Written Testimony of Dr. Marion Coe

Psychedelic-Assisted Therapies for Veterans: The Path Forward

November 18, 2026 hearing of the Health Subcommittee of the House Committee on Veterans Affairs

Madam Chair Miller-Meeks, Ranking Member Brownley, and Members of the Subcommittee:

Thank you for the opportunity to provide testimony on the responsible integration of psychedelic-assisted therapies into the Department of Veterans Affairs (VA) healthcare system.

I am Dr. Marion Coe, Director of Clinical Development and Post-Marketing Surveillance at Pinney Associates, where I advise pharmaceutical companies on the development of central nervous system medications, including psychedelics and other treatments for post-traumatic stress disorder (PTSD) and substance use disorders. My work includes clinical development, FDA regulatory strategy, abuse potential assessment, and risk management.

I also led the effort to synthesize responses to the 2024 Congressional Protecting Public Health and Safety with Psychedelics Advancing Therapies (PATH) Caucus Request for Information (RFI), issued by co-chairs Representatives Jack Bergman and Lou Correa. The resulting white paper, *Summary and Recommendations on the Safe, Ethical, and Equitable Integration of Psychedelic-Assisted Therapy in the United States*, reflects input from a broad range of stakeholders, including clinicians, researchers, patients, advocacy organizations, Indigenous leaders, and healthcare providers.

Although the RFI was not specific to veterans or the VA, many of its findings have direct relevance to the questions facing this Committee. The responses highlighted both the potential of psychedelic-assisted therapies and the substantial work required to make them available safely, ethically, and equitably. They also revealed areas of disagreement, particularly around provider credentialing and models of treatment delivery. However, several themes emerged consistently: the importance of patient protections, a qualified workforce, appropriate clinical infrastructure, equitable access, and long-term monitoring of outcomes.

My comments in the hearing and this written submission are made in effort to communicate findings based on comments submitted to the PATH RFI. However, I am also providing comments that reflect my overall assessment of the state of the science, regulatory considerations, and implication for the care of veterans and active-duty

personnel by the VA. These comments reflect discussions with Jack Henningfield and other colleagues at Pinney Associates but do not necessarily reflect the official views of Pinney Associates. Furthermore, no clients of Pinney Associates have had any input into my comments, nor has any client provided financial support for my efforts or to reimburse travel expenses. Pinney Associates has provided the resources for me to be able to contribute at this hearing.

1. Psychedelic medicines should not be treated as a single therapeutic class.

One of the most important considerations is that psychedelic medicines are not interchangeable. Compounds such as psilocybin, MDMA, and ibogaine have substantially different pharmacological properties, safety profiles, and potential therapeutic applications. Their risks, monitoring requirements, and appropriate treatment settings may differ considerably depending on the compound, indication, dose, and patient population.

In that regard, and of relevance to this hearing, is the fact that three psychedelic substances that have potential for treatment of major depression, addiction, and PTSD that afflict many veterans and contribute to their high rate of suicide. Of these, the safety and efficacy has been best documented for psilocybin and MDMA. Two New Drug Applications for Psychedelic Assisted Therapy (PAT) using psilocybin have been submitted to the FDA by Compass Pathways and the Usona Institute for treatment resistant depression, and major depressive disorder, respectively, and it is possible that one or both will be approved by FDA in 2027. An MDMA medication for treatment of PTSD was submitted to the FDA in 2023 by Lykos Therapeutics (Now Resilient Pharmaceuticals) leading to FDA's request for additional information in 2024 to address efficacy and safety issues that were raised by the 2024 FDA advisory committee. The NDA was resubmitted in August 2026, and a 2027 approval is possible.

The third potential psychedelic treatment that has gained significant attention and has been widely discussed in the media recently is ibogaine. Over the past 25 years, ibogaine has been investigated by NIH and others for its potential therapeutic effects across several conditions, as well as its toxicity and safety risks. Most of this work was conducted in animals, and the available evidence is not yet sufficient to establish its safety or efficacy in humans. Well-controlled clinical studies are needed. Of particular concern are its cardiovascular effects, including QTc prolongation and potentially serious cardiac arrhythmias. These risks will require careful evaluation during clinical development to determine whether ibogaine's potential benefits outweigh its risks and, if it is ultimately approved, whether additional post-marketing risk-management measures would plausibly be necessary.

