MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Volume XXX
Number 1

Special Edition
BULLETIN

Psychedelics: Commercialization and Access

Spring 2020

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Research • Education • Advocacy • Access

In addition to our worldwide research programs, our top-priority programs include:

- **Empowering communities** through our international psychedelic peer support and harm reduction program, the Zendo Project
- **Training practitioners** to deliver MDMA-assisted psychotherapy through professional education in ethics, safety, and therapeutic methods
- **Supporting psychedelic science and education** through policy change and advocacy

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"I've been an artist my entire life. For me, art is a way of understanding my world - internal and external. My process - from the conception of the idea through the execution to the completion of a piece - is an exploration of this thing that is 'being human' and I hope that process can inspire others in their own worlds."

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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

MAPS furthers its mission by:

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

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ISSN 1080-8981

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MAPS Bulletin interior pages are printed on reter.

Correction: The editors sincerely apologize for mistakenly crediting MAPS Policy and Advocacy Director Natalie Ginsberg as author of an article in the Winter 2019 edition of the MAPS *Bulletin*, entitled "Policy and Advocacy News." Ginsberg did not write the article, and it contained incomplete and out-of-date information. Thus, it has been withdrawn in its entirety from the online edition. We take attribution errors seriously and are taking steps to improve our editorial process.

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Introductory Note from Associate Editor Bia Labate, Ph.D.

I am very excited to present here the Spring 2020 Special Edition of the Multidisciplinary Association for Psychedelic Studies (MAPS) *Bulletin*, focusing on the now-timely topic of "Psychedelics: Commercialization and Access." I am especially grateful, as I have just been promoted to Associate Editor of the *Bulletin*, working side-by-side with Chief Editor Brad Burge, who has been diligently dedicated to promoting MAPS' voice, identity, and media for the last decade. My new responsibilities as Public Education and Culture Specialist are part of the changes MAPS is experiencing, along with the arrival of Ana LaDou, our new Chief Operating Officer, who is moving and shaking things around at MAPS, leaving the fresh perfume of new female leadership in the air. I like to think that my own work at MAPS reflects MAPS's recognition that culture, education, and policy are not just the "cherries on top of the cake," but, rather, are central to our mission. At the same time, all can benefit from more critical and reflective perspectives as psychedelics go mainstream.

We are currently facing an explosion of interest in psychedelics and the spread of drug reform policies all across the US. From Michael Pollan's bestselling book *How to Change Your Mind*; to reports from Hollywood celebrities like Gwyneth Paltrow; positive right-wing media reporting; new psychedelic retreats and business popping up at lightspeed; waves of new would-be experts, entrepreneurs, and venture capitalists circling around to find the best bet to invest in; millennials creating a new psychedelic technological culture; patent lawyers lining up, and so much more; everything seems accelerated and we in the movement are left both confused and intrigued. What is happening in the emergent psychedelics industry and ecosystem? Are we all being dragged into a new era of psychedelic market competition and economic individualism? Are psychedelics the locus of a new "gold rush"?

Similar queries follow in the field of regulation: Does decriminalization negatively affect progress with clinical trials? Is decriminalization preferable to legalization, or vice-versa? Should we favor decriminalizing just psilocybin, all plant medicines, or all drugs? Are the psychedelics going through U.S. Food and Drug Administration (FDA) clinical trials for specific ailments more desirable then psychedelics being used outside research for therapies and self-exploration? Do we need licensed practitioners, or do we trust communities' abilities to self-regulate? Or are these all false dichotomies? How are we including Native Americans and disfranchised communities in these conversations?

These topics and others related to changing regulations around psychedelics have been generating passionate disputes in our community. For some, psychedelics are sacred; they believe we need to honor ceremony and the traditional populations that brought them to our attention, and that our health care system is broken, and that FDA trials inevitably limit healing potentials and unnecessarily restrict access. Others believe FDA-approved clinical trials offer the safest, most effective, and most legitimate way to mainstreaming psychedelic medicines. And there are others who feel that, because we live in a global society, only Big Pharma has the power to scale up healing for the millions who suffer, and claim it is naïve to think that corporations will stay out of the game. Still others think that the solution lies in hybrid models that mitigate the danger of a capitalist takeover of psychedelic potentials. They suggest that stakeholder inclusivity, distributed local ownership, and cooperative structure represents the ideal way forward, and advocate that we foster and steward companies that prioritize accountability, ethics, and accessibility. These discussions have become increasingly ironic and complex because regulatory structures are not yet in place. Despite all the progress, we still have work to do. Recently, I personally experienced rejection from three different banks when I tried to open an account for a non-profit that had the word "psychedelic" in the name.

This special edition of the MAPS *Bulletin* is an attempt to give a bit of a narrative and framework to the times we are living in. Whereas we don't provide specific answers and solutions, and the articles reflect the authors' views and not our own, we feel it's important to promote a collective conversation around these issues. We are an interdependent species and, as a movement, we need to build collective trust to move forward. Having these hard conversations is the first step.

We would like to use this opportunity to affirm that both MAPS and MAPS PBC have signed the Statement Towards an Ethos of Equity and Inclusion in the Psychedelic Movement (chacruna.net/towards-an-ethos-of-equity-and-inclusion-in-the-psychedelic-movement), and that we will no longer join events or conferences that exclusively feature white males. As a queer Latin woman and first-generation immigrant to the United States, it feels good to affirm that we embrace women and diverse minorities as psychedelics enter this new decade full of hope and promises of healing.

Bia Labate, Ph.D

Public Education
& Culture Specialist, MAPS

From the Desk of Rick Doblin, Ph.D.

At a time of increased social stress, anxiety, depression, and trauma, amidst a global public health and financial crisis, it's all the more important that we think proactively about how to address the potential commercialization of psychedelic-assisted psychotherapy. The need for access to psychedelic-assisted psychotherapy, both self-paid and through insurance coverage, will likely increase, as will the number of people actively seeking out these therapies after they have been approved for prescription use by the U.S. Food and Drug Administration (FDA) and other regulatory agencies around the world.

The commercialization of psychedelic psychotherapy and associated services are made even more complex due to rising interest from new for-profit companies, seeking to use investor funds to maximize profit. These for-profit companies have now joined the handful of non-profits seeking to maximize public benefit rather than profit, like the Multidisciplinary Association for Psychedelic Studies (MAPS) and its wholly-owned for-profit MAPS Public Benefit Corporation (MPBC), the Usona Institute, Heffter Research Institute, and the Beckley Foundation, that have in the past been virtually the only funders of psychedelic research. Alongside legal patient access, there will also be issues to address related to city and state decriminalization initiatives and legislative actions for psilocybin and other plant-based psychedelics. These may be similar to policies already in place in the Netherlands and Jamaica that have allowed businesses to sell psychoactive mushrooms and truffles and to provide supportive contexts for psychedelic experiences.

The articles in this special edition of the MAPS *Bulletin*, with the forward-looking theme of "Psychedelics: Commercialization and Access," are wide-ranging and thought-provoking, with discussions about commercialization issues relevant to MDMA, psilocybin, ketamine, ayahuasca, cannabis, ibogaine, and peyote, along with discussions about strategies to provide legal and/or non-criminalized access to psychedelics, ranging from FDA approval to decriminalization initiatives and legislative campaigns, to broad-based drug policy reform efforts. These articles discuss a variety of options for how to provide access, and how to create financial and regulatory safeguards in light of the profit incentives motivating many of those seeking to sell psychedelics and psychedelic-related services. All these articles and approaches have in common the understanding that simply providing legal access to psychedelics is insufficient to ensure the maximization of positive outcomes and the minimization of harmful outcomes. These safeguards will play a key role in whether this new move to commercialization and access will result in further mainstreaming, or in a backlash similar to what happened a half a century ago which criminalized psychedelics and shut down psychedelic research around the world.

MAPS' primary strategy is FDA drug development. The corporate structure we have chosen is the creation of the for-profit MAPS Public Benefit Corporation (MAPS PBC) which is wholly owned by the non-profit, MAPS. Our goal is to obtain insurance coverage for prescription use of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD), in the US, Europe and around the world, then for other clinical indications of MDMA, and then to obtain prescription use and insurance coverage for other psychedelics and cannabis. At the same time, MAPS supports policy change efforts to provide legal access to adults in licensed legalization regulatory frameworks for personal use outside of medical or religious contexts, with appropriate quality control, honest education, and widespread harm reduction services such as our Zendo Project. MAPS has explicitly chosen an anti-patent strategy, and firmly believes that these substances' therapeutic potentials should be used for the benefit of humanity. MAPS does not oppose for-profit psychedelic drug development and services, though we feel that non-profit and public benefit companies can help keep for-profits from focusing solely on profit-maximization in the short-term. Our work has in part paved the way for the emergence of new for-profit efforts, and we call on our new collaborators in the field to move forward with ethics and accessibility at the forefront of their minds.

I'm writing now semi-quarantined from my home, practicing social distancing with my wife, two adult daughters, and our dog. One positive side effect of the coronavirus is that people all over the globe are seeing how interconnected we all are. Not only that, but people are vividly seeing how interconnected humans are with the web of animal, plant, fungal, bacterial, and viral life on our precious planet.

A core element of the mystical experience, whether catalyzed by psychedelics, prayer, meditation, walking in nature, sex, art, or gratuitous grace, or anything else, is the realization of our fundamental interconnectedness. Over time, as the coronavirus subsides, our work at MAPS, and the work of the authors in this special "Commercialization and Access" issue of the MAPS *Bulletin*, and others working with psychedelics in any capacity, will hopefully provide ever larger numbers of people with healing from clinical conditions, inspiration, and a sense of place, purpose, and meaning.

To Phase 3 and beyond,

Rick Doblin

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

Research News

Treating PTSD with MDMA-Assisted Psychotherapy

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

On December 20, 2019, the U.S. Food and Drug Administration (FDA) agreed to MAPS' application for an Expanded Access program for MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD).

The purpose of the Expanded Access program is to allow early access to potentially beneficial investigational therapies for people facing a serious or life-threatening condition for whom currently available treatments have not worked, and who are unable to participate in Phase 3 clinical trials.

"We commend FDA for recognizing the great unmet medical need of PTSD by allowing access to MDMA-assisted psychotherapy on a compassionate basis for people with treatment-resistant PTSD," said MAPS Founder and Executive Director Rick Doblin, Ph.D. "We are delighted to begin generating real-world evidence about this potential new treatment."

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

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

Up to 10 qualifying treatment sites will be selected to begin the Expanded Access program, to be announced in the next few months. Over 120 site applications have been received to date. Once the program begins, patients can apply to the individual Expanded Access sites.

"The resurgence of research into using drugs such as MDMA to catalyze psychotherapy is the most promising and exciting development I've seen in my psychiatric career," said Michael Mithoefer, M.D., Acting Medical Director for MAPS Public Benefit Corporation. "Combining the powerful effects of pharmacology with the potential depth of psychotherapy is a compelling model for harnessing advances in neuroscience and psychopharmacology without ignoring the complexity, richness and innate capacity of the human psyche. I'm delighted that the Expanded Access Program will now allow some patients to access to this modality as MAPS' Phase 3 research continues."

MAPS' Expanded Access protocol must still be approved by the U.S. Drug Enforcement Administration (DEA) and the Institutional Review Board (IRB). Based on the FDA's review as well as the DEA and IRB's existing support of MDMA-assisted psychotherapy clinical trials, MAPS does not anticipate delays in those approvals.

This is the second time that a government agency has allowed such a program for MDMA-assisted psychotherapy. On February 3, 2019, the Israeli Ministry of Health announced the approval of Compassionate Use for MDMA-assisted psychotherapy for PTSD, which will also allow 50 patients to receive the treatment. Patients with PTSD will be eligible to receive treatment at four sites throughout Israel.

MAPS is currently sponsoring ongoing Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD at 15 sites in the U.S., Canada, and Israel. In August 2017, the FDA granted Breakthrough Therapy Designation to MDMA-assisted psychotherapy for PTSD. The Phase 3 trials are expected to be completed in 2021, meaning that the FDA could approve the treatment as early as 2022. MAPS is also initiating Phase 2 trials in Europe, starting this month.

Phase 3 Trials of MDMA-Assisted Psychotherapy for PTSD

Our FDA-regulated Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) are taking place at 15 locations across the United States, Canada, and Israel.

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

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

The Phase 3 trials are being conducted at the following study sites:

- Los Angeles, CA | private practice
- San Francisco, CA | research institution
- San Francisco, CA | private practice
- Boulder, CO | private practice
- Fort Collins, CO | private practice
- New Orleans, LA | private practice
- New York, NY | research institution

- New York, NY | private practice
- Charleston, SC | private practice
- Madison, WI | research institution
- Boston, MA | private practice
- Montreal, Canada | private practice
- Vancouver, Canada | research institution
- Be'er Ya'akov, Israel | research institution
- Tel HaShomer, Israel | research institution

As of September 17, 2019, all 15 Phase 3 sites have officially enrolled a subject.

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

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

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

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

Israel Approves Compassionate Use of MDMA-Assisted Psychotherapy for PTSD

On February 3, 2019, the Israeli Ministry of Health announced the approval of Compassionate Use for MDMA-assisted psychotherapy for PTSD, which will allow 50 patients to receive the therapy within a treatment protocol. Patients with PTSD will be eligible to receive treatment at four sites throughout Israel, including Rambam Medical Center in Haifa and psychiatric hospitals in Be'er Yaakov, Lev Hasharon, and Be'er Sheva.

"The ministry is taking this seriously and with appropriate caution, an in-depth investigation has been carried out. There is a considerable population in Israel of people suffering from PTSD that is resistant to other treatment," said Bella Ben-Gershon of Israel's Ministry of Health to Haaretz Newspaper.

Phase 2 Open-Label Lead-In Study of MDMA-Assisted Psychotherapy for PTSD: Data Under Review

On December 10, 2019, MAPS Public Benefit Corporation (MAPS PBC) completed an interim lock of the existing database for our Phase 2 open-label lead-in study of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) at sites across the United States and Canada. A total of 42 people were enrolled in the study, with 37 treated, and a total of 36 participants completed the study. With this preliminary set of data from 36 subjects, the research team will analyze the data for submission to FDA and will write a paper for submission to a peer-reviewed scientific journal. The purpose of this study is to provide the final training and supervision for our co-therapy teams as they work with one study participant with PTSD. The same treatment approach will be used in Phase 3. We have developed a long-term follow-up protocol for this multi-site open-label Phase 2 study, which will assess symptoms of PTSD in participants 12 months after completing treatment.

Therapist Training Study: 89th Participant Enrolled, New Trial Location Approved in Santa Fe, New Mexico

Locations: Charleston, South Carolina, and Boulder, Colorado, and Santa Fe, New Mexico

Principal Investigators: Zhenya Gelfand, M.D. (Charleston), and Marcela Ot'alora G., M.A., L.P.C. (Boulder), George Greer, M.D. (Santa Fe)

As of January 17, 2020, 89 participants have enrolled in our Phase 1 study of the psychological effects of MDMA when used in a therapeutic setting by healthy volunteers. Enrollment in this multi-site study is limited by invitation only to therapists in training to work on MAPS-sponsored clinical trials of MDMA-assisted psychotherapy for PTSD.

We have launched a third study location in Santa Fe, New Mexico, for our ongoing therapist training study, which also takes place in Boulder, Colorado, and Charleston, South Carolina. The new study site in Santa Fe has received Drug Enforcement Administration (DEA) and Institutional Review Board (IRB) approval and will be led by Principal Investigator George Greer, M.D. The study site in Boulder is led by Principal Investigator Marcela Ot'alora, M.A., L.P.C., and the study site in Charleston is led by Principal Investigator Zhenya Gelfand, M.D.

Startle Testing with MDMA: 29th Participant Completes Experiment

Ongoing Study

Location: Emory University in Atlanta, Georgia

Principal Investigator: Barbara Rothbaum, Ph.D.

On March 4, 2020, the 29th participant completed their participation in our ongoing study of the effect of MDMA on startle testing in healthy volunteers. Led by Principal Investigator Barbara Rothbaum, Ph.D., this study is conducted at Emory

University in Atlanta, Georgia. If you have tried MDMA and live near Atlanta, you may be eligible to enroll in this study investigating the effects of MDMA on the startle response. For more information, please contact callan.m.coghlan@emory.edu.

MDMA Therapy Training Program Update

Training Program

Director of Training and Supervision: Shannon Carlin, A.M.F.T.

Happy Spring from the MDMA Therapy Training Program! The Training and Supervision Department is currently focused on supervision, adherence rating, and video programs to support Phase 3 studies in the United States, Canada, Israel, and European Union. The MDMA Therapy Training Program is currently training approximately fifty therapists preparing to work on the upcoming Expanded Access program for MDMA-assisted psychotherapy for PTSD. In addition to Expanded Access, MDMA Therapy Training Program is focusing efforts towards competency framework and curriculum development to support the growing body of MDMA therapy professionals. The MDMA Therapy Training Program is not currently enrolling; stay tuned to the MDMA Therapy Training Newsletter for more updates. Sign up at mapspublicbenefit.com/therapy-training!

While MAPS PBC is not currently recruiting new sites and the MDMA Therapy Training Program is not actively enrolling new trainees, qualified and interested sites and therapists may still submit an application to be considered at a later date. Information about application requirements and instructions to apply and can be found at mapspublicbenefit.com/training/program-application-requirements.

The MAPS PBC Therapy Provider Connect Portal (connect.mdmatherapytraining.com) is a community discussion forum for therapy providers, physicians, and facilities to connect with one another to develop a site or treatment staff, in order to become eligible to participate in a MAPS PBC MDMA/PTSD protocol.

MEDICAL MARIJUANA RESEARCH

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

Study Completed: February 20, 2019

Location: Phoenix, Ariz.

Coordinating Principal Investigator: Marcel Bonn-Miller, Ph.D. (University of Pennsylvania)

Co-Investigator/Site Principal Investigator: Sue Sisley, M.D. (private practice)

Co-Investigator: Paula Riggs, M.D. (University of Colorado)

On February 8, 2019, MAPS-sponsored researchers officially completed the first-ever clinical trial of smoked marijuana (cannabis) as a treatment for PTSD symptoms, with all 76 veterans enrolled and treated. The data from the study are now being analyzed and prepared for publication in a peer-reviewed biomedical journal.

"We are thrilled to finally be at the finish line of this nearly 10-year saga trying to get this crucial clinical trial completed," said Site Principal Investigator Sue Sisley, M.D. "We are immensely grateful to all of the study's supporters, especially the veteran service organizations who helped us with patient recruitment."

Disclaimer: This study was supported by funding from the Colorado Department of Public Health and Environment (CDPHE). The content and opinions are those of the grantee/authors and do not represent the official views of CDPHE.

AYAHUASCA RESEARCH

Data Collection Survey Continues

Ongoing study

Principal Investigator: Jessica Nielson, Ph.D.

We are currently collecting responses for the revised version of our anonymous questionnaire about the potential risks and benefits associated with using ayahuasca in treatment for PTSD. The data collection is sponsored by MAPS, with Jessica Nielson, Ph.D., as Principal Investigator. We welcome participation from anyone that has tried ayahuasca in any context or setting, including those who took the first version of the survey. To participate in the survey, visit surveymonkey.com/r/AyaPTSD.

IBOGAINE TREATMENT FOR DRUG ADDICTION

Observational Research Published in American Journal of Drug and Alcohol Abuse

Study Completed

Locations: Mexico and New Zealand

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

On May 25 and April 12, 2017, the promising results of MAPS-sponsored observational studies of treating opioid dependence with ibogaine-assisted therapy were published in the peer-reviewed American Journal of Drug and Alcohol Abuse. Download both articles for free at maps.org/ibogaine.

Participate in Research

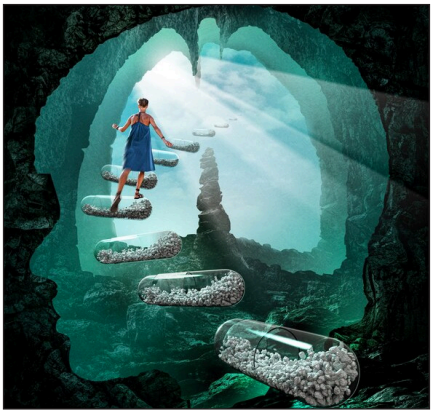
MAPS sponsors clinical trials around the world that require human participants. Our studies have strict enrollment criteria based on the goal of the study and the condition the study is investigating.

Phase 3 trial participant enrollment is open at multiple sites. Please bookmark our Participate in Research page and check it frequently for updates.

maps.org/participate/participate-in-research

MAPS in the Media

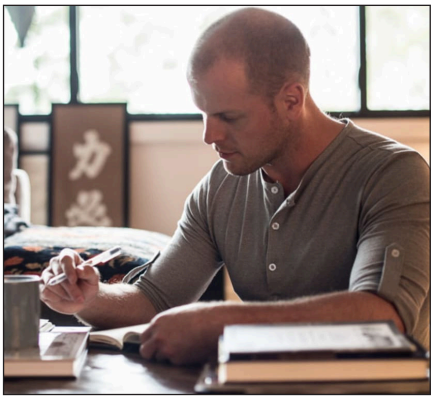
The Washington Post



Anxious and Depressed as a Scary Disease Destroyed Her Lungs, She Turned to MDMA for Relief. by Sarah Hogate Bacon • November 18, 2019

The Washington Post explores the benefits and risks of MDMA-assisted psychotherapy through the lens of the author, Sarah Hogate Bacon, who undertook various alternative treatment methods for anxiety and depression symptoms associated with her life-threatening illness, including MDMA-assisted psychotherapy. The article highlights published data from completed clinical trials of MDMA-assisted psychotherapy for PTSD, an update on ongoing FDA-regulated Phase 3 clinical trials, and a brief interview with study participant Ed Thompson. "Like any therapy, MDMA-guided psychotherapy is a process, not a quick fix," explains Sarah Hogate Bacon of The Washington Post.

FORTUNE



Business Gets Ready to Trip: How Psychedelic Drugs May Revolutionize Mental Health Care by Jeffrey M. O'Brien • February 17, 2020

"Across science, culture, politics, and business, a diverse community of supporters is forming to push psychedelics out of the shadows and into the mainstream," explains Fortune in an in-depth report on the expanding psychedelic renaissance. The article encompasses a spectrum of topics ranging from the growing support from influential donors such as author Tim Ferriss to the role MAPS has played in shifting public opinion about psychedelics through clinical research. "MAPS has played a key role in lowering cultural resistance to psychedelics over the past three decades, and it continues to bang the drum."

The New York Times

Taking Ayahuasca When You're a Senior Citizen by Casey Schwartz • Oct. 17, 2019

Scientific data on older people using ayahuasca is elusive but anecdotal evidence is growing," explains The New York Times in a piece that features insights from senior citizens who participate in ayahuasca ceremonies. The article highlights prominent voices in the psychedelic community contributing to the conversation about age and psychedelics, including MAPS Founder Rick Doblin, Ph.D., who notes that older age groups can become more sensitive to psychoactive substances.

Forbes

Enthusiastic Donors Pony Up In Support Of Psychedelic Research, Harm Reduction Efforts by David Carpenter • Nov. 18, 2019

Forbes reports on growing donor support for psychedelic research and harm reduction efforts, including the Zendo Project's psychedelic peer support services. The article attributes compelling results from clinical research conducted by MAPS and other esteemed organizations to the growing shift in public acceptance towards psychedelics, which may coincide with the expanding donor support for psychedelic research, harm reduction, and education.

KQED

Psychedelic Therapy Available to More People During Clinical Trials by Lauren Klivans on February 10, 2020

KQED speaks with MAPS Founder Rick Doblin, Ph.D., and Army SGT (R) Jon Lubecky about the Food and Drug Administration's recent decision to grant Expanded Access to MDMA-assisted psychotherapy for PTSD. "The FDA is recognizing that there's a humanitarian crisis with many, many millions of people that have treatment-resistant PTSD," explains Doblin.

CNN

Can the Mind-Blowing Effects of Psychedelics Help Heal Our Traumas? by Sandee LaMotte on January 27, 2020

"Today there is a true renaissance of research on the role of psychedelics on mental health," explains CNN as it explores the history and expansion of psychedelic research, highlighting MAPS-sponsored trials for both MDMA-assisted and LSD-assisted psychotherapy. The article also explores the growing shift in acceptance of psychedelic medicine in mainstream culture.

