Leith J. States, MD, MPH, MBA, FACPM
Founder and Principal, States Strategies, LLC
Former Acting Assistant Secretary for Health, U.S. Department of Health and Human Services

House Committee on Veterans' Affairs
Subcommittee on Health

Psychedelic-Assisted Therapies for Veterans: The Path Forward

November 18, 2026

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

I. INTRODUCTION AND SUMMARY OF RECOMMENDATIONS

Thank you for the opportunity to testify. I am a preventive medicine physician, a former Navy Medical Corps Officer, and a combat veteran. As a Battalion Surgeon, I had the privilege of deploying alongside the Marines and Sailors of 1st Battalion, 1st Marines, in support of Operation Enduring Freedom.

From October 2018 through September 2025, I served in senior roles at the U.S. Department of Health and Human Services (HHS), including as Acting Assistant Secretary for Health. My responsibilities included policy and program development, and interagency coordination. That work included coordinating federal efforts on emerging therapeutics, including psychedelic-assisted therapies, beginning early in the previous administration and continuing into the early months of the current administration.

I also bring a personal perspective as a veteran receiving all my health care through the Veterans Health Administration (VHA). My experience caring for service members and coordinating federal health policy informs my recommendations, but so does knowing what it means to depend on VHA for my own care. That experience keeps me attentive to the trust veterans place in this system and the difference its decisions make in their daily lives.

I ask Congress to take three actions.

1. Support research that answers the clinical questions veterans and clinicians face. Prioritize safety, effectiveness, durability, and the care needed to sustain improvement, including in veterans with complex clinical needs.

2. Require VA to establish and report milestones for clinical readiness and access. Support staffing, training, referral, and coordinated care through VA's existing clinical services. Funding research cannot substitute for preparing to deliver treatment.

3. Hold VA accountable for patient safety and lasting improvement in veterans' lives. Ask VA to track who receives treatment, who remains unable to access it, whether benefits persist, and what harms occur. Require VA to explain how those findings inform clinical practice and decisions about expanding care safely and responsibly.

II. VETERANS' NEEDS MUST GUIDE TREATMENT AND ACCESS

Serving alongside Marines and Corpsmen, I learned how much people will carry for those who depend on them. That sense of responsibility does not end when we come home. It can keep us going, but it can also keep us silent. We tell ourselves we can manage, that others have it worse, that asking for help can wait. I heard those words from people I served alongside. Eventually, I heard them in my own voice. By the time a veteran asks for help, they may have spent years finding reasons not to. Our response must be worthy of the trust that request represents.

Veterans come to care with different histories, needs, and goals. Their experiences include combat, military sexual trauma, injury, loss, and challenges that may have begun before service or developed afterward. They deserve care that responds to those circumstances.

For many, the goals are recognizable and deeply personal (e.g., sleeping through the night, being present with their children, returning to work, rebuilding a relationship, or feeling able to participate in their community). Those goals should guide how we evaluate treatment. Symptom improvement matters. So do functioning, relationships, safety, and whether improvement lasts.

Veterans need a range of behavioral health treatments, including care for substance use disorders. Medicines, psychotherapy, and other established interventions each have a place. Emerging therapies should expand the options available to veterans and complement the care they already receive.

Existing treatments help many veterans, but important needs remain unmet. In a large VA study, prolonged exposure and cognitive processing therapy both improved symptoms of post-traumatic stress disorder (PTSD), yet roughly half of participants left treatment before completing it. Leaving early does not necessarily mean treatment failed, but it underscores the need for care that veterans can engage in and complete.[1]

Our obligation is to strengthen effective care today while investigating approaches that may help those who continue to struggle.

III. THE EVIDENCE SUPPORTS PREPARATION AND CONTINUED EVALUATION

General Mattis offers three questions that guide his approach to sharing information. "What do I know? Who needs to know? Have I told them?"

Those questions help explain my responsibility as a witness today. Members need a clear account of what the research supports, what remains uncertain, and what decisions follow from that distinction.

For this discussion, the most relevant clinical evidence concerns 3,4-methylenedioxymethamphetamine (MDMA)-assisted therapy for PTSD and psilocybin-assisted therapy for major depressive disorder (MDD), and treatment-resistant depression (TRD). TRD describes depression that has not responded adequately to prior treatment, commonly at least two adequate courses of antidepressant medication.

