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DEPARTMENT OF VETERANS AFFAIRS  
BEFORE THE  
COMMITTEE ON VETERANS' AFFAIRS  
U.S. HOUSE OF REPRESENTATIVES**

**"EMERGING THERAPIES: BREAKTHROUGHS IN THE BATTLE AGAINST  
SUICIDE?"**

**OCTOBER 19, 2023**

Good afternoon, Chairwoman Miller-Meeks, Ranking Member Brownley and distinguished Members of the Subcommittee. Thank you for the opportunity today to discuss ongoing clinical trials within the Department of Veterans Affairs (VA) involving emerging therapies, and specifically, psychedelic assisted therapy and immersive technology, like virtual reality that supplements treatment Veteran treatment. Accompanying me today is Dr. Ilse Wiechers, Deputy Executive Director, Office of Mental Health and Suicide Prevention and Dr. Rachel Yehuda, Patient Care Center Director.

**VA Psychedelic Research for Post-Traumatic Stress Disorder**

VA is committed to studying interventions that promote the health of the Nation's Veterans. In line with this goal, VA conducts studies under stringent protocols at various facilities Nation-wide to identify if compounds such as MDMA (3,4-Methylenedioxy-methamphetamine) and psilocybin in combination with intensive psychotