundraising services to arts organizations and cities throughout Northern California and Nevada. She received her B.A. in International Relations from San Francisco State University, and her M.B.A. from Santa Clara University.



Brian Brown, Communications and Marketing Associate, studied medical anthropology and visual culture at the University of California, Santa Cruz where he researched social prospects for psychedelics using a community centered approach. Brian is now developing MAPS' membership base by assisting with education and outreach efforts.



Kynthia Brunette, Operations Associate, has a B.A. in Political Science, an M.S. in Human Computer Interaction, and a lifelong interest in models of personality and development. Her interests have evolved over the years into a fascination with the design of institutions, organizations, and experiences that serve as vehicles for transpersonal growth.



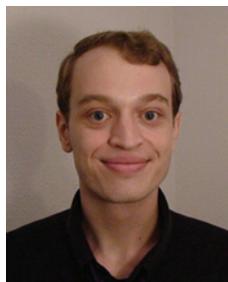
Tess Goodwin, Development Assistant, has a B.A. in Psychology from the University of California, Santa Cruz, where she focused most of her time on social psychology and newspaper production. She is a mycophile, artist, and language enthusiast.



Sarah Jordan, Publications Associate, earned her B.A. in Environmental Policy with a minor in Journalism from the University of California at Santa Cruz. Prior to joining MAPS, she was Communications and Development Assistant at Firelight Foundation in Santa Cruz, CA.



Ilsa Jerome, PhD, Research and Information Specialist, earned a Ph.D. in psychology from the University of Maryland. She helps MAPS and other researchers design studies, gathers information on study drugs by keeping abreast of the current literature and discussion with other researchers, creates and maintains documents related to MAPS-supported studies, and helps support the MAPS psychedelic literature bibliography.



Bryce Montgomery, Web and Multimedia Associate, studied film production at West Valley College, joining MAPS as Social Media Intern in the summer of 2011. Bryce now serves as Multimedia Associate, bringing his background in film production and social media to public education about psychedelics.



Linnae Ponté, Executive and Clinical Research Assistant and Harm Reduction Coordinator, earned her BA in Biological Psychology from New College of Florida. She's assisted data collection and analysis at University of South Florida's Cardiovascular Psychophysiology Laboratory, MOTE Marine Mammal Aquarium Psychophysical Laboratory, East-West College of Natural Medicine, and the West Mamprusi Civic Union in Ghana, West Africa.



Berra Yazar-Klosinski, PhD, Lead Clinical Research Associate, earned her Ph.D. in Molecular, Cell, and Developmental Biology from University of California Santa Cruz, where she also served as president of the Graduate Student Association. After attending Stanford University, she worked as a Research Associate with Geron Corporation and Millennium Pharmaceuticals.

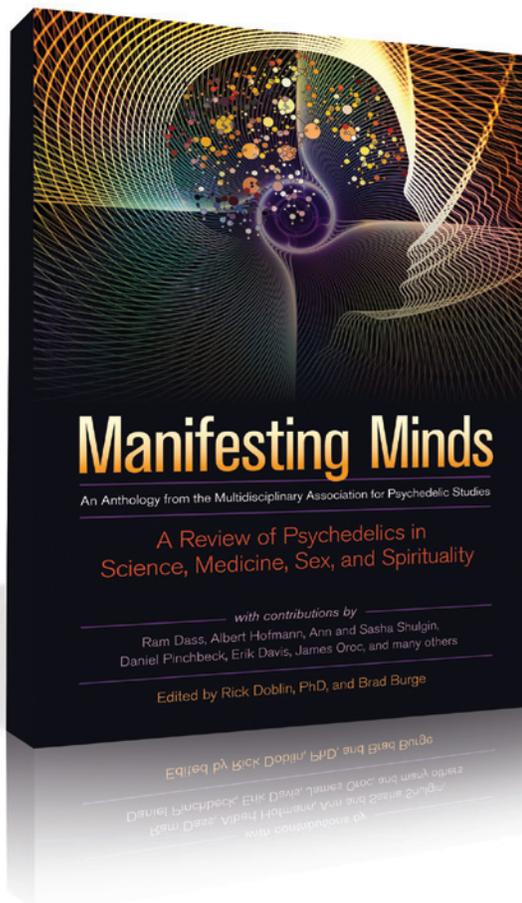
Manifesting Minds

A Review of Psychedelics in Science, Medicine, Sex, and Spirituality

by Rick Doblin, Ph.D., and Brad Burge

“The varieties of psychedelic experience are boundless and beyond words, but this enlightening anthology manages to map much of that ineffable territory. Thank you, MAPS, for helping us understand the science and the spirit that support this endless journey.

—Don Lattin, author of *The Harvard Psychedelic Club* and *Distilled Spirits*



A “best of” collection of articles and essays previously published in the *MAPS Bulletin*, featuring essays and interviews with Timothy Leary, Aldous Huxley, Ram Dass, Albert Hofmann, Alexander (Sasha) Shulgin, Daniel Pinchbeck, Tim Robbins, Arne Naess, and electronic musician Simon Posford.