Accordingly, the VA should avoid adopting a one-size-fits-all approach to evaluating or implementing these treatments. Each medication should be assessed on its own evidence, with clinical protocols and safeguards tailored to its specific risks and potential benefits.

There is growing interest in psychedelic-assisted therapies for conditions that disproportionately affect veterans, including PTSD, depression, and substance use disorders. Many individuals continue to struggle despite receiving currently available treatments. While these emerging therapies will not be appropriate for everyone, they may offer another option for some patients who have not achieved adequate improvement with existing approaches.

The goal should be to ensure that promising treatments are rigorously evaluated and, when supported by sufficient evidence, made responsibly available to veterans who may benefit.

2. Safety, provider training, and treatment delivery must be priorities.

The PATH Caucus RFI responses reflected considerable disagreement about the appropriate model for provider training, credentialing, and treatment delivery. Some stakeholders favored restricting treatment to licensed healthcare professionals, while others supported broader, competency-based approaches that could include trained facilitators, peer-support professionals, and other members of a multidisciplinary care team.

Based on RFI responses, there is unlikely to be consensus around a single model. However, there should be broad agreement that a safe, supportive therapeutic environment, appropriately trained personnel, and robust clinical safeguards are essential to protecting patients and optimizing treatment outcomes.

Depending on the medication and treatment model, psychedelic-assisted care may involve much more than medication administration. It can include medical and psychiatric screening, preparation, psychological support, monitored dosing sessions, and follow-up or integration. These components require thoughtful coordination and a workforce equipped to recognize and respond to both psychological and medical complications.

The VA has an opportunity to develop flexible, multidisciplinary models that draw on its existing clinical infrastructure. Physicians, psychologists, nurses, social workers, and other appropriately trained professionals may be able to share responsibilities under clearly defined roles, with appropriate supervision and escalation procedures.

The VA might be an ideal organization to also evaluate group-based approaches where clinically appropriate, including models that may be particularly meaningful for veterans with shared experiences and conditions. Such approaches could potentially improve

access and reduce the resources required to deliver care, while maintaining appropriate individual screening and safeguards. Group treatment models have the potential to help the VA treat more people and perhaps more effectively from veterans who desire and are thought may benefit from group approaches.

Patient protections must remain central to any model. These should include comprehensive informed consent, appropriate medical and psychiatric screening, trauma-informed care, clear professional boundaries, emergency response procedures, adverse-event monitoring, and mechanisms for reporting and addressing misconduct. Particular attention should be given to protecting individuals who may be vulnerable during periods of altered consciousness and emotional openness.

FDA-required Risk Evaluation and Mitigation Strategies (REMS) can provide an additional layer of protection when FDA determines that special safeguards are necessary to ensure that a drug's benefits outweigh its risks. Depending on the product, a REMS may include enforceable requirements for prescriber training or certification, certified treatment settings, patient monitoring, documentation, and other measures intended to reduce serious risks.

Especially importantly, REMS can specifically prohibit off-label use of psychedelic medicines by health professionals, thereby addressing the concern by some that once approved, healthcare providers will use such medicines, essentially as they see fit as is the case for medicine that do not have REMS that prohibit off label use.

REMS requirements should be tailored to the specific medication and its safety profile. They can help establish consistent minimum safeguards while allowing room for the VA to develop treatment models that reflect the needs of its patient population. The goal should be to protect veterans without creating unnecessary administrative or logistical barriers that undermine access.

Importantly, REMS are not a substitute for the VA's own clinical governance, professional standards, or ongoing quality oversight. They should be viewed as one component of a broader patient-safety framework.

3. The VA must begin preparing its clinical infrastructure and workforce before FDA approval if it is to be ready to expand access as rapidly and as safely possible.

Until medicines receive approval, treatment of veterans and active-duty personnel will be restricted to research, and perhaps expanded access (“compassionate use”) programs. The latter has the potential to help more veterans more rapidly prior to approval than conventional Phase 3 clinical trials alone, but this could be an administratively burdensome approach, and streamlining this process could be discussed with the FDA.

Because the lead psychedelic substances are Schedule I drugs, the DEA must also be involved and must approve the VA's approach.

Thus, the central challenge is not simply whether these medicines can work. It is whether we can build the infrastructure necessary to deliver them safely, ethically, and to the veterans who need them, and help as many patients who could benefit as safety and other considerations allow.

