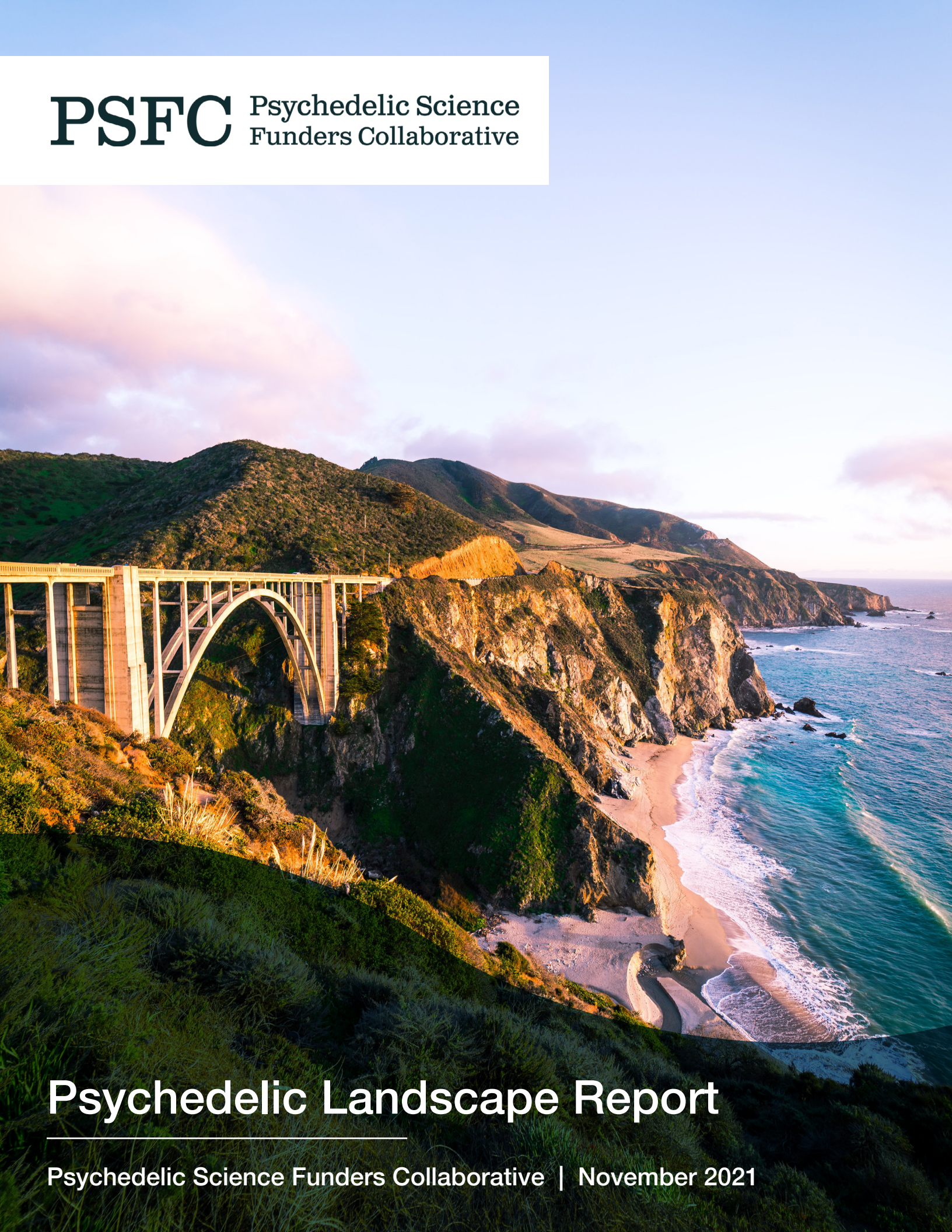
PSFC Psychedelic Science Funders Collaborative



Psychedelic Landscape Report

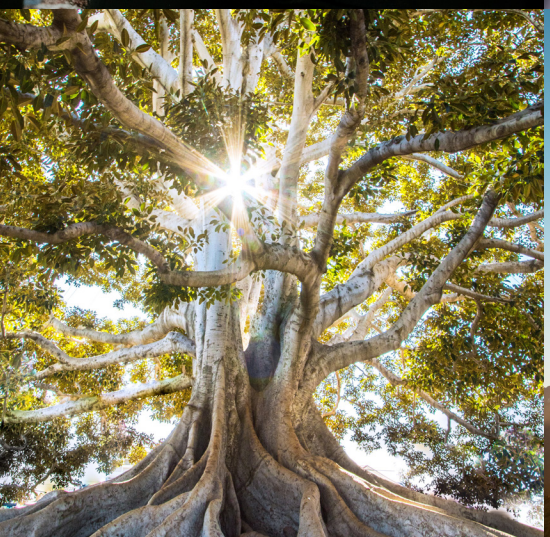
Psychedelic Science Funders Collaborative | November 2021









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Letter From the Founders

As 2021 draws to a close, it is staggering to think we are likely less than two years away from legal access to psychedelic therapy under both federally-approved (FDA) and state-approved, regulated models.

When psychedelic research restarted in the 90's after being dormant for decades, the distant hope was that it would someday lead to FDA approval and legal medical access. The vast majority of the resources over the past three decades have gone into research and clinical trials towards this goal. When we founded Psychedelic Science Funders Collaborative (PSFC) in 2017, it was a wide open question whether any psychedelic would one day be available by prescription or whether broad access to psychedelics outside of a medical context would be possible in any form. Since our founding, we have seen the field of psychedelics migrate from a question of "if" psychedelic healing will be made legal and accessible, to a question of "how".

Over the last four years, we have also seen the field experience a period of rapid expansion, with the introduction of a growing number of nonprofit and for-profit organizations - each aiming to play their part in building out a thriving psychedelic ecosystem. Recognizing the increasing complexity of this growing field, in late 2020, PSFC set out to "map the landscape". In doing so, we aimed to:

- Gain a better understanding of the growing variety of organizations, companies and individuals advancing the field;
- Gain an understanding of the relationships and interdependencies between these groups that will be necessary to create the robust care delivery system needed;
- Identify the highest impact areas for funding to support the field's continued growth and maturation.

Our team undertook a process of both primary and secondary research - interviewing 59 key leaders and stakeholders throughout the ecosystem, while also conducting a thorough review of key studies, trials, literature, and industry reports.

The result is PSFC's Psychedelic Landscape Report, which we are now thrilled to share with the broader psychedelic community. It is our hope that this report, and the strategic recommendations outlined herein, will serve as a tool for stakeholders to better understand the various components necessary to enable a thriving psychedelic ecosystem – and to inform decision-making regarding high-impact funding opportunities.

Since sharing an initial version of this report with our members earlier this year, PSFC has used it to help crystallize our two key priorities:

1. Continued support for the accessibility of high-quality MDMA-assisted therapy in the United States
2. Ensuring Oregon's psilocybin therapy program provides a high-quality model for psychedelic healing in a non-prescription context that could be replicated in other states

With work underway to ensure the major components of the Oregon Psilocybin Therapy Services Initiative are on track to launch in January 2023, and FDA approvals for the prescription of MDMA possible later that same year, there is much to be done over the course of the next 12-18 months to ensure the infrastructure is in place to create robust, safe, effective and accessible systems of psychedelic care delivery under each model.

The stakes are high for both MDMA by prescription and psilocybin in Oregon. Both will draw national attention while also setting precedents for the rest of the psychedelic field. We believe this is a pivotal moment in which we have an opportunity to show that psychedelic healing can be beneficially integrated into society. However, if this integration does not go well, we risk repeating some of the dark side of the 60s and the ensuing backlash.

Thus, PSFC is focusing its philanthropic resources to ensure successful care delivery under these two systems. As a community of funders, we recognize the power of working as a collective. We also recognize the important role that philanthropy will continue to play in enabling the build out of critical infrastructure for psychedelic care delivery – particularly for organizations or initiatives that would otherwise go underfunded.

To meet our goals, we are forming several member-led working groups which, with PSFC staff and outside experts, will analyze the sector in depth to understand the gaps in the field that are not being sufficiently supported or funded, but whose growth are critical for the development of a psychedelic delivery system that is safe and accessible. We will vet key non-profit organizations in the sector, recommend philanthropic funding opportunities to our members, and provide support and oversight for grantee organizations in the form of both financial resources and expertise in business, policy, regulation, advocacy, science, and organizational design.

In the coming months, we look forward to sharing additional details regarding the work emanating from our working groups, while amplifying the work of the various organizations and initiatives with whom we will collaborate.

In the meantime, we invite stakeholders throughout the ecosystem to be in touch with us to discuss the contents of this report, to explore possible areas of collaboration, or to inquire about PSFC membership. Inquiries can be directed to: info@psfc.co.

We hope you find value in the Landscape Report and we are very grateful to all who made it possible. We are honored to be able to share in our service to the psychedelic field, and in the advancement of a vision for safe, effective and accessible psychedelic healing for all who stand to benefit.

In gratitude,

Graham Boyd and Joe Green
PSFC Founders

Executive Summary

A Global Mental Health Crisis; A Global Opportunity for Healing

The global mental health crisis has reached an alarming state. Better treatments are urgently needed to address depression, PTSD, addiction, and other debilitating conditions affecting hundreds of millions worldwide. A growing body of clinical research suggests that psychedelic compounds—long-stigmatized in the medical and scientific fields—hold significant promise as potential breakthrough mental health treatments. After years of research funded largely by philanthropy, Food and Drug Administration (FDA) approval of the first psychedelic-assisted therapies is now on the immediate horizon.

In 2023, just two years from now, it is likely that psychedelic-assisted treatments will be legally available in the U.S. for the first time through two systems: MDMA-assisted therapy for PTSD by prescription regulated by the FDA and psilocybin therapy for anyone who can safely benefit in Oregon regulated by the Oregon Health Authority. Decades of hard work have led up to this moment, and the coming years will be pivotal for broadening access to psychedelic healing.

As this "renaissance" in psychedelic research and treatment emerges, philanthropy, once the primary financial engine driving the psychedelic field, now sits alongside commercial investment and soon government funding as well. This report aims to help philanthropists and other stakeholders map the rapidly evolving landscape of the psychedelic field. Building on interviews with PSFC members and leaders in the field, it also lays out an ambitious, but achievable vision for what psychedelic healing could look like in five years, and outlines pathways and funding opportunities to help get there.

A vision of what might be possible for psychedelic medicine by 2026:

- Psychedelics currently in clinical trials have become FDA-approved mental health treatments.
- Psychedelic research is prolific, strategic, and government-supported. Its focus has broadened from "are psychedelics effective?" to "how can we optimize treatments for patients and make them more accessible?"

- Tens of thousands have been trained as psychedelic therapists, and psychedelic care has been introduced at clinics around the country.
- Oregon, the first state to authorize supervised psilocybin therapy, has become a model for expanding access to psychedelic care outside of a prescription context, prompting other states to adopt similar initiatives.
- Reciprocal support for Indigenous-led conservation efforts has addressed threats to wild sources of plant-based psychedelics and protected Indigenous healing systems
- Extensive public education and political engagement efforts have cultivated broad-based support for access to psychedelic treatments.

Meeting the Challenges Ahead: From Research Breakthroughs to Delivering Healing

While this is an opportune moment for philanthropists to dream big about the future of psychedelics, thorny challenges lie ahead before research breakthroughs can make their way to patients and provide treatments that are safe, effective, and accessible. This report outlines several high-priority goals for advancing the field:

Create pathways for legal access to psychedelic healing.

In spite of their promising therapeutic applications, psychedelic-assisted therapies are not yet legal in the US or globally. A critical initial step will therefore be to secure legal access to these treatments:

- **Obtain regulatory medical approval for MDMA-assisted therapy to treat PTSD.** The world's first regulatory approval of a psychedelic-assisted therapy would be a catalytic event, giving millions of patients access to a breakthrough treatment and legitimizing the field. This has been PSFC's core focus to date.
- **Support state-level approval of psilocybin-assisted therapy**. Oregon's state-regulated psilocybin therapy program will open access to supervised treatment for a much larger population that could benefit from psychedelic therapy but does not have a diagnosed condition. This program could also become a hub for research and therapist training while serving as a model for other states.
- **Obtain regulatory medical approval for psilocybin-assisted therapy,** which would fully usher in a renaissance of psychedelic therapy and allow for the treatment of depression, substance use disorders, and other conditions.

Build the infrastructure needed to deliver psychedelic care.

To bring psychedelic care to the millions who could benefit, it will be critical to develop rigorous standards of care, train tens of thousands of therapists, and ensure treatment is accessible to those who need it most:

- **Enable the precedent-setting rollout of the first psychedelic-assisted treatment** by supporting planning for the delivery of MDMA-assisted therapy.
- **Train and support the first 100,000 psychedelic therapists needed to treat 1 million patients per year by**

2031 by recruiting therapists, funding training programs, and supporting therapists entering practice.

- **Ensure psychedelic-assisted therapy is as safe and effective as possible** by building strong standards of care and supporting research to further optimize treatment.
- **Make care accessible and affordable for patients** through insurance coverage, patient assistance programs, equity initiatives, and networks of impact-focused clinics.

Cultivate a broader ecosystem of supporting organizations in the research, public engagement, and political fields.

A range of organizations and initiatives will be needed to promote acceptance and understanding of psychedelics in medical and academic research communities, the political sphere, and the public at large. In parallel, it will be important to protect Indigenous plant medicine healing traditions and address ecological threats to plant-based psychedelics:

- **Foster a thriving, coordinated, and cooperative research ecosystem** supported by robust government funding and embraced by the scientific mainstream.
- **Develop public education and integration support initiatives** to increase understanding of psychedelic therapy and keep adverse events to a minimum.
- **Build political and advocacy infrastructure** to support policy engagement on psychedelics and ensure the long-term viability of psychedelic medicine.
- **Partner with Indigenous-led plant medicine conservation efforts** to sustain traditional healing systems and restore wild sources of plant-based psychedelics.

Conclusion: Working Towards a Collaborative Philanthropic Agenda

Philanthropy has a pivotal role to play in the years ahead for psychedelic healing, and PSFC sees delivering safe, effective, and accessible psychedelic care as a critical priority for philanthropic support. Funders have an opportunity to shape this field by establishing safeguards for treatment and aligning the broader psychedelic ecosystem around shared values for delivering care and broadening access. First issued in May 2021 to PSFC members, this report introduces PSFC's key priorities – supporting the accessibility of high-quality MDMA-assisted therapy in the United States and ensuring Oregon's psilocybin therapy program provides a high-quality model for psychedelic healing in a regulated context that could be replicated in other states. With the release of this report to the broader public in December 2021, PSFC hopes that it will serve as a tool for all stakeholders throughout the psychedelic field to understand the rapidly evolving and increasingly complex landscape, as well as the ways in which both philanthropic and investment capital can support its continued growth and maturation.

Much of the growth and evolution of the psychedelic landscape will continue to be fueled by philanthropic support. PSFC is committed to serving as a resource for philanthropists seeking advice and community as they explore the most effective ways to support the increased accessibility of psychedelic healing.

To learn more about high-impact philanthropic opportunities and the PSFC community, please contact us at info@psfc.co.

For media inquiries, please contact media@psfc.co.

Introduction

The Possibilities and Challenges Ahead for Psychedelic Healing

The field of psychedelic science is entering a critical period of rapid growth. Amid a global mental health crisis, psychedelics have the potential to bring relief to many people for whom existing mental health treatments have not proven effective.

Promising early findings from research suggest that psychedelics have the potential to bring about a paradigm shift in mental health treatment. For example, results from the first Phase 3 trial with MDMA-assisted therapy showed that two-thirds of patients no longer qualified for a post-traumatic stress disorder (PTSD) diagnosis 12 months after treatment.[1] In other clinical trials, psilocybin treatment for patients with a terminal diagnosis who also had depression led to an 80 percent reduction in depression symptoms.[2]

Psychedelic research is now being conducted at some of the most prestigious universities around the world. This work is uncovering ways to meaningfully address conditions that affect hundreds of millions of people worldwide, such as depression, anxiety, addiction, and PTSD. Alongside this academic research, there is a growing ecosystem of nonprofit and for-profit organizations working to broaden access to psychedelic healing and prepare for the delivery of psychedelic care.

Although psychedelic healing holds immense promise, major challenges lie ahead: While psychedelic-assisted healing may become legally available as early as 2023, nearly all of the infrastructure needed to deliver care remains to be built. Meanwhile, research in this field is still in its early stages and remains underfunded by governments and major foundations.

2/3 of patients who participated in an MDMA-assisted therapy trial **no longer qualified for a PTSD diagnosis** 12 months after treatment

The Scope of the Mental Health Crisis

Globally

- Mental illness is the most common cause of disability worldwide
- 800 million people suffer from a mental health issue
- More than 264 million people suffer from depression
- More than 350 million people suffer from PTSD[3]
- ~800,000 people die from suicide each year (one every 40 seconds)
- Over 70% of people with mental illness do not receive treatment
- Depression and anxiety alone are estimated to cost the global economy $1 trillion annually[4]

In the United States

- Nearly one in five adults live with a mental illness (51.5 million in 2019)
- 16.2 million adults, or 6.7% of all American adults, have a major depressive episode each year
- One in six adults is unable to access professional help for emotional distress
- PTSD affects an estimated nine million adults, or 3.6% of American adults, every year
- Suicide is the tenth leading cause of death overall and the second leading cause of death for individuals between the ages of 10 and 34
- In 2012, lost earnings and public disability insurance payments due to mental illness amounted to a combined total of at least $467 billion[5]

The State of the Psychedelic Funding Landscape

The '50s, '60s, and '70s, were a vibrant era of scientific research on psychedelics such as LSD, mescaline, and psilocybin. Researchers investigated many applications for psychedelics, including psychotherapy, combating addiction, and stimulating creativity.

