BRAINFUTURES

Psychedelic Access Pathways

DIFFERENTIATING MEDICAL, WELLNESS, AND RELIGIOUS ACCESS TO PSYCHEDELICS

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Key Takeaways

1. There are important legal distinctions between medical, religious, and wellness uses of psychedelic compounds.

2. Public discourse and media coverage about psychedelics often do not reflect these distinctions.

3. Advocates and journalists can reduce confusion, lower risks for psychedelics users, and contribute to a thriving psychedelic ecosystem by using clear language and being transparent about the legal and safety structures that apply to psychedelic use in each context.

Introduction

Headlines about the healing potential of psychedelics are seemingly everywhere. More than a year before the first psychedelic drug is likely to be approved by the U.S. Food and Drug Administration (FDA), media coverage is often bullish on the potential of psychedelics to treat a vast array of maladies, especially mental health and substance use disorders.

Over the course of one week in April 2023, headlines from major publications included:

- "A Psychedelic Trip Brought Sensation Back to My Body" in *Insider* (Joj, 2023),
- "My Rugby Injuries Made Me Suicidal–Psychedelic Drugs Saved Me" in *The Telegraph* (Deevoy, 2023), and
- "Ayahuasca, the Next Psychedelic Drug for Mental Health" in *El Paìs* (Mediavilla, 2023).

These headlines are representative of the media's overall optimistic stance toward psychedelics, which has been bolstered by a resurgence of scientific studies with promising results over the past 15 years.

Beneath the headlines, readers find stories about psychedelic drug use in a wide variety of settings: ayahuasca retreats in places like Peru and Costa Rica, indigenous cultural and religious practices, "underground" experiences guided by facilitators that operate widely (but illegally) in the United States, ritual use by federally recognized religious groups such as the Native American Church, and clinical trials at prestigious institutions like Yale and Johns Hopkins. As facilitators in Oregon prepare to offer regulated psilocybin experiences as soon as summer 2023, yet another means of accessing psychedelics will soon become available.

The media's current coverage often does not distinguish between medical, religious, wellness, and recreational psychedelic use, often viewing it all through a mental health treatment lens. As media reports have repeatedly shown, individuals have found healing from psychedelic experiences in many different settings, including clinical trials, psychedelic retreats, religious ceremonies, and the psychedelic "underground." There are, however, fundamental differences between these access pathways that the media, participants (those taking a psychedelic substance), and the public will benefit from understanding.

In part one of this issue brief, BrainFutures describes three psychedelic access pathways that are available in the United States (see above for full definitions): medical access, wellness access, and religious access. Each can be useful depending on the participant's goals, and each also has its limitations. BrainFutures' work focuses primarily on the advancement of medical access to psychedelics, but we recognize that there are important and legitimate uses of psychedelics aside

DEFINING PSYCHEDELIC ACCESS PATHWAYS

Medical access to psychedelics, often referred to as the "medical model," treats a specific diagnosis by pairing an FDA-regulated psychedelic drug with psychotherapy or psychological support before, during, and after the patient takes the drug.

Wellness access is a system that allows the public to consume psychedelic drugs under the supervision of a licensed facilitator at a designated service center, where the administration of the drug and subsequent psychedelic experience or "journey" take place.

Religious access means the sacramental use of psychedelic substances such as peyote or ayahuasca in the context of sincere religious exercise (Thorne, 2020).

from medical treatment—including Indigenous use, which predates Western medical use by millennia. Each "setting" requires different legal and regulatory structures.

In part two, we make the case for the importance of distinguishing between these three models. This clarity is necessary because participants deserve to be well-informed about the purpose, legal structure, and limitations of the access pathway they choose. Additionally, the practices of medicine and psychotherapy are protected by law and regulations at the state and federal levels. Practitioners (e.g., facilitators, therapists, or psychedelic religious leaders) must ensure they understand the legal boundaries they are practicing within to avoid violating these laws. Finally, the public should understand that evidence of improved health outcomes from clinical trials is primarily generalizable to medical settings, though it is commonly used to justify practice and participation in other access pathways. In medical settings, psychedelics are given after rigorous medical screening and with significant psychological support or psychotherapy from a licensed health professional, a model that can differ significantly from wellness and religious access. Evidence from controlled trials which validates that psychedelics are efficacious for treating mental health and substance use disorders can also identify the risks and side effects of psychedelic drugs, and this information can be useful in a wellness or religious setting. However, the clinical outcomes of medically supervised research trials should not be relied upon to predict outcomes in settings with substantially different protocols.

At the end of part two, we make four actionable recommendations for reducing risks and promoting clarity in the public conversation around psychedelics:

1. **Psychedelic practitioners and advocates should inform participants about the purpose, risks, and legal limits of the access pathway they operate within using easy-to-understand language.**
2. **Discussions about psychedelic use should avoid broadly generalizing across pathways or conflating one pathway with another.**
3. **Practitioners and advocates in any access pathway should avoid making unvalidated claims about health benefits.**
4. **Psychedelic practitioners should take care to avoid the unlicensed practice of medicine or psychotherapy.**

By proposing clear definitions of each access pathway and delineating the boundaries between them, BrainFutures hopes to encourage thoughtful discourse on psychedelics. We believe that clearer rhetoric and communications will enhance safety and transparency throughout the psychedelic "ecosystem," helping protect participants from harm and legal risk.

PART ONE

Defining Psychedelic Access Pathways

In this issue brief, psychedelic access pathways are defined as the legal structures that allow U.S. residents to access psychedelics. BrainFutures defines psychedelics as "compounds that affect neurochemistry, causing shifts in experiential perception and mood, often accompanied by vivid mental imagery and altered auditory processing" (Sky, 2022). Except for ketamine (which is not a "classic" psychedelic but is often included in discussions of psychedelics due to its effects on perception and consciousness), nearly all commonly known psychedelic drugs are classified as Schedule I substances under the Controlled Substances Act (CSA) passed in 1970 (84 U.S.C. § 202). Schedule I substances are defined as having "no currently accepted medical use in treatment in the United States" and "a high potential for abuse" (21 U.S.C. § 812(b)(1)) and are therefore illegal to possess in almost all circumstances except for government-approved and strictly regulated scientific research or through a small number of religious communities (DEA, n.d.). After a short background section, we will dive deeper into each access pathway to describe its purpose, legal structure, and limitations.

