

2012 Annual Report
BULLETIN





Team meeting in Colorado



Autumn in Colorado



Reviewing the treatment protocol

Second U.S. MDMA-Assisted Psychotherapy for PTSD Study Site Trains a New Generation of Therapists

Our new study in Boulder, Colorado, will explore the safety and effectiveness of MDMA-assisted psychotherapy for PTSD when one member of the co-therapist team is an experienced therapist and the other an intern working under supervision for credit towards licensure. The use of interns is an effort both to reduce costs and to train the next generation of therapists trained in our treatment method.

From September 21-23, 2012, MAPS Director of Clinical Research Amy Emerson and Lead Clinical Research Associate Berra Yazar-Klosinski, Ph.D., visited the study site. They met with Principal Investigator Marcela Ot'alora, L.P.C., co-investigators, and other study staff to conduct a final training on the protocol and study documents, as well as to review our MDMA Investigator's Brochure and new safety data from completed MAPS clinical trials.

\$497,000 estimated study cost / \$372,000 still needed

Study Timeline

February 2013 (estimated): Subject screening begins
 October 25, 2012: Business license issued for study site
 September 21-23, 2012: Study initiation meeting (pictured)
 July 31, 2012: DEA requires new business license after site inspection
 May 15, 2012: DEA approves protocol

May 4, 2012: FDA approves protocol
 April 8, 2012: Therapist teams complete training
 March 9, 2012: IRB approves protocol
 December 9, 2011: Planning meeting takes place at MAPS' 25th anniversary conference



Boulder MDMA-assisted psychotherapy for PTSD study team



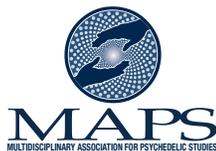
MAPS Lead Clinical Research Associate Berra Yazar-Klosinski, Ph.D.



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



MAPS Director of Clinical Research Amy Emerson



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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Cover Art: *Rolling Thunder* by Simon Haiduk

48" x 24" Digital Painting

Limited Edition Giclee Print: Retail Price \$450.

Purchase this piece at maps.org/store.

50% of proceeds benefit MAPS research and education projects.

Growing up in British Columbia, **Simon Haiduk** developed strong foundations in visual arts, music and an affinity with nature. In 1999 he attended a Fine Arts program at UCC in Kamloops and soon discovered that he would rather travel and learn more on his own. This led Simon to various parts of Central and South America. In 2004 he gravitated towards painting as a full time endeavor. As a mostly self-taught artist, Simon has explored various mediums, and subjects, with a strong influence in spiritual themes. After some time touring in art shows and festivals with a group of similarly themed artists, Simon decided to further his skills in Digital Design, graduating from Vancouver Film School in 2007. He currently works out of his studio as a freelance artist, while continuing to explore an ever-expanding palette of creative endeavors. Simon's art continues to be shown in various public and private galleries throughout the world.

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From the Desk of Rick Doblin, Ph.D.



Rick Doblin, Ph.D.

PROGRESSIVE CHANGE IS IN THE AIR. President Obama was re-elected; the US Senate has shifted slightly to the left; gay marriage passed in Maine, Maryland, and Washington; marijuana was legalized in Washington and Colorado; and Massachusetts became the 18th state, along with the District of Columbia, to have approved the medical use of marijuana. The implications for MAPS of a gradual progressive shift could be profound.

We're in the early stages of working to prepare a grant application for MDMA-assisted psychotherapy for PTSD research to the National Institute of Mental Health (NIMH), which would probably happen in collaboration with a major research university (*page 12*). As far as I know, if such a grant application is eventually accepted, this would be the first time in over 40 years that NIMH, or any other US government agency, has funded psychedelic psychotherapy research.

MAPS is also working to start a study of MDMA-assisted psychotherapy for active duty soldiers with PTSD. For the first time in 15 years of effort, we have the opportunity to submit a protocol to an Institutional Review Board (IRB) at a Dept. of Defense facility. Our current study in veterans with PTSD is generating promising results. However, the VA is not actively referring subjects to our study. Rather, veterans with PTSD who have not been successfully treated by the VA are volunteering on their own, with hundreds on our waiting lists.

MAPS is even making some slow but steady progress with the protocol for our planned study of marijuana for veterans with PTSD, which was approved by the FDA on April 28, 2011. On September 16, 2011, the protocol was rejected (a more accurate word would be “trashed”) by the Public Health Service (PHS) reviewers who evaluated the protocol from the perspective of basic science rather than drug development. As a result, the National Institute on Drug Abuse (NIDA) refused to sell us any of its marijuana. This killed the study since NIDA has a monopoly on the supply of marijuana legal for use in federally regulated clinical research. On October 25, 2012, we managed

to obtain approval for the study from an IRB at the University of Arizona, which accepted all our key protocol design elements but added some safety procedures and measures. This IRB approval places us in an excellent position to return to the PHS reviewers to request marijuana for the study as currently designed (*page 22*).

Our 11-year legal struggle with the Drug Enforcement Administration (DEA)—seeking to end the NIDA monopoly by obtaining a DEA license for Prof. Lyle Craker of UMass-Amherst to produce marijuana under contract to MAPS for federally regulated research—is now awaiting a ruling from the First Circuit Court of Appeals. Oral arguments were held on May 11, 2012, with Prof. Craker receiving outstanding pro-bono legal representation from the major Washington, DC, law firm Covington & Burling LLP, and the ACLU. We anticipate a ruling soon (*page 14*).

The importance of MAPS' research into the healing of PTSD has been highlighted by tragic news taking place as I write this message. I've just learned that the start of MAPS' Israeli MDMA-assisted psychotherapy for PTSD study may be delayed due to the possibility that some of the psychiatrists and therapists conducting the study may be called into the reserves for a potential invasion of Gaza. I was also sent a picture of a rocket coursing through the sky immediately over an Israeli medical marijuana production facility. Sadly and paradoxically, our efforts to treat PTSD in a small number of subjects may be postponed as the result of a war that will create many new cases of PTSD in Israel and Gaza (*page 12*).

We ask for your continued and expanded support so that we can fund our research into the treating of PTSD. May the technology of healing spread faster than the technology of war.

*May the
technology of
healing spread
faster than the
technology
of war.*

A handwritten signature in black ink that reads "Rick Doblin". The signature is written in a cursive, flowing style.

Rick Doblin, Ph.D.

MAPS Founder and Executive Director

Annual Financial Report

RICK DOBLIN, PH.D.

OUR YEAR-END FINANCIAL REPORT from the Multidisciplinary Association for Psychedelic Studies (MAPS) is a key element in our commitment to transparency. This report complements our year-long focus on strategically and efficiently leveraging the 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.

Our goal with this Financial Report is to enable MAPS supporters and the public to see our priorities in action through how we allocate our limited funds. Should you have any questions about any items in this financial report, you are invited to inquire at askmaps@maps.org.

As I write this report, we are in the midst of having our books reviewed for the second year in a row by a team of independent auditors. We're paying for these audits on our own initiative with the hope to eventually obtain financial support from major foundations or government research agencies, which require audited financials as a prerequisite for funding. We're anticipating needing to raise ever-larger amounts as we work to complete our Phase 2 pilot studies of MDMA-assisted psychotherapy for PTSD, then to initiate the pivotal Phase 3 multi-site studies required to prove safety and efficacy prior to FDA approval for prescription use. Similarly, though with an in-house team, we're monitoring the data in our Phase 2 studies to build organizational capacity for operating at the level of pro-

fessionalism and accountability needed for our pharmaceutical drug development research.

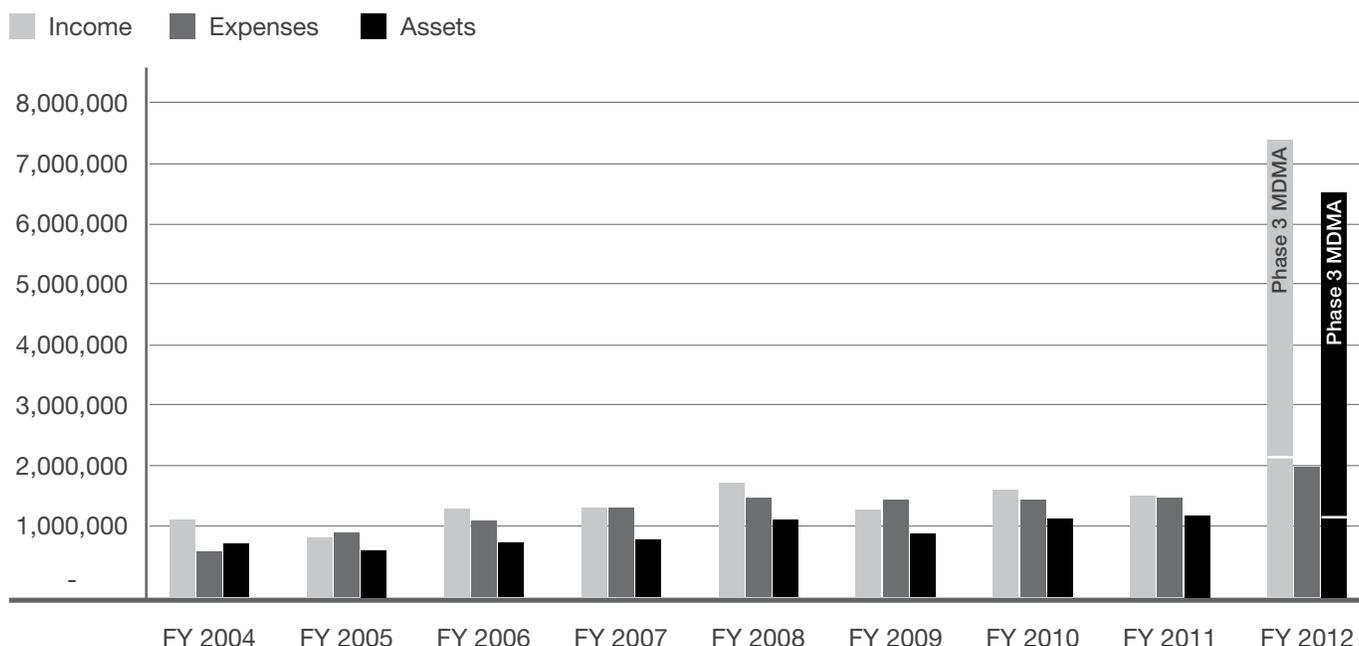
What follows is a comprehensive reporting and discussion of MAPS' income and expenses for FY 11-12 (June 1, 2011 to May 31, 2012).

OVERVIEW FY 11-12

MAPS' income in FY 11-12 was \$7.37 million, expenses were \$1.99 million, changes in net assets were \$5.38 million, and total assets at the end of FY 11-12 were \$6.54 million. This compares to income in FY 10-11 of \$1.47 million, expenses of \$1.38 million, changes in net assets of \$90,000, and total assets at the end of FY 10-11 of \$1.16 million.

The most significant financial development in FY 11-12, and also the saddest, was the bequest that MAPS received from the estate of Board of Directors member Ashawna Hailey, amounting to an estimated \$5.5 million. This is an estimated number because, according to auditing procedures that we are adopting this year, the full estimated amount of the bequest needs to be allocated in the year the bequest was received. This is the case even when not all the funds are actually disbursed in that fiscal year, as with Ashawna's bequest since it will take some time to sell all of the assets. MAPS actually received \$3.2 million of the bequest in FY 11-12, and has received another \$800,000 so far in FY 12-13. In addition, some of Ashawna's assets are not liquid and may eventually be sold for less than book value.

Chart 1. MAPS Fiscal Year 2004 - 2012 Income, Expenses & Assets



MAPS' change in net assets in FY 11-12 was \$5.38 million, about \$170,000 less than the \$5.5 million booked from Ashawna's bequest. Without Ashawna's bequest, MAPS had a net loss of about \$170,000. However, MAPS would otherwise have received \$200,000 from Ashawna for unrestricted operational expenses. In the absence of the bequest but with that \$200,000, MAPS would have brought in about \$30,000 more than we spent in FY 11-12.

The amount Ashawna bequeathed to MAPS represents half (4/8) of his charitable bequests, with another 1/8 given to the Marijuana Policy Project (which they used to help legalize marijuana in Colorado), another 1/8 to the Drug Policy Alliance (for drug policy reform), another 1/8 for the American Civil Liberties Union (for drug policy reform), and the remaining 1/8 to the San Jose Second Harvest food bank. The

recipients of Ashawna's bequest illustrate the direct link he saw between scientific research with psychedelics and marijuana and drug policy reform.

Ashawna cared most about MAPS' work developing the therapeutic use of MDMA. As a result, MAPS' Board of Directors has chosen to restrict \$200,000 of his donation to start a new study of MDMA in adults on the Autism Spectrum and the remaining \$5.3 million to our Phase 3 studies of MDMA-assisted psychotherapy for PTSD, which will start within the next three years at a cost we currently estimated to be \$10-\$15 million. There's a wide range of estimated Phase 3 expenses since the costs will depend on the design of the Phase 3 studies, which will be determined at an End-of-Phase 2 meeting with the FDA in two to three years. By restricting Ashawna's bequest in this manner, our goal is to leverage his donation in

Chart 2. Statement of Activities

Statement of Activities

Revenue and Support	FY11-12
Support from Individuals	6,434,201
Support from Foundations	257,500
Event Income	257,297
Sales	71,101
Investment and Other Income	353,687
Total Revenue and Support	\$ 7,373,786
Cost of Goods Sold	(32,043)
Gross Profit	\$ 7,341,743
Expenses	
Research	718,258
Education	595,986
Total Programs	1,314,244
Fundraising	186,661
Operations	455,905
Total Expenses	\$ 1,956,810
Other Income (Expense)	(2,692)
Change in Net Assets	\$ 5,382,240

**These funds are restricted to Phase 3 drug development of MDMA-assisted psychotherapy for the treatment of posttraumatic stress disorder.*

Chart 3. Statement of Financial Position

Statement of Financial Position

Assets	FY11-12
Cash and Equivalents	4,274,610
Pledges Receivable	2,328,630
Other Current Assets	43,553
Total Assets	\$ 6,646,793
Liabilities	FY11-12
Accounts Payable and Accrued Expenses	103,588
Total Liabilities	\$ 103,588
Net Assets	FY11-12
Unrestricted	652,286
Board Restricted	5,531,613
Temporarily Restricted	359,306
Total Net Assets	\$ 6,543,205
Total Liabilities and Net Assets	\$ 6,646,793

Chart 4. Temporarily Restricted, Board Restricted & Other Restricted Funds

	Temporarily Restricted May 31, 2012	Board Restricted May 31, 2012
MDMA Studies		
US MDMA/PTSD Veterans	196,238	
US MDMA/PTSD Interns	57,284	
US MDMA/PTSD Phase 3		5,331,613
US MDMA Adult Autism		200,000
US MDMA Training		
Canada MDMA/PTSD		
Israel MDMA/PTSD		
Jordan MDMA/PTSD	26,398	
Total MDMA	\$ 279,920	\$ 5,531,613
Ibogaine Studies		
New Zealand Ibogaine	9,141	
Mexico Ibogaine	4,620	
Total Ibogaine	\$ 13,761	
Marijuana Studies		
Vaporizer Study	10,364	
Start Up Fund (UMass Amherst)	4,900	
MJP1-1	2,748	
Total Marijuana	\$ 18,012	
LSD/Psilocybin Studies		
LSD/Psilocybin General	32,408	
LSD Swiss Study	13,205	
Total LSD/Psilocybin	\$ 45,613	
Other Studies		
Ketamine Research	1,000	
Creativity Study	1,000	
Total Other Studies	\$ 2,000	
Total Temporarily Restricted and Board Restricted Funds	\$ 359,306	\$ 5,531,613
Other Non MAPS Funds Available for Projects		
Swiss LSD Study	4,822	
Total Other Funds	\$ 4,822	

the most efficient way possible. Raising the remaining funds for Phase 3 will be easier since we will already have a significant fraction of the funds we need, so we hope donors will see that it is not such an insurmountable sum to raise. In addition, we reason that reserving funds for Phase 3 will make it easier to raise the roughly \$3 million we estimate we still need to complete Phase 2, since the chances we'll be able to conduct and complete our Phase 3 studies is now more realistic.

In addition to Ashawna's bequest, MAPS received \$350,000 in one-time net income in FY 11-12 from the sale of a remainder interest in a home in La Jolla, Calif., which MAPS received in a bequest from Eric Bass in FY 94-95. MAPS also received \$75,000 in FY 11-12 from a bequest from Larry Thomas. MAPS also received \$350,000 from Larry Thomas's bequest in FY 10-11 and will receive a final payment of about \$25,000 in FY 12-13, making the total value of Larry Thomas's bequest about \$450,000. The three largest donations in MAPS' 26-year history have all come from bequests. For those reading this report, please consider adding MAPS to your wills.

In addition to the bequests from Ashawna and Larry Thomas, MAPS received most of our other income from our top 18 donors, who collectively donated \$869,127. Peter Lewis donated \$225,000; David Bronner, Adam Wiggins, and the Keeler Foundation each donated \$100,000; the Mental Insight Foundation and the Riverstyx Foundation each donated \$60,000; Robert Barnhart donated \$51,850; the Libra Foundation donated \$35,000; Matt Bowden donated \$25,000; John Gilmore donated \$20,000; Vanya Palmers donated \$16,152; Bill Linton donated \$12,500, as did an anonymous donor; Larry Haggman donated \$11,100; Ian Brown donated \$10,025; Gerald Gaines donated \$10,000, as did Wendy Grace and Rene Ruiz/Sue Mosher. MAPS received an additional \$176,487 from 38 other donors of amounts between \$1000 and \$10,000.