The Controlled Substances Act in 1970 made these compounds illegal, and largely halted government-sanctioned psychedelic research for decades. The resurgence in psychedelic research since the early 2000s was funded predominantly by a small group of philanthropists giving directly to institutions such as MAPS, the Heffter Research Institute, and the Beckley Foundation. Most research was done on shoestring budgets and interviewees from these organizations have noted how gifts under $100,000 could initiate entirely new research efforts.[6]

To date, government funding for psychedelic research has remained very limited. The US National Institute of Mental Health (NIMH) operates with a budget of over $1.5 billion but has not provided funding for psychedelic research. However, recent developments suggest that the attitudes of government funding bodies towards psychedelic research are changing. In April 2021, the National Institutes of Health (NIH) granted a career development grant for psychedelic neuroimaging research, and in September 2021 the National Institute of Drug Abuse (NIDA) awarded the first substantial US government grant to psychedelic research since the 1960s. While it will take several years for government funding to become more readily available to support psychedelic research, these first grants mark the success of years of compelling work and evidence enabled almost entirely by charitable giving. Philanthropic support has been a cornerstone of this work, and charitable funding can continue to have an outsized impact in this field. As author and PSFC member Tim Ferriss concluded, "Where do you have the opportunity to have billions of dollars of impact with a million dollars? There just aren't that many places."

Philanthropic Funding for Psychedelics: By the Numbers

$125 million
Raised by MAPS since its founding and over **$45 million in 2020**

$40 million
Raised by The Usona Institute since its founding

$15 million
Raised by The Heffter Research Institute or studies to date

$17 million
Gifted to Johns Hopkins University to launch the Center for Psychedelic Consciousness Research in 2019

$10 million
Raised by NYU to open a psychedelic research center

£3 million
Raised by Imperial College London to launch their Centre for Psychedelic Research

Several US academic institutions have raised single-digit millions recently

Commercial Funding for Psychedelics: by the Numbers

$658 million

Raised in 2020 by 65 companies working in the psychedelics ecosystem

85%

Of these companies are located in North America: 30 in Canada, 25 in the US, and 10 in Europe

Total Amounts Raised By Major Companies in the Commercial Ecosystem

$347 million ATAI Life Sciences	**$175 million** MindMed
$124 million Cybin	**$116 million** Compass Pathways
$114 million Beckley Psytech	**$95 million** Field Trip
$23 million Revive Therapeutics	**$21 million** Numinus[8]

In the past few years, increased interest in this space has birthed a commercial ecosystem and a rapid influx of capital, attracted by what some investors characterized as "an arbitrage opportunity between good science and bad policy."[7] As the psychedelic ecosystem and the funding supporting it evolves, the role of philanthropy will need to adapt in turn. Funding sources for the psychedelic field are diversifying, and philanthropy will no longer need to move the entire field forward by itself. Instead, it will need to play several key roles alongside other funding sources: creating new pathways for accessing care, safeguarding the integrity of the therapeutic model, and ensuring that treatment is accessible to those who need it most.

> "Where do you have the opportunity to have billions of dollars of impact with a million dollars? There just aren't that many places.
>
> - Tim Ferriss

About PSFC and Our Work to Date

Psychedelic Science Funders Collaborative (PSFC) is a 501(c)(3) nonprofit founded in 2017 as a community of philanthropists dedicated to supporting the psychedelic field. We work to identify high-impact funding opportunities, serve as a resource for funders interested in this field, and foster connections among funders, researchers, and others working to advance psychedelic healing. PSFC's operations are supported by voluntary dues from our members, which enables us to pass through 100 percent of donations to support the field.

At our founding, we began with the thesis that FDA approval of a psychedelic-assisted therapy would be a catalytic event that could bring the psychedelic field into the medical and scientific mainstream, unlock funding from new sources, and open the door for other psychedelic treatments. We then engaged expert due diligence and concluded that thanks to decades of work by MAPS, MDMA was the psychedelic closest to Food and Drug Administration (FDA) approval for prescription use. To advance this effort, PSFC and our members have provided funding and expert support for MAPS's clinical trials, including by partnering with MAPS on the Capstone Campaign in 2020, which raised $30 million to support the final stretch of the FDA approval process for MDMA-assisted therapy for PTSD.[9] PSFC has also supported MAPS's planning for delivery of care by bringing in and funding experts, including the Boston Consulting Group. PSFC has supported several other organizations across the psychedelic ecosystem as well and in 2021, we raised $1 million to support implementation of the Oregon psilocybin therapy initiative.

Report Scope and Research Process

After our intense focus on the Capstone Campaign, followed by initial funding support for Oregon implementation, PSFC identified the need to explore how to best support the larger, rapidly growing psychedelic ecosystem. This report surveys the landscape, outlines PSFC's strategic vision, and highlights high-impact funding opportunities. Our goal is for it to serve as a resource for our members, as well as for other funders and collaborators in the psychedelic field. Although the report does cover some non-US research, organizations, and initiatives, given that most PSFC members are US-based, our main focus is on psychedelic research, care delivery, and policy developments in the US.

Our research process involved a review of studies, trials, literature, industry reports, and other documents. We also interviewed 59 leaders and key stakeholders in the field, including researchers, funders, advocates, nonprofit leaders, and commercial executives. These included:

- 23 philanthropic funders, including 18 current PSFC members
- 23 researchers and nonprofit leaders
- 10 investors or executives at venture-backed companies

PSFC's Vision for Psychedelic Healing

During our research and interviews with PSFC members and experts in the field, a few shared values and aspirations rose to the top. The vision we introduce below illustrates PSFC's overarching goal: **safe, effective, and accessible psychedelic healing for as many as possible, as soon as possible, while ensuring care is introduced equitably and reaches those who could benefit most.** This is not an exclusive priority, however, as access to healing depends on a thriving psychedelic ecosystem beyond the clinic, as the following imagined future for psychedelic healing shows.

From Vision to Strategy: PSFC's Core Focus and the Structure of this Report

While the above is only one of many possible visions for the future of the psychedelic field, it illuminates the priorities and values underpinning the funding approach we outline in this report. PSFC sees developing the care delivery systems for psychedelic healing as the most important philanthropic priority for the field. Psychedelic-assisted treatments will be legally available as soon as 2023, and it will be critically important to be ready to deliver them to patients safely, effectively and at scale. As such, PSFC's focus over the next 12-18 months will focus on offering continued support for the accessibility of high-quality MDMA-assisted therapy in the United States; and ensuring Oregon's psilocybin therapy program provides a high-quality model for psychedelic healing in a non-prescription context that could be replicated in other states.

The three chapters of this report outline a broad set of goals for funders aligned with this objective of delivering psychedelic healing. Although we mention several organizations for illustrative purposes, these have not been independently diligenced by PSFC and are not included as specific funding recommendations. Rather, our recommendations highlight funding areas we see as strategic and in need of financial support. We envision this report as a tool for funders to understand the rapidly evolving, and increasingly complex landscape, as well as the ways in which both philanthropic and investment capital can support its continued growth and maturation.

The first chapter focuses on the objective of **creating and expanding legal access to psychedelic healing**. In it, we evaluate several pathways to broadening access to legal psychedelic healing, such as prescription access and ballot initiatives. We conclude by recommending support for clinical trials of MDMA and psilocybin alongside support for state-level non-prescription therapeutic access to psychedelic therapy.

The second chapter looks at the **challenge of delivering psychedelic healing** in a prescription and non-prescription context. After assessing companies and organizations working on psychedelic care delivery, we highlight the rollout of the first prescription psychedelic-assisted therapy, MDMA-assisted therapy for PTSD as a critical funding priority. We then turn to field-wide care delivery challenges and the interconnected roles of philanthropy and impact investment in meeting them. Top priorities for support include setting treatment standards and therapist certification systems, scaling training of psychedelic therapists, and researching improved treatment protocols. We conclude by looking at the path ahead to make psychedelic care accessible and affordable, with particular attention to the challenge of reaching underserved patient populations. We will need to work with private insurers, government health systems such as the

Image Credit: MAPS

Note on PSFC's affiliations with organizations mentioned in this report

PSFC's co-founders currently serve in volunteer leadership positions at the Multidisciplinary Association for Psychedelic Studies (MAPS) and MAPS Public Benefit Corporation (MAPS PBC). Joe Green joined the MAPS board in 2020 and Graham Boyd has participated in MAPS PBC board meetings as a non-voting observer since 2020. PSFC also jointly raised funds for MAPS through the Capstone Campaign and has provided additional grants to MAPS on behalf of PSFC members. Graham is also a co-founder and member of the Board of Directors for the Healing Advocacy Fund, the Founder and Director of New Approach Political Action Committee and New Approach Advocacy Fund, and in those capacities was involved in the Oregon Measure 109 campaign. Graham serves as an unpaid legal advisor to Center for Consciousness Medicine and unpaid advisor to Beckley Waves. (He was paid for those roles during part of 2021.)

Looking Backwards from 2026: A Possible Future for Psychedelic Healing

In 2026, psychedelic healing is truly going mainstream with psychedelic-assisted therapy clinics open around the country. This year marked a milestone, with over **50,000 across the US receiving psychedelic treatment** in both medical and non-medical settings.

Psychedelic-assisted therapy was initially available at a few specialty clinics following the approval of the first prescription psychedelic-assisted therapy, MDMA in 2023. But just three years later, several major hospital chains now have psychedelic therapy practice groups. Following FDA approval, **the first health insurers began to cover psychedelic treatment, first tentatively and then enthusiastically** once the benefits to patients and cost savings to health plans from these treatments became clear. The Veterans Administration (VA) has launched pilot initiatives at its hospitals around the country and is considering adopting MDMA-assisted therapy as its new "gold standard" treatment for PTSD. The thousands of newly-trained therapists specializing in psychedelic-assisted therapy are barely able to keep up with demand for treatment, even with training programs opening at universities around the country.

Following the rollout of psilocybin therapy outside of a prescription context in Oregon in 2023, the state drew national attention as **a new model for safe and effective delivery of care, not just for healing, but for personal wellness**. Other states are now following Oregon's lead and adopting similar psilocybin programs through legislation and ballot initiatives.

Early philanthropic support for therapist recruitment and training alongside investments in impact-focused

clinics are beginning to bear fruit: Baltimore, Charleston, Portland, and Austin now vie with the San Francisco Bay Area for the title of the leading hub for psychedelic treatment. **These thriving networks of clinics are rewriting expectations about the reach of mental health care in the U.S**. Beginning with the first cohorts of "early access" patients, patient outreach and assistance programs have enabled treatment to heal a significant and growing number of individuals from communities that experience high rates of trauma but had previously had the greatest difficulty accessing affordable and effective care.

Psychedelic medicine is now a thriving frontier for academic and clinical research, and the field is a sought-after career path for some of the best and brightest early- and mid-career researchers. Rapidly making up for decades of lost time during prohibition, research is building a more nuanced understanding of various psychedelics and their effectiveness for a range of mental health conditions. Psychedelic-assisted therapy for treating major mental health disorders now appears in most psychiatry textbooks. **Researchers are expanding their focus from investigating whether psychedelics are safe and effective to optimizing treatments for the greatest number of patients and conditions** and deepening our understanding of how psychedelics work in the brain.

Around the globe, **Indigenous-led conservation efforts are halting declines in wild sources of plant-based psychedelics**. This has minimized ecological impacts from rising global demand for psychedelics and ensured Indigenous healing systems that had been under threat—and whose traditional knowledge made the psychedelic renaissance possible—could continue to provide healing.

On the policy and public awareness front, thanks to extensive public education efforts and psychedelic support and integration services, adverse events remain rare, even as psychedelics grow in popularity. Patients, veterans, and psychedelic therapist advocacy now have significant presences in Washington. Both the National Institutes of Health and National Institute of Mental Health have issued major grants to dozens of institutions for psychedelic research: Half a century after it had banned psychedelics altogether, the US Government has become a major supporter of psychedelic research.

Chapter I:

Expanding Legal Access to Psychedelic Healing

Introduction

> Psychedelic-assisted psychotherapy could provide needed options for debilitating mental-health disorders including PTSD, major depressive disorder, alcohol-use disorder, anorexia nervosa, and more that kill thousands every year in the United States, and cost billions worldwide in lost productivity.
>
> - Nature, January 2021[10]

Existing treatments are insufficient to address critical mental health and substance abuse disorders, and better options are urgently needed. Psychedelic-assisted therapy can yield rapid and large reductions in depression, anxiety, PTSD, and possibly treat other psychiatric conditions. Importantly, these results are sustained over time without the need for ongoing use of psychedelics. Mirroring these therapeutic applications, neuroimaging studies with humans have found that psychedelics produce significant and meaningful changes in brain areas associated with self-regulation, emotional regulation, and areas that play a role in depression, anxiety, and addiction.

Despite their promising therapeutic applications, access to psychedelic therapies is currently illegal in the United States and most of the world. **A critical initial step will therefore be to enable legal access to psychedelic healing.** Starting in 2017 and following a due diligence process to identify the fastest and highest-impact strategy, PSFC's initial focus has been to bring MDMA-assisted therapy to treat PTSD past the US regulatory finish line. This led to PSFC partnering with MAPS to support the completion of the MDMA-assisted therapy trial and FDA approval process.

Thanks to these efforts, US Food and Drug Administration (FDA) approval for this first psychedelic-assisted therapy is in sight for 2023, but broad access to healing both inside and outside a prescription context will require more pathways. Unlike MDMA, psilocybin is considered a classic psychedelic substance, and is the closest to legal therapeutic access through two possible approval pathways. Therefore **the next critical objective to enable legal access after MDMA approval will be to bring psilocybin therapy to the US both through FDA approval (as early as 2025) and state-level authorizations such as the supervised psilocybin therapy framework created by Oregon Measure 109 (2023).** This latter pathway enables broader access to those who may not have severe treatment-resistant mental disorders, but who may nevertheless benefit from psychedelic therapy.

Many PSFC members feel that the world would be a better place if people had legal access to psychedelics in a context that encouraged safe and responsible use, and many are mindful of the backlash generated in the 60s by rushing toward that vision. In this modern reboot of seeking broad access, we agree with leaders like Rick Doblin and Roland Griffiths that the most certain route to sustainable progress lies with the medical model, where safety and efficacy are demonstrated by rigorous science. But few of the modern leaders believe that the benefits of psychedelics should be reserved only for the "sick," i.e., for those with a diagnosed mental illness.

> "Achieving medical approval of individual treatments is a vital part of bringing the benefits of psychedelics to a larger population, but we need broader societal and policy change to create access on the kind of scale we aspire to. Political change takes time, resources, and a careful strategy. With the right support, we can change both laws and public perception to open up psychedelic healing and wellness in much more wide-ranging ways.

- Graham Boyd
Co-founder and Executive Director, PSFC

Access to Healing Primer

Background on clinical trials leading to FDA approval

Bringing a new drug and therapy to market in the US is a highly regulated process involving multiple steps from basic research to clinical trials in numbered phases leading up to potential FDA approval.

Basic research and **preclinical** studies in animals and humans serve to determine physiological effects, safety, and toxicity. Then, following an Investigational New Drug (IND) application, a given molecule enters **clinical trials**, where it is evaluated for safety and efficacy for the treatment of a specific condition in humans.

Clinical research trials consist of three phases of randomized controlled trials (RCTs) which are carried out under the purview of the FDA. The EU has a similar process for drug approval and most other countries will authorize based on either US or EU approval.

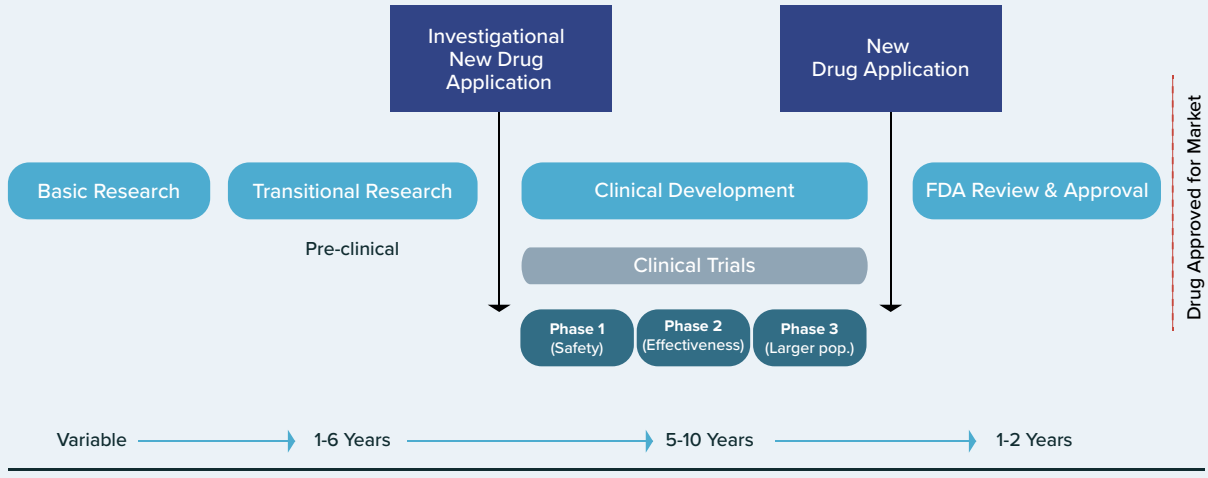
In order to determine whether a treatment works for a certain condition, researchers test it against an inactive placebo in a process called double blinding, in which participants are randomly assigned to the placebo or drug group without the knowledge of the participant or experimenter. Blinding is a particular challenge in psychedelic research as their profound effects tend to be easily noticed by both participants and researchers.

- **Phase I (safety)** studies aim to establish safety in healthy human subjects.
- **Phase II (effectiveness)** studies test the treatment in a small cohort of patients to establish efficacy and monitor safety.

- **Phase III (therapeutic confirmation or pivotal)** studies evaluate the safety and efficacy in a larger study population to determine whether the treatment is actually effective against the condition in question.