LEGAL, SEMI-LEGAL, OR ILLEGAL?

While psychedelic use may be legal under state law in certain places, it remains federally illegal across the country. We use the term "semi-legal" to connote that there is a contradiction between state and federal laws, but in reality all Schedule I drug activity that is not explicitly permitted by the federal government is illegal. It is not yet clear whether the federal government will act to enforce the CSA by charging psychedelic drug offenses, or rather, deprioritize the prosecution of conduct that is legal under state laws. The Department of Justice took the latter approach toward enforcement of marijuana control under the guidance of the Cole Memo (Silva, 2020).

BACKGROUND

There is certainly an argument to be made, based on numerous clinical studies, that psychedelics such as psilocybin, LSD, or MDMA are "over-scheduled." Scant evidence suggests that classic psychedelics are addictive, while evidence is mounting that they can aid in psychotherapy, leading to impressive findings in many clinical trials across indications such as depression, post-traumatic stress disorder (PTSD), and smoking cessation (Sky, 2022). As of summer 2023, there are several policy and legal efforts underway to reschedule psychedelics. Until the law changes, however, there are only two fully legal pathways for accessing psychedelics: medical access, currently through rigorously controlled clinical trials and eventually through FDA approval and prescription use,[1] and religious access through one of a very small number of federally recognized religious organizations that use psychedelics ritually.

Another semi-legal access pathway is currently taking shape in multiple states: state-regulated wellness access. In 2020, Oregon voters approved Measure 109,

1 The FDA also allows for a small number of expanded access sites, which are discussed further in the next section.

which established a mechanism for the state to license and regulate facilitated psilocybin services (Psychedelic Alpha, 2023b). Implementation of psilocybin services began in January 2023. Similarly, in 2022, Colorado voters passed Proposition 122, which will provide access to "natural medicines" at "healing centers" regulated by the state (ibid). These state initiatives legalize access to psychedelics in certain contexts under state law, though such access remains federally illegal.

Many states and localities are also decriminalizing psychedelic drug possession.[2] Decriminalization refers to the reduction or removal of criminal penalties for possessing psychedelic drugs (usually within certain limits) and in some cases for cultivating or transferring these substances (Marks, 2022). Decriminalization stops short of legalization—it reduces consequences but does not make drug activity legal or establish regulated markets for buying and selling psychedelic drugs. Since decriminalization efforts are rarely conflated with psychedelic access in the other three pathways and the legal issues surrounding decriminalization are qualitatively different, an in-depth analysis of decriminalization is beyond the scope of this issue brief. For an in-depth description of the many varieties of drug decriminalization policies implemented in the U.S. and internationally, see Greer and colleagues' 2022 paper, "The Details of Decriminalization."

The following sections discuss medical, wellness, and religious access in detail.

MEDICAL ACCESS

Purpose

Medical access to psychedelics is for the purpose of treating a diagnosed medical condition. Patients may experience a reduction in symptoms or in some cases full remission from their condition after treatment (e.g., Multidisciplinary Association for Psychedelic Studies [MAPS], 2020).

Currently, mental health and substance use disorder diagnoses are at the forefront of psychedelic research. However, early-stage research and anecdotal evidence suggest that psychedelics may also be useful for treating nonpsychiatric indications, including traumatic brain injury (Khan et al., 2021), Parkinson's disease, and chronic pain (Sky, 2022).

Definition and Legal Structure

Medical access to psychedelics, often referred to as the "medical model," treats a specific diagnosis by pairing an FDA-regulated psychedelic drug with psychotherapy or psychological support before, during, and after the patient takes the drug. This treatment model is known as psychedelic-assisted therapy. It is BrainFutures' position that the term psychedelic-assisted therapy should **only** be used to refer to the medical access pathway because "therapy" implies treatment for a health concern. As psychedelics are developed as treatments for nonpsychiatric conditions, medical access may expand to include delivery of care with less psychological support.

Psychedelic drugs for medical access are heavily regulated by the FDA and the Drug Enforcement Agency (DEA). The FDA requires that drug sponsors apply for investigational new drug (IND) status before testing a substance on humans (FDA, 2022b). Once the FDA approves an application, INDs can enter clinical research, which is typically broken into three phases. Phase 1 usually involves trials on a small number of healthy volunteers; Phases 2 and 3 are progressively larger and longer-term and include patient populations for the targeted indication (e.g., depression, bulimia) (FDA, 2018). At the conclusion of Phase 3, a drug sponsor can submit a New Drug Application, which is a formal request for FDA approval. The FDA reviews these applications with the primary purpose of evaluating the safety and efficacy of the drug.

Currently, there are two psychedelic drugs in Phase 3 clinical trials. MAPS Public Benefit Corporation has completed its second Phase 3 trial of 3,4 methylene-

2 *Psychedelic Alpha* maintains an excellent tracking tool for psychedelic drug policy reform on its website.

dioxymethamphetamine (MDMA) for the treatment of PTSD and is expected to submit a New Drug Application in the coming months, with a decision from the FDA anticipated in late 2024 (Psychedelic Alpha, 2023a). COMPASS Pathways is early in its first Phase 3 trial of psilocybin for treatment-resistant depression (ibid). In some cases, the FDA may approve a psychedelic drug-assisted therapy rather than the drug itself as a standalone (e.g., MDMA-assisted therapy).

While clinical trials are underway, the FDA has discretion to grant IND access to patients outside of the clinical trial process through its expanded access program (FDA, 2022a). Expanded access is only available to patients who have exhausted all other treatment options and cannot join an ongoing clinical trial. Thus far, expanded access to psychedelic drugs has been quite limited. Additional expanded access slots would not only benefit ongoing research efforts, but more importantly would provide access to these new therapies for patients in dire need of new treatment options.