That treatment history matters when interpreting results and considering which veterans might benefit. The psilocybin evidence includes studies in broader MDD populations and studies specifically enrolling people with TRD. To understand what these findings mean for veterans, we must consider who participated in each study, what treatment they received, and which condition each drug application seeks approval to treat.

A. Clinical trials demonstrate benefit in selected patients.

A 2023 randomized phase 3 trial involving 104 participants with moderate to severe PTSD compared MDMA with placebo, with both groups receiving the study's therapy protocol. Among participants assessed at the study endpoint, approximately 71 percent in the MDMA group and 48 percent in the placebo group no longer met diagnostic criteria for PTSD, a difference of about 23 percentage points. Functioning also improved more in the MDMA group. These findings demonstrate benefit beyond that observed with the therapy protocol and placebo, although difficulty concealing treatment assignment complicates interpretation.[2]

For TRD, a 2022 randomized trial enrolled 233 adults whose current depression had not responded to two to four adequate treatment trials. All received psychological support. At three weeks, depression scores improved more with 25 milligrams of psilocybin than with the 1-milligram control dose. Approximately 29 percent in the 25-milligram group met remission criteria, compared with 8 percent in the control group. Those remission figures were secondary outcomes, and the findings did not establish a clear advantage in sustained response through 12 weeks.[3]

For MDD, a Usona-sponsored phase 2 trial published in 2023 enrolled 104 adults and compared a single 25-milligram dose of psilocybin with niacin, an active placebo. Both groups received psychological support. Participants receiving psilocybin showed greater improvement in depressive symptoms and daily functioning through six weeks. Approximately 42 percent met criteria for sustained response, compared with 11 percent in the niacin group. This secondary outcome reflected a reduction in depression scores of at least half at successive assessments, rather than remission. Adverse events were more frequent with psilocybin, and the six-week study did not establish longer-term durability.[4]

More recently, Compass Pathways reported that two phase 3 trials of its psilocybin formulation for TRD met their primary endpoints at six weeks. These findings build on the earlier trial results, although they remain sponsor-reported and should be considered separately from peer-reviewed analyses and FDA's independent assessment of benefits and risks.[5]

B. Broader effectiveness, safety, and durability remain unresolved.

The percentages above describe different outcomes in different populations. They should not be used to rank the treatments against one another. These studies provide important evidence of potential benefit, but they do not establish how well these treatments will work across the diverse population of veterans receiving VA care.

Important questions remain about which patients benefit, who may deteriorate, how long improvement lasts, when additional treatment is needed, and how outcomes change with coexisting conditions or complex medication histories. We also need to understand how much benefit depends on the accompanying care and whether ordinary clinical services can reproduce the outcomes achieved by research teams.

VA clinical trials can help establish safety and effectiveness in veterans, while implementation research can identify how to deliver treatments within VA clinical services when supported by sufficient evidence and appropriate regulatory authorization. Quality improvement efforts can then use routine care data to refine delivery and follow-up. These efforts should build on the broader evidence, with each compound evaluated for the specific condition being treated and the care protocol used. For ibogaine, any

consideration of broader clinical implementation must depend on adequate evidence of safety and effectiveness and an appropriate regulatory pathway.

The case for action is that meaningful benefit has been demonstrated and important needs remain unmet. The responsibility that follows is to prepare for appropriate access while continuing to resolve uncertainty about safety, durability, and delivery.

C. Regulatory progress requires concrete clinical readiness milestones.

Compass Pathways has announced completion of its New Drug Application (NDA) to FDA for an investigational psilocybin formulation for the treatment of TRD. Public reporting also indicates that Usona has submitted an NDA for an investigational psilocybin formulation for the treatment of MDD and that Resilient has resubmitted its NDA for MDMA assisted therapy for PTSD. These submissions make VA preparation for potential approval more pressing. FDA must assess each application independently and, if approved, determine the indication, labeling, and required safeguards.[6-8]

Urgency should be matched by disciplined execution. Sponsors are responsible for complete and reliable evidence, appropriate monitoring, and timely responses to regulatory concerns. Congress can help address identifiable barriers and seek clear accountability across agencies while respecting FDA responsibility to assess each application on its merits.

This Subcommittee has already pressed VA on its readiness to deliver these treatments. As applications advance, that oversight should focus on concrete milestones: what preparation VA has completed, what remains dependent on FDA decisions, and what clinical teams need to move forward.

VA can identify responsible clinical teams, assess staffing and training needs, and plan referral and follow-up processes while regulatory review proceeds. Final delivery protocols must reflect the approved indication and any FDA-required safeguards, including a Risk Evaluation and Mitigation Strategy (REMS), if required. Uncertainty about review timelines should inform the pace of preparation without becoming a reason to defer it.

Our responsibility is to reduce the avoidable distance between an appropriate regulatory decision and a veteran's ability to receive responsible, safe, and ethical care.

D. Biological findings inform care design but do not establish clinical benefit.

Studies in animal models, alongside early research in humans, are testing whether these treatments can open a window in which the brain becomes more receptive to learning from experience.

Neuroplasticity refers to the nervous system's capacity to change its structure and function. Studies have found that psychedelic compounds can promote changes in connections between neurons, including persistent changes in dendritic spines after exposure to psilocybin in mice.[9,10]

Metaplasticity changes how readily neural circuits respond to later experience by adjusting their capacity for further plasticity.[11] A critical period is a window during which experiences have a stronger influence on those circuits. Work led by neuroscientist Dr. Gül Dölen examines whether these compounds can reopen such windows in adulthood. A 2023 study compared reopening of a critical period for social reward learning in adult mice across several compounds, including ibogaine. The findings showed different time courses, summarized below.[12]

Compound	Social reward learning window observed in adult mice
Ketamine	Open at 48 hours, closed by one week
Psilocybin	Open at two weeks, closed by three weeks
MDMA	Approximately two weeks
Lysergic acid diethylamide (LSD)	Open at three weeks, closed by four weeks
Ibogaine	Still open at four weeks; closure was not established

These are observations at tested intervals, not exact biological deadlines. Related experiments supported a metaplastic mechanism involving responsiveness to oxytocin in reward circuitry.

Dölen and Makenzie Wilkinson's 2026 review places these findings within a broader framework connecting critical periods, metaplasticity, and remodeling of the extracellular matrix, the material surrounding and supporting cells. It advances a learning-based explanation for why the effects of these treatments may depend on subsequent experience and context.[12]

For this Committee, the distinction matters. The duration of an acute drug experience, the duration of a potential learning window, and the duration of clinical benefit are separate questions. The mouse findings do not establish corresponding treatment windows in people, and a longer window does not establish that a compound is safer or more effective.

Ibogaine's comparatively prolonged effect in this model is a reason to investigate its mechanisms and clinical implications carefully. It does not establish superior outcomes for veterans.

The practical research question is what care should accompany a potential window of increased receptivity. We need to determine whether the timing, content, and continuity of therapeutic support influence benefit, and whether different compounds require different approaches.

This gives preparation before treatment and integration afterward a clear scientific purpose. Integration helps patients make sense of the treatment experience and apply what they learn in daily life. If a treatment creates an opportunity for learning, the therapeutic support and experiences that follow may shape its effects. Research should test how preparation and integration can support durable recovery while protecting patients from harm.

IV. TOUGH MINDS AND TENDER HEARTS MUST GUIDE RESPONSIBLE, SAFE, AND ETHICAL CARE

In the opening chapter of Strength to Love, Dr. King calls us to cultivate "a tough mind and a tender heart." Drawing on Matthew 10:16, he joins rigorous thinking with compassion, asking us to think critically while remaining sensitive to the suffering and humanity of others.[13] I have returned to this teaching in my own writing and in how I think about medicine and public service. For me, it means examining systems critically, investigating problems with curiosity, and remaining open to challenge

while maintaining empathy for the people those systems serve. Without that heart, our expertise loses its purpose.

Applied here, a tough mind examines promising findings carefully and asks what would change our conclusions. A tender heart keeps us attentive to the veteran seeking relief and the family sharing that burden. Together, they call us to be honest about what treatment can offer and responsible for the full course of care.

Before treatment a veteran should understand the expected benefits, possible harms, alternatives, and remaining uncertainties. Clinical teams need appropriate screening, training, supervision, and plans for responding to medical or psychological complications. Professional boundaries must be clear, and patients need a safe way to raise concerns.

After treatment, responsibility continues. Someone must be available to assess deterioration, help the veteran make sense of the experience, and coordinate subsequent care. The veteran returns to a life that includes relationships, responsibilities, and other health needs. An emerging treatment should fit within that life and within the broader continuum of behavioral health care. Existing clinicians and therapeutic relationships can be essential sources of continuity.