The Commercial Chemistry of MDMA: From Research to Patient Access

HEATHER CLOUTING

Nearly 20 years ago, during our final year of university while studying for our Bachelor's in chemistry, I thought that two fellow students and I were rebels for suggesting that our organic chemistry assignment be on the history, culture, and synthesis of 3,4-Methylenedioxymethamphetamine (MDMA). It was one of the most politicized recreational drugs in the UK at the time, with a broad stigma based on highly publicized events.

Through that project I learned all about MDMA's therapeutic use prior to criminalization; not too long afterward in 2009, the famous quote from psychopharmacologist David Nutt made front-page news in the UK. Dr. Nutt compared the risks of taking ecstasy to those of horse riding, and followed in 2010 with a detailed and comprehensive comparison of legal and illicit drugs in *The Lancet* ("Drug harms in the UK: a multicriteria decision analysis," 2010). It brought into question the science behind the current UK approach to perceived harm and drug scheduling.

However, never did I think that one day I, or anyone else, would be working on the commercial manufacture of MDMA—let alone through a non-profit psychedelic research organization focused on relieving important metal health challenges such as posttraumatic stress disorder (PTSD). But surely as the tutor accepted our idea and we indeed wrote 10,000 words on MDMA, MAPS is currently in the late phase of the first-ever active pharmaceutical ingredient (API) manufacturing campaign which will generate the initial MDMA produced for licensed, prescribed patient access.

MAPS champions transparency and open science, values that align with my own personal principles. Our intention is for our scientific advancements and learnings to be shared widely, not only so they are made publicly available, but also so they can't be privately appropriated. This is quite different from the usual pharmaceutical company approach, and one of the benefits of working within a hybrid, mission-based organization (see the MAPS Policy & Advocacy Department's article in this *Bulletin*) for more information).

An article purely about the current MDMA chemistry data gathered by MAPS and its subsidiary MAPS Public Benefit Corporation (MAPS PBC) could be very long, technical, and for most, dry and uninteresting, so I have therefore chosen to include some of my more personal perspectives on the topic. For those who are eager to know more about the pure chemistry, MAPS will be working to publish more articles on the topic in late 2020.

My father had a Ph.D. in electronics and my mother was a devoted nurse, and I pretty much came out a 50/50 mix of the two. I am strongly analytical with a desire to organize, categorize, and put everything in its rightful and predicable place in a vain attempt to control this very unpredictable world. At the same time, I am emotionally and empathetically driven, feeling that no matter how much we try to draw these lines, we live in a world that transcends any model or equation.

During my A-levels (the UK's version of high school), I made the choice to drop art class and take up chemistry. I had come to really enjoy chemistry during my school years, and eventually it seemed like a better option for me to study than art, which felt too abstract—chemistry is exact and predictable, right? What I learned throughout those years and my subsequent chemistry degree, however, was something different: Science is not exact, and our understanding is constantly evolving. It started to seem like a relentless attempt to place evermore complex sets of round pegs in square holes.

Having said that, it is not as though the results of these human scientific endeavors aren't astounding and necessary, as they include feats of engineering and medicine. The point is that even those feats are imperfect; they are not always fully understood and can carry risks. Just like the building that won awards for structural and architectural brilliance can have unknown faults and fail years later, the drug that is shown to be highly effective in its target indication can bring unknown side effects that surface after licensure.

This background helps me understand why the chemistry of MDMA, a well-known molecule first developed in 1912 and patented by Merck in 1914, is not exact, not yet fully known,

and still requires detailed, stringent analyses and controls.

There are many methods available to synthesize MDMA, some including naturally derived starting materials such as safrole (found in sassafras plants, among others) as was used in the original Merck patent. However, unlike much of the MDMA that has been synthesized in the last decades (up until relatively recently), the synthetic pathway used for the MAPS synthesis of MDMA does not include safrole or related starting materials. Our key starting material is 5-bromo-1,3-benzodioxole, and its precursor, 1,2-methylenedioxybenzene, is likely synthesized in one step from catecho, a bulk commodity chemical made in thousands of tons per year from crude oil. Due to the relatively small quantities currently being made (less than 30 kg per year), the relevant regulatory authority in the country of manufacture has deemed that no environmental impact assessment is needed because this quantity of drug production is considered low-risk and small-scale.

In the context of drug manufacture, the word "commercial" is an important distinction, as it indicates a different standard of production. As we move through the study phases, the requirements for manufacture, analytical testing, and release change and become more stringent for both investigational (unlicensed, clinical-only) active pharmaceutical ingredient (API) and for drug product (the finished dosage form, e.g., capsule or tablet). Good manufacturing practices (GMPs) apply to all, but the level of detail and documentation required increases with exposure and risk. In other words, the regulatory requirements for an investigational drug used in small early-phase trials, manufactured on a small scale without the need for multiple-batch reproducibility, is different than for investigational drugs used for larger, late-phase trials or commercial products (wherein batch sizes can be many orders of magnitude larger and are part of multiple-batch, routine manufacture).

In the last three years, MAPS has been moving through these stages of chemistry development as we transitioned from our early Phase 2 trials to our current Phase 3 trials, and now as we work towards patient access following the first planned approval of MDMA for PTSD in the US.

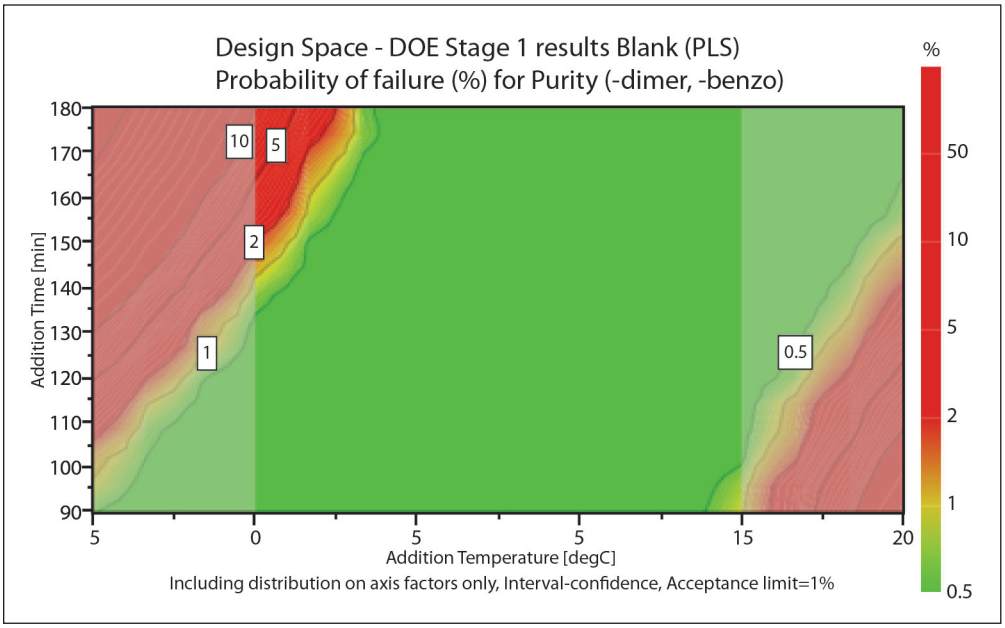
This year, a contract manufacturing organization (CMO) overseen by MAPS PBC is on track to manufacture 16-20 kilograms of commercial MDMA to provide Chemistry, Manufacturing, and Controls (CMC) documentation and data for the eventual MDMA-PTSD New Drug Application (NDA), and to provide the actual active ingredient that will be used for the initial supply chain.

At the same time, development work for the manufacture of the first-ever commercial MDMA "drug product" batches will begin. As with the "active ingredient" above, this campaign will provide CMC data for the NDA and be used for the first fully packaged and labelled drug (i.e., the finished capsules) which will be provided to patients outside of clinical trials after approval. These campaigns will produce the most comprehensive, thorough, and detailed data to date for MDMA API and drug product (as required for a commercial drug).

The path for a molecule, therefore, from early-phase API and drug product to a commercial product, is an iterative one. It involves increased levels of understanding around the synthesis, potential impurities, isomers, crystalline forms, and physical properties—all of which need to be controlled and understood to the fullest, as they can have an effect the safety and pharmacology of the drug.

The chemistry of MDMA is not a given, and requires expert development to get to the commercial standard we need to ensure patient access and safety at scale. However, it should not be expected that we will stop learning about the chemistry of this compound; changes in manufacturing process, scale, and product formulation can bring with them new challenges and lessons.

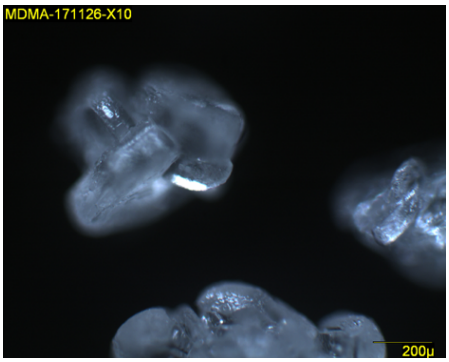
Since the first late-phase GMP API campaign carried out by the MAPS CMO, there has been much development work



Example of Experimental Design Space – Stage 1 MDMA Synthesis

around the four-stage chemical synthesis which forms the basis of the manufacturing process. The chemical purity of the API used by MAPS in any clinical trial has always been extremely high, >99.9%, and that standard has been maintained through scale-up. The focus of the development work on the planned commercial synthetic route has been to support batch reproducibility at a higher scale, validation through intermediate parameters, and ease of stage reaction processing and optimized yield—put more simply, making the reaction easier and cleaner with a higher output of material for the same inputs.

This activity has been carried out through multiple ascending-scale reaction experiments for each of the stages, culminating in 15 experiments for each of the intermediate reactions, to define what is called a "design space" that gives the parameters offering the desired purity and yield.



MDMA Crystals via Microscopy

However, even with this appropriately thorough approach from small-scale to large-scale development, the design space that was defined for Stage 2 of the reaction was shown to not completely predict the outcome. The model that was produced was just a model, and one that produced an unexpected result. More experiments were then completed to understand the issues that related broadly to the larger-scale equipment and the different agitation levels required to get the purity needed for intermediate stages of the synthesis.

Another significant lesson from the last 12 months of API development work was the discovery of two new polymorphic forms of MDMA, never seen previously in the literature. A polymorph refers to a well-defined crystalline structure, where the molecules are attached to each other in a repeatable pattern. A good example of this is C6 (carbon). Carbon will bond to itself six times to form the commonly known "benzene ring" molecule. However, the way these C6 molecules bond to each other can take different crystalline or polymorphic forms, such as diamond vs graphite. Both polymorphs are the same molecule—but one, diamond, is the hardest substance known and the other, graphite, one of the softest. This is an extreme example, but clearly shows why it is so important to understand the chemistry of any molecule that is being developed for human use.

Thankfully, in the case of MDMA, the polymorphism is not as extreme as carbon. But previously in the literature, based on the limited investigations, there was thought to be only one polymorph form of MDMA ("The ecstasy and the agony; compression studies of 3,4-methylenedioxymethamphetamine [MDMA]", Acta Crystallographica Section B Structural Science, Crystal Engineering and Materials, 2015).

This MDMA polymorph form is the same that has been used in all MAPS sponsored studies to date, now known as "Form 1," previously characterized through X-ray powder diffraction (XRPD). It is by far the most stable of the forms, and to force the MDMA molecules into the new polymorphs (Form 2 and Form 3) it requires manipulation using different solvents and crystallization techniques. Both Form 2 and Form 3 are metastable to Form 1, meaning that they easily revert to Form 1. However, now that their presence is known, identification of these forms has been added to the release and stability specifications via a method sensitive enough to identify them (even in small quantities relative to Form 1).

Although the commercial development of the MDMA drug product is yet to start, the first drug product batches manufactured via an automated process have provided us clear areas for improved understanding of the physical properties of MDMA and its the current excipients, the substances used to provide flowability and lubrication during the encapsulation process.

From our API development work specifically around crystallization we have found no way to ensure the MDMA crystals are uniform in size. Therefore, no particle size distribution specification has been set to date. As we move into commercial drug product development, where not only the chemical but physical properties need to be controlled and uniform from batch to batch, this will be the next focus. What is our desired particle size? How does this affect the excipient compatibility, flowability, and ultimate content uniformity of our drug product?

As with our ongoing clinical trials to understand the MDMA safety and efficacy profile to its fullest, the chemistry of MDMA is an ongoing development process. We are continuously gathering data on both the API and the drug product, and communicating our findings to the relevant regulatory authorities to align our current understanding of shelf life and release controls. We look forward to continuing to share and publish this data, in line with MAPS' values of transparency and open science

The chemistry of MDMA is a work in progress, and it's an exciting time to be a part of it, especially as the output of these fully validated commercial batches of API and drug product will be those that are available for the first patients to receive MDMA-assisted psychotherapy outside of clinical trials. Commercial MDMA will therefore support broad patient access post-licensure, something that MAPS has been working toward for over 35 years.

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R/evolutionary Medicine, R/evolutionary Industry: The Role of Conscious Policy and Corporate Structures in Psychedelic Healthcare

BY THE MAPS POLICY & ADVOCACY DEPARTMENT

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The non-profit Multidisciplinary Association for Psychedelic Studies (MAPS) has spent over three decades ushering MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) through the U.S. Food and Drug Administration (FDA) approval process to allow safe and effective access to MDMA-assisted psychotherapy for serious mental health concerns, with FDA approval for PTSD expected by 2022.

The non-profit Usona Institute has taken a similar path with psilocybin for major depressive disorder. Other non-profit efforts are emerging to steward education, governance, and ethical practices in the field, and new for-profit companies are simultaneously forming to participate in the psychedelic industry. Compass Pathways and its parent company, Atai Life Sciences, comprise the largest for-profit psychedelic drug development company; Compass is also developing psilocybin for treatment-resistant depression, and Atai recently purchased a portfolio of (non-psychedelic) ibogaine-related patents. Today, venture capital is beginning to hone in on psychedelics, leading to the proliferation of infant funds and start-ups interested in capitalizing on the psychedelic industry. Highlighting this trend, a recent Fortune headline announced that "Psychedelic Drugs Might Transform Mental Health Care: And Big Business Is Ready to Profit from the Revolution."

MAPS has chosen to conduct its drug development through a public benefit corporation, ensuring that our work remains in alignment with service-oriented healing traditions. MAPS Public Benefit Corporation (MAPS PBC) is a wholly-owned subsidiary of MAPS; in other words, MAPS is the the sole investor in MPBC. This hybrid corporate model allows MAPS to prioritize developing MDMA into a medicine as a benefit to the public, instead of being legally bound to prioritize maximizing profit for shareholders. As traditional companies and venture capital begins to enter the space, and as local and state efforts to create psychedelic access begin to gain momentum, it is critical that policymakers create space for and encourage approaches that put access and care, rather than profit, first.

MAPS' non-profit status gives us the mission discipline necessary to devote ourselves to addressing the social harms that are typically ignored and externalized in a free market. Assessing and repairing these social harms requires intentionality and impact, key characteristics of MAPS' hybrid corporate form. Our non-profit, public benefit strategy removes the impetus of a quick profit turnaround to drive our work, instead focusing on the greatest possible public good.

Local movements to decriminalize psychedelic plants and fungi have recently formed, shedding bits of light into the underground and creating legal gray spaces. These approaches may constitute a significant piece of the foundation for a future legal psychedelic industry. The city of Denver, Colorado, made possession of psilocybin

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mushrooms by adults the lowest law enforcement priority by ballot initiative in the summer of 2019. Following that lead and expanding upon it, a citizen group, Decriminalize Nature ("DN"), successfully persuaded the city council of Oakland, California, to pass a resolution that reduced the prosecution of crimes related to personal possession and use of psychedelic plants and fungus to the lowest law enforcement priority. DN is now aiding like-minded activists in pursuit of similar measures in jurisdictions all over the United States, and is undertaking the first city-level effort at developing a framework for the distribution and sale of these substances in Oakland.

Additionally, state level movements are devising ballot initiatives to create alternate forms of regulated markets. In Oregon, a state-level initiative seeking a spot on the 2020 ballot has fashioned an imaginative, regulated psilocybin services industry. The "services" in this case would extend access beyond the medicalized, FDA-regulated approach. Meanwhile, an enthusiastic grassroots contingent is trying to get a different initiative on the 2020 ballot in California to decriminalize and legalize (read: lightly regulate) psilocybin mushrooms.

Commercialization in Context

Drug prohibition has made drug-related activity more dangerous. Prohibition and stigma have disincentivized or prevented people who use drugs from seeking support or accessing accurate education about safe practices. With intention and accountability, moving currently-illicit substances into the sunshine of the "above-ground" can provide an opportunity to remedy some of the lasting harms from the "War on Drugs."

Our community has the opportunity to create a re-imagined psychedelic industry which attempts to repair some of the harms of old-fashioned drug policies, as long as the changes we implement include meaningful involvement from as many diverse stakeholders as is feasible. Imagine if the psychedelic industry could be driven by collective benefit, rather than just profit maximization for individual companies? What combination of infrastructure, policies, and norms would create the optimal set of incentives? What is the playbook for the pro-social mainstream integration of psychedelic substances?

Ultimately, no one form or framework alone will be adequate. Creating new healthcare systems and structures will happen most effectively and safely in a collaborative landscape that intentionally empowers non-profit organizations, cooperatives, public benefit corporations, and other public and private institutions to operate and ethically partner together.

MAPS' statement on Considerations for the Regulation and Decriminalization of Psychedelic Substances (maps.org/policyreform) is anchored in valuing life, dignity for people who use drugs, evidence-based policy, stewardship and integration of cultural knowledge, and collective health and well-being. MAPS implements these values in tandem with its subsidiary MAPS PBC. These early days of the new psychedelic industry are already inspiring imaginative and iterative policy-making, and we hope that MAPS' hybrid organizational structure will help model the embodiment of these stated values while operating within the broader context of existing institutions. We also hope that the intention and implementation of this hybrid corporate form can act as a harm reduction intervention for some of the inherent or previously recognized harms associated with pharmaceutical healthcare delivery.

Reducing Harm

Our statement referenced above discusses "full-spectrum harm reduction," which incorporates all people who use all drugs in all ways, as well as the political, social, and environmental contexts surrounding that use. The guiding principles are the same as traditional harm reduction, but incorporates a wider number of factors associated with drug use to further reduce stigma and indignity.

This approach can also be applied to the harms that inherently come with the scaling and establishment of an industry. Some of the risks of commercializing and "above-grounding" controlled substances can be observed in the story of cannabis reform, where the people most marginalized by society who need the medicine are still unable to receive insurance coverage, and cannot afford state-legal prices or social stigma still attached to cannabis. Healthcare driven solely by profit maximization continues to cause unintended harm. The psychedelic industry can, and must, be intentional to be different.

Other circumstances, like MDMA's current placement in Schedule I of the Controlled Substances Act and the associated stigma, builds additional guardrails into the mainstreaming process MAPS is navigating. While some may see the challenges of non-profit drug development of stigmatized substances as overly onerous, we appreciate the additional level of external oversight and review, recognizing it as valuable and even essential to achieving our desired outcome of safe, effective psychedelic-assisted medicine. Victoria Hale's article in this issue expands upon this idea in more detail.

Health Equity, Privacy, and Dignity

MAPS has also witnessed and participated in cannabis policy reform; however, after over 30 years of advocacy, numerous barriers to cannabis research and medical care continue to exist. The pursuit of profit over community welfare has generally failed to create the proper incentives for a socially-conscious industry. Thankfully, the longer run-up time to legal psychedelic medical access has allowed us to engage in a robust dialogue about how to create market and social incentives most likely to lead to just outcomes.

Health equity is a framework that brings awareness to the impact that discriminatory policies have on the wellbeing of individuals, communities, and ecosystems. The goal of health equity is to leverage healthcare interventions and policy towards repairing related disparities in medical and psychological care. Actors in the psychedelic healthcare space should strive to counteract the impacts of health inequity, and policy should ensure that creative solutions are given resources and support. This

extends beyond clinics or companies developing drugs to cross-sector partnerships, in order to create more holistic and effective systems of wrap-around care.

As psychedelic interventions are paired with technology in the age of big data, new ethical dilemmas will emerge, such as the use of medical (or medical-adjacent) records and psychological profiles. Digital information has become a powerful resource in our society, and hasty or predatory data use practices could have unforeseen consequences for people simply seeking mental wellness. Such practices may disproportionately harm people already at risk of being targeted by law enforcement or unscrupulous corporations. MAPS is committed to the safety of the physically, economically, legally, and digitally vulnerable people who ought to have access to psychedelic care, and we do everything we can to encourage up-and-coming industry actors to be accountable and transparent.

Obstacles and Incentives

Non-profit research and development fills a gap in society which for-profit businesses and government have not yet had sufficient incentives to pursue. This has historically been true with Schedule I substances, which have faced more regulatory hurdles and public stigma than most new drugs. Pharmaceutical firms typically rely on patent monopolies and projected earnings to justify entry into a new market, and have therefore been unwilling to take the cultural and financial risks associated with securing approval for psychedelic substances.

These profit-oriented motives in healthcare delivery have also negatively impacted the quality or availability of care—so how can the psychedelic industry optimize patient care without relying on traditional business methods? How can we work to ensure that primarily growth-driven companies don't automatically outpace those that grow with intention and place the patient first?

In addition to bringing otherwise neglected modalities to market, charitable, social impact, and benefit-oriented initiatives have the opportunity to use their unique roles to re-imagine institutional structures and implement visionary healthcare innovations. This could mean guarding against ineffective over-regulation, incentivizing cooperative ownership, arranging charitable caregiving services for the delivery of care, and/or creating partnerships and strategies to subsidize treatment for low-income people.

Transformational Alternatives

In summary, the medical approval of psychedelics could provide essential access to millions of people who are diagnosed with PTSD and other mental health disorders. However, this only represents a limited segment of the population who might benefit from the careful use of psychedelics in their lives. Legal shifts will continue to create more points of access, such as through decriminalization or other regulated legal frameworks. To ensure the most secure backdrop of support, partnerships between non-profit, public, and private institutions should be driven by principles of harm reduction and equitable access. MAPS' non-profit/public benefit approach hopes to inspire more ingenuity in our collective shift toward collective well-being. Such hybrid pharmaceutical frameworks offer an alternative, competitive force to traditional for-profit healthcare.

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Natalie Lyla Ginsberg, M.S.W., Director of Policy and Advocacy, received her B.A. in history from Yale, and her master's of social work (MSW) from Columbia. Before joining MAPS in 2014, Natalie worked as a Policy Fellow at the Drug Policy Alliance, where she helped legalize medical cannabis in her home state of New York, and worked to end New York's race-based marijuana arrests. Natalie has also worked as a therapist at an alternative-sentencing court for prostitution and drug-related offenses, and as a middle school guidance counselor. At MAPS, Natalie works to disentangle science from political partisanship on Capitol Hill, at the United Nations, and beyond. She is also co-developing a psychedelic peace-building study with Imperial College, working with Palestinians and Israelis. Natalie is particularly inspired by the potential of psychedelics for healing systemic, intergenerational trauma, for building empathy and community, and for inspiring creative and innovative solutions.

The Unified Field Theory of Psychedelic Integration and Portugal Style Decriminalization

DAVID BRONNER

How non-profit psychedelic drug development harmonizes with efforts to decriminalize plant medicines and legalize psilocybin therapy for all; and how all support broad-based Portugal style decriminalization

Editor's Note: In this article MAPS Board Member David Bronner, Cosmic Engagement Officer (CEO) of Dr. Bronner's Magic Soaps, shares his views about how psychedelic policy reform initiatives such as Decriminalize Nature and Oregon's PSI 2020 support, rather than interfere, with efforts to make psychedelic-assisted therapies into FDA-approved treatments, and how all can harmonize with the broad-based Portugal-style decriminalization campaigns in Oregon and Washington this year.

Both the leaders and the community of supporters involved in each strategy noted above are motivated by deep experiences of healing pain and trauma in themselves, their families and communities, and in deeply traumatized people from diverse walks of life: veterans, first responders, victims (and perpetrators) of rape and sexual violence, and victims (and perpetrators) of colonial and patriarchal racism, homophobia and sexism, whether overt violence is involved or not. (Often, perpetrators are themselves victims—and I reflect on my own process of seeing, owning, and renouncing my homophobic and sexist mindset that warped my own soul and inflicted pain by a thousand cuts on my then-partner.) Some degree of trauma affects pretty much everyone on Earth, and if we can all exorcise and heal the demons and trauma ricocheting down the generations, and reconnect ourselves to nature and our deeper selves, then we might have a real shot at peace on Earth, in sustainable relationship to the miraculous living natural world that we are one with. The vectors and dynamics involved in trauma, depression, and addiction are different, but psychedelic-assisted therapy and the intentional ceremonial use of plant medicines hold the keys to deep healing that traditional Western pharmaceutical and therapy approaches lack.

