Summary and Recommendations on the Safe, Ethical, and Equitable Integration of Psychedelic-Assisted Therapy in the United States

In response to the congressional request for information by the Congressional Protecting Public Health and Safety with Psychedelics Advancing Therapies (PATH) Caucus, dated August 2024

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Finalization date: 24JUL2026

Disclosures:

Through Pinney Associates, Marion Coe, Megan Harris-Stephenson, and Jack Henningfield provide scientific & regulatory consulting on a broad range of CNS-active substances and drug products including psychedelic substances, and new chemical entities.

Funding:

Apollo Pact, a 501(c)3 nonprofit patient advocacy group, contracted Pinney Associates to review and summarize comments submitted in response to a Congressional Request for Information (RFI) issued by the bipartisan Psychedelic-Assisted Therapy to Heal (PATH) Caucus and prepare for and participate in briefings in Washington, DC. Apollo Pact had no input into the writing of this report, its methods, or its conclusions.

I. Purpose and Context

In response to the Congressional Request for Information (RFI) issued by the bipartisan Psychedelic-Assisted Therapy to Heal (PATH) Caucus, a wide range of responders provided input including medical professionals, researchers, veterans' advocates, medicinal developers, Indigenous leaders, community organizations, payors, state regulatory bodies, and patients. Their wide-ranging comments provide insights into how psychedelic-assisted therapy (PAT) could be safely and ethically integrated into United States (U.S.) healthcare and community settings.

As reflected in this summary, there are areas of agreement, tension, concern, and hope that require consideration, discussion, and further input to ensure that actions going forward are supported by policies related to safe access and participant and patient protections in PAT research. These policies must ensure that the potential benefits are based on patient needs and minimally restricted by geography across the U.S. in rural and urban areas. Policies should be put in place to support coordinated national data systems to monitor benefits as well as potential unintended consequences of PAT and provide an evidence-base to ensure the best possible patient care that evolves in approach with the diverse emerging pipeline of new medicines and potential medical applications over time.

This document is intended to provide a synthesis of the perspectives from the responders as to address the congressional RFI and potentially inform legislative, regulatory, and policy efforts to address PAT development. It appears to the authors and reviewers of this document, that this summary may be especially useful to Food and Drug Administration (FDA) staff who will be contributing to the potential approval of psychedelic medicines as well as their labeling and risk management programs in an effort to minimize risk and maximize benefits to patients and the broader public health of the U.S. Ideally, it would seem in coordination with the Department of Defense (DoD) and Veterans Administration (VA), Department of Justice (DOJ) with its Drug Enforcement Agency (DEA), and the Department of Health and Human Services' (DHHS) National Institutes of Health (NIH), and Centers for Disease Control and Prevention (CDC).

The authors and reviewers of this summary have made every effort to reflect responds to the PATH RFI in an unbiased manner and have not provided their own opinion. Thus, the main body of this document does not contain any opinion or recommendation outside of those found in the responses. An external advisory board was convened to provide additional expert context and recommendations, and those can be found in the appendix of this report. We encourage interested members of congress, their staff, and federal agency staff to review the responses themselves to explore them in greater depth.

II. Public Health Perspective

Behavioral Health Burden and Unmet Need

Across responses, there is broad agreement that the U.S. faces a substantial and worsening burden of behavioral health challenges including constantly evolving substance-use disorders (SUDs) and other addictive disorders. Suicide rates remain high (especially among veterans and people with chronic pain) treatment-resistant conditions (e.g., major depressive disorder, post-traumatic stress disorders [PTSD], etc.) are common, and existing therapeutic options leave many without effective, acceptable, or accessible care. Multiple responders to the RFI noted that

veterans, terminally ill individuals, some ethnic minority populations, socioeconomically disadvantaged people and families, people with chronic illnesses, senior citizens, rural populations, and others face disproportionate burden of behavioral health issues and barriers to currently available health care and encourage efforts to ensure that, after approval, psychedelic treatment access is not unduly restricted.

Although there are FDA-approved medicines to treat or manage most of these disorders (though there are limitations for those that can help with PTSD, SUD, and no approved medicines for stimulant use disorders), there is recognition of broad unmet or at least under met needs. Many patients find current first-line treatment options ineffective, and/or with undesirable side effects, and feel that current treatment options are unable to help them achieve the quality of life that they strive for, which makes life personally worth living[1-9].

There is broad agreement among responders to the RFI that psychedelic-based medicines and assisted therapies can help some of those who are not satisfactorily helped by current medicines. Further, the FDA itself has given breakthrough therapy designations to at least 7 different psychedelic-based drug products at the time of this writing and that, itself, reflects the belief of many at the FDA that these medicines have substantial potential.

Another important but indirect line of agreement exists in the willingness of pharmaceutical developers, large and small, to invest in psychedelic medicines development. In this context, it must be made clear that there is no illusion among the individuals and organizations that commented that psychedelic medicines are "magic bullets," "medicinal panaceas," or without risks. Rather, it is recognized that PAT, when delivered within structured, well-supervised protocols, are regarded as a potentially transformative, but not universally appropriate, care modality.

Evidence from clinical trials suggests meaningful improvements in PTSD, depression, end-of-life distress, several types of addiction, and other medical conditions. Multiple studies demonstrated that for several disorders, PAT helped patients achieve desired outcomes with improvements in emotional and physical functionality and well-being. This has fueled public interest and contributed to state-level regulatory frameworks such as those exemplified by comments based on the experiences in Oregon and Colorado. This evidence has also expanded research programs within the VA and NIH, and among psychedelic medicinal developers and academic research-based organizations. Additionally, psychedelic research has created philanthropic interest.

III. Regulatory Perspective

Systems Fragmentation and Emerging State Models

The current U.S. regulatory landscape is highly fragmented across states. Federally, psychedelics remain Schedule I substances. This means that possession, manufacturing, or distribution of these substances is considered a felony offense, with potential severe penalties including imprisonment and fines. The Controlled Substances Act (CSA) provides a pathway for research that is highly restricted and burdensome with requirements that greatly restrict all research, and can take a year or more for approval by the DEA and FDA, as well as the research institution to be approved for research and even to modify the research program, and other burdens that

increase the time and cost to conduct research[10-11]. Potential additional barriers include state level laws that are intended to facilitate research and/or therapeutic use. For example, Oregon and Colorado have created separate regulated-access models with their own training mandates, informed consent protocols, adverse event (AE) monitoring, and licensing systems.

Another consideration for policy makers is that there are potentially thousands of traditional, ceremonial, and "underground" community-based practices operating outside of state regulatory frameworks and federally regulated research institutions. Certain traditional and ceremonial practices by Indigenous Peoples are protected in the U.S. by law as is also the case internationally[12-13]and has been discussed elsewhere[14-17] .Importantly, among psychedelic substances, peyote is unique in that its ceremonial use receives explicit federal legal protection for members of federally recognized Native American tribes participating in bona fide traditional religious practices, particularly through the Native American Church.

Thus, under the American Indian Religious Freedom Act Amendments of 1994, Native Americans are permitted to possess, transport, and use peyote for traditional ceremonial purposes notwithstanding its status as a Schedule I controlled substance. No comparable statutory exemption exists under federal law for other classic psychedelics, including psilocybin, LSD, mescaline (outside of peyote), or DMT. As a result, peyote remains the only psychedelic substance that is expressly protected by federal law for religious use by Indigenous communities in the U.S. Comments indicate that it is important that federal laws continue to provide protection, with updates in laws to ensure that pharmaceutical development and patents do not inadvertently adversely affect such practices or introduce patents and use protections for drugs approved by FDA that rely on religious, ceremonial, and traditional practices as discussed elsewhere.[16-18]

In addition, PAT programs are operating within the VA, through expanded access (also known as 'compassionate use') programs, and being held by pharmaceutical developers with FDA-accepted investigational new drug (IND) applications. Responders agree that federal leadership is needed—not to override local and cultural autonomy, but to provide consistent and safe baselines for training, ethical conduct, manufacturing standards, participant protection, and data collection.

Need for Federal–State–Tribal Coordination

Across submissions, there is strong support for coordinated leadership from the DHHS, Substance Abuse and Mental Health Services Administration (SAMHSA), FDA, NIH, VA, DoD, Centers for Medicare and Medicaid Services (CMS), the Office of National Drug Control Policy (ONDCP), and DEA, alongside state governments and Tribal Nations/Territories. Federal alignment is viewed as essential to reduce regulatory bottlenecks, ensure insurance coverage/reimbursement, establish safety standards, protect cultural knowledge, and integrate longstanding Indigenous customs into policymaking.

Regarding underground practices involving Schedule I substances that are not protected by state or federal laws, there does not appear to be a consensus for a return to the federal efforts of the 1960s and 70s characterized by 'heavy handed' enforcement and prosecution or participants and leaders, despite the fact that many are in violation of state and/or federal laws. However, neither

do the majority of responders encourage removal of appropriate and balanced federal control and restrictions to minimize inappropriate and potentially dangerous patterns of use and abuse. A precedent and parallel is the apparent tolerance or at least low prioritization of prosecution of cannabis users that has been increasing over the past one to two decades, with many states passing laws that "decriminalize", or even legalize "medical" and "recreational" cannabis use (see discussion in US DHHS 2024 Marijuana CAMU[19] and 8FA[20].

Balancing Safety and Accessibility

Balancing safety and accessibility is widely recognized as a major challenge and numerous responders provided examples of approaches that seem to provide balance between patient-focused models in clinical studies that include elements to assure safe use and medical practice that appear transferable to real-world treatment settings with potential FDA-approved psychedelic medicines This concern seems especially evident with respect to veterans who are geographically spread across the U.S. and whose disease and living conditions complicate their access to healthcare.

The balance of safety and accessibility is among the urgent issues that should be addressed in the near term to prepare for the potential day that the first psychedelic medicines are approved. If the indication(s) include depression, depressive disorders, PTSD, generalized anxiety disorder (GAD), or SUDs, there could be many thousands if not millions of potential patients who could benefit nationwide. Ensuring fair access based on medical need by patients and their caregivers, and not geography, financial resources, and other factors that contribute to current health care disparities will take planning and infrastructure building as has been discussed in published articles[14, 21] and richly addressed in the RFI responses.

Ultimately, the principal tension across responses concerns how best to balance:

- Rigorous training and credentialing within the broader medical model that does not exclude experienced (but perhaps non-credentialed) community-based and Indigenous practitioners
- Globally standardized safety protocols vs. specialized protocols with relevance to wide-ranging patient populations and flexibility in care delivery to meet various individual and population needs
- Post-treatment safety monitoring that is not overly burdensome (i.e., in regard to time, cost, and other resources) to patients and providers
- FDA-approved risk evaluation and mitigation strategies (REMS) that address the serious risks without being unnecessarily expensive or burdensome (e.g., pretherapy screening and patient protection, longer than warranted medically supervised attention following the end of the PAT session)

Responders consistently warn against implementing overly narrow rules that treat psychedelics as uniquely dangerous or alternatively as so safe and low in abuse potential as to not warrant CSA scheduling and other safeguards. Concurrently, they caution against under-regulation, particularly in settings involving vulnerable participants. This is especially relevant to research

with Schedule I drugs where approaches may require congressionally developed modifications of the CSA that streamline the processes without removal of appropriate safeguards.

IV. Summary of Key Findings Across the Five PATH Domains

Domain 1: Service Delivery

Key Findings
There is a need for national guidance and credential verification systems. This is urgent and the process should begin before the first psychedelic drug approval, ideally led by FDA, to ensure that it is harmonized with potential FDA labeling and risk management conditions that will likely be required to assure safe use. Guidance documents should address safety monitoring, crisis protocols, ethical boundaries, documentation, cultural awareness to ensure fair access to treatment, and the "set and setting" dimensions of the supportive therapies that are appropriate to various populations as illustrated, for example, among veterans. Federal–State Coordination is essential to ensure that as state rights are respected federal guidelines will support efforts to ensure broad geographical access. Comments relevant to the approach discussed the need for interagency cooperation (VA, SAMHSA, NIH, CMS, DHHS) and public–private partnerships. Responders had significant disagreement regarding appropriate credentialing requirements for practitioners. For example, some comments proposed limiting credentialing to licensed healthcare professionals while others proposed broadening this to spiritual and community practitioners. Seemingly compelling rationales were presented for both the narrower and broader approach. Whereas the broader approach is less conventional than the most typical medical models in the U.S., the importance of efforts to reach more wide-ranging populations more quickly than might occur if it is limited to licensed health care practitioners seems worthy of consideration. From a practical perspective, the fact that PAT is more caregiver driven than many areas of medical practice, means that overly burdensome credentialling could limit access. As has been demonstrated in PAT research by many of the PATH responders, people without graduate and medical degrees can be trained to provide continuous patient support from the time they receive their medicine to the often 6 to 12 hours before it may be safe to allow them to be discharged from the facility while still receiving careful monitoring for several days or more following the PAT itself. It would seem urgent to begin this process of developing credentialling standards transparently and with input from a wide-range of stakeholders (i.e., those providing regulatory oversight as well as practitioners themselves). Federal rule-making processes that include public meetings to inform the development of credentialing requirements and then following the drafting of initial requirement would seem to provide a practical workable model for such development. It

is urgent to begin this process as soon as possible, as it is possible that the first psychedelic medicine approvals by FDA could occur by the end of 2026 and with one or more per year and subsequently for many years to come given the numbers of medicines that are under development and in Phase 2 and 3 clinical efficacy and safety trials.

Domain 2: Participant Protections

Key Findings
Responders agree that comprehensive, evidence-based, bias-free information on risks and benefits is essential for participant safety, as well as supporting potential IND applications, likely FDA Advisory Committee deliberations, and public trust. Standardized AE monitoring must be conducted with rigorous adherence to FDA guidances and ideally with FDA input for each new drug development effort as different substances and indications may raise different issues, and new evidence may contribute to evolution in FDA thinking. Approaches must take into consideration, expected disease-related symptomology to help FDA and others understand whether certain adverse effects are attributable to the drug or part of the symptoms of the disorder, e.g., cognitive impairment, disorientation, and fear. In some cases, the etiology of the symptomology may not be clear but careful documentation, and appropriate mitigation efforts are important for both patient safety as well as eventual labeling and warnings for drugs that are approved by FDA. Some AE, e.g., euphoria, may be considered by the investigators and others to be desirable effects that contribute to therapeutic efficacy (especially for example in people with depression and PTSD), however, these must be reported and appropriately documented as AEs because, regardless of their potential therapeutic benefits, they are also relevant to understanding the abuse potential of the substance, and should potentially be considered for inclusion in labeling. During trials, baseline evaluations and appropriate comparators (e.g., placebo and/or active comparators) are vital, and continuous monitoring during sessions and structured post-session follow-up interviews are critical. Ethical guidelines should address individual needs and desires as well as the institutional ethical boundaries, personal space policies (e.g., in some studies participants and patients are asked if touching is acceptable to provide comfort and reassurance if strong feelings of fear and anxiety emerge, or if physical contact is considered unacceptable or only with limitations accepted by the participant). This is vital to prevent actual and potentially perceived sexual and other misconduct. Views differ on whether PAT should require two staff to be continuously present as has been and continues to be required in some institutions, but there is consensus around the need to prevent misconduct, protect vulnerable participants, and ensure accountability by appropriate staffing and safe-guards

Responders generally supported FDA risk management programs that could include the legally enforceable REMS to prevent serious risks and assure safe use. These can require specialized training and, in some cases, certification-like programs to manage risk, with pharmacist/provider training, tracking, and AE reporting. Responders stress the need for comprehensive informed consent, risk screening, AE monitoring, trauma-informed practices, ethical safeguards, and pharmacovigilance programs.

