

Psychedellic Science Quarterly Update #3 from PSFC

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PSFC Psychedelic Science
Fundors Collaborative

Psychedellic Science Quarterly Update

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****Confidential - Please do not circulate****

Dear PSFC Community,

Thank you for reading our third quarterly update email. It's been a busy fall for us at PSFC and a remarkable few months for the psychedelic field. A few highlights from this edition:

- MDMA commercialization planning, including upcoming new hires at MAPS
- Fundraising for MDMA-assisted psychotherapy studies with veterans
- Developing business tools and a scholarship fund to support psychedelic therapists
- Public opinion research findings and upcoming trainings
- News and updates from PSFC's collaborators and the wider psychedelic field, including fundraising for VA studies, a transformative gift to Johns Hopkins, and lots more...

Updates from PSFC

Bringing MDMA to patients: MAPS working group progress, upcoming hires, and studies with veterans

A major focus of PSFC's work this year has been collaborating with MAPS on their plans to integrate MDMA-assisted psychotherapy into the medical system (also known as "commercialization" in the pharmaceutical industry) in anticipation of potential FDA approval. This spring, we helped MAPS recruit a working group of experts to guide this process. We are grateful that MAPS devoted a full day of their July board meeting for the working group to meet in person. Since July, the working group has begun developing a strategy for bringing MDMA to patients and is now moving forward with adding staff focused on regulatory compliance and care delivery.

At the July working group kickoff meeting, MAPS leadership were joined by Dr. Atul Pande, a drug development expert formerly with GlaxoSmithKline and PureTech Health, Dan Grossman of the Boston Consulting Group, Paul Jeffries, an expert on pharmaceutical development formerly with Pfizer, Brian Zorn, a commercialization expert with the consulting firm SmartPharma, and MAPS board member Victoria Hale of Medicines360. PSFC was honored to be invited by MAPS to help organize the meeting, which involved a series of discussions facilitated by Graham and others on key challenges ahead for bringing MDMA to patients, including:

- Building a team to guide the MDMA commercialization process
- Branding and drug pricing
- Engaging with prospective patients, providers, and health care payers
- Post-launch regulatory compliance and marketing procedures
- Scaling therapist training



The MAPS commercialization working group in action at the intergalactic (?) headquarters of Dr. Bronner's

Since the meeting, the working group set out to develop a comprehensive plan for bringing MDMA to patients. First, it conducted a landscape analysis of payers, providers, and patients for MDMA-assisted psychotherapy with the support of the SmartPharma team. MAPS PBC also reviewed its organizational structure and identified two staff roles that need to be filled in order to move forward with commercialization. With PSFC's financial and recruiting support, MAPS will be hiring for these positions (which include a director-level hire) to enable it to engage with health care payers and providers, support patient access to treatment, and fulfill anticipated regulatory compliance needs. Stay tuned as we will be asking for your help with finding candidates for this director position later this year. We anticipate this will be a pivotal hire for MAPS and in our view, it just might be the most exciting job opening in the entire pharmaceutical industry! We are genuinely excited to continue to support MAPS as they move forward with MDMA commercialization planning. And it was encouraging to hear Amy Emerson, Executive Director of MAPS PBC say that, "if PSFC wasn't offering to help facilitate, to work with us, and to support some of these positions, we just couldn't get through the next steps of planning greater access at the time of approval."

Alongside PSFC's collaboration with MAPS on commercialization, we are also working with university-based researchers to support studies to demonstrate the effectiveness of MDMA for target patient groups, including veterans. This fall, we have been working with Professor [Trisha Suppes](#) of Stanford University to raise funds for a study at

Stanford and the Palo Alto Veterans Administration (VA) hospital comparing MDMA-assisted psychotherapy to the VA's current "gold standard" treatment for veterans with PTSD. We are also excited about research planned by Professor [Rachel Yehuda](#) of the Mt. Sinai School of Medicine and the Bronx VA. She anticipates conducting a study of MDMA group therapy to treat veterans with PTSD. Read below for more on her study and Ron Beller's fundraising efforts to support her work in the next section.

Progress with MDMA phase 3 trial enrollment and ongoing negotiations with the FDA

MAPS's phase 3 MDMA trials continue to move forward with enrolling and treating patients. The rate of patient enrollment has been slower than initially anticipated, and the FDA has placed a hold on MAPS's therapist training protocol, although MAPS is making progress on solutions to both of these challenges.