Once the FDA approves a psychedelic drug or psychedelic-assisted therapy, the drug must still be rescheduled by the DEA within 90 days before patients will have access through their healthcare providers (Improving Regulatory Transparency for New Medical Therapies Act, 2015). State-level controlled substance laws that prohibit or restrict access to psychedelic drugs may also need to change, though some states have trigger laws that ensure automatic conformity with federal drug scheduling (Institute of Medicine (US) Committee to Study Medication Development and Research at the National Institute on Drug Abuse, 1995). Once these legal hurdles are cleared, appropriately licensed medical professionals who are registered with the DEA will be able to prescribe the approved drug to their patients. It is highly likely that the FDA will also require Risk Evaluation and Mitigation Strategies (REMS) to enhance patient safety since psychedelics do carry some risks (Davis & Lampert, 2022).

Medical access to psychedelics confers significant benefits to participants in terms of safety measures and, possibly, affordability. Experts in psychedelic-assisted therapy widely believe that the primary health risks of this treatment are psychological rather than physiological, which is why great care is taken to support patients throughout the process (Sky et al., 2022). Typically, patients work with psychotherapists to prepare extensively for the psychedelic medication administration session and are supported by these same therapists during the session. Afterwards, the patient works with their therapists to process their experience and make changes to their life during the phase known as integration. In clinical trials, patients are often supported by two people, at least one of whom is a licensed mental health provider such as a psychologist, clinical social worker, or marriage and family therapist. These clinicians are trained (and licensed) to identify treatment-emergent events and conditions such as panic, suicidality (Johnson et al., 2008), or mania (Hendin & Penn, 2021). Additionally, medical staff are available during medication administration sessions in case of emergency.

Once a psychedelic drug becomes legally available for prescription use, health insurance companies might offer coverage for these treatments. Equitable access to psychedelic-assisted therapy is dependent on insurance coverage; without coverage, the out-of-pocket expense to patients could easily total tens of thousands of dollars for the therapy alone (Davis & Lampert, 2022). Drug costs are not yet known since there are no approved compounds on the market.

Limitations

By definition, the medical access pathway is only available to patient populations, meaning those with a specific diagnosis that can be treated using a psychedelic drug. However, clinical research has repeatedly shown that the medication administration session can have profound impacts on patients aside from symptom reduction. Specifically, research participants often report that it is among the most spiritually significant or meaningful experiences of their lives, often ranking alongside the birth of a child (Griffiths et al., 2006). Advocates for nonmedical access pathways often argue that access to altered states of consciousness and deeply meaningful experiences occasioned by psychedelics should not be gatekept by the medical community, or limited to those with a diagnosis for which psychedelics are indicated (Marks, 2020). Further, many Indigenous leaders and researchers have criticized the

medicalization and commercialization of psychedelics as forms of cultural appropriation and colonization (Celidwen et al., 2023).

Another problem inherent to the medical access pathway is the cost associated with care delivery, although insurance coverage could make it affordable for some patients. The costs of multiple providers (in most cases, a prescriber and a therapist at minimum), compliance with REMS, facilities, and other overhead associated with medical care will all inflate the overall price tag associated with medical access. Although still nascent, the psychedelic-assisted therapy field is ripe for innovation. BrainFutures explores potential cost-reduction strategies that should be evaluated by future research in our mini-brief, "The Future of the Field" (BrainFutures, 2022).

There are also significant time delays inherent to the medical model because the drug development and approval process can take many years. For example, MDMA was given "breakthrough therapy" status by the FDA in 2017 based on the results of its Phase 2 trial (MAPS, 2021). This status was intended to make the rest of the trial and approval process more efficient, yet a final decision and potential FDA approval will not come until at least 2024. The multi-year (and in some cases, multi-decade) time investment required to bring a drug to market requires large amounts of capital from drug developers, which can drive up the price that consumers eventually pay. Additionally, while a drug candidate works its way through development, clinical trials, and FDA review, many people who could benefit from it will not have access.

Finally, the model of psychedelic-assisted therapy shown to work in clinical trials is also quite costly in terms of patients' and clinicians' time, often requiring 12 or more hours of psychotherapy in addition to a daylong medication administration session. This time commitment will not be feasible for many people. It will also require significant resources from mental health systems that are already operating at capacity, often with long wait times for psychiatric and psychotherapeutic services (Parker-Pope et al., 2021; Glastra, 2023).

WELLNESS ACCESS THROUGH STATE REGULATION

Purpose

Wellness access to psychedelics through facilitated psychedelic administration sessions is intended to support participants' personal growth, self-exploration, and wellness (Acker, 2017). In 2023, Oregon became the first state to enact a statute meant to permit access to psilocybin services under state law.

Individuals may experience health benefits after a wellness psychedelic session, though there is not yet evidence to suggest this will be the case. Wellness access could become a complementary or alternative health approach that may support a participant's health goals in the same vein as supplements, contemplative practices, or massage (U.S. Department of Health and Human Services, 2021). However, it is important to distinguish the purpose of wellness access from the purpose of medical access. In the final rules issued by the Oregon Health Authority, the state has taken the position that wellness access is not intended to treat medical or clinical conditions (Oregon Administrative Rules [OAR] 333-333-5040), and it is "dishonest conduct" under Oregon law to make "representations or claims that the psilocybin product has curative or therapeutic effects" (OAR 333-333-6040).

Definition and Legal Structure

Wellness access is a system that allows the public to consume psychedelic drugs under the supervision of a licensed facilitator at a designated service center, where the administration of the drug and subsequent psychedelic experience or "journey" take place.

States are beginning to create their own nonmedical access pathways for psychedelics that bring activity currently practiced "underground" (illegally and without government oversight) into a regulated framework. We call these places "wellness states." Unlike in the medical access pathway, participants do not need a diagnosis to participate and facilitators are not required to be licensed healthcare professionals (e.g., physician, nurse, or social worker).