Domain 3: Community Engagement

Key Findings
Responders agreed that we must preserve Indigenous and religious rights to use psychedelics in ceremonial contexts without government intrusion or forced disclosure of knowledge. Provide low-barrier, culturally competent access for vulnerable and marginalized groups. Involve Federally Qualified Health Centers (FQHCs) in service delivery for broad reach to underserved groups. Support peer and community-based outreach to sustain engagement post-treatment. Submissions call for meaningful inclusion of Indigenous leaders, veterans, marginalized populations, and community groups in decision making. Protections against commercialization, ecological harm, and exploitation of protected medicine (i.e., peyote) are essential.

Domain 4: Fair Access

Key Findings
Cost is a potential substantial barrier to fair access as illustrated by veterans who vary widely in their financial resources.. For example, apart from FDA-approved treatment with esketamine, most other ketamine-based treatments are currently out-of-pocket, and predominantly available in urban areas. Responders widely support insurance coverage of psychedelic treatment itself, as well as delivery options (i.e., service centers, telehealth, community-based programs, mobile treatment options, etc.) through Medicaid, Medicare, VA, private insurers, and perhaps new programs. Enforcement of Mental Health Parity and Addiction Equity Act (MHPAEA)[20] is was mentioned by several RFI responders. It was noted that fair access and health care coverage may require new permanent codes for PAT programs in the near term (e.g., for major depression and PTSD), as well as PAT programs that are earlier in the development pipeline

(such as for treatment of SUDs, obsessive compulsive disorder, and as adjunctive therapies for chronic pain patients).

RFI responders asked that cultural and community-based access be protected alongside clinical models.

Responders generally support insurance reimbursement, public funding for training and clinics, use of existing Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) codes, group models to reduce costs, and regulatory reforms that encourage broad access while maintaining safety. Cost is viewed as a central, and perhaps the largest, future barrier.

Domain 5: Data Standards

Key Findings
National or Coordinated Registries should be considered with care taken not to make them overly burdensome to patients and caregivers, and to maximize their potential to provide an evidence base for detecting unintended consequences and continuously improving treatment over time. Considerations and potential approaches include: Tracking long-term outcomes and AEs across various treatment settings. Capturing both effectiveness and safety to compare psychedelics with traditional pharmaceuticals. Distinguishing between product sources (FDA-approved, state-supported) to identify safest and most effective "set and setting" characteristics. Employing uniform data frameworks that must be adopted by a critical mass of providers. Drawing from existing systems (e.g., NIH, public-private surveillance partnerships, poison control networks). Current International Classification of Disease (ICD) codes are inconsistent and non-specific; poison center data are miscoded and incomplete. Responders highlight the need for coordinated registries, standardized measures, improved surveillance systems, and integration of demographic and access data – with some responders placing emphasis on addressing these needs before additional FDA-approved products come to market. Current tools (ICD codes, poison center reports, electronic medical records [EMRs]) are inadequate for tracking psychedelic use and outcomes.

V. Recommendation Summary

The following recommendations should not be viewed as a consensus across RFI responders or reviewers but rather as a list of recommendations that the authors and reviewers consider representative of the individual respondents. The numerical order does not reflect priority. As shown in the responses and summarized here, responders envision wide-ranging, multidisciplinary service models that include clinical settings, community-based environments, faith and ceremonial practices, group sessions, and FQHCs. Emphasis is placed on integration services, PAT delivery options and care teams, and long-term follow-up.

Recommendations are as follows:

1. Establish National Guidance for Safe and Ethical Service Delivery

Federal agencies, led by DHHS, SAMHSA, and NIH, should collaborate with VA, DoD, state regulators, Tribal Nations/Territories, and community leaders to develop national guidelines on preparation, screening, administration, integration, crisis management, and aftercare. Guidance should be flexible enough to accommodate various care settings.

2. Support Multidisciplinary, Culturally Competent Care Teams

Federal guidance should endorse team-based models that may include physicians, psychologists, nurses, social workers, peer supporters, spiritual leaders, and Indigenous leaders, with clear role definitions, scope of practice, and safety responsibilities.

3. Create Flexible, Tiered Credentialing Pathways

Credentialing should balance safety with accessibility. Pathways may include options for licensed clinicians, trained facilitators, peer support practitioners, and Indigenous experts. Requirements should emphasize competency, ethics, trauma-informed care, and crisis intervention.

4. Protect Indigenous and Religious Practices

Federal frameworks must continue to explicitly protect long-standing Indigenous practices and ceremonial use of natural compounds. When appropriate, policymaking should occur in partnership with Indigenous leaders, with compensation for expertise and safeguards against ecological harm and commercialization of natural compounds.

5. Standardize Informed Consent and Screening Protocols

DHHS and SAMHSA should develop consent templates, risk assessment tools, and screening parameters that incorporate cultural awareness, personal space (i.e., related to touch), medication interactions, and exclusions for high-risk conditions (e.g., active psychosis, severe cardiovascular instability).

6. Implement Robust Adverse Event Monitoring and Pharmacovigilance

A coordinated national system that leverages FDA REMS-like structures, poison control surveillance, EMRs, crisis line reporting, and state-level examples of reporting adverse outcomes, should track acute and delayed risks, including rare persistent perceptual changes or psychological dysregulation.

7. Develop Federal Reimbursement and Financing Mechanisms

CMS, VA, DoD, and private insurers should explore coverage pathways using existing CPT/HCPCS codes, the Collaborative Care Model, Medicaid waivers, and pilot reimbursement programs. Training and clinic infrastructure should be supported through grants from Health Resources and Services Administration (HRSA), NIH, SAMHSA, and DoD.

8. Promote Low-Barrier Access Through Flexible Care Models

Federal policy should support group sessions, telehealth for preparation and integration, mobile clinics for rural areas, and partnerships with FQHCs, community centers, and faith-based organizations, provided they meet safety and competency standards.

9. Strengthen Ethical Safeguards and Accountability Systems

Federal guidelines should establish expectations for personal space (i.e., touch policies), documentation, incident reporting, and zero tolerance for misconduct. Options for anonymous reporting, two-person teams (where justified), and independent ethics boards should be considered.

11. Build National Registries and Standardized Data Frameworks

NIH, SAMHSA, and CDC should support national or federal registries that collect uniform safety, efficacy, demographic, and product-source data across clinical and non-clinical settings. Systems should distinguish between FDA-approved, state-regulated, and illicit sources.

12. Improve Surveillance and Coding Systems

Enhance ICD coding for psychedelic exposures, create product-specific identifiers, and expand poison control reporting to capture context, setting, and product origin. Models such as Vaccine Adverse Event Reporting System (VAERS) and Coordinated Registry Networks (CRNs) offer templates.

13. Ensure Fair Access, Data, and Outcomes

All federal guidance and data systems should incorporate demographic categories including age, race, ethnicity, sexual orientation, gender, markers of socioeconomic status, and geography (e.g., rurality) to monitor differences in access based on these factors.

14. Safeguard Against Over-Commercialization and Monopolization

Federal policy should prevent exclusionary patents on natural compounds with a long history of human use, ensure open access to training pathways, and support community-based and non-profit service delivery options alongside for-profit models.

15. Support Ongoing Research, Education, and Workforce Development

Federal agencies should expand research on efficacy, safety, economic impacts, implementation models, and long-term outcomes. Investments in workforce training, continuing education, and potential policy initiatives are necessary.