There are different important strategies to destigmatize and integrate these sacred medicines and therapies into the mainstream. Rick Doblin, Jedi founder and leader of MAPS, has the fires of the Holocaust behind him, informing his strategic vision to integrate psychedelics via the U.S. Food and Drug Administration (FDA) approval process, paving the way to a post-prohibition world generally. Sheri Eckert also shares the trauma of the Holocaust, and along with her husband Tom Eckert works closely with victims and perpetrators of domestic violence every day. As architects of Oregon's Psilocybin Service Initiative (PSI 2020), the Eckerts understand the healing power of psychedelic-assisted therapy for addressing the cycle of trauma and abuse. Carlos Plazola, Chair and co-founder of Decriminalize Nature, was able to heal and purge the colonial violence and trauma he and marginalized communities of color deal with every day, through self-medicating with a high dose healing mushroom journey, and disciplined integration work after.

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Leading therapists involved in FDA-reviewed studies properly caution that high dose psychedelic sessions for psychedelically naïve people without a trained facilitator present can be like birthing a baby without any help. You want to be sure that your midwife or doctor knows what he or she is doing and can help navigate through to a successful outcome. Indeed, even I initially had an uninformed prejudice that the Decriminalize Nature movement was irresponsibly advocating the decriminalization of powerful fungi and plant medicines without guidance on best practices. I gained a better understanding after talking to Kevin Matthews of Decriminalize Denver and SPORE and Larry Norris of Decriminalize Nature and ERIE. I realized how central education and destigmatizing access for marginalized communities of color is to the

Decriminalize Nature project, with its emphasis on set and setting, sitting for each other, and integration work after. I think most people, like myself, had not bothered to read the Oakland Decriminalize Nature provision that passed City Council last June, and which informs other Decriminalize Nature campaigns across the country. It's eye-opening how thorough and deep in different dimensions it is, and I highly recommend reading it at decriminalizenature.org.

Carlos Plazola's critique of those who support medical uses of psychedelics but don't support the Decriminalize Nature movement is his observation that the position could be based on a hidden elitist mindset: that certain cultural (educated, affluent) elites can be trusted to safely and properly engage with psychedelic medicine space outside of strictly medical settings, but that other communities (i.e., people of color) can't. Western psychedelic therapeutic practice ultimately owes its existence to the underground therapeutic movement, which in turn was deeply influenced by the long lineage of indigenous ceremonial plant medicine traditions. Carlos points out that the traumatized populations most in need of treatment often can't afford the cost of therapy, but can grow their own medicine for themselves, their families, and communities; and can create the set and settings needed to facilitate safe, healing outcomes. We have an inalienable right to heal ourselves with the natural plants and fungi that grow in the ground (or for that matter with their chemical cousins that are produced in a laboratory). Communities like Denver which have decriminalized psychedelic mushrooms and like Oakland which have decriminalized all plant and fungus medicines, and other cities that are following the Decriminalize Nature model, are demonstrating (along with closely allied groups like ERIE and SPORE) that educating people about set, setting, preparation, and integration practices, is integral to the movement.

Chicago, New York City, and Washington, D.C. all have strong Decriminalize Nature campaigns that Dr. Bronner's is supporting, to one degree or another, with a special focus on D.C.: Dr. Bronner's DC-based social action team is helping lead and coordinate the campaign there, the same team that legalized cannabis in 2014 in D.C. in partnership with the Drug Policy Alliance (DPA). The Decriminalize Nature D.C. press release (available at decriminalizenaturedc.org] links to powerful written testimonies from: the main proposer Melissa Lavasani, who healed debilitating ante- and post-partum depression with an ayahuasca ceremony and microdosing mushrooms; veterans with PTSD healing their own and their comrades' trauma with ayahuasca, mushroom, and ibogaine therapy such as Marcus Capone (former Seal Team Six and co-founder of Veterans Exploring Treatment Solutions), Jesse Gould (former Army Ranger and founder of the Heroic Hearts Project), and Wyly Gray (former Marine and founder of Veterans of War); and Daniel Carcillo, the former NHL player and two-time Stanley Cup winner who leads the Decriminalize Chicago effort who healed his deep depression from repeated brain injury and childhood abuse with high-dose mushroom therapy, and is now helping heal fellow traumatized former professional athletes and first responders through his Chapter 5 Project.

Importantly, the Native American Church (NAC) has conveyed to the Decriminalize Nature movement the importance of understanding and respecting their historical indigenous perogative to access peyote medicine, without increasing the demand from non-indigenous sources. The peyote gardens in Texas and Mexico are in a state of collapse, and the NAC has requested that peyote not be specified in any future Decriminalize Nature legislation, and for it to include instead a more general reference to mescaline-containing cacti (which would also cover San Pedro, the preferred mescaline-containing plant medicine for non-indigenous people to work with and heal themselves). Per the advice of the Decriminalize Nature leadership, the D.C. Decrminalize Nature campaign made sure to remove explicit mention of peyote.

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As much as I appreciate and support what the FDA drug development track and

Decriminalize Nature movements are doing—and Dr. Bronner's is financially and organizationally supporting both in a huge way—I am equally if not more invested in seeing a model like what Tom and Sheri Eckhert of PSI 2020 are proposing. PSI 2020 proposes to organize a formal, licensed, state-regulated program that would, after a two-year program development period, allow access to psilocybin-assisted therapy in licensed facilities, under the supervision of practitioners specifically trained in psychedelic facilitation. Among its many careful provisions, PSI 2020 would ensure quality training of facilitators by setting minimum criteria for third-party therapist training programs. An example of a stellar training direction would be one laid out by Francoise Bourzat, author of the incredible Consciousness Medicine, who bridges traditional shamanic and modern western therapeutic approaches.

Excitingly, PSI 2020 has already convened a Training Program Advisory Board, co-chaired by Francoise Bourzat and Tom Eckert, that will be soliciting rock stars from both traditional and indigenous perspectives to join. Their mission is to advance appropriate criteria to the Oregon Health Authority for the eventual development, approval, and oversight of psilocybin facilitator training programs in the state of Oregon. The Board will represent a diversity of perspectives from experts who are qualified to clarify training standards for the provision of psychedelic services. Francoise, Tom, and the Board are defining detailed criteria for approving training programs, including experiential components and didactic education covering the history of plant medicines, contemporary research, philosophical foundations (indigenous and modern), risk assessment and contra-indication criteria, components of psychedelic therapy, facilitator skills and competencies, ethics and responsibilities, as well as legal, regulatory, and professional considerations. The board will also stipulate tiered training opportunities that yield certifications reflecting the needs of the client population, from the generally "healthy" to those suffering with significant mental illness or addictions. Finally, the Board will address issues like accessibility of services, community building, and other social imperatives.

If we want to get to world peace, in harmonious relationship with nature, before we drive off the climate change cliff, we need to provide safe well-structured access to all who can benefit.

PSI 2020 also has important regulations to prevent a "big cannabis" style takeover of psilocybin mushroom production and therapy. In this framework, no person or entity may have more than one license for a single grow operation, which would be limited in size to enable a good livelihood for a grower while preventing huge corporate grows. No branding or marketing of the medicine would be allowed. On the service center side, a single license holder/entity can have no more than five service centers/clinics where psilocybin therapy will be administered. So, no "chain clinics" delivering substandard care will be allowed. Carlos Plazola and Decriminalize Nature, for their part, are also building out regulations in Oakland to serve as a model of non-profit driven, community-based healing centers, with low barriers to entry enabling fair and equitable access, while still supporting and enabling a grow, gather and gift model.

The power of PSI 2020 is that it takes the spirit of rigor from the FDA clinical trials and applies it to a therapeutic setting which will broaden its treatment impact. A broad swath of the population, including my mom and most people's moms, will be most helped and comfortable accessing psilocybin medicine in a professional therapeutic container (the Western analog to the indigenous ceremonial space), and won't access it otherwise. But the FDA approval route, while resulting in the kind of medical access point we need, will not afford health insurance-covered access to anyone without a narrow qualifying diagnosis (though there is the possibility of self-pay covered off-label use, which would be expensive and only available for the privileged few). Almost every person on Earth can benefit from some deep healing from the struggles of life, and facilitate their personal healing and growth. PSI 2020 would allow affordable access to anyone who might safely benefit and is not contra-indicated (e.g. schizophrenic).

If we want to get to world peace, in harmonious relationship with nature, before we drive off the climate change cliff, we need to provide safe well-structured access to all who can benefit. We owe everything to the FDA researchers who have moved the

culture to the point we are at now, with their impeccably designed studies and protocols optimizing the healing potential and outcomes of psychedelic-assisted therapy. But the culture is now primed and ready for the necessary next phase, which is what PSI 2020 proposes—alongside and complementary to Decriminalize Nature.

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I want to address briefly some clinical researchers' concerns about Decriminalize Nature and PSI 2020 potentially interfering with the FDA approval process. Some imagine worst-case scenarios, however implausible, of someone running out of a treatment center into the middle of traffic, jumping out of a building, or otherwise dying some kind of sensationalist death. They worry that if there are negative stories in the media about therapy sessions gone wrong, that will compromise the FDA approval route. This resonates with drug warrior D.A.R.E.-style paranoia, forgetting that it is prohibition itself and the cultural stigma it perpetuates which, by preventing education about set, setting, preparation, and integration, result in the kind of irresponsible and uninformed use of psychedelics which lead to bad outcomes. Decriminalize Nature is all about destigmatizing the cultural attitude towards these medicines, enabling real education to permeate the culture, much like in indigenous cultures. In the case of PSI 2020, no one can access the therapy except at a licensed and supervised facility, under the supervision of a trained and licensed facilitator who ensures proper preparation and integration as well as an optimized setting. While most underground therapists are competent, some are not, and PSI 2020 aims to bring the underground community aboveground and to minimize predatory or incompetent facilitators and facilitation. PSI 2020 also imposes a two-year program development period that is purposely timed to take effect alongside, not before, FDA approval of psilocybin-assisted therapy in 2023. Regardless, while a high-dose psychedelic session can go sideways, harm is much more likely under prohibition than under decriminalization and legalization.

Even more importantly, contradicting these concerns and frankly surprising me and many, for the past 20 years, the FDA approval process has been shown to be relatively immune from politicization. As study after study has been approved, Phase 3 trials greenlighted, Breakthrough Therapy Designation granted, and Expanded Access ("compassionate use") approved, the cultural stigma that researchers used to face is rapidly decreasing. Even when stigma was much more of a factor 20 years ago, it still did not stop FDA from approving early studies. There is growing recognition that these medicines and therapies can help address great suffering, and researchers like Steve Ross of NYU have publicly communicated that FDA is bending over backward to facilitate MDMA and psilocybin therapy, and neither Decriminalize Nature nor PSI 2020 has been a factor at all with FDA. That said, of course, FDA is a bureaucracy and the risk of politicization is not zero; but lessening the cultural stigma is helpful not harmful via responsible Decriminalize Nature and PSI 2020-style efforts.

One final point here is the example of cannabis in our culture: drug warriors justified their opposition to medical cannabis in part by pointing to FDA approval of synthetic THC (Marinol) as the way we as a society should approve and integrate the medicine. The ongoing and successful effort to integrate cannabis in natural forms outside of FDA pharmaceutical regulation has, if anything, exerted pressure on FDA to approve the synthetic form of THC, which is exactly what is happening with pharmaceutical psilocybin.

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The other major fault line in the movement is the concern over whether Decriminalize Nature efforts may implicitly promote drug exceptionalism around psychedelics and reinforce the stigma associated with the use of other drugs, and whether

they do in fact lay the groundwork for broader Portugal-style drug decriminalization. Carlos of Decriminalize Nature does not see a conflict between the two approaches. As he eloquently explains, Decriminalize Nature is about destigmatizing and enabling access to natural plant medicines for traumatized communities of color, and other traumatized populations, to heal the underlying trauma that in part drives the epidemic of addiction in the first place. My take is that Decriminalize Nature is making an incredibly important improvement that helps with the bigger picture. By the same logic of drug exceptionalism, the drug policy movement should cease all efforts to end cannabis prohibition in red states which will lead to ending cannabis prohibition at the federal level. Also by this logic, we should stop efforts to move psilocybin and MDMA through the FDA approval process as well, since focusing on integrating the "good drugs" that have incredible healing potential somehow compromises the effort of broad-based decriminalization and ending mass incarceration. In fact each of these crucial incremental steps help the overall project of moving us to a post-prohibition world. More importantly, we need to get psychedelic healing to as many people as possible, as fast as possible, not only to heal and save lives, but also to open them to considering and supporting more rational, compassionate, and sustainable policies across the globe—including ending the disastrous War on Drugs, which is continuing to traumatize people's lives in communities worldwide, especially people of color.

Integrating psychedelic therapy and medicine into our culture completely harmonizes with the project of decriminalizing the possession of all drugs, ending mass incarceration, and getting people the help they need, especially in the form of psychedelic-assisted therapy.

An example of why a constructive dialogue between the leadership of the movements is so vital recently occurred in D.C., where the Decriinalize Nature campaign and local DPA office missed the opportunity to coordinate with each other about the Decriminalize Nature inititiave before it went before the D.C. Board of Elections. The good result, though, is that both the D.C. and Oregon situations are precipitating a conversation between the leadership of the movements which will in turn inform the respective coalitions, and which I've been trying to facilitate as well. There are also examples of lack of awareness, support, and solidarity in the Decriminalize Nature and PSI 2020 movements regarding the broad-based decriminalization reform that DPA is championing. The idea that we should only decriminalize psychedelic medicines but not other drugs is just as short-sighted and off-base. Regardless of whether a controlled substance has medical value, addiction is not a crime, and we should get people the help they need without further ruining their and their families' lives. The deep solidarity work at the national leadership level is well underway, and Carlos and Larry of Decriminalize Nature and Tom and Sheri of PSI 2020 already completely support broad-based decriminalization. Ellen Flenniken, DPA's Managing Director of Development who has been a strategic ace helping the Drug Addiction, Treatment and Recovery Act (DATRA) effort in Oregon, has confirmed her solidarity with Decriminalize Nature as well as PSI 2020. But the leadership of all the efforts need to communicate effectively within their respective coalitions so they truly understand each other, can help each other, and not undermine each other. Integrating psychedelic therapy and medicine into our culture completely harmonizes with the project of decriminalizing the possession of all drugs, ending mass incarceration, and getting people the help they need, especially in the form of psychedelic-assisted therapy. The local leadership of the D.C. Decriminalize Nature effort along with myself have conveyed that we would love to work with DPA in D.C. in the next election cycle on broad-based reform there.

I believe we are reaching a tipping point in our cultural trajectory, where we can combine efforts in a single measure, and hope the result of this election convinces the different coalitions and funders that we should do so. Oregon is ground zero, with all campaigns and efforts in play. In solidarity with our allies at DPA, the PSI 2020 campaign removed the decriminalization of mushrooms from the PSI measure, given DATRA was moving forward in Oregon and would decriminalize not only mushrooms and plant medicines, but also all other psychedelic allies, along with all other drugs in a Portugal-style harm reduction model. This is a crucial approach, and we should all be in support of it. However, the cutoffs and allowances under DATRA for plant medicines and fungi

are far too low for home cultivation. Further, DATRA is not communicating at all with voters about using plant and psychedelic medicines to heal trauma and addiction, with proper attention to set, setting, preparation, and integration. Plus, DATRA is not guaranteed to win. For these reasons, I support Decriminalize Nature in Oregon as well as nationally, although prefer to win through city council process in 2020 in Portland, like in Oakland and Santa Cruz, even if we need to go to the ballot in Portland next year so that voters aren't confused by the two different decriminalization measures on the same ballot in November this year (although if that happens we'll still rock it).

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In summary, the FDA track, the PSI 2020 effort, and Decriminalize Nature are all about integrating life-saving medicines into our culture, are complementary, and do not interfere with each other. Each is making important progress and serving a different population and need. The broad-based Portugal style "treatment not jail" decriminalization efforts in Oregon and Washington which will end mass incarceration have their compelling logic that addiction is not a crime, and that the racist drug war that disproportionately targets people of color needs to end. But it's a big mistake to think these are separate efforts. We should work to integrate them in parallel, ideally in the same campaign, as there is no better treatment for addiction than psychedelic-assisted therapy. Integrating these medicines and therapy alongside efforts to secure broader access to treatment, health, and harm reduction associated with broad-based decriminalization campaigns makes perfect sense.

We at Dr. Bronner's are supporting all these efforts with substantial financial and organizational resources, and ideally we would like to see a future ballot measure combine broad-based DATRA-style decriminalization with higher cultivation cutoffs for plant and fungal entheogens, allowing for home cultivation and community healing per Decriminalize Nature, combined with a program for licensing therapist training programs per PSI 2020. Our hope is that victory across the board of the different efforts in this election cycle will pave the way to this combined measure in the next election cycle, so that we are efficiently spending movement resources and hitting multiple birds with one (non-lethal philosopher's) stone. And in turn as momentum builds state by state, this will inspire national and international policy changes. Right now, in this election cycle, our hope is we can inspire funders to support all of these incredible efforts with the firepower they need to effectively communicate their respective truths with voters and win. My article here is part of that process, and we're also putting our money where our mouth is: Dr. Bronner's has dedicated $500,000 to PSI 2020 in Oregon; $500,000 to DATRA and the parallel effort in Washington; and $250,000 to Decriminalize Nature campaigns (especially Washington, D.C.) and allied organizations ERIE and SPORE. Decriminalize Nature/ERIE and SPORE, working closely with city officials, community leaders, and other stakeholders in Oakland and Denver respectively, are creating the model for responsible access and integration of entheogenic fungi and plant allies for other cities to follow (Sara Gael, Director of Harm Reduction of MAPS Zendo Project, is also a member of Denver's Psilocybin Mushroom Policy Review Panel). We've also dedicated $1 million a year to MAPS for five years and $100,000 a year to Usona for five years to move MDMA and psilocybin through the FDA approval process. Plus, we are giving another $1 million this year to ending prohibition of cannabis in six red states, setting up the end game at the federal level next year. All these efforts need a lot more funding, and we'd love to see other funders recognize that we should power all these movements and cultural leverage points, not just the FDA approval route, and that all together they will get us sooner versus later to a responsible post-prohibition world, psychedelically healed and opened, and ready to enact collective policies and behavior change that truly can make a heaven on Earth. All-One!

David Bronner is the CEO (Cosmic Engagement Officer) of Dr. Bronner's, the family-owned top-selling natural brand of soap in North America. David along with other family execs cap their compensation at 5 times the lowest paid warehouse position, and donate all profits not needed for business development to the causes and charities they believe in. David graduated with a degree in Biology from Harvard in'95, and by end of that year graduated with a real degree from the school of psychedelic medicine in Amsterdam, heart and mind blown wide open, and dedicated his life to responsible integration of cannabis and entheogens into American and global culture. He joined the board of MAPS in 2015. He also serves on the board of the Regenerative Organic Alliance, which promotes regenerative organic agriculture and ethical dietary choice, to support a more humane, sustainable and fair farming system worldwide (www.regenorganic.org).


Sage Institute: A Model for Accessible Psychedelic Therapy and Training

GENESEE HERZBERG, PSY.D

HEATHER VALDEZ, LCSW

As psychedelic medicine enters the mainstream, moving towards legalization, commercialization, and greater public acceptance, some important questions arise: Who will have access to these treatments? How will the treatments be taught and used as they propagate? How will financial interests and new technologies impact the way these medicines are used?

While the answers to these questions are not yet clear, we can imagine the psychedelic movement taking a direction that excludes many, dilutes the richness and profundity of the work, uses technology in the place of human contact, and makes use of psychedelics to accumulate profit. The online graphic novel "We Will Call It Pala" (aurynproject.org/pala) depicts one such future unfolding. In response to the daunting potential outcomes, Sage Institute has created a model that offers an alternative: a clinic which is financially accessible, values the representation of diverse identities in the hiring of staff and interns, holds the work in an ethical and equitable way, and is run without the influence of financial interest or material gain; one that makes use of technology only so far as it supports greater access and affordability, without sacrificing the essential and human elements of this work.

The Sage Institute Model

Sage Institute is a non-profit organization founded in 2019 by a group of therapists interested in furthering the psychedelic psychotherapy movement by: (1) increasing accessibility for underserved communities, (2) training the next generation of psychedelic therapists from diverse backgrounds by experts in the field, and (3) helping to build the body of research on the efficacy and safety of psychedelic therapy for diverse populations. Our mission is to provide high-quality training and sliding-scale psychedelic-assisted psychotherapy, fostering culturally-responsive treatment for underserved communities in the Bay Area. Sage Institute offers ketamine-assisted therapy and plans to offer other psychedelic-assisted treatments as they become legal.

Accessibility

To facilitate accessibility, we use the widely accepted model of a training center with a sliding scale community mental health clinic, allowing us to drastically reduce the cost of treatment. We will also offer groups to facilitate accessible services and to build community. Beyond limited financial resources, there are a range of additional barriers to accessing psychedelic psychotherapy in the communities we serve. These are discussed extensively in "Blinded by the White: Power & Privilege in Psychedelic Medicine" (on chacruna.net), and include unstable housing, lack of community support, inadequate or mis-information about psychedelics, a lack of diversity amongst therapists trained in psychedelic work, systemic racism, and lack of cultural humility. We are working to address access on all levels. We proactively recruit intern therapists who reflect the cultural backgrounds of the communities we serve, diversifying the ecosystem of trained psychedelic psychotherapists and creating unique relational and engagement opportunities to encourage marginalized communities to participate and remain in mental health treatment. We partner with other organizations that provide complimentary services to create a safety net and are developing a robust program of community offerings, groups, and educational activities.

Training

We hold depth and relational psychotherapy, trauma-informed care, social justice, and liberation psychology as theoretical frameworks to inform our training model. Rigorous engagement with depth psychotherapy provides interns with a dynamic theoretical lens for engaging the images, visions, symbols, synchronicities, and other expressions of the deep psyche arising within psychedelic spaces. Our trauma-informed approach aims to help clients feel an established sense of safety with providers through unconditional empathy, titration of intense affective states through careful attention to nervous system arousal and coregulation, attunement to dissociation, and engagement with dissociated self-states. We support our practitioners in addressing acute, developmental, and cultural trauma as well as systems of oppression affecting the wellbeing of our clients and communities. We use an intersectional lens to explore complex issues surrounding accessibility, power and privilege, cultural sensitivity to indigenous origins of psychedelic medicines, and reflections on the incorporation of indigenous wisdom in the face of colonization and cultural appropriation.

Research

Sage Institute is committed to helping build the body of research investigating psychedelic psychotherapy, with particular attention to actively engaging the communities we serve through a participatory action research framework and developing culturally responsive treatment protocols aimed to support marginalized groups such as communities of color, LGBTQIA+, gender non-conforming and non-binary, and beyond. The goals of our research program are to (1) collect quantitative and qualitative data for use in ongoing, high-level research assessing the efficacy of ketamine-assisted psychotherapy and other psychedelic treatments as they become legal; (2) partner with other key players in the field to promote the advancement of psychedelic medicine; and (3) measure outcomes in order to assess safety and efficacy and for purposes of program monitoring. Our research outcomes can then be used to encourage insurance companies to cover these treatments.