Following successful Phase III clinical trials, study data are submitted to the FDA for review. If FDA reviewers deem the "New Drug Application" (NDA) satisfactory, the drug is approved and can become available for prescription. After receiving FDA approval, future research focuses on optimizing treatments and monitoring safety in broader patient populations as well as new indications. **The figure below illustrates the FDA process; MAPS's Phase 3 MDMA trials have started in 2018.**

The Drug and Therapy Development Pipeline



Clinical research is most commonly directed toward achieving FDA approval for a new drug. However, clinical research that focuses on "treatment optimization" can inform when and how the new drug can best be used and can evaluate the drug in broader patient populations. In the psychedelic research field, such studies currently investigate therapeutic modalities, group delivery settings, optimal dosage and context, patient preparation, and integration strategies. These are important for lowering costs and enabling broader access.

Another important type of research done in partnership with a sponsor entity conducting drug clinical trials are Investigator-Initiated Trials (IITs): studies with scientific and medical merit developed and sponsored by an independent investigator or academic sponsor. An IIT may be a clinical or non-clinical study conducted with the participation of the drug sponsor, for which the IIT sponsor requests that the sponsor provide either funding, drug product or both.

Background on Oregon Measure 109's regulatory framework

In November 2020, Oregon voters passed Measure 109, the "Psilocybin Mushroom Services Program Initiative" with 56 percent of the vote, approving the creation of the first state-regulated psilocybin therapy program in the United States. The measure directs the Oregon Health Authority (OHA), in collaboration with a newly created Psilocybin Advisory Board, to develop rules, training requirements, and a licensing process over a two-year implementation period. By the end of 2022, the OHA must be prepared to issue licenses to facilitators, service centers, and psilocybin producers so that the program can begin serving clients.

> "[The Oregon Model] is based on the idea that psilocybin has the potential to change our lives for the good, whether we are sick or well, and so it is worth investing in the frameworks and safeguards so that it can be used safely and productively. It would be foolish to posit psilocybin-assisted therapy as an answer to all that ails our society, or even our mental health system. But it would be one more option for those who need it, and both evidence and anecdote suggest it would be life-changing for many. That would be enough. That would be so much.
>
> - Ezra Klein
> New York Times, March 2021

As laid out in Measure 109, the program will include numerous safety provisions. All prospective clients will go through a required health screening. Psilocybin can only be administered by a trained and licensed facilitator in a licensed service center. Psilocybin will not be sold to patients, and no one will be allowed to leave the service center while still under the influence of psilocybin. Clients will also have at least one post-experience integration session with the facilitator.

Importantly, the Oregon model moves beyond the illness model: clients will not need a doctor's recommendation or a medical diagnosis to access psilocybin therapy. Instead, as with conventional talk therapy, people can seek facilitated psilocybin therapy to deal with specific concerns or for personal growth and exploration. The same way that talk therapy done early enough can prevent severe mental health consequences such as a burn-out or suicide, psychedelic-assisted therapy could also play a preventive role. Oregon's program will set a precedent for broadly therapeutic psychedelics access outside the prescription context and can become a valuable center for research and training.

State of the Landscape:
Current Status of Access Initiatives

Legal access to psychedelic healing in the US can be achieved through multiple pathways. Each approach to access offers different potential for reimbursement, access, safeguards, and criminal justice reform.

TABLE 1. PATHWAYS TO LEGAL ACCESS TO PSYCHEDELIC THERAPY

Pathway	Status	Accessible to	Reimbursement potential	Extent of safeguards
FDA/Prescription access	**FDA Phase II:** Psilocybin for major depressive disorder, treatment resistant depression, and alcohol use disorder; Ketamine for reduction of alcoholic relapse and suicidal ideation and behavior; LSD for cluster headaches and anxiety disorders; MDMA for eating disorders, anxiety associated with life-threatening illness, and social anxiety in autistic adults **FDA Phase III:** MDMA for PTSD	People with specific diagnoses and eventually others through off-label use	High	High - through REMS and traditional healthcare safeguards
Regulated access to supervised psychedelic treatment	Statewide access to psilocybin-assisted therapy has been authorized by ballot initiative in Oregon	People seeking medical healing or non-medical use	TBD	In Oregon: Medium/High - through standards, enforced by new regulatory model
Decriminalization	City-level decriminalization initiatives have been passed in Denver, Santa Cruz, Oakland, Ann Arbor, DC, Somerville, Cambridge, Northampton, Seattle, Detroit, and Arcata	Anyone in decriminalized municipality or state	None	Use and possession threshold
Religious Freedom Restoration Act (RFRA)	Santo Daime, União do Vegetal, and others	Members of a designated church with a federally-granted exemption	None	Determined through exemption process
Right to try	Approved in 40 states	End-of-life patients	Unknown	Unknown

FDA/Prescription Access

Receiving FDA approvals for MDMA and psilocybin are linchpin goals for the psychedelic field to open up access to treatment for millions and leads to rescheduling at the federal and state levels. They represent the first major milestones in bringing psychedelic-assisted psychotherapy into the healthcare system and paving the way towards the first care delivery. These approvals would be a catalytic event towards removing the stigma attached to psychedelics.

FDA approval is an acknowledgment of a drug's medical value and safety by the federal government. This approval seems likely to be achieved in the next few years with MDMA for PTSD (MAPS), as well as psilocybin for major depressive disorder (Usona), treatment-resistant depression (Compass Pathways), and/or alcohol use disorder (B.More).[11] The table below provides an overview of these and other psychedelics being studied for specific indications, their current clinical trial stage, and the organization carrying out the studies.

Stage of Research					
PRE-CLINICAL	CLINICAL				FDA REVIEW & POST-MARKET SURVEILLANCE
	FDA Phase 1 Safety	FDA Phase 2a Dosing	FDA Phase 2b Efficacy	FDA Phase 3 Comparison	
Ketamine	Healthy individuals - **Perception Neuroscience** Suicidal ideation - **Seelos Therapeutics**		PTSD - **Department of Defense and New York University Study**		Treatment-resistant depression - **Janssen**
MDMA		Anorexia & binge-eating disorder, social anxiety in autistic adults, and anxiety associated with life threatening illnesses - **MAPS** Alcohol use disorder - **Awakn**		PTSD - **MAPS**	
Psilocybin	Demoralization in AIDS survivors - **UCSF** + **Heffter** Cancer-related anxiety - **NYU**	Anorexia - **Compass Pathways** Cluster headaches, obsessive-compulsive disorder - **CH TAC** Cocaine addiction - **University of Alabama** **PTSD - Mydecine**	Treatment-resistant depression - Compass Pathways Major depressive disorder - **Usona** Alcohol use disorder - **B.More, NYU**		
LSD		Generalized anxiety disorder; cluster headaches; ADHD - MindMed			
Ibogaine	Methadone detoxification -**MAPS**	Noribogaine for opioid use disorder - **ATAI**			
Related compounds & analogs	Mescaline for alcohol use disorder - **Journey Colab**	18-MC for opioid use disorder - **Mindmed** DMT for depression - **Small Pharma**			

Legend: Non-profit/government funding, commercial funding

Source: https://psilocybinalpha.com/data/psychedelic-drug-development-tracker

FDA approval only creates legal access to a specific approved protocol for specifically approved diagnoses, such as MDMA-assisted therapy for treating PTSD. However, once a drug has been approved by the FDA, some clinicians may begin prescribing it for "off-label" use, meaning use for a medical condition different than what it was initially approved for. Off-label prescribing is quite common in the U.S. and it can be a way to broaden access to a treatment without having to wait for the completion of another FDA approval process. However, early prescribers and even drug sponsors can face liability if it is determined that they are providing or guiding access outside of a recognized standard of care.[12] Whether an off-label use meets a recognized standard of care depends on the evidence available to support that use and how the prescriber used that evidence to guide their recommendation. Off-label use of a drug is generally more likely to meet a standard of care in situations where there is a large amount of scientific research backing that use.[13] For psychedelic therapies, substantially more research will be required to establish off-label use as a norm.

Merits of the FDA approval access pathway:

- Nationwide (pending state de- or rescheduling) coverage
- Potential for insurance coverage
- Regulations will establish clear safety guidelines, reducing potential for adverse events
- Established drug safety program as well as standards of care

Risks/Limitations of the FDA approval access pathway:

- Access will be restricted to those with diagnosed mental health conditions or other qualifying criteria
- Costs may be high, given the regulatory oversight and restrictions
- Off-label use presents risks for prescribers and drug sponsors before robust evidence is supportive
- Off-label use is unlikely to receive insurance coverage

State and Local Policy Change

State and local policy reform has significant potential to create broad-based legal access to psychedelics outside of the prescription context. In recent history, changes in U.S. drug policy have started at the local and state levels first, often driven by ballot initiatives that directly reflect the will of voters. That pattern is so far holding true for psychedelics. Cities including Denver, Seattle, Detroit, Santa Cruz, Oakland, Ann Arbor, and Washington, D.C., have voted to decriminalize possession and use of psilocybin and (in some cases) other naturally occurring psychedelics. In 2020, Oregon's voters passed a first-of-its-kind psilocybin therapy initiative. In the first half of 2021, the Texas legislature passed a law funding psilocybin research. And states including California, Connecticut, Maine, and New Jersey are considering bills in their legislatures related to psychedelic policy and research.

State and local drug policy changes can be roughly categorized as either legalization (often with attendant regulations) or decriminalization. Generally speaking, legalization involves a proactive move to make a drug or substance legal for the adult population (usually 21+) to obtain and consume within certain parameters (e.g., from licensed sellers or providers). Decriminalization, on the other hand, involves removing criminal penalties for possession or consumption, or directing police to deprioritize enforcement of drug laws. It's important to note that neither legalization nor decriminalization at the state or local level actually removes the risk for federal prosecution. Substances included in

the federal Controlled Substances Act, including psychedelics, are still considered illegal by federal law enforcement, regardless of conflicting state or local laws. In analogous situations such as state cannabis legalization, the federal Department of Justice has adopted a policy of non-interference in recent years. It is reasonable to expect that they may do the same for psychedelics, especially in states that create a regulated system for access, but it is certainly not guaranteed. Federal interference could take the form of the DEA arresting clients or facilitators for violation of the Controlled Substances Act, or it could involve less direct action, such as revoking the Schedule 1 prescription drug license of a facilitating physician, sending threatening letters to state lawmakers, regulators, and landlords, or asset forfeiture actions to seize the property of those directly involved.

Legalization efforts typically take place at the state level, either via ballot initiatives or in state legislatures.

Ballot initiatives allow proponents to go straight to the voters, bypassing the complications and cautiousness of a legislative process. Many of the more substantial policy changes of the last two decades, such as the legalization of gay marriage and cannabis policy reform, started as ballot initiatives in hospitable states. Ballot initiatives can also give supporters more direct control over the design of a legalization program, as some details can be written into the language of the initiative, but the ability to do this varies greatly from one state to the next.

The primary downsides to ballot initiatives are cost and availability. The process of drafting, qualifying, and then running a campaign for a ballot initiative frequently runs into the millions of dollars and can involve a year or more of work in each state. (The largest line items come from the expensive signature drives required to qualify an initiative for the ballot and the costs of advertising and other persuasion during the campaign itself.) In addition, the ease with which policies can be changed via ballot initiative runs a broad spectrum from state to state, including a fair number of states where it is virtually impossible.

Merits of the state and local policy change access pathway:

- Reduces or eliminates risk of state-level arrest and prosecution
- In a supervised therapy model, increases access within a regulated framework
- Legitimizes use cases outside of the prescription medicine/disease treatment modality, such as the “betterment of well people”
- Increases therapist training opportunities by establishing a safe place for therapists to train and practice, which is critical for expanding access
- Allows for business model experimentation and data-gathering

Risks of the state and local policy change access pathway:

- Federal prosecution is still a risk
- Potential to elicit backlash from the medical establishment
- Potential for poorly managed adverse events if rollout is poorly designed or regulated

Other Pathways

Three alternative pathways enabling some level of legal access are decriminalization, religious exemptions and compassionate use. They are described briefly here as they are not part of the focus of this report.

There has been a flurry of decriminalization activity in recent years. Denver, Santa Cruz, the District of Columbia, Cambridge, Seattle, and other cities/districts have decriminalized some plant-based psychedelics, and others are actively considering similar measures.. In 2020, Oregon (through the Measure 110 ballot initiative) became the first state to remove criminal penalties for use or possession of all drugs at the state level. Although decriminalization initiatives are often proposed primarily to address the harm of incarcerating people for drug possession rather than as a tool for advancing psychedelic therapy, it can reduce stigma and allow for safer use by enabling nonprofits to openly support psychedelic preparation and integration. However, decriminalization does not allow for legal ways to produce or obtain psychedelic substances and the less-regulated environment it creates potentially increases risk of adverse events.

The Religious Freedom Restoration Act (RFRA) allows people to seek protections to offer psychedelic sacraments as part of their religious practice. There are a handful of churches using psychedelics.[14] This pathway to broadening access is a complex one, with several distinct approaches, each with different challenges. The settings in which psychedelics are being taken at these churches are not strictly therapeutic but oftentimes provide a structured setting for guided use and integration within a community. Due to the lack of oversight regarding protocols and the training of the guide, as well as the overall absence of standards, this path comes with risks. Whereas it could be a more expeditious path to increasing access, speed is only one factor to consider and may be outweighed by concerns about stigmatization, limited reach, media backlash, and more. It also requires considerable legal coordination and preparation, with no guarantee of positive results.

Because it takes a long time for a new pharmaceutical treatment to move from initial discovery to market approval, the FDA's Expanded Access program, created in 1987, is designed to allow patients with serious illnesses to access treatments that are still undergoing clinical investigation. Often informally referred to as the compassionate use program, the Expanded Access program allows patients with serious illnesses to use unapproved, investigational drugs if they have exhausted approved treatment options and are unable to participate in a clinical trial involving the drug. The FDA has granted MAPS initial approval to 50 patients for Expanded Access PTSD treatment with MDMA and MAPS plans to scale this Expanded Access program once its real-world efficacy has been established. The Right to Try Act (RTT) applies to patients who match the above criteria and suffer from a life-threatening condition. To qualify for both programs, drugs must have successfully completed a Phase I trial and remain under active investigation (MDMA and psilocybin would qualify, and possibly LSD and ibogaine as well). These programs could allow a restricted number of individuals to legally benefit from psychedelics assisted psychotherapy prior to FDA approval.

Successful "Right to Try" Access to Psilocybin in Canada

Canada is the first place in the world where patients can legally be prescribed psilocybin-assisted psychotherapy. TheraPsil is a non-profit patient advocacy group formed in 2019, assisting terminally ill Canadians facing end-of-life distress in applying for personal exemptions so they may use and possess psilocybin legally with a physician's recommendation. Patient and healthcare professional exemptions are being approved on a case-by-case basis by the Federal Minister of Health. To date, TheraPsil has supported 41 patient exemptions for treatment, and 19 exemptions for healthcare professionals so they may use and possess psilocybin as part of their professional training in accordance with TheraPsil's training protocol and curriculum. In January 2021, Health Canada announced a public consultation on a special access program that would make it easier for patients to access psilocybin and MDMA. This may result in a robust access program years earlier than the medical drug approval route.

Key Goals and Recommendations
to Expand Access to Psychedelic Healing

Achieving legal access to MDMA and psilocybin are the first major milestones in bringing psychedelic-assisted therapy into the medical and scientific mainstream. This section discusses what PSFC sees as three pivotal goals in this area in the coming years:

- Obtain regulatory medical approval for MDMA-assisted therapy to treat PTSD
- Obtain US federal medical approval for psilocybin-assisted therapy
- Support state-level approval of psilocybin-assisted therapy

Goal #1: Obtain regulatory medical approval for MDMA-assisted therapy to treat PTSD

Rationale

This foundational goal of PSFC was initially chosen in 2017 because in our analysis, MDMA was the psychedelic that was furthest along in the clinical trial process and had the highest likelihood of success. FDA approval would unlock access to these therapies for patients in the US and prompt increased interest by government and other funding sources. Central to PSFC's initial rationale for supporting MAPS, this could also legitimize the field for mainstream researchers, clinicians, funders, and healthcare stakeholders. Approval of the prescription use of MDMA-assisted therapy for PTSD is likely to result in a substantial reduction of suffering for people burdened by PTSD, a reduction in suicides related to chronic PTSD, and the generation of further funding, resources, and cultural support for the global renaissance in psychedelic research. Furthermore, given that MDMA is off-patent and that the clinical trials are run by a nonprofit-owned Public Benefit Corporation (MAPS PBC), this first-in-the-world approval of a psychedelic-assisted therapy would lead to a care delivery rollout that will prioritize patient outcomes and equitable access over profits.

Critical Pathways and Recommendations

A. FDA approval for MDMA-PTSD (PSFC's core focus to date)
MAPS is on the cusp of FDA approval of MDMA for PTSD but success is not guaranteed. Once phase 3 results are finalized, a new drug application will have to be submitted to and reviewed by the FDA. FDA approval would make MDMA legally available as an adjunct to psychotherapy for PTSD in the US, then in Israel and Canada. This has been the core focus of PSFC's fundraising and grantmaking to date. It has been successfully funded through the Capstone campaign and it is included here not as a funding recommendation but for context on the evolution of PSFC's strategy from this initial core focus.

B. Global approval for MDMA-PTSD
Whereas the Capstone campaign enabled MAPS to fund Phase 3 trials for US approval, there remains the matter of enabling approval in Europe and the rest of the world. There are 9 million people with PTSD in the US and over 350 million worldwide, illustrating the potential to address a global unmet need by opening up treatment internationally.

Goal #2: Obtain regulatory medical approval for psilocybin-assisted therapy

Rationale

Although both ketamine and MDMA-assisted therapy are considered "psychedelic therapy", neither ketamine nor MDMA are "classical psychedelics'' and their therapeutic use was not actively researched in the first psychedelic era. Classic psychedelic substances such as LSD and psilocybin act very differently and have been known to trigger mystical experiences conducive to treating conditions such as depression, end-of-life anxiety, and substance use disorders. FDA approval of a first classical psychedelic would cement the renaissance of psychedelic therapy as started in the 50s. Furthermore, it will allow for the treatment of additional conditions and patients, and diversify the field. This process will likely benefit greatly from the experience learned through the MAPS/FDA process and could lead to medical approval estimated early 2025.