VI. Conclusion and Potential Implications for Federal Policy Initiatives

Responders across the country share a vision of safe, ethical, evidence-based PAT that is accessible to all communities, respectful of cultural and Indigenous traditions, and grounded in strong patient and participant protections. Achieving this vision will require coordinated federal leadership, rigorous but flexible guidance, substantial investment in workforce and infrastructure, and robust data systems capable of tracking long-term outcomes.

Potential policy initiatives include the following:

- **Expand congressional support for DoD and VA research.** Increased funding could both benefit active-duty service members and veterans and generate critical data to inform potential drug approvals, particularly if these agencies coordinate with FDA to share data and clinical experience relevant to IND applications.

- **Strengthen NIH research funding.** Support for intramural programs (including the NIH Clinical Center) and extramural grant-funded research is essential to advance independent evaluations of safety, efficacy, and novel therapeutic applications. Such research often addresses questions beyond those required for regulatory approval but is critical for safeguarding public health and expanding clinical use. Notably, many FDA-approved treatments for psychiatric and neurological disorders, including those for addiction and pain, have been substantially advanced through NIH-supported research.

- **Expand access through Expanded Access ("compassionate use") programs.** Many patients are willing to participate in research due to unmet medical needs. Broadening these programs could provide earlier access to investigational therapies while also contributing real-world data to support FDA's evaluation of safety and efficacy, provided that patients give fully informed consent acknowledging the investigational status of these treatments.

- **Encourage prioritization within U.S. DHHS and U.S. FDA.** Congressional engagement may be needed to ensure that promising psychedelic therapies are reviewed with appropriate urgency and consistency, particularly in light of the agency's designation of several such therapies as Breakthrough Designation Therapies. A more predictable and transparent regulatory approach would help avoid periods of both rapid advancement and unexpected delays in development timelines.

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Appendix 1. Advisory Board Comments from Paul Mavis

Appendix 2. Advisory Board Comments from Veronica Magar

Appendix 3. Advisory Board Comments from Kari Rockhill

Appendix 4. Advisory Board Comments from Leith States

Appendix 5. Advisory Board Comments from Swami Nathan

Appendix 6. Advisory Board Comments from Peter Hendricks

Advisory Board Commentary

Paul Mavis

Participant Perspective on Psychedelic-Assisted Therapy Implementation

I am writing from the perspective of a participant in the New York University Langone Health clinical trial evaluating psilocybin-assisted therapy for Alcohol Use Disorder under the leadership of Dr. Michael Bogenschutz.

Unlike most contributors to this effort, I am neither a clinician, researcher, regulator, policymaker, nor industry participant. My perspective is that of a patient whose life was profoundly improved through participation in a highly structured therapeutic protocol.

I believe the white paper generally reflects the major themes and concerns expressed throughout the submitted comments. In particular, it accurately captures the emphasis on patient protections, professional training, ethical safeguards, equitable access, reimbursement challenges, and the importance of collecting meaningful long-term outcomes data. It also fairly reflects the significant diversity of viewpoints regarding credentialing, community participation, Indigenous practices, and implementation models.

My purpose here is not to repeat those observations but rather to offer a perspective based on lived experience.

My Experience

I entered the NYU study in early 2019 after decades of struggling with Alcohol Use Disorder. Before entering the study, I underwent extensive medical and psychiatric screening. I then worked closely with Dr. Jeffrey Guss and Dr. Elizabeth Nielson over a period of approximately one year that included preparation, dosing sessions, integration work, and follow-up.

One aspect of my experience is particularly relevant to the current policy discussion.

I later learned that my first two dosing sessions were placebo sessions rather than psilocybin sessions. At the time, I did not know this. Having never used recreational drugs or psychedelics, I believed I had received the active medication. Only during a later open-label session did I experience the dramatic subjective effects typically associated with psilocybin.

Yet the most significant therapeutic changes in my life had already begun.

This experience has shaped how I think about psychedelic-assisted therapy.

The Therapy Matters

The public discussion surrounding psychedelics often focuses on the compound itself. While I have no doubt that psychedelic medicines may play an important therapeutic role for many patients, my own experience has led me to believe that the therapy is not simply an adjunct to the medicine. Rather, the medicine and the therapeutic process appear to work together in ways that are difficult to separate.

What changed my life was not merely participation in a dosing session.

It was the combination of:

- rigorous screening and preparation;
- skilled, experienced therapists;
- a safe and carefully structured environment;
- thoughtful integration of insights into daily life; and
- ongoing support and accountability over an extended period.

In my case, the therapeutic process appeared to begin producing meaningful changes before I received an active psychedelic drug.

This does not diminish the value of psychedelic medicines. Instead, it reinforces the importance of understanding psychedelic-assisted therapy as a comprehensive intervention rather than simply the administration of a compound.

The Central Implementation Challenge

After reviewing the RFI, the submitted comments, and the draft white paper, I believe the greatest challenge facing policymakers is not whether psychedelic medicines can be approved.

The greater challenge is how to responsibly deliver the therapeutic model that appears to contribute substantially to positive outcomes.

The original PATH Caucus Request for Information repeatedly emphasized training, credentialing, participant protections, service delivery, equitable access, and implementation infrastructure. Having participated in one of the landmark clinical trials in this field, I believe this focus is well placed.

FDA can approve a drug.

FDA cannot approve a therapeutic relationship.

FDA can evaluate safety and efficacy.

FDA cannot create a workforce of highly skilled therapists, facilitators, supervisors, and integration specialists.

Yet the quality of those human relationships may be among the most important determinants of patient outcomes.

For this reason, I believe workforce development deserves even greater attention than it currently receives.

Access and Equity

I strongly support efforts to make psychedelic-assisted therapy available to patients who may benefit from it.

However, approval alone does not guarantee access.

Without reimbursement mechanisms, workforce development, training infrastructure, and community-based implementation models, psychedelic-assisted therapy risks becoming available primarily to individuals with significant financial resources living near major metropolitan treatment centers.

Several participants in the RFI process raised concerns about equitable access. I share those concerns.

The challenge is not simply making medicines available.

The challenge is making high-quality care available.

Recommendations

Based on my experience as a participant, I respectfully offer the following recommendations:

1. Continue to prioritize patient protections, informed consent, screening, and ethical safeguards.
2. Treat workforce development as a critical implementation priority rather than a secondary consideration.
3. Recognize that access to psychedelic-assisted therapy requires access to qualified therapeutic support, not merely access to medication.
4. Ensure that reimbursement policies support the therapeutic components of care, including preparation and integration services.
5. Encourage continued research into the relative contributions of medication, therapeutic support, preparation, and integration so that future implementation efforts can be guided by evidence rather than assumptions.
6. Maintain a clear distinction between FDA-approved psychedelic-assisted therapy and broader discussions regarding legalization, decriminalization, or non-medical use.

Closing

More than six years after my participation in the NYU trial, the most enduring aspect of my experience is not my memory of a dosing session.

It is my gratitude toward the clinicians who guided me through the process and helped me achieve lasting change.

As policymakers consider how best to support the development and implementation of psychedelic-assisted therapies, I encourage them to view these treatments not merely as novel pharmaceutical products, but as complex care-delivery systems that depend upon skilled professionals, strong ethical safeguards, and sustained human relationships.

If psychedelic-assisted therapies ultimately fulfill their promise, I believe it will be because we succeeded in preserving the integrity of the therapeutic process while expanding access to those who need it most.

Appendix A

Supporting Themes Observed in PATH Caucus RFI Submissions

The observations contained in my advisory commentary were developed primarily from my personal experience as a participant in the NYU Alcohol Use Disorder clinical trial. However, after reviewing a representative sample of the submissions received in response to the Congressional PATH Caucus Request for Information, I was struck by how many stakeholders independently raised concerns and recommendations that parallel my own experience.

The following themes appeared repeatedly across submissions from academic institutions, nonprofit organizations, provider groups, patient advocates, and public health experts.