Chart 5. MAPS FY12 Actuals & FY13 Projected Detail Expenditures

	FY11-12 Actuals	FY12-13 Projected
Research		
Ayahuasca		
Ayahuasca-Assisted Treatment for Addiction (Canada)	14,880	
Total Ayahuasca	\$ 14,880	
Ibogaine		
Ibogaine-Assisted Therapy for Addiction (Mexico)	8,603	13,306
Ibogaine-Assisted Therapy for Additction (New Zealand)	5,859	9,137
Total Ibogaine	\$ 14,462	22,443
LSD/Psilocybin		
LSD-Assisted Psychotherapy for Anxiety (Switzerland)	42,233	18,812
Total LSD/Psilocybin	\$ 42,233	18,812
Marijuana		
Medical Marijuana Production Facility (Massachusetts)	4,978	1,000
Marijuana for Symptoms of PTSD in Veterans of War (Arizona)	1,443	6,203
Marijuana for Symptoms of PTSD	4,449	2,000
Total Marijuana	\$ 10,870	9,203
MDMA		
MDMA Literature Review	3,764	9,076
MDMA-Assisted Psychotherapy for PTSD (Australia)	11,759	237
MDMA-Assisted Psychotherapy for PTSD (Canada)	2,433	75,644
MDMA-Assisted Psychotherapy for PTSD (UK)	372	500
MDMA-Assisted Psychotherapy for PTSD (Israel)	44,062	164,495
MDMA-Assisted Psychotherapy for PTSD (Jordan)	1,866	500
MDMA-Assisted Psychotherapy for PTSD: Caps Comparison	71	
MDMA-Assisted Psychotherapy for PTSD (Switzerland)	25,794	2,653
MDMA-Assisted Psychotherapy for PTSD (US-Colorado)	27,468	138,675
MDMA-Assisted Psychotherapy for PTSD: Long-Term Followup (US-South Carolina)	8,656	
MDMA-Assisted Psychotherapy for PTSD: Pilot Study (US-South Carolina)	8,092	10,017
MDMA-Assisted Psychotherapy for PTSD: Relapse Treatment (US-South Carolina)	19,571	10,000
MDMA-Assisted Psychotherapy for PTSD: Veterants (US-South Carolina)	233,060	422,867
MDMA-Assisted Psychotherapy for PTSD: US Department of Defense		10,000
MDMA Research Support	55,298	43,969
MDMA Supply, Transportation, and Storage	3,941	8,750
MDMA-Assisted Psychotherapy: Therapist Adherence Criteria	449	15,377
MDMA-Assisted Psychotherapy Training Protocol (US-South Carolina)	13,041	25,629
MDMA-Assisted Psychotherapy for PTSD: Treatment Manual	1,001	7,020
MDMA-Assisted Therapy for Adults on the Autism Spectrum (US)	7,852	82,818
MDMA NIMH		5,379
MDMA-Assisted Psychotherapy for PTSD: Researcher Supervisory/Public Education Time	52,854	20,000
MDMA-Assisted Psychotherapy for PTSD: Therapist Training Program	4,656	5,000
Total MDMA	\$ 526,060	1,058,607
Other		
Statistical Software and Hardware	6,001	28,965
Clinical Research (General)	103,752	63,971
Total Other	\$ 109,753	92,936
Total Research	\$ 718,258	1,202,001

Donations less than \$1,000 came from about 2,000 additional donors and amounted to \$117,576. These unrestricted donations of less than \$1,000 are a crucial part of MAPS' success. These donations help us to cover some of our operational expenses, are part of building the MAPS community, lead to word-of-mouth contacts with new donors, and are the way some major donors began to get to know MAPS by enabling them to evaluate our work from the perspective of a member.

MAPS also brought in \$71,101 from sales of books, art, clothes and other items. Event income was \$257,297.

MAPS' expenses in FY 11-12 amounted to \$1.95 million. Of that amount, \$718,000 (37%) was for research; \$595,000 (30%) was for education; \$455,000 (23%) was for management and general operations, cost of products sold, employee benefits and office equipment; and \$186,000 (10%) was for the cost of fundraising.

A more detailed description of MAPS' expenses is provided here. From this list, the breadth of MAPS' activities can be seen more clearly, as can our strategic priorities.

	FY11-12 Actuals	FY12-13 Projected
Education		
Conferences and Events		
Psychedelic Science 2013	3,816	340,902
MAPS 25th Anniversary: Cartographie Psychedelica	352,426	
Psychedelic Harm Reduction Services	5,503	8,500
Outreach Events	45,207	27,601
Total Conferences & Events	\$ 406,952	377,003
Publishing		
MAPS Bulletin, Book Publishing and Brochures	39,527	34,000
Web and Internet Hosting	7,861	8,000
Web Administration	6,010	3,500
Social Media	2,424	19,500
Email Newsletter	7,279	7,500
Web Content Development	10,334	2,500
Advertising	20,713	7,165
Education Staff and General Expense	94,886	77,031
Total Publishing	\$ 189,034	159,196
Total Education	\$ 595,986	536,199
Total Programs (Research & Education)	\$ 1,314,244	1,738,200
Administration		
Fundraising		
Events	29,194	2,204
MAPS International (Canada and Hungary)	32,141	5,000
Fundraising Staff and General Expense	125,326	143,315
Total Fundraising	\$ 186,661	150,519
Operational		
Business Expenses	21,364	23,250
Audit	25,714	12,500
Information Technology	17,754	35,696
Facilities and Equipment	14,618	10,301
Occupancy	42,166	38,050
Office Expenses	44,180	36,154
Staff	260,736	251,995
Staff Development	16,935	8,000
Travel	12,438	6,000
Total Operations	\$ 455,905	421,946
Total Administrative Expenses	\$ 642,566	572,466
Total Expenses	\$ 1,956,810	2,310,666

CONCLUDING COMMENTS

MAPS faces a major fundraising challenge in FY 12-13. In FY 11-12, we benefited from a one-time net gain of \$350,000 from the sale of our remainder interest in a home in La Jolla, Calif. We also received a donation of \$100,000 from the Keeler Foundation that will not be repeated this year. In addition, we received \$75,000 from the bequest of Larry Thomas and will receive the final payment of about \$25,000 this year (\$50,000 less than last year). This means that we received income of half a million dollars in FY 11-12 that will not be repeated in FY 12-13. In

addition, we're expanding our research agenda in FY 12-13 by about half a million dollars. In order to balance income and expenses in FY 12-13, we will need to bring in about \$1 million in new donations, while sustaining our other donations at the same level. This is a daunting challenge, especially after a U.S. presidential election year that consumed an estimated \$6 billion in non-taxable donations for all local, state, and federal races.

Nevertheless, MAPS' fundraising goals for FY12-13 are attainable. The need for research into the healing potential of psychedelics is profound, we are building a track record of

Chart 6. MDMA Research Projects

Key MDMA/PTSD Research Projects	Actuals 2009-10	Actuals 2010-11	Actuals 2011-12	Projected 2012-13	Projected 2013-14	Projected 2014-15	Projected 2015-16	Projected 2012-16
US MDMA/PTSD Pilot	110,000	19,241	7,239	10,017	0	0	0	10,017
US MDMA/PTSD Relapse	0	5,845	19,567	19,252	5,335	0	0	24,587
US MDMA/PTSD Veterans	35,806	147,600	202,867	463,124	276,890	55,212	13,600	808,826
US MDMA/PTSD Intern	0	0	19,172	138,675	140,288	140,820	26,394	446,177
Swiss MDMA/PTSD	33,500	30,666	25,544	2,653	0	0	0	2,653
Israel MDMA/PTSD	27,308	33,696	43,861	164,495	129,402	6,490	0	300,387
Canadian MDMA/PTSD	9,814	8,615	2,433	75,644	134,114	158,637	99,579	467,975
Jordanian MDMA/PTSD	31,456	21,458	1,831	0	0	0	0	0
UK MDMA/PTSD	0	1,347	372	500	0	0	0	500
Total Key MDMA Research Projects	\$ 247,884	268,468	322,887	874,360	686,029	361,159	139,573	2,061,122
Associated Projects								
End-of-Phase-2 Meeting with FDA	0	0	0	0	0	25,000		25,000
MDMA Literature Review	3,256	6,063	3,764	9,076	3,500	3,500		16,076
MDMA Therapist Adherence Criteria	0	0	0	15,377	5,000	5,000		25,377
MDMA Treatment Manual	8,752	5,219	1,001	7,020	1,000	1,000		9,020
MDMA Therapist Training Protocol	15,038	17,652	12,592	25,629	60,210	100,120		185,959
MDMA Researchers Retreats	27,067	2,092	0	0	25,000	0		25,000
Mithoefer Supervisory & PR	27,951	33,975	49,701	25,000	25,000	25,000		75,000
Site Differences in CAPS Scores	0	400	71	0	2,000	2,000		4,000
MDMA Research General	11,404	54,911	32,294	43,969	45,000	40,000		128,969
Clinical Research General	38,036	38,885	40,583	63,971	55,000	50,000		168,971
Total Associated Projects	\$ 131,504	159,197	140,006	190,042	221,710	251,620	0	663,372
Total MDMA Key and Associated Costs	\$ 379,388	427,665	462,893	1,064,402	907,739	612,779	139,573	2,724,494
Multi-Year Projected Costs	\$ 1,269,946 <i>over past three years</i>							
Multi-Year Projected Costs	\$ 2,724,494 <i>over next four years</i>							

Chart 7. MAPS 2012-2013 Projected Financials

Statement of Activities

Revenue and Support	FY12-13
Support from Individuals	1,169,215
Support from Foundations	202,500
Event Income	297,025
Sales	90,000
Investment and Other Income	61,200
Total Revenue and Support	\$ 1,819,940
Cost of Goods Sold	(36,000)
Gross Profit	\$ 1,783,940
Expenses	
Research	1,202,001
Education	536,199
Total Programs	1,738,200
Fundraising	150,519
Operations	421,946
Total Expenses	\$ 2,310,666
Change in Net Assets	\$ (526,726)
Temporarily Restricted Assets	(310,634)
Board Restricted Assets	(82,818)
Unrestricted Assets	(129,318)

success, and interest in our work is growing. As this year-end Financial Report is being written, we are looking forward soon to the publication in the *Journal of Psychopharmacology* of our scientific paper about the results of MAPS' long-term follow-up study to our initial U.S. study of MDMA-assisted psychotherapy for PTSD. In the initial study, we reported results at the follow-up two months after the last MDMA-assisted psychotherapy session. In our long-term follow-up, we've gathered data at a mean of 45 months (more than 3½ years) after the last MDMA-assisted psychotherapy session. We've found that, on average, the decline in PTSD symptoms was sustained over time, demonstrating that there are lasting benefits from our experimental treatment. We can now demonstrate that the therapeutic benefits are more than just a psychedelic afterglow, and instead represent profound and lasting changes.

The publication of our scientific paper will be covered by *The New York Times*, CNN, NPR, and other media. We're anticipating this will increase interest in MAPS' MDMA/PTSD research from PTSD researchers, military officials, the public, and both current and new donors.

In February 2013, the results of our successful Swiss MDMA/PTSD pilot study will be published in the *Journal of Psychopharmacology*. This study further demonstrates that MDMA-assisted psychotherapy can be safely and effectively administered to people suffering from chronic, treatment-resistant PTSD. The publication of these two papers should help with fundraising for the expansion of our Phase 2 MDMA/PTSD studies, with our Israeli, Canadian, and second U.S. study location in Boulder, Colo., all likely to enroll and treat their first patients in FY 12-13.

We're also working in FY 12-13 to write a scientific paper about the results of our completed Swiss study of LSD-assisted psychotherapy for end-of-life anxiety, which demonstrated safety and trends toward efficacy. This paper, when published, will also raise MAPS' profile and is likely to generate additional support for MAPS' research agenda.

Additional attention will be drawn to MAPS' research as a result of our Psychedelic Science 2013 conference, cosponsored by MAPS, the Beckley Foundation, the Council on Spiritual Practices, and the Heffter Research Institute. This will be the largest number of psychedelic researchers at the same conference ever to occur in the U.S. CNN has already contacted us about attending, so it will be well-reported. We invite you to join us for this historic event, with large-scale conferences like this switching back to Europe, perhaps in 2015 and 2017.

MAPS' mission has always been ambitious. Our fundraising challenges for FY 12-13 are the most challenging in the entire 26-year history of MAPS. As you contemplate your charitable donations, we offer this detailed report on our income and expenses from FY 11-12 for your review. Please consider making a generous donation to MAPS and mentioning MAPS in your wills. 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. 🌍



mdmmaps.org

Clinical Research Update

Treating PTSD with MDMA-Assisted Psychotherapy

Long-Term Follow-Up Results Published in *Journal of Psychopharmacology* Charleston, South Carolina

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

This study is completed and has been fully funded

On November 20, 2012, the outstanding results of our long-term follow-up of subjects who participated in our initial proof of principle study of MDMA-assisted psychotherapy for PTSD were published online in the *Journal of Psychopharmacology*. The follow-up study extends the promising results of the initial study, published in 2010, which found that 83% of those receiving MDMA-assisted psychotherapy no longer qualified for a PTSD diagnosis two months after treatment. The long-term follow-up, conducted an average of 45 months (over 3.5 years) after MDMA-assisted psychotherapy, showed that these remarkable benefits were sustained over time.

Subjects included survivors of sexual assault and abuse and a military veteran. None of these subjects had responded adequately to existing psychotherapies and drug treatments for PTSD. Subjects had suffered from PTSD for an average of over 19 years. "With such encouraging data, including evidence of long-term effectiveness after only two or three MDMA-assisted psychotherapy sessions, there is now no doubt that this research should be expanded to larger clinical trials," said Dr. Michael Mithoefer, the study's principal investigator.

The publication of these results received widespread media coverage in *The New York Times*, CNN, NPR, Military.com, Stars & Stripes, Care2, and many more.

"MDMA-assisted psychotherapy helped me move past that feeling of needing to be in control," one subject reported. "I felt like me, probably for the first time. That was what I'd been looking for: the feeling that I was OK."

U.S. Veterans Study Expanded, Local Firefighter Receives Treatment Charleston, South Carolina

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

\$1,260,000 estimated study cost / \$526,000 still needed

As of November 2012, 11 subjects (out of 24) have received at least one experimental treatment session in our ongoing

U.S. Phase 2 Study of MDMA-assisted psychotherapy study for veterans with chronic, treatment-resistant PTSD. Three subjects have completed the entire study, including the long-term follow up. One subject dropped out after one successful MDMA-assisted psychotherapy session, reporting that he felt so improved that he needed no further treatments with MDMA or any other drug; his improvement was confirmed in a 12-month follow up evaluation.

On February 22, 2012, the FDA accepted an amended protocol increasing the study size from 16 to 24 subjects and added the option of including firefighters and police officers suffering from PTSD as a result of their service. On October 11, the study enrolled a local firefighter with service-related PTSD; this subject was treated on October 26. We hope that investigating a treatment for this especially vulnerable group will eventually lead to research funding from the U.S. Department of Defense and/or the Veterans Administration. Including firefighters and police officers in the study will provide further evidence of MDMA-assisted psychotherapy's effectiveness for people suffering from PTSD, and will help reduce costs by increasing local recruitment. Nearly 300 people have joined the waiting list to be screened for participation, demonstrating the widespread need for new treatments for chronic PTSD.

Zoning Office Approves Site for New Intern Study in Boulder Boulder, Colorado

Principal Investigator: Marcela Ot'alora, M.A., L.P.C.
\$497,000 estimated study cost / \$372,000 still needed

On October 25, 2012, the Zoning Office for the City of Boulder, Colorado, issued the business license for the site for our upcoming study of MDMA-assisted psychotherapy for PTSD. This license was required before the Drug Enforcement Administration would grant a Schedule I license to the study physician, and required multiple rounds of renovations and inspections as well as a complete relocation before it was approved. Needing to comply with unexpected Boulder zoning regulations delayed our estimated start date for the study by about six months, and we are hoping to start screening subjects in February 2013.

The new study will explore the 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 working under supervision for credit towards licensure. The use of interns is an effort both to reduce costs and to train the next generation of psychedelic psychotherapists.

From September 21-23, 2012, MAPS Director of Clinical Research Amy Emerson and Lead Clinical Research Associate Berra Yazar-Klosinski, Ph.D, visited the new study site. They met with Principal Investigator Marcela Ot'alara, L.P.C., co-investigators, and other study staff to conduct a final training on the protocol and study documents, as well as to review our MDMA Investigator's Brochure and new safety data from completed MAPS clinical trials (*see inside front cover*).

First Subject in Relapse Study Completes Follow-Up Evaluation after Successful Treatment Charleston, South Carolina

Clinical Investigator: Michael Mithoefer, M.D.
\$55,000 still needed

On April 27, 2012, the first subject in our relapse study completed their follow-up interview, two months after a single MDMA-assisted psychotherapy session. This study will enroll two subjects whose PTSD symptoms eventually returned after participating in our U.S. proof-of-principle study of MDMA-assisted psychotherapy for PTSD, which was completed in July 2010. This is an open label proof-of-principle study, investigating whether one additional MDMA-assisted psychotherapy session combined with multiple non-drug psychotherapy sessions can once again free these subjects from a diagnosis of PTSD.