Critical Pathways and Recommendations

A. FDA approval for psilocybin-assisted therapy for alcohol use disorder (AUD)
Non-profit lifescience company B.More, in collaboration with the NYU Center for Psychedelic Medicine, is running a Phase 2 clinical trial on the use of psilocybin-assisted therapy to treat alcohol use disorder (AUD). The organization's ultimate goal is to bring psilocybin through the FDA process and see it approved as a prescription treatment for AUD.

B. FDA approval for psilocybin-assisted therapy for depression
Usona Institute and Compass are currently performing phase 2 clinical trials to treat depression: major depressive disorder (MDD) and treatment-resistant depression (TRD) respectively. Whereas Compass is a private, investor-backed company, Usona is a not-for-profit. There is some tension between the for-profit and not-for-profit approaches as Compass has taken steps that some have claimed could limit the ability of others to manufacture medical-grade psilocybin.[15]

Goal #3: Support the successful implementation of Oregon's psilocybin therapy program and expand this model to new states.

Rationale

Non-prescription therapeutic access to psychedelics is an important consideration for the psychedelic field because it will evolve on a parallel track to medicalized psychedelic therapy, with the potential to benefit a much larger population. Those without diagnosed mental health conditions might still benefit from psychedelic therapy in the same way that many people without an acute diagnosis still benefit from traditional talk therapy, for personal growth and to prevent future mental health problems. Making psychedelic-assisted therapy available without a prescription can also help enable equitable access to psychedelic healing. Populations lacking the resources or the historical trust to navigate the healthcare system may be more open to psychedelic therapy offered with fewer barriers.

Oregon's creation of a state-regulated psilocybin therapy program via ballot initiative is an opportunity to demonstrate avenues of non-medicalized access to psychedelics that are safely executed and effectively regulated. If implementation is successful, not only will many more people have access to psychedelic therapy, but Oregon could become a hub for research, therapist training, and care delivery model testing. The success of Oregon's implementation will also be an important signal to other states considering similar ballot measures and legislative reforms.

Success is not guaranteed. The implementation process involves complex decision-making about rules and regulations for clients, facilitators, and service centers, and will almost certainly include challenges from the medical establishment or other concerned groups. Getting Oregon's implementation right is critical to establishing this path as a viable option for other states. Failure could lead to backlash from regulators, the medical community, and the media.

Critical Pathways and Recommendations

A. Successful Oregon psilocybin therapy implementation

Implementation of the Oregon psilocybin therapy program is in the hands of the Oregon Health Authority, with guidance from the newly established Psilocybin Advisory Board. However, given how much new ground the Oregon program is breaking, there is more space than usual for experts and knowledgeable organizations to wield influence and enforce accountability as details are established.

Key members of the campaign team that shepherded Measure 109 to success in 2020 are now in leadership positions with a newly established nonprofit organization called the Healing Advocacy Fund (HAF). The mission of HAF is to ensure that the program is implemented successfully and maintains the spirit of the initiative as approved by voters. Affiliated organizations and individuals are collaborating with HAF to help shape standards of care, training requirements, and equitable access.

B. Supporting an Oregon-based research consortium

Oregon can become a valuable venue for gathering data about the efficacy of psychedelic therapy outside of controlled academic environments. The data sourced throughout the state can inform the rollout of therapist and facilitator training efforts, as well as all the other care delivery building blocks including self-pay uptake and potential insurance coverage requirements. Many interviewed felt that centralized data collection should be baked into the regulatory architecture that emerges to support psilocybin-assisted therapy and retreat

activities. This could be achieved by an independent multi-stakeholder consortium. Experts with experience in the workings of the FDA also suggest that "real-world" data collected from the Oregon program could be considered highly valuable by federal researchers and regulators, so it's in the interest of the program to collect that data accurately and effectively.

C. Replicating the Oregon Model in Additional States

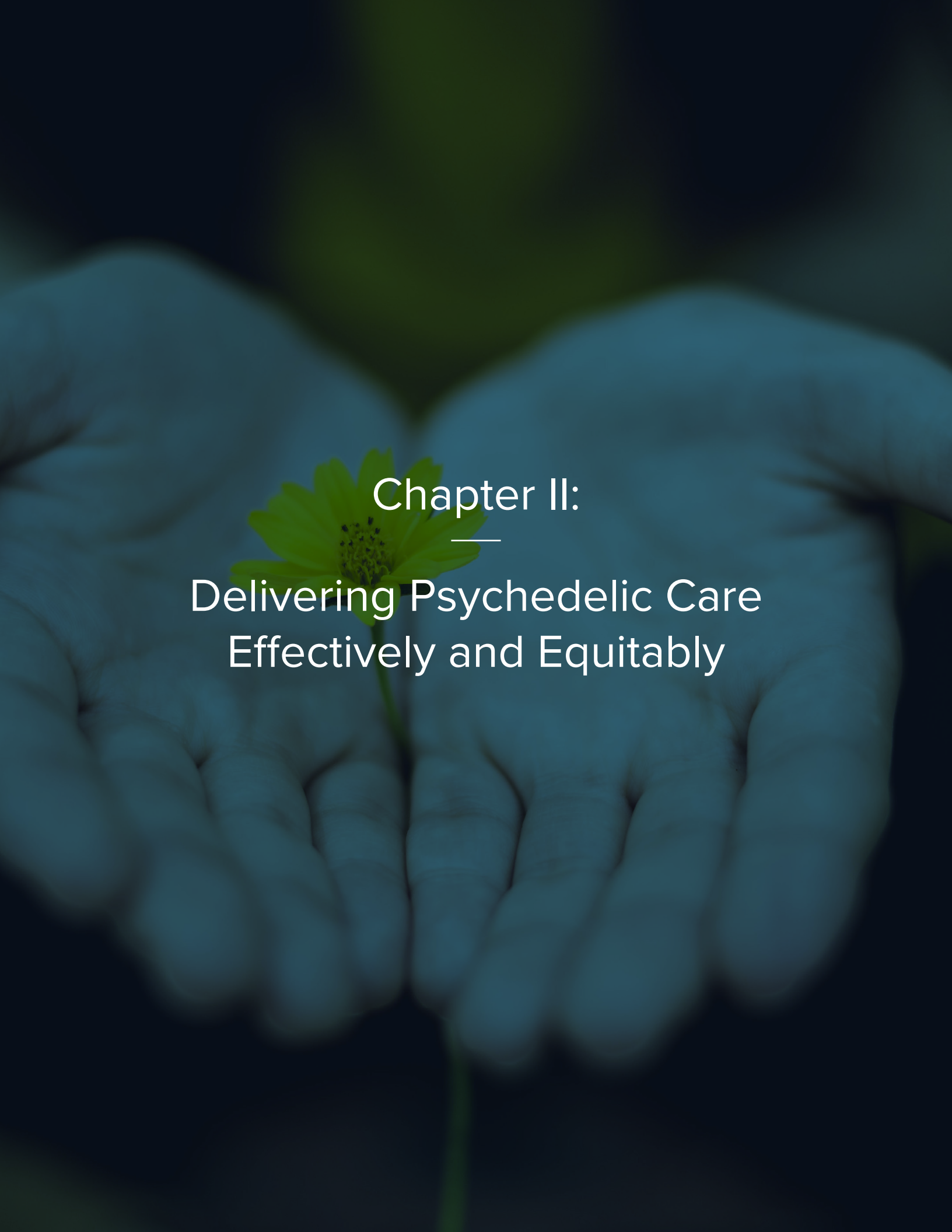
Opening up legal access to psychedelic treatments within a therapeutic, non-prescription context is arguably the most effective way to spread the benefits to as many people as possible while mitigating the risk of adverse events and backlash. To that end, a political strategy designed to target a succession of viable states and either run ballot initiatives or support legislative campaigns would be a valuable contribution to the goal of expanding legal access to care.

It should be noted that certain direct political efforts, such as funding a ballot initiative campaign, cannot be supported with nonprofit dollars and thus fall outside the scope of PSFC. However, many politics-adjacent activities, such as public opinion research or education and advocacy in targeted states, can be funded by 501(c)(3) contributions. And some donors may choose to contribute directly to campaigns or to other political entities, independent of PSFC.

Ideally, the majority of funding for these policy change initiatives will be channeled through strategically coordinated efforts guided by political expertise. Carefully vetted and targeted campaigns, pursued on a well-considered timeline, can lead to momentum-building victories. Scattershot efforts conducted with passion but not savvy can do the exact opposite.

Conclusion

The psychedelic resurgence comes at a time when new approaches are direly needed to address global mental health and substance abuse challenges. Philanthropic support has played a key role in bringing psychedelic therapy closer to mainstream acceptance, opening the doors to legal access to psychedelic-assisted therapy via both FDA approval and state policy changes. As encouraging as these trends are, there remains much work to be done to finalize FDA approval of MDMA and to pursue federal and state approval of the first classical psychedelic, psilocybin. Even though obtaining legal access to psychedelic therapy is the required first step to achieve PSFC's vision, getting approval is useless without a clear care delivery program and infrastructure.



Chapter II:

Delivering Psychedelic Care Effectively and Equitably

Introduction

Once psychedelics become legally available for healing, the task before us is to deliver safe and effective care. Getting these medicines into the hands of clinicians and caregivers to deliver safely is an especially consequential task—if we get it right, millions of people may be spared needless suffering, but if we get it even a little bit wrong, the backlash could blow us back to the 60's (without the great music), or worse.

It won't be enough to just get the medicine right—expert therapist guidance and well-designed care delivery systems will be critical. The demand will be high. Our standards for training and care must be even higher.

The private sector will play a growing role in delivering psychedelic care in the coming years. And yet the influx of private capital into the field has raised concerns: Will price or other barriers leave care out of reach of those who could benefit the most?

This chapter looks at the emerging organizations, systems, and standards involved in rolling out psychedelic-assisted therapy. **In PSFC's view, delivering safe, effective, and accessible care will be the central challenge of psychedelic healing over the next five years.** Both philanthropy and impact investment will be needed to fill critical gaps the private sector cannot address alone, such as training therapists, ensuring care is accessible and delivered equitably, setting rigorous standards, and funding research to further improve treatment protocols. **With MDMA-assisted therapy and psilocybin therapy in Oregon both potentially becoming available as early as 2023, this care delivery infrastructure will need to be built quickly and carefully.**

> "Scaling up for therapist training and licensing for therapists is really important. Developing clinical best practices with a means of disseminating that information is going to be critical.

- Roland Griffiths
Professor of Psychiatry and Neuroscience,
Johns Hopkins School of Medicine

> "We want psychedelic medicines to be effective and approved by the appropriate regulators. Moreover, we need to make sure that they are accessible by all people who may benefit—including underserved and low-income populations (with or without health insurance).

- Alex Cohen
President,
Steven & Alexandra Cohen Foundation

Care Delivery Primer

What is psychedelic care delivery?

Psychedelic-assisted therapy (PAT) care delivery is still in its earliest days. Aside from ketamine, no psychedelics are currently legally available as medical or wellness treatments. In the future, psychedelic care will likely be delivered both inside and outside a prescription medical context—addressing diagnosed mental illness, as well as promoting better mental health and wellness. If and when treatments are approved by the FDA, **patients could receive PAT via prescription in a clinic, hospital setting, or a private practitioner's office.** With the passage of Measure 109, Oregon's psilocybin therapy ballot initiative, **PAT will likely also be available in a non-prescription context,** first in Oregon, and potentially elsewhere in coming years. Regardless of how it is delivered, this care will require training, certification, and regulatory oversight of therapists; standards for treatment and systems to pay for treatment; physical infrastructure for delivery of care; and refinement of a variety of inpatient and outpatient delivery models.

Where is care available today?

Only a tiny handful of practitioners are delivering psychedelic-assisted therapy in the US today. Outside of research trials, ketamine is the only legally-available psychedelic treatment in a medical setting, with over four hundred ketamine-focused independent practitioners and clinics operating in the US. Very few of these use a therapy-assisted protocol—most deliver ketamine infusions to patients under medical supervision without a psychotherapy component.[16]

Apart from clinics providing ketamine-assisted therapy, treatments in which psychedelics are provided as adjuncts to psychotherapy are currently only available to participants in clinical trials.[17] Following FDA approval of MDMA and psilocybin, we expect that psychedelic-assisted treatments will become widely available by prescription.

Outside of a medical context, psychedelic treatment is available through an unknown (but presumptively small) number of underground therapists offering guided treatment, and psychedelic retreat centers operating outside the US. However, these experiences are unregulated, illegal in some cases, accessible only to those who can pay their own way, and highly variable in quality.

We choose to use the term "therapist" to encompass both conventional psychotherapists and people trained in the delivery of PAT who do not have the conventional training and licensure of Ph.D and Master's psychotherapists. Some call the latter group, mostly working in the underground, "guides," but we envision a future in which the skilled, trained, licensed providers of care include both categories.

Common elements of today's care delivery models

Supported psychedelic therapy is currently practiced in a range of formats. These have been shaped by the decades of experience of underground practitioners, by findings from the first wave of academic psychedelic research in the '60s and '70s, and by centuries of Indigenous ceremonial practice. The following are common elements of the patient journey today:

- **Screening** involves assessing a patient's personal and medical history, their goals for treatment, and whether they meet the criteria for being treated safely with a particular psychedelic therapy.
- **Preparation** ensures a patient is psychologically and physically ready for the actual treatment session. This typically involves psychotherapy sessions to set intentions for the psychedelic-assisted session and establish client-therapist rapport. Preparation for some patients may involve tapering medications or conducting medical tests.
- **Treatment** refers to the actual experience with the psychedelic substance.
- **Integration** refers to post-treatment psychotherapy sessions and other support provided to patients to help them reflect on and integrate key insights from the treatment session into their lives.

Some psychedelic treatments, such as ketamine infusion diverge from this model and omit therapist guidance and integration altogether. And as we will discuss later in this chapter, treatment formats will likely evolve in the future based on clinical experience and research.

State of the Landscape:
Psychedelic Care Delivery

Several companies and nonprofits are already working in areas related to psychedelic care delivery. Table 3 summarizes the organizations and companies focused on therapist training, clinic operations, and related domains.

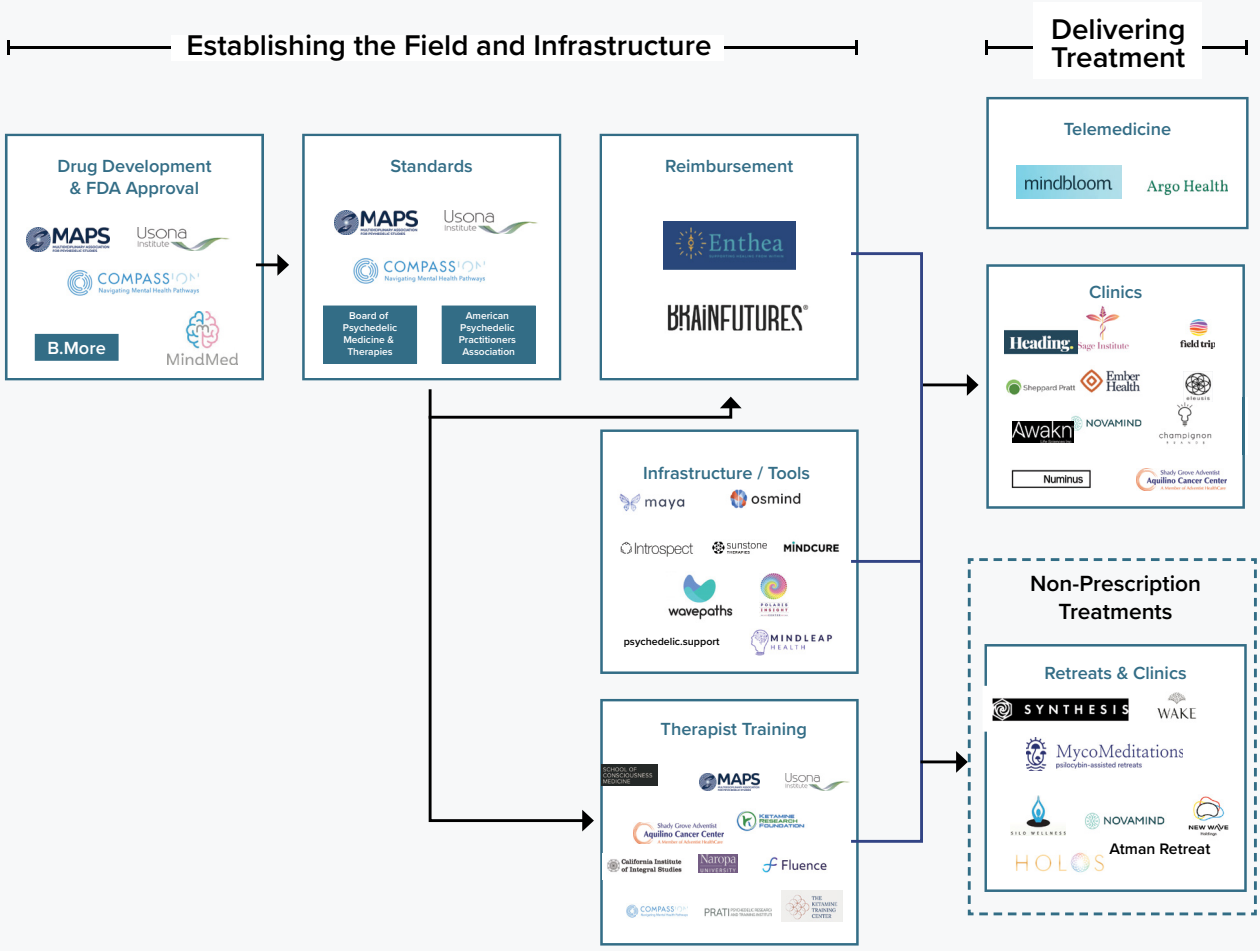
TABLE 3: THE STATE OF PSYCHEDELIC CARE DELIVERY INFRASTRUCTURE

Care delivery area	Description	Organizations by the numbers (as of January 1, 2021)
Standards and certification infrastructure	Associations, nonprofits, and companies working to establish standards of care and certification systems for psychedelic therapy and therapists, Including accountability systems to address violations of standards	Two standard-setting initiatives have been launched
Reimbursement	Companies (typically drug trial sponsors such as MAPS) and organizations facilitating or advocating for private healthcare payors (e.g. insurance companies) or government payors (e.g. Medicare or Medicaid) to pay for PAT	Two nonprofit organizations are working in this area, in addition to sponsors of various clinical trials
Therapist training	Organizations and academic institutions that train therapists in PAT	13 in operation across the US (3 drug developers, 3 universities, and 7 stand-alone training organizations). As of November 2021, approximately 1,800 therapists have completed or are currently enrolled in the MDMA training program offered by MAPS
Infrastructure and tools	Companies providing back-end clinic and electronic health record platforms, digital therapeutics to enhance PAT for patients, and clinic management services	12 companies in the US and Canada are working on digital treatment tools and support services for clinics
Clinics	Medical facilities where PAT is offered by prescription. In the US, medical providers are currently only able to offer ketamine infusions and ketamine-assisted psychotherapy, excluding clinical trials and expanded access sites. Post-FDA approval, many of these ketamine providers may also provide PAT	465 ketamine infusion clinics in the United States.[18] A smaller number of clinics provide ketamine-assisted psychotherapy
Retreats	Healing centers located outside of the US (in jurisdictions where compounds are not illegal) in which psychedelic treatments are given, either individually or in group settings, often in a ceremonial context	58 resorts or healing centers - Most using ayahuasca and half in Peru[19]

The linkages between these areas will be important for the evolution of psychedelic care delivery, and the graphic below shows how these areas are interdependent. For example, **establishing strong standards** of care will be critical for shaping therapist training programs and securing coverage by insurance and other payors. **Unblocking bottlenecks in therapist training** will be crucial to adequately meet the anticipated patient demand for treatment both in a prescription and non-prescription setting. And **securing reimbursement for psychedelic care** from private insurers and government payors will enable clinics to scale much more rapidly.

THE PSYCHEDELIC CARE DELIVERY LANDSCAPE: CONNECTIONS AND DEPENDENCIES

(NOTE: Organizations included below are provided as representative examples and do not represent an exhaustive inventory of care deliver organizations)



To date, funding for care delivery infrastructure has largely been overshadowed by funding for psychedelic research and drug development. The vast majority of the funds raised by commercial and nonprofit organizations in the psychedelic field went to drug development. The limited philanthropic giving for care delivery has primarily supported therapist training programs and a small number of nonprofit clinics.

Care Delivery Challenges

From therapist training programs to treatment standards, the core components of an effective care delivery system for psychedelic treatment still need to be built. PSFC sees five central challenges ahead for psychedelic care delivery:

Training therapists

Trained psychedelic therapists are in short supply and will need support to set up their practices. If left unaddressed, therapist training bottlenecks will severely limit the reach and impact of psychedelic therapy. The need for treatment is massive. For example, an estimated nine million Americans currently suffer from PTSD, and four million are in treatment. Therapist training is currently being conducted by a few independent companies and nonprofits, university-based programs, and sponsors of psychedelic clinical trials such as MAPS, Usona, and Compass. These initiatives will need to replicate and scale rapidly to meet potential demand for treatment.

Legal restrictions on psychedelic treatment create another training bottleneck, as working with psychedelic-assisted therapy patients is not yet legal outside of a clinical trial context. Training programs are currently able to conduct didactic training—the reading and lectures that impart the basic concepts of being a psychedelic therapy practitioner. But they are not able to provide the second, experiential half of training—the trainee having their own guided psychedelic experience and being supervised while providing treatment to an actual patient. These latter steps are crucial components of a complete training process. With the passage of Measure 109, new opportunities will become available for training institutions to operate in Oregon. This will enable trainees to work directly with psilocybin-assisted treatments and break down a key barrier by allowing therapists to gain important experiential training. Similarly, investigator-initiated trials of MDMA-assisted therapy conducted by university-based researchers in parallel with the MAPS phase 3 trials also create important opportunities for therapist trainees to gain treatment experience with patients.

Post-training, therapists will also need operational and business support to start practicing, as psychedelic-assisted therapy will involve an entirely new economic model. A recent provider survey found that 75 percent of therapists reported they would be unlikely to provide PAT if it meant a reduction in their income, so making the practice economics feasible for therapists will be important.[20]

To ensure psychedelic care reaches those who are most impacted by trauma and other mental health issues, it will also be critical to recruit and support trainees from a range of gender, racial, treatment experience, and geographic

backgrounds. Marginalized communities, including communities of color, often experience much higher rates of trauma while simultaneously facing the greatest barriers to accessing mental health care.[21] Serving these and other populations will require careful attention to recruiting, funding, and training therapist cohorts who can provide culturally competent care. As Monnica Williams, Professor and Research Chair in Mental Health Disparities at the University of Ottawa noted, "I think with psychedelic therapy, it's actually much more important that you're culturally attuned than with other kinds of therapy because of extreme vulnerability of the client."

Creating standards of care

Standards of care are needed to ensure treatment meets a baseline level of effectiveness and safety. As Tim Chang, PSFC member and Partner at the Mayfield Fund suggested, "The mission of establishing something like the [American Medical Association] is important—we don't really have a hippocratic oath for this space but need one." Beyond establishing such an oath, we will need strong standards of care aligned with certification standards for therapists. These standards will also be an important foundation for securing coverage for treatment by insurance providers.

If psychedelic care does not meet high standards of safety and efficacy, patients could be put at risk and the reputation of the field could be jeopardized. Lia Mix, Founder and CEO of Enthea Health reflected, "We are facing both a higher bar and a smaller margin of error in legitimizing psychedelic therapies." Due to the vulnerable mental states involved with psychedelic treatment, safe and ethical conduct by therapists is of utmost importance. PAT is a new field of treatment with a short track record, so substandard care by even a few providers risks tarnishing the reputation of the field as a whole. Standards must anticipate the potential for negligence or abuse, and the profession needs to have reliable means to redress misconduct, as the mere existence of standards will not ensure that all therapists actually comply with them.

Therapist training organizations will also need to align their curricula with these standards to ensure therapists are trained on them. As MAPS Founder and Executive Director Rick Doblin noted, "the big thing I am worried about—right after [MDMA-assisted therapy] is approved, is getting a lot of bad stories as a result of therapists who are not properly trained."

Alongside care delivery standard-setting in a prescription medical context, therapeutic access to psilocybin therapy in non-prescription settings will also require the development of standards for practitioners. Following the passage of Measure 109 in Oregon, the state will be developing a regulatory framework for delivering care, and therapist training and certification standards will need to be developed in parallel. Though these standards will likely need to be separate from those developed for prescription psychedelic therapy, it will be critical that they be similarly rigorous and comprehensive to ensure comparable levels of safety and efficacy.

Treatment optimization research

Further research will be needed to optimize psychedelic-assisted therapy protocols in order to treat the widest possible range of patients and conditions effectively. The mindset of a person undergoing psychedelic treatment, and the physical and social environment at the time of their experience (referred to as "set and setting") are believed to be important factors in treatment outcomes of PAT. More research is needed to validate these assumptions and understand the significance of a patient's mindset and setting. As Fred Barrett, Professor of Psychiatry at Johns Hopkins School of Medicine observed, "set and setting are great, but we don't know anything about them."

In addition to studying various factors at the time of the experience, researchers have also highlighted a need for further study of the impact of post-treatment integration sessions on patient outcomes. Other understudied elements

of the psychedelic-assisted therapy experience include the role of the therapist, group vs. individual therapy, the number of treatment sessions, the use of music, as well as treatment safety in combination with common medications. Understanding these could further improve the effectiveness and lower the cost of PAT.

Studies involving underserved populations will also be critical for ensuring psychedelic treatment meets the needs of groups that are disproportionately impacted by trauma. For example, a survey of psychedelic research studies found that 82.5% of study participants were white and concluded that, "[g]iven the high prevalence of depression, anxiety, PTSD, and substance use in communities of color, psychedelic medicine may provide a promising new avenue for treatment; yet without the inclusion of diverse participants in such studies, this remains an empirical question. Researchers will need to employ culturally specific—and sometimes extensive—strategies to ensure that people of color are included in clinical studies."[22] In addition to race, we need to understand how different socio-economic contexts affect treatment outcomes, especially for people facing homelessness, incarceration, or extreme poverty. These are among the most traumatized individuals in the US, and we know the least about how PAT works for them.

Securing insurance coverage and patient access

Insurance and institutional payor coverage for PAT does not exist yet. Currently available psychedelic therapy providers such as ketamine clinics operate on a self-pay basis, leaving treatment out of the reach of many. 60 percent of behavioral health services in the US are paid for by insurance and over 100 million people are covered by Medicare and Medicaid, so coverage by private insurers, government payors, and federal health systems such as the VA will be important steps towards making PAT affordable and accessible.[23] And while the 2008 Mental Health Parity Act requires insurers to cover mental health care on an equal basis to medical and surgical care, insurers are often reluctant to cover new mental health treatments or apply needlessly restrictive conditions on their use.

In addition to securing coverage for PAT by insurers, it will be important to address other financial barriers to accessing care. Out-of-pocket costs for mental health care can be prohibitively high for lower-income patients even if they have insurance. Patient assistance funds run by independent nonprofits will also be needed for uninsured patients and Medicare and Medicaid patients, as the latter groups cannot receive supplementary copay support from drug companies.

Supporting clinics

Psychedelic practitioner infrastructure will need to scale quickly without compromising the safety or integrity of the healing experience. Unlike standard outpatient psychotherapy, PAT involves pharmaceutical treatment and multi-hour treatment sessions during which it is especially important for physical spaces to support a therapeutic set and setting for patients. PAT care delivery systems will likely evolve in a variety of directions, differing in terms of outpatient vs. inpatient settings, solo vs. group formats, and in-person vs. virtual components. As care delivery scales to meet patient demand, investors, philanthropists, practitioners, and regulators alike will need to consider factors such as safety, quality, cost, and accessibility. Finally, making the practice economics of PAT work for clinics will be important as well—many effective, FDA-approved treatments have never scaled because they cannot be delivered profitably.

There will likely be room for innovation in designing PAT clinical settings and models, but it will be important to build on existing clinics and systems where possible rather than creating new ones from the ground up. As Cody Swift, PSFC member and Co-Director of the Riverstyx Foundation noted, "Psychedelics may situate best integrating into preexisting clinical models. That will help maintain cultural groundedness because it'll be a paradigm people are comfortable with. There are a lot of really good clinicians out there who are primed to incorporate this into their practices." While the

vision of holistic psychedelic healing centers seems to currently attract the most entrepreneurial energy, broad access to care will also depend on individual therapists expanding their solo practices to include psychedelic modalities.

It will also be critical to ensure clinics meet rigorous safety, ethical, and quality standards. As the online illustrated story *We Will Call it Pala* highlights, pressure from competitors and investors could lead even the most well-intentioned psychedelic clinic operator to cut corners with patient care.[24]

Image Credit: MAPS

Key Goals and Recommendations
to Support Psychedelic Care Delivery

Addressing these interconnected care delivery challenges will be a major undertaking: **now is the time to plan and build the infrastructure to ensure PAT can be delivered safely and effectively.** Philanthropy and impact investment both have an opportunity to play catalytic roles in seeding the infrastructure to ensure PAT can heal at scale. This section discusses four pivotal psychedelic care delivery goals for the coming years:

- **Enable the precedent-setting rollout of the first psychedelic-assisted treatment** by supporting MAPS' planning for the delivery of MDMA-assisted therapy
- **Train and support the first 100,000 psychedelic therapists needed to treat 1 million patients per year by 2031** by funding training institutions, recruiting diverse cohorts of therapists, and supporting them in establishing their practices
- **Ensure PAT is as safe and effective as possible** by building strong standards of care, and supporting research to optimize treatment
- **Make care accessible and affordable to patients** through coverage by private health insurers and government payors, patient assistance programs, and networks of patient-centered clinics

Below, we'll analyze each of these and discuss how philanthropists and impact investors can help meet them.

Goal #1: Enable the precedent-setting rollout of the first psychedelic-assisted treatment by supporting MAPS's planning for the delivery of MDMA-assisted therapy

Rationale

FDA approval of MDMA as the first PAT available by prescription will be a catalytic event for the psychedelic field. Similarly, the rollout of MDMA-assisted therapy to patients post-FDA approval will also be precedent-setting and foundational. From creating treatment standards to training therapists and securing reimbursement from insurers, MAPS will be the first to grapple with all of the care delivery challenges discussed in this chapter. If they succeed with the rollout of MDMA-assisted therapy, they will clear the way for other psychedelic compounds to reach patients.

MAPS Public Benefit Corporation's structure as a benefit corporation owned by a nonprofit has enabled them to conduct the clinical trial of MDMA-assisted therapy without the added pressure of meeting investor return expectations. This has enabled them to take a collaborative and open approach to the trials, including by sharing treatment protocols publicly and following an "anti-patent" strategy to keep the uses of MDMA in the public domain. MAPS does intend to generate revenue from MDMA-assisted therapy during the six-year data exclusivity period following FDA approval and beyond in order to fund its parent nonprofit organization and support future research. The example MAPS sets for balancing economic, ethical, and equity considerations for care delivery will set the standard for commercialization of all psychedelics that follow.

Critical Pathways and Recommendations

A. MAPS's care delivery preparation

PSFC has been working closely with MAPS since 2019 to plan and raise funds for delivering care to patients following FDA approval. Thanks to the support of PSFC members and others, MAPS raised an initial round of funding to support laying the groundwork for care delivery as part of the Capstone campaign in 2020 and a separate care delivery fund in 2019. In early 2021, MAPS partnered with the Boston Consulting Group (BCG) with funding from PSFC to plan its MDMA assisted therapy rollout. The BCG analysis included projections of the substantial financial resources MAPS will require to support commercialization of MDMA – including resources needed to expand their team, fill anticipated marketing, government affairs and compliance roles, fund patient assistance programs, and engage with health insurers and other payors. As of Fall 2021, MAPS is preparing to seek additional funding to support the development of their care delivery plan in anticipation of potential FDA approval as early as 2023.

B. Health equity and early access initiatives for MDMA-assisted therapy

Alongside MAPS's overall delivery of care planning work, they are focused on two crucial challenges: training therapists and ensuring care is rolled out equitably and reaches patient populations that experience the highest rates of trauma. In 2020, MAPS introduced its Health Equity Plan to tackle both challenges. This $5.4 million initiative will expand MAPS's therapist training to create treatment and training access opportunities for those historically marginalized by the mental health field and society at large.[25] Recruiting and training a diverse and inclusive cohort of therapists will be critical for reaching patient populations that experience the highest rates of PTSD and trauma, including patients of color. To address this, the Health Equity Plan creates a fund to subsidize patient care, therapist training, and clinic startup costs to enable early access to treatment and get clinics up and running through an Expanded Access program. Together, these elements will create treatment and training access opportunities for those historically marginalized by the mental health field and society at large.

Goal #2: Train and support the first 100,000 psychedelic therapists needed to meet anticipated patient demand by funding training institutions, recruiting diverse cohorts of therapists, and supporting them in entering practice

Rationale

The bottom line for psychedelic care delivery is that the demand for therapists will be orders of magnitude greater than anticipated supply when treatments are first introduced, both within the medical system and in a wellness context. Given the millions of people who could benefit from these therapies, scaling therapist training is a top

priority. Therapist training will also be important for securing insurance coverage for prescription psychedelic therapy as insurance companies often evaluate "network adequacy"—whether a sufficient number of trained practitioners exist to provide treatment—when deciding whether to extend coverage.

Modeling by the Boston Consulting Group estimated that 22,000-40,000 therapists will be needed to meet an aspirational goal of treating 400,000 PTSD patients per year by 2031. This is roughly ten times the 3,000 therapists MAPS expects to have trained in time for FDA approval in 2023. Looking beyond MDMA to the medical psychedelic field as a whole, this analysis suggests treating one million psychedelic therapy patients with a mental health diagnosis per year by 2031 would require training 55,000-100,000 therapists in ten years (approximately 10-17% of the US mental health workforce). Estimating the number of clients outside of a prescription context is far more speculative at this point. But taking into account Oregon's program, as well as additional states that are likely to legalize psilocybin therapy in the coming years, it seems safe to assume that a similar number of therapists will be needed in the wellness space (with overlap between medical and wellness practitioners). Reaching these goals and delivering care at this scale would enable psychedelic therapy to make meaningful progress towards addressing the U.S. mental health crisis.

Meeting these ambitious goals will require scaling and expanding a range of therapist training pathways, from specialty schools to continuing medical education programs, existing residency and graduate programs, and programs at clinical trial sponsors such as MAPS, Usona, and Compass. Philanthropy will play a catalytic role in scaling existing training programs and launching new ones, as most existing programs are structured as nonprofits and will require philanthropic support or impact capital to start up and scale.

Beyond creating the training programs themselves, recruiting a diverse pool of therapists will be important for meeting the wide-ranging treatment needs of various patient populations, as will adapting training curricula and treatment protocols to meet the needs of these populations. Once recruited, scholarship funding will enable therapists to complete training regardless of financial need. Scholarships could also be structured as forgivable loans to incentivize therapists to become certified to professional standards and deliver care. This support will also help therapists train in advance of FDA approval, since they will need to wait until at least 2023 to begin treating patients.

After completing training, therapists will also need tools and training to make the financial and operational aspects of their practice work. This support for therapists will help them expand their practices to include psychedelic modalities in a financially sustainable way. Most psychotherapists work as solo practitioners. As they seek to include psychedelics in their practices, they will face novel operational challenges such as working with a prescribing physician, as well as exposure to elevated malpractice risks.

Critical Pathways and Recommendations

A. Create and scale therapist training programs

Funding therapist training programs will be a top priority for psychedelic care delivery over the next decade. Near-term, it will be important to prioritize support for programs that can offer experiential training, including supervised experiences with actual psychedelic treatments, which will help address the current field-wide training bottleneck. In addition, locating training sites in Oregon could also help address this bottleneck following the rollout of psilocybin therapy there in 2023.