1. Psychedelic-Assisted Therapy Should Be Viewed as More Than Drug Administration

Several respondents emphasized that therapeutic outcomes cannot be understood solely through the lens of medication administration. Preparation, therapeutic support, integration, and ongoing clinical engagement were repeatedly identified as critical elements of successful treatment.

This observation strongly aligns with my own experience. The most meaningful changes in my life were associated not only with dosing sessions, but with the broader therapeutic process that surrounded them.

Representative Sources:

- Johns Hopkins University researchers and educators
- Academic clinical researchers
- Multiple provider organizations and nonprofit respondents

2. Workforce Development May Become the Greatest Barrier to Successful Implementation

Numerous submissions expressed concern regarding the limited number of clinicians with meaningful experience delivering psychedelic-assisted therapies.

Stakeholders raised questions regarding:

- training standards;
- supervision requirements;
- credentialing pathways;
- continuing education;
- clinical competency assessment; and
- workforce capacity.

Many respondents noted that even if psychedelic medicines receive FDA approval, there may be insufficient numbers of qualified professionals available to deliver care safely and effectively.

This concern appears particularly important given the growing public demand and the possibility of future approvals.

Representative Sources:

- Academic institutions
- Clinical training organizations
- Professional provider networks
- Public health respondents

3. Access Requires More Than Approval

A recurring theme throughout the submissions was that FDA approval alone will not ensure equitable patient access.

Stakeholders repeatedly highlighted:

- reimbursement challenges;
- insurance coverage;
- Medicare and Medicaid participation;
- geographic disparities;
- rural access limitations; and
- workforce shortages.

Many respondents warned that absent deliberate policy interventions, access may be concentrated among patients with greater financial resources and proximity to major metropolitan treatment centers.

This concern mirrors my own belief that access to psychedelic-assisted therapy ultimately means access to qualified therapeutic support rather than access to medication alone.

Representative Sources:

- Federally Qualified Health Center advocates
- Community health organizations
- Public health experts
- Provider networks

4. Participant Protection Remains Essential

Perhaps the strongest area of agreement among respondents involved participant protection.

Stakeholders consistently emphasized:

- informed consent;
- medical and psychiatric screening;
- adverse event monitoring;
- ethical safeguards;
- boundary protection;

- therapist accountability;
- emergency preparedness; and
- post-treatment follow-up.

The comments reflected broad recognition that psychedelic-assisted therapies involve unique vulnerabilities that require thoughtful safeguards.

My own experience within a highly structured clinical environment reinforced the importance of these protections.

Representative Sources:

- Coalition for Psychedelic Safety and Education (CPSE)
- Academic researchers
- Public health organizations
- Clinical providers

5. Long-Term Outcomes Data Will Be Critical

Many respondents emphasized the importance of collecting meaningful long-term outcomes data rather than focusing exclusively on short-term clinical endpoints.

Stakeholders discussed:

- registries;
- pharmacovigilance systems;
- real-world evidence;
- long-term safety monitoring;
- patient-reported outcomes; and
- comparative effectiveness research.

This recommendation appears particularly relevant as implementation moves beyond clinical trials and into broader clinical practice.

Representative Sources:

- Public health researchers
- Academic institutions
- Drug development organizations
- Surveillance and safety experts

6. Implementation May Ultimately Be More Difficult Than Approval

One of the strongest impressions I took away from reviewing the submissions was that many stakeholders view implementation—not approval—as the central challenge facing the field.

Although respondents often disagreed about specific solutions, many recognized that successful implementation will require coordinated attention to:

- training;

- reimbursement;
- credentialing;
- public education;
- patient protections;
- data collection;
- ethical oversight; and
- workforce development.

This observation closely mirrors my own conclusion after participating in a psychedelic-assisted therapy trial and reviewing the comments submitted in response to the PATH Caucus RFI.

Closing Observation

Although respondents frequently disagreed on specific policy approaches, a broad pattern emerged across many submissions: successful implementation of psychedelic-assisted therapy will depend not only on the medicines themselves, but on the quality of the systems, professionals, safeguards, and support structures that surround them.

This reinforces my central recommendation that policymakers view psychedelic-assisted therapy as a comprehensive care-delivery model rather than solely as a pharmaceutical intervention.

Additional Considerations for Future Federal Policy, Research, and Implementation of Psychedelic-Assisted Therapy

Veronica Magar, DrPH, MPH, MA, BSN

Disclosure: Veronica Magar serves as a Fellow with the Usona Public Education Program (U-PEP). The views expressed are solely her own.

The PATH Caucus report is a thoughtful and important contribution to an evolving field and provides a strong foundation for future federal policy discussions on psychedelic-assisted therapies (PAT). As these therapies move from clinical research toward broader integration into health and community systems, the central policy challenge will extend beyond demonstrating efficacy and safety. Increasingly, the question will be how PAT can be implemented safely, effectively, affordably, and sustainably across diverse real-world settings while expanding access and maintaining public trust.

The considerations presented here are intended to complement the report by highlighting several strategic priorities that may help inform the next phase of federal policy, research, and implementation. They are offered from the perspective of global public health, health systems, implementation science, community-based care, and Indigenous partnerships.

This perspective draws on more than three decades of experience in global public health, including senior leadership at the World Health Organization (WHO); community-based program design, implementation, monitoring, and evaluation across more than 30 countries; public health nursing in Los Angeles; and more recent research, policy, and advisory work focused on psychedelic public health, implementation science, Indigenous partnerships, and community-based models of care.

1. Elevate Public Health as a Central Policy Framework

While much of the current dialogue appropriately focuses on biomedical, regulatory, and clinical considerations, future policy discussions would benefit from positioning PAT equally as a public health and health systems challenge.

Beyond efficacy and safety, policymakers will need to consider broader questions including access for rural, low-income, and historically underserved populations; workforce capacity; financing and reimbursement; sustainability; continuity of care; unintended consequences; and integration within existing mental health and substance use systems.

Importantly, FDA approval alone does not ensure implementation readiness, affordability, broad access, or meaningful population-level impact. Future federal efforts may benefit from making a clearer distinction between regulatory approval and successful implementation within real-world health and community systems.

2. Prioritize Implementation Science

Implementation science will be essential for translating promising interventions into routine practice and achieving meaningful public health impact.

While considerable attention has appropriately been devoted to efficacy, safety, regulation, and workforce training, substantially less attention has been given to the conditions required for successful implementation across diverse real-world settings. Evidence that an intervention works under controlled conditions does not necessarily indicate that it can be delivered effectively, affordably, sustainably, or at scale.

- What factors enable or inhibit adoption across different care settings?
- Which service-delivery models are feasible, acceptable, scalable, and sustainable?
- What adaptations are necessary for different populations, communities, and cultural contexts while maintaining safety and effectiveness?

- What workforce, supervision, and quality-assurance models are required?
- How can implementation expand access and avoid widening existing disparities in mental healthcare?
- What conditions support long-term sustainability and integration within existing health and community systems?

Implementation outcomes—including acceptability, feasibility, appropriateness, reach, uptake, fidelity and adaptation, cost, sustainability, and access—deserve greater attention alongside efficacy and safety outcomes. Implementation research should also examine PAT across a broad range of delivery settings, including specialty mental health services, primary care, Federally Qualified Health Centers, Veterans Health Administration settings, community-based organizations, group-based programs, and rural or otherwise underserved communities.

A stronger implementation science perspective will help policymakers anticipate challenges related to scale-up, workforce capacity, financing, quality assurance, continuity of care, and broad access before these become barriers to successful integration.

3. Adopt a Systems-Thinking Perspective

Successful integration of PAT will depend not only on treatment delivery, credentialing, and clinical safety, but also on the readiness of broader health and community systems.

PAT should be viewed as one component of a larger ecosystem involving workforce development, referral pathways, financing and reimbursement mechanisms, continuity of care, community trust, health information systems, quality improvement, and coordination across health and social sectors.