Regarding training protocol negotiations with the FDA, Amy Emerson, Executive Director of MAPS PBC noted: "The FDA has recently placed clinical holds on MAPS' protocol for therapists to receive MDMA as part of their training in MDMA-assisted psychotherapy for PTSD, and on the Expanded Access/Compassionate Use protocol for treatment-resistant PTSD. FDA, among other issues, rejected the MAPS proposal that the lead person in its two-person co-therapy team be a licensed masters-level therapist. FDA is requiring that the lead person be an MD or Ph.D./PsyD. This requirement does not fit with the clinical practice requirements for psychotherapy in the United States as it effectively precludes masters-level psychologists and clinical social workers from being the leader of a two-person team. Requiring an MD or Ph.D. or equivalent as the lead person in the two-person therapy team increases costs and limits access without any evidence of significant benefit or risk reduction. FDA is trying to superficially tighten up requirements, which are working remarkably well as is. MAPS has requested a meeting to discuss this and other issues. Resolving it will probably take another 2 to 2 ½ months."

Amy also discussed elements of MAPS's response to this issue: "Janis Phelps PhD, who is the Director of The Center for Psychedelic Therapies and Research at the California Institute of Integral Studies has offered to help with our response to FDA. Janis has reached out to collect letters from professionals affiliated with universities which support allowing the Lead facilitator to have a masters-level degree and that requiring MDs or Ph.Ds or equivalent is misplaced prioritization of credentials over therapeutic competence. These letters will help to document for FDA that MAPS has support from other professionals who believe that the Lead facilitator can be either a psychiatrist or someone with at least a master's-level degree and licensed to practice. The letters will include opinions that these credentials are appropriate as part of a two-person co-therapy team, with either another licensed co-therapist, student or intern."

On the issue of patient enrollment, MAPS received a very encouraging decision from the FDA just last week, which will enable accelerated patient enrollment in phase 3 and

signals that the agency may have returned to a more reasonable approach to engaging with MAPS. Rick Doblin, Founder and Executive Director of MAPS noted: “Yesterday, we received great news from the FDA. For MAPP2 [the second group of patients for phase 3], FDA permitted us to expand eligibility to moderate to severe PTSD, changing from enrolling only severe PTSD. We’ve had many people screen out from enrollment due to having moderate but not severe PTSD so this change will make a significant difference in enrollment for MAPP2. For MAPP1 [the first group of patients in phase 3], for which we’ve enrolled about 64 of the first 100 people, we can now accept people with lower initial scores on the PTSD Checklist (PCL) though we will still only enroll people with severe PTSD in the first of two Phase 3 studies for FDA. We’ve had 39 people screen out for this reason. This should also help enrollment in MAPP1.”

Rick concluded: “In this communication from FDA, they have returned to reasonable and rational review. We still have our struggles with FDA on MT2 [MAPS’s protocol for therapists to receive MDMA as part of their training] and with Expanded Access but are preparing our additional responses and data submissions and have some hope these protocols will be approved and the requirement that the lead facilitator must be an MD or Ph.D. will be ended. We shall see...”

MAPS therapist training strategy retreat and forthcoming PSFC scholarship fund

On November 7th and 8th, Graham and Joe joined a MAPS retreat in San Diego focused on expanding the therapist training pipeline. Graham facilitated the retreat, which was hosted by Shannon Carlin, Director of Training and Supervision at MAPS PBC and convened MAPS leadership, board members, therapist trainers, and outside experts. Participants discussed current constraints on training new therapists in MDMA-assisted psychotherapy and explored options for expanding the therapist training pipeline to meet the potentially enormous future demand for therapy from patients with PTSD.

This workshop followed extensive discussion about therapist training at the MAPS board meeting and the working group meeting in July discussed above. We are looking forward to supporting MAPS’s next steps in this area, including through a fund to support patient access to care and therapist training. Expect to hear more from us soon about this fund as we work towards launching it next year.