Given the need to scale training rapidly in multiple regions, funding will need to be spread across a number of organizations. At the same time, training standards must be consistently high across the board—compromising training quality in pursuit of therapist numbers would be a risky mistake. Coordinating due diligence of training programs (and potentially funding collaboratively through a pooled fund) would enable PSFC members and

other funders to identify and support programs committed to rigorous screening and training standards as they scale.

B. Launch scholarship funding and outreach initiatives for therapists
Funding will also be needed to enable therapist recruitment as well as scholarship initiatives to ensure therapist cohorts have the expertise and background necessary to treat a range of patients, including those from underserved populations and communities. Recruitment and outreach efforts will need to reach prospective therapists from diverse practice expertise, race, gender, sexual orientation, and geographic backgrounds. For example, MAPS has already conducted one therapy training retreat focused on communities and therapists of color and is planning to expand this initiative. More broadly, the MAPS Health Equity Plan could be replicated in other training programs or as an industry-wide initiative.

C. Support organizations that enable therapists and clinics to transition to psychedelic practice
Post-training, therapists will need support with both the economic and operational aspects of setting up a practice. This support could take the form of additional training, such as the Psychedelic Research and Training Institute's philanthropically-subsidized seminar on the business of psychedelic medicine. Funding could also be directed to support the creation of specialty consultancies offering the technical expertise required to develop a psychedelic practice. Finally, philanthropic funding and impact investment could support therapists with clinic start-up costs, enabling them to scale quickly alongside increasing therapist demand, while offering services at reduced rates.

Goal #3: Ensure PAT is as safe and effective as possible by establishing strong standards of care and funding treatment optimization research

Rationale

Developing a unified set of standards for delivering psychedelic care will be a critical foundation for ensuring that patients can access safe and effective care. Efforts to create standards of care for PAT in a medical context are underway involving leaders from MAPS, the California Institute for Integral Studies, Enthea, and other organizations. Meanwhile, in Oregon, the governor-appointed Psilocybin Advisory Board is expected to collaborate with experts to make recommendations regarding the standards of care for practice in the wellness, or non-medical, space.

Funders could consider efforts to synchronize and support these efforts towards a goal of creating comprehensive, aligned standards for the field.[26] It will be important to engage commercial actors as part of the standard-setting process in some form, but philanthropically-funded initiatives would have maximum freedom to set standards of care that prioritize patient safety and healing. Once created, these standards will need to be integrated into training programs and certification systems for psychedelic therapists. These standard-setting efforts and certification systems will need initial philanthropic funding, but can become self-supporting over time as membership dues, certification exam fees, and continuing professional education courses provide revenue.

Over the longer term, it will also be important to further improve psychedelic therapy protocols through treatment optimization research. Findings from these studies will help therapists better tailor treatment protocols and therapeutic support to the needs of each patient. While some private sector drug developers may self-fund some studies on particular protocols, we expect that philanthropy will play a central role in advancing this research agenda.

Treatment optimization research also has the potential to lower costs and scale access to care. For example, research on group therapy could be particularly important for broadening access to treatment, and initial research

in this area shows promise. A study of psilocybin-assisted group therapy intervention for older HIV survivors showed that group therapy is a viable therapeutic modality for psilocybin-assisted therapy.[27] Similarly, an observational study of group psychedelic sessions found that experiences of togetherness felt by participants were associated with enduring increases in well-being and social connectedness.[28]

Research can also help break down barriers to care and optimize treatment protocols for populations that face high burdens of trauma and mental illness. For example, researchers such as Monnica Williams at the University of Ottawa have begun studying culturally-informed approaches to psychedelic care for patients of color, who face higher rates of trauma due to exposure to racism, violence, poverty, and other factors.[29] In addition, women are more than twice as likely as men to develop PTSD and gender differences have been observed in the subjective effects of psychedelics, but psychedelic research has yet to examine psychedelic treatment through a gender lens.[30] Several researchers have also suggested that studies should investigate how psychedelic treatments could better meet the needs of LGBTQI+ patients, who experience much higher rates of mental illness due in part to experiences of stigma linked to homophobia and transphobia.[31] Targeted research to optimize treatment could also benefit several other populations that bear high burdens of trauma and mental illness, such as veterans, medical professionals, emergency responders, and individuals facing homelessness or incarceration.[32]

Finally, research on ketamine, which is currently available by prescription, could deepen our understanding of treatment protocols, benefits, and potential risks associated with the only legally-available psychedelic. Ketamine infusion treatment often diverges from the psychedelic-assisted therapy model by omitting therapist guidance and integration altogether. This treatment model is lower-cost but has prompted concern among some psychedelic researchers and practitioners who view therapist guidance during treatment and integration as critically important for patients. Research on existing models of ketamine therapy both with and without therapeutic guidance could therefore build an evidence base to improve ketamine therapy practices and inform the delivery of other psychedelic treatments in the future.

Critical Pathways and Recommendations

A. Align and support initiatives to develop standards of care and professional certifications

PSFC has identified two organizations operating at a national level to lead standard-setting efforts for PAT in a medical context. The first is the American Psychedelic Practitioner Association, a professional association which will establish standards of care; provide accreditation for training programs; offer continuing education to members; promote advocacy on behalf of practitioners to payers, regulators, and policy makers; and provide public education. The second is the Board of Psychedelic Medicine and Therapies which will define the role of a psychedelic assisted therapist and develop and administer an exam to certify practitioners that state agencies and insurance payers will recognize in licensing and credentialing processes. Initial philanthropic funding for both organizations will support them until such time that revenue from sources such as membership dues, continuing education courses, and certification exam fees enable them to be self-sustaining. Separate efforts will likely be needed to set care delivery standards for healing- and wellness-focused psychedelic care outside of a prescription context in Oregon and elsewhere. Supporting and aligning standards across both prescription and non-prescription psychedelic care will enable all psychedelic treatment to meet similarly rigorous benchmarks of safety and efficacy.

B. Fund treatment optimization research focused on safety, efficacy, and equitable access

Funding for treatment optimization research will enable sustained progress on a research agenda focused on improving the safety, efficacy, and accessibility of psychedelic care. Fully developing this research agenda will require consultation with academic researchers and other experts on clinical care delivery and mental health accessibility. But PSFC's preliminary survey has identified the following potential themes to explore:

- Understanding the role of therapist guidance and integration support
- Set, setting, and dose optimization
- Researching the effectiveness of group therapy
- Addressing barriers to care and optimizing treatment for underserved and high-need patient populations
- Studies on ketamine infusion treatments and ketamine-assisted psychotherapy
- Research on patient experiences with wellness and healing-focused therapy outside of a prescription context in Oregon

Beyond funding studies themselves, it will also be important to **support research dissemination efforts**, including through therapist certification bodies, professional associations, and training programs so that findings can inform and improve treatment.

Goal #4: Make care accessible and affordable to patients through coverage by private health insurers and government payors, as well as patient assistance programs and social impact-focused clinics

Rationale

The anticipated high cost of psychedelic therapy and the complexity of the US healthcare system will require a multi-layered approach to making psychedelic healing accessible. Securing coverage by private insurers and government health systems will be essential for making treatment broadly available. Innovative funding mechanisms will be needed for the wellness space, since medical insurance is very unlikely to cover people without a diagnosis.

First, building the health economics research base will help persuade private health insurers and government payors to cover psychedelic-assisted therapy. Health economics research will be a key persuasion point for these payors, as they typically evaluate the cost-effectiveness of new treatments when deciding whether to cover them. An initial cost effectiveness study of MDMA-assisted therapy demonstrated promising results, concluding that payors would save money by covering treatment for PTSD patients and that the "payback period" was just three years.[33] Future cost-effectiveness research could expand on these findings by studying different patient populations and psychedelic treatments to help persuade payors that PAT will reduce their mental health cost burdens.

Second, pilot initiatives with key payors and health systems will accelerate coverage and treatment adoption. Given the prevalence of PTSD in the veteran population, the VA system is a strong candidate for early adoption of PAT.[34] A fully integrated health care system with locations around the country serving nine million veterans, the VA is already providing mental health care services to a diverse population that is likely to benefit greatly from psychedelic treatment.

Medicaid and Medicare are also strong candidates for early adoption of psychedelic therapy.[35] As Michael Cotton, PSFC member and former COO and Executive Vice President at Meridian Health suggested, "Among the biggest questions around delivery of care—if you're looking through the lens of who could benefit the most from these therapies, it's how do we get adoption from Medicaid and Medicare? These populations are at the intersection of poor, sick, and sometimes elderly where health literacy rates are very low. This also largely encompasses marginalized communities where social determinants of health need to be addressed. If Medicaid and Medicare are incentivized, they'll be your best partner on patient engagement. It's a good place to focus." For example,

Medicaid has a waiver program for demonstration projects to pilot new health care coverage programs at the state level.[36] Some of these local- and state-level pilot programs have been funded as public-private partnerships with philanthropic backing. A comparable Medicaid pilot program covering psychedelic-assisted therapy could be an important step towards broadening coverage of PAT for low-income patients.

Third, patient assistance programs will be needed to defray out-of-pocket treatment costs. For patients with insurance, out-of-pocket and copayment costs for major procedures and mental health care can be prohibitively high. Both direct support from drug manufacturers and external patient assistance funds coordinated by nonprofit organizations can address this financial gap for psychedelic-assisted therapy. Patient assistance funds that are not directly affiliated with drug companies are especially important for patients covered by Medicare and Medicaid, which prohibit direct patient assistance from drug manufacturers.

For PAT, embedding patient assistance programs within broader health equity initiatives will maximize their reach with target patient populations. These initiatives will need to engage in proactive outreach efforts. Building relationships with community institutions like churches and communicating about the benefits and risks of psychedelic-assisted therapy with prospective patients will help to attract a more diverse patient population. As Dr. Mellody Hayes, founder of How We Heal noted, "I desire communities of color to know that there is a door. Once you know there's a door, you want to know what keys work to open it."[37]

Fourth, align clinics and investors around a set of values that prioritize patient access. Clinics are where the rubber will truly meet the road for making care accessible and delivering it with integrity. Broad access to PAT will require clinics to make accessible and affordable care a priority. Initiatives such as North Star have begun to convene investors as well as for- and non-profit organizations in the psychedelic field around a shared set of values and ethics, including equitable access to care.

Access to capital will be a powerful leverage point for putting these values into practice. Impact investors, including members of the philanthropic community could support the creation and growth of clinics dedicated to high-integrity and accessible care. Investors could prioritize clinics that focus on patient access through sliding-scale pricing or community outreach programs. They could also invest in clinics with impact-focused or stakeholder-inclusive business models, such as benefit corporations or clinics that include community stakeholders in their governance structures.[38]

Critical Pathways and Recommendations

A. Fund research on cost effectiveness

Funding for health economics research on PAT will help to build the evidence base in support of insurance reimbursement. Research in this area could be accelerated through either stand-alone studies or health economics studies conducted in tandem with existing and planned psychedelic research. These tandem studies could use data on health care utilization of trial participants to analyze how PAT affects the mental health care cost burden.

B. Pilot patient access initiatives at the VA and through Medicaid or Medicare

Strategic, coordinated research and care delivery programs at VA hospitals will be a crucial entry point for psychedelic-assisted therapy into the VA system. As care delivery capacity expands, pilot initiatives with Medicaid or Medicare should be considered as well. Medicaid pilots could be especially promising because of its low-income patient population and its waiver program for local demonstration projects. These projects can be funded by either public or philanthropic sources and could enable early, localized access to PAT in partnership with state Medicaid agencies.

C. Develop equity-focused patient assistance funds

Philanthropically-funded patient assistance funds can be a "bridge" to support access to treatment for low-income and underserved patient populations following FDA approval of PAT, when insurers and government payors may not have initiated coverage yet. To maximize reach with underserved patient populations, patient assistance programs should be integrated with broader health equity initiatives that include education and outreach to underserved patient populations. Patient assistance could also be linked to therapist training support initiatives by making therapist tuition forgiveness conditional on treating a certain number of low-income and underserved patients at free or reduced rates.

D. Identify social impact principles and drive investment towards values-driven practitioners and clinics

Funders will need to support and engage with initiatives to identify principles for impact-focused clinics and other companies in the psychedelic field. Once these principles are refined, investors could then deploy capital to help "gold-standard" clinics scale. Impact capital will be beneficial across the psychedelic field, but especially important for clinics, enabling them to prioritize impact goals such as making healing accessible to low-income and underserved groups.

Conclusion

As psychedelics move closer to the medical mainstream, the strictures of bureaucratic, for-profit medicine in the U.S. contrast sharply with the profound inner experiences that can be occasioned by these substances. As Bob Jesse, PSFC member and Council of Spiritual Practices convenor reflected, "For people who divide their life into the before/after phase of a high dose of a classical psychedelic, how does it feel to be taking the conventional forces of commercialization, profit structures, etc. and applying those tools to psychedelics? Most hours of most days it feels pretty lamentable." And yet as this chapter suggests, psychedelics might open a door to a different way of psychological and emotional healing: one that could heal those who have been left behind by the current mental health care system alongside millions more, and heal in a way that is in integrity with our highest aspirations for the future of the field.

> "For people that divide their life into the before/after phase of a high dose of a classical psychedelic, how does it feel to be taking the conventional forces of commercialization, profit structures, etc. and applying those tools to psychedelics? Most hours of most days it feels pretty lamentable.
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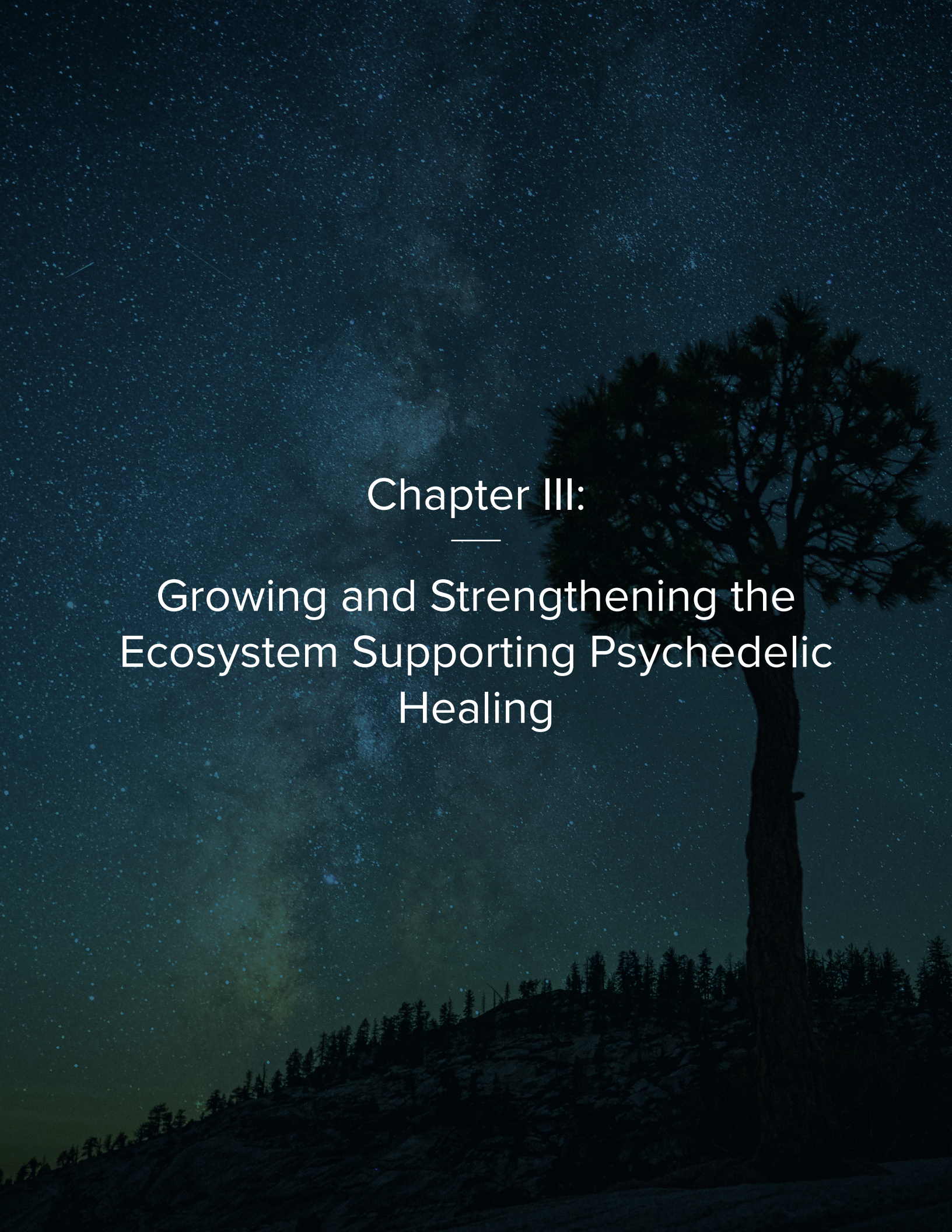
> - Bob Jesse
> PSFC member and Council of Spiritual Practices



Chapter III:

Growing and Strengthening the Ecosystem Supporting Psychedelic Healing

Introduction

For psychedelic healing to roll out successfully, a supportive ecosystem will be needed to enable psychedelics to integrate into the academic research community, the political sphere, and the public culture at large. This ecosystem in many ways begins with a network of research centers dedicated to studying psychedelics and the mind. However, it should also include education and awareness for the broader public about the potential for psychedelic healing, as well as multiple avenues of support for individuals seeking to integrate learnings from their psychedelic experiences or resolve issues raised by challenging or negative experiences. Political organizations and coalitions will also be needed to work for the long-term sustainability and accessibility of psychedelic healing. Finally, it will be crucial to conserve natural psychedelic plant medicines and support the continued thriving of Indigenous healing practices.

A healthy psychedelic ecosystem will facilitate future research breakthroughs, encourage ethical use of psychedelics, and cultivate the networks and organizations needed to preserve and expand access to psychedelic healing. A robust ecosystem will also be vitally important to address potential backlash against psychedelics. As Michael Pollan, author and Professor at UC Berkeley's Graduate School of Journalism put it: "Part of the strategy for thinking about the next ten years is 'how do you head off potential f*ck-ups?'"