MAPS in the Media

Landmark Study Shows Long-Term Benefits of MDMA-Assisted Psychotherapy for PTSD
Results published in the *Journal of Psychopharmacology*

The New York Times

A 'Party Drug' May Help the Brain Cope With Trauma

by Benedict Carey

November 19, 2012

"The feeling I got was nothing at all for 45 minutes, then really bad anxiety, and I was fighting it at first," said Anthony, the Iraq veteran, who patrolled southwest of Baghdad in 2006 and 2007 amid relentless insurgent harassment and attacks with improvised explosive devices. "And then—I don't know how to put it, exactly—I felt O.K. and messed up at the same time. Clear. It was almost like I could go into any thought I wanted and fix it."



PTSD Study Findings Reinforce Case for Ecstasy

by Bryant Jordan

November 20, 2012



New Study Confirms MDMA's Effectiveness in Psychotherapy

by Jacob Sullum

November 20, 2012



Research Points to Clear Benefits of MDMA for Post-Traumatic Stress Disorder

by Craig Comstock

November 21, 2012



MDMA Keeps Severe Stress at Bay

by Arran Frood

November 20, 2012



Ecstasy Effective in Treatment of Lingering PTSD, New Study Finds

by Matthew M. Burke

November 20, 2012



Ecstasy May Help Treat Post-Traumatic Stress Disorder

by Join Together Staff

November 20, 2012

More headlines at maps.org/media

MAPS Seeks Funding From National Institute of Mental Health

On October 16, 2012, MAPS Executive Director Rick Doblin, Ph.D., and the MAPS clinical team met via teleconference with a member of the grants administration staff at the National Institute of Mental Health (NIMH) in Washington, D.C. Earlier in October, Rick Doblin contacted NIMH Director Thomas Insel about whether NIMH would be willing to review a grant application from MAPS for research into MDMA-assisted psychotherapy for PTSD. Dr. Insel responded immediately and encouraged us to apply. The MAPS clinical team will continue working with NIMH staff to develop a grant proposal with the greatest chance of success. The proposal would be due in either February or June 2013.

As far as we know, the last time NIMH funded psychedelic psychotherapy research was over 40 years ago. NIMH has recently funded research into the use of ketamine in the treatment of refractory depression; however, in this case the ketamine was not used as an adjunct to psychotherapy but rather as an independent pharmacological treatment.

Should MAPS succeed in obtaining NIMH funding for a Phase 2 study of MDMA-assisted psychotherapy for PTSD, it's possible that NIMH might be open to a larger grant supporting Phase 3 studies. "For NIMH, multi-year grants of several millions of dollars are not unusual," said MAPS Executive Director Rick Doblin, Ph.D. "We can always dream!"

MAPS and PRISM Work to Start Australian Study of MDMA-Assisted Psychotherapy for PTSD

Australia

\$125,000 estimated study cost / \$50,000 still needed

MAPS is working with the Australian non-profit organization Psychedelic Research in Science and Medicine (PRISM) to obtain approval for an Australian study of MDMA-assisted psychotherapy for PTSD. On February 22, 2012, the Ethics Committee rejected the protocol, citing issues that MAPS and PRISM addressed in their May 31 response. On July 13, the Committee reiterated their decision to reject the protocol. PRISM and MAPS are still working to initiate MDMA-assisted psychotherapy research in Australia. This study will compare the safety and effectiveness of MDMA-assisted psychotherapy for 12 subjects with chronic, treatment-resistant PTSD using two different dosages of MDMA combined with psychotherapy.

Health Canada Approves Pharmacy for New Vancouver Study

Vancouver, British Columbia, Canada

Principal Investigator: Ingrid Pacey, MD and Andrew Feldmar, PhD

\$511,000 estimated study cost / \$496,000 still needed

On November 8, 2012, after five inspections and over 15 months of resulting delays, an inspector from Health Canada finally approved the security measures at the Vancouver pharmacy where the MDMA will be stored for our upcoming study of MDMA-assisted psychotherapy for PTSD in Canada. New security regulations created after the initial inspection required us to make numerous expensive changes to the pharmacy, including hiding the safe with a wooden cabinet, moving the safe and cabinet to a new room with a solid (rather than glass) door, installing multiple new alarm systems, adding bulletproof polycarbonate over the windows, and placing additional warning labels on the study drug.

We have been working for 2½ years (since Health Canada approved the protocol) to obtain an import permit for the study drug. Once Health Canada grants the Controlled Substances License to the study pharmacist, we will know whether we will be able to import the MDMA into Canada and initiate the study, or if there will be further delays. We are optimistic that we will be able to initiate the study and begin enrolling subjects in early 2013.

New Israeli Study Prepares to Enroll Subjects, Threatened by War

Israel

Clinical Investigator: Moshe Kotler, M.D.

\$381,000 still needed

On August 30, 2012, the official study kickoff meeting took place for our new Israeli study of MDMA-assisted psychotherapy for PTSD. Israeli CRA Mimi Peleg traveled from Israel to meet with MAPS Lead Clinical Research Associate Berra Yazar-Klosinski, Ph.D., in Turkey for training prior to the kickoff meeting in Israel. The meeting took place at Beer Yaakov Mental Health Center, where the study will be conducted.

The study will explore the safety and efficacy of two doses of MDMA as an adjunct to psychotherapy in 10 subjects with chronic, treatment-resistant PTSD. The Israeli Defense Forces will refer some subjects, allowing us to learn whether the treatment could help active duty military personnel.

We had planned to begin enrolling subjects in late 2012, and expect to complete

the study within only 12 months of initiation since we are working with three (rather than two) co-therapist teams. Sadly, as this *Bulletin* was going to print, we learned that some of the psychiatrists and psychotherapists involved in the study may be called into military service due to increasing conflict in the region. We hope that the conflict will be resolved quickly and that we will be able to initiate the study soon.

Swiss Study Results to be Published in *Journal of Psychopharmacology* Solothurn, Switzerland

Clinical Investigator: Peter Oehen, M.D.
This study is completed and has been fully funded.

On September 21, 2012, the paper describing the results of our Swiss pilot study of MDMA-assisted psychotherapy was accepted for publication in the *Journal of Psychopharmacology*. The paper is co-authored by Clinical Investigator Peter Oehen, M.D., and Ulrich Schneider, M.D., former president of the International Society for Traumatic Stress Studies. The study demonstrated clinically significant reductions in scores on the CAPS scale—larger than those associated with Zoloft and Paxil, the only currently approved medications for PTSD. The small number of subjects in this preliminary pilot study contributed to the results falling just short of statistical significance. The study also demonstrated that the low dose of MDMA (25 mg

with a supplemental 12.5 mg two hours later) created a successful double-blind as compared to the full dose (125 mg followed by 62.5 mg). The paper will appear in the January 2013 edition of the *Journal of Psychopharmacology*.

Therapist Teams Complete MDMA-Assisted Psychotherapy Training Protocol Charleston, South Carolina

Principal Investigator: Michael Mithoefer, M.D., with co-therapist Annie Mithoefer, B.S.N.
\$265,000 still needed

From April 8-11, 2012, the therapist teams for our new MDMA-assisted Psychotherapy for PTSD Study in Boulder, Colorado, completed our therapist training protocol in Charleston, South Carolina. Several co-therapists from our Israeli study have also participated. This protocol is designed as a Phase 1 study of the psychological effects of MDMA in healthy volunteers, with subjects limited to people in MAPS' therapist training program. In addition to providing new information about the effects of MDMA-assisted psychotherapy in healthy volunteers, the study will enable us to train therapists to conduct future MDMA/PTSD studies. Our training protocol study is led by MDMA-assisted psychotherapy researchers and co-therapists Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N.

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MDMA-Assisted Therapy for Adults on the Autism Spectrum

MAPS is currently developing a protocol for a study of the use of MDMA-assisted therapy for adults on the autism spectrum. The main objective of this study is to examine whether MDMA-assisted therapy could influence social interactions for adults on the autism spectrum. The research team has been selected and protocol development began in February 2012. We hope that the protocol will be approved and the pilot study ready to start by June 2013.

MAPS initially seeded the study with a \$10,000 award to the selected research team for protocol development. On January 25, 2012, the MAPS Board of Directors allocated \$200,000 from Ashawna Hailey's bequest to the study if we are unable to raise the funds from other sources. We have a goal of obtaining grants from leading autism advocacy groups and will seek federal funds available through the NIH, though based on fundraising history these funds are most likely to come from individual donors.

Ibogaine Research for Addiction Treatment

Last Subject Completes Follow-Up in Mexico Ibogaine Study

Mexico

Principal Investigator: Thomas Brown, Ph.D.
\$41,000 estimated study cost / \$6,625 still needed

On September 10, 2012, the 30th and final subject completed the 12-month follow-up in our observational study of ibogaine treatment for addiction in Mexico. This will be first long-term outcome study ever conducted with ibogaine in the treatment of addiction. In this study, Principal Investigator Thomas Kingsley Brown, Ph.D., is observing the long-term effects of ibogaine treatment for individuals undergoing treatment at an independent clinic in Mexico. Data from this study will be compared with our concurrent, ongoing study of ibogaine treatment for addiction in New Zealand. (See Thomas Kingsley Brown's article on page 32.)

New Zealand Ibogaine Study Enrolls First Five Subjects

New Zealand

Principal Investigator: Geoff Noller, Ph.D.
\$15,000 raised (additional funds provided by co-sponsor)

On November 9, 2012, the fifth participant was enrolled in our ongoing observational study of ibogaine treatment for addiction in New Zealand. All participants had been receiving methadone treatment for opiate addiction and are being treated

for methadone dependence at independent ibogaine clinics in New Zealand. The study was approved by the IRB on February 22, 2012, and lead investigator Dr. Geoff Noller, Ph.D., began enrollment shortly thereafter. This study is the second in our international series of observational studies of the safety and long-term effectiveness of ibogaine treatment for addiction, building on our nearly completed study in Mexico.

Medical Marijuana Research

FDA and Review Board Approves Protocol of Marijuana for Veterans with PTSD: Will NIDA Agree?

Phoenix, Arizona

Clinical Investigator: Sue Sisley, M.D.

\$20,000 cost of protocol development and approval process / \$10,000 still needed

On October 25, 2012, the Institutional Review Board at the University of Arizona notified Principal Investigator Sue Sisley, M.D., that they had approved the protocol for our planned study of marijuana for symptoms of PTSD in 50 U.S. veterans. The IRB approved all of the key elements of the protocol design, and added several safety procedures and measures. The Food and Drug Administration had previously approved the protocol in April 2011, though the study has been blocked by the National Institute on Drug Abuse/Public Health Service, which unanimously rejected the protocol, since September 2011. We are hoping that protocol approval from both the IRB and the FDA will help persuade the reviewers to approve the study and allow NIDA to sell us the marijuana needed for the study.

UMass Professor's Lawsuit Against DEA Awaits Ruling

Boston, Massachusetts

On May 11, 2012, the U.S. First Circuit Court of Appeals in Boston, Mass., heard oral arguments in the case of *Lyle E. Craker v. Drug Enforcement Administration*. The arguments are the culmination of 11 years of administrative and legal proceeding in response to the DEA's denial of a license to Craker to start a production facility under contract to MAPS to grow marijuana exclusively for privately funded, federally regulated medical research. We are expecting to receive the court's ruling soon. Meanwhile, the DEA is succeeding in preventing our medical marijuana research from moving forward.

LSD-Assisted Psychotherapy for Anxiety Related to Advanced-Stage Illness

Solothurn, Switzerland

Principal Investigator: Peter Gasser, M.D.

This study has been completed and is fully funded.

From September 3-7, 2012, MAPS Lead Clinical Research Associate Berra Yazar-Klosinski, Ph.D., visited the study site to monitor our completed Swiss study of LSD-assisted psychotherapy for anxiety associated with advanced-stage illness. This was the final closeout meeting with Principal Investigator Peter Gasser, M.D. The last long-term follow-up interview was conducted on August 8, 2012. The results are currently being prepared for publication.

Ayahuasca Treatment for Addiction

British Columbia, Canada

Principal Investigator: Gerald Thomas, Ph.D.

This study has been completed and is fully funded.

On September 27, 2012, researchers affiliated with MAPS Canada presented the findings from their now-completed MAPS-supported study of ayahuasca-assisted therapy for addiction and dependence to the Canadian First Nations Band involved as subjects in the study. Combining Western psychotherapeutic techniques with South American shamanic healing practices, this study gathered preliminary evidence about the safety and effectiveness of ayahuasca-assisted therapy. Treatment consisted of participation in a five-day retreat in British Columbia, facilitated by a Peruvian Shaman assisted by Gabor Maté, M.D., that included ayahuasca-assisted therapy. The research team is currently working on a paper for submission to a scientific journal, and will present the study results at Psychedelic Science 2013. 🌐



Visit MAPS' online events calendar maps.org/calendars.



Ian Richardson

MDMA-Assisted Psychotherapy for PTSD: Momentum Towards Phase 3 and Beyond

IAN RICHARDSON

PSYCHOLOGY, AS A RELATIVELY YOUNG SCIENCE trying to deal with some of the most complex issues of human existence, is still in the process of developing effective diagnostic methods and treatment procedures for some of the field's most widespread and debilitating issues. As a result, complicated conditions like posttraumatic stress disorder (PTSD), end-of-life anxiety, and addiction remain highly resistant to most available treatments and lead to a great deal of suffering.

"Counseling and treatment had shown no measurable improvements in my life. I was stuck in an unhappy place" (subject quote). Words like these are probably all too familiar to anyone who has suffered from one of these conditions or knows someone who has. It is that suffering that creates the pressing need for researchers and organizations with a willingness to advance the scientific testing of new procedures for treatment and, more importantly, to utilize the results of that science to find new ways to help people in need.

This is precisely the role that MAPS has filled since 1986. After first acknowledging the vast potential presented by the therapeutic use of psychedelics (a potential that is heavily supported by the medical and psychological research of the latter half of the 20th century), MAPS has sought to apply that potential to a wide range of treatment-resistant conditions. With studies currently underway and in development to test the viability of therapy in conjunction with ayahuasca and ibogaine to treat addiction and compulsive behavior; LSD to treat anxiety in the terminally ill; and with MDMA (and cannabis alone) to treat PTSD, MAPS is currently conducting the promising research that may ultimately lead to more effective treatments for these debilitating conditions (maps.org).

★

Nowhere is the significant progress MAPS has made toward the development of such treatments clearer than in its work testing the use of MDMA in conjunction with psychotherapy for the treatment of PTSD. As MAPS' top priority, the MDMA-Assisted Psychotherapy for PTSD program seeks to navigate labyrinthine FDA clinical trial procedures with the ul-

timate goal of seeing MDMA reclassified as a prescription drug for use in conjunction with therapy. The complicated FDA drug trial process requires research to complete three phases: Phase 1 uses healthy volunteers "to determine the drug's most frequent side effects" and how the drug moves through the human body. Phase 2 "aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition." Phase 3 seeks to gather more information about safety and effectiveness from a larger subject population across multiple sites. Altogether, this process can take years, or even decades, to complete and requires a great deal of careful planning, perseverance, and funding to achieve (fda.gov).

Over the years, MAPS has shown an abundance of both focus and perseverance (and so far has found sufficient funding) since the inception of its MDMA research program, recently culminating in the completion of its first Phase 2 pilot study in 2010 under the supervision of Dr. Michael Mithoefer. Now, in addition to a protocol training future therapists to use this powerful new tool, MAPS is conducting a series of Phase 2 studies to treat PTSD generally and in veterans, which are expected to be completed the second quarter of 2014. These studies are taking place in countries as diverse as Canada, Israel, Switzerland, Australia, and the U.S. MAPS' MDMA research program could, with funding and a bit of luck, proceed to Phase 3 in the fourth quarter of 2015, with completion of Phase 3 and approval of MDMA as a prescription medicine estimated around 2020. At that point, the field of psychiatry will have gained access to a therapeutic tool with nearly unmatched potential for the first time since it was criminalized in 1985.

The results of MAPS' Phase 2 pilot study and its long-term follow-up (LTFU) were remarkable. PTSD tends to be characterized by a combination of three types of symptoms: fear and hyper-arousal, intrusive re-experiencing of traumatic experiences, and numbing and withdrawal. PTSD is also incredibly difficult to treat and has a high rate of relapse, comorbidity, drug/alcohol abuse, and suicide. Furthermore, there are currently only two FDA-approved medications for the treatment of PTSD and only three treatment procedures recommended by

the American Psychological Association. Altogether, they leave 25–50% of PTSD patients (a group making up between 6 and 10% of the U.S. population, and between 15 and 35% of U.S. veterans) feeling that treatment is ineffective.

When the results of the Phase 2 pilot study (which involved 20 patients with an average PTSD duration of over 19 years) indicated that 83.3% of the experimental group subjects showed a clinical response (defined as a 30% or greater reduction in score on the CAPS test, which is widely used to assess the severity of PTSD symptoms) compared to only 25% in the group that received only therapy and active placebo, there was significant reason to be optimistic (*Mithoefer et al 2010*). These highly positive results indicate the discovery of—potentially—the most powerful therapeutic model ever found for the treatment of PTSD.