A systems-thinking perspective can help policymakers anticipate interactions among these components and support more resilient, sustainable, and accessible models of implementation.

4. Support Diverse Community-Based and Group-Based Models of Care

As policymakers consider future models of care, greater attention to community-based and group-based PAT approaches is warranted, particularly from the perspectives of affordability, scalability, cultural responsiveness, and access.

Given anticipated workforce shortages and cost barriers, highly individualized, specialist-intensive models alone are unlikely to meet population-level need. Federal research and demonstration programs should therefore examine a wider continuum of safe delivery approaches, including group preparation, group-based PAT sessions where clinically and legally appropriate, group integration, community-based follow-up, and models that connect clinical services with ongoing social and peer support.

Task sharing and carefully designed task-shifting approaches should also be evaluated. Not every component of PAT necessarily requires delivery by the most highly specialized clinician. With appropriate competencies, training, supervision, referral procedures, and quality safeguards, selected responsibilities may be shared among licensed clinicians, community health workers, trained peer-support specialists, recovery coaches, and other appropriately prepared members of the care team.

Peer-support models may be especially valuable during preparation, integration, and longer-term recovery or wellbeing. They may strengthen continuity, reduce isolation, improve engagement, and provide forms of practical and relational support that time-limited clinical services cannot always sustain. Research should determine which functions can be safely shared, what training and supervision are needed, and when escalation to licensed clinical care is required.

Emerging initiatives provide useful examples. Chris Stauffer and colleagues have contributed to research on group-based approaches in Veterans Health Administration contexts. Hanifa Nayo Washington and the Psychedelic Mental Health Access Alliance (PMHA Alliance) have also advanced community-informed and group-based approaches designed to expand access.

Federal agencies could support comparative research across individual, group-based, community-based, peer-supported, and hybrid models. Such studies should examine safety, effectiveness, participant experience, workforce requirements, cost, reach, sustainability, and suitability for different populations and settings.

5. Expand Access Through a Social Determinants of Health Lens

Future policy efforts may benefit from broadening how access is conceptualized and operationalized.

Access should be considered not only in terms of the availability of treatment, but also through the social and economic conditions that influence whether people can realistically enter, complete, and benefit from care. These include income, insurance status, geography, transportation, language, disability, housing stability, employment conditions, caregiving responsibilities, digital access, community trust, and the availability of culturally responsive services.

Without this broader perspective, PAT could unintentionally become concentrated among affluent, privately insured, and urban populations while remaining unavailable to many people with substantial mental health and substance use needs.

Many factors shaping treatment access and outcomes extend beyond healthcare systems alone. Future federal guidance may therefore benefit from encouraging collaboration across behavioral health, primary care, housing, education, employment, veterans' services, social services, and community organizations.

Federal research and monitoring should also assess who is reached, who is excluded, where people encounter barriers, and whether differences in access and outcomes narrow or widen as PAT is implemented.

6. Build Reciprocal Partnerships with Indigenous Peoples and Traditional Knowledge Systems

The report appropriately recognizes Indigenous rights and ceremonial traditions. As the field evolves, future policy discussions should move beyond consultation or inclusion toward meaningful Indigenous leadership, governance, partnership, reciprocity, and shared decision-making.

Many psychedelic medicines and practices under study have roots in Indigenous and traditional knowledge systems across the Americas and elsewhere. These systems encompass not only medicinal knowledge but also broader approaches to preparation, ethical guidance, community support, ritual, meaning-making, integration, accountability, relationships with land and ecology, and intergenerational healing.

Indigenous peoples and knowledge holders should have meaningful leadership and governance roles in decisions affecting their medicines, knowledge, cultural practices, communities, and territories. Engagement should occur early enough to shape priorities, research questions, governance structures, commercialization decisions, and definitions of benefit—not only after major decisions have already been made.

Future policy discussions should consider:

- Establishing Indigenous leadership and governance mechanisms within relevant research, policy, funding, and decision-making bodies.
- Respecting the right of Indigenous peoples to determine whether, how, and under what conditions their knowledge, practices, cultural expressions, biological resources, and medicines may be studied or used.
- Applying free, prior, and informed consent to research and other activities involving Indigenous communities, knowledge systems, medicines, biological resources, or cultural practices.
- Avoiding extractive relationships and recognizing Indigenous epistemologies, ethical frameworks, relational practices, and systems of accountability.
- Recognizing that Indigenous and traditional knowledge systems include sophisticated systems of care and delivery—not solely knowledge about particular substances.
- Learning from longstanding community-based and group-based approaches that emphasize preparation, peer and family support, collective care, continuity, social containment, and integration.
- Establishing fair and tangible benefit-sharing arrangements, particularly as intellectual property development and commercialization accelerate.
- Ensuring reciprocity through sustained relationships, community-defined benefits, capacity strengthening, shared resources, and the return of knowledge and research findings in useful forms.

- Supporting ecological sustainability and protection of sacred medicines, plants, fungi, and the ecosystems upon which they depend.
- Protecting sacred, restricted, or culturally sensitive knowledge from forced or inappropriate disclosure.
- Engaging respectfully with diverse healing systems without requiring their validation by, or assimilation into, biomedical frameworks.

A balanced and reciprocal approach may foster responsible innovation while reducing the risks of cultural erasure, exploitation, inappropriate commercialization, ecological harm, and missed opportunities for mutual learning.

7. Promote Global Learning and International Collaboration

Although this report focuses on the United States, PAT is developing within an increasingly global landscape. The United States has an opportunity both to contribute to and learn from international efforts through reciprocal collaboration, shared implementation experience, international safety surveillance, ethical standards, and partnerships with low- and middle-income countries, Indigenous peoples, and community-based practitioners.

Federal agencies could support cross-country implementation research, responsible data sharing, comparative analysis of regulatory approaches, and learning across different health-system and community contexts. International partnerships should be designed collaboratively and should strengthen local leadership, institutions, research capacity, and decision-making rather than reproduce one-directional models of technical assistance.

Global collaboration may accelerate learning while helping ensure that implementation approaches remain ethical, context-responsive, and informed by models developing outside the United States.

8. Measure Success Beyond Clinical Outcomes

As PAT evolves, future research, surveillance, and evaluation frameworks may benefit from assessing outcomes across multiple levels of impact.

Individual-level outcomes may include:

- Mental health and substance use indicators, including depression, post-traumatic stress, anxiety, substance use frequency or severity, craving, relapse, and overdose risk.
- Symptom severity and remission.
- Social, occupational, educational, and daily functioning.
- Quality of life and wellbeing.
- Adverse events and safety.
- Recovery, resilience, and sustained benefit over time.

Community-level outcomes may include:

- Social connectedness and social support.
- Family and caregiver effects.
- Community trust in care systems.
- Stigma reduction.
- Community engagement and reach.
- Availability of culturally and linguistically responsive services.

Health-system outcomes may include:

- Access and utilization.
- Workforce readiness and provider capacity.
- Continuity of care.
- Feasibility, acceptability, and appropriateness.
- Reimbursement pathways and affordability.
- Quality assurance and referral capacity.
- Sustainability and reach across geographic and socioeconomic groups.

Population- and policy-level outcomes may include:

- Differences in access and outcomes across populations.
- Population mental health and substance use indicators.
- Cost-effectiveness and economic impact.
- Unintended consequences.
- Long-term surveillance of benefits and harms.
- Effects on existing mental health and substance use systems.

A multilevel public health framework may provide a more comprehensive understanding of whether PAT improves not only individual symptoms, but also health-system performance, community wellbeing, and population-level outcomes.

9. Balance Safety with Scalability, Affordability, and Access

Strong safeguards remain essential. At the same time, policymakers should consider whether overly restrictive or highly specialist-dependent models could unintentionally limit access primarily to affluent urban populations while leaving rural, publicly insured, low-income, and other underserved communities behind.