Our Values

Sage Institute operates on a core set of values. These values guide our work at the micro (individual), mezzo (community) and macro (system) levels we seek to impact. They include:

- Health and Wellbeing: supporting health and wellbeing within the communities we serve
- Access: increasing access to the most effective, client-centered forms of mental health treatment
- Ethical Practice: commitment to upholding the work in a way that centers the safety and autonomy of the people we serve and the integrity of medicines we use
- Competence: ensuring the competence of the therapists we train through rigorous training, thorough evaluation, and immersion in time-tested practices and traditions
- Diversity: valuing and centering diverse voices
- Inclusion: centering those who have been historically excluded from the conversation
- Cultural Responsivity: adapting the work to the communities we serve
- Healing Through Relationships: centering the therapeutic alliance, built on trust and safety
- Community: supporting a sense of connection through community building
- Harm Reduction: meeting people where they are at on their path of growth, and finding tailored ways to help them reach their self-defined goals
- Education: increasing public knowledge about the safe medical use of psychedelics
- Integration: placing special attention on the integration of psychedelic experiences as an integral part of the process of healing
- Commitment to Personal Growth: engaging in our own healing work, knowing our limits, seeking help when needed, and developing our knowledge of the medicines we work with
- Accountability: holding each other accountable within a community of psychedelic practitioners, offering support, skill development, guidance, and feedback

OUR RESPONSE TO COMMERCIALIZATION

Public Benefit

In the face of the impending commercialization of psychedelics, Sage Institute hopes to offer a counterpoint to soaring costs, profiteering, exclusivity, and the dehumanization and de-souling of psychedelic medicine. For-profit, investor-funded corporations are driven by pressure to meet the requirements and revenue expectations of their investors often at the expense of the populations they serve; community wellbeing becomes a lower priority. We are committed to implementing strategies to steer the psychedelic movement away from profit-driven models towards public benefit. As a nonprofit organization, Sage Institute is aimed at uplifting the communities we serve without concern for the financial gain of owners or investors. Our services are intended to increase access to effective mental health treatments, reduce health disparities by addressing social determinants of health, and improve mental health outcomes.

Quality Assurance

A major concern within the psychedelic community is that the work will be diverted, distorted and diluted by the new generation of relatively naive and inexperienced people entering the field. We are building an ethical framework for the medical use of psychedelics that prioritizes quality of care, efficacy, ethical practices, relational safety, and honoring traditional practices. While our model offers a structure for reducing the cost of psychedelic psychotherapy, we are committed to upholding a high standard of service alongside lower fees. To ensure the quality of our services, we prioritize rigorous training of our therapists by experts in the field, thoughtful and discerning gatekeeping involving thorough evaluation by supervisory staff, and thoroughly vetted safety protocols and quality assurance mechanisms.

Our training supports intern therapists in developing a solid grounding in foundational clinical skills, and careful attention to the basic tenets of psychedelic work regarding set and setting, preparation, and integration. We situate psychedelic psychotherapy as a relational modality, where the potential benefits from both psychedelics and psychotherapy are catalyzed by the qual-

ity of the relationship between therapist and client. Our intern therapists undergo a rigorous and multi-step evaluation process to demonstrate their readiness to begin ketamine-assisted therapy. Psychedelics are used as a tool only when deemed appropriate by the practitioner team through an extensive assessment of the client's symptoms, needs, history, expressed treatment goals, support structure, and level of readiness. Although we hope to shape this movement with new and creative ideas, we are aware of the need to work within already established healthcare systems. We borrow vital quality assurance mechanisms for the safe use of medicines in tandem with psychotherapy, and plan to build new models and safety mechanisms that are specific to the uniqueness of the psychedelic field.

Open Praxis

The commercialization of psychedelic medicines, when motivated by profit, is at risk of promoting a competitive atmosphere amongst businesses in the field. To support an attitude of collaboration and mutual support as we explore these new terrains together, we value an open praxis approach as delineated in the Statement on Open Science for Psychedelic Medicines and Practices (chacruna.net). We plan to develop a manual describing our operational model that we will make available, along with our outcome data, to assist others in developing similar programs and propagate like-minded research projects. In doing so, we hope to support the proliferation of low-fee psychedelic clinics in communities across the country and the collective effort to legitimize psychedelic psychotherapy. It is critical that we work from a social justice lens in order to develop a model that has a far reach and is replicable within diverse communities.

During the ketamine sessions I was able to think about things that normally would overwhelm me, without experiencing the intense body anxiety I would normally feel.

Implementation of Our Model

To open our doors and begin offering sliding scale psychotherapy services, we gathered volunteers who are passionate about our mission to make up our interns, faculty and staff. Our staff and interns offered their time in-kind for the first several months of operation, and our faculty are volunteering their time for our first year of operation. Intern therapists see clients at a reduced rate in exchange for intensive training and supervision culminating in hours towards clinical licensure, and a certificate from our training institute showing two years of dedication and experience in psychedelic psychotherapy. By gathering volunteers, we have been able to run on a very lean operating budget for our first year in order to launch the program. Though this was an effective strategy to open our doors, we value not only creating accessible treatments but also developing a model that is sustainable for therapists and staff.

Sage Institute is currently one of very few clinics nationwide offering long-term lower-fee psychedelic-assisted therapy, and demand is high. Our waitlist is currently several months long. There has been notable interest in our services coming from BIPOC and LGBTQIA+ communities. It is critical that we grow our capacity, and we will do so annually by bringing on new cohorts of therapists; we anticipate doubling in size in our second year of operation as we recruit a second cohort of intern therapists to begin in the Fall of 2020. It is even more critical that we carefully build a replicable model of quality, accessible care.

We plan to move towards greater sustainability of our organization through the development of additional programming including public educational events and a certificate program for licensed providers that are offered for a fee. We have received significant interest from practitioners seeking training in psychedelic-assisted therapy. These programs will help us to further our mission by educating and building the capacity of therapists and healthcare providers across the country to provide psychedelic therapies in their communities in a sensitive, ethical, and socially just way.

Access to affordable and effective mental health treatment is a long-standing problem within our healthcare systems. Recent research suggests that psychedelic psychotherapy has the potential to accelerate and improve mental health outcomes. In the upcoming months, we aim to develop our research and education efforts, demonstrating the validity of these therapies in order to move them further towards prioritization by funders, donors and the general population. In building the credibility of these treatments, we hope to inspire interest in collaboration with healthcare, educational, and insurance systems to further our efforts towards greater accessibility.

A Call to Action

We opened our doors in September of 2019 and could not have imagined the impact this organization would have on all of our lives and the lives of our clients and communities. We love our work, and get regular reminders of the life-changing impact it is having on the people we serve. After completing a ketamine-assisted therapy treatment with one of our talented therapists at Sage Institute, one client noted:

"I feel like it's made a huge difference in my life. I had been struggling with PTSD and depression for a long time and despite therapy and learning tools to improve I wasn't able to implement them because I was so focused on just surviving while constantly on edge. Ketamine therapy and my work with [my therapist] gave me the boost I needed to be able to get past surviving and focus on really improving everyday...[My therapist] helped me to process everything, and made it feel like a safe environment, which is something I've had trouble feeling

in other therapy settings...During the ketamine sessions I was able to think about things that normally would overwhelm me, without experiencing the intense body anxiety I would normally feel. That really helped me to reprogram how I thought about my trauma."

Though our work is both in demand and effective, we are not able to cover our overhead with our client revenue alone. Until we can implement the steps delineated above towards greater financial sustainability, fundraising through grants, donations, and other opportunities is essential. With many donors in the psychedelic movement focused on legalization and decriminalization, and as a new and small organization hoping to help shape the direction of the field as psychedelics become legal, we have yet to secure major sources of funding. As we continue our efforts to make quality psychedelic therapy equitable and accessible, we need to cultivate new networks of support and we ask for your help in doing so.

It is essential that we work together to promote an ethical approach to psychedelic medicine as early as possible in this renaissance of the movement. To do so we are focusing our efforts on building the capacity of diverse therapists to do this work in a sensitive, compassionate, and competent way while simultaneously increasing access to these treatments. Reducing costs and expanding the diversity of therapists in the field will encourage the engagement of marginalized people typically left out of the conversation. We hope that our values and training model will help to disseminate cultural awareness throughout the psychedelic community and shift the popular "magic pill" mentality towards one that views the therapeutic relationship as central to healing. We will continue to educate and bring together healthcare, education, and funding stakeholders to collaboratively invest in and bring forward this work in a way that positively impacts our communities. We hope to inspire and support other clinics across the country to put equity, accessibility, and quality of care over profit.

Genesee Herzberg, PsyD is a licensed psychologist practicing in Berkeley, CA. She obtained her doctorate in clinical psychology from the California Institute of Integral Studies, where she was awarded the Kranzke scholarship for her research on the phenomenology and sequelae of MDMA-assisted psychotherapy. In June of 2018, Dr. Herzberg co-founded Sage Integrative Health, a holistic health and psychedelic psychotherapy clinic in Berkeley that offers ketamine-assisted therapy and has applied to offer MDMA-assisted psychotherapy through an Expanded Access program. In 2019, she co-founded and currently serves as executive director for Sage Institute, a sliding scale ketamine-assisted therapy and community mental health clinic in Oakland. Dr. Herzberg is also a therapist and sub-investigator for MAPS' MDMA-assisted psychotherapy for PTSD research. She is passionate about increasing the accessibility of psychedelic medicine and supporting the field in moving towards greater inclusivity of diverse and traditionally marginalized voices. She has published several articles on these topics.

Heather Valdez, LCSW, is a licensed clinical social worker and nonprofit development consultant based in Oakland and Berkeley, CA. She is co-founder and board member of Sage Institute, a nonprofit organization focusing on increasing accessibility of psychedelic-assisted therapies. She is a psychotherapist at Sage Integrative Health, a clinic with a holistic approach to wellness, where she offers Ketamine-Assisted Therapy. She is also a trainee in the MDMA-Assisted Therapy Training Program through MAPS in anticipation of Expanded Access approval. Heather is social justice-oriented and passionate about working to improve mental health outcomes for LGBTQIA+ populations and communities of color, both of which she identifies with. She has extensive experience in this area via program development, fund development, committee consultation, training, and managing clinical case management programs. She values working to uplift un/underserved and marginalized communities by working to ensure access to healthcare and other vital services to promote equity, equality, and well-being.

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Promise, Power, and Profit: The Economics of Ketamine Treatment

RAQUEL BENNETT, PSY.D

ALEXANDER BELSER, PH.D

There has been a recent explosion of interest in ketamine, a synthetic chemical with powerful antidepressant and visionary properties. Originally developed in the 1960s as short-acting surgical anesthetic, ketamine was primarily used for sedation, pain management, and as a recreational party drug. A small group of researchers and clinicians have been investigating the uses of ketamine in psychiatry and psychotherapy for two decades, but in early 2019, ketamine burst into public awareness with the FDA approval of esketamine (a filtered ketamine product). The in-fighting among different kinds of clinicians that has ensued, and the insane cost of the filtered product, which was brought to market by a pharmaceutical giant, has much to teach the psychedelics communities about the economic challenges that lie ahead on the road to legalization and commercialization.

The current system encourages pharmaceutical giants to invent ways to monetize existing generic drugs by creating proprietary variants of these drugs that have no demonstrable clinical advantages.

Regular ketamine is a racemic mixture with two isomers (esketamine and arketamine). Regular ketamine is off-patent (i.e., multiple drug manufacturers are allowed to make it), it is dirt cheap, the DEA has placed it in Schedule III, it is FDA-approved for anesthesia and analgesia, and it is widely available as a medical supply. After many pharmaceutical companies failed in their attempts to develop a ketamine derivative that they could patent and profit from, Johnson & Johnson turned to a different strategy: They filtered regular ketamine to create esketamine (also known as Spravato™) and then undertook an arduous and expensive process to get FDA approval for esketamine for treatment-resistant depression.

It costs a few pennies to manufacture a dose of ketamine, and the end-cost to a provider is less than $2 per dose of ketamine. In contrast, Johnson & Johnson has set the price at $850 for a dose of esketamine. Sticker shock aside, perhaps the price is warranted because esketamine is more effective? Sadly, no. There is no clinical evidence whatsoever to date that shows that esketamine is more helpful in treating severe depression than regular ketamine. (For further commentary on this, please see "The new ketamine-based antidepressant is a rip-off" in VICE and "What is the deal with esketamine?" in Psychiatric Times). What is clear is that the FDA approval of esketamine over generic ketamine results from a system of perverse incentives. The current system encourages pharmaceutical giants to invent ways to monetize existing generic drugs by creating proprietary variants of these drugs that have no demonstrable clinical advantages.

There is also some good news for the burgeoning field of therapeutic ketamine. With the FDA approval of esketamine for refractory depression: (1) it established the efficacy of a ketamine product for a psychiatric indication, (2) it established that it is safe to use this medicine in the lower dose range in an outpatient setting, (3) it moved the administration of this medicine away from anesthesiology and under the purview of psychiatry, the right home for a mental health treatment, and (4) it signaled the importance of multi-modal treatment by stating explicitly that a ketamine product alone is insufficient for treating refractory depression.

Another interesting aspect of ketamine treatment is that there is tremendous disagreement in the field about the optimal way to provide therapeutic ketamine, and

the different options come with different price tags. Dr. Bennett outlined three different approaches for ketamine treatment in a previous MAPS *Bulletin* article (Spring 2019). In thinking about the costs of ketamine treatment, it is important to parse out the different components of the total cost: the cost of medication, the cost of other medical supplies and equipment, the cost of the provider's time (which reflects their level of expertise and experience), compensation for the amount of legal risk, and practice overhead. It is also important to make a clear distinction between "optimal" ketamine treatment and the many sub-optimal iterations that are proliferating. These clinical considerations are outside the scope of this paper, and will be explored in another publication.

However, the fundamental problem is the same across many different approaches to ketamine treatment, namely that the experience doesn't fit neatly into a standard 50-minute clinical hour. Plain ketamine infusion (without individual attention) takes at least two hours. Ketamine-facilitated psychotherapy takes at least two hours. Ketamine in the psychedelic dose range takes at least three hours. Even low dose (sub-psychedelic) esketamine administration comes with the requirement that the provider directly supervises every patient on the premises for a minimum of two hours post-treatment. The clinician's time is a substantial cost. This obstacle to treatment will only be addressed when the cost of mental health care is fully covered by insurance or subsidized in some other systemic way.

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When considering the future economics of ketamine treatment, we propose the following systemic considerations and recommendations:

1. Educate patients. It is important for patients to have a clear understanding of the spectrum of ketamine services that are available, and what they are paying for.

2. Find ways to reduce the cost of ketamine treatment. Here are some easy ways to bring down the cost: (a) use generic ketamine because it is cheap and effective; (b) use injectable ketamine, also known as IM ketamine, because it is precise, has high efficiency and bioavailabity, is easy to administer, is cheaper than compounded lozenges, and does not require an expensive infusion process; (c) offer ketamine groups when clinically appropriate, e.g., two trained providers can work with six patients; and (d) train more clinicians to meet the demand for services.

3. Examine and change the FDA approval process. The current FDA approval process is so difficult and expensive that it usually only makes sense for a company or institution to go through the process if they stand to make a huge profit from a patented product (though non-profits such as MAPS and the Usona Institute are succeeding). There are typically too many obstacles and few incentives to get FDA approval for a new clinical indication using an inexpensive or generic drug such as ketamine. Instead, the current system rewards Big Pharma for making irrelevant changes that have no clinical value (e.g., a likely irrelevant filtration system for esketamine.) This results in expensive and clinically dubious variants of existing drugs, increased profits for shareholders, and increased cost of care for patients. What is still missing is FDA approval for generic ketamine for a psychiatric indication. There are currently scores of scientific papers in the peer-reviewed literature demonstrating safety and efficacy, but FDA approval for ketamine for depression is required in order for health insurance companies to cover the costs of this treatment.

4. Reform the structural bias in business ownership laws. In many states, a person(s) with a medical degree must have the majority share in a business that offers a medical treatment, such as ketamine administration. These corporate practice of medicine (CPOM) laws were meant to protect physicians from being unduly influenced by business concerns in providing clinical care. However, these laws now serve to block psychotherapists from having an equal stake in a clinic that provides ketamine treatment, and make it impossible for therapists to be equal partners in the decision-making process or to have an equal financial stake in the success of the business.

5. Embrace a psychedelic model that is open-source, locally owned, decentralized and guided by compassionate care. We should be wary of people who want to "invest" in the psychedelic space. We have grown weary of dinners spent listening to venture-capital backed entrepreneurs selling a vision of psychedelic centers franchised from sea to shining sea. This model concentrates profit and wealth in the hands of the few founders and shareholders. It requires complex corporate structures using management service organizations to funnel profits out of the clinical practice and into the pockets of distant owners. As with other ownership consolidation trends in health care toward conglomerates, it also systemically incentivizes hiring cheaper and less experienced clinicians, reducing the staffing ratios, and reducing time spent on preparation and integration. Instead of this wealth concentration model, we envision a new psychedelic mental health infrastructure: open-source rather than proprietary, clinician- and community-owned rather than VC-owned, decentralized rather than centralized, guided by a principle of compassionate care rather than profit maximization. This vision is consistent with the "pollinator approach" articulated by Dr. Bennet A. Zelner (see article in this volume), The Statement on Open Science and Open Praxis, and the non-profit clinic model being developed by Nautilus Sanctuary (nautilussanctuary.org) in New York City. We must

embrace expanding capacity and access to psychedelic medicine in sustainable, decentralized ways so that psychedelic medicine is not just set apart, but fully integrated into our mental health infrastructure.

6. Acknowledge and compensate our psychedelic teachers. The concept of visionary medicine is not a new phenomenon; it is deeply embedded in spiritual traditions from all over the globe that stretch back for centuries. In this country, modern psychiatry and psychotherapy owe a debt of gratitude to the people in our communities who risked their personal freedoms in order to keep this information alive over the past five decades under repressive governmental policies. One part of ketamine's heritage comes from the psychedelic underground. As sacred medicines become legalized, medicalized, mainstreamed, and professionalized, there may be a huge economic impact on some of the most senior providers as they lose their livelihoods. It is problematic that experienced ketamine guides are being pushed out of the field, and being replaced by physicians and therapists who may have no training and no personal experience in working with ketamine. Is there a way to respect and incorporate these individuals and their accumulation of knowledge into legal practices?

7. Assess the risk of harm from unsupervised ketamine use. Some medical providers are now writing prescriptions, mostly in form of lozenges, for patients to use at home. While there is no doubt that this practice is beneficial and cost-saving for some patients, we feel that this needs to be done with much thoughtfulness and discretion. The recent rise of loose ketamine prescribing practices will surely lead to many terrible outcomes: including injury to self (e.g., falling while under the influence of ketamine); injuries to others (e.g., driving under the influence of ketamine); and death (e.g., drowning under the influence of ketamine). We need to consider the possible financial and emotional costs of using ketamine in a careless way.

8. Address the systemic flaws in healthcare that penalize illness. It is absurd to ask ill people to pay for medical treatment, especially when they have severe, chronic, complex, or refractory conditions. These individuals are less likely to be fully employed, less likely to have private healthcare benefits, and less likely to be able to afford expensive treatments, because they are ill! It is ludicrous to produce a medication such as esketamine, restrict its availability to patients with refractory depression, and then expect those same patients to pay exorbitant costs out-of-pocket for a treatment, when by definition these patients have functional impairment. The costs of mental healthcare, and medical care in general, should be a socialized or communal cost where the cost of treatment is shared within a community of people.

The most economically efficient way to work with ketamine is to use cheap, generic, injectable ketamine as much as possible. Incorporate it into existing mental health services, rather than offering it in separate facilities. Provide group ketamine to the degree that it is clinically appropriate, and subsidize individual ketamine treatment for individuals who truly need it. Clinicians also need to work together using multi-site date collection software to apply for FDA approval for generic ketamine for a variety of mental health concerns, so that this treatment will be covered by medical insurance.

Ketamine treatment is the crest of the wave of novel, experiential, visionary medicines. We believe there is much to learn from the economics of ketamine that applies to MDMA, psilocybin, and other emerging psychedelic medicines. We can look to what is happening in the ketamine space as a frontrunner model, for good and ill, of how psychedelic medicine can be offered in the existing legal socio-medical infrastructure. We need to educate our patients, find ways to reduce the cost of treatment, redress the FDA approval process, reform structural bias in clinic ownership laws, respect and compensate our psychedelic ancestors, and reduce misuse and harms. Finally, we must tackle the flaws in the healthcare system so that treatment reaches the people who need it most. This is how we embody the promise of ketamine as a medicine to heal. We ignore power dynamics and profit-making at our own peril. We must strive to align our economics with our ethics, such that we build a psychedelic mental health infrastructure that works in the service of equitability, accessibility, and compassionate care.

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The FDA and Psychedelic Drug Development: Working Together to Make Medicines

VICTORIA HALE, PH.D

The Multidisciplinary Association for Psychedelic Studies (MAPS), the Usona Institute, and Compass Pathways are each pursuing U.S. Food and Drug Administration (FDA) approval of an investigational psychedelic medicine. One of the biggest objections to the FDA regulation of psychedelic medicines is the medicalization of a tool that people believe they learned to use successfully without government regulation, interference, or control. (MDMA was legal prior to being assigned Schedule 1 status.) The purpose of this article is to provide my perspective that FDA involvement is beneficial to increasing acceptance of psychedelic medicines as mainstream therapies.

Psychedelics are unusual in that the vast majority of new medicines do not reach humans until there is extensive knowledge about mechanism of action, chemical contaminants produced during synthesis, drug distribution, and animal safety and efficacy. Try to view the FDA as a vehicle to address the gaps in scientific knowledge resulting from human use of these agents prior to pursuing the conventional drug development path. Further, as MDMA is a synthetic chemical (and is not derived from plants or fungus), the Federal Food, Drug, and Cosmetic Act, which governs how FDA operates, requires that specific scientific knowledge be ascertained before the compound can be made available to the public as a medicine.

The FDA is a public health agency, under Health & Human Services (HHS), along with the Public Health Service (PHS), National Institutes of Health (NIH), and Centers for Disease Control (CDC). Thus, the FDA is responsible for protecting the American public from unscrupulous or untested drugs that may cause significant harm to patients if misused. In my view, the FDA takes its public health mission seriously.

However, despite the fact that psychedelic compounds are regulated by the Drug Enforcement Administration (DEA) under Schedule 1 of the Controlled Substances Act, the FDA reviews psychedelics the same as other investigational psychiatric drugs. FDA is required to base its decisions on the scientific data submitted by the research sponsor (pharmaceutical company); if FDA provides a negative response, it is often the case that the sponsor failed to provide adequate scientific data to support its arguments.

Pharmaceutical companies (or sponsors) submit their Investigational New Drug (IND) Applications to the Center for Drug Evaluation & Research (CDER) at FDA. Note the use of the word drug: FDA refers to new chemical entities as drugs, because in the FDA's vocabulary they are chemicals intended to treat disease; but the psychedelic community often refers to psychedelics as medicines.

Prior to establishing a drug or medicine is both safe and effective, the FDA labels new chemical entities as "investigational." Therefore, the adjective "investigational" should be used prior to FDA approval. Thus in 2020, MDMA and psilocybin are investigational medicines.

Throughout the development process, the sponsor performs studies and submits data to FDA for review. The FDA website provides guidances and guidelines for the

One of the biggest objections to the FDA regulation of psychedelic medicines is the medicalization of a tool that people believe they learned to use successfully without government regulation, interference, or control.

entire investigational drug development process. It is customary for all sponsors (even large pharmaceutical companies) to have multiple meetings with FDA prior to submission of the New Drug Application. The relationship that each company has with the FDA varies widely.

I believe that it is always best to maintain a friendly, mutually respectful relationship with any regulatory body. Both the FDA and research sponsors can learn much from each other. The FDA has analyzed the data from thousands of investigational medicines and knows much more than they can share publicly. What may initially seem to be a conservative FDA position or response may in reality result in improved patient safety or efficacy, and perhaps even save a sponsor time and money.

At the time of this writing, both MDMA and psilocybin have been granted Breakthrough Therapy Designation by the FDA, signifying FDA's agreement that MDMA and psilocybin may offer substantial benefits over existing therapies for some serious or life-threatening conditions. By granting this designation (which not every drug gets), the FDA is demonstrating its commitment to facilitating the development of new therapeutics that may improve the health status of Americans, as demonstrated by the granting of this designation to three out of three investigational psychedelic medicines currently in development.

After the sponsor submits volumes of data and reports to FDA over many years, what does the FDA do exactly? It is the FDA's job to review everything that is submitted and reanalyze the most important datasets. FDA may even discard some data that it believes are problematic or unreliable, so FDA's final calculations often differ from what the sponsor submits. The final work product of FDA is the new drug labeling. It is that large document with very fine print that includes warnings, clinical trial effectiveness, side effects, whether pregnant women can use the medicine, dosing instructions, storage conditions, etc. Every word on the label is chosen carefully and negotiated by the sponsor and the FDA, as the label forms the basis of all allowable promotional efforts post-approval.