The legal status of psychedelic services in wellness states is complicated and may be confusing to the public. Since the state government is heavily involved in all aspects of regulating and implementing wellness access, the program appears to be legal and above-board to many lay people. However, psychedelics remain Schedule I substances. Per the Supremacy Clause of the U.S. Constitution, federal law takes priority over any state laws and state constitutions are subordinate to federal law, so psychedelics remain illegal across the United States (U.S. Const. art. VI, § cl. 2.). The statute which established psilocybin services in Oregon implicitly reflects this fact, stating that the law "may not be construed…[t]o require a person to violate a federal law; [or] **to exempt a person from a federal law** or obstruct the enforcement of a federal law" (emphasis added, OR Rev Stat § 475A.215; Samenow et al., 2023).

States and localities typically bear the heaviest burden of enforcing drug laws, especially for simple possession and use. In the case of wellness states, only the federal government could prosecute state-legal psychedelic drug activity, which would ordinarily be handled locally (Thomas, 2022). It is not yet clear whether the federal government will defer to wellness states' legalization schemes by deprioritizing enforcement of state-legal psychedelic activity (Samenow et al., 2023). Such a policy would also be subject to change.

Oregon is currently in the implementation phase of its psilocybin services program, though the first facilitated sessions will not take place until the second half of 2023 due to the ramp-up period needed to license service centers and facilitators. Colorado will be the next wellness state. It has until September 2024 to design and implement a psilocybin services program (Psychedelic Alpha, 2023b).

After Measure 109 was approved in Oregon, the state created the Oregon Psilocybin Advisory Board to advise the Oregon Health Authority in implementing psilocybin services. The Oregon Health Authority created extensive rules that govern this system with input from the Oregon Psilocybin Advisory Board, public hearings, and public comment (Oregon Health Authority, n.d.b). Implementation of the psilocybin services program began on January 2nd, 2023. The remainder of this analysis relies primarily on Oregon's program since it is the most advanced example, though many observers expect Colorado to follow a similar path due to similarities between the ballot measures in both states.

Adults 21 and older are allowed to participate in facilitated psilocybin services under Oregon law, so access is quite broad. Before consuming psilocybin, participants must attend a preparation session with the facilitator (Oregon Health Authority, n.d.a). They are also required to fill out a client information form that includes many questions about physical and mental health, as well as an informed consent form. However, unlike medical access, a diagnosis is not required, and in some cases could restrict participation if it is viewed as a risk factor for side effects (Harbin, 2022).

Oregon regulates businesses along the entire psilocybin services value chain. Manufacturers, testing labs, training programs, service centers, and facilitators are all subject to oversight and either licensure or approval from the state (Oregon Health Authority, 2022a). Of particular importance for this issue brief are the rules governing facilitators. To become a licensed facilitator, applicants must have a high school diploma or equivalent, pass a background check, and complete an approved training program (Oregon Health Authority, n.d.d). Upon successful completion of the training program, prospective facilitators must also pass a state-administered examination prior to gaining licensure. Some facilitators may be licensed healthcare or mental health providers, but these facilitators are barred from exercising the privileges of those licenses while acting as a psilocybin facilitator (OAR 333-333-5130(3)). According to the Oregon Psilocybin Services website, "Many individuals who currently hold professional licenses in Oregon may be interested in becoming licensed facilitators. An individual should work with their professional licensing boards for further guidance on any risks associated with being licensed under ORS 475A [as a psilocybin facilitator]" (Oregon Health Authority, n.d.c).

Limitations

One of the primary limitations of the wellness model is that it does not permit practitioners to treat any medical diagnosis, including mental health and substance use disorders. While wellness access shares some of the same elements as medical access (presence of another person apart from the participant during administration, preparation and optional integration sessions), it is explicitly not for treatment and does not take place in a healthcare context. Unlike states that allow doctors to prescribe or recommend medical cannabis, state-level legalization and regulation regimes have so far not permitted any medical access to psychedelic drugs. Allowing medical access at the state level would create yet another access pathway with new legal complexities.

Psychedelics are powerful drugs that carry risks to users, especially psychological risks (Sky et al., 2022; Johnson et al., 2008). Unlike the rigorous screening procedures that typically characterize medical access, wellness access may not require participants to undergo evaluation by a physician or other advanced practice provider (though medical screening is recommended in some circumstances under Oregon's rules) (Oregon Health Authority, 2022b). Additionally, Oregon Psilocybin Services facilitators are not required to be licensed healthcare providers and those who do hold other licenses (e.g., social work or professional counseling) are barred from practicing in that capacity while acting as psilocybin facilitators. If major adverse effects occur—for instance, episodes of psychosis or suicidality—the facilitator may not be able to provide appropriate care for the participant(s). Even if the facilitator has the professional training to do so, they will be limited by the scope of practice for the facilitator role.

In Oregon's psilocybin services program, facilitators are not required to disclose their level of training to participants, and the informed consent form that participants must sign gives only a limited list of potential side effects (Oregon Health Authority, 2022c). Ideally, participants should be well-informed about the skill level of the facilitator and understand the full range of potential risks. Unfortunately, while studies have identified some of the risks and side effects of various psychedelics, there is no definitive list of side effects for psilocybin or any other psychedelic drug because this is still an area of active research (Sky, 2022). Wellness practitioners and participants would benefit from education on the state of scientific knowledge regarding the drugs' side effects and contraindications. Future wellness states, including Colorado, may wish to incorporate this into the design of their psychedelic services programs.

Another limitation of wellness access is that it will not be covered by health insurance because it is explicitly nonmedical. Oregon's statute explicitly states that the law "may not be construed…to require a government medical assistance program or private health insurer to reimburse a person for costs associated with the use of psilocybin products" (OR Rev Stat § 475A.210 - 475A.722). As a result, participants will need to pay for psilocybin services out of pocket. These costs are not yet known, but experts predict prices will start at $600 and easily reach $3,000 per session in Oregon (Haas, 2023). In May 2023, the first licensed service center in Oregon advertised a price of $3,500 per person for a single high-dose psilocybin session (Busby, 2023).