The low availability of effective treatment bears most of the responsibility for the poor prognosis associated with PTSD. Yet even when conventional therapy succeeds in reducing PTSD symptoms, the fact that relapse tends to occur within 18 months must be considered an important—if not equal—part of what makes it such a debilitating disease. The LTFU showed that 14 of the 16 patients who completed the treatment had no statistical differences between their CAPS scores at the end of their second MDMA-assisted psychotherapy session (which were consistent with complete remission of PTSD symptoms) and at the LTFU taken an average of 3.8 years later (*Mithoefer et al 2012*). Thus, there is strong reason to believe that MDMA-assisted psychotherapy helps more successfully with PTSD treatment—both through initial reduction of symptoms and through maintenance of that reduction over the long term—than any other form of treatment.

★

What, specifically, is it about this new model that makes it so seemingly effective in countering these issues? Many elements need to be discussed in order to answer this question (and many will be in what follows), but it is probably best to start with another question: What is so different about MDMA-assisted psychotherapy compared to others used for PTSD treatment?

The answer, again, is “a lot,” so perhaps it is even better to begin with what many consider to be the most objective (or at least quantifiable) realm of psychological science: biopsychology (neurology, psychopharmacology, etc.). The symptoms of PTSD are, according to the neurocircuitry model, caused by a deficit in the extinction of conditioned fear responses related to increased activity in the amygdala (the part of the brain responsible for fear, aggression, and most autonomic response) and decreased activity in both the hippocampus and the medial

pre-frontal cortex (an area associated with decision making and emotional control/processing). One of the many problems with the medications currently being used to treat PTSD—such as anti-depressant SSRIs—is that very little is known about the mechanism of action of these drugs when used in attempts to confront these issues.

On the other hand, a great deal is known about the pharmacological action of MDMA as it relates to the same problems. Positron emission tomography (PET) scans have shown that MDMA increases blood flow to the medial prefrontal cortex while reducing flow to the amygdala (essentially reversing the neurological effects of PTSD). In other words, MDMA actually seems to create the ideal neurological conditions for a PTSD sufferer to benefit from therapy.

Little is known about MDMA’s unique ability to simultaneously speed up the release of serotonin and slow the reuptake of other neurotransmitters into the brain cells where they have their effects, yet this may be one of the qualities that make it so effective as a treatment adjunct. Serotonin contributes to emotional regulation, feelings of well-being and happiness, mood, and some cognitive functions (among other things). As such, the boosting of serotonin levels in the brain may be a positive precursor to the therapeutic state.

MDMA’s action on serotonin also causes the body to release increased amounts of the naturally occurring hormones prolactin and oxytocin. Prolactin may play a role in the sense of relaxation that MDMA produces, yet it is oxytocin (commonly referred to as “the cuddle hormone” for its role in pair-bonding) that probably has the largest hand in MDMA’s pharmacological benefits for therapy. As a neurochemical that has been shown to increase affiliation, trust, gregariousness, sociability, and accuracy of emotional perception (as well as being partly responsible for the decreased amygdalar activity associated with MDMA ingestion), oxytocin is hypothesized to play a role in MDMA’s ability to attenuate the fear response and decrease defensiveness without blocking access to memories or preventing a deep and genuine experience of emotion (*Metzner et al 1988*).

Participants are able to experience and express fear, anger, and grief with less likelihood of feeling overwhelmed by these emotions. MDMA seems to engender an awareness that such feelings arise as an important part of the therapeutic process. In addition, feelings of empathy, love, and deep appreciation often emerge, along with a clearer perspective of the trauma as a past event and with a heightened awareness of the support and safety that exist in the present (Treatment Manual).

As a result of these qualities, such statements from PTSD patients who have received MDMA-assisted psychotherapy as

These highly positive results indicate the discovery of—potentially—the most powerful therapeutic model ever found for the treatment of PTSD.

“Maybe one of the things the drug does is let your mind relax and get out of the way, because the mind is so protective of the injury,” and, “It’s helped me in so many ways; it feels like it’s gradually rewiring my brain,” can be seen played out in neurochemistry.

★

If MDMA does all of this on its own, then why bother with psychotherapy? MDMA may be a powerful catalyst, but just as with most pharmacological interventions it is difficult to produce sustained results and without also using therapy to resolve the underlying issues. As one subject in a MAPS study noted: “As interesting as the [MDMA] sessions are, it’s more interesting what happens after the sessions when you’re making connections.” In other words, “MDMA is not in itself the therapy but is rather a powerful tool for both clinician and participant” (*Treatment Manual*). While MDMA helps create the neurochemical conditions for healing to occur, those conditions are less likely to take root and grow without the care of a therapeutic system.

MDMA is a powerful pharmacological tool requiring the use of a therapeutic model that is distinct from most other methods used in conventional psychotherapy. For example, the use of MDMA requires that a great deal of attention be given to set and setting. The idea that the set (mental and informational preparation, as well as the creation of a safe psychological space) and the setting (the creation of a safe, supportive, and aesthetically pleasing physical environment) are of paramount importance to the therapeutic experience is one of the characteristic elements of any therapy involving the use of psychedelic compounds. This is because these tools produce a state of significantly heightened physical and psychological vulnerability and seem to make important subconscious material more accessible, which can lead to profound—and often intense—emotional and physical effects.

In addition to set and setting, there are numerous aspects of psychotherapy that, without the implementation of careful procedures, could increase the risk of the treatment being problematic or ineffective. The use of MDMA magnifies the importance of these aspects. Key examples of these aspects include (1) the subject’s relationship with the psychotherapist (whose sensitivity, talent, and background are all integral to how the patient responds to therapy); (2) the use of somatic procedures (breathwork, focused bodywork, sensory stimulation via music, etc.); and (3) the development of the therapeutic alliance (a relationship between therapist and subject that makes openness, trust, and progress more possible) (*Treatment Manual*).

MAPS’ *Treatment Manual for MDMA-Assisted Psychotherapy for the Treatment of PTSD* outlines these important issues in novel and effective ways. In fact, this manual—which is being independently rated for effectiveness as both an experimental and

a training tool—lays out well-developed guidelines for how a two-person male-female therapy team can most safely and productively approach each of the above aspects of MDMA-assisted psychotherapy. With regards to mental preparation, it suggests thorough discussion of session parameters, the making of specific therapist-subject agreements (subject will refrain from self-harm, therapist will provide for all physical needs immediately, etc.), the addressing of specific fears prior to experimental sessions, and general therapist-subject collaboration in creating a safe space for therapy. The manual also makes suggestions about the nature of the setting, wherein the provision of pre-selected musical programs, basic needs reassurance (availability of a kitchen, sleeping arrangements, etc.) eye-shades, privacy, quiet, comfort, and general aesthetic agreeableness are all carefully considered.

Some of the manual’s suggestions concern what many consider to be a controversial issue in psychology: the acceptability and utility of physical contact between therapist and sub-

ject. Some practitioners worry that such contact is counter-productive to therapy, but with the ability of MDMA to bring to the surface strong emotional forces that can be experienced in the form of physiological tension, physical contact

can be an important element of MDMA-assisted psychotherapy. Of course, this contact must always and absolutely be appropriate, beneficial, and driven by the needs of the subject. So, the use of focused bodywork (generally, providing resistance for the subject to push against) and nurturing touch (hand-holding, hugging, etc.) can be an important catalyst for resolving psychological issues caused by a condition like PTSD. Interestingly, subjects’ need for physical contact is rare in actual experimental MDMA sessions. More likely are cases in which such physical contact is used to help people work through possible residual effects in integrative sessions following the MDMA session, rather than during the MDMA session itself.

Along with the possible benefits, there are also risks and challenges involving the use of physical contact by the therapist. Touch may be distracting or misinterpreted by the subject, be motivated by the therapist’s conscious or unconscious sexual desires or desire to fulfill the role of therapist, or may even create a feeling in the subject that he/she cannot be healed without the aid of outside intervention. Any of these issues could have deleterious effects on the subject and the therapeutic process. As such, it is imperative to have clear protocols in place in the MDMA-assisted psychotherapy model to guide the acceptable use of bodywork and touch by the therapist. MAPS’ *Treatment Manual* provides such a protocol in the form of an 8-step process (designed by Stanislav Grof) specifically for that purpose, as well as suggestions for how to follow the process:

The above steps should be offered to participants as possible ways of working with their symptoms if they so

choose. Participants should never be pressured to do focused bodywork or to be touched in any way. Participants should be encouraged to ask for whatever they feel they need, even if it is quite different from what they or the therapists would have predicted (Treatment Manual).

If the therapist follows these directives, body work or touch can have the greatest possibility of assisting with the therapeutic process.

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The therapeutic alliance (the partnership established between therapist and patient) is one of the most important and difficult-to-measure issues in all of clinical psychology. Almost all therapeutic professionals agree that a safe, trusting, and open therapist-patient relationship is integral to any effective therapy, but problems tend to arise when attempts are made to move toward standardizing this process. This is likely due to the wide variety of therapeutic approaches, and even wider variety of therapist and patient personalities. MDMA-assisted psychotherapy, however, may represent a major step forward on the path to understanding the therapeutic alliance.

MDMA seems (as previously mentioned) to create optimal neurological conditions for the strengthening of the therapeutic alliance, which means that MDMA-assisted psychotherapy may help the world of clinical psychology better quantify that alliance. As a pharmaceutical therapeutic alliance catalyst, MDMA may be able to augment this imperative relationship with consistency.

The MDMA, however, does not work alone—MAPS' treatment approach is specifically designed to maximize the possibility for creating an effective therapeutic alliance. MAPS' MDMA-assisted psychotherapy protocol includes a substantial amount of work with non-drug psychotherapy (in fact, non-drug sessions constitute the vast majority of the treatment protocol)—and this therapy, without the drug, is essential for establishing the alliance. This involves discussing questions and fears, creating plans and agreements, and establishing trust and safety—all of which may improve the effectiveness of the MDMA-assisted sessions.

Letting the patient's internal experience guide the session is an additional aspect of MDMA-assisted psychotherapy that may contribute strongly to the positive outcomes that MAPS has seen in its early studies. Most psychotherapeutic treatments for PTSD direct the patient's attention to the troubling memories and emotions at the heart of their condition; however, this can create problems for the therapeutic alliance (and therapy in general) when it imposes a structure that does not match the patient's own cognitive processes, or when it demands that the patient go places that he/she may not be psychologically prepared to confront. The MDMA-assisted psychotherapy model attempts to solve this problem by repositioning the therapist as someone who is there to support the experiences of the subject as they arise, to provide guidance and comfort when needed,

and to ensure a safe and trusting environment in which the experiences can go where they must. Therapists often find that the subject's own consciousness knows best what to reveal and when. In this way, MDMA-assisted psychotherapy aims to create a powerful support system that makes it more possible for the inherent healing process to have a significant and lasting effect.

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This carefully designed form of psychotherapy combined with the powerful effects of MDMA is one of psychiatry's greatest opportunities to confront PTSD and to better quantify the therapeutic alliance. It gives subjects, often for the first time, an opportunity to see their situation in a new light. As one MAPS subject reflected, "I was stuck in an unhappy place...this study changed all that and gave me the possibility of a different outcome." Another stated that "when I let the waves of fear and anxiety come up, it feels like the medicine is going in and bringing them up, and then they dissipate." Another: "It's like PTSD changed my brain, and MDMA changed it back."

It is an exciting time to be part of the journey that MAPS is undertaking to transform psychology and psychiatry. This is true not only because of the historic nature of MAPS' work, but also because of the vast potential that MDMA-assisted psychotherapy has to reduce suffering in instances where conventional therapies have been ineffective. That is the real mission of those working to make MDMA-assisted psychotherapy a legal treatment: the alleviation of suffering and the provision of means for psychological growth. With continued support, MAPS will continue to build momentum as it helps the field of psychology take massive steps toward these ends. 🌱

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Foreword to *Healing with Entactogens: Therapist and Patient Perspectives on MDMA-Assisted Group Psychotherapy* by Torsten Passie, M.D.

RAPLH METZNER, PH.D.



Ralph Metzner, Ph.D.



Torsten Passie, M.D.

Healing with Entactogens: Therapist and Patient Perspectives on MDMA-Assisted Group Psychotherapy by Torsten Passie, M.D., is now available in the MAPS Store (maps.org/store). Published by MAPS (see inside back cover).

DURING THE 1980s, MDMA, WHICH WAS originally explored as an effective adjunct to psychotherapy, with remarkable anxiety-reducing effects and minimal if any visual or cognitive alterations, escaped out of the offices of a few dozen psychotherapists in the U.S. and Europe, and became the recreational party drug “Ecstasy,” consumed by thousands at all-night rave-dance events. Predictably, as the Ecstasy-fueled rave subculture grew in numbers, laws were passed in all relevant countries making possession of the drug illegal and thereby largely unavailable to therapists to use in their practice—even those (like myself) who had previously used it with good results.

This story was an almost exact replay of the story of how LSD was introduced into the culture in the 1960s: At first, reports from psychiatric researchers showing dramatic evidence of its effectiveness as an adjunct to psycholytic therapy in a range of conditions, including alcoholism, various forms of neurosis, as well as the stimulation of religious experiences and the enhancement of creativity. Then, after enthusiastic reports from the therapists who themselves experienced it and its availability in the underground market, the therapy drug LSD became the “acid” of long dance parties with light shows and psychedelic rock music, and was subsequently made illegal and therefore unavailable to established medical-psychiatric researchers.

Now, another generation later, the mainstream culture seems to be opening up again to the therapeutic possibilities of these substances (and others like DMT, ibogaine, and ayahuasca) and serious research on possible applications is again being done in the U.S. and in Europe as well as Israel. In the meantime, there is a flourishing underground culture in which thousands of people experiment with psychedelic substances on their own accord and create cultural artifacts (books, music, and art) inspired by them. This paradoxical situation was highlighted at a recent MAPS conference, in which a presenter asked how many people had participated as subject in a psychedelic research project and about a half dozen people raised their hands; when he asked how many people had themselves experienced psychedelics, virtually the entire audience raised their hands.

Torsten Passie, a German psychiatrist working at the Hannover Medical School in Germany, is a leading researcher in this field and has done several studies on the therapeutic applications of psycholytic (or psychedelic) drugs. In this book he presents his research findings on the therapeutic possibilities of MDMA, with MDE and LSD also considered in a minor way. It is a qualitative research study, in which his data are the experience reports and interviews from psycholytic individual and group psychotherapy sessions.

He reports that the primary findings are a marked reduction of anxiety, along with physical relaxation and the ability to think calmly about one’s emotions and interpersonal difficulties, making connections and producing acceptance and understanding. These results basically confirm the observations from several earlier published studies with MDMA in psychiatric populations. They are also consistent with the reports from a wide range of people that I collected in a book I edited and published in the mid-1980s called *Through the Gateway of the Heart*, under the pseudonym that I used at that time (Sophia Adamson).

I want to say a word here about terminology. Torsten Passie, who is a friend as well as a colleague of mine, uses the word entactogen to describe the class of drugs like MDMA whose primary neuropsychological action is a marked decrease of interpersonal and intrapsychic fear—thereby facilitating a seemingly effortless reintegration of previously defended traumatic memories and perceptions. This is in marked contrast to the primary effect of the classical psychedelics (e.g., LSD, mescaline, and psilocybin) which involve visual and affective amplification of all psychic contents and processes, including fear—thereby making difficult or “hellish” trips much more likely than with MDMA (where they are virtually absent). *Entactogen* means something like “touching within,” or getting in touch with one’s own inner processes.

In a friendly debate I had with several of my colleagues in the pages of the *MAPS Bulletin* (Vol. 4, No. 2., Summer 1993), I suggested that “touching within” doesn’t really distinguish the MDMA-type experience from the LSD-type experience. My own preferred term for these substances (and the experience they can facilitate) is *empathogenic*—generating a state of empathy, both empathy with others and empathy with one’s own self in past or present conflict situations. This to me is the basis for the heightened affective understanding—the integration of emotion and reasoning consequent upon the absence of fear and anxiety—that Dr. Passie’s study demonstrates.

If there is one complaint I have about his presentation in this study it is the lack of attention paid to empathy. In the treatment of trauma, which is one of the main and most promising applications of MDMA-therapy, it is the ability to consider the effects and impacts of the traumatizing event in one’s life calmly and without fear. In such experiences, it is as if the remembered fear is recognizably there, associated with the recalled events, but *sotto voce*: not overwhelming or paralyzing. Considering the central and essential role that empathy plays in the therapeutic process, I think one (thus far) underestimated important application of MDMA is in the training of psychotherapists—for whom the ability to experience and authentically express empathy is crucial.

Torsten Passie’s research not only deals with the amplified psychotherapy possible with MDMA, but also with the neurophysiological and neurochemical correlates of the experience. His observations and conclusions here are particularly insightful. He states, on the basis of his studies, that MDMA deactivates the amygdala (the seat of fear-rage emotional reactivity) and reciprocally activates prefrontal brain circuits (which underlie calm thinking). This is the neurophysiological counterpart to the empathic understanding of self and others reported by the patients. There is also a massive release of serotonin, the neurotransmitter associated with a non-depressive, non-fearful attitude.

In such experiences, it is as if the remembered fear is recognizably there, associated with the recalled events, but sotto voce: not overwhelming or paralyzing.