A paper I coauthored on research and implementation within the VHA addresses the work needed to connect scientific progress with the practical requirements of care.[14] That work deserves sustained attention. The treatment experience and the system supporting it must be considered together.

V. CONGRESS SHOULD ADVANCE THREE COMPLEMENTARY PRIORITIES

A. Support research that resolves the clinical questions that matter to veterans.

Congress should support research that identifies who benefits, who may be harmed, how long improvement lasts, and what care sustains it so clinicians and veterans can make informed treatment decisions. Studies should measure changes in functioning and quality of life alongside symptoms and determine how the drug, psychological support, and other elements of treatment contribute to outcomes.

The evidence must become more representative of the veterans who will seek care. Veterans with coexisting conditions and complex medication histories need deliberate consideration as studies develop. As evidence permits, later-stage studies, including appropriately designed open-label phase 3 studies, can broaden eligibility, and examine treatment in more clinically complex populations. Open-label design alone does not accomplish that goal. Eligibility criteria and clinical support must address who can participate safely.

Independent assessment, transparent safety reporting, and publication of unfavorable findings remain essential. Research has served its purpose when it improves a decision, including a decision to modify or stop an approach.

A stronger research portfolio is necessary, but it cannot substitute for a strategy to provide care.

B. Require a practical path to treatment through existing clinical services.

For a veteran who remains seriously ill despite treatment, progress must mean more than another study opening. Congress should ask VA to account for the options available to that veteran today and the steps needed to make additional treatments accessible as evidence and regulatory decisions permit.

Expanded access, sometimes called compassionate use, and the federal Right to Try law can help individual patients, but they are distinct mechanisms and neither guarantees treatment. Access depends on a willing supplier, eligible patients, qualified clinicians, resources, and compliance with applicable requirements. For Schedule I substances, additional controlled-substance requirements also apply. These pathways may offer valuable opportunities, but their administrative demands and dependence on sponsor participation limit their reliability as a broad access strategy. Their contribution should be measured by the patients they actually reach.[15,16]

The broader task of VA is to build dependable clinical capacity by designating the teams that will deliver treatment, planning how veterans will enter and move through care, and setting deadlines for completing that preparation. Teams can begin this work now in anticipation of FDA approval and finalize treatment protocols once the approved uses and required safeguards are established. A staged approach allows sites to establish readiness, learn from experience, and expand when justified. “Crawl, walk, run” should describe purposeful progress, with clear expectations at each stage.

Congress should support VA’s preparation and delivery of care through its existing authorities, clinical programs, and funding mechanisms. Congress should fund this work through VA’s clinical services budget, directing resources to the teams delivering care rather than increasing funding for the Office of Research and Development. The priority is to equip the teams responsible for veterans’ care with protected staff time, training, clinical support, and coordination across sites. Using existing programs keeps resources close to the people delivering care and maintains clear responsibility for patient safety and outcomes.

Clinical teams should have structured opportunities to share practices, review complications, and identify differences in outcomes. Knowledge gained at one site should help others improve, and emerging treatments should remain connected to the broader continuum of behavioral health care.

Practical access must be part of that preparation. Veterans may need transportation, time away from work, support for caregiving responsibilities, or coordination between distant specialists and local clinicians. Planning should address the needs of rural and geographically isolated veterans, veterans living in U.S. territories, veterans from Tribal communities, and other underserved veteran populations. Veterans can safely participate in and benefit from treatment only when both the clinical service and the practical support needed to use it are in place.

C. Hold VA accountable for patient safety and lasting improvement in veterans’ lives.

Accountability should follow the veteran from seeking care through treatment and beyond. Congress should ask VA to report who receives treatment, who remains unable to access it, whether benefits persist, and what harms occur. VA should explain how these findings inform clinical practice and decisions about expanding care.

We should assess both how patients fare after treatment and whether veterans with unmet needs can obtain it. Strong outcomes among a small group of treated patients can coexist with substantial barriers for everyone else. Understanding who remains unable to obtain care, and why, is therefore essential.

VA should track symptoms, functioning, adverse events, treatment completion, durability, and the need for additional care, with veterans and caregivers helping define meaningful improvement. When outcomes differ across sites or groups of veterans, clinical teams should investigate why and use those findings to improve practice, strengthen training, and guide the pace of expansion.

VA should also measure costs and staffing requirements, test claims of future savings, and assess how introducing these treatments affects access to established services. Expansion should strengthen the broader continuum of care and equip clinical teams to sustain it. Success ultimately means that veterans can reach appropriate treatment and experience lasting improvements in the lives they hope to regain, including their relationships, daily functioning, and participation in their communities.