The PATH Caucus RFI responses repeatedly identified workforce development and clinical infrastructure as major barriers to successful implementation. Even if psychedelic medicines receive FDA approval, there may not be enough appropriately trained professionals or adequately prepared treatment settings to meet demand.

The VA need not wait until FDA approval to begin addressing these challenges. Preparation will require identifying potential clinical sites, developing training and supervision programs, establishing treatment protocols, and ensuring that pharmacy and controlled-substance procedures are in place to meet DEA requirements and approval.

This preparation requires dedicated resources. Congress might need to ensure that the VA has the funding and operational support necessary to build the infrastructure for future care delivery. Research funding alone cannot substitute for the resources needed to train personnel, prepare clinical sites, establish pharmacy operations, and integrate new treatments into routine healthcare.

The recent HHS-VA memorandum of understanding provides an important foundation for collaboration around workforce development, evidence-based clinical protocols, research, real-world evidence generation, and data sharing. The next challenge will be translating those commitments into funded implementation plans, accountable leadership, measurable site-readiness milestones, and clear pathways for incorporating approved treatments into VA care.

The VA has a unique opportunity to build on its existing healthcare infrastructure and experience treating veterans with complex medical and psychiatric needs, but it may need additional resources that could be discussed with Congress.

4. Access should be based on clinical need, not geography.

Ensuring that veterans can access appropriate treatment regardless of where they live is vital in implementation planning to enable across-the-nation access because veterans are geographically dispersed and specialized treatment centers may be difficult for some to reach, particularly for those living in rural areas. If psychedelic-assisted therapies require

highly specialized facilities and personnel concentrated in a small number of metropolitan areas, access could be limited for many of the veterans who might benefit.

The RFI respondents describe a broad range of service-delivery models, including regional treatment centers, partnerships with qualified community providers, and telehealth for appropriate components of care, such as preparation and follow-up. Group-based approaches may also offer opportunities to expand capacity where clinically appropriate. Thus, there are many potential approaches that the VA could give consideration to.

Access also requires more than making the medication available. Veterans must be able to access the therapeutic support and follow-up that may be part of the treatment model. Workforce shortages, transportation, cost, and the availability of appropriate services can all affect whether a veteran can realistically receive and complete treatment.

The VA is uniquely positioned to address some of these barriers through its integrated healthcare system. However, doing so will require deliberate planning, adequate funding, and flexibility in how services are delivered.

5. The VA could consider establishing systems for long-term evidence generation with as much attention to adverse events as therapeutic benefit as this could be important in supporting continuous improvement in delivery approaches.

The VA could take advantage of its ability to follow veterans over time and collect meaningful information about treatment outcomes in real-world clinical settings.

Clinical trials are essential for establishing the safety and efficacy of new medications, but their eligibility criteria may exclude individuals with complex medical and psychiatric histories. Patients with these complexities are likely typically the types of patients the VA may encounter in routine clinical practice.

Systematic collection of real-world data can help us better understand how treatments perform in broader veteran populations, including individuals with multiple diagnoses, prior treatment failures, and concomitant medications. This information can complement clinical trial findings and help the VA identify which patients benefit, which do not, and what additional safeguards or modifications may be needed.

The VA may be able to adapt its existing standardized systems to collect information on PAT related adverse events, clinical outcomes, patient-reported outcomes, longer-term functioning, and quality of life. Follow-up should extend beyond the immediate treatment period to assess the durability of benefits, potential delayed adverse effects, and the need for additional treatment.

Data collection should also help identify differences in access and outcomes across geographic regions and patient populations. This will be important for determining whether implementation is reaching the veterans who need these treatments most.

Where appropriate, standardized and interoperable data systems could also facilitate collaboration and data sharing with FDA and other federal agencies. This would allow the VA's experience to contribute to the broader understanding of these medications, inform evolving treatment approaches, and potentially support future regulatory decisions.

Real-world evidence should complement, not replace, the controlled clinical trials necessary to establish efficacy and safety for FDA approval. But the VA can make an important contribution by generating evidence about how these treatments perform in the populations and clinical settings where they may ultimately be used.

Conclusion

Ultimately, the VA should not have to wait until every implementation question has been answered before beginning to prepare for the responsible use of these potential treatments. Nor should veterans have to wait years after FDA approval because the necessary workforce, clinical infrastructure, and systems have not been established.