To my mind the most provocative of his findings is that MDMA results in a massive release of prolactin, the hormone associated with breast-feeding, and oxytocin, sometimes called the “cuddle hormone.” Both of these hormones are released during non-sexual post-orgasmic intimacy. As Dr. Passie points out, this release of non-sexual intimacy hormones correlates perfectly with the often-remarked subjective experience of MDMA-users—that they feel intimate with others, wanting to touch and be physically close, but not sexually aroused. Even couples that were intimately involved have reported that with MDMA, the sexual drive is often just not there.

Being non-sexually but emotionally intimate with another human being is not a very common experience, particularly with men (though women who are mothers obviously do know it from the infant bonding situation). It is, however, a supremely useful kind of connection to cultivate in a therapeutic situation, including for the therapist, where the slightest hint of sexual interest is likely to set off all kinds of alarm signals in both therapist and patient. (This is not to advocate for the use of MDMA by the therapist in the therapy, but rather for its use in the training of therapists.)

This is a unique aspect of MDMA that contributes to what Dr. Passie calls its “astonishing efficacy in enhancing psychotherapeutic communication.” Or, as one of his therapy patients reported, “you don’t have a wall around yourself anymore. It’s not that you take it down—it just isn’t there.” His book deserves to take its place as an essential milestone in the integration of MDMA-type drugs into psychotherapy practice. 🌍

Ralph Metzner, Ph.D. is a recognized pioneer in studies of consciousness and its transformations. He is a psychotherapist and Professor Emeritus at the California Institute of Integral Studies. His books include edited collections on the science and phenomenology of ayahuasca and psilocybin mushrooms; a newly republished collection on MDMA, *Through the Gateway of the Heart*; and *The Well of Remembrance, The Unfolding Self, and Green Psychology*. Further reading can be found at greeneearthfound.org. Ralph can be reached at ralph@greeneearthfound.org.

Torsten Passie, M.D., M.A., is Professor of Psychiatry and Psychotherapy at Hannover Medical School (Germany) where he serves as the Director of the Laboratory for Neurocognition and Consciousness. He is currently Visiting Professor at Harvard Medical School. Dr. Passie also serves on the Board of Directors of the Swiss Physicians Society for Psycholytic Therapy (SAePT). Dr. Passie has conducted extensive research on the psychophysiology of altered states of consciousness, and is a leading European expert on the pharmacology and therapeutic use of psychedelic drugs.

An Update on MAPS Medical Marijuana Initiatives: Can Marijuana Ease Symptoms of PTSD for War Veterans?

MELODY PUPOLS, PH.D.



Melody Pupols, Ph.D.

THROUGHOUT 2012, MAPS WORKED TIRELESSLY to cut through key areas of red tape in order to begin a clinical study on the use of marijuana as a treatment for symptoms of chronic posttraumatic stress disorder (PTSD). Medical doctors have reported anecdotal evidence for well over a century that patients who smoke or ingest the flowering buds of *Cannabis sativa*, or marijuana, have reduced physical pain as well as reduced insomnia, anxiety, and depression, all of which are common symptoms of PTSD.¹⁻² Recognizing the need for thorough scientific analysis of these claims, MAPS has taken the initiative to diligently support clinical research into the safety and effectiveness of marijuana as a therapy.

One such proposal is a MAPS-sponsored study to be conducted at the University of Arizona under the direction of Principal Investigator Dr. Sue Sisley, to examine the safety and efficacy of five potencies of smoked or vaporized marijuana for symptoms of PTSD in 50 US veterans.³ While MAPS gained approval to conduct the study from the FDA in April 2011, a host of competing federal and state policies have prevented its initiation and made it impossible for researchers to conduct a scientific analysis of the merits of marijuana as a medicinal therapy.

Marijuana is now legally available for eligible patients in 18 states and the District of Columbia, and two states legalized marijuana for recreational use in November 2012.⁴ In spite of this growing tolerance for medical marijuana at the state level, the federal government often blocks research into the medicinal applications of marijuana. It accomplishes this blockade through the Schedule I classification of marijuana combined with the maintenance of a monopoly on the control and distribution of marijuana for federal research by the National Institute of Drug Abuse (NIDA).

Even though marijuana was on the U.S. formulary prior to 1937 as an approved medical compound and was supported by the American Medical Association at that time as a useful therapeutic agent, the Cannabis Tax Act of 1937 raised numerous policy roadblocks that still obstruct marijuana research today. An assessment by *The Boston Globe* rings true: While clinical research rigorously validating the therapeutic benefits of the marijuana plant might be modest, “that says more about the difficulty of studying an illegal substance than it does about the inherent medical value of the plant.”⁵

The most significant blockade to MAPS’ marijuana research efforts has been NIDA’s refusal to provide the marijuana needed to conduct the study in Arizona. It is not currently possible to obtain marijuana for FDA-reviewed research studies from any source except NIDA, which grows, stores, and sells marijuana to researchers who



study the adverse effects of the plant, from a single farm located at the University of Mississippi managed by marijuana scientist and entrepreneur Mahmoud ElSohly. In such a hostile climate for federally-reviewed marijuana research, it came as no surprise when—in September 2011, five months after the FDA cleared the study—NIDA and its parent agency the Public Health Service (PHS) conducted an independent review of the study protocol and decided it did not have scientific merit. One of the reasons the reviewers cited was that the protocol had not yet been scrutinized by an Independent Review Board (IRB), which reviews studies primarily with an eye for the safety of subjects.

MAPS has now secured approval of the proposed research protocol by the University of Arizona IRB in addition to the previous thorough review by the FDA. After careful assessment and three rounds of review, the IRB indicated their

satisfaction with the overall study design and their assessment that the protocol provides sufficient safety measures for patients who enroll in the clinical trial. The final review of the study protocol by the IRB occurred on October 23, 2012. Now, with approvals from both the FDA and IRB clearly supporting the scientific merit of the study, there is mounting pressure on NIDA and the Drug Enforcement Administration (DEA) to reform their stance on these issues, to allow the much-needed research on alternative therapies for the 18-20% of young adult veterans and many others who suffer from PTSD after returning from combat duty in Iraq.⁶

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The pressure on the federal government to allow medical marijuana research is also mounting on a different front, in the case of *Lyle E. Craker v. Drug Enforcement Administration*. In many

states, *Cannabis* plants can be grown for personal medicinal use and in Arizona, where the PTSD study would occur, it is now legal for eligible patients to grow up to 12 plants for medical uses. However, it remains illegal for an independent grower to supply marijuana for research into the medicinal qualities of the plant.

With support from MAPS, Lyle Craker, Ph.D., a professor of horticulture at the University of Massachusetts specializing in medicinal plants, spent nearly 11 years enduring internal DEA administrative reviews of his application to establish a production facility to grow marijuana with the controlled precision required for research purposes. These administrative proceedings ended on August 15, 2011, when DEA administrator Michelle Leonhart signed the final order denying Craker's request.

This final administrative denial opened the door for Craker's lawsuit, allowing him to take the case beyond the closed doors of the DEA and into the public forum of the U.S. Court of Appeals for the First Circuit in Boston, Mass. The opening brief was delivered in December 2011, and the court heard the first oral arguments in May 2012. The Appeals Court will be reviewing the rationale that the DEA used to reject an earlier 80-page report (issued by an Administrative Law Judge in 2007) recommending that it would be in the public interest for the DEA to issue a license to Professor Craker. A ruling in Craker's favor in the federal appeals court would force the DEA to reopen its administrative review of Craker's petition and conduct a new assessment of his request.

Dr. Craker is supported by MAPS along with pro bono legal services from Washington, DC-based law firm Covington & Burling LLP, one of the foremost law firms representing the pharmaceutical industry. The American Civil Liberties Union (ACLU) is also supporting Craker in the case.⁷

The U.S. Court of Appeals also heard testimony in October 2012 in the case of *Americans for Safe Access v. Drug Enforcement Administration* over the declassification of marijuana as a Schedule I

substance—the first time a federal appeals court had considered marijuana’s reclassification since 2002.⁸

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While the federal government stalls, a significant amount of state-level reform is underway that could facilitate the initiation of MAPS’ study of marijuana for veterans with PTSD, to be conducted by Dr. Sisley at the University of Arizona.

In 2010, Arizona voters approved Proposition 203, which allowed qualifying registered patients to obtain marijuana for specific debilitating medical conditions from 100 state-approved non-profit dispensaries. Unfortunately, legal opposition from Arizona Governor Janice Brewer and state Attorney General Tom Horne has prevented the bill from being fully implemented.

Since the passage of Prop 203, a \$6 million surplus of voter-protected funds has accumulated to support the implementation of the bill, with \$12 million projected for 2013. This capital could be used to conduct marijuana research in the state of Arizona if the Biomedical Research Commission, a committee controlled by Governor Brewer, specifically allocates these funds for these studies. At the time of this writing, no portion of these surplus funds has been allocated for research purposes.

In April 2012, in a separate initiative to block voter-approved Prop 203, Governor Brewer signed a bill into law that effectively banned marijuana studies from being conducted on university campuses. Dr. Sisley, the lead investigator of MAPS’ blocked study, is a vocal advocate for the credibility a university campus confers on a study of marijuana, and feels strongly that the university location would also provide benefits for the veterans suffering from PTSD who are waiting to enroll in the trial.

“Without the ability to conduct the study at an educational institution, this research can only legally be conducted at a location distant from a school campus. This does not provide the best options for patients, as many buildings will not rent space for a team to conduct a marijuana study, and others that will be not as clean and safe as we would like,” said Dr. Sisley. “I have worked with hundreds of combat veterans with PTSD who have admitted to using marijuana and tell me that it is the only thing that helps to ease their symptoms. I feel strongly that these veterans deserve scientific investigation into the effectiveness of marijuana for PTSD and that they be permitted a respectable location at which to participate in that study.”

Dr. Sisley is currently working with dedicated volunteers and a pro bono legal team in Arizona to draft two state-level amendments, one of which would amend the language to Gov-

ernor Brewer’s 2012 bill to allow clinical marijuana studies to take place at university campuses, including the University of Arizona. The second amendment, which also carries the support of the Arizona Medical Association, would ensure that some of the surplus funds from Prop 203 are specifically allocated for marijuana research purposes. This would require a supermajority vote (support from 3/4 of the state legislature) and will be submitted for review in January 2013. “If these policy changes can be successfully secured in the coming year, a renaissance for marijuana research would then be possible in Arizona,” says Dr. Sisley.

With FDA and IRB support for MAPS-sponsored marijuana research as a treatment for PTSD, and with the increasing number of states attempting to ensure that patients have safe access to medical marijuana, the outdated policies of

NIDA and the DEA are being systematically destabilized and pressure is building for reform. By challenging the obstructionist policies of NIDA and the DEA through multiple channels, the opportunity for the careful scientific assessment of marijuana as medicine will soon emerge. 🌿

“I have worked with hundreds of combat veterans with PTSD who have admitted to using marijuana and tell me that it is the only thing that helps to ease their symptoms.”—Dr. Sue Sisley

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Can war veterans with PTSD manage symptoms effectively with marijuana?

Up to 20% of Iraq combat veterans suffer from posttraumatic stress disorder (PTSD)
50% of PTSD patients who seek treatment with current therapies remain symptomatic

MAPS-sponsored study: Enroll 50 PTSD veterans in a clinical trial to determine the safety and efficacy of 5 potencies of marijuana vs. placebo to control symptoms

2011
April

FDA review and approval of clinical study protocol

Fact: The Food and Drug Administration (FDA) is responsible for ensuring drugs are safe and effective

2011
Sept

NIDA rejection of clinical study protocol

Fact: The National Institute on Drug Abuse (NIDA) is responsible for studying drug abuse and addiction (not safety, efficacy, or medicinal uses for drugs)

Fact: NIDA is the sole supplier of marijuana for research purposes in the United States

2012
Oct

Arizona IRB review and approval of clinical study protocol

Fact: The Institutional Review Board (IRB) must ensure the safety of human research subjects and deemed this study to be sufficiently safe and scientifically worthy of investigation

Current Status: Study on hold pending NIDA approval

2001

First request to Drug Enforcement Administration (DEA) to allow Dr. Lyle Craker to operate a medical marijuana facility for the sole purpose of supplying research studies

2011

Final DEA denial of Dr. Lyle Craker's request (August 2011)

Case enters U.S. Federal Court of Appeals (December 2011)

2012

First oral arguments in Federal Court of Appeals (May 2012)



Spotlight on Arizona



Sue Sisley, MD

Professor, University of Arizona

Lead Clinical Investigator,
Marijuana / PTSD Clinical Trial

2010

Proposition 203 approved by >50% of Arizona voters: 100 dispensaries for safe access to medical marijuana for qualified patients, up to 2.5 ounces

2012

\$6 million surplus of funds from stalled implementation of Prop 203 due to opposition from Governor Brewer

2013

Convince Arizona state legislature to dedicate portion of Prop 203 surplus funds for research into safety and efficacy of marijuana & to allow clinical studies to occur at a school campus

Did you know?

- Marijuana is available for medical use in 18 states and the District of Columbia
- Colorado and Washington became the first states to legalize marijuana for recreational use on November 6, 2012, for anyone over the age of 21



Zendo Project 2012: Harm Reduction in the Black Rock Desert

LINNAE PONTÉ



Linnae Ponté

FOR MOST ATTENDEES, THE YEARLY FESTIVAL in Black Rock City, Nevada, is a break from normal life and an opportunity to build community among a thriving city of art, music, and entertainment. For me this year, it was one of the most challenging, but also productive and rewarding weeks I've experienced during my time with MAPS. Kynthia Brunette, MAPS Operations Associate and co-coordinator of the Zendo Project, and I traveled to Black Rock City to establish a harm reduction space for individuals having a difficult psychedelic experience to receive compassionate care. With the help of 60 volunteers, including 12 medical professionals and many trained therapists, we provided space, water, and care for over 100 guests throughout the week.

Let's face it: Large art festivals already have the ingredients for an intense, mind-expanding experience. For first-timers, who typically represent the majority of guests in harm reduction spaces, a week of ongoing auditory and visual stimulation, physical exertion, and sleep deprivation is enough to propel many to search for solace. Toss in a dose of LSD or psilocybin, and you might be in for an overwhelming experience. In the famous words of Humphrey Osmond, who coined the term "psychedelic" in 1965, "to fathom hell or soar angelic, just take a pinch of psychedelic." Often times, when an individual is having a difficult trip, having someone to talk about what's going on, or simply the presence of another person, can make a big difference.

Our presence on the playa this year had great significance for another reason, being the first time in five years that MAPS has independently offered harm reduction services at festivals. MAPS began offering support at festivals, starting at BOOM in Portugal in 2001, where KosmiCare was established. In 2003, Valerie Mojeiko, MAPS Director of Operations, and others volunteered with Black Rock Rangers who were sympathetic to the need of harm reduction services, and this collaboration grew to become quite large over the five years that followed.

Unfortunately, as the U.S. Drug War continued to escalate, so did the perverse criminalization of harm reduction services, and over time MAPS' involvement in Sanctuary at Burning Man came to an end, while KosmiCare, in Portugal where drugs are decriminalized, has flourished.

Today, BOOM's KosmiCare is the world's closest model to a post-prohibition world, with on-site thin layer chromatography pill testing and a centralized space sponsored by both the festival and the local government. KosmiCare works with the local hospital, fire department, paramedics, security, and regional harm-reduction teams. This past July, MAPS Executive Director Rick Doblin and I attended BOOM and worked with KosmiCare volunteers, who provided support for approximately 200 guests. While on-site services are important, we also recognize that making honest and accurate information about drugs available to the public is just as essential to harm reduction, and we're grateful to Erowid (erowid.org) for creating and maintaining the online psychoactive vault, which receives about 100,000 visitors daily.

When we decided to bring the Zendo Project to the playa this year, we knew there would be many challenges. Our biggest concerns were finding enough volunteers willing to commit their time and energy to the project, and being prepared for any potential medical or psychological crises. After sending out a call for volunteers via the MAPS Email Newsletter and Evolver's email list, we received an enormous number of replies, so many that we had to stop accepting applications weeks before the event, speaking to the enthusiasm and momentum of the endeavor. Still, it was unclear whether we would have enough medical professionals for at least one physician, nurse, or EMT to be present each shift to triage guests experiencing a medical emergency, if the need arose. We met our goal in early August and also purchased two MURS radios so we would be able to communicate directly with the festival's medical services.

Our four-hour training took place on Tuesday, August 28,

with 81 attendees present. Trainers included Marcela Ot'alara, M.A., L.P.C., the Principal Investigator of the upcoming MAPS study in Boulder that will investigate MDMA-assisted psychotherapy for posttraumatic stress disorder in U.S. veterans and survivors of sexual abuse, assault, and rape. Marcela provided information about therapist self-care and techniques for working with trauma. Katherine MacLean, PhD, of the Johns Hopkins research team that is conducting empirical investigations of psilocybin and spirituality, shared techniques and principles of psychedelic harm reduction. Annie Oak, founder of the Women's Visionary Congress and the Saraswati Tea House, shared the code of ethics she has created after years of harm reduction experience. Rick Doblin shared the history of MAPS' involvement in this part of our mission as well as tips for working with a difficult psychedelic experience. Additionally, three medical professionals presented on potential medical issues that volunteers might encounter, such as dehydration and overheating, along with ways to distinguish between a psychedelic state and signs of psychosis.