Graham facilitating at the MAPS therapist training planning retreat in November

Support for psychedelic clinic development

Alongside PSFC's work to support the MAPS team on their overall strategy for MDMA commercialization and therapist training, we have also begun ramping up support for future psychedelic clinics. This summer and fall, Graham has been working with Dr. [Scott Shannon](#) to develop trainings and tools to support therapists interested in opening psychedelic-assisted therapy practices. As Scott notes, “[a] number of psychedelic medicine supporters have concerns that the strong interest in psychedelic medicine training by psychotherapists and psychiatrists will not translate well into the business of setting up and running clinics for this type of care. We are concerned that the lack of business expertise will create a roadblock for this paradigm shift in mental health.” To fill this gap, PSFC provided a seed grant to Scott and his colleagues to develop practical trainings about how to set up and run a psychedelic clinic. This training would aim to help individuals without business or start up experience feel more comfortable about starting a new clinic focused on psychedelic-assisted treatments.

Findings and upcoming trainings on public opinion research

In our last update, we shared some of the headline data from public opinion research PSFC commissioned on psychedelics earlier this year. With support from the communications experts at Precision Strategies, we've analyzed the findings and pulled some highlights together in a [summary presentation](#). As Graham notes in the presentation, we see three key takeaways from the research:

- For messaging purposes, a therapeutic frame is better than a decriminalization frame.
-

Finding the right message matters, as some of the positive messages tested by the research were significantly more effective than others at shifting opinions.

- We are vulnerable to negative messages, as certain negative messages substantially eroded support for both psychedelic research and decriminalization.

On November 14th, we will hold the first of three trainings for psychedelic researchers and advocates building on findings from this research in San Francisco. There may be a few extra seats available so please let us know if you would be interested in attending. We will also hold similar trainings for researchers and advocates working on psilocybin research, FDA strategy, and some of the emerging state and local ballot measures.

Psychedelic Superband mixer at Burning Man

We were very happy to see many of you at Burning Man at the third annual Psychedelic Superband Mixer. Highlights included Rachel Yehuda sharing her personal journey from psychedelic skeptic to working to bring MDMA assisted therapy into the Bronx VA hospital as well as several “Legalize Rick Doblin” shirts. (Order yours [here](#) and support *Prescription X*, a forthcoming documentary about Rick.) Many thanks to David Bronner and Fomogenesis for hosting, and to Abraxas the dragon for the sunset cruise!



Psychedelic Superband Mixer guests riding on honorary PSFC member Abraxas the dragon

Book launch event for Francoise Bourzat's *Consciousness Medicine* in New York

In October, we worked with PSFC member Austin Hearst to organize a book launch event for Francoise Bourzat's new book, *Consciousness Medicine* at Pioneer Works in New York City. It was exciting to see a packed house welcome Francoise to the east coast! We featured the book in our last update and highly recommend it as an introduction to the theory and practice of how psychedelics can support healing and growth.



Austin introducing Francoise at Pioneer Works in New York City



News from PSFC members, our network, and the psychedelic field:

Major donation to support MDMA group therapy trial at the Bronx VA

This fall, PSFC Steering Committee member Ron Beller teamed with Jade Netanya Ullman of MAPS to provisionally raise \$550,000 to support a trial for MDMA-assisted group psychotherapy for veterans with treatment-resistant PTSD at the Bronx VA hospital. The trial will be run by leading PTSD expert [Rachel Yehuda](#), Professor at the Icahn School of Medicine at Mount Sinai who we introduced above. Professor Yehuda has been at the forefront of research on PTSD and resilience, and her team includes experts in depression, anxiety, suicidality, eating disorders, and substance abuse. This promising trial has the potential to provide evidence from inside the VA on the effectiveness of MDMA-assisted psychotherapy for veterans.

Mt. Sinai and the Bronx VA are also developing a center for psychedelic research under Dr. Yehuda's leadership. She notes: "Capitalizing on Mount Sinai's expertise in training and education, as well as clinical and biological psychiatry, the center will train therapists, perform clinical trials to evaluate the efficacy of psychedelics for mental health indications such as MDMA-assisted psychotherapy for PTSD, and will research the mechanisms of action of these drugs, including their effects on the brain and consciousness. Understanding the underlying neuroscience of psychedelics will allow us to identify essential targets of resilience and mental well-being, and to develop and deliver more specific treatments with greater precision and scalability. The application of psychedelic compounds for healing and recovery is the next frontier in mental health innovation for stress and trauma related conditions."

Transformative gift to support psychedelic research at Johns Hopkins

PSFC members Tim Ferriss and Matt Mullenweg made headlines in September by joining with the Steven and Alexandra Cohen Foundation and other donors to make a transformative \$17 million gift to support psychedelic research at Johns Hopkins. The donation will create the Center for Psychedelic and Consciousness Research at the university and fund several studies of psilocybin for treating a range of conditions, including anorexia, PTSD, Alzheimer's, opioid addiction, alcohol addiction, and Lyme disease. The *New York Times* covered the [gift](#) as well as Tim's [philanthropic work](#) in the context of the recent groundswell of interest in supporting psychedelic research.