Just as landmark buildings and bridges are legacies of architects, a few medicines become legacies of pharmaceutical scientists and professionals.

I strongly support moving psychedelic medicines forward through the FDA because:

1. FDA approval would validate the efficacy of psychedelic-assisted psychotherapy for select psychiatric disorders. Rightly or wrongly, the FDA is acknowledged by many to be the world's premier health regulatory agency. It has strict standards and an FDA approval is a huge accomplishment (even for a large pharmaceutical company).

2. Secondary indications for the medicine are facilitated by the first FDA approval. The first clinical indication (e.g., PTSD for MDMA; depression for psilocybin) involves the most effort, time and money; secondary indications can be faster and less expensive, especially if the dosing regimen, protocol, and formulation remain unchanged.

3. The FDA requires the same formal safety reporting of all psychiatry medicines. Because all psychiatry drugs are developed with the same requirements, it is then easier for prescribing psychiatrists to determine the relative safety of psychedelic medicines for their specific patients, since they were not included in their medical education (such as specific adverse events, percentage occurrence, severity, contraindications).

4. The FDA is a good teacher. Teams in new, small pharmaceutical companies learn a lot about the drug development process through every step with FDA. Drug development cannot be taught at a university—it is an apprenticeship. Unsuccessful experiences with regulators often result in the biggest learnings (which is true for failures in life as well).

5. FDA approval facilitates insurance coverage. Americans expect insurance to cover part of the cost of treatments, therapists need to be compensated, and pharmaceutical companies need to be able to support these efforts. More people will have access to MDMA- and psilocybin-assisted psychotherapy when insurance companies cover a large portion of the treatment cost.

6. FDA approval expedites physician and psychotherapist education. Today, many people ask their physicians or therapists about therapeutic options. Fifty years of Schedule 1 designation has taught society that psychedelic drugs offer no benefit and may produce harm. FDA approval would provide an expedited path for physician, psychotherapist, and healthcare provider re-education by the sponsor through continuing education.

7. FDA approval would allow for the possibility of direct-to-consumer advertising and education. Direct education of the public offers an efficient (though costly) way to reach large numbers of individuals who otherwise might not learn about the availability of new medicines for their conditions. All promotional content is derived from studies performed and submitted by the sponsor and approved by FDA. Note: The ability to promote a new medicine to the public can be restricted by FDA if the medicine has significant safety issues.

8. FDA approval would achieve the goal of making psychedelic medicines legal, albeit available only through a prescription.

9. The quality of a new medicine would be assured after FDA approval. A major focus of regulatory agencies is the quality of medicines. Western regulatory agencies (e.g., the FDA, the European Medicines Agency, and Health Canada) set high manufacturing standards so that patients know that these dosage forms provide the dose indicated, release the medicine in a predictable and reproducible way, have few contaminants, and have known stability.

10. MDMA and psilocybin are being developed for use

with psychotherapy administered by trained psychotherapists. The psychedelic research community recognizes the need for individuals using psychedelics to be accompanied by guides, sitters, or therapists. In the future, as the total number of patients using psychedelics increases, sponsors may work with the FDA to expand or modify the approach to include group therapy, for example. Any such changes would require FDA approval of clinical trials and positive outcomes in the trials.

11. FDA approval often leads to expedited global regulatory approvals. Together, the sponsor's NDA and the FDA's approval documents provide the core materials to support subsequent submissions and regulatory approvals around the world. Every regulatory agency asks for the regulatory approval history in other countries and an FDA approval is a valuable and strategic early asset.

12. Rescheduling of psychedelic medicines, although the purview of the DEA, will require FDA approval. Because Schedule 1 classification states these chemicals have "no currently accepted medical use and a high potential for abuse [harm]," it is incumbent on the sponsor to prove efficacy and safety before rescheduling may occur. FDA approval would be based upon the demonstration of at least some human efficacy and reasonable safety in select conditions (risk-benefit assessment).

13. FDA approval would likely open up new research avenues and NIH funding. FDA approval, accompanied by rescheduling, would enable academics and research institutes access to quality medicine for research purposes and potential funding from traditional U.S. government sources. Scientific and clinical research by others would result in publications and potential media reporting, expanding knowledge of these modalities.

14. The FDA approval process is a partnership between the sponsor and the U.S. government. Subsequent relationships with other government agencies such as the Department of Defense (DoD) or Veterans Administration (VA) system are thereby facilitated.

15. The FDA provides a path that allows for some medicines to convert from prescription-only status to over-the-counter (OTC) status. This has been accomplished for some antihistamines and vaginal antifungals, for example. Note: One of the requirements for these medicines is that a healthcare provider is not required for safe and effective use of the medicine; psychedelic medicines will require trained psychotherapists. Nevertheless, the FDA's prescription-to-OTC switch pathway demonstrates that the FDA is open to demedicalization of some products over time.

There are some down sides of the FDA path to legal access, such as that this path requires about a decade, costs tens or hundreds of millions of dollars, and requires tremendous effort by a large interdisciplinary team of experienced professionals. One could argue that the FDA path also elevates the cost of access. The specific business model and corporate structure of each company (MAPS is a non-profit) have significant impact on final drug pricing and therefore access, unless specific access programs are developed.

The goals of a pharmaceutical company developing psychedelic medicines for psychiatric disorders are to:

- Provide patients with new, safe and effective, high quality treatment options
- Provide new therapeutics to assist psychotherapists in the treatment of patients
- Offer prescribers new, safe, and effective treatment options
- Provide insurance companies the data they need to justify paying for new therapies
- Produce the evidence necessary to reschedule psychedelic medicines
- Create legal pathways for use of psychedelic medicines

The FDA path of new drug development is long, challenging, and expensive, but an FDA approval assists a pharmaceutical company in achieving all of these goals.

Just as landmark buildings and bridges are legacies of architects, a few medicines become legacies of pharmaceutical scientists and professionals. Think of the Empire State Building or the Golden Gate Bridge. Buildings, bridges, and medicines each require considerable time, money, technical expertise, and regulatory engagement. The finest buildings provide comfort and protection with elegance, for decades or centuries. Likewise, medicines that are strategically developed with thoughtful consideration and anticipation of future use can be highly valued and enduring. Consider penicillin, insulin, or the polio vaccine. The intention and hope of the psychedelic community is for the investigational psychedelic medicines currently under development to eventually offer a similar legacy of benefit to humanity. The FDA is a pivotal member of, and key contributor to, our community's efforts to build a bridge for psychedelic medicines to cross into mainstream medicine.

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Psychedelic Medicalization: How Do We Get It Right?

GREG KEARNS

While much of the clinical research has focused on the impact of psychedelic medicines on the individual, many in the psychedelic community understand the deep healing and growth that can occur when the medicines are used with intention in a safe and supportive group environment.

As clinical trials for the use of medicines like MDMA and psilocybin in psychedelic-assisted psychotherapy (PAT) continue to advance through the U.S. Food and Drug Administration (FDA) review and approval process, there are a number of factors to consider as we prepare for the broader adoption and integration of these therapies within the larger health care delivery system.

This article is intended to highlight ways in which stakeholders in the psychedelic community and in the existing U.S. healthcare system can and should collaborate to support the successful adoption and implementation of PAT in communities around the country. While we will acknowledge some of the concerns about the medicalization of psychedelics– we will focus our attention principally on considerations that should help ensure maximum benefit is derived from the medicines, with a particular focus on access, education and treatment of the whole person.

I think we in the psychedelic community can agree that the current U.S. healthcare system does not sufficiently meet the needs of all people. Given that today's system does not enable equal access and affordability for all, the psychedelic community has very valid concerns when considering poor or marginalized populations who might stand to benefit significantly from psychedelic medicines may be prevented from accessing them for lack of an ability to pay.

The U.S. healthcare system is complex; difficult to navigate; inefficient to administer; lacking in price transparency; and so expensive that even insured patients run the risk of potentially finding themselves drowning in medical debt. It is a system that leaves nearly 28 million people uninsured, creating major barriers to accessing care (Tolbert, et.al., 2019). Despite per capita spending that is nearly twice the average of other wealthy, developed countries, the U.S. system does not lead to better health outcomes, and in some common health metrics like life expectancy, infant mortality and unmanaged diabetes, actually performs worse ("How does the U.S. healthcare system compare", 2019).

So why should the psychedelic community work towards integration with the healthcare system for the delivery of PAT?

If we adopt the World Health Organization's definition of health as "a state of complete physical, mental and social well-being," it will be imperative that we introduce PAT as part of a broader, tightly coordinated continuum of services that also holistically addresses the physical and social needs of individuals. Recognizing that psychedelics are not a panacea, the following sections are intended to identify ways in which partnership and collaboration with existing healthcare service and community-based providers could not only lead to greater overall health of patients, but also play a significant role in transforming our broken delivery system.

Considerations for Insurance Model Design

One cannot begin a conversation about access to healthcare services without

first addressing the issue of insurance coverage. According to a 2014 study published in JAMA Psychiatry, only about 55% of psychiatrists accept private or government-sponsored insurance. This is in comparison to an average of 89% for all health care professionals (Bishop, et.al., 2014). It is quite common to find psychologists and other mental health providers that do not accept insurance – a factor that is largely understandable given that, according to the American Psychological Association, many insurance companies have not increased reimbursement rates for 10 or even 20 years despite rising administrative costs ("Does Your Insurance Cover", n.d.).

Given the significant time commitment (and therefore costs) involved in the delivery of PAT, it is possible that the only way millions of people will be able to gain access to the medicines is if they have insurance coverage that actually covers the costs of the therapies. Of course, it will be imperative that insurance models sufficiently reimburse PAT providers at rates that will incentivize them to participate as in-network providers for any given plan, while also ensuring efficient, non-cumbersome administration systems for providers to submit claims and receive payment.

As insurance models are designed to cover PAT, stakeholders should consider the comprehensive cost benefit analysis of the impact of the therapies to, in turn, justify the development of sufficient reimbursement rates that will be attractive to and accepted by providers. Today, mental health and substance use disorders are among the top ten leading causes of death in the U.S.; the leading cause of years lost to disability; and the leading cause of disease burden (Kamal, 2017). In 2020, annual spending on Mental and Substance Use Disorders is projected to total $280.5 billion (SAMHSA, 2014).

This, however, only paints a portion of the picture. People with mental and substance use disorders are more likely to have untreated and preventable chronic illnesses like hypertension, diabetes, obesity and cardiovascular diseases – increasing the likelihood that they may die decades earlier than the average person not to mention the high costs in treating them ("What is Integrated care?", n.d.). National health care costs for chronic diseases totaled $1.1 trillion in 2016; and when lost economic productivity is included, the total economic impact was $3.7 trillion (Waters and Graf, 2018).

Thus, recognizing the promising research results that we are seeing in the treatment of mental and substance use disorders with psychedelic medicines, insurance model design needs to account for improvements that occur in both the mental and physical health of patients. This will require tracking reductions in total health care utilization costs across the full continuum of health care services, in addition to improvements in both mental and physical health outcomes.

Recognizing the improvements and cost reductions for any given patient will likely manifest over multiple years, we should anticipate challenges from payers to taking this long-term view, however. Given the turnover that payers experience as beneficiaries switch insurance carriers from one year to the next (e.g. with job changes, etc.), payers may push back on covering the expense for PAT if they run the risk of not recognizing cost savings. Alas – we must not shy away from the negotiations as we advocate for adequate coverage of mental health benefits for all.

Care beyond the healthcare setting

Providers of PAT should be aware of the valuable roles that health care systems (particularly those that operate as not-for-profit, tax-exempt systems) can play for their patients that go far beyond the treatment of physical health issues.

Following the passage of the Affordable Care Act in 2010, tax-exempt hospital organizations are required to conduct a Community Health Needs Assessment (CHNA)

every three years (IRS, 2019). The CHNA is a systematic, data-driven approach to identifying barriers and gaps in services and resources that improve the health and well-being of community residents. These comprehensive assessments typically evaluate the social determinants of health (SDoH) – factors that include availability and access to resources such as safe and affordable housing; healthy food; educational, economic and job opportunities; transportation; public safety; and social support systems. Data has demonstrated these SDoH often contribute more to a person's health than clinical care, so it is critical to focus on these influencers of health as well.

Tax-exempt hospitals and health systems are required to develop implementation strategies that describe how they plan to address the health needs identified during the CHNA process. In developing these plans, they often find themselves engaging and coordinating with other community stakeholders (city and state health departments; housing, food and educational providers; churches and other community-based organizations; etc.) to address the needs identified in the CHNA.

As we work to ensure access to PAT for poor and marginalized populations in an effort to support their mental, emotional and spiritual health needs, PAT providers would be wise to build collaborative relationships with their local health systems that will, in turn, facilitate access to services that also meet their patients' physical and social needs. These collaborative relationships may prove to be crucial to achieving and sustaining optimal outcomes from PAT for the most vulnerable in our society.

Diversity and inclusivity expert Ariel Vegosen also reminds us that another crucial factor in ensuring optimal outcomes from PAT for marginalized populations is the need for sufficient numbers of trained therapists who understand the specialized needs of these communities – including people of color, queer, trans and any community that is not represented in the dominant paradigm (Vegosen, 2019). Recognizing that broader plans for the training of sufficient numbers of therapists to meet the expected demand for PAT is an important topic – for purposes of this article we will focus discussion of training and education on other key stakeholders.

Educating the Mainstream

Despite growing attention in recent years, psychedelic medicines still carry significant stigma that is deeply rooted in moral, religious and cultural views of many in our society. To overcome this stigma, there is a need to develop a comprehensive array of educational materials with messages tailored for a variety of audiences – including other health care practitioners, administrators, payers, patients, government leaders, religious and spiritual leaders, and the community at large. This will be an incredibly important step requiring many efforts and time to fully re-educate.

At the very least, educational materials should include information on the definition of psychedelics; their history; an overview of how PAT works; key facts on safety and efficacy; and information on potential risk factors, side effects, and any potential for abuse. Certain audiences might also benefit from a section focused on dispelling myths or misinformation.

The time to develop and disseminate these educational materials is now. Given the pace at which decriminalization efforts are progressing in communities across the country, and the substantial increased attention that psychedelic medicines are receiving in the mainstream media, more and more people are finding their way to the medicines both inside and outside of the U.S., mostly via underground channels. In an effort to support harm reduction, health systems can and should take an active role in supporting their communities by assisting in the dissemination of educational materials and preparing their workforces to understand where to go to retrieve reliable information to share with their patients. Access to information is as critical to access to the treatments.

It will be especially important to develop detailed education that can be shared broadly with members of the medical and mental health professional communities as it is likely to become increasingly common for patients to approach health care professionals asking about the safety and efficacy of psychedelic medicines. Providers need to be equipped with information to share with patients who may have certain health conditions (e.g. cardiovascular, neurological or psychiatric conditions) and are interested in seeking out a psychedelic experience.

Recognizing that decriminalization efforts are occurring in parallel to efforts to advance the delivery of psychedelic medicines under medical models, it will be important for these movements to stay in close concert with each other as they each have potential to bring about substantial transformation and healing in communities throughout the country. As the psychedelic renaissance continues to play out, it is likely that individuals will have a variety of options by which to seek out psychedelic experiences – both inside and outside of the healthcare system. Community members will benefit from information that allows them to distinguish between their options so they

can determine which is best for their personal circumstances.

Integrative Healing Models

As we begin structuring the PAT delivery system, there are concerns that medical models will neglect important aspects of the psychedelic experience that one may find in non-medical settings. For instance: is there room for spiritual practice (e.g. ritual and ceremony) to be incorporated into health care offerings? While there is precedent for the incorporation of spirituality in health care, spiritual practices with patients are most often reserved for pastoral care staff, clergy, and hospice and palliative care practitioners. Recognizing that psychedelic medicines are known to occasion mystical experiences that have lasting and meaningful spiritual impacts (Griffiths, et.al., 2006), it seems important that patients in a health care setting at least be given the option to approach the therapy in the context of a spiritual practice, while also ensuring that providers are adequately prepared to support them through the experience.

Other aspects of traditional ceremony that should be considered by the health care community include the opportunity for patients to experience interpersonal connection and learning by seeking PAT in a group setting. While much of the clinical research has focused on the impact of psychedelic medicines on the individual, many in the psychedelic community understand the deep healing and growth that can occur when the medicines are used with intention in a safe and supportive group environment. It is worth acknowledging that there is precedent for group therapy offerings in health care – particularly in the context of treatment for mental and substance use disorders, as well as through group education and support for the management of certain chronic diseases such as diabetes. Providing an option for group PAT sessions could not only serve to reduce the cost of treatment by creating efficiencies in the delivery system, it could also support the restoration of social connections within communities- a promising proposition in today's digital age of social isolation and disconnection.

As psychedelic medicines are ushered into the health care system, it will be especially interesting to see which other integrative wellness modalities (yoga, meditation, breath work, acupuncture, etc.) are embraced more fully. It is my personal hope that the introduction of PAT, delivered in coordination with other primary and preventative health services, may be what it takes for us to finally transform the U.S. health care system from one that is more focused on the treatment of disease, to one that is focused on holistic wellness and the advancement of thriving individuals and communities.

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The Pollination Approach to Delivering Psychedelic-Assisted Mental Healthcare

BENNET A. ZELNER[1,2]

In this article I outline a novel economic approach for delivering psychedelic-assisted mental healthcare, the Pollination Approach. The Pollination Approach focuses on the intrinsically interdependent production of individual and community wellness. It contrasts sharply with the current pharmaceutical-centered approach to mental healthcare, which focuses on the management of symptoms rather than the production of wellness, and reflects divisive economic conceptions that have contributed to rising rates of mental distress.

In the next section I describe the economic conceptions animating the pharmaceutical approach. In the following section I discuss the relationship among these conceptions, the disruption of community social and economic systems, and mental health. In the third section I present the Pollination Approach, describing how all of its facets–the design of treatment sites, the conduct of integration activities, the configuration of ownership and decision-making structures, and the financial structures used to create and allocate shared prosperity–promote the production of wellness through the renewal and recirculation of community resources.

The Pharmaceutical Approach

The pharmaceutical approach to mental healthcare portrays mental disorders as clusters of biologically-based symptoms susceptible to being treated primarily with drugs, much like a physical disease. This approach has benefited drug manufacturers, whose U.S. revenues from the sale of psychiatric drugs rose from $2.8 billion in 1987 (the year in which Prozac was introduced) to $34 billion in 2010. [3,4] Yet despite the fact that antidepressants alone represent the most prescribed category of pharmaceuticals among the U.S. non-geriatric adult population,[5] American mental health has reached a crisis state. The national suicide rate has increased to its greatest level in 50 years and continues to rise.[6] The U.S. also has the highest rate of death from mental health and substance abuse disorders among peer countries.[7]

The dire state of our collective mental health is linked to widely-held economic conceptions that have contributed to the pharmaceutical approach's financial profitability. The first such conception is that of economic individualism. When psychiatric drugs were first introduced in the 1950s, patients were viewed as socially embedded individuals whose mental illness reflected both psychosocial and biological factors, and for whom pharmaceutical treatment was considered an adjunct to psychological and social remedies. Pharmaceutical manufacturers actively promoted the reconceptualization of mental illness as a constellation of biologically-based symptoms, and of patients as atomized consumers devoid of psychological and social context. These shifts, which leveraged an ascendant cultural view of people as individualistic market participants, promoted the long-term consumption of medication as the primary modality for treating mental distress. [8,9]

The second widely-held economic conception that has contributed to the pharmaceutical approach's financial profitability is the belief that unconstrained market processes produce the best economic outcomes. American drug manufacturers have leveraged and promoted this belief, sponsoring numerous economic studies intended to convince policymakers that a hands-off approach to the economic regulation of the industry would maximize innovation, with high drug prices representing the cost of progress.[10] Prescription drug spending in the U.S. has increased dramatically as a result, rising more than 1,800% between 1980 and 2015 and outpacing that in other developed countries.[11]

The Disruption of Community Systems and the Impairment of Mental Health

The economic conceptions animating the pharmaceutical approach have impaired our collective mental health through their influence on an expanding array of policies and practices over the past four decades. Market competition is now widely regarded as the best and most natural organizing principle for all human relations,[12] and economic individualism has come to represent not just independence and self-reliance, but the prioritization of self over relationships, and of individual success over the common good.[13]

The reason that these divisive conceptions have been so damaging is that they conflict with basic human nature. We possess an evolutionary drive to connect and cooperate with each other because doing so helped our ancestors survive.[14] The primary structures in which we have traditionally expressed and fulfilled this drive are residential communities, complex systems of people and resources linked in interdependent social, economic, ecological, and other interrelated systems. As in nature, healthy systems promote individual and collective well-being. However, the ascent of the economic conceptions discussed above has disrupted the functioning of community systems.

First consider community social systems. Americans no longer come together as they once did: They now have fewer interactions with friends and family, and are less likely to belong

to organizations that provide opportunities for social interaction.[15, 16] This crisis of connection[17] is reflected in a loneliness epidemic[18] that has fueled rising rates of depression, anxiety, and addiction.[19]

Paralleling the crisis of connection in social systems is a crisis of extraction in economic systems. In localities throughout the U.S., outposts of large corporations have displaced locally owned businesses. As a result, locally produced income is extracted by distant shareholders rather than being recirculated within the community to fund local (re)investment, contributing to economic inequality. Further, the extraction of decision-making authority by remote corporate managers with no direct connection to local ecosystems results in the unsustainable use of local resources, depleting the human, natural, and other forms of productive capital available to provision ongoing local economic activity.

The crises of disconnection and extraction in community social and economic systems have fueled rising rates of disorders such as depression and addiction. Disconnection is a core feature of depression 20 and addiction represents an adaptive response to disconnection.[21] Economic stress increases vulnerability to both conditions.[22, 23] Large-scale statistical analysis supports these ideas, demonstrating that countries with greater income inequality – reflecting the promulgation of policies and practices embodying the individual-centric, hyper-competitive economic conceptions discussed above–exhibit higher rates of depression and illegal drug use (a proxy for addiction).[24] A comprehensive approach to the delivery of mental healthcare must counteract these divisive conceptions' damaging psychological influence by facilitating the repair of community systems, complementing and contributing to individual healing.

The Pollination Approach

The Pollination Approach to delivering mental healthcare recognizes the mutually reinforcing relationship between individual and collective wellness. It is rooted in the ecological principle that the production of wellness depends on the continual renewal and recirculation of system resources (versus their extraction or depletion). [25] Pollinator organizations facilitate the renewal and recirculation of resources in community systems as pollinator organisms do in natural systems.[26]

Community Reconnection

The delivery of psychedelic-assisted mental healthcare under the Pollination Approach facilitates, first and foremost, the renewal and recirculation of human resources. Psychedelic medicines possess a documented ability to foster connection, and the shift from disconnection to connection represents a key mechanism in the healing process.[27] The Pollination Approach harnesses this shift by (re)connecting patients to social, economic, and other community systems, contributing to individual healing and the revitalization of the systems themselves.

Treatment sites enacting the Pollination Approach function as wellness centers, gathering places where community members may participate in a range of healing and community-building activities in addition to psychedelic-assisted therapy. Explicit reconnection activities for those who have undergone therapy include group integration sessions as well as community reintegration programs conducted in partnership with local organizations, such as businesses, cultural institutions, civic organizations, religious organizations, and others. These organizations may also serve as points of access, especially in communities where psychedelic medicines are viewed with skepticism.

Local Wisdom

The identification of specific partner organizations and adaptation of other delivery-of-care elements to community needs and customs are undertaken in close consultation with local wisdom keepers. Community elders, social workers, ER workers, spiritual leaders, union representatives, local business owners, and others may all possess distinctive knowledge of common trauma patterns, recirculatory gaps in community systems, and sources of resource depletion and extraction. The integration of such wisdom with more generalized knowledge of therapeutic techniques and psychedelic medicines optimizes the delivery of care in a given community.

Governance Principles

The ownership and governance of wellness centers under the Pollination Approach also support the production of wellness through the renewal and recirculation of community resources. Two core principles inform choices in this area. The first is stakeholder inclusivity, the notion that an organization should operate for the explicit benefit of its stakeholder groups including customers, employees, community members, and others. The principle of stakeholder inclusivity naturally supports the inherently inclusive process of wellness production.