Over the course of the week, we had 108 guests in the Zendo, 46 of whom had taken psychedelics prior to their arrival. The other 62 guests came to the Zendo seeking support to integrate a previous experience, to rest, or in search of information about psychedelics. The substances guests most often reported having taken before seeking help at the Zendo were LSD (25 guests) and psilocybin (10 guests). Luckily, we did not have any medical situations, besides the minor cut or scrape, for which the first aid kit came in handy.

While the Zendo provides a service to the community, it also offers the opportunity for individuals trained in psychedelic-assisted therapy to share their techniques with other therapists, doctors, and students. There are many individuals who are well versed in the theoretical components of psychedelic-assisted psychotherapy, but have little to no practical experience applying the methods. The Zendo is a space where this is possible, if and when a guest is open to a therapeutic approach. Of course, because the community of psychedelic-assisted psychotherapists is so small and mostly underground, most everyone played the role of both teacher and student during their shifts in the Zendo.

Volunteers and guests were asked to provide feedback about their time in the Zendo verbally or via written feedback forms submitted on-site or after the event. Many individuals reported that they felt more comfortable during the week just knowing the Zendo was available if they or someone they knew needed assistance. Many guests, after having a positive experience, expressed interest in returning next year to volunteer. It was apparent from the start of the burn that the Zendo needs to be farther away from the sound stage next year, as the booming bass of Fractal Nation felt quite cacophonous to many. Additionally, a separate space for volunteers to hang out seems important, and we'll try to make this happen so there is more space for guests in need.

An organizer from Nectar Village, home to the Hee-

BeeGeeBee Healers, Steam Bath Project, and Camp Contact, expressed interest in hosting the Zendo Project next year. We decided, instead, to setup a satellite Zendo space in their camp. With Nectar Village near Center Camp, Saraswati Tea House at 9:00, and the Zendo at 2:00, we'll have harm reduction spaces at all ends of the playa. In order to shuttle guests and volunteers from one place to another, we'd also like to have a psychedelic art car. David Bronner has offered to provide part (but not all) of the funds for the art car and we still need volunteers willing to help with the build and transportation.

We estimate that the Zendo Project 2012 cost roughly \$10,000, including construction, tickets, transportation, accommodations, staff time, and supplies. With twice the volunteers needed next year, our expenses will definitely be greater. Generously, Zendo volunteer Lucas Jushinski has pledged \$10,000 for the Zendo Project 2013, stating:

"I believe that harm reduction should be a part of every festival. It makes sense to create a space filled with loving people who care about the health and well being of others. A space where people who are having challenging psychedelic experiences can come and get help from trained counselors who understand what guests are going through. I mean, who wouldn't want to support a beautiful project like this?"

MAPS would like to thank everyone who volunteered their time to work in the Zendo, as well as those who donated money and resources to enable MAPS to organize the project. Appropriately enough, the theme for this year's festival was "Fertility." It's a new beginning for MAPS' involvement in harm reduction, and we hope to see the Zendo Project grow as abundantly in future years as it has in 2012. 🌱

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

THE ZENDO PROJECT MISSION STATEMENT

The mission of the MAPS Zendo Project is to:

- Provide a supportive space for individuals undergoing difficult psychedelic experiences or other psychological challenges in order to transform potentially traumatic experiences into valuable learning opportunities, 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.

Exploring Ayahuasca at Psychedelic Science 2013

STEPHAN V. BEYER, PH.D., J.D.

BIA LABATE, PH.D.

PSYCHEDELIC SCIENCE 2013 WILL HOST the largest international gathering in history of researchers in the field of ayahuasca, reflecting a virtual explosion of both scholarly and popular interest in the nature, effects, and uses of ayahuasca and its components.

Thanks to the organizing efforts of Bia Labate of the Centro de Investigación y Docencia Económicas in Aguascalientes, Mexico, the conference will feature 25 research presentations, a full-day post-conference ayahuasca workshop, a film presentation and discussion, and a community gathering to discuss current questions regarding the safety, ethics, and commercialization of ayahuasca use in spiritual tourism and the cultural appropriation of ayahuasca in the West.

International speakers on ayahuasca will include Gabor Maté, MD, the Hungarian-born Canadian physician specializing in the study and treatment of addiction; Sidarta Ribeiro, PhD, Brazilian neuroscientist and Director of the Brain Institute at the Universidade Federal do Rio Grande do Norte; his colleague Dráulio de Araujo, PhD, a specialist in brain imaging; Jacques Mabit, MD, French director of the Takiwasi Center in Tarapoto, dedicated to developing and testing an ayahuasca-based approach to drug rehabilitation and related research on traditional healing practices; and clinical psychologist José Carlos Bouso, PhD, of the Human Experimental Neuropsychopharmacology group in Barcelona.

Other scheduled presentations by scholars and researchers from multiple disciplines will showcase a wide range of scientific and humanistic approaches to the biochemistry, cognitive psychology, anthropology, ethnology, history, and therapeutic potential of ayahuasca. Of particular importance will be presentations—some for the first time—of new

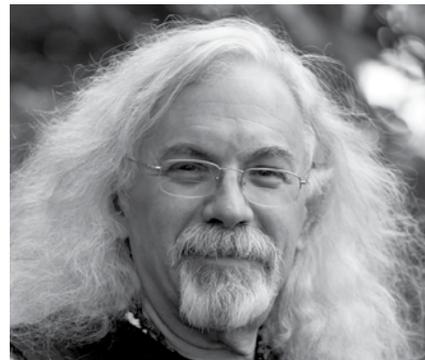
research from South America and of the ongoing work of young and rising scholars in the field.

Particular attention will be paid to claims of the potential of ayahuasca for the treatment of addiction and problematic substance use, with a full third of the presentations—a full day—devoted in whole or in part to the subject. Additional presentations will discuss recent epidemiological studies of mental health and self-perception among members of the ayahuasca-using Brazilian new religious movements, as well as related questions of ritual transfer, cultural translation, legal pluralism, and transnational economics.

The Ayahuasca Track will include discussions ranging from the botany, chemistry, and pharmacology of traditional ayahuasca admixture plants, to the human metabolism of ayahuasca, to the relation of ayahuasca visions to both mental imagery and dreaming. Anthropological presentations will address the nature of healing in ayahuasca's traditional mestizo and indigenous ceremonial settings.

In addition, an open community-wide forum at the conference will encourage discussion about spiritual tourism, the commodification of ayahuasca, and ways to balance risk and safety for people drinking ayahuasca in ceremonial and other contexts, especially in relatively remote settings. There will also be a premiere showing of the documentary film *AYA: Awakenings*, about the experiences of ayahuasca pilgrims in Peru.

Following the three-day conference, there will be a full-day workshop on the ethnobotany, safety, and expansion of ayahuasca, which will allow for longer, in-depth presentations and more comprehensive interactive discussion of significant questions in the anthropology,



Stephan V. Beyer, Ph.D., J.D.



Bia Labate, Ph.D.

ethnobotany, biomedical research, and phenomenology of ayahuasca use.

Psychedelic Science 2013 promises to be tremendously exciting, and there is a plan to publish a volume of the presentations on the therapeutic potential of ayahuasca from the conference. The number of prominent scholars and researchers, their diversity of interests and approaches, and the length of time that will be available for presentations and discussions will create a unique opportunity for learning, inspiration, and networking. It should not be missed.

For more information about Psychedelic Science 2013 and to register visit psychedelicsscience.org.

Stephan V. Beyer, Ph.D., J.D. is an independent researcher in ethnobotany, shamanism, and ethnomedicine. He can be reached at steve@singingtotheplants.com.

Bia Labate, Ph.D. is Visiting Professor at the Drug Policy Program of the Center for Economic Research and Education (CIDE), Aguascalientes, Mexico.

Consideration of Ayahuasca for the Treatment of Posttraumatic Stress Disorder

JESSICA L. NIELSON, PH.D.

JULIE D. MEGLER, MSN, NP-BC

THERE IS A GROWING AMOUNT OF RESEARCH on the development of PTSD and its various treatments. The fact that many people who suffer from PTSD struggle with the currently approved therapeutic options that are available to them suggests that we need to start exploring alternative strategies to treat this disorder.¹ With the large number of veterans returning home from war that may have or will develop PTSD, we must have a diverse framework of therapy and integration in place for them.

Alternative options that are currently being explored for the treatment of PTSD include MDMA-assisted psychotherapy² and marijuana.³ Current research indicates that ayahuasca mimics mechanisms of currently accepted treatments to PTSD, and its use as an alternative treatment for other types of disorders are also being considered.⁴ However, in order to understand the implications of ayahuasca in the treatment of PTSD, we need to understand how PTSD develops, which involves memory formation.

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Memory can be divided into three types: perceptual memory, episodic memory, and semantic memory.⁵ Before it reaches conscious awareness, information from the outside world first passes through the sensory cortices of our brain. This is perceptual memory. Sensory input then travels up to higher processing regions. Within our limbic system lies the hippocampus and amygdala. The cognitive aspect of memory occurs in the hippocampus. There we are able to perceive the sensory information and form “episodic” memories. The amygdala links the episodic memory to the associated emotions.⁵ At this stage, when an event is recalled the original sensations and emotions are replayed with it.

Over time, relevant information from episodic memory is transferred to the neo-cortex to create semantic memory networks. Here the information is integrated into your general knowledge, and becomes available for understanding events in the future. It is in the cortex that we assign meaning to our memories. A feedback loop from the cortex to the hippocampus then tells it to weaken the episodic memory.⁵ The memory can then be recalled without provoking the original sensations and emotions.

In PTSD, the brain fails to appropriately consolidate and integrate episodic memories into the semantic memory system.⁵ The memory and its associated emotions become trapped in the hippocampus, so that whenever the adverse memory is triggered



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it is recalled as if the traumatic event is being re-experienced. The resulting hyperarousal leads many trauma victims to develop maladaptive coping mechanisms. In an attempt to prevent stimulation of intense fear, they seek ways, such as substance abuse, to avoid or numb out to triggers.

The American Psychiatric Association (APA) outlines three approaches to the treatment of PTSD: psychopharmacology, psychotherapy, and education and support. The goal of treatment is to eliminate or decrease flashbacks, nightmares, and other intrusive symptoms, allowing avoidance and arousal symptoms to subside.⁶ Successful recovery requires the disrupted process of cortical memory consolidation and integration to be reestablished. The patient must be able to discuss the traumatic event without replaying the original emotional intensity.

Once the images are no longer intrusive the event can be integrated into regular life. Only then will the victim come to understand their past trauma, and thus come to terms with it.⁷ In PTSD, the blockade of hippocampal outflow to the cortex needs to be reestablished so that the episodic memory can be weakened and the semantic memory created. Because it is limited to the cortical level of the brain, simple catharsis (expression of the traumatic event) is not sufficient to successfully treat PTSD symptoms. Effective treatments must target the limbic system.

When using psychotherapeutic treatments, many professionals in the field believe fear must be experienced before it can be reduced or eliminated. Exposure therapy is considered to be any therapy where the client is exposed to a fear memory as part of the therapy.⁷ With sufficient exposure, clients adapt to the trauma by altering its meaning in a way that desensitizes them to trauma-related triggers, thus reducing their experienced fear.⁶

Three types of exposure therapies that are recognized as evidence-based practice for treatment of PTSD include: prolonged exposure (flooding), cognitive restructuring, and eye movement desensitization and reprocessing (EMDR) therapy.⁸ These exposure therapies target the emotional aspects of fear memories mediated by the amygdala. Stimulation to these areas releases the memories to the cortex so they can finally be processed and integrated into the victim's life with meaning.

From the psychotherapeutic standpoint, ayahuasca is similar to exposure therapy. Intention-setting is a common ritual in many ayahuasca practices. Users with traumatic histories have the opportunity to set their intentions to their traumas. Recent studies indicate that the amygdala, and other brain areas associated with emotional processing, is activated with the administration of ayahuasca.⁹ Activation of the amygdala, the very region of the brain that is the source of fear-associated symp-

toms of PTSD, is seen with ayahuasca as well as exposure-based approaches.

Due to the heterogeneity and complexity of PTSD, and to the variety of therapeutic options available including psychedelic-assisted therapy, it may be difficult to fully understand their nature and relationships to each other. The authors of this article propose a new approach to understand and assess them both. This approach is currently used by Dr. Nielson and her colleagues at the University of California, San Francisco, and uses bioinformatics to understand the complex nature (syndrome) of spinal cord injury and its potential therapies.¹⁰ This approach involves mining raw data from preclinical and clinical trials, incorporating them into a large, heterogeneous, and flexible database, running statistical pattern detection algorithms on it, and deriving novel patterns about the underlying biological mechanisms that are conserved across paradigms.¹¹

By using this bioinformatic methodology on psychedelic therapies for PTSD, we hypothesize that we can both more accurately define the entire syndrome of PTSD,¹⁰ and assess appropriate therapeutic options for patients, including those still being tested in clinical trials.² Additionally, these methods enable us to rapidly visualize the syndrome space,¹² making this a very user-friendly and effective framework to identify various syndromes.¹⁰

If we use this bioinformatics approach in combination with rapid data visualization and analysis, we hypothesize that we can identify risk factors for PTSD that may be a useful screening tool to assess whether a patient is ready for exposure

therapy, and which treatment will be the best route to maximize their long term recovery. Additionally, we can begin to address whether ayahuasca could be a beneficial therapy for PTSD by collecting data from subjects with PTSD who are voluntarily using it, and assessing their recovery.

We have started a collaboration with the Paititi Institute near Iquitos, Peru (paititi-institute.org), who have already treated and will continue to treat patients with PTSD and other health disorders with ayahuasca. Our goal is to gather enough retrospective data from this center to provide rationale for an observational study, and potential future clinical trials with ayahuasca for PTSD.

Additionally, numerous studies have been conducted to assess the safety of ayahuasca. Under the appropriate settings and with supervision, and no prior consumption of contraindicated substances and foods¹³ or pre-existing conditions, ayahuasca has been shown to be safe and non-addictive.¹⁴ In fact, it is being explored for its therapeutic potential from multiple perspectives and mechanisms, including the potential to treat substance abuse.⁴

From the psychotherapeutic standpoint, ayahuasca is similar to exposure therapy. Intention-setting is a common ritual in many ayahuasca practices. Users with traumatic histories have the opportunity to set their intentions to their traumas.

To ensure that the proper measures of caution are considered, it may be useful to pre-screen interested participants and patients that want to take ayahuasca to treat their PTSD. Because there are contraindications for the monoamine oxidase inhibitor (MAOI) component¹³ of ayahuasca, pre-screening patients for the presence of these substances is important. Additionally, careful assessment during pre-screening is important to determine whether the patient is ready for this kind of therapy, because exposure therapies run the risk of being re-traumatizing. These should be taken into consideration before taking ayahuasca. This is especially important for people with PTSD who may be on various medications.

This study into the therapeutic potential of ayahuasca for PTSD is in the preliminary stages. The initial connections in this framework have been made, and we welcome additional collaborators, data donors, and funders to contact us regarding working towards this project. 🌱

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Conference Report: Global Ibogaine Therapist Alliance (GITA) Vancouver, Canada, October 2–6, 2012

THOMAS KINGSLEY BROWN, PH.D.

BETWEEN OCTOBER 2ND AND 6TH, The Global Ibogaine Therapist Alliance (GITA), hosted its 3rd international conference on iboga and ibogaine research and practice in Vancouver, Canada. This event consisted of four days of private meetings for GITA members and one day of public presentations. In addition, several GITA members offered a two-day post-conference training module (October 8th to 9th), the first of its kind, attended by physicians and aspiring lay therapists.

Last summer, as the conclusion of our Mexico-based ibogaine outcomes study drew near, Jonathan Dickinson, the organizer of the GITA conference, invited me to discuss the ibogaine study twice at this conference: first to the GITA members (ibogaine providers and others working with ibogaine) and also as part of a panel open to the public. I was excited about the prospect of meeting ibogaine providers and researchers from all over the world and discussing the MAPS-funded ibogaine study, which will soon become the first published study of long-term outcomes for people receiving ibogaine-assisted treatment for drug dependence.

On the morning of Friday, October 5, I spoke in a session open only to GITA members. My overall aim was to show the importance of documenting and publishing the outcomes data and to suggest that ibogaine providers add to our knowledge by maintaining records of treatments and by sharing treatment results from their clinics.

I started by discussing the dearth of research on outcomes for ibogaine treatment. The few research outcomes available for ibogaine treatment agree with the pre-clinical studies, which show that ibogaine can greatly reduce withdrawal symptoms and cravings in the days following treatment; there are virtually no published data on long-term outcomes. I then provided an overview of our observational study and presented preliminary results. I noted that the results seem to show a huge decline in usage of opiates—both in frequency of use and in dosage per use—post-treatment, even though the majority of the 30 participants “relapsed” within the first three months.

I then revealed that of the 10 study participants who made it past the three-month mark without using opiates again, four

of them appear to have been “clean” from opiates for the entire 12-month follow-up period (after only a single treatment). I also discussed the low rates of aftercare, with only six subjects receiving aftercare following treatment.

Finally, I put out a call for a collaborative research effort. I mentioned that between this study and Dr. Geoff Noller’s current MAPS-sponsored study in New Zealand, we would enroll 60 participants, a number that pales in comparison to how many people receive ibogaine treatment each year and to the number of subjects typically enrolled in clinical trials for pharmaceuticals. MAPS’ studies of ibogaine will show significant results because the effects are quite dramatic (especially in comparison with many pharmaceuticals, for which a large number of subjects is often required to show a significant difference as compared with a placebo since the effects are so small). However, I argued, we could collectively gather data on hundreds or thousands of treatments as well as their outcomes, and the compiled data would make a difference even if not gathered in

such a rigorous fashion as in our studies.