Finally, there are legal and privacy risks to participants and practitioners since psychedelics remain illegal at the federal level. Even if Congress or the DEA reschedules individual psychedelics and states legalize them after FDA approval, it is likely that those compounds would still be heavily regulated and that nonmedical possession, distribution, and use (along with various "accessory" activities) would remain federally illegal. Additionally, since the Health Insurance Portability and Accountability Act (HIPAA) will not apply in wellness settings, client data (such as informed consent and client information forms) may not be subject to the strict privacy safeguards that are part and parcel of medical access (Marks, 2022). These considerations are of particular importance for federal employees and contractors, first responders, military, and others who may be at risk of losing their employment if they consume illegal substances. Theoretically, client information could also be used in future prosecutions.

RELIGIOUS ACCESS

Purpose

Psychedelics are used sacramentally by some religious groups to access spiritual or mystical experiences, occasion insightful visions (Harvard University, n.d.), or to "increase spiritual perception" (Centro Espírita Beneficente União do Vegetal in the United States, n.d.). Many indigenous peoples around the world use psychedelics ritually and have done so for millennia.

Definition and Legal Structure

Religious access means the sacramental use of psychedelic substances such as peyote or ayahuasca in the context of sincere religious exercise (Thorne, 2020).

The U.S. Constitution protects the free exercise of religion under the First Amendment. People and groups who want to use psychedelics for religious purposes are nevertheless restricted by the CSA, which forbids nearly all uses of scheduled psychedelics. Since the passage of the CSA in 1970, a small handful of religious groups have been able to secure exceptions to the law through administrative, legislative, and judicial action. These include the Native American Church, Santo Daime, and O Centro Espírita Beneficente União do Vegetal (UDV) (Thorne, 2020; *Gonzales v. O Centro Espírita Beneficente União do Vegetal*, 2006).

The Religious Freedom Restoration Act states that the government may not "substantially burden a person's exercise of religion" even in situations when a law generally applies to all people, unless the government can demonstrate that the burden is "in furtherance of a compelling governmental interest" *and* "is the least restrictive means of furthering that compelling governmental interest" (42 U.S.C. § 2000bb-1, 2020). The DEA maintains what it claims to be a guidance document but is in fact a permit requirement for religious use of controlled substances (DEA, 2020). While there is limited public data about the number of groups that have submitted petitions to the DEA, no exemptions have been granted other than two instances secured by court order—for UDV and Santo Daime (*Gonzales v. O Centro Espírita Beneficente União do Vegetal*, 2006; *Church of the Holy Light of the Queen v. Mukasey*, 2009).

WHAT MAKES BELIEFS RELIGIOUS?

Although an individual's belief may be sincerely held, that does not necessarily make it a religious belief in the eyes of the courts. This distinction is very important because RFRA only provides protection for sincere religious exercise based on religious beliefs. The question of what makes a belief religious rather than philosophical or personal is complicated, but there is some case law that may be informative for religious groups who wish to practice with scheduled psychedelics.

In *United States v. Meyers*, the 10th Circuit Court of Appeals set out numerous criteria by which it would judge if the defendant's beliefs were religious, including whether the following aspects are present:

- **Ultimate ideas** about life, death, cosmology, and other similar matters
- **Metaphysical beliefs** about transcendent reality
- **A moral or ethical system** that distinguishes good from evil or requires certain acts
- **Comprehensive beliefs** that speak to many aspects of life
- **Accoutrements of religion** such as a prophet or teacher, sacred places or writings, and rituals (*United States v. Meyers*, 1996).

In *Meyers*, the defendant appealed his conviction on marijuana charges on the grounds that his use was protected by RFRA. The court ultimately found that "Meyers' beliefs pertain to marijuana's medical, therapeutic, and social effects, which the court deemed to be secular, not religious..." and his conviction was upheld (Chacruna Institute for Psychedelic Plant Medicines & Hoots, A., 2021). Other cases have similarly treated beliefs about the medicinal effects of controlled substances as non-religious in nature.

Religious use advocates argue that the DEA's de facto petition process is unlawful under RFRA and various other constitutional provisions (Griffen Thorne, personal communication, May 12, 2023). Therefore, many religious groups opt to simply incorporate psychedelics into their religious practices, though without explicit exemption from the DEA. Other groups have sued the DEA seeking a court order that the petition process is unlawful.

Chacruna, a nonprofit that educates the public about psychedelic plants, has produced an in-depth guide for religious groups that use psychedelics and are attempting to navigate their rights under RFRA (Chacruna Institute for Psychedelic Plant Medicines & Hoots, A., 2021). The guide contains a detailed explanation of the tests the government and courts use to evaluate religious exemption requests.

Limitations

Currently, DEA-exempted religious access to psychedelics is officially limited to a handful of small religious groups in the United States.[3] Even if more churches were to gain exemptions to practice psychedelic rituals, access would still be narrow since psychedelic use in religious sacraments is not currently a mainstream practice (Margolin & Hartman, 2021).

While some research exists suggesting that use of certain psychedelics within specific religious groups is generally safe, these studies generally have small sample sizes and are not generalizable to all substances in all religious settings (Da Silveria et al., 2005; de Rios et al., 2005). Churches may or may not have screening criteria in place to restrict access to individuals who are most likely to suffer harm from psychedelic use (though religious use advocates strongly encourage these safety measures) (Chacruna Institute for Psychedelic Plant Medicines & Hoots, A., 2021). At-risk individuals could include people with personal or family histories of psychosis or those with certain cardiovascular conditions (Sky et al., 2022). If adverse events occur during sacramental use and sufficiently trained personnel are not available to assist participants, this could pose a serious safety risk.

ACCESS PATHWAYS SUMMARY

As of Spring 2023, there are only two fully legal pathways for accessing psychedelics: through the medical system—at this time in clinical trials and expanded access sites—and through membership in religious organizations with exemptions to the CSA. A third semi-legal wellness pathway has emerged in 2023 through state legalization and regulation of specific psychedelics, led by successful ballot initiatives in Oregon (2020) and Colorado (2022).