VI. CONCLUSION: DO OUR DUTY AND EARN VETERANS' TRUST

My mentor, retired Lieutenant General Martin Steele, often recalls the words Staff Sergeant Karl Taylor spoke to him on the day of his commissioning, "Lieutenant, do your duty." Taylor later died saving fellow Marines in Vietnam and received the Medal of Honor posthumously. That guidance became a touchstone for Steele, shaping his character, guiding his decisions, and defining how he leads and serves others. That lesson has shaped my own understanding of duty and the responsibility I bring before this Subcommittee today.

Doing our duty means investigating promising treatments with urgency and discipline, speaking plainly about what we know, and preparing the people and systems needed to deliver responsible, safe, and ethical care. Veterans' needs should determine our priorities as we build on useful work across administrations, examine shortcomings honestly, and sustain the progress clinicians and researchers need to improve care. Congress, VA, HHS, researchers, clinicians, and veterans have distinct responsibilities. Each must fulfill them, communicate clearly, and remain accountable for what happens in veterans' lives after treatment.

The veteran who asks for help is placing trust in all of us. We earn that trust by supporting sound research, making appropriate care reachable, and measuring success through lasting improvement in the lives veterans hope to regain. Thank you for the opportunity to contribute to this work.

References

1. Schnurr PP, Chard KM, Ruzek JI, et al. Comparison of prolonged exposure vs cognitive processing therapy for treatment of posttraumatic stress disorder among US veterans: a randomized clinical trial. JAMA Netw Open. 2022. Source

2. Mitchell JM, Ot'alora G M, van der Kolk B, et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. Nat Med. 2023;29:2473–2480. Source

3. Goodwin GM, Aaronson ST, Alvarez O, et al. Single-dose psilocybin for a treatment-resistant episode of major depression. N Engl J Med. 2022;387:1637–1648. doi:10.1056/NEJMoa2206443 Source

4. Raison CL, Sanacora G, Woolley J, et al. Single-dose psilocybin treatment for major depressive disorder: a randomized clinical trial. *JAMA.* 2023;330(9):843–853. doi:10.1001/jama.2023.14530.

5. Compass Pathways. Compass Pathways successfully achieves primary endpoint in second phase 3 trial evaluating COMP360 psilocybin for treatment-resistant depression. Published February 17, 2026. Sponsor-reported results.

6. Compass Pathways. Compass Pathways completes COMP360 psilocybin new drug application to U.S. FDA for treatment-resistant depression. Business Wire. Published November 9, 2026. Source

7. Hardman J, Smith N. Usona files psilocybin for depression NDA as race with Compass tightens. Psychedelic Alpha. Published November 2, 2026. Reported submission, based on unnamed sources; Usona declined comment. Source

8. Multidisciplinary Association for Psychedelic Studies. MAPS responds to report of progress for MDMA-assisted therapy for PTSD with FDA. Published August 10, 2026. Statement responding to reporting of Resilient's NDA resubmission. Source

9. Ly C, Greb AC, Cameron LP, et al. Psychedelics promote structural and functional neural plasticity. Cell Rep. 2018;23:3170–3182. Source

10. Shao LX, Liao C, Gregg I, et al. Psilocybin induces rapid and persistent growth of dendritic spines in frontal cortex in vivo. Neuron. 2021. Source

11. Nardou R, Sawyer E, Song YJ, et al. Psychedelics reopen the social reward learning critical period. Nature. 2023. doi:10.1038/s41586-023-06204-3 Source

12. Dölen G, Wilkinson ML. The emerging neurobiology of psychedelics: critical periods, metaplasticity, and extracellular matrix remodeling. Annu Rev Neurosci. 2026;49:495–515. doi:10.1146/annurev-neuro-112723-045129 Source

13. King ML Jr. Strength to Love. Harper & Row; 1963.

14. Wolfgang AS, McClair VL, Schnurr PP, et al. Research and implementation of psychedelic- assisted therapy in the Veterans Health Administration. Am J Psychiatry. Published online December 30, 2024. Source

15. US Food and Drug Administration. Expanded access; expanded access: information for patients. Overview; Patient information

16. Federal Right to Try Act, Pub L No. 115–176 (2018). Approved May 30, 2018. Public law. See also: US Food and Drug Administration. Right to try. FDA explanation