This call for collaboration was well received. After the talk several people, including Bob Sisko and Anwar Jeewa (an ibogaine provider currently in Durban, South Africa), asked me for my card and

requested that I send the slide presentation to them. Dr. Jeewa later gave me a file with data on 341 patients he has already treated in South Africa. I hope that this data will be the first of many such data sets submitted for inclusion in a collection available to the ibogaine community.

I had met Dr. Ken Alper, who has been involved in research on ibogaine for well over a decade, before I made my presentation. Afterwards, he and I joined several other conference attendees for lunch. Ken told me that he was the first reviewer of my manuscript for *Current Drug Abuse Reviews*, which was recently accepted for publication in a special volume on psychedelics in the treatment of substance dependence. Ken also advised me that there are some effective ways to deal with the complicated data we’ve got from the Addiction Severity Index-lite (our primary outcome measure) including ways to deal with

...people in the ibogaine community are linked by a commitment and passion for increasing awareness about how to safely and effectively provide a treatment they have seen helping people over and over again.



Thomas Kingsley Brown, Ph.D., (second from left) participates in a panel at the GITA conference in October 2012.

missing data points. He told me he knows a statistician in New York who he will recommend to MAPS for advice on analyzing our ibogaine outcomes data.

On Saturday morning, October 6, I joined a few dozen conference attendees for a drug activism tour of Vancouver that included a tour of the Herb Museum. The tour was informative and fascinating, and it gave me a chance to talk at length with some of the other GITA attendees.

For me, the best conversation of the entire visit was the one I had with Tanea Paterson, an ibogaine provider based in Dunedin, New Zealand. Among other things, we discussed the idea of starting a web-based repository for ibogaine treatment data and a web forum for GITA members to share and discuss best practices. We also began to discuss ways to address a well known problem encountered by seekers of ibogaine treatment: the Internet is perhaps the most common place for people to start looking for such treatment, but the information one can find online is generally unhelpful and often conflicting or even misleading. We talked about forming a moderated web site in which best practices (for safety and for treatment efficacy) are discussed, and where providers can endorse other providers. Tanea and I have since connected via the Internet, and we are both quite keen on keeping the ball rolling and on including many other people in this endeavor.

The public forum on ibogaine treatment took place on Saturday afternoon. Five of us (in order: Ken Alper, myself, Sandra Karpetas, Tanea Paterson, and Clare Wilkins) spoke for about 15-20 minutes each, and then fielded questions from the audience. Clare brought everything together as she spoke about the “ibogaine family tree” that connects everyone from Howard Lotsof (who serendipitously discovered ibogaine’s anti-addictive properties about 50 years ago and treated many people with ibogaine) to the ibogaine providers present in the auditorium. The discussion was very inclusive; on a few occasions practitioners in the audience (including Anwar Jeewa and Christopher Laurence, who is in Nayarit, Mexico) stood and addressed questions. The spirit of the event was one of cooperative learning.

The final conference event was a dance party on Saturday night, which gave me the chance to speak with several people I’d not yet met. As the evening progressed, I noticed that for a long while there were people from six continents dancing together on the same floor, and everyone at the party seemed to be having fun. Meanwhile people shared stories and became better acquainted.

Talking with people there and witnessing the group discussions that occurred throughout the conference showed me that people in the ibogaine community are linked by a commitment and passion for increasing awareness about how to safely and effectively provide a treatment they have seen helping people over and over again. I am pleased that Jonathan Dickinson has distributed the contact list of attendees to all of us and that there are ways for us to continue the conversations that occurred at the conference.

The conference was certainly informative. In all, though, meeting people and discussing issues relevant to the study and to the ibogaine medical subculture were the most valuable aspects of the conference from my perspective. Before the conference I had the sense that I was working on one piece of a larger puzzle: *How can we demonstrate ibogaine’s efficacy and increase awareness of ibogaine in the scientific and lay communities?* Now I feel that I’m part of the whole—and I’m very excited about the things that I see growing out of that conference. 🌐

Thomas Kingsley Brown, Ph.D., will be presenting the latest ibogaine research results at *Psychedelic Science 2013*, taking place from April 18-23, 2013, in Oakland, Calif. Visit psychedelic-science.org for more details and to register. Tom can be reached at tom.k.brown@gmail.com.

The official Global Ibogaine Therapist Alliance conference summary is available at ibogainealliance.org/vancouver-2012.

For more information about MAPS’ international research on ibogaine for drug addiction, visit maps.org/ibogaine.

Psychedelics Advance in Higher Education

Adapted from *The Psychedelic Future of the Mind*

(forthcoming January 2013)

THOMAS B. ROBERTS, PH.D.



Thomas B. Roberts, Ph.D.

THE MAPS WEBSITE'S RESOURCES FOR STUDENTS (maps.org/resources/students) lists 13 institutions of higher education which offer instruction about psychedelics. This article alerts readers to the new listing of Northern Illinois University and 3 others not yet listed as of the time this article was written.

NORTHERN ILLINOIS UNIVERSITY

One reason I started my course in 1981 was my hope that if I could teach it at Northern Illinois University, it would serve as an icebreaker for professors elsewhere. Until the last three or four years, I was disappointed, but now that a more rational, evidence-based approach to psychedelics is spreading in both science and society, hope for higher education blooms again. "Foundations of Psychedelic Studies" is currently taught once a year as a seminar limited to Honors Program students. Its syllabus and related materials and PowerPoints are available at niu.academia.edu/ThomasRoberts.

COLLEGE OF DUPAGE

At the College of DuPage, a community college in suburban Chicago, "Psychedelic Mindview" is geared toward people in the human services field like mental health professionals and addiction counselors as well as others with an interest in the topic. In addition to being taught live, starting in mid-March 2013 it will be taught online and available to students worldwide.

SOFIA UNIVERSITY

"Psychedelics: Theory, Research, and Clinical Applications" at Sofia University in Palo Alto, California (formerly the Institute for Transpersonal Psychology), is primarily for graduate students who plan to become mental health professionals. According to its catalog description, "This course explores therapeutic issues involving the use of psychedelic substances. It covers clinical research on psychedelic drugs as adjuncts to psychotherapy for the treatment of addiction, PTSD, and existential distress at the end of life, as well as how to address psychedelic experiences that clients bring into psychotherapy. Ancient, shamanic, and modern uses of psychedelics will be examined to provide broad cultural perspectives."

NYU LANGONE MEDICAL SCHOOL BELLEVUE HOSPITAL

NYU-Bellevue is the world leader in psychedelic medical education. There, doctors Stephen Ross and Jeffrey Guss teach “Psychedelics in Psychiatry.” In case there is any doubt about the range of professionals who are interested in psychedelics, Dr. Guss describes their students this way:

The class was open to a broad variety of individuals. We invited the Fellows in Addiction Psychiatry in the NYU Department of Psychiatry, and there was one senior resident (PGY-IV) who was doing a selective in PRG (the Psychedelic Research Group, the psilocybin/cancer anxiety research program). In addition we invited people from a diverse group of professional categories who had expressed an interest in our research. There were doctoral students in psychology from the New School, as well as NYU, doctoral students in Cognitive Neuroscience, research associates from Ken Alper’s ibogaine program, nursing students, social workers involved with addiction treatment and addiction program development, as well as numerous non-clinical individuals (meditation enthusiasts with degrees in consciousness studies), researchers from the Manhattan Veterans Administration, and so forth.

In addition to providing psychotherapy for their patients and testing their hypotheses, the NYU-Bellevue course enriches the general discourse. As a center for bringing together knowledge from the participants’ own academic areas and alternative medicine, the course helps students and instructors meet with other like-minded medical and academic professionals to share ideas; ideas about meditation, Buddhism, drumming, and similar mind/body topics cross-fertilize discussions. From an institutional perspective, in addition to familiarizing the participants with the specific treatment protocols and staff, the course is a forum for graduate students at NYU to discuss their personal ideas for research in a supportive environment.

UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE AND HEALTH

Professor Nicholas Cozzi includes a one-hour lecture on psychedelics in his “Integrated Neurosciences” course primarily for second-year medical students.

UNIVERSITY OF MINNESOTA’S CENTER FOR SPIRITUALITY AND HEALING

U of M offers a course by Dennis McKenna which includes components on psychedelics: “People, Plants and Drugs: An Introduction to Ethnopharmacology.” Ethnopharmacology is the scientific investigation of biologically active substances utilized by humans. Its focus is usually, but not always, on indigenous, traditional, historic, or non-Western cultures. By definition, ethnopharmacology is interdisciplinary and eclectic;

the scope and tools of ethnopharmacological studies are derived from pharmacology and toxicology, pharmacognosy, chemistry, medicine, botany and ethnobotany, medical and cultural anthropology, and other disciplines.

PROPOSAL FOR PSYCHEDELIC COURSE DEVELOPMENT AWARDS

How can more colleges and universities be encouraged to offer courses in psychedelic medicine and research? A high-benefit funding opportunity exists for foundations and wealthy individuals. Colleges and universities take an academic field seriously if grants are available in that field. While funders have been generous in their donations to support research, funding new courses on psychedelics would be relatively cheap and long-lasting. Unlike a research study, once a course is established, it can continue for decades. More than that, it lends legitimacy to its topic. Of course this might be done various ways, but the way to have the biggest impact may be a three-round award contest system.

In Round One, instructors who want to design and establish such a course would be invited—such as with an announcement in *The Chronicle of Higher Education*—to submit letters of intent to establish such courses, with brief descriptions of their qualifications and their institution’s willingness to support it.

Round Two would invite winners of the first round to submit a course design grant. The selected instructors would design their courses and submit their syllabi accompanied by a letter from their department chairs or someone similar confirming that, if funded, the course would be offered and otherwise supported. Winners would be awarded a sum (e.g., \$2,000) to assist with proposal development for Round Three.

In Round Three, several proposals would be selected and the writers would be awarded with a larger sum (e.g., \$15,000) with co-awards to their departments of a similar amount to help pay for the instructor’s salary while teaching the course and for overhead expenses. To increase the impact, Round Three awards might be extended for two or three years, or longer. Besides colleges and universities, specialized institutions of higher education such as medical schools and other professional schools, seminaries, and theological schools, law schools, and similar organizations could be eligible to apply for psychedelic course development prize awards too.

As psychedelics return to respectability, I expect we’ll see more courses throughout the systems of higher education. Research on psychedelics’ clinical uses are taking the lead. Now we need courses that broaden psychedelic studies to consider their academic implications and uses throughout the humanities, arts, religion, sciences, and social sciences. 🌐

Thomas B. Roberts, Ph.D. is Professor Emeritus in the Honors Program at Northern Illinois University. He can be reached at troberts@niu.edu.



Amanda Feilding

Reforming Psychedelic Science and Policy: An Update from the Beckley Foundation

AMANDA FEILDING

THE BECKLEY FOUNDATION HAS HAD a very successful year, with much progress on our dual fronts of Science and Policy.

In January the *Beckley Foundation–Imperial College Psychedelic Research Programme* published two ground-breaking scientific papers on the effects of psilocybin on cerebral blood flow and brain activity, using brain-imaging technology correlated with subjective reports. The findings reveal how psilocybin decreases blood flow and thereby diminishes the activity of a network of key “hub centres,” which are responsible for filtering and coordinating information. By decreasing this censoring activity, psilocybin allows a freer, less constrained state of consciousness to emerge.

One of the “hubs” deprived of blood flow by psilocybin is known to be *overactive* in chronic depression, a condition characterised by rigidly negative thought patterns. By lowering the activity of this “hub,” psilocybin may allow the excessively rigid negative thinking to be reset. On the back of these findings, the UK’s Medical Research Council has awarded a substantial grant to investigate the potential of psilocybin in the treatment of depression. It is a major breakthrough for a psychedelic study to receive government funding.

We also found that another “hub” centre, which is *overactive* in cluster headaches, has its activity reduced by psilocybin. This finding lends neuroscientific support to the anecdotal evidence that magic mushrooms and LSD can provide effective relief for this agonising condition.

The second paper, published in the *British Journal of Psychiatry*, details how psilocybin produces extraordinarily vivid and lifelike memories in comparison with placebo. The results highlight the valuable potential of psilocybin as an aid to psychotherapy in enabling the subject more easily to access, and therefore work through, traumatic memories.

A third Beckley/Imperial psilocybin paper has recently been published in the *Schizophrenia Bulletin*. Our results show

that the changes in connectivity between brain regions brought about by psilocybin resemble those seen during meditation and early psychosis: The networks responsible for *inner focus* and *external attention*, normally acting in opposition to one another, become more closely coupled. This can result in a blurring between “inner” and “outer” worlds in all these states—for example the “ego-dissolution” and “unitary state of awareness” reported both after taking psychedelics and in the mystical state.

Another Beckley/Imperial study, into the neural basis of the effects of MDMA, was televised in September on Channel 4 in the UK and watched by over two million people. In response to *positive* memories, MDMA was found to *increase* the response of the brain’s sensory cortex. By contrast, during recall of *negative* memories, brain areas associated with *negative* emotions—such as the amygdala—showed *decreased* activity under MDMA.

This observation provides a neuroscientific explanation for the success that MAPS has reported in using MDMA-assisted psychotherapy in posttraumatic stress disorder (PTSD). When memory recall is less traumatic, patients can more easily engage with, and work through, their traumatic memories.

In the coming months, we plan to continue the Beckley/Imperial collaboration with brain imaging research on LSD and cannabis, for which protocols have been prepared.

Another Beckley study, in collaboration with Johns Hopkins, is the first in modern times to use a psychedelic as an aid in the treatment of addiction—in this case, to nicotine. Although the trial has had only a handful of participants so far, its findings to date have been amazing, with all the participants remaining long-term abstinent. The study has recently benefitted from funding from the Heffter Research Institute, enabling it to develop more rapidly to the next phase.

Our research into the neuroscience and therapeutic effects of cannabis is also moving forward. A Beckley study in collaboration with Harborside Health Center in California and



University College, London is producing a unique database on the medical efficacy of different strains of cannabis in relation to their different chemical compositions. This will provide a valuable resource for future clinical research, as well as evidence for policy-makers.

Our long-running collaboration at King's College London investigating the different characteristics of THC and CBD has produced much valuable data, such as showing that CBD counteracts the effects of THC, reducing both the paranoia and the memory impairment that THC can induce. Further results recently published show that CBD can counteract symptoms of prodromal psychosis. High-potency street cannabis tends to be high in THC, with little or no CBD—precisely the combination that can have the greatest potential for harm. With a regulated market, content could be labelled.

Our programme of psychedelic research is not only opening up new avenues of treatment, but also shedding new light on the mechanisms underlying consciousness, arguably the last and greatest mystery for mankind. Substances that alter consciousness as profoundly as psychedelics are vital for this research, yet only very recently has any systematic investigation become possible. Even now, progress is throttled by a cumbersome prohibitionist regime that shuts out all but the most determined searchers. The Beckley Foundation is proud to be at the forefront of this research.

The Beckley's Policy Programme is also making exciting progress. In July, at the invitation of President Otto Pérez

Molina, we opened a *Latin American Chapter* in Guatemala. The Chapter is advising the President and his Government on drug policy matters, including developing a sophisticated range of policy options aimed at reducing violence and corruption

in Guatemala and the wider region.

In late 2012 we are to launch a new global campaign website, in partnership with the *Global Commission on Drug Policy*, Virgin

United and Avaaz, to coincide with the release of the film *Breaking the Taboo*. The campaign, whose Mission Statement is the Beckley Public Letter, will aim to collect over a million signatories calling for an end to the War on Drugs. The Letter (printed on page 38) has already been signed by eight Presidents and twelve Nobel laureates.

We have also just released a major new report, *Roadmap to Reforming the UN Drug Conventions*, which details how a group of countries could set about amending the UN Conventions to allow them the freedom to formulate national drug policies better suited to their special needs and circumstances, in place of the failed prohibitionist approach of “one size fits all.” 🌐

Amanda Feilding is Founder and Director of The Beckley Foundation. She can be reached at beckley@beckleyfoundation.org.

Founded in 1998, the **Beckley Foundation** aims to scientifically investigate altered states of consciousness, and to change global drugs policy to reflect a more rational, evidence-based ideology. To learn more, visit beckleyfoundation.org.

THE GLOBAL WAR ON DRUGS HAS FAILED IT IS TIME FOR A NEW APPROACH

WE THE UNDERSIGNED call on Governments and Parliaments to recognise that:

Fifty years after the 1961 UN Single Convention on Narcotic Drugs was launched, the global war on drugs has failed, and has had many unintended and devastating consequences worldwide.

Use of the major controlled drugs has risen, and supply is cheaper, purer and more available than ever before. The UN conservatively estimates that there are now 250 million drug users worldwide.

Illicit drugs are now the third most valuable industry in the world, after food and oil, estimated to be worth over \$350 billion a year, all in the control of criminals.

Fighting the war on drugs costs the world's taxpayers incalculable billions each year. Millions of people are in prison worldwide for drug-related offences, mostly personal users and small-time dealers.

Corruption amongst law-enforcers and politicians, especially in producer and transit countries, has spread as never before, endangering democracy and civil society. Stability, security and development are threatened by the fallout from the war on drugs, as are human rights. Tens of thousands of people die in the drug war each year.