The principle of stakeholder inclusivity contrasts sharply with the creed of shareholder primacy guiding most corporate decision-making. The latter ascended in conjunction with the divisive economic conceptions discussed above. It holds that the sole purpose of a corporation is to serve the interests of shareholders by maximizing financial profits, as reflected in the pharmaceutical approach's emphasis on managing symptoms. The production of wellness is less lucrative for pharmaceutical shareholders because it reduces the need for ongoing medical intervention.

The second principle informing the ownership and governance of wellness centers under the Pollination Approach is distributed local ownership. Local ownership supports the health of community economic systems by promoting the recirculation of income, creating an economic multiplier effect from the local (re)investment that such recirculation enables. Local ownership also promotes the sustainable use of a community's human, natural, and other productive resources because owners and managers participate directly in the local ecosystem, attuning them to local conditions. Distributed local ownership–ownership that is spread widely among local community members

from different stakeholder groups–amplifies these benefits by dispersing financial returns and diversifying the information sources contributing to decision-making. Collaborative ties between wellness centers and non-local organizations in the psychedelic-assisted mental healthcare ecosystem, such as MAPS and MAPS PBC, complement local ownership by promoting the circulation of global resources, such as knowledge gained through experiential learning.

Cooperative Organization

The organizational form that most naturally supports the principles of stakeholder inclusivity and distributed local ownership is a cooperative structure, which distributes ownership and control among the members of stakeholder groups such as workers or customers. [28] Treatment sites enacting the Pollination Approach may distribute ownership and control most widely by adopting a multi-stakeholder cooperative structure, in which the cooperative's owners include members of both of these groups as well as other community stakeholders.

Cooperatives are typically organized as corporations or LLCs, legal forms that distribute the financial returns from community wellness centers among stakeholder-owners. Though non-profit organizations are more commonly associated with the production of social returns, existing legal classifications do not readily accommodate entities producing both types of return because they reflect an ingrained assumption that the two are incompatible.

An organization's legal form also does not by itself guarantee a given behavior pattern. For example, some non-profit hospitals have been criticized for accumulating large cash reserves that are not being used to benefit the community,[29] while the Business Roundtable–an association of corporate CEOs that has traditionally endorsed shareholder primacy–recently proclaimed that a corporation's purpose is to promote "an economy that serves all Americans."[30] The extent to which a wellness center's specific incentive and decision-making structures support the mission objectives and governance principles discussed above is thus more consequential than its legal form.

Financial Structures for Sharing Prosperity

As discussed above, multi-stakeholder cooperative organization enables community stakeholders to share in the financial returns generated by local wellness centers enacting the Pollination Approach. Symmetrically, wellness centers may finance their ongoing operations by sharing in the economic prosperity they enable for patients and communities. Mechanisms such as deferred payment plans linked to patients' post-treatment income, employer-sponsored insurance coverage of consciousness-focused healthcare, and government grant funding based on reduced public welfare spending facilitate the collection of revenues from the provision of psychedelic-assisted therapy. Similarly, the performance of contract research for entities such as MAPS, and the provision of therapy sessions and apprenticeships to trainees in external credentialing programs, create revenues and control costs by tapping into shared value co-created with other participants in the psychedelic-assisted mental healthcare ecosystem.

Financial funders play a critical role in this ecosystem. The equitable sharing of jointly enabled prosperity between funders and other stakeholders requires innovation because traditional funding structures reflect the dichotomy between the production of social and economic returns embodied in the legal distinction between non-profit and for-profit enterprise. On the one hand, philanthropic funders may be unwilling to contribute to wellness centers organized as for-profit entities due to the ingrained belief that non-profits specialize in the production of social returns, an assumption that is reinforced by the favorable tax treatment of non-profit donations under the U.S. federal tax code. On the other hand, conventional venture-style mechanisms for the external funding of for-profit startups focus on the production of concentrated financial returns for the benefit of shareholders who retain a long-term equity stake, [31] which conflicts with the governance principles discussed above. Wellness centers funded with such mechanisms would be deterred from generating wider social and economic returns through the renewal and recirculation of community resources, and also from engaging in the prototyping necessary for continual learning.

Financing mechanisms that transcend these institutionalized trade-offs are currently under development. One example is a structure that builds on recent innovations in venture capital financing intended to align the long-term incentives of founders and funders. It works by paying initial funders a capped return drawn from wellness centers' operating cash flows; transferring funders' original equity claim to a stakeholder pool; and distributing or selling shares in this pool to workers, patients, and members of other local stakeholder groups.[32] Ultimately, these local owners would go on to pollinate additional local economic activity by investing their financial dividends (and perhaps their knowledge, labor, and social capital) into other community enterprises.

Conclusion

Psychedelic-assisted mental healthcare holds revolutionary potential for treating various forms of mental distress. In order to fully realize this potential, it should be delivered using an equally revolutionary economic approach. The Pollination Approach outlined above seeks to meet this aspiration by serving as more than a conventional business model, and as a source of healing itself.

NOTES

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2. I am grateful to many people who have contributed to the ideas in this article. Special thanks go to David Armistead, Daniel Lawhon, and Katharine Milano for offering invaluable insights and suggestions; and to Stephen Torrence for providing excellent research assistance.

3. Frank et al., 2005
4. Smith, 2012
5. Martin et al., 2019

6. Koons, 2019
7. Kamal, 2017
8. This paragraph draws on Braslow (2013).
9. Psychiatric medication is no doubt effective in some cases, but the widespread use of antidepressants – the most prescribed category of drug for the US non-geriatric adult population – does not align with data on their efficacy. The most comprehensive metanalysis of prior research to date indicated modest effects for relatively few groups (Carroll, 2018; Cipriani et al., 2018).
10. Zaitchik, 2018
11. Sarnak et al., 2017
12. Monbiot, 2016
13. Way et al., 2018
14. Hawkley & Cacioppo, 2010
15. Putnam, 2000
16. McPherson et al., 2006
17. Way et al., 2018
18. Cigna, 2018
19. Hawkley & Cacioppo, 2010
20. Karp, 2017
21. Alexander, 2010
22. Shaw et al., 2011
23. Sturgeon et al., 2016
24. Wilkinson & Pickett, 2009
25. Regenesis Group, 2016
26. Michael Shuman (2015) introduced the term "pollinator" in the field of community economics.
27. Watts et al., 2017
28. Schneider, 2018
29. Jaquis, 2016
30. Business Roundtable, 2019
31. Brandel et al. 2017
32. Thanks to Daniel Lawhon for this suggestion.

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A North Star for the Emerging Psychedelics Industry

LIANA SANANDA GILLOOLY
KAT CONOUR

The field of psychedelics is rapidly expanding, with a Cambrian explosion of new entities forming to advance these powerful tools into mainstream use. Many willing hands, eager minds, and open hearts from every background are receiving the calling to serve this mission. They are drawn by the power of these medicines, the possibility to create social change, and what promises to be a massive global market.

For the past century, the field of psychedelics has been marked by cooperation over competition, including the open sharing of knowledge, methods, and materials. Now, this movement is grappling with what it means to birth a new industry and field of medicine, not in the sanctity of the underground or lab, but into the very system that has contributed to the underlying traumas psychedelics so effectively treat. The side effects of the dominant operating systems are being felt across the world, as income and racial inequality, environmental degradation, climate crisis, mass consumption, and diseases of despair all continue to trend upward, unmitigated. Capitalism marches on, these symptoms rippling outward in its wake.

[N]o one wants to put their life's work into creating an organization that ends up doing harm, regardless of the profits to be made along the way.

The many risks of this moment draw our attention—our story, "We Will Call It Pala" (aurynproject.org/pala), attempts to bring some of them to life. Yet it is inevitable that capitalism, with all its externalities, is the setting into which psychedelic healing will be delivered to the world. This process will not wait for the legacy community's permission. Therefore it is not a question of if, but of how.

The model of "business as usual" is all too familiar. To see how it intersects with psychedelics, we need look no further than the giant at our doorstep: major pharmaceuticals. Last year Spravato, a mystical experience-avoiding, antidepressant ketamine nasal spray, patented by a Johnson & Johnson subsidiary, received FDA approval. A dose of generic ketamine is roughly $1.50-$2.00. A dose of Spravato can be upwards of $750. There is no evidence that Spravato is more effective compared to the generic. And yet, it is 50,000% more expensive, and is intended for long-term use.

The organizations forming today will build the infrastructure which, three to five years from now, will be delivering psychedelic medicines to the world. The footprints they leave along the way— their consciousness and intention, their methods and models, the blind spots and traumas brought by their leaders and perpetuated by the organizations—will grow in impact as they scale. Five years from now, these patterns will be etched into grooves. They will be the default mode network of the entire field.

How the tension is handled between the need to rapidly scale solutions to address the millions of people suffering, and the friction that may be required to responsibly expand access to these substances, will define this emergent field.

This begs a question: What if we could collectively embody the insights and values the medicines provide us, and build them into the entities that will deliver these medicines?

Changing capitalism itself will be like shifting the currents of an ocean—but how about shaping the way that capitalism intersects with psychedelics? At the moment, it is still only a small pond. We have a unique window of time to impact how commercialization emerges. This is our project at North Star: to bring together the stakeholders in the psychedelic movement to generate a culture of responsibility, co-create a code of ethics, and collectively determine guiding principles for the commercialization of psychedelics. North Star is an ethical trade association for the psychedelic field, incubated and accelerated by Auryn Project.

We trust in good faith that no one wants to put their life's work into creating an organization that ends up doing harm, regardless of the profits to be made along the way. What we need is a Hippocratic oath for psychedelic business. Here "do no harm" means more than ensuring a safe trip. North Star has put together a worksheet that organizations, entrepreneurs, or investors can review to mitigate the risks unique to the field. This is especially important if they are structured to create a shareholder return, and if the plan for that is built upon the promise

of an exit. Here good intention will only go so far. The business model creates the set and setting for the company. Great care must be taken to employ structures that increase the potential of beneficial outcomes, and decrease the potential for harm.

North Star is maintaining a compendium of business and economic models that can be applied to organizations forming in the psychedelic field. Despite the hype, it remains to be seen how applicable the Silicon Valley-style "high-risk, high-reward" venture capital funding models will be to this field. The returns and outcomes expectations are likely to be too aggressive and mis-aligned with a sensible and healthy growth path for psychedelic care providers. Instead, there are alternative funding models that may be more appropriate to seed businesses in this field, such as steady yield-oriented structures that Real Estate Investment Trusts (REITs) adopt for brick-and-mortar operations, or Community Development Financial Institutions (CDFIs), credit unions and co-ops designed for greater financial inclusivity. There is a growing movement in impact investing, with $228 billion dollars invested into the sector, which is reported to have doubled from 2017 to 2018. Companies everywhere are taking up the banner of Corporate Social Responsibility, with varying degrees of effectiveness. Beyond the existing systems, there are also exciting new progressive corporate and investment models worth considering, inspired by efforts in parallel movements from Regenerative Agriculture to Impact Investing. Some noteworthy examples include:

1. B Corporation and Public Benefit Corporations (PBCs): a Certified B Corporation is a private certification issued to for-profit companies by B Lab. B Corp certification is an example of how for-profit companies can establish regenerative and charitable principles within their corporate charters to drive positive impact. MAPS Public Benefit Corporation is an excellent case study on how a non-profit can establish revenue generating and profitable business units leading to a more self-sustaining model for NGOs to thrive outside of donations alone (e.g. non-profits leveraging business models and practices of for-profits for healthier financial viability)

2. Crowdfunding and Micro-Lending Networks: Steward provides an inspiring example of a crowdfunding platform to support independent farmers in regenerative agriculture. Applying the Steward model to this field could look like patient, reasonable loan terms extended to fund independent, local clinics, and supporting them with a full software suite of tools for booking, billing, reporting, accounting, etc., that would allow clinicians to focus on care without becoming experts in business operations. Kiva is a microlending platform set up as a non-profit for lenders to perpetually re-loan their capital as each loan gets repaid. A similar offering in the psychedelic medicine field could allow for "evergreen" business loans on fair and reasonable terms to therapists and startup clinics, while also providing accountability and transparency on use of proceeds and milestones. Furthermore, this could also allow DAFs and other philanthropic capital pools to achieve high-leverage on the same amount of donated funds—e.g., the re-lending of the same donation to multiple clinics over time.

3. Additional practices and models that promote long term impact and center ethics:

- Capped return investment vehicles (e.g. OpenAI)
- Funds that donate portions of profits and carried interest to support non-profit efforts that benefit the community (e.g. Lionheart Ventures)
- Cooperative Funds that provide financial support to co-ops (e.g. Cooperative Fund of New England)
- Conscious investors formally incorporating values and ethics into their investment terms, e.g. Obvious Ventures' World-Positive Term Sheet for early-stage tech startup investment rounds
- Inclusive stakeholder capitalism such as Joon Yun's "Interdependent Capitalism"
- Founder and Operator collectives to fund other founders in a specific field and geography (e.g. The Fund NY)
- Socially Responsible Investments (SRI) using ESG measurements (Environmental, Social and Governance): a class of investments that seek positive returns and long term impact on society, environment, and business outcomes.
- Commitments from businesses & entrepreneurs to empower altruism:
- 1% for the Planet: committing at least 1% of sales to funding environmental causes.
- Salesforce's 1-1-1 pledge model: giving 1% of product, 1% of equity and 1% of employees' time to philanthropic causes and the non-profit sector.
- Founder's Pledge: entrepreneurs make a binding pledge to donate a chosen percentage of personal proceeds at the point of liquidity.

4. Metrics, scorecards, and tools for measuring a company's impact:

- B Labs Impact Assessment - a comprehensive tool to measure a company's impact on its workers, community, customers, and environment.
- IRIS Measure – a set of standardized metrics that can be used to measure and describe the social, environmental, and financial performance of organizations and businesses receiving impact investment.
- JUST Scorecard - a voluntary disclosure tool to help organizations optimize policies that improve social equity
- SDG Compass: Maps existing indicators against the UN Sustainable Development to help organizations report their contributions to SDGs. You can also use B Labs' SDG Action Manager tool, found online at bimpactassessment.net.

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North Star is co-creating an ethical pledge for people and organizations operating in the psychedelic field, drafted through an intensive process of inclusive stakeholding. The North Star team is currently hosting a series of learning conversations with healthcare professionals, therapists, clinicians, community builders, wisdom keepers, elders, activists, policy makers, philanthropists, entrepreneurs, investors, and patients to shape this pledge and the direction of North Star's work. The pledge, with initial signatories, will be available for signing on April 15th. We welcome your input at northstar.guide..

Our movement, and our society, has a pattern of not centering marginalized voices. The opportunity and urgency of the commercial era of psychedelics creates a pressure that makes embodying our values even more difficult. Good intentions are not enough, considerate action is required. For that reason, we strive to not only bring people to the table—to not only listen to these voices—but to incorporate their wisdom into this work. North Star has created a living set of principles to guide our action, reflecting the insights of many elders, mentors and influences. These principles orient our action as a team, and we extend an open invitation to use them if they may be valuable.

Principle #1: As Within, So Without
How we are internally determines how we act externally, the quality of work we do, and the impact we will make. If we are to participate in this field mindfully, we must be continuously engaged in our own personal inquiry and rigorous self-work.

Principle #2: The Process is the Outcome
How we do something is as important as what we are trying to do. This means we must model the world we seek to create in the actions we take to get there.

Principle #3: Move at the Speed of Trust
Trust is essential for partnership. It is built through authenticity, vulnerability, and deep listening. This process calls us to slow down to build the relationships that truly drive change.

Principle #4: Inclusive Interdependence and Decentralization
Each individual and entity must recognize themselves as part of a larger system, whose health depends on the health of all.

Authority is rooted in collective will. Special attention must be paid to ensure that all voices and perspectives are sought, listened to, and empowered to make change.

Principle #5: Lean into Tension as an Opportunity for Growth and Learning
Each person brings their own lineage, shadow, and biases into this work, which will inevitably lead to tension. These tensions should be received as an opportunity for growth and learning. The goal is to open ourselves up to understanding: the widest perspective possible.

Principle #6: Honor and Share Collective Wisdom for the Benefit of All
We commit to honoring the sources of our knowledge, and openly sharing insights that accelerate the collective learning, for the benefit of the ecosystem overall.

Principle #7: Reciprocity, Reparation, Reclamation
An unjust and unequal system has unevenly distributed trauma, resources and opportunity. The psychedelic movement stands on the shoulders of indigenous knowledge and practices, victims of the War on Drugs, visionaries, activists, and scientists who have open-sourced their work. Those who accrue wealth from this wisdom have a responsibility for understanding and repairing the harm that has been done in getting us here, and giving back to the collective.

Principle #8: Continuous Iterative Learning and Evolution
"Expertise" is a process, not an outcome. Dynamic systems demand dynamic ways of learning. We are never fully aware of our blind spots, or the facts on the ground as they evolve. As people and organizations we must actively keep ourselves on a constant learning curve, avoiding the static thinking in which growth stalls. We must constantly seek to ask better questions.

Principle #9: I am Part of Something Greater than Myself
This movement is decades old. The use of these medicines dates back millennia. Our actions impact its future. We have a responsibility to its past. We must each strive to be good members of this movement, to nurture it, and work in service of its potential. These powerful substances can spiritualize us and bring us into right relationship with nature. May we give reverence to the forces of life that flow through us, and work diligently to keep these teaching plants and molecules sacred.

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We envision a culture for the field of psychedelics guided by these principles.

To the new arrivals to the psychedelic field, we say this: Welcome. We are glad you're here. You have an essential role to play. There is so much work to do. We humbly remind you, as our elders so often remind us, that work starts with you, and with each one of us, each and every day.

To those who have dedicated their lives to laying the foundation of this field: You have the opportunity to welcome and guide this new energy, to help shape how these medicines get delivered, and to set the ethical bar high and ask that those seeking your expertise and influence meet you there. If value-holders stand on this ground, a powerful force of positive peer pressure will be generated. Together, we can create a critical mass to establish another pathway forward, beyond "business as usual."

There is a better future out there, and the era of psychedelic commercialization could help us realize it. It's up to us to do it right. Will you join us in this amazing opportunity?

Join the journey at northstar.guide.

Liana Gillooly is an accomplished activist and movement builder, who is dedicated to liberating the healing potential of psychedelics and ending the war on drugs. She is currently Development Officer at MAPS where she leads fundraising efforts. Liana is also the co-founder of Auryn Project, and founder of North Star, the first trade association for the psychedelic field, focused on the ethical stewardship of psychedelic commercialization. Liana actively advises multiple efforts in psychedelic decriminalization, drug policy reform, as well as startups, non-profits, and conferences operating in the realms of psychedelics, mental health and consciousness. Prior to MAPS, she helped grow the leading investment network for the emerging cannabis industry, The Arcview Group, where she also advocated for legalization, lobbied congress on behalf of the National Cannabis Industry Association, and supported the Marijuana Policy Project. Earlier in her career, Liana founded a visionary art gallery in Los Angeles, helped launch a non-profit providing psychedelic therapies to special forces veterans suffering from PTSD and TBI, and launched a conference bridging the realms of psychedelics and cryptocurrencies. Liana has been a featured speaker at TEDx, SXSW, Summit Series, Future Frontiers, Boom Festival, Symbiosis, Awakened Futures, and multiple documentaries and podcasts. She is trained in psychedelic peer support, death midwifery, and permaculture design, and attended Boston University where she studied International Relations. She can be treached at liana@aurynproject.org

Kat Conour, LMFT, brings her background in psychology, non-profits, philanthropy, corporate consulting and facilitation in service of empowering leaders and organizations in the field of psychedelics to turn their values and vision into aligned action. An Emergent Strategy fangirl, Kat recognizes that a movement is only as strong as the relationships and systems upon which they are built. As Executive Director of Auryn Project and co-founder of North Star, her work currently focuses on ensuring that equity, ethics, and accessibility are embedded in practice within the scaling of psychedelic medicines. Additionally, she is a ketamine-assisted psychotherapist at Sage Integrative Health and being trained by MAPS in MDMA-assisted therapy. Kat also served on the board of Threshold Foundation and Emergent Fund Advisory Council and currently sits on the Advisory Board of the Chacruna Institute for Psychedelic Plant Medicines. In a former life she was a yoga teacher, trainer and early collaborator in the development and scaling of an affordable and expertly taught yoga method called yogahour. In her free time she can be found romping in fields with her super mutt Abby Rose or sweating it all out on the dance floor. She can be reached at kat@aurynproject.org.

Expanding Ancestral Knowledge Beyond the Sale of Molecules: Iboga and Ibogaine in the Context of Psychedelic Commercialization



RICARD FAURA, PH.D
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JOSÉ CARLOS BOUSO, PH.D

From Gabon to all corners of the globe, practices with iboga and ibogaine are rapidly expanding. With this expansion, several important considerations arise, particularly around what happens when two seemingly disparate worlds collide: the world of traditional healing systems and the Western world that is hopeful for solutions to the problems of addiction and social and spiritual dislocation. Like all liminal spaces, this encounter is not always comfortable. ICEERS (the International Center for Ethnobotanical Education, Research and Service) has been working within this space for over a decade and we propose that it is full of opportunity—the opportunity to move beyond seeing traditional psychoactive plant medicines as molecules commodities and towards a sophisticated engagement with bio-cultural knowledge systems in service to a true revolution in mental health care.

Background

Tabernanthe iboga, or simply Iboga, is a shrub from the Apocynaceae family native to Central Africa and its root bark is considered a spiritual sacrament among the Bwiti who use it in initiatory and healing rituals. Iboga was used for centuries among Bantou communities of Gabon and was likely practiced among Pygmies in earlier times. Importantly, in its original context, iboga is considered a spiritual and community "binding" tool.

Ibogaine, an alkaloid found in Tabernanthe iboga, is being extracted for use in therapeutic and psychospiritual contexts outside of Africa. As with other psychoactive plants and fungi, such as psilocybin, these molecules are being extracted both literally and metaphorically from their original biocultural ecosystems and developed as products for the international pharmaceutical market. This phenomenon presents a clash between traditional stewardship of complex social systems and the commercialization of molecules disconnected from traditional wisdom. As with the growing interest in psychedelic pharmacology, the production and marketing of iboga and ibogaine is generally embedded within the biomedical approach that prevails in the scientific and commercial models of the Global North.

Iboga plant in Ebieng, Ogooue-Ivindo province, Gabon, 2019

Sustainability, a Growing Concern

As with other psychoactive plants, the legal context for iboga and ibogaine internationally adds complexity. It is currently illegal in 10 countries (the U.S. and nine European countries, namely, Belgium, Denmark, France, Hungary, Ireland, Italy, Norway, Switzerland, and Sweden); there are three countries where it is regulated (Australia, Israel, and Canada); and three more countries where it is legal as a prescription pharmaceutical substance, under "compassionate use," or extended access (New Zealand, South Africa, and Brazil). The most concerning issue arising from an unregulated market for both iboga and ibogaine (typically extracted from Tabernanthe iboga) is that of plant sustainability. In a recent engagement project led by ICEERS (iceers.org/ibogareport), respondents reported that iboga in the wild is on the brink

Iboga plant nursery, Woleu-Ntem province, Gabon, 2019

of being endangered, primarily due to improper harvesting and poaching. The Union for Conservation of Nature's Red List of Threatened Species has listed Tabernanthe iboga as a plant of concern, however not as endangered. Further, in February 2019, the Gabonese government halted all exports, stating concerns for the sustainability of the plant.

A recent promising development is that there are community associations are starting to cultivate iboga for sale within a regulated international market, however they are still awaiting export permits from the Government of Gabon. One such project has been initiated by the community association Ebyeng-Edzuameniene (A2E, located in a community forest in the province of Ogooue-Ivindo near Makokou) that is receiving support from the organization Blessings of the Forest.

However, despite these measures, international black-market sales are putting pressure on the plant and its ecosystems as well as on the indigenous communities who are having increasing difficulties accessing root bark. Participants in our initiative also warned about the poor reliability of many vendors, who may in fact be distributing impure products with low levels of (or no) alkaloid content, fake iboga, or iboga that has been adulterated.

Ancestral Wisdom As a Cure for Extractivist Mindsets

The opioid epidemic in North America has increased the interest in ibogaine by media and investors. Currently, ibogaine therapy is inaccessible due to cost and there is inconsistency in the quality of treatments available, resulting in risks for patients. In the West, addiction is seen through the lens of disease, overlooking its social and cultural roots. Ibogaine is presented as the "magic pill" cure for addiction, seeking to "fix" the person without regard for the illness located within social systems. Extracting ibogaine from iboga and the traditional wisdom that has held it for generations results in a significant loss, as does the extraction of ibogaine from iboga without regard for reciprocity with the peoples and ecosystems at the source. Commercialization and medicalization of psychedelics rarely take an ecosystems-based approach.