Currently, among these pathways, only medical access can legally provide treatment for individuals living with mental health and substance use disorder diagnoses, but access is severely limited during the trial phase. With FDA approval expected for MDMA-assisted therapy in 2024 and psilocybin-assisted therapy in 2026, medical access may soon catalyze access to psychedelics for millions of patients in the United States. There is a large population of healthcare professionals who could potentially provide these therapies, and the focused training of this workforce to provide psychedelic-assisted therapy could quickly scale up access in the years following FDA approvals. Eventually, the wellness pathway may become available to the greatest number of people since there are fewer requirements for participation compared to medical and religious access. At the time of this writing, however, facilitated psychedelic sessions have not yet begun in Oregon or Colorado and it is difficult to determine how fast these services will scale up. Regulatory hurdles and their associated costs will likely slow this process in the first few years. Finally, the scope of religious access will likely remain very limited for the foreseeable future, especially given the DEA's history of denying or ignoring exemption requests.

3 The American Indian Religious Freedom Act also protects Native American Church members from prosecution under state laws, while RFRA provides no such protection to UDV and Santo Daime members.

PART TWO

The Importance of Distinctions Between Access Pathways

BrainFutures sees a critical need to make clear distinctions between medical, wellness, and religious access to psychedelics, especially as public awareness and consumption of psychedelics are both increasing (Columbia University Mailman School of Public Health, 2022). In part two of this issue brief, we explain in depth why drawing clear boundaries between access pathways is important. But first, it is useful to see a few real-world examples of confusing rhetoric that illustrate the problem.

Media coverage of psychedelics often conflates medical access with wellness or religious access. For example, a January 3, 2023 *New York Times* article titled "Legal Use of Hallucinogenic Mushrooms Begins in Oregon" describes the rollout of Oregon's psilocybin services program (wellness access), but contextualizes it using findings from clinical trials (medical access):

> *On Jan. 1, Oregon became the first state in the nation to legalize the adult use of psilocybin, a naturally occurring psychedelic that has shown significant promise for treating severe depression, post-traumatic stress disorder and end-of-life anxiety among the terminally ill, among other mental health conditions (Jacobs, 2023).*

It is important to understand that clinical studies that have "shown promise" for these conditions do not evaluate the efficacy of psilocybin alone, but in combination with hours of psychotherapy. The title of the piece also obscures the fact that possession and distribution of psilocybin mushrooms remains illegal nationwide under federal law.

Another recent example of confusing media coverage can be found in a longform story from the Associated Press. In an article about psychedelic churches that aim to make use of potential religious exemptions to the CSA, the author does not question or problematize the interviewee's assertion that religious use of psychedelics can be a form of mental health treatment:

> *Courtney Close, [psychedelic church] Hummingbird's founder who credits ayahuasca with helping her overcome cocaine addiction and post-partum depression, believes the designation as a church helps show that participants are "doing this for religious reasons." But when it comes to defining it as a religion, Close stresses much depends on individual participants' experience...*
>
> *Since holding the church's first ceremony in Joshua Tree five years ago, Close has seen Hummingbird's numbers grow and its demographic change — mostly from young hipsters to older, **working-class people desperate for mental health treatment** (emphasis added, Casey, 2023).*

The piece could have provided further context for readers by explaining that CSA exemptions through RFRA are only granted for the purpose of sincere religious exercise, not for mental health treatment (see "What Makes Beliefs Religious?" on page 12).

This confusing language is not limited to media coverage, and it may stem from the framing used by psychedelics proponents. Advocates of wellness access often speak about the Oregon and Colorado programs using words like "therapy" and "mental health," while citing data and outcomes from clinical trials as rationale for creating or funding such programs (Healing Advocacy Fund Testimony in FAVOR of SB 5525, 2023). For example, the ballot language of Oregon Measure 109 directly cited clinical literature on psychedelic-assisted therapy and data about widespread mental health problems in Oregon as justifications for establishing

the psilocybin services program (Oregon Psilocybin Services Act, 2019). Similarly, in Colorado the ballot measure for establishing wellness psychedelic services in that state is called the Natural Medicine Health Act. Section 1a of the Act states:

> *"Colorado's current approach to **mental health** has failed to fulfill its promise. Coloradans deserve more tools to address mental health issues, including approaches such as natural **medicines** that are grounded in **treatment**, recovery, health, and wellness rather than criminalization, stigma, suffering, and punishment" (emphasis added, Natural Medicine Health Act, 2022).*

These examples are emblematic of what BrainFutures sees as a clear challenge for proponents of psychedelics through any access pathway. Below, we illustrate three key reasons why the media, public figures, and psychedelics advocates should draw clearer boundaries between these models. We also make actionable recommendations to help the media and leaders in the field ensure that these distinctions are clear.

PARTICIPANTS AND PRACTITIONERS DESERVE TO BE WELL-INFORMED ABOUT THE PURPOSE, LEGAL STRUCTURE, AND LIMITATIONS OF THE ACCESS PATHWAY THEY CHOOSE.

It is crucial that participants in any of the three access pathways have clear information about what each model can and cannot do, as well as the legal boundaries that govern each of them. This knowledge will allow participants to make an informed choice about the access pathway that best meets their needs. Without a clear understanding of the different purposes, participants may not select the appropriate access pathway. For example, someone seeking relief from a specific diagnosis through a wellness program or religious ceremony would not be given a medical treatment, and their experience could be counterproductive if they are not supported by a healthcare provider or provider team.

Medical access also has its limitations. For example, it is not the best setting for someone seeking spiritual exploration or enlightenment. Notably, some Indigenous peoples view the nonceremonial use of certain psychedelics as inherently problematic or taboo (Celidwen, 2023; UMIYAC, 2019). BrainFutures does not deny that experiences imbued with spiritual significance are common among psychedelic-assisted therapy participants (e.g., Johnson et al., 2016; Agin-Liebes et al., 2020), but these spiritual effects are usually not primary endpoints in clinical studies and are not the focus of clinicians who are treating patients for specific health concerns in medical settings. Furthermore, medical providers may not be well-equipped to discuss matters of religion and theology, which can be addressed fulsomely in a religious setting.