Future policy development will benefit from balancing safety and rigor with affordability, scalability, cultural responsiveness, and broad access. This includes testing graduated and team-based workforce models, group-based approaches, task sharing, peer-support services, and appropriate community-clinical partnerships rather than assuming that a single intensive clinical model will be suitable for all populations and indications.

Safeguards should be proportionate to evidence and risk, regularly evaluated, and designed to protect participants without creating unnecessary barriers that make responsible care inaccessible.

Concluding Perspective

The PATH Caucus report represents an important contribution to a rapidly evolving field.

As psychedelic-assisted therapies move from research toward broader implementation, future policy discussions will increasingly need to address questions that extend beyond efficacy and safety. The next generation of federal leadership will require equal attention to implementation science, public health, systems thinking, affordability, access, workforce innovation, community- and group-based models, Indigenous leadership and knowledge systems, and global learning.

Addressing these dimensions early offers an opportunity to support models of care that are not only clinically effective, but also accessible, sustainable, culturally responsive, and capable of improving population health. In this regard, the PATH Caucus is well positioned to help shape a broader national vision for the responsible integration of psychedelic-assisted therapies.

June 22, 2026

Disclosure: KR has no personal disclosures, the views expressed here are her own. She is employed by Rocky Mountain Poison & Drug Safety (RMPDS), a division of nonprofit Denver Health and Hospital Authority, a subdivision of the State of Colorado. RMPDS is funded for work that provides independent surveillance, research, and reporting services to government agencies, pharmaceutical manufacturers, and non-government organizations.

A Public Health Perspective on the Integration of Psychedelic Medicines

As a pharmacoepidemiologist with over a decade of experience in drug safety surveillance, regulatory science, outcomes research, and real-world evidence generation, I believe the United States is approaching an important inflection point in the integration of psychedelic medicines into healthcare: how to integrate these medicines and associated therapies in a way that maximizes public health benefit while minimizing preventable harm.

The primary policy challenge is not whether psychedelic medicines should exist within the healthcare system but a coordinated federal approach that reflects the reality of how these substances are used in the real world. Psychedelics are already being used through multiple channels, including unregulated use, indigenous and ceremonial practices, state-regulated programs, Veterans Affairs initiatives, and existing FDA-approved products such as esketamine. Future FDA-approved psychedelic medicines will become one additional pathway within this larger ecosystem. While regulatory authorities may oversee these channels separately, the individuals who use psychedelics will not. Patients will move between healthcare systems, state programs, personal use settings, and federally regulated treatments.

From a public health perspective, three priorities should guide policy development: patient safety, fair opportunity for access, and continued evidence generation. These goals are intertwined. For exmpale, safe implementation depends on robust evidence and access depends on understanding how benefits and risks vary across diverse populations.

My greatest concern is that current approaches to safety monitoring applied to psychedelics will capture only a narrow portion of the psychedelic experience. Traditional post-marketing systems of psychoactive drugs focus primarily on serious adverse events, abuse/diversion, and elements that assure safe use. While important, they do not provide a complete understanding of long-term outcomes, differential effectiveness across populations, patterns of cross-channel use, or the broader spectrum of potential benefits and risks. If we focus on the more narrow portion of the psychedelic experience, we risk transferring unknown risks to new populations and not optimizing the full potential of these therapies. FDA approval should be viewed as the beginning of evidence generation for psychedelic medicines, not the end of it. Clinical trials are essential, but they often enroll highly selected participants whose experiences may not represent the patients ultimately receiving treatment in real-world settings. Real-world evidence will be critical for understanding outcomes among populations frequently underrepresented in trials including individuals with complex psychiatric histories, varying substance use patterns, and different age groups, and pregnant, postpartum, and lactating individuals, to name a few.

To address these challenges, federal agencies should begin building the infrastructure necessary to support long-term surveillance and evidence generation, before widespread implementation occurs. This can include improving coding systems that allow psychedelic-related outcomes to be identified within electronic health records, enhancing poison center and public health monitoring systems with psychedelic-specific data elements (such as substance source, set/setting, and contextual factors), expanding national surveys, and supporting long-term patient registries for FDA-approved products. Over time, data systems should be designed to evaluate outcomes across multiple access channels to better understand how different care models influence safety and effectiveness. Patients will not experience psychedelics in silos, and therefore our evidence generation needs to be flexible providing a more complete understanding of real-world use and outcomes to improve patient safety.

The FDA will play a critical role in product approval and post-marketing oversight, but successful implementation will require broader coordination across federal agencies. NIH, CDC, SAMHSA, CMS, VA, and DEA all have distinct responsibilities that will influence how psychedelic medicines are researched, monitored, reimbursed, and delivered. Congress should support a national implementation framework that clearly defines these roles while investing in surveillance infrastructure, research, and appropriate safeguards.

In my experience, policymakers are often influenced by powerful individual stories. These stories matter, and they must be reviewed collectively with rigorous scientific evidence. Policymakers must also recognize that psychedelics are not a single intervention. Different substances have distinct pharmacology, risk profiles, and implementation considerations that require careful evaluation and may require different regulatory and implementation approaches.

Looking ahead, success should not be measured solely by the number of approved products or psychedelic-assisted treatment centers. Success would mean that ten years from now the United States has established a standardized, nationwide infrastructure capable of generating high-quality evidence that informs future policy decisions. Success would be reducing barriers to care while maintaining appropriate safeguards to improve patient care and have documented progress torwards mental health healing and increased well-being. Most importantly, success would mean that patients, providers, and policymakers can make informed decisions based on a comprehensive understanding of both the risks and benefits of these therapies.

The question before policymakers is whether we will build the systems necessary to understand their real-world risks and benefits and guide their integration responsibly. A coordinated federal framework focused on balancing surveillance, evidence generation, patient safety, and access offers the strongest path forward.

Respectfully,

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Federal Policy and Implementation Considerations for Psychedelic-Assisted Therapy

Leith J. States, M.D., M.P.H., M.B.A., FACPM

Disclosure: Dr. States is Senior Vice President for Strategic Military Initiatives at Sunstone Therapies, which conducts and supports clinical research and health-system readiness activities involving psychedelic-assisted therapies, including veteran-focused programs. He is also Founder of States Strategies, LLC, and Board Secretary of the Ibogaine Health Policy Institute. These roles may create professional and financial interests in policies affecting psychedelic drug research, approval, access, reimbursement, and implementation. The views expressed are his own and do not represent the views of any current or former employer, client, federal agency, or military service.

These observations supplement the white paper from a federal implementation perspective. The central policy task is to align rigorous drug development, controlled-substance authorities, and health-system readiness so that promising products can move from investigation to lawful, scalable, evidence-based care. This update incorporates the July 13, 2026, HHS-VA memorandum of understanding (MOU) and FDA's July 2026 final guidance for industry on clinical investigations of psychedelic drugs.

Fund VA readiness and care delivery, not research alone

- Continued research is necessary, but the critical need for the Veterans Health Administration (VHA) is to build the operational capacity required to deliver future FDA-approved rapid-acting psychiatric treatments safely, consistently, and equitably. Congress should therefore ensure that implementation resources are available through the VA Medical Care appropriation, particularly the Medical Services account, to support workforce training, site readiness, pharmacy and controlled-substance operations, clinical protocols, data systems, referral pathways, community-care coordination, and long-term outcomes monitoring. Medical and Prosthetic Research funding cannot substitute for care-delivery infrastructure. Clinical trials are expensive and restrictive, and their eligibility criteria often exclude veterans with the complex comorbidities most likely to be encountered in routine practice.
- The new HHS-VA MOU materially advances this objective by committing the departments to workforce training, evidence-based clinical protocols, research and real-world evidence generation, data sharing, and preparation for responsible deployment of future FDA-approved products. Its value should be measured through execution: funded implementation plans, designated accountable leaders, site-readiness milestones, interoperable data arrangements, and explicit pathways for moving an approved product into routine VHA care.