The drug-free world so confidently predicted by supporters of the war on drugs is further than ever from attainment. The policies of prohibition create more harms than they prevent. We must seriously consider shifting resources away from criminalising tens of millions of otherwise law abiding citizens, and move towards an approach based on health, harm-reduction, cost-effectiveness and respect for human rights. Evidence consistently shows that these health-based approaches deliver better results than criminalisation.

Improving our drug policies is one of the key policy challenges of our time. It is time for world leaders to fundamentally review their strategies in response to the drug phenomenon.

At the root of current policies lies the 1961 UN Single Convention on Narcotic Drugs. It is time to re-examine this treaty which imposes a 'one-size-fits-all' solution, in order to allow individual countries the freedom to explore drug policies that better suit their domestic needs.

As the production, demand and use of drugs cannot be eradicated, new ways must be found to minimise harms, and new policies, based on scientific evidence, must be explored.

Let us break the taboo on debate and reform. The time for action is now.

Yours faithfully,

President Otto Pérez Molina
President of the Republic of Guatemala

President Jimmy Carter
Former President of the United States, Nobel Prize winner

President Fernando H. Cardoso
Former President of Brazil

President César Gaviria
Former President of Colombia

President Vicente Fox
Former President of Mexico

President Ruth Dreifuss
Former President of Switzerland

President Lech Wałęsa
Former President of Poland, Nobel Prize winner

President Alexander Kwasniewski
Former President of Poland

Jaswant Singh
Former Minister of Defence, Minister of Finance, Minister for External Affairs (India)

Thorvald Stoltenberg
Former Minister of Foreign Affairs (Norway), UN High Commissioner for Refugees

Louise Arbour, CC, GOQ
Former UN High Commissioner for Human Rights

George P. Schultz
Former US Secretary of State

Mario Vargas Llosa
Writer, Nobel Prize winner

Dr. Kary Mullis
Chemist, Nobel Prize winner

Professor Sir Harold Kroto
Chemist, Nobel Prize winner

Professor John Polanyi
Chemist, Nobel Prize winner

Professor Kenneth Arrow
Economist, Nobel Prize winner

Professor Thomas C. Schelling
Economist, Nobel Prize winner

Professor Sir Peter Mansfield
Physicist, Nobel Prize winner

Professor Sir Anthony Leggett
Physicist, Nobel Prize winner

Professor Martin L. Perl
Physicist, Nobel Prize winner

Wisława Szymborska
Poet, Nobel Prize winner

Dr. Jan Wiarda
Past President of European Police Chiefs

Carel Edwards
Former Head of the EU Commission's Drug Policy Unit

Javier Solana, KOGF, KCMG
Former EU High Representative for the Common Foreign and Security Policy

Professor Noam Chomsky
Professor of Linguistics & Philosophy, MIT

Bob Ainsworth, MP
Former Secretary of State for Defence

Peter Lilley, MP
Former Secretary of State for Social Security

Lord MacDonald, QC
Former Head, Crown Prosecution Service

Nicholas Green, QC
Former Chairman of the Bar Council

Sir Peregrine Worsthorne
Former editor, Sunday Telegraph

Professor Peter Singer
Professor of Bioethics, Princeton University

Professor David Nutt
Former Chair of the Advisory Council on the Misuse of Drugs

Professor Sir Partha Dasgupta, FRS, FBA
Professor of Economics, Cambridge University

Professor Niall Ferguson
Professor of History, Harvard University

Dr. Muhammed Abdul Bari, MBE
Former Secretary General of the Muslim Council of Britain

General Lord Ramsbotham
Former HM Chief Inspector of Prisons

Professor Lord Piot
Former UN Under Secretary-General

Sir Richard Branson
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Sting
Musician and actor

Yoko Ono
Musician and artist

Bernardo Bertolucci
Film Director

Carlos Fuentes
Novelist and essayist

Gilberto Gil
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Former Secretary-General of the International Chamber of Commerce

John Whitehead
Former Chairman of Goldman Sachs and US Deputy Secretary of State

Professor AC Grayling
Master, New College of the Humanities

Professor Sir Ian Gilmore
Past President, Royal College of Physicians

Lord Rees, OM
Astronomer Royal and former President of the Royal Society

Amanda Feilding
Director of the Beckley Foundation

TREATING PTSD WITH MDMA-ASSISTED PSYCHOTHERAPY

What is PTSD?

Posttraumatic Stress Disorder (PTSD) can be a chronic, devastating illness that severely impacts quality of life. Sufferers often struggle to maintain healthy lives and relationships.



PTSD can be caused by:



war sexual assault childhood abuse torture accidents other stressful events

1 in 7 U.S. service members returning from Iraq and Afghanistan suffers from PTSD.

What is MDMA-Assisted Psychotherapy?

A treatment that combines psychotherapy with the administration of MDMA, which catalyzes the therapeutic process.



MDMA is not Ecstasy. Substances sold illegally under the name "Ecstasy" often do not contain MDMA and sometimes contain harmful adulterants.



MDMA is a synthetic compound that decreases **fear and defensiveness** while increasing **trust and empathy**, making it easier for patients to be comfortable between the extremes of fear and avoidance.



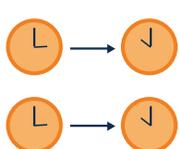
MDMA is not the therapy in itself, but a **tool for the therapist and patient.**

How does MDMA-Assisted Psychotherapy work?

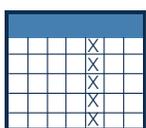
MDMA can make it easier for people with chronic, treatment-resistant PTSD to confront their traumatic memories. In a study of the efficacy of MDMA-assisted psychotherapy for treating PTSD:



subjects were given either **MDMA** or **placebo**



during **2 8-hour sessions**, **3-5 weeks** apart



along with **weekly** non-drug psychotherapy sessions

83% of participants were no longer diagnosed with PTSD at the 2-month follow-up. Even more importantly, a long-term follow-up conducted a mean of 3.8 years later showed that the **benefits were (on average) maintained over time.**



All subjects reported at least some persisting benefit from the study



Study found no negative effects on cognitive function associated with MDMA use



Many participants said the treatment gave them a new start on life

The results show long-lasting, clinically meaningful benefits and absence of harm from just a few MDMA-Assisted Psychotherapy sessions for PTSD. Additional clinical trials are being planned or conducted around the world.

For more information and to help make this treatment available for people suffering from PTSD, visit MDMAPSTD.ORG

Psilocybin as Medicine: An Update from The Heffter Research Institute

DAVID E. NICHOLS, PH.D.

THE HEFFTER RESEARCH INSTITUTE CONTINUES to make huge strides in our attempts to gather sufficient clinical data to support our goal of having the medical utility of psilocybin recognized so that it can be rescheduled and developed as a therapeutic agent.

As MAPS readers will recall, we have two ongoing clinical programs using psilocybin to alleviate the anxiety and depression that accompany a cancer diagnosis. One study is at New York University, under the direction of Dr. Steven Ross, where the cancer patients must have a terminal diagnosis. This study is an extension of the Heffter study that was undertaken and published by Dr. Charles Grob at UCLA. The NYU study is progressing very well now that patient recruitment issues have been solved. The other study is taking place at Johns Hopkins University under the direction of Dr. Roland Griffiths and is also moving along well. The Johns Hopkins study does not require patients to be terminal, but only to have anxiety and depression related to their cancer diagnosis.

We continue to support Dr. Franz Vollenweider's work at the Heffter Research Center, Zurich. Dr. Vollenweider is using state-of-the-art brain imaging and EEG techniques to understand how changes in brain chemistry are related to emotions and mental functions. Dr. Vollenweider has been the most productive scientist in the world carrying out basic clinical neuroscience involving the use of psychedelics, and has received numerous awards for his work. We are quite proud to include Dr. Vollenweider as a Heffter Board member. Readers can visit the National Library of Medicine (PubMed) and search for "Vollenweider, F.X." to see the range of his accomplishments.

We are also supporting studies at Johns Hopkins University to examine the value of psilocybin in a smoking cessation program. A small pilot study has already demonstrated remarkable efficacy in helping long-time smokers quit smoking when all other approaches have failed.

Currently, a small pilot study of psilocybin in treating alcoholism is being carried out at the University of New Mexico, Albuquerque, under the direction of



David E. Nichols, Ph.D.



Dr. Michael Bogenschutz. This study was planned before the recent meta-analysis was published showing that LSD had a significant effect in helping alcoholics return to sobriety. We are therefore optimistic that psilocybin will have an effect similar to LSD, which would allow us to move to a much larger study. If psilocybin can be shown to be effective in treating alcoholism, it would be a significant and major public health advance. Of course, as each study produces positive results, it allows us to show further that psychedelics have medical value, a finding necessary to moving psilocybin into a lower DEA schedule so that it can ultimately be used by physicians.

Finally, we note our support of preclinical studies in the laboratory of Dr. Charles Nichols, at the LSU Medical Center in New Orleans, where he is evaluating the potential of psychedelics to treat asthma. He had previously discovered that the hallucinogen known as DOI had remarkable potency in preventing the biochemical cascade of events that occurs during inflammatory processes. Many of the anecdotal reports of persons gaining relief from a variety of inflammatory and allergic conditions after taking a psychedelic might actually have a scientific basis.

There are a number of additional studies now in the plan-

ning stages. We encourage readers to visit our web site (heffter.org) and look at the list of research publications supported by the Institute over the past two decades. News items relevant to Institute activities are also posted there.

If psilocybin can be shown to be effective in treating alcoholism, it would be a significant and major public health advance.

As an additional note, Heffter Board member Robert Barnhart (who also serves on the MAPS Board) is the executive producer of a new educational documentary about psychedelics titled *The*

Medicine: Science & Psychedelics. A number of Heffter scientists are interviewed in the documentary. This is a not-for-profit project, and the producers are seeking additional funding to complete the project. Visit themedicinescienceandpsychedelics.com to learn more. 🌐

David E. Nichols, Ph.D. is President of the Heffter Research Institute. He can be reached at drdave@purdue.edu.

Founded in 1993, **The Heffter Research Institute** promotes research of the highest scientific quality with the classical hallucinogens and related compounds (sometimes called psychedelics) in order to contribute to a greater understanding of the mind leading to the improvement of the human condition, and to alleviate suffering. Learn more at heffter.org.

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

**Can MDMA-assisted
psychotherapy help?**

mdmaptsd.org



Rick Doblin, Ph.D., Founder and Executive Director, earned his Ph.D. 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, M.D., 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, B.S.N., 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, 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.



Valerie Mojeiko, Director of Operations, earned her B.A. from the California Institute of Integral Studies. In her work with MAPS' psychedelic harm reduction project, she has trained over 200 volunteers with skills for helping people who are undergoing psychedelic emergencies.



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, Development 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, Ph.D., 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, 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.

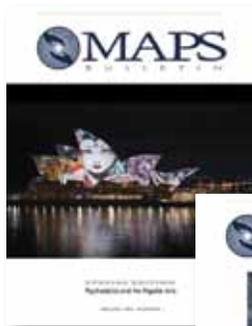
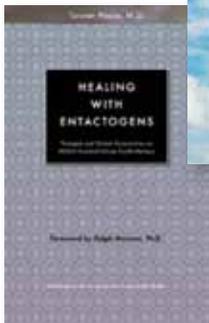
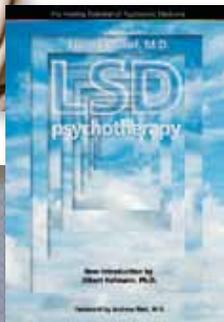


Linnae Ponté, Executive and Clinical Research Assistant, earned her BA in Biological Psychology from New College of Florida. She's assisted data collection and analysis at University of South Florida's Cardiovascular Psychophysiology Laboratory, MOTE Marine Mammal Aquarium Psychophysiological Laboratory,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



Berra Yazar-Klosinski, Ph.D., 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.

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- Honor Thy Daughter* by Marilyn Howell, Ed.D., 208 pgs, \$16.95
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- The Pot Book (Special MAPS Edition)* edited by Julie Holland, M.D., 576 pgs, \$19.95
- The Secret Chief Revealed: Conversations with a Pioneer of the Underground Psychedelic Therapy Movement* by Myron J. Stolaroff, 176 pgs, \$12.95
- The Ultimate Journey: Consciousness and the Mystery of Death* by Stanislav Grof, M.D., Ph.D., 356 pgs, \$19.95

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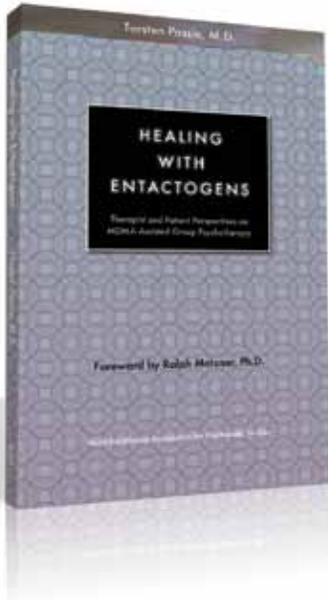
Give \$250 or more and we'll send a MAPS-published book to a friend of your choice

Give \$500 or more and we'll give a one-year subscription to the *MAPS Bulletin* to a friend of your choice

Give \$1,000 or more and receive a personal phone call from MAPS Founder Rick Doblin, along with the above benefits

Healing with Entactogens: Therapist and Patient Perspectives on MDMA-Assisted Group Psychotherapy

by Torsten Passie, M.D.



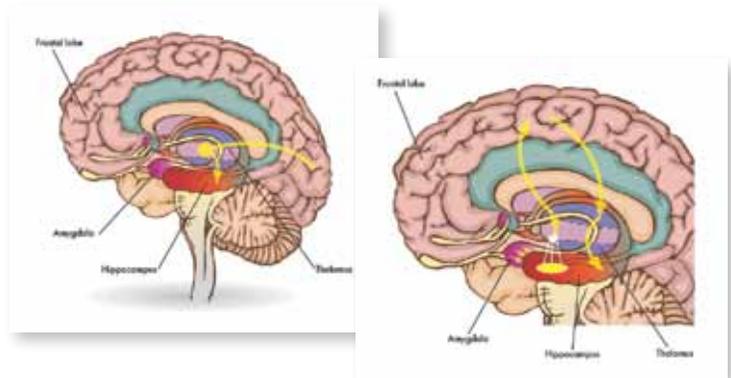
This booklet explores MDMA and other entactogens as pharmacological adjuncts to group psychotherapy. It presents intimate insights into entactogenic experiences from first-hand accounts of clients who participated in group therapy sessions, and crucial background on the neurobiological and psychospiritual components of those experiences.

The word “entactogen” refers to a class of psychoactive compounds like MDMA that “produce a touching within.”

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“Torsten Passie’s research not only deals with the amplified psychotherapy possible with MDMA, but also with the neurophysiological and neurochemical correlates of the experience. His book deserves a place as an essential milestone in the integration of MDMA-type drugs into psychotherapeutic practice.”

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Full-color diagrams explain how MDMA and similar compounds can improve the effectiveness of psychotherapy



About the Author

Torsten Passie, M.D., M.A., is Professor of Psychiatry and Psychotherapy at Hannover Medical School (Germany) where he serves as the Director of the Laboratory for Neurocognition and Consciousness. He is currently Visiting Professor at Harvard Medical School. Dr. Passie has conducted extensive research on the psychophysiology of altered states of consciousness, and is a leading European expert on the pharmacology and therapeutic use of psychedelic drugs.

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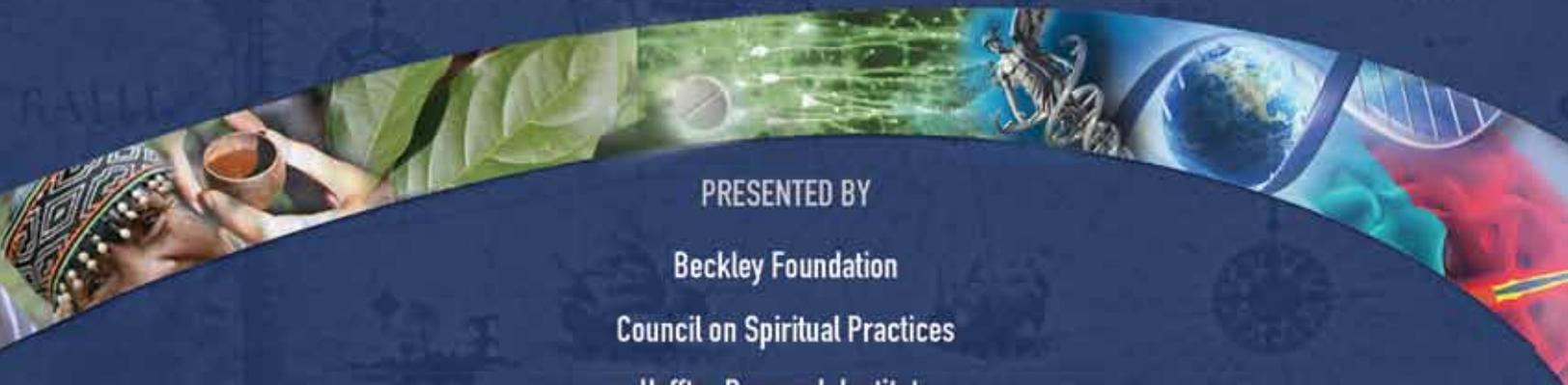
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