There are also significant safety and legal risks to participants and practitioners if they do not understand the differences between access pathways.

Safety Risks

The safety risks associated with wellness or religious access are different from those in the medical model. On one hand, the risks may be higher in a medical setting because psychedelic-assisted therapy serves a vulnerable patient population with significant mental health concerns. On the other hand, medical access includes built-in safeguards such as professional training for licensed healthcare professionals, rigorous medical screening, and evidence-based treatment protocols. All of these can reduce (but not eliminate) risks. These elements may not be present in other access pathways.

Participants in religious and wellness access pathways should understand that facilitators, clergy, and/or co-participants may not be sufficiently trained to assist in the case of adverse events or emergencies. While most psychedelics are generally considered to be safe, major side effects do occur in some people. These can require care from licensed healthcare professionals, who may not be immediately available in nonmedical settings. In one tragic case, a 22-year-old man died while attending a psychedelic church retreat (Goggin, 2023). Church leadership did not call for emergency services until three hours after the man began acting erratically, and he was unresponsive by the time aid arrived.

Because of the potential for significant differences in safety protocols and participant populations, adverse events that occur in the context of religious or wellness access should not be construed as a reflection on the safety of medical access, and vice versa. However, practitioners in all access pathways should maintain awareness of adverse event reports in any context and plan for safety accordingly.

Legal Risks

Participants and practitioners should take care to align their individual purpose for using psychedelics with the correct access pathway to avoid legal exposure. As mentioned above, RFRA allows exemptions from the CSA only for sincere religious practice. Someone participating in a psychedelic religious ceremony for recreation or other nonreligious purposes could face prosecution or put their organization's religious exemption from the CSA or tax-exempt status at risk.

Facilitators in Oregon and other wellness states that follow a similar model must also clearly communicate that they are not able to offer treatment for any diagnosis and cannot act as healthcare professionals while providing psilocybin services, even if they are licensed as such. A facilitator who promises to treat or cure any medical condition would likely be found in violation of state law and could face penalties. This is often an area of confusion for the public: Oregon's Measure 109, for example, is commonly misapprehended as a "psilocybin therapy" regime, which is inaccurate under the current regulations.

THE PRACTICES OF MEDICINE AND PSYCHOTHERAPY ARE PROTECTED BY LAW.

There is widespread confusion about whether wellness access can be used for treatment. The cooption of medical language to justify wellness access is not only confusing for participants but could also lead to misunderstanding among facilitators who will be licensed to provide psychedelic services. Practitioners must draw very clear boundaries to ensure that they are not practicing medicine (or another protected profession) in the course of their work with clients.

In the U.S., state governments have jurisdiction over the practices of medicine and psychotherapy, so laws governing practice vary from state to state. However, it is illegal in all states to practice medicine or psychotherapy without a license (Rowthorn et al., 2019). A representative definition of the practice of medicine can be found in Maryland's Annotated Code: "to engage, with or without compensation, in medical diagnosis, healing, treatment, or surgery" (Maryland Health Occupations Code Ann, 2013). In Oregon, psychotherapy is part of the scope of practice for several different mental health professions, including psychology, clinical social work, and marriage and family therapy.[1] As in all states, Oregon law protects the privileges of each of these professions and forbids unlicensed psychotherapy practice, except under very narrow circumstances (such as supervised graduate training) (OR Rev Stat § 675.010, 2021). Other health professions that may participate in the delivery of psychedelic-assisted therapy, such as nursing, are also protected in many states (e.g., Ohio Administrative Code [OAC] 4723-8-03).

It is important to remember that the Oregon psilocybin facilitator's scope of practice explicitly excludes the practices of medicine and psychotherapy (OAR 333-333-1010). Language that frames wellness facilitators as healers or mental health providers risks confusing both participants and facilitators.

EVIDENCE FROM CLINICAL TRIALS HAS LIMITED GENERALIZABILITY.

Evidence supporting the efficacy of psychedelic-assisted therapy for treating a range of psychiatric and other medical conditions is mounting (Sky, 2022). Compel-

1 For example, "'Practice of psychology' means rendering or offering to render supervision, consultation, evaluation or therapy services to individuals, groups or organizations for the purpose of diagnosing or treating behavioral, emotional or mental disorders" (OR Rev Stat § 675.010, 2021).

ling new studies have shown that psychedelic-assisted therapy can make a difference, even in treatment-resistant cases of PTSD and depression (Mitchell et al., 2021; Goodwin et al., 2022). However, as evidence for the medical model grows, participants and proponents should understand that clinical trial study populations are disproportionately male, white, and wealthy compared to the general population of the U.S. Although some argue that it is reasonable to assume that these studies' promising findings will be consistent across other demographic groups, future studies should test this assumption by including diverse participants.

It is not yet known to what degree psychedelic-assisted therapy study outcomes are due to the effects of the drug, the effects of the psychotherapeutic "container," or an interaction between the two. Many experts believe that the drug acts as an adjuvant to psychotherapy and that without intensive psychotherapy, clinical results would be greatly attenuated (Sky et al., 2022). BrainFutures' 2022 paper, *An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy*, describes the multiphase and multifaceted approach that characterizes modern clinical trials involving psychedelics: screening and assessment, preparation, establishment of set and setting,[2] medication administration session, and integration (Sky et al., 2022). All of these elements are also supported by extensive safety measures. Generalizing outcomes from clinical trials should be done cautiously, even in clinical settings, because real-world results often diverge from those in carefully controlled studies (He et al., 2020).

There is observational evidence suggesting that religious use of psychedelics does not cause harm and may support positive mental health outcomes (Halpern et al., 2008; Thomas et al., 2013).[3] However, there is no rigorous research evidence supporting wellness access as a means of promoting mental health since the first facilitated sessions have yet to occur in Oregon. BrainFutures looks forward to tracking new studies that evaluate outcomes from Oregon Psilocybin Services and supports efforts to rigorously study these programs. With further data, wellness access may emerge as a viable complementary or alternative health option. Regardless of new evidence that may emerge on the mental health benefits of religious and wellness access, clinical trial evidence should not be construed to apply in circumstances that are significantly different from the treatment approach described above. Similarly, Indigenous communities that traditionally use psychedelics have their own ways of knowing how to work with those substances and this knowledge should not be assumed to be applicable outside of the cultural and spiritual tradition from which it originated (Fotiou, 2020).