Dr. Bronner's donation to Oregon Psilocybin Service Initiative/PSI 2020

In September, PSFC Steering Committee member David Bronner also made headlines with Dr. Bronner's announcement of a \$150,000 contribution to the Oregon Psilocybin Service Initiative (PSI 2020), a ballot measure that would legalize and regulate psilocybin therapy in Oregon. Earlier this year, the leaders of PSI 2020 collaborated

with David, Graham, and fellow PSFC Steering Committee member Les Szabo to revise the language of the ballot measure, and the final version proposes a collaborative process for setting standards for state-licensed centers where psilocybin would be responsibly utilized. David's [blog post](#) announcing the Dr. Bronner's donation is worth a read, as he makes a compelling case that PSI 2020 is a "strategic tightly-regulated and well-timed model to introduce into the culture, of responsible adult access to psilocybin therapy outside the pharma medical system."

Introducing psychedelic researcher Katrin Preller, University of Zurich

Starting with this update, we're excited to highlight a new scientist at the forefront of psychedelic research each quarter: Dr. [Katrin Preller](#) of the University of Zurich has been working in the field of psychedelic research for almost 10 years. She has contributed to increasing our understanding of the neurobiology of psychedelic substances by showing how they alter the communication between brain areas. She has also investigated the receptor pharmacology of psychedelics in humans and has provided evidence that psychedelics are powerful modulators of social cognition – an effect that may be critical for therapeutic efficacy. These results are important for increasing our understanding of altered states of consciousness and are critical for uncovering the full clinical potential of psychedelics. They furthermore provide a scientific roadmap for developing personalized medicine approaches and potential biomarkers as well as predictors of treatment effects.

Katrin is currently working on testing the efficacy of psilocybin in major depression disorder and alcohol use disorder. She and her team are aiming at investigating how psilocybin-assisted therapy is interacting with non-pharmacological treatment approaches leveraging technological advancements with the aim to optimize psychedelic-assisted therapy and increase efficacy.

Upcoming study of ibogaine for opioid dependency by ICEERS

Benjamin De Leonen, Executive Director of the International Center for Ethnobotanical Education, Research and Service ([ICEERS](#)) shared an update about his organization's work: "ICEERS has just celebrated its first decade of work at its [World Ayahuasca Conference](#) where 1400 people from nearly 50 countries came together behind collective strategies forward for the integration of ayahuasca practices in our globalized world. As we have entered a strategic planning phase for the next decade to come, our focus is now to conduct an important clinical trial with ibogaine for opioid dependency, using a novel treatment protocol approved last Spring."

"Ibogaine holds a lot of promise for the future of addiction treatment, with overdose now the number one cause of death in the US in the population younger than 50. Since no solid clinical trials have ever been conducted in the past, except for a trial with extremely low doses (20mg total per participant), an experimental clinical trial with ibogaine is key to building an argument for drug development on the one hand, and

special access or emergency status on the other hand. The extreme nature of the overdose crisis sets the right climate for change, so we feel that now is the moment.”

“Our study, which is partly sponsored by MAPS, is approved by the IRB of the most renowned drug treatment clinic in Spain, Hospital Sant Joan de Reus, south of Barcelona. Catalonia has the most advanced harm reduction in the world, with 12 safe drug use sites in Barcelona alone, free drug quality testing, and drug treatment that involves systemic therapy approaches. Aside from MAPS, the government is also supporting the study. If you are interested in learning more about ICEERS or supporting the study, please email Benjamin at bendeloenen@iceers.org.”

PSFC members organizing gift to celebrate the career of psychedelic legend Stan Grof

A group of PSFC members are planning a gift to celebrate the career and support the living expenses of psychedelic legend Stan Grof. Stan continued to lead workshops through his 89th birthday, but his recent stroke has caused him to finally stop working. Several PSFC members have banded together to support Stan, and they are asking that we all consider contributing. Stan’s wide-ranging contributions to our understanding of psychedelic-assisted therapy, transpersonal psychology, and non-ordinary states of consciousness have been transformational. The psychedelic research field is deeply indebted to him and the foundation he helped to lay for today’s research breakthroughs on psychedelic medicine. His latest book, *The Way of the Psychonaut* is essential reading. Oleg Gorelik brought Stan’s situation to our attention. While Stan neither asked for this help nor is aware that this gift is being assembled, Oleg is confident that Stan would welcome of small group visit with him and even a breathwork session under his guidance. PSFC is honored to pass along Oleg’s invitation to join them in organizing a gift for Stan. Please reply to us if you would be interested in learning more and we would be happy to connect you with Oleg.