State of the Landscape:
The Research Ecosystem

The current resurgence of psychedelic therapy has been enabled first and foremost by a strong research backbone, upon which the entire current ecosystem is built. The field's actions must continue to be anchored in rigorous scientific evidence.

> "We need more clinical research to obtain regulatory approval, we need more pre-clinical research to understand who can benefit to include more patients criteria and new diseases, we need more care delivery research to understand how to optimize effectiveness and reduce cost and we need basic research, including animal studies to elucidate the mechanisms and potentially to design more targeted or novel therapies.
>
> - Kevin Ryan
> PSFC member and Founder/CEO of AlleyCorp

After a 50-year hiatus, the past decade has seen a resurgence in psychedelic research. Randomized clinical trials now support the safety and efficacy of MDMA in the treatment of PTSD and psilocybin in the treatment of alcohol use disorder, depression and cancer-related anxiety, with greater effect sizes than those of current treatments. The 2019 launches of psychedelic research centers at Imperial College and Johns Hopkins University put psychedelic research prominently on the academic map as a re-emerging field. Concurrently, drug development nonprofits and companies will be embarking on "last-mile" (i.e. patient-reaching) efforts to bring these medicines to market through clinical trials. This section provides an overview and map of the academic, nonprofit, and commercial activity driving research forward.

Academic research

Academic research into psychedelics resumed in the late '90s and spans various disciplines, from chemistry and psychopharmacology to cognitive neuroimaging, clinical interventions, and health economics. The work done to date has laid a strong foundation by demonstrating the safety of psychedelic-assisted psychotherapy, its potential benefits for conditions ranging from depression to PTSD to substance use disorders, and its mechanisms of action.

Over the past three decades, a number of principal investigators and academic centers have emerged as key players in the field, each with their own specific expertise and focus. In addition to the centers at Imperial College and Johns Hopkins University, a handful of other dedicated psychedelic research centers have since emerged at several academic institutions.

Generous support from philanthropists has created psychedelic research centers at leading universities led by pioneering researchers with longstanding track records. These centers lay the foundation for a well-structured, legitimate, and sustainable psychedelic research environment, supporting researcher salaries, ambitious research programs, and training opportunities for the next generation of scientists and therapists in the field. They are also an important platform for public outreach, often garnering positive coverage from leading media outlets and signaling that reputable institutions endorse psychedelic science as a worthwhile pursuit. Such centers also enable young researchers to plan for a career in psychedelic science, something unthinkable only a few years ago from both funding and reputational standpoints.

> *Johns Hopkins Opens New Center for Psychedelic Research.*
> **The research center, with $17 million from donors, aims to give 'psychedelic medicine' a long-sought foothold in the scientific establishment.**
>
> - New York Times, September 9th, 2019[39]

Non-profit research associations, foundations and institutes

Due to the decades-long hiatus on psychedelics following their international ban in 1971, researchers willing to work on them faced a harsh regulatory landscape, a complete lack of funding opportunities, and reputational risks as publicly mentioning interest in them was akin to "academic career suicide". In this context, most early psychedelic research has been carried out by tenured, senior researchers in the pharmacology and mental health fields who already had well-established lines of research and treated these psychedelic projects as 'side-projects' funded mostly by modest private donations. Most of the psychedelic research support has come from a small number of philanthropic contributions, frequently through the pioneering guidance of organizations such as MAPS, the Heffter Research Institute, the Beckley Foundation and the Council on Spiritual Practices. These entities have a deep knowledge of the field, a strong network, and well-established expertise to review, vet and support promising research projects. More supporting organizations have since emerged in this domain. Following the first promising randomized clinical trial results for MDMA and psilocybin, new entities were created that are either fully non-profit or incorporated as benefit corporations associated with existing nonprofits, with the specific purpose of conducting clinical trials leading to FDA approval. This was the case for MAPS Public Benefit Corporation, Usona Institute, B.More, and Beckley Psytech.

For-profit research

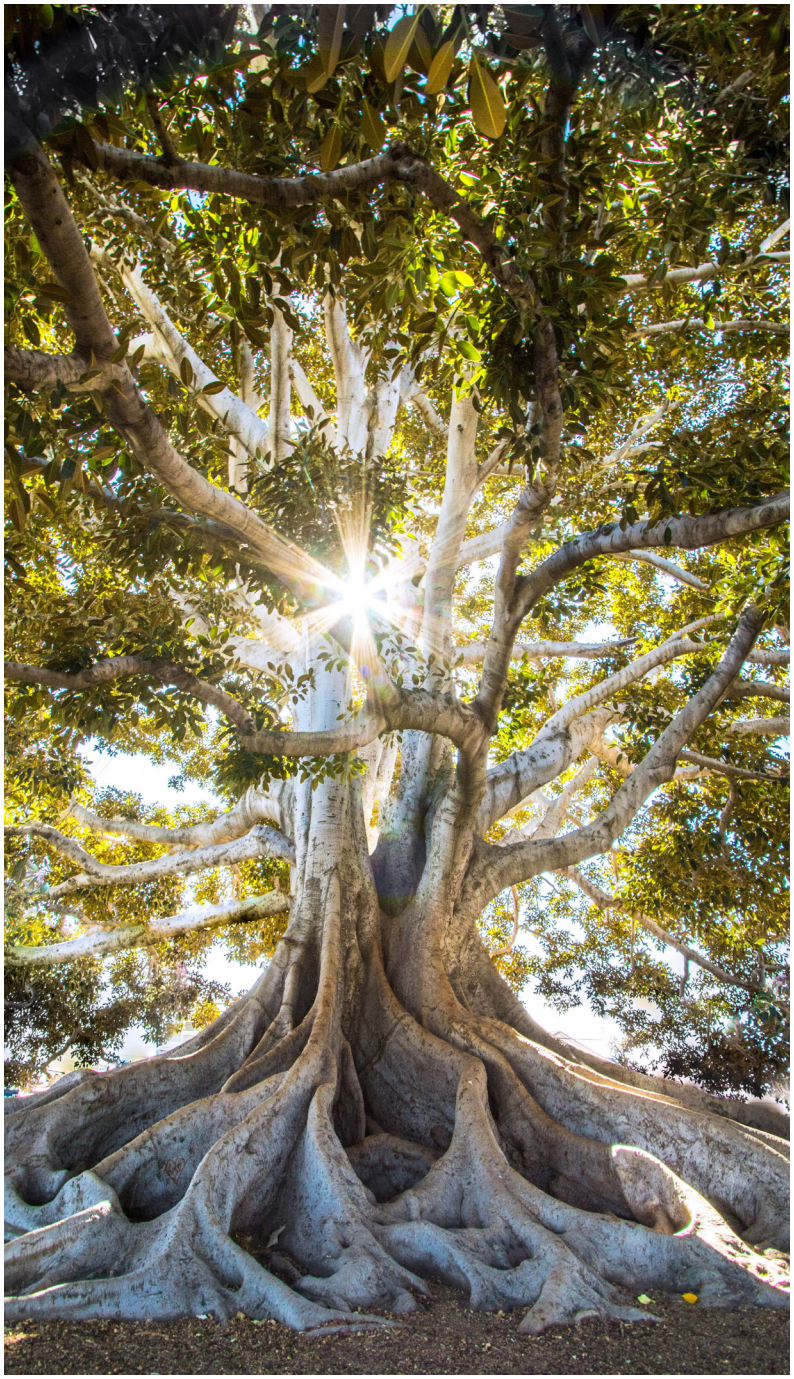
Multiple steps are involved in the successful translation of promising research from laboratory trials to patient access in the real world (i.e. from "bench to bedside"). The final steps of this research translation are usually carried out and led by pharmaceutical corporations, sometimes in partnership with academic investigators. Drug development is a process that takes many years and potentially hundreds of millions (even billions) of dollars through approval and patient access rollouts. Some companies intend to discover new molecules that are potentially more efficacious, have reduced toxicity or side effects, are safer, have a shorter duration, are not psychoactive, or have different applications. Of the capital raised by private companies in 2020, 84 percent was focused on drug discovery efforts.[40]

Intellectual property and psychedelic research

Intellectual property protection is a hot-button issue for the psychedelic field as commercial activity grows. Several PSFC members and other stakeholders interviewed for this report expressed concern that research and care delivery efforts could be negatively affected if particular companies lock up compounds through patents and restrict the efforts of talented researchers through non-compete clauses. The first generation of prescription psychedelics have long been in the public domain and in some cases are naturally-occurring substances (MDMA, LSD, and ketamine being notable exceptions). This weakens the ability to block competition through conventional patent strategies and has prompted for-profit companies to seek to develop patented variants of compounds.

Because psychedelics are not amenable to standard patent protection, psychedelic research has historically relied heavily on nonprofit drug development efforts. However, there is an alternative to patent protection called "data exclusivity" that allows some cost recovery through the protection and exclusive use of clinical data submitted to the FDA for market approval. Data exclusivity creates a limited period of time (five years) during which such data cannot be relied on by other companies to obtain market approval without the holder's authorization, though other companies can still invest substantial amounts to do independent research to generate their own data to obtain FDA approval.

PSFC's perspective is that patents are not inherently problematic for the psychedelic field. But while some patent activity is necessary to protect genuine innovation and novel compounds, other patents may enable patent holders to monopolize that which is already in the public domain, and in doing so, obstruct development in the field. Such monopolizing tactics also raise ethical concerns when the intellectual "property" derived from naturally occurring compounds draws upon the traditional knowledge of Indigenous communities, and disregards international treaties asserting Indigenous rights to their intangible cultural heritage.[41]



State of the Landscape:
The Public and Political Ecosystem

The development of a thriving research landscape is an important complement to the second part of our psychedelic ecosystem—the public and political sphere. In the spring of 2018, PSFC sponsored an expansive opinion research project, including both polling and focus groups, to better understand public perceptions and persuadability around psychedelics. This research, later bolstered by similar polling conducted in Oregon during the Measure 109 campaign, indicates that citing studies from recognizable institutions like Johns Hopkins and Harvard is one of the most potent ways to boost public acceptance of psychedelic therapies.

But that opening is only the first step. It must be followed by education, both about the benefits of psychedelic therapy and about the ways psychedelic treatment can take place and be supported safely. Communicating these messages will be important for increasing public acceptance and political support for psychedelic healing.

Public awareness, education, and integration support

While recent events and research have created the stirrings of a psychedelic renaissance, history teaches us that psychedelic science and policy gains can quickly be erased if the public's perception of psychedelics is driven by sensationalism, inaccuracies, or a disproportionate focus on adverse events. Recent media coverage of the psychedelic field has been largely positive, but this trend could change quickly.

Opinion research conducted in Oregon following the success of the Measure 109 campaign gives us a window into some of the most valuable—and most damaging—messages for the general public to hear about psychedelics. More than a quarter of "Yes" voters said the most important driver of their support was hearing about scientific research indicating psilocybin's promise as a new mental health treatment. Another 19% said they voted "Yes" because they felt the initiative would help people suffering from depression and anxiety. By contrast, 42% of "No" voters said they voted "No" because they felt there wasn't yet enough research on psilocybin, while another 32% were opposed because they believed that a regulated psilocybin therapy program would inevitably lead to full legalization and recreational use.

Taken together, these sentiments give us a sense of how important it is to educate the public on what science tells us about psychedelic healing and take a serious, careful approach to reassuring them about the risks and how they can be managed.

As psychedelic therapy scales up, we can expect isolated negative incidents, such as adverse reactions to treatment or irresponsible behavior by therapists, to occur and receive attention. We also know that even well-conducted experiences can present integration challenges for participants, both in the moment and in the days and weeks that follow. If the individuals affected by potential adverse events are not properly supported, or negative incidents are not properly contextualized within the broader landscape of psychedelic therapy, these incidents could create backlash that threatens the field's progress thus far.

Finally, because psychedelic treatments have operated underground for decades, accessibility has often been limited to those with the resources and the privilege to find opportunities and to risk law enforcement interactions. As a result, public awareness and understanding about psychedelics, especially their therapeutic benefits, is not equitably distributed across socioeconomic and cultural lines.

Building the political foundation

In addition to the specific political and policy efforts discussed in the first chapter of this report, broad-based, coordinated initiatives will be needed to build support for psychedelic therapy by political decision makers in statehouses and Washington, D.C.

With a few notable exceptions, the current advocacy and political landscape for psychedelics is made up of small organizations driven by passion for the cause. Their missions overlap in many ways and their impact could be more substantial with strategic coordination and resourcing. These can be grouped into a few categories discussed below: (The logos in each category are of representative organizations and are not an exhaustive list.)

Organizations advocating for psychedelic medical advancement and healthcare integration

These organizations focus on unlocking research funding, laying the foundation for insurance reimbursement, and finding other ways to integrate psychedelic therapy into the existing healthcare system. This category includes some of the longest-standing and most influential psychedelic organizations, such as MAPS and the Heffter Research Institute.

Organizations advocating for the rights and access of specific groups

These organizations focus on advancing access to psychedelic healing for veterans, Indigenous communities, economically disadvantaged populations, cancer patients, and other groups. They help work towards equitable and inclusive access to psychedelic healing and can play a critical role in engaging with policymakers.

Organizations advocating for policy change

This category includes organizations focused on changing laws at the city, state, or federal level. At their best, these groups draw on political savvy and experience to mobilize a range of groups to advance policy changes.

Organizations yet to be created

We also anticipate the emergence of new industry associations, patient advocacy groups, business ethics groups, professional certification organizations, and others as the psychedelic field develops.

At the federal legislative level, psychedelic policy reform is in its earliest stages, although opportunities for incremental progress are beginning to arise. For now, supporters in Congress are primarily focused on increasing research funding, including through a formal inquiry by Congressman Mark Takano (D-CA) and Sen. Brian Schatz (D-HI) asking why NIMH and NIH are not more actively looking at psychedelic research. More concrete legislative efforts could include targeting funds for research or creating safe harbors for people and practitioners involved in state-legal programs like Oregon's psilocybin therapy initiative.

Given President Biden's history with drug policy, it seems unlikely that psychedelic policy reform will receive substantial attention in the current White House. That said, Biden has prioritized mental health issues over the course of his career, and a focus on psychedelics in a healing context might break through. Ibogaine therapy was also apparently a notable component of Hunter Biden's addiction treatment and could present an opening for dialogue.

On the state level, nascent policy efforts are underway in California, Vermont, Hawaii, and Texas, but there is little consistency in the details of these proposed reform efforts or the messaging supporting them. The field is in need of politically savvy coordination, as well as thoughtful policy and messaging development in order to create sustainable momentum for state-level reforms.

State of the Landscape:
Plant Medicines and Indigenous Healing Systems

Although psychedelic medicine is a new domain for western medical and scientific systems, many Indigenous healing traditions around the world have incorporated psychedelic plant medicines for millennia. However, a number of these healing systems are at risk due to ecological threats such as habitat destruction and overharvesting. In particular, peyote, iboga (the source of ibogaine), and ayahuasca are threatened, as is the Bufo alvarius toad, the animal source of 5-MeO DMT.[42]

For example, Indigenous healing traditions face acute threats in North America, where Indigenous communities have used peyote in religious rituals for thousands of years. Today, peyote is considered to be a sacrament by the 400,000-member Native American Church (NAC) and an integral part of their faith. A small and slow-growing cactus, peyote is now critically threatened due to overharvesting and habitat loss from agriculture and cattle grazing. This, in turn, threatens the long-term survival of the NAC itself.[43] In the Amazon, Indigenous healing traditions that incorporate ayahuasca face similar threats such as forest destruction and overharvesting.

Key Goals and Recommendations
to Grow and Strengthen the Psychedelic Ecosystem

Supporting the broader psychedelic ecosystem offers something for every kind of philanthropist: science and research, education and awareness, integration support, equitable access, politics, conservation, and support for Indigenous healing traditions. This section outlines four goals that will be integral to a thriving and sustainable psychedelic field:

- **Cultivate a thriving, coordinated and cooperative research ecosystem** supported by robust government funding and embraced by the scientific mainstream.
- **Develop public education and integration support initiatives** to increase understanding of psychedelic therapy and keep adverse events to a minimum.
- **Build political and advocacy infrastructure** to support policy engagement on psychedelics and ensure the long-term viability of psychedelic medicine.
- **Partner with Indigenous-led plant medicine conservation efforts** to sustain traditional healing systems and restore wild sources of plant-based psychedelics.

Below, we'll analyze each of these goals and outline roles for philanthropy to address them.

Goal #1: Cultivate a thriving, coordinated and cooperative research ecosystem, supported by robust government funding and embraced by the scientific mainstream

Rationale

A thriving research ecosystem will ensure that drug development efforts and broader knowledge generation about psychedelics continue to advance, deepening acceptance of psychedelic science by the mainstream scientific community. Reputable academic research on the safety, efficacy, applications, and risks of psychedelic medicine has arguably been the single greatest antidote to the stigma surrounding these substances. The field, though emerging, is still on the fringes. For greater mainstream acceptance, further waves of scientific inquiry, communicated outwardly through strategic channels, will be critical.

Normalizing psychedelic research in the eyes of government funding agencies is critical for ensuring mainstream acceptance of the field. Institutes such as the NIH, NIMH, NIAA, and NIDA are a core piece of the federal funding puzzle and are expected to provide resources as they do in other areas of research. In what seems like a promising trend, several of these institutions recently awarded their first grants dedicated to psychedelic research since the 1960s. In April 2021 the NIH, the world's largest public funder of medical research, granted a $190,000 career development award to Benjamin Kelmendi from Yale. In September 2021 NIDA granted $4 million to a team of researchers from John Hopkins, University of Alabama and NYU led by Matthew Johnson to study the potential of psilocybin-assisted therapy for the treatment of tobacco use disorder. A similar trend is observed abroad with the Australian Government allocating $15 million for psychedelic clinical research in March 2021.