Too many veterans are still suffering, and we are losing too many lives. Available behavioral therapies and medicines for depression and other disorders help many people but do not meet the needs of thousands of others. The evidence suggests that psychedelic-assisted therapies can help some of these people. But psychedelic therapies are not a solution for everyone, and we need to be as careful not to over-hype them as to downplay their risks, as we do our best to serve our veterans and others.

The PATH Caucus RFI demonstrated that stakeholders across the country recognize both the potential of these therapies and the importance of strong safeguards. It also made clear that successful implementation will require more than FDA approval. It will require trained professionals, appropriate clinical settings, patient protections, sustainable delivery models, equitable access, and systems to monitor outcomes over time.

The VA has an opportunity to contribute to infrastructure development and develop additional evidence addressing risks as it also does its best to serve veterans. Some might argue that the VA should follow the same models as those developing medicines for FDA approval, but we understand the VA’s first mission is serving veterans, endeavoring to produce the best possible outcome to each. That is a different model than FDA approval studies in which many people receive placebo and the behavioral and psychological support is generally not adjusted as per the individual needs of the patient because they might threaten the integrity of a trial designed to get the drug approved.

My colleagues and I are working on multiple efforts to get psychedelic medicines approved, and approval will help many more veterans than would be possible with unapproved drugs. But we do hope that the VA will continue to view its foremost mission as doing its best to help all veterans.

Steps that the VA is already taking in its psychedelic research and expanding those efforts would seem consistent with its mission of ensuring that veterans have access to safe, evidence-based treatment options when they need them, regardless of where they live. With appropriate congressional support, the VA can help lead the responsible expansion of FDA-approved psychedelic-assisted therapies and make a meaningful, lasting difference in the lives of veterans.

The VA's Primary Mission Should Be Caring for Veterans, Not Serving as a Clinical Development Organization

The VA should prioritize its central mission: providing care to veterans. Although clinical research is important, the VA should not be expected to function primarily as a clinical development organization or assume responsibility for conducting the regulatory-grade clinical trials needed to establish the safety and efficacy of investigational products for FDA approval.

The FDA is responsible for independently evaluating the safety and efficacy of new therapies and determining whether the evidence supports approval. Pharmaceutical sponsors should remain responsible for developing their products and generating the evidence necessary to meet FDA's regulatory standards. The VA can and should contribute to this process through research partnerships and studies that address questions particularly relevant to veterans, but this role should complement—not replace—the broader clinical development and regulatory review process.

There is an important distinction between conducting trials to establish whether a drug works and preparing a healthcare system to deliver an approved treatment safely and effectively. For the VA, the priority should be the latter. This means investing in trained personnel, clinical sites, pharmacy and controlled-substance infrastructure, treatment protocols, referral pathways, and the systems needed to monitor outcomes and manage risks. It also means ensuring that veterans can access appropriate treatments once they are approved, rather than allowing gaps in infrastructure or workforce capacity to create additional delays.

Conclusion

The VA has a unique opportunity to generate valuable evidence about how these treatments perform in veteran populations, and the most effective ways to address the

needs of its diversely located veteran population. Such experience will also contribute to reaching the broader population across the United States. The VA has already initiated research on treating veterans with psychedelic assisted therapies. By accelerating this, the VA's findings and experience may contribute to FDA evaluations of new therapies that may occur in 2027 and beyond and thereby contribute to potential approval as well as the labeling, and risk management approaches to ensure safe use. Post approval data collection for these treatments will further contribute to the potential improvement of how these therapies are administered to optimize effectiveness and safety over years to come.

Such efforts can help identify which veterans benefit, how outcomes vary across populations, and how treatments can be delivered most effectively within the VA healthcare system. These are important contributions that build on the VA's strengths and directly support its mission.

The VA may also decide to collaborate in the development of new therapies as does the National Institutes of Health and academic institutions, working with pharmaceutical developers. However, my colleagues and I see the major goal of the VA to serve veterans and active-duty personnel to provide veterans with safe, evidence-based access to effective treatments for the disorders they may develop over time including those that result in part because of their service to our nation. Research should support that mission—not displace it.

Thank you for this opportunity to submit testimony.

Disclosure:

As an employee of Pinney Associates, I provide scientific and regulatory consulting on a broad range of central nervous system-active substances and drug products, including psychedelic substances and new chemical entities, including psilocybin, MDMA, and ibogaine.