In Gabonese Bwiti traditions, rituals are enacted with the intention of creating harmony. When someone is struggling (i.e., is unwell or disconnected), the community seeks to re-integrate them. In this world view, no problem is strictly individual but rather is connected to the community in the broadest sense (which includes the natural and spirit worlds). Therefore, the community does not marginalize the community member but rather supports healing through complex collective rituals. Iboga is not at the center, but rather is part of the whole.

Hence, beyond the intrinsic value that any molecular compound present in sacred plants have, this holistic approach places the experience within a broader social and spiritual context. The result is the integration of everyone into the community, which is perhaps the greatest contribution of these generations-old approaches. This holistic view is absent in the dominant

Bwiti ceremony in Gabon. This is a Nzame Fang, which is a syncretic Bwiti-Christian rite, conducted the Ebieng community, in the Ogooue-Ivindo province, close to Makokou, Gabon, 2019

biomedical approach to the commercialization of "promising new products" within psychedelic pharmacology.

The World Health Organization's Global Mental Health (GMH) approach posits that people have the right to access evidence and human rights-based care. GMH advocates suggest that traditional practices based on community-perspectives are important in addressing growing mental illness epidemics. Yet current application of this framework seeks to apply models from the Global North to the Global South—models for mental healthcare such as the wide application of pharmaceuticals that haven't proved effective, perhaps because mental health is conceived as an individual problem originating in a person's brain.

The lack of evidence for the effectiveness of iboga and ibogaine in supporting healing has presented a tremendous barrier for how this medicine can be incorporated into models for mental health and addictions treatments. ICEERS is involved in two of the first ibogaine clinical trials (one for alcoholism and one for methadone dependency), research that provides an opportunity to explore how to situate clinical evidence within a larger framework that incorporates perspectives on community health.

Traditional practices work from a community perspective, so rather than exporting ineffective therapies, an optimal future for Global Mental Health could incorporate the wisdom from traditional healers, community-based models, and clinical research. This type of approach could also serve to shift the commodity-based approach and inform a new standard of reciprocity within business models, wherein those at the source also benefit and sustainability for the plants is ensured.

In closing, rather than narrowly focusing on molecules found in traditionally-used plants, a true revolution in mental health care may be possible if we expand our vision—looking beyond the molecules and even the plants themselves and seeing the interconnected social and cultural elements of traditional knowledge and nature and their potential for supporting individual, community, and planetary healing.

Ricard Faura holds a PhD in social psychology and a Master's Degree in social anthropology. He is an international project developer and evaluator, and an associate professor at the Open University of Catalonia (UOC). He is currently the Coordinator of the Iboga/ine Community Engagement Initiative for the International Centre for Ethnobotanical Education, Research, and Service (ICEERS), where he's been engaging with many African and International perspectives and voices to create a powerful opportunity for influencing how iboga and ibogaine are globalizing, bridging perspectives and strengthening intercultural connections between local, African stakeholders and the global iboga/ine community.

Andrea Langlois is the director of engagement at the International Centre for Ethnobotanical Education, Research, and Service (ICEERS). Andrea is passionate about dialogue, social movements, community engagement, Indigenous rights, Amazonian conservation, and plant medicine. She holds a Master's Degree in Media Studies from Concordia University in Montreal and a BA in Women's Studies from the University of Victoria. Prior to joining ICEERS, Andrea worked for over a decade in the harm reduction, drug policy, and HIV/AIDS sector. She is co-lead of the Iboga/ine Community Engagement Initiative at ICEERS.

Jose Carlos Bouso is a psychologist and has a PhD in Pharmacology. He has been the Scientific Director at International Centre for Ethnobotanical Education, Research, and Service (ICEERS) since 2012, where he oversees research on ayahuasca, ibogaine and cannabis. He is the co-Principal Investigator of the first clinical trial assessing the safety and efficacy of ibogaine in the treatment of methadone dependence. His main area of research now is studying the role of traditional medicines involving psychoactive plants through the lens of Global Mental Health.

The Commercialization of Ibogaine to Treat Substance Use Disorders and Other Psychiatric Conditions in the United States: A Doctor's View

JEFFREY D. KAMLET, M.D

While literally (and somewhat accidentally) on my way to attending the beginning of medical school, I experienced the effects of a potent plant-based medicine considered a psychedelic drug. I had an extremely positive, profound experience that was so outside the paradigm of language as to be impossible to describe. The next morning, in my naivete, I thought, "Oh my, this drug has tremendous therapeutic value as a medicine, and if everyone would take it, they would have the same experience I had, and the world would be in order." It is now over 30 years later, and I have since learnt otherwise.

Many others who have their first plant medicine experience have the same reaction and want to work with these plant medicines. Yet if these medicines are to be given in a safe, therapeutic model to treat specific diseases in the United States, they will need to be handled by those with medical credentials and expertise to administer them safely and effectively for specific conditions seen as illnesses in the U.S. medical diagnosis code book. Whatever the plant medicine, credentialed therapists, specifically trained for treating patients with specific plant medicines, will be a critical component before, after, and sometimes during the ingestion of the medicine. With this preparation, we could achieve the goal of obtaining sustainable positive results that surpass today's pharmacopeia, and bringing more joy into our patients' lives.

Every decision, career path, and patient I have treated since has been greatly affected by what I learned from that initial psychedelic journey. From the beginning of medical school, it was my hope to someday incorporate plant medicines into psychiatry and medicine in general. I coined a term for this as a young medical student: "neuropsychiatric immunology," the power a plant-based substance has to assist one's brain in healing itself. After finishing medical school and completing my residencies and additional trainings, I worked in the field of Emergency Medicine for over a decade. My journey took me far away from my original optimism of using plant medicines in the United States.

The current U.S. healthcare system is not a model of "well-care" but one of "sick-care" based on profits and actuarial tables. We wait until patients get sick and then try to find drugs that alleviate and occasionally cure those conditions. Big Pharma and insurance companies in a capitalistic society exist to turn profits for their shareholders, as perhaps they should. However, in this model, no drug is a good drug unless patients must take it forever. Drugs that are taken infrequently or may actually be disease-modifying or curative can cost many thousands of dollars, making access for the majority of those people who need those drugs impossible.

Around 1997, a Ph.D. of renown from the University of Miami approached me of about a plant-based African medicine called ibogaine. Ibogaine is derived from the root part of the African plant Tabernanthe iboga. It has been used by indigenous tribes in Gabon for centuries in its natural form as a rite of passage. Ibogaine exists in many forms, from root bark to extract to others. For the purpose of this article, I am speaking of 98% pure ibogaine hydrochloride (ibogaine HCL), chemically extracted from the plant to produce an orally administered medication that can be given on a milligram per kilogram basis to treat specific substance use disorders (SUDs). That scientist

claimed to me that a single dose of Ibogaine HCL could greatly ameliorate opioid withdrawal symptoms in less than 24 hours, as well as being extremely beneficial for patients who suffered from other SUDs. Being a scientist, I was very skeptical.

As coincidence would have it, at the time I met this researcher, I had many years of opiate abstinence myself, freeing myself from opioid dependence the hard way, on my own and going through 90 days of abject hell. I became Board Certified in Addiction Medicine, detoxifying patients on a daily basis and always thought, "There has to be a better way ".

I possessed a unique skillset that this researcher needed to begin giving ibogaine to a large number of addicted patients in a highly monitored setting: I was an internist with additional training in cardiology who was Board Certified in Addiction Medicine, had treated a vast array of cardiovascular and respiratory emergencies during my years as an emergency room physician, and was a recovering addict myself. In addition, I had experienced the benefits of psychedelic introspection myself.

I remember the first few patients who received treatment on Saint Kitts, British West Indies. What I witnessed was nothing short of a miracle. I saw patients with massive opioid dependencies who had failed many cycles of the best treatments available in the U.S. feel well within 24 hours post-ibogaine flood dosing. They were in the same physical and mental state, 24 hours post ibogaine treatment, that would take a patient 90 days of suffering to achieve in the U.S. model of pharmaceutical substitution detoxification followed by aftercare treatment. Aside from rapid amelioration of withdrawal symptoms, cessation of cravings, and diminution of withdrawal severity, patients have relate gaining valuable insight into their behavior equivalent of years of perfect psychotherapy done in one day.

Here we are in 2020, on the verge of major breakthrough in psychedelic medicine. Psychedelics as medicine is a hot topic of discussion in the media, science, and business world. Esketamine has been FDA-approved as a treatment for refractory depression, and there are currently Phase 3 clinical trials in the U.S. using psilocybin for the treatment of major depressive disorder and treatment-resistant depression, and using MDMA to assist with psychotherapy for posttraumatic stress disorder (PTSD). This comes with a lot of optimism, but also many caveats.

I have served as a principal investigator in dozens of U.S. clinical trials for pharmaceutical companies to get new medications FDA-approved. The complexity and expense of bringing out a single new drug to the US market boggles the mind. Many ibogaine clinics have opened up all over the world in countries where use of the drug is not illegal. Aside from the St. Kitts data, we have 25 years of testimonials from severely addicted patients that ibogaine not only saved their lives, but gave them get valuable insights into their self-destructive behaviors. Yet, getting FDA approval for ibogaine clinical trials remains an uphill battle. Ibogaine has been called a "vast uncontrolled experiment," and is still a Schedule I drug in the United States, making its use outside of research illegal and subject to severe criminal consequences.

As the first and lead physician in a team of researchers to give flood dosages of Ibogaine to many SUD patients in St. Kitts, I found that ingestion of ibogaine was not without risk. Although we had no deaths in the St. Kitts trails, ibogaine deaths have been reported. I have reviewed each death where data was available, and found that all of those deaths could have been avoided had a proper a protocol been followed by medical professionals who possessed the skills and knowledge to treat the possible known adverse events that can occur during ibogaine flood dose treatment.

Ibogaine can cause cardiovascular issues such as hypotension, bradycardia, QTc prolongation, HeRG blockade, and complex cardiac arrythmias. The reports of these deaths, some by well-intentioned lay providers, have fueled an anti-ibogaine sentiment being perpetuated by those who continue to make billions of dollars from selling pain medications and other medications for SUD's such as methadone, buprenorphine. These medications can be prescribed legally in the U.S. but leave patients dependent upon them, yielding significant profit for the pharmaceutical industry.

Is this the best we can do? I think not. I, along with a select few other physicians, have overseen thousands of successful ibogaine flood dose treatments with zero mortality, due to the specific strict medical protocols we have followed and the medical skills we possessed.

Proper ibogaine treatment includes not only diligent

pretreatment consisting of medical/psychosocial history and examination but also comprehensive labs, cardiovascular assessment, and pre-ibogaine therapy. The importance of having a firm aftercare plan with trained therapists to achieve sustainable recovery is of critical importance. In addition, ibogaine as a drug must be standardized as a product to ensure that all providers are giving exactly the same drug orally based on bodyweight. Constant IV access and cardiac monitoring, and the presence of a medical physician who is not only Advanced Cardiac Life Support certified but also experienced treating complex cardiac arrythmias and other possible flood-dose complications must be bedside at all times. All providers must be intimately familiar with what the patient will experience while under the effects of a flood dose of ibogaine.

Let's parallel the Ibogaine flood procedure to another standard accepted medical procedure in the U.S.: a screening colonoscopy. When you need a colonoscopy, you don't go to someone who thinks they can do a colonoscopy because they had one; instead you see a gastroenterologist who has many years of training in that specialty and that procedure. Prescreening labs, medical history, and cardiovascular status are reviewed prior to the procedure to ensure the colonoscopy can be done safely. The day of your colonoscopy, you arrive, an IV is placed, and you are given anesthesia by an anesthesiologist, who is present throughout the procedure which is done under constant cardiac monitoring. This anesthesiologist is well qualified to handle any adverse effects that may occur, including hypotension, bradycardia, arrythmias, and other abnormalities. This procedure is considered so safe that it is the standard of care in the U.S. for anyone over the age of 55 and is suggested to be repeated every five years.

I assert that if such diligence is followed for ibogaine flood dosing in the US, hundreds of thousands of lives would be saved per year, and the morbidity and mortality would match that of a simple procedure like a colonoscopy. In the face of an opioid epidemic, there is a massive amount of anecdotal and scientific evidence that ibogaine flood dosing, administered in a very specific medical model which would be considered the "standard of care" for this treatment, can be given safely and effectively in the U.S., resulting in significantly improved outcomes when compared to any model of SUD treatment that exists in the United States to date.

Under a patient's inalienable "right to try," should an addict who has failed multiple cycles of standard U.S. treatment not be allowed to try ibogaine flood dosing with full informed consent? Many barriers exist to this happening, including:

- Big Pharma's model that no drug is a good drug unless you must keep taking it (ibogaine flood dosing is a single dose treatment for detoxification for opioid dependence)
- The lengthy, exorbitantly costly FDA model of obtaining approval for the use of a new drug for specific disorders in the U.S.
- The fact that ibogaine's efficacy would greatly cut into the profits already being made by pharmaceutical stakeholders and those currently vested in the for-profit system of addiction treatments that exists in the U.S. today

Aside from those barriers, many of the world's leading ibogaine experts who possess advanced credentials as scientists, researchers, and clinicians are seeking ways to own the rights to use ibogaine and other psychedelic drugs to treat a myriad of conditions in a profit-based model of finding a drug that Big Pharma would like. As a clinical trial principal investigator, scientist, and a physician, I have no financial interest in this medicine.

For over two decades, I have advocated for a science-based, ethical, and affordable model of ibogaine flood dose administration in the United States. I have asked myself: How many lives could have been saved—how much pain and suffering alleviated—had this drug been approved after the initial off-shore trials were completed?

It is clear through the hard-fought diligent efforts of organizations like MAPS that we are at the dawning of a new era in which psychedelics are accepted medical treatments for specific psychiatric maladies, including SUDs. In the face of a global opiate epidemic which is exponentially growing without any relief in sight, it is my hope that ibogaine may gain emergency drug status approval in the near future.

Ibogaine, in my opinion, is far superior to any treatments we have today in the United States not only for opiates, but also for alcoholism, cocaine dependency, methamphetamine dependency, and perhaps psychiatric disorders such as depression, obsessive compulsive disorder, and PTSD. With the help of organizations such as MAPS and Ibogaine Research Institute (IRI)—a not for-profit company trying to get clinical trials expedited in the U.S.—the future remains optimistic. As I often say: "Be realistic: expect a miracle."

Jeffrey D. Kamlet is a Medical Doctor in the United States with expertise in many fields of medicine, including Internal Medicine, Cardiology, Emergency Medicine, Addiction Medicine, Pain Management and several fields of Forensics. He has also served, and continues to be, a Principal Investigator for US pharmaceutical clinical trials. He is the first physician to give ibogaine en-masse in a clinical setting in St. Kitts, B.W.I. and continues to administer and study the effects of ibogaine in countries where it is legal. His work has been featured in major publications and media, as well as National Geographic's Breakthrough series. Dr. Kamlet is recognized as the world's leading safety expert on the administration of ibogaine. He can be reached at jeffrey@irinstitute.org.

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Photo Credit: Jesse Orrico, www.unsplash.com

The Growth of Psychedelic Harm Reduction

ADAM RUBIN

I HAVE JUST RETURNED FROM coordinating and providing psychedelic peer support and harm reduction services at a music festival located in the southwest of the United States. At this event, I was hired by a medical team that understands the importance of creating a supportive environment for someone undergoing a psychedelic emergency. Our goal, of course, was to reduce the possibility of psychological trauma and encourage a psychologically healing experience. To do this, our team of trained psychedelic peer support volunteers staffed our quaint and calm sanctuary space, ready to support festival attendees who unexpectedly find themselves in intense states of consciousness.

As momentum grows towards legalization in the field of psychedelic research and therapy, it is important to state that psychedelic usage and culture has been alive and thriving outside of clinical settings since the 60s. Large-scale art gatherings, music festivals, and concerts have historically been settings where people come together to collectively experience something outside of the framework of their ordinary state of consciousness, whether they choose to ingest a substance or not. 10 years ago, psychedelic harm reduction was not a common term, let alone approaching an event to offer such services. What has changed in the past decade or so is a normalization of psychedelic difficulties, an acceptance around the wide spectrum of experiences psychedelics can offer, and a statement of compassion from those within the psychedelic community saying "we can help people through it." We are also seeing that as awareness of these substances becomes more accepted by the mainstream, event producers and event emergency teams are recognizing the importance and value of incorporating psychedelic harm reduction and peer support services.

At this time, psychedelic harm reduction is a rapidly growing field and there is honestly no limit to being a part of this movement. It's catching on quickly and the demand is way higher than the supply. Worldwide, there are too many events to name that would benefit from these services and as of now do not provide them. Some of the obstacles towards spreading these services have to do with either the perspectives of event producers themselves, legal considerations, and/or limited resources for harm reduction providers. Little by little, these obstacles are slowly dissolving, thanks to the efforts and encouragements from various harm reduction organizations, pro-harm-reduction event medical and security teams, and festival producers who understand and support the work. The more support and attention psychedelic harm reduction gains, and the more society recognizes the need for a more compassionate and caring approach to assisting those in distress, the easier it will be to expand into events that are new to these services. The end goal is that psychedelic harm reduction services become standard in forming a complete event safety team where one might expect attendees to ingest these substances.

Psychedelic harm reduction is a form of activism, and activism, by its nature, is motivated by a passion to transform the status quo.

While psychedelic peer support services and harm reduction operate primarily from volunteers within the communities they are serving, it is not separate from the budding psychedelic industry. In some sense, we can say that before people seek professional help for challenges that may arise in connection to psychedelic use, they may be more likely to reach out to their peers, friends, family, or community. With new professions such as integration coaches and psychedelic therapists, peer support and harm reduction services can act as a gateway into deeper professional care, should the need arise.

Psychedelic harm reduction is a form of activism, and activism, by its nature, is motivated by a passion to transform

the status quo. As in the field of social services, people don't do this for money, but out of genuine care. Because of this, models for these services are based on volunteerism and community service. Most psychedelic harm reduction organizations are non-profits and rely on donations, fundraisers, and compensation from the events themselves to at least break even. There are those of us who have devoted our lives to this form of service, and it is generally not considered a clear path to financial livelihood at this time.

Volunteer culture is actually a core component to psychedelic peer support. If we are going to discuss the commercialization of psychedelics in relation to psychedelic harm reduction services, there are a couple important sides to mention here. On one hand, volunteer culture is paramount to creating a sustainable, well-staffed, and effective peer support service at an event. The primary motivation for peer support needs to come from a desire to be of service for it to be most effective. Also, it would be unrealistic to expect to have the funding to pay a full staff of peer support workers, given that it is already difficult to generate money just to set up the services and pay the those who manage the team of volunteers. Harm reduction volunteerism is a great way for people from many different backgrounds to spend time helping others in a meaningful way. It also serves as helpful adjunct experience for those looking to pursue other avenues of work in the psychedelic field, such as research and therapy. On the other hand is the year-round or more regular psychedelic harm reduction worker, devoted to the service and traveling to as many events as possible to offer that compassionate presence to those having psycho-spiritual breakdowns in the midst of a festival. As it exists today, there is little financial security or stability in this work for those who wish to focus their lives in being a professional psychedelic peer support worker. The only avenue I have seen in generating any kind of income is in being in team coordination positions or running one's own psychedelic harm reduction organization. Even for those in these leadership positions, which require long hours, challenging work, and require a unique and diverse skillset, harm reduction isn't typically a path to financial stability. In this way, it is akin to some other forms of public health and service, such as being a paramedic, EMT, or teacher. Similar to the public service sector, and one factor that makes psychedelic harm reduction unique amongst other emerging professional opportunities in the psychedelic field, is that those who receive care obviously do so free of charge.

Perhaps psychedelic harm reduction will become a more lucrative professional path as the world and culture continue to evolve with more understanding of these powerful tools of consciousness. Perhaps it is actually necessary or preferred to keep psychedelic peer support and harm reduction in the field of non-profits, community service, and volunteerism. Whatever the business structure may be, perhaps the peer support model can evolve to find new ways to support a culture of volunteers and paid higher-level peer support specialists, recognizing the value and honoring the time, energy, and skills required for this important work. In summing up, the needs for psychedelic peer support and harm reduction services have existed well before the current wave of mainstream psychedelic awareness. As the psychedelic movement provides more acceptance and understanding of these important psychoactive substances, it is allowing psychedelic harm reduction efforts to grow as well. Event producers and medical teams are catching on to the importance of these services. The hope is that we are able to create financially supportive models to those pouring their love and devotion into this form of community care. To all the volunteers, organizers, and supporters of psychedelic care teams, thank you so deeply.

ZENDO
PSYCHEDELIC HARM REDUCTION

MAPS Zendo Project: Providing Safety & Support for Festivals and Events

MAPS has been providing peer support services at festivals and events since the early 2000's. The Zendo Project has been a presence at domestic and international festivals and events since 2012, successfully assisting over 6500 guests undergoing difficult experiences, substance related or otherwise. The Zendo Project provides emotional support services in a comfortable setting for individuals coping with the difficult mental and emotional effects that can arise from the use of psychedelic substances at festivals and events. We empower communities by providing hands-on educational workshops, training, and outreach.

To help grow psychedelic harm reduction services, reach out to events you might be attending and inquire if services already exist. Another way is to support groups that already exist through volunteering and donations.

Adam Rubin is a psychedelic harm reduction activist and crisis counselor. He has devoted his life to supporting others experiencing extreme states of consciousness and creating safety systems at events where people might choose to ingest a psychedelic substance. He has worked over 45 events around the world since 2015 with many different organizations including the Zendo Project, White Bird Rock Med, RGX Medical, and Take 3 Presents, as well as manages his own teams. He has given trainings to peer support volunteers, local psychedelic communities, and event medical teams in attempts to bring deeper understandings around effective ways to support people undergoing a psychedelic emergency. He has also written a series of zines titled "The It's Okay Psychedelic Harm Reduction Series" and distributes them for free to spread information, safety, and community support.

Psychedelic Legalization: An Opportunity to Change Our Perspective on Equity

AMBER SENTER

Since psychedelics were discovered, human beings have used them to detach from harmful mental patterns, reassess their lives and get over traumas. For a century, drug criminalization has been a heavy source of trauma for people of color. It has atomized our communities, pushing people in and out of cages, their partners through trials of economic strife and housing insecurity, our wealth forever out of reach, unable to accumulate into a source of security. As we open the conversation on decriminalizing and eventually legalizing psychedelics, we come face-to-face both with the legacy of criminalization and the power of psychedelics to deliver us from trauma.

The legacy of cannabis criminalization is a massive scar on American history, one that is only beginning to heal. The legacy of cannabis legalization is already a few chapters in, and it's an uneven history. Yes, decades of awful policy are ending (though far from ended), but efforts to use legalization as a tool to heal communities of color have been scattershot and wholly inadequate. I work to lower barriers of entry for people of color in cannabis through Supernova Women (supernovawomen.com), and while we have made big strides through advocacy, education, and networking, it is an uphill battle when state and local governments do little for equity and still show the same racist arrest patterns from the days of criminalization.

Even localities which have instituted equity programs have often had little in the way of positive results. Oakland's equity program helps very few people—hardly surprising when one of the barriers to entry to start a cannabis business there is raising around a quarter of a million dollars. Oakland created a "buddy system" that pairs equity and conventional cannabis businesses to streamline licensing, but many potential equity businesses have been left out in the cold due to insufficient resources, difficulty finding real estate, or their "buddy" departing for another locality. Then again, at least Oakland tried. In most places with legalized cannabis, the status quo is a "free market" that benefits the wealthy and well-connected, mixed with sinuous local control regulations which advantage those with lawyers and the capital to move quickly when opportunity strikes.

As it has with countless individuals, psychedelics, used carefully, can help provide a fresh start. We can start with a simple question: What happens when we center community health and community equity? With cannabis legalization, this was an afterthought. With psychedelics, we can do better. To do that, we need to zoom out and ask ourselves what "equity" really means. Social and legal equity get the most attention, and they certainly deserve our energies, but what about health equity? Environmental equity? Economic equity?

Dr. Rachel Knox, who works at the intersection of cannabis research and health equity, addresses this issue head on: "We must decolonize nature and the pervasive

methodologies used to control it," she explained in an email to me. "The reprisal of interest in integrating plant medicines into conventional culture must include the contemplation, development, and execution of measurable plans, programs, and innovations that ensure that plant medicines and the economies their commoditization creates serve all people."