The 50-year hiatus in psychedelic research means that an entire generation of psychedelic researchers has been lost. There is a pressing need to train the new generation and ensure they can be mentored by the few leading experts. As stigma continues to dissipate, top talent will be attracted and high-quality science will result, creating a positive feedback loop. Additional researchers, institutions, and funders will flock to psychedelics as credibility improves, hype is moderated, and the stigma washes away. As the evidence base builds, clinicians will be able to advise patients based on science instead of stigma.

A robust ecosystem creates a secure foundation for researchers to advance their work and move science and medicine forward. In addition to clinical research for those with diagnosed mental illnesses, researchers may begin exploring the betterment of well people and even the nature of consciousness. Psychedelics are a promising tool toward understanding open questions in psychology and psychiatry as well as a mechanism to bridge the gap between psychology and neuroscience.

Critical Pathways and Recommendations

A. Supporting research and researchers around a coordinated agenda

Given the incipient nature of this field, there is an opportunity to set the tone and norms for the culture of how research is conducted, collaborated on, and shared. There is ample interest in funding academic research by individual funders, but, funders will need to coordinate, share learning, align the field around key research priorities, and support the training of a new generation of researchers in order to maximize philanthropic impact.

Though the field is small and relatively close-knit today, coordination and collaboration will be increasingly important as it grows. Academic research is highly competitive by nature and incentives are often misaligned between stakeholders ranging from academic research to delivery of care. Philanthropic leaders have an opportunity to help lay out a bold research agenda to meaningfully influence the direction of the field. To do so, funders can incentivize coordinated efforts such as multi-site studies, shared databases, and collaborative grant competitions targeting the goals identified in the previous two chapters. They can bring together a diverse array of stakeholders (e.g. researchers, physicians, hospitals, insurers, and patients) to work collaboratively as a community. This can be achieved by convening strategic high-impact funding competitions, with scoring of proposals rewarding collaboration, accountability, impact, and equity/diversity criteria.

Another limiting factor to attracting and retaining top talent in the field is that until very recently, psychedelic research did not offer viable career paths to young researchers. Supporting the careers of graduates and early stage researchers through career awards and fellowships can ensure that top talent enters and stays within this field. Enshrining of psychedelics in the university can be assisted by the creation of new multi-disciplinary chairs in psychedelic science.

B. Engaging leading researchers and stakeholders outside the psychedelic field

The psychedelic community is growing but is still a small bubble. One of the ways to attract people to the field and potentially unlock federal research funding is to engage well-known researchers and stakeholders from other disciplines. For instance, psychedelic research centers could seek out leading researchers on PTSD, depression, or substance use disorders who are already receiving federal funding. This would add psychedelics as a new dimension in their scope of research and showcase the potential of these substances to a wider audience. A recent psilocybin study on depression received $2 million from the German government, in part because the principal investigator was a leading mainstream researcher.

Leading researchers could be engaged by creating ad-hoc grant programs specifically designed to attract established researchers who could partner with researchers in the psychedelic research field. Engaging key stakeholders can be done by designing studies and treatments to reach specific groups in order to gain mainstream acceptance. For example, funding psychedelic research studies within government-run organizations such as the VA will serve the critical purpose of raising awareness with regulators and other government officials. Not only would this help to reduce future friction with regulators and governmental approvals, but completing studies within VA hospitals would increase the likelihood of PAT treatment protocols being adopted across the VA system. One might also want to strike partnerships with existing patient groups and research consortia currently working on relevant clinical conditions.

C. Building a strong, high-standards academic community

While it will be important to engage commercial entities in a variety of areas, philanthropists must consider how best to ensure that researchers and research institutions do not get co-opted by commercial interests. Philanthropists should aspire toward the preservation of the intellectual commons while promoting innovation. Over the long term, basic research on psychedelics could be transformative in ways we cannot predict yet, so it is important to cultivate a thriving field and not just fund targeted studies. We can learn from the example of the contemplative science field that went from fringe to highly reputable and accepted by the medical mainstream.

Scientific-focused events and communities, and targeted workshops for psychedelic science interest groups will all help establish a rigorous field. High-profile, scientists-only activities at mainstream academic institutions have the power to involve individuals who otherwise wouldn't be inclined to participate in psychedelic symposia. The New York Academy of Science's seminars on psychedelics in psychiatry are prime examples of such high-profile reputable events. Additionally, inspired by established reputable international scientific societies, the recently-founded International Society for Research on Psychedelics aims to provide scientific networking and advancement of empirical science regarding psychedelics.

Goal #2: Develop public education and integration support initiatives to increase understanding of psychedelic therapy and keep adverse events to a minimum

Rationale

As discussed earlier in this chapter, recent opinion research indicates that providing basic education about the research-driven promise of psychedelic healing can substantially increase public support for policies that open up access. Furthermore, in a well-nourished public information environment, isolated negative incidents are more likely to receive proportionate coverage with appropriate context. In the absence of such an environment, potential negative incidents could engender the kind of backlash that stopped psychedelic research in its tracks decades ago.

Another way to minimize the impact of adverse events is to minimize the number and severity of those events. Organizations and individuals offering integration support or similar services can help. In some cases, immediate support will be available in the form of a guide, facilitator, or therapist, and defined therapeutic protocols often include follow-up integration sessions as well. However, as access becomes more widely available (and not always within defined protocols), the need for other forms of community-based integration support will increase in turn.

Finally, education efforts to demystify psychedelic therapy and its benefits can help make the population of those receiving treatment less of an "exclusive club" and less intimidating to join for those who have not considered psychedelics a viable option in the past. This will be an important step towards ensuring treatment can reach historically underserved populations.

Critical Pathways and Recommendations

A. Public awareness and education initiatives

A certain amount of psychedelic awareness and education marketing will likely be done by commercial operators, who have an interest in generating enthusiasm for the treatments they offer. However, education driven by marketing priorities will not always align with the broader mission of psychedelic therapy access.

Philanthropic funding can support more mission-driven dissemination of information. Funding for education, fellowships, and programs for journalists and other influential communicators would prepare them to approach psychedelic therapy as a credible, science-based topic. This could help ensure that their audiences are regularly receiving credible information about the opportunities and risks of psychedelic therapy in medical and non-medical contexts, and that bad news is covered responsibly and proportionately.

Michael Pollan posited that a good step forward might be to "proactively launch a public relations strategy and journalist training program akin to the environmental movement, which has trained journalists through fellowships and grants." He pointed out, "Public opinion is a bit of an insurance policy, one of the few you have." On the journalistic front, Pollan noted, "We don't yet have a cadre of beat reporters committed to this subject. And they could become an interesting bulwark against backlash, or they could clear up information." (For more on a coordinated effort to measure and shape public opinion, as well as influence political actors, see the "National Coordinating Hub" concept discussed in the next goal section.)

Another option for funding is to bypass the "gatekeepers" and directly support the creation and dissemination of content focused on the messages we want the public to hear and understand. Documentaries, public awareness campaigns, and direct outreach campaigns through community-based organizations can all contribute to a more supportive public perception of psychedelic therapies. There are opportunities to highlight some of the most compelling healing stories in a credible, and sober manner that emphasizes the therapeutic promise of psychedelics.

B. Integration support

As many new people are being inspired to try psychedelics and psychedelic therapy, we must build safeguards to ensure these experiences are as safe as possible. This includes ensuring psychedelic therapy participants have clear and easy access to integration support to help them through challenging experiences.

While some medical and therapeutic regimens include integration support by default in the form of facilitators or therapists, many psychedelic experiences take place outside those contexts. Philanthropic funding can support the growth of organizations that train and provide direct access to community support for individuals

going through challenging psychedelic experiences or seeking to gain as much as possible from their post-experience integration.

The current psychedelic ecosystem includes organizations that provide in-person services and phone hotlines such as the MAPS-led Zendo Project and the Fireside Project. These will require substantial new resources in order to scale to meet the need if psychedelics become more accessible. With more resources, these organizations and others like them can not only serve more individuals directly, but also provide education for family and community members seeking to support someone else's integration experiences.

Goal #3: Build political and advocacy infrastructure to support policy engagement on psychedelics and ensure the long-term viability of psychedelic healing

Rationale

The way in which psychedelics are treated by policymakers will play a significant role in the way the larger population perceives and has access to psychedelic healing. A well-crafted and supported policy and advocacy strategy could best expand and protect access to psychedelic treatment.

Building a nationally coordinated political presence to represent the interests of the psychedelic field will serve those looking to advance psychedelic therapy in a number of ways. On the research front, the National Institutes of Health (NIH), National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), Department of Defense, Defense Advanced Research Projects Agency (DARPA), and the VA are all potential sources of federal funding and resources for psychedelic research. The VA also offers a potentially valuable environment for care delivery initiatives. While not directly accountable to voters, these entities are all ultimately funded and guided by Congress and the presidential administration, and the way they set priorities can be influenced by political mobilization and advocacy.

Similarly, while FDA decisions are intended to be insulated from political influence, reality suggests that careful messaging and strategic coalition-building can help smooth the path for decisions that could be considered "controversial." Conversely, not attending to the politics leaves open a vulnerability toward ideological attacks that have been known to derail approvals in the past.

In addition, while congressional action on psychedelics is unlikely over the near-term, education and lobbying of federal lawmakers increases understanding, reduces stigma, could unlock additional government funding, and creates the necessary foundation for broader policy reform in the future. Strengthening the political advocacy ecosystem for psychedelics can also provide protective cover for state-level efforts to increase access, such as Oregon's psilocybin therapy program, as well as contribute to an environment more capable of withstanding general backlash or political attacks.

Philanthropy is in a prime position to be a catalyst and bridge-builder for these efforts, funding coordinated efforts that bring together many of the advocacy players to pursue a thoughtful strategy.

Critical Pathways and Recommendations

A. National coordinating hub for earned media, research, and policy

There is an immediate need for leadership on politically sound psychedelic messaging and policy development. Current policy efforts are often ad hoc and not yet guided by a consistent set of principles or savvy model language. Current communications efforts are largely decentralized and often rely on voices that are either not well-suited or not well-prepared to move psychedelic policy reform toward mainstream support.

A low-overhead, politically savvy hub for psychedelic policy and messaging would create a central resource for media, policymakers, and advocates, with the goal of amplifying messages and policies with the highest likelihood of success at expanding legal access to psychedelic healing. The hub could include:

- A central repository of psychedelic policy reform ideas, including model legislation
- A central resource for effective psychedelic policy reform messaging
- Coordinated public opinion research to track evolving policy and messaging needs
- A key contact point for media, policymakers, advocates, and activists
- A network of spokespeople and experts

B. Constituency-specific advocacy organizations

Advocacy organizations focused on specific constituencies such as veterans, assault survivors, or front-line medical workers can be extremely powerful elements of a policy change strategy. Tying a policy reform effort to human stories from populations who are either highly sympathetic or highly relatable is one of the most effective ways to create a sense of urgency among both the public and lawmakers.

Ideally, constituency-specific advocacy organizations would work in either formal or informal coordination with other advocacy groups throughout the field. While their specific priorities may differ, their general policy aims are likely to align. A policy effort that features effective advocates from several different groups has a much higher likelihood of success. These types of organizations also provide important avenues for education and outreach that are tailored to the unique needs of particular populations, making it more likely that treatment will reach the people represented by these groups.

Goal #4: Partner with Indigenous-led plant medicine conservation efforts to sustain traditional healing systems and restore wild sources of plant-based psychedelics

Rationale

As psychedelic treatment becomes available in the U.S. and elsewhere, it will be important to protect traditional plant medicine systems that are already providing healing for Indigenous communities around the world. Some of these communities are suffering from high levels of substance misuse, suicide, depression, and other health issues. It is essential that they have continued access to healing in the formats that meet their needs, so supporting Indigenous healing traditions and addressing ecological threats to the plant medicines they depend on will be critical.

Indigenous communities also hold the legacy knowledge of how to best utilize these medicines. Through respectful engagement that acknowledges the need for reciprocity and repair, members from these communities

may continue to share and inform the psychedelic renaissance as it mainstreams. As expert stewards of land, Indigenous communities are also often directly engaged in conserving native habitat of plant medicines and should be empowered and supported to ensure ecological sustainability as use increases.

> **"As [this] renaissance unfolds, demand pressure threatens the wild sources of these medicines as well as disrupting their cultures and communities. We need to support responsible Indigenous-led bio-cultural preservation projects, for both harvesting and cultivating the medicine, to the benefit not detriment of these communities.**
>
> - David Bronner
> PSFC board member and CEO, Dr. Bronner's

These plant-based healing traditions are part of the intangible cultural heritage of the communities that have stewarded this healing knowledge for thousands of years. For example, a 1957 *Life* magazine article on sacred mushroom healing practices of the Mazatec people in Mexico prompted initial scientific research on psilocybin in the US and Europe.[44] Pharmaceutical development of psilocybin, mescaline, ibogaine, and other naturally-occurring psychedelics is indebted to these traditional systems of healing knowledge. Patent-holders, commercial actors, and other beneficiaries of traditional knowledge about psychedelics should therefore attend carefully to their reciprocal obligations to the communities that sustain this knowledge. As Miriam Volat, PSFC member and Co-Director of the Riverstyx Foundation noted, "This is about setting a standard for what we as a society want psychedelic pharma to do as a business model."[45]

Critical Pathways and Recommendations

A. Indigenous-led plant medicine conservation initiatives

One of the most effective and sustainable ways to preserve wild sources of psychedelic medicines is by empowering communities to lead conservation efforts themselves. Indigenous-led, community-based conservation and cultural preservation initiatives to protect plant medicines are underway globally. For example, the International Peyote Conservation Initiative is an Indigenous-led initiative that has preserved wild peyote habitat and supported the continued ceremonial use of peyote by the Native American Church in the U.S. Similar initiatives are underway in other regions, such as the Union of Indigenous Yagé Medics, which works to protect ayahuasca healing practices in Colombia. Two initiatives created in 2021, the Indigenous Plant Medicine Fund and the Indigenous Reciprocity Initiative of the Americas are working to raise funds for organizations such as these.

B. Reciprocal support for Indigenous communities by commercial actors

Investors, drug developers, and other commercial actors that benefit from traditional knowledge about psychedelics can engage in reciprocal support for Indigenous healing traditions, including by embedding it in their governance models. For example, Journey Colab, a company developing synthetic mescaline-based treatments has allocated 35 percent of its shares to "the team developing the therapies, the therapists who will administer them, and the Indigneous communities from which the work originates."[46]

Conclusion

It can be easy for those of us in the psychedelic "bubble" to dive into the detailed challenges of creating and expanding access, while forgetting that we are still a long way from broad societal and cultural understanding of the field. Even as we debate the specifics, we must also keep a careful eye on the big picture. Failing to do so risks repeating the regrettable history of psychedelic research and cultural perception five decades ago. Preserving access to psychedelic healing will require both attention to detail and careful strategy to ensure hard-won progress continues over the long-term.

Conclusion

Philanthropy, Community, and the Future of Psychedelic Healing

In his study of gift exchange in cultures around the world, the anthropologist Marcel Mauss concluded that gifts are about much more than a transfer of value between individuals: gift-giving is rich in social meaning that extends well beyond the giver and recipient. To Mauss, gift exchange is a powerfully symbolic ritual that deepens networks of reciprocity and shared meaning among community members. Gifts link both giver and recipient to a broader community, and bring the community's values to life.

Mauss's thinking connects to PSFC's work and the path of the psychedelic field in two ways. First, psychedelics are gifts in and of themselves. Psychedelic experiences can be almost superabundant with meaning, transformation, and healing. They can inspire deep gratitude, a pull to community to process and integrate insights, and a desire to share the experience with others.

Second, gift-giving has been part of psychedelics since well before prohibition. Pathbreaking researchers such as Ann and Sasha Shulgin, Stan Grof, and many others dedicated their careers to advancing knowledge about psychedelics. And visionary philanthropists made gutsy bets on the possibility that, somehow, someday, psychedelic healing might be legal and accessible.

That day is nearly upon us. And so the role of philanthropy in the field is shifting. Things are becoming more complex as psychedelics enter the messy nexus of the medical system, politics, and capitalism. In the '60s, many enthusiasts made the mistake of promoting psychedelics as a panacea for personal liberation and global transformation while overlooking their limitations and risks. Today, we must dream big while keeping our feet on the ground. Let's avoid the mistake of setting our sights too narrowly: If what we are left with in five years is a set of treatments that heal some but are out of reach of most, the psychedelic field will have missed an opportunity to make major progress towards mass mental health.

As the big question for psychedelic healing shifts from "what if?" to "how and for whom?" its capacity to inspire will shift too: to stories of people healed, connection restored, and lives uplifted. The challenge will no longer be about (re)discovering these discarded treasures, but stewarding and sharing their gifts.

What comes next for PSFC, too, will shift and evolve in turn. This report sets the stage and points towards possibilities. We hope it will spark conversation and inspire us to work together in support of this field at a pivotal moment in its history.

Acknowledgments

PSFC is grateful for the many people who helped make this report possible.

Alex Simon and Kevin Weiss led our external research, interview, and drafting team and were supported by Zach Haighney as a co-author with additional contributions from Lidia Reznick, Blake Mandell, Laura Berk, and David Burstein.

The landscape research project and PSFC's internal review, editing, and drafting process were led by Ben Collins and Alexandre Lehmann, with contributions from Taylor West, Catherine Porter, Gonzo Nieto, Jennifer Childs, and Greg Kearns as well as review by Graham Boyd and Joe Green.

We're especially grateful to Michael Cotton, Jeff George, George Greer, Carey Turnbull, and Dan Grossman for their extensive comments and feedback, and to members of the PSFC Steering Committee for their support and guidance.

Many thanks to those who reviewed and shared feedback on drafts, including Katrin Preller, Alan Fournier, Miriam Volat, Dick Simon, Henry Harbin, Tamara Hall, Ben Unger, Tamar Todd, Kris Lotlikar, Liana Gillooly, Bennett Nemser, Michael Pollan, Mark Green, Jason Pyle, and Rick Doblin. Thanks also to Katie Pananen for her beautiful design and layout work.

Special thanks to the many stakeholders and PSFC members who volunteered their time and expertise for interviews.

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