What we’re reading



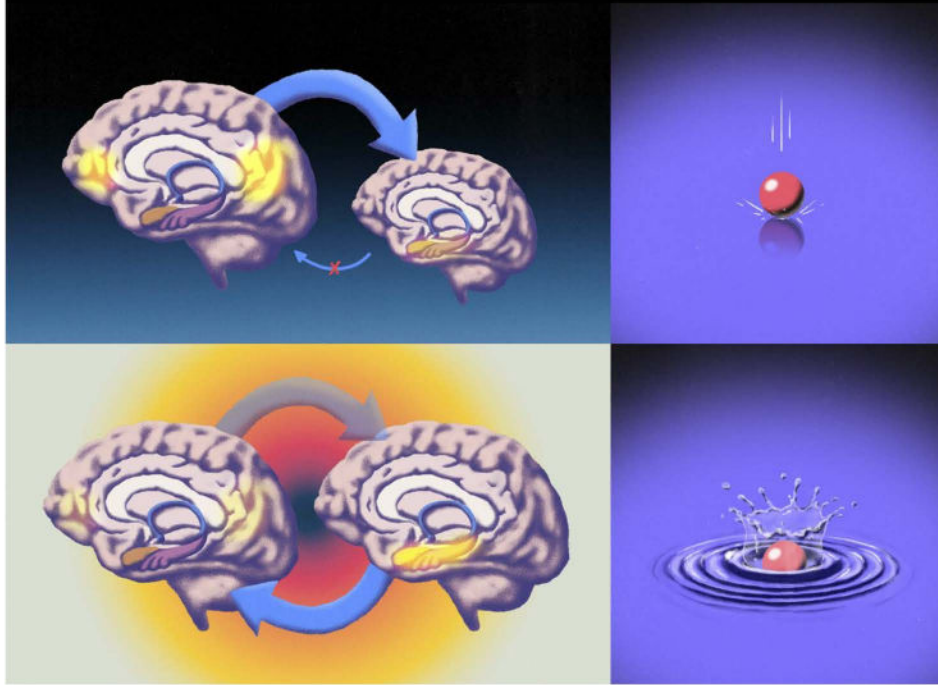
It may be a gorgeously illustrated and immersive work of fiction, but don't mistake [Pala](#) for light reading. This brilliant and provocative online short story invites the reader to imagine the near-future of the psychedelic field through the eyes of an entrepreneur following her dream of building a psychedelic therapy business. We encourage you to engage with the difficult questions *Pala* raises about the potential future of psychedelic medicine, such as how aspirations to create psychedelic therapies that are patient-centered are likely to conflict with pressures to scale up and maximize returns. Please let us know what you think as we would love to hear your thoughts and reflections on this very timely issue!

Psychedelic science media highlights

In October, PSFC member George Sarlo discussed his transformative experiences with ayahuasca in a *New York Times* [story](#) on ayahuasca use by senior citizens. Anderson Cooper's in-depth [segment](#) for *60 Minutes* explores psilocybin research at Johns Hopkins. *NPR* also [covered](#) a Johns Hopkins study of psilocybin for smoking cessation. *Double Blind*, the new print magazine focused on psychedelics [interviewed](#) psychedelic researcher Monnica Williams on race, psychedelic trials, and MDMA for racial trauma. And the *Economist* [noted](#) growing interest in psychedelics among investors.

Parting thought

REBUS & the anarchic brain



This is a bit of a longer read, but we highly recommend it! In July, a remarkable paper by leading psychedelic researchers proposed a framework for understanding how psychedelics work in the brain. The model they propose, “Relaxed beliefs under psychedelics (REBUS) and the anarchic brain” is a fascinating one and their [paper](#) is an interesting grand tour of some of the most significant research on psychedelics to date. Give it a read and impress your friends and family with your newfound psychedelic science knowledge at Thanksgiving...

Best wishes,

Joe, Graham, Ben, and JJ