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2 "Set is the mind-set or expectation one brings to the experience, and setting is the environment in which it takes place" (Pollan, 2018).

3 Observational evidence is collected by observing or surveying a study population in real life. It is distinct from experimental evidence, which involves collecting data on the results of an experimental intervention on treatment and control groups (O'Neil et al., 2014).

RECOMMENDATIONS

BrainFutures recommends four actions that the media, psychedelics advocates, and practitioners can take to promote clarity and safety across all psychedelic access pathways:

RECOMMENDATION 1

Psychedelic practitioners and advocates should inform participants about the purpose, risks, and legal limits of the access pathway they operate within using easy-to-understand language.

Before participants are offered psychedelic drugs in any context, they should have a clear understanding of the purpose for taking them, potential risks, and the legal structures that govern the drugs' use. It is the responsibility of practitioners to clearly communicate this information and ensure that participants understand it before they are allowed to proceed with drug consumption. Advocates and governments (in wellness states) also have a duty to educate the public and support participants' ability to make informed choices about psychedelic use.

RECOMMENDATION 2

Discussions about psychedelic use should avoid broadly generalizing across pathways or conflating one pathway with another.

It is critical that the public understands the differences between medical, wellness, and religious access to psychedelics. Media figures, practitioners, and proponents of psychedelics in any access pathway should make these distinctions clear by identifying the purpose and legal scope of the access pathway under discussion.

RECOMMENDATION 3

Practitioners and advocates in any access pathway should avoid making unvalidated claims about health benefits.

Health outcome data from clinical trials involving psychedelics have limited applicability to psychedelic use outside of the model used in studies. Meanwhile, peer-reviewed evidence on health outcomes from religious and wellness access participants is limited. Despite this, evidence from clinical trials is regularly used to promote or contextualize wellness and religious access, despite differences in screening, setting, and other key aspects. While BrainFutures discourages this practice, application of evidence across pathways must at minimum be explicitly identified. It is best practice to explain that outcomes from studies conducted with one set of circumstances and protocols have limited generalizability to other circumstances and protocols.

Additionally, the laws governing wellness and religious access do not allow for medical treatment, including mental health treatment. Therefore, proponents and practitioners of wellness and religious use should not make unvalidated health claims or offer "treatments" to avoid confusing or misleading participants.

RECOMMENDATION 4

Psychedelic practitioners should take care to avoid the unlicensed practice of medicine or psychotherapy.

State laws across the country forbid the unlicensed practice of medicine and psychotherapy with some limited exceptions. Other relevant health professions (e.g., nursing) may also be subject to state legal protection. Practitioners should consult with legal counsel to ensure they are not intentionally or unintentionally crossing these boundaries.

Conclusion

Although BrainFutures' work on psychedelics is focused on medical access, we do not promote one pathway over the others as the best option for everyone. Rather, we encourage participants to select the pathway that best meets their needs, be it mental health treatment (medical access), self-exploration and wellbeing (wellness access), or religious practice (religious access). Recognizing that medical access is currently extremely limited, BrainFutures supports opening expanded access to many more patients, who may be suffering needlessly while waiting for FDA approval of MDMA- or psilocybin-assisted therapy. Addressing the demand for psychedelic-assisted therapy through expanded access would enable participants to select the right pathway rather than just the pathway that is within their reach.

BrainFutures believes that consistently using clear definitions for psychedelic access pathways will reduce confusion, enhance participant safety, reduce legal risks, and ultimately support the development of each of the three psychedelic fields outlined in this issue brief. Making these distinctions clear is especially important in this moment as the public becomes more aware of psychedelics and the number of people using these substances increases rapidly.

We urge everyone who has a platform to speak about psychedelics to utilize the definitions in this issue brief and articulate their position in the psychedelic ecosystem clearly. The media, psychedelics advocates, and practitioners all have a role to play in ensuring that the entire ecosystem can operate safely and with minimal legal exposure. Delineating clear boundaries between access pathways is fundamental to that cause.

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About BrainFutures

BrainFutures advances the practical applications of promising brain health interventions and expands access to treatments and technologies. To overcome barriers to access and inspire institutional action, we work with subject matter experts to conduct research, engage in advocacy, and execute high-leverage projects.

OUR REPORTS ON PSYCHEDELIC-ASSISTED THERAPY

In 2021, BrainFutures launched a three-part issue brief series and coalition-building effort focused on psychedelic-assisted therapy. Since then, BrainFutures has released three reports and an accompanying mini-brief in hopes of laying an unbiased foundation for the regulatory and reimbursement work needed in the field.

- *Psychedelic Medicine: A Review of Clinical Research for a Class of Rapidly Emerging Behavioral Health Interventions*
- *Expediting Psychedelic-Assisted Therapy Adoption in Clinical Settings*
- *An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy*
- *The Future of the Field (Mini-Brief)*

SUPPORTING THE PSYCHEDELIC-ASSISTED THERAPY FIELD

BrainFutures collaborates with dozens of key stakeholders from multiple disciplines to develop issue briefs that inform the field of psychedelic-assisted therapy. We disseminate knowledge about the field to stakeholders in healthcare, government, civil society, and philanthropy.

BrainFutures will release a medical coding guide in summer 2023 that describes a reimbursement strategy to enable psychedelic-assisted therapy providers to receive equitable reimbursement from payers for these services. Future issue briefs will include guides for addressing reimbursement challenges, analysis of and proposed changes to state-regulated access models for psychedelics (e.g., Oregon and Colorado), leveraging the Mental Health Parity and Addiction Equity Act to increase access, and talking points for advocates and practitioners to talk to policymakers.

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