Topics include the healing use of marijuana and psychedelics—including MDMA, ibogaine, LSD, and ayahuasca—for PTSD, anxiety, depression, and drug addiction, as well as the positive effects of these substances in the realm of the arts, family, spirituality, ecology, and technology.

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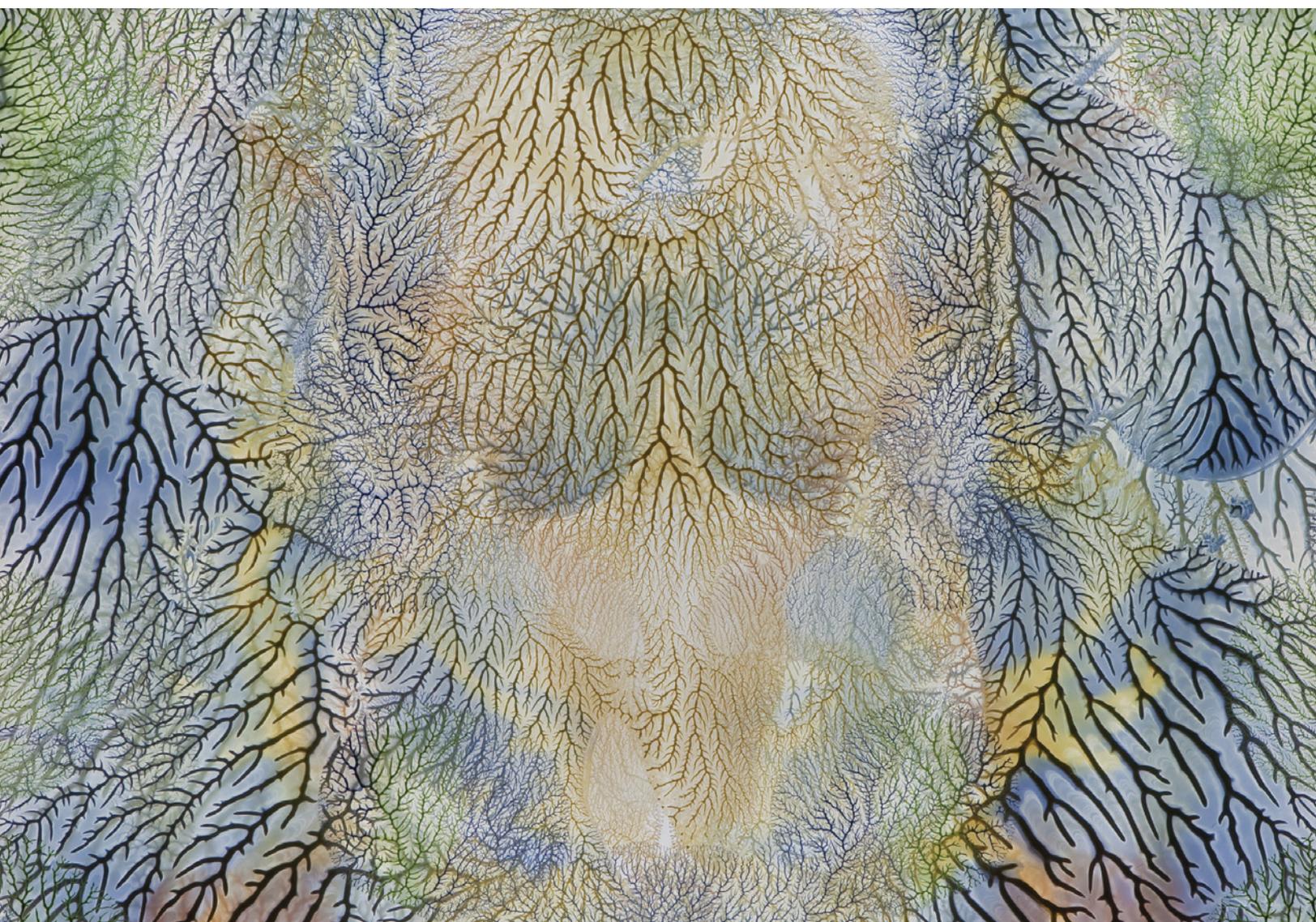
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Rick Doblin, Ph.D., is the founder and executive director of the Multidisciplinary Association for Psychedelic Studies (MAPS). He received his doctorate in Public Policy from Harvard’s Kennedy School of Government, where he wrote his dissertation on the regulation of the medical uses of psychedelics and marijuana. He founded MAPS in 1986, and lives in Boston with his wife and three children.

Brad Burge is the director of communications and marketing for the Multidisciplinary Association for Psychedelic Studies (MAPS). His graduate work focused on the political, scientific, and cultural changes required to make illicit drugs into legitimate medicines. His professional work is dedicated to helping people develop responsible relationships with themselves, each other, and their pharmacological tools.



Front cover: *Cosmic Vitruvian* by Brian Scott Hampton

Back cover: *No. 230* by Peter Bynum

Artist information on page 3