This is too big an idea to be shoehorned into policy after the fact. Real equity happens when it is written into the policy's DNA. Knox argues that the first priority of our laws and economy as we integrate plant medicines should be to "measurably serve those most harmed by prohibition— black, indigenous, and other peoples of color, and patients—and ensuring that policy establishes regulatory pathways...that educate, destigmatize, accommodate responsible use, improve the environment, and economically stimulate the most at-risk communities first."

Tax revenue from cannabis and other plant medicines provides a natural funding source for dynamic programs that address several of these dimensions at once. That can start with psychedelic therapy and education for communities which have been terrorized by the War on Drugs. Due to a number of factors largely stemming from criminalization, plant medicines and other psychedelics are ill-understood. Their power to heal is limited by access, and knowledge of these plants and what they can do when used properly is the first step. Education around psychedelics can open eyes and opportunities.

What knowledge we do have didn't come out of nowhere. Many plant medicines are associated with particular indigenous communities that developed cultivation practices, understandings of preparation and dosage, and healing rituals over centuries. If these communities were start-ups and this knowledge belonged to them as intellectual property, they would be poised to make billions, licensing their IP or selling directly to customers. As money flows into this space, it is our collective obligation to ensure that these communities are included and compensated. This could come from legislation, but also the directives of investors and companies looking to profit from what they built. Include these communities, listen to them, and allow them to benefit from the growing acceptance of the plant medicines with which they work.

There are, of course, more ways to help a community than just cash (though cash helps). Community gardens can bring people together, clean the air and relieve food deserts. Clean water is a human right, and is essential to health and educational outcomes. Equity-focused job programs can bring a steady income and work experience that can lead to long-term economic stability. Some focused funds and sustained effort can go a very long way.

"We must wield policy that favors health equity," says Knox. "In what better way can we do this than through the legalization and conscious regulation of plant medicines? This is the very nature of nature—it truly belongs to nobody and exists to benefit us all equitably."

There are many good ideas out there that can begin to heal the communities that have been trampled on for decades. The key thing is to want it. Once we instill a desire for equity in every part of our society, the door will be open to using plant medicines to heal our societies, our communities, and ourselves. Legal access to psychedelics is coming. That can be a good thing or a transformative thing. It all depends on the intentions we have going in.

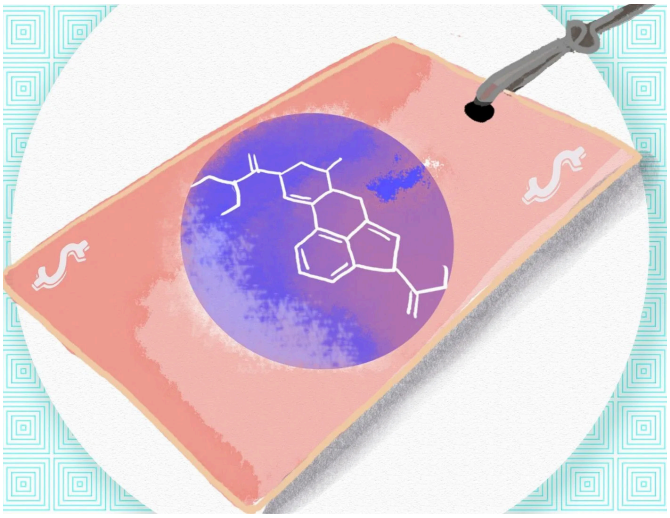
Amber E. Senter is founder and CEO of Breeze Distro, a licensed lifestyle and infused cannabis product and distribution company located in Oakland, CA. She is also co-founder and executive director of Supernova Women, a women of color–led organization dedicated to empowering people of color to become self-sufficient cannabis industry shareholders.

The Emergence of a New Market: Psychedelic Science Conferences

BIA LABATE, PH.D

I confess I am a conference nerd. I love conferences: I like to attend them, to speak at them, and most of all, I deeply enjoy to organize them. They are a mix of intellectual stimulation, community building, networking, and, often, my main opportunity to have a trip and mini vacation. I enjoy all of it: from the cushy pillows at the free hotels; to the non-stop, vibrant, magical environment of ideas; to the fast connections; to the local flavor and all the adjacent activities in new places. Back when I was a social sciences student, we used to crash conferences secretly because we could not afford the tickets. It was so much fun.

I certainly love to organize conferences. I organized my first conference, The Ritual Use of Ayahuasca (CURA – Congresso sobre o Uso Ritual da Ayahuasca, an acronym for "healing" in Portuguese), when I was a young master's student at UNICAMP in 1997. It was an amazing two-day international



gathering, the first one on this topic in a mainstream university in Brazil. Since then, I have created dozens of events, conferences, panels, and gatherings in Brazil, Mexico, the US, Germany, the UK, Spain, and Holland. I also volunteered or was hired by institutions in the field to produce their conferences or curate tracks of it. I am proud to have supported MAPS, ICEERS, Breaking Convention, OPEN, and Horizons among other friends, in several of their events through the last two decades.

Many are talking about the "commodification of psychedelics" or the "new psychedelic businesses" or "corporations"; however, this boom is affecting all areas of our field. I feel an important piece missing from the conversation: the emergence of the new psychedelic science conference market.

With the advancement of clinical trials, and the perspective that both MDMA and psilocybin will be legal for medical prescriptions, and with the decriminalization movement spreading quickly throughout the country, many new people are entering into the space. And, with that, big money, either from big pharma, the cannabis business or tech. Whereas we are all thrilled and fascinated with the perspectives of these medicines being more culturally accepted and incorporated to our legal and medical healthcare systems, many of us also feel nauseous with the pace at which things are advancing. Many are talking about the "commodification of psychedelics" or the "new psychedelic businesses" or "corporations"; however, this boom is affecting all areas of our field. I feel an important piece missing from the conversation: the emergence of the new psychedelic science conference market.

This piece is meant to alert both conference speakers, conference organizers, and the public, on what to take into account when you produce or choose to attend a conference as speaker or as audience member

Since we live in a complex world, it's always a challenge to understand and interpret what is going on. As with so many situations, this is a multifaceted phenomenon that cannot be separated from the increase in trainings, conferences, and the "market of ideas" or "expert voices" that emerge on multiple fronts. Certainly, psychedelics are entering the circuit of professional trade conferences. I am not going to do any major sociological reflection here, but simply point out some very concrete observations. This piece is meant to alert both conference speakers, conference organizers, and the public, on what to take into account when you produce or choose to attend a conference as speaker or as audience member:

- Is this the first edition of the conference, or has it been in the field for a while?
- Is there inclusion, diversity, and gender balance, or is it heavily dominated by white males?
- Is there a sliding-scale system and scholarships or only one price?

- Does the price seem reasonable in comparison to other conferences in the field? (for example: $1,000 is a lot for a two-day conference!)
- Does the conference have a program for volunteers?
- Who are the organizers of the conference? Are their photos and bios displayed online? Is it an individual or a business? Often conferences that are strictly commercial do not offer information about who the organizers are.
- Even if the organizers are displayed, do they have ties to the community? Do they have any particular intellectual expertise or contribution to the field?
- What is the intellectual vision of the conference? Is there a theme, a specific identity or approach, or it is a random mishmash?
- Beyond the flashy images and promotion, what is the intellectual quality of the conference? Are the biographies of speakers carefully edited and presented, and are titles and abstracts to their presentations offered?
- Are the invited or guest speakers' traveling expenses covered?
- Are academic researchers included, or just mainstream psychedelic corporations or celebrities?
- Are their community partners or promotional partners that are solid and recognized in the field?
- Does the conference seem like a trade show for businesspeople?
- Does the vendor's area receive more attention than the conference itself?
- Is there an afterparty that seems mainly a money-generating event?
- Are the videos of the conference shared for free online afterward?
- Who are the sponsors of the conference? Are these legitimate players in the field?
- How much do the packages to sponsor cost? Are these numbers reasonable compared to other initiatives in the field (numbers range from $5,000 to $10,000 depending on the size of the conference).
- If the conference is strictly business oriented, does it offer any kind of reciprocity to the field?
- What is the quality of the speakers? Do they have real expertise or are they being included because they are promoting similar conferences that perhaps offer cross-promotional benefits?
- Are speakers pushing too hard to present in your conference?
- Are continuing education credits offered?
- Are community and promotional partners offered a courtesy ticket?

Established researchers and research institutions should also think of the question of reciprocity and legitimacy.

Established researchers and research institutions should also think of the question of reciprocity and legitimacy. When you attend a conference as a speaker, or join as promotional partner or sponsor, you lend legitimacy to it. How much does that cost? And is that even for sale?

Supporting a conference (either as a speaker, partner or sponsor) is certainly an exchange, as you will get visibility, the chance to network, learn, debate, etc. However, if you accept the invitation to participate in or support a conference, you are both helping to add credibility to it, and, perhaps, having less time or resources of your own to attend other conferences potentially more intellectually enriching to you and more beneficial to the field as a whole. You might also choose to do so, while being fully aware of the implication of these choices.

Speakers should ideally be compensated for their time and expertise with payment of an honorarium. However, the offering of honorariums depends, of course, on the means available to the organizing team or institution. As with the majority of academic conferences, grassroots non-profits or research-based institutions frequently cannot afford honorariums.

In sum, please chose carefully where you lend your name and brand, as other speakers will see you there and assume it's a worthwhile initiative and do the same. Your support potentially has a "domino effect."

This article was originally published at https://chacruna.net/the-emergence-of-a-new-market-psychedelic-science-conferences/ on February 12, 2020

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Sacred Peyote Conservation: Respecting Indigenous Traditions

SANDOR IRON ROPE
REFINA SMITH
STEVEN MOORE

Youth and children's harvest on native lands, Peyote gardens, South Texas

This is a powerful moment in human history. Almost eight billion people live on planet Earth, each seeking health, happiness, and a future for their children. Water, land, safety, mental health, and consciousness are all of deep concern—no matter your level of direct impact by economic, climate, political and cultural change.

For the indigenous peoples of North America, these deep concerns are playing out in the context of our sacred lifeways. Our people are intimately connected with Mother Nature and her bounty, whether we are the buffalo people of the American plains, the salmon people of the Pacific Northwest, or the Peyote people of Mexico, the United States, and Canada. As the Earth experiences profound changes, holding on to our sacred lifeways becomes more essential.

Indigenous tribes have been misunderstood for centuries; they are sometimes as invisible as the air we breathe. There are many misconceptions about our viewpoints in the world. As the world gets more populated and more complicated, indigenous peoples have an ever-growing, now urgent, desire to protect what is sacred for the coming generations of our children and grandchildren. We have a constant battle of healing and survival, and the Peyote Religions, popularly known as the Native American Church in the U.S. and Canada, is growing because it is a healing home. It gives us hope that for the coming generations there will be more and more healing. So, we are asking ourselves about how to care for and nurture our medicine, espe-

Spiritual offering in the gardens, Peyote gardens, South Texas

cially in the native lands where the Peyote grows, for our future generations. You will understand that even more when you become a grandparent. And as you get older these issues of what you are going to leave your grandkids becomes at the forefront of your mind, your being, and your movements.

The Indigenous Peyote Conservation Initiative (IPCI) was formed in 2017 by the National Council of Native American Churches, after the Peyote Research Project (PRP), commissioned by the Native American Church of North America. The PRP showed us that the sacred plant Peyote was threatened, both in terms of populations and quality of the plant, and also in terms of the expression of indigenous sovereignty over the medicine, pilgrimage, and spiritual harvest. It was time to reconnect to conservation, direct responsibility, and renewed spiritual relationship to the entire growth cycle of our medicine.

As the Earth experiences profound changes, holding onto our sacred lifeways becomes more essential.

Peyote, and the indigenous Peyote Religions, have been around for thousands of years. Our brothers and sisters from the south—living in what is now known as Mexico—have been utilizing this ancestral medicine as long as they have lived and moved throughout the Sierra Madre mountains all the way to the Pacific Ocean. Those of us living in the U.S. and Canada today utilize this medicine for our healing and reconnection to the ways of our ancestors. Peyote is fundamentally woven into our existence and has led to many healings of people, families and communities.

Whether we live in the U.S., Canada, or Mexico, all indigenous Peyote peoples have challenges to the sustainability of our medicine, our lifeways, and our medicine supply. These challenges are due to exploitive and imbalanced land management practices. Mining, oil and gas development, wind turbine development, rancher root plowing, cattle grazing, poaching, over harvesting and improper harvesting by the current licensed dealers ("peyoteros") and their contract pickers, all contribute to the crisis we face.

We are uniting the indigenous peyote peoples of North America to preserve and conserve this medicine, our sacred plant Peyote, through IPCI. Today, collectively, our intent and goal is to learn from the medicine by living with it, nurturing it firsthand, and embracing conservation values at every level,

Tipi in the morning sky, Peyote gardens, South Texas

from the health of the land, to every stage of the growth cycle, to spiritual and ecological harvesting, and supporting bona fide indigenous churches and governance structures.

With the generosity of several philanthropists, including Riverstyx Foundation and Dr. Bronner's, 605 acres of land were secured in southern Texas in the heart of Peyote country. We now have the ability to be first-hand on the land, to see and feel and connect with the medicine. Through this organic experience, for ourselves and our children and grandchildren, we learn how to listen, conserve, and protect this sacred plant for our continued way of life. We use this as a spiritual homesite or home base for indigenous peyote tribes. In these last couple years, IPCI is building (with community labor) a home for a caretaker, pilgrimage hosting capacity, a welcome center, youth programs, and education for families. We are hosting ceremony and regional conservation, engaging in our own indigenous regulation.

As a "controlled substance," Peyote has been under the criminal law control of the federal government and the government of Texas for half a century. In the early 1970s, with the enactment of the federal controlled substances law, Peyote was classified as a Schedule 1 drug. Native peoples were allowed an exemption to utilize their medicine by the federal Drug Enforcement Agency (DEA). In the United States Peyote only grows in the state of Texas. The Texas licensed distribution ("peyotero") system was a regulatory companion to the federal exemption for Native religious use of Peyote.

The Texas distributors legally harvest, sell, and distribute, but do not necessarily consider our values of spiritual and ecological sustainability. We are working within the structure and framework of these federal and state laws, cooperatively, to forge a new and creative way to Peyote conservation and sustainability to ensure spiritual harvest for the next seven generations and beyond. The rancher community in south Texas is an ally in this initiative. We respect them as the longstanding landowners and caretakers of the Peyote Gardens. Today we have an opportunity to take the initiative to further our own healing and be the caretakers of our medicine firsthand, through our own land, and lease partnerships with our fellow neighboring ranchers. For the first time in 100 years, we have a chance to once again be full respectful stewards of the plant, its conservation, and to ensure its access and distribution is spiritually (with proper offerings and prayer) and ecologically managed. As we return to spiritual harvest, where we always give back with prayer, offerings, and regenerative care, our youth, elders, and family are regaining medicine sovereignty and taking responsibility.

When you look at the challenges of Peyote access today, we are in a new era, with the supply and demand crisis we have known about and new threats to our medicine, including new efforts to decriminalize all "plant medicines." We are listening and watching; our membership is learning what these changes mean and how they will affect Peyote. Without being consulted in these movements, we are left wondering and concerned. The Western mind and the psychedelic movement are for sure playing catch-up on understanding the indigenous view of life and

experience in this country. Though it is difficult: Imagine walking a mile in someone else's moccasins! Like different children, each medicine needs its own care, tending, and attention, and respect for its stewards as well. Maybe some will develop some empathy towards indigenous tribes and the daily struggle for our cultural survival. What does it mean to have a sacred medicine—relied upon for survival, fought for throughout history in decade after decade of persecution by all governments, local, state, and federal, and mainstream religious organizations —still be threatened?

So, we are learning what "decrim" means and whether it will affect us in a negative or positive way. Will it lead to increased pressures and another colonial imposition on our medicine? Or will this new movement respect indigenous sovereignty and responsibility? We do not want our way of life and our medicine to be part of the sixth wave of species extinctions happening today.

Like with water in our dominant culture, we don't realize its preciousness and that we are taking advantage of it. It's the same with this Peyote medicine: How we approach it is of upmost importance. If we don't understand these implications, maybe we can take our cue from the indigenous peoples who have stewarded this medicine for centuries, and think about it before we take it without understanding what that would mean for the indigenous peoples of this land. What does it look like to not just think of this as a plant containing a psychedelic compound, but as a whole way of life to be respected and not tampered with?

As this "psychedelic renaissance" takes place, it is very important that we not repeat the mistakes of the past: broken treaties, stolen lands and natural resources, and stolen religions and rituals. IPCI asks that we respect indigenous sovereignty over the medicine as this renaissance happens. For practical purposes, this means understanding that the indigenous use of Peyote is a way of life that was also born to address health and trauma. These are communities that have addiction, youth suicide, and poverty beyond any other population in the United States. Rather than feel entitled to this medicine, it would be good to support indigenous communities the way they want to be supported, by allowing them to regulate and have jurisdiction over this medicine in a way that is entwined with their community, mental health needs, and the futures of health and cultural vitality they seek for their grandchildren.

The community engaging in the psychedelic renaissance has the choice to allow this cultural change to happen without stealing, once again, from the Native peoples of the Americas. We believe people committed to healing are capable of rising to the occasion of understanding the complexity and nuance associated with this particular medicine and will not brush native peoples concerns about the pressures and problems with use and interest in mainstream culture and inclusion of the word Peyote in decriminalization measures. Be an example of support from brothers and sisters of different backgrounds, and support keeping this way of life alive through respect. Supporting indigenous peoples' medicine sovereignty is part of weaving the unity between all cultures required to realize the preservation of diversity and health on Earth in these times.

What this means practically:

- Disseminate information about Peyote conservation issues
- Do not buy Peyote
- If you are non-indigenous, please look for alternative plant medicines, i.e., use medicine for your own health and well-being that does not have the ecological or historical/cultural issues of Peyote
- Do not use outside of a bona fide Native American Church context
- Don't assume Western fixes (like nursery production in urban areas) are respectful
- Support and give funding to Native-led organizations

For more information go to www.IPCI.Life or feel free to contact us directly at info@ipci.life.

Authors' Note: No part of this article or the information within in shall be utilized or reprinted for any reason without reference to the authors or IPCI.

Sandor Iron Rope, President, an enrolled member of the Oglala Lakota Oyate from Pine Ridge South Dakota. Mr. Iron Rope received his B.A. in Human Services and American Indian Studies from the Black Hills State University. He supports Tribes in the U.S., Canada and Mexico, serving as President of the Native American Church of South Dakota and former chair of Native American church of North America. He is also the executive director of 'TTO', a small non-profit committed to peyote conservation and the preservation of Lakota Culture and Health.

Refina Sandra Smith is Navajo and an enrolled member of Wichita Caddo / Choctaw Nation of Oklahoma. She takes care of the grandmothers return and watches over the land in S. Texas. She has a 30 year career in the US Airforce with active duty overseas. Refina brings organizational and contracting skills to IPCI, supporting developments on the land.

Steve Moore, Senior attorney at NARF, Mr. Moore has been supporting Native American Church of North America since 1983, providing legal protections for access to their peyote sacrament as well as water rights, sacred land rights, and repatriation of human remains. Mr. Moore's legal experience and relationship to the NAC is crucial to the peyote conservation efforts.

MAPS: Who We Are

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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

MAPS furthers its mission by:

- Developing psychedelics and marijuana into prescription medicines.
- Training therapists and establishing a network of treatment centers.
- Supporting scientific research into spirituality, creativity, and neuroscience.
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MAPS envisions a world where psychedelics and marijuana are safely and legally available for beneficial uses, and where research is governed by rigorous scientific evaluation of their risks and benefits.

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

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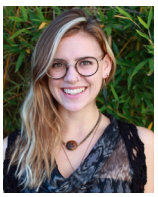

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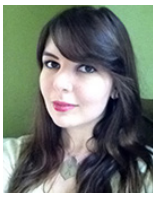

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MAPS Public Benefit Corporation (MAPS PBC) catalyzes healing and well-being through psychedelic drug development, therapist training programs, and sales of prescription psychedelics prioritizing public benefit above profit. Founded in 2014, MAPS PBC is a wholly-owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS) a 501(c)(3) nonprofit.

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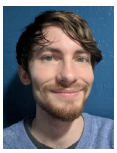
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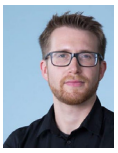
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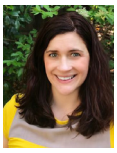
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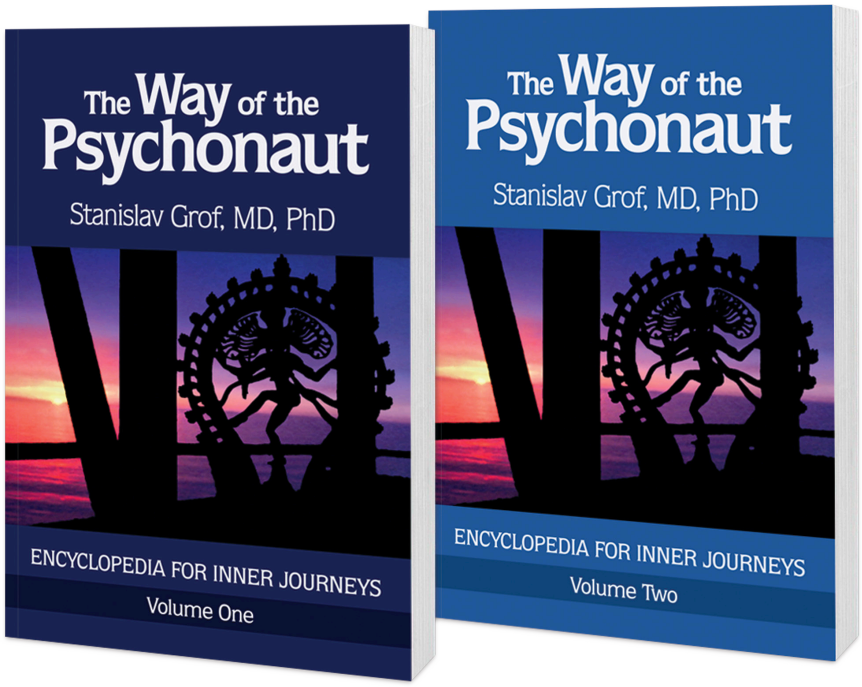

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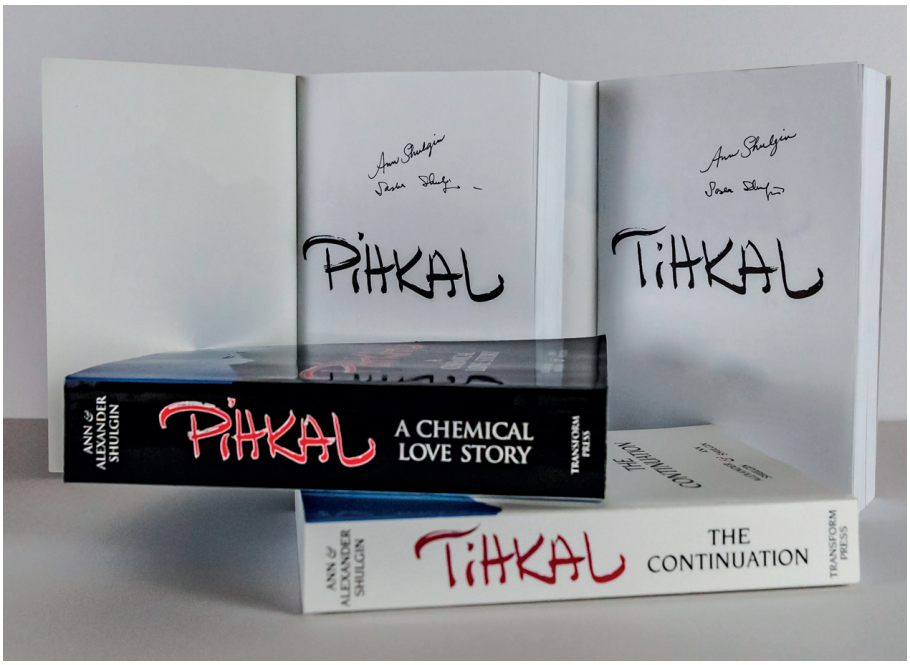

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