Resolve the Schedule I access gap; Expanded Access alone will not scale

- Expanded Access can be valuable for individual patients, but it remains individualized, administratively burdensome, institution-dependent, difficult to finance, and poorly suited for broader implementation. The principal structural problem is the misalignment between FDA pathways for investigational treatment and Controlled Substances Act/Drug Enforcement Administration requirements for administering Schedule I investigational therapies outside research. Congress should consider the Freedom to Heal Act of 2025 (S. 3346/H.R. 6434, 119th Cong.), which would amend section 303 of the Controlled Substances Act (21 U.S.C. § 823) to require a special DEA registration process for physicians directly administering Schedule I eligible investigational drugs to eligible patients under the federal Right to Try law. The proposed process would require evidence of

sponsor supply, relevant clinician training and credentials, state-law authority, site controls, quantity limits, and safeguards against diversion.

- This is not an argument to bypass FDA approval standards. It is an argument to make congressionally authorized preapproval access operational while preserving safety and product controls. Interagency agreements can improve coordination and information sharing, but they cannot by themselves create the required controlled-substance registration authority.

Preserve FDA rigor and focus oversight on sponsor execution

- Psychedelic drug candidates should be evaluated under the same statutory and evidentiary standards applied to other drug-development programs. Therapeutic promise, public urgency, or breakthrough therapy designation does not justify therapeutic-class exceptionalism. FDA's final guidance confirms this principle while identifying field-specific challenges: chemistry, manufacturing, and controls; current good manufacturing practice; abuse-potential assessment; functional unblinding and expectancy bias; appropriate control conditions; durability and repeat dosing; the contribution of psychotherapy or psychological support; representative study populations; rigorous adverse-event documentation; and qualified session monitoring and emergency coverage.
- The most actionable federal recommendation is therefore to promote sponsor readiness and disciplined regulatory execution: early and sustained FDA engagement, auditable data integrity, protocol adherence, standardized monitor training and supervision, effective misconduct safeguards, manufacturing quality, and timely correction of identified deficiencies. Congressional oversight should concentrate on identifiable statutory or structural barriers and on agency consistency and transparency, not pressure FDA to reach a preferred outcome for a favored therapeutic class.

References: *Freedom to Heal Act of 2025*, S. 3346 and H.R. 6434, 119th Cong. § 2 (introduced Dec. 4, 2025); HHS-VA partnership announcement and MOU (July 13, 2026); FDA, *Psychedelic Drugs: Considerations for Clinical Investigations*, Final Guidance for Industry (July 2026).

Comments from Swami Nathan, MBA

Disclosure: I consult with or advise several companies including those that are developing psychedelic therapies.

As psychedelic therapies advance through clinical development and potential FDA approval, policymakers should encourage public health surveillance systems to distinguish between FDA-approved psychedelic products and psychedelic substances obtained through other channels. Where feasible, this distinction should be incorporated into adverse event reporting systems, epidemiologic datasets, emergency department records, poison center databases, and other public health monitoring programs.

The rationale for this distinction is scientific and public-health related. FDA-approved psychedelic products are expected to be manufactured under current Good Manufacturing Practices (cGMP), administered according to an approved label, and, in many cases, dispensed under a Risk Evaluation and Mitigation Strategy (REMS). In contrast, exposures involving products from other sources may differ with respect to product quality, dose certainty, route of administration, patient screening, clinical supervision, and monitoring. Aggregating these distinct exposure categories into a single reporting bucket may obscure meaningful differences in safety outcomes, effectiveness, and patterns of use.

As with other controlled substances that may exist in both FDA-approved pharmaceutical forms and non-pharmaceutical forms, meaningful public-health surveillance requires the ability to distinguish among sources of exposure rather than treating all exposures involving the same active ingredient as equivalent. Such distinctions are important to ensure that safety signals, utilization patterns, and clinical outcomes are interpreted within the appropriate regulatory, manufacturing, and clinical context.

Accordingly, federal agencies should consider encouraging the collection of information regarding the source of psychedelic exposure, including whether the exposure involved an FDA-approved product, another regulated source, or a product of unknown provenance. Such distinctions would improve the quality of pharmacovigilance, strengthen epidemiologic analyses, support evidence-based policymaking, and provide clinicians, researchers, regulators, and patients with a more accurate understanding of the benefits and risks associated with different forms of psychedelic use.

Comments from Peter Hendricks, PhD

Disclosure: PSH has received grant/research support from Beckley Psytech, Heffter Research Institute, National Institutes of Health, Reunion Neuroscience, and Usona Institute. He has consulted for Bright Minds Biosciences, Eleusis Benefit Corporation, Journey Colab Corporation, Negev Labs, Otsuka Pharmaceutical Development & Commercialization, Reset Pharmaceuticals, and Reunion Neuroscience. He has equity or stock options with AtaiBeckley and Negev Labs and is co-founder of Equulus Therapeutics and Mycelial Health.

Engagement with Indigenous and religious communities. The reviewer supports engagement with tribal and religious communities and suggests it is most defensible, and most likely to earn broad support, where it is anchored to documented histories of use. In the United States, the clearest example is peyote use within the Native American Church, with federal religious-use protections also extending to the ayahuasca-using UDV and Santo Daime churches. Naming these examples explicitly would strengthen the discussion. By the same token, recommendations calling for Indigenous co-leadership of policymaking should be scoped to substances and contexts where a traditional-use history exists; for synthetic compounds without such history in the United States (e.g., LSD, MDMA, methylone), the rationale for such involvement should be articulated or the recommendation narrowed. The reviewer also notes that the ceremonial traditions cited are syncretic religions, and suggests the document avoid language implying that deference to particular religious institutions is a precondition of implementation; neutral phrasing (e.g., continued protection of existing religious-use rights) accomplishes the same aim without raising church–state sensitivities.

Workforce development and credentialing. Once psychedelic-assisted therapy is delivered within medical systems, credentialing and licensure will be required; the reviewer suggests presenting this as a given rather than a point of contention. A constructive framing is to pair tiered credentialing pathways with concrete supports. Tuition and training costs for experienced community-based practitioners could be covered by philanthropic or other funding sources, for example, giving them a genuine route to clinical licensure rather than leaving them to be described as "excluded." Where the document refers to concerns about exclusion, the reviewer recommends specifying what practitioners fear being excluded from, given that existing religious-use protections remain in place. The reviewer further notes that established professional ethics codes (e.g., in clinical psychology) already address consent, boundaries, and misconduct, and recommends the document build on these frameworks rather than implying an ethical vacuum.

Methodological standards. Regarding expectancy and blinding, the reviewer recommends an evenhanded framing: when blinding integrity is formally assessed, it is poor across psychiatric

drug classes, including antipsychotics, ADHD medications, and cannabinoids. Psychedelics should not be held to a uniquely elevated standard. In addition, determining whether an intervention is safe and effective is a distinct question from fully disentangling pharmacologic and extra-pharmacologic contributions to benefit; with psychedelics, complete separation of these factors may not be achievable, and the field may need to be comfortable with that.

Requests for clarification. Several comments request clarification rather than revision: which decision-making and implementation processes are envisioned for Indigenous, spiritual, and community leaders, and on what rationale; whether the claim that certain drug-development activities rely on religious, ceremonial, or traditional practices applies to any product currently in development; and whether Section V presents the authors' own recommendations or a synthesis of respondent recommendations, a distinction that should be made explicit.

Collectively, these comments aim to preserve the substance and diversity of respondent perspectives while ensuring that the summary itself reads as rigorous, precise, and politically neutral. These are the qualities most likely to earn it a fair hearing from policymakers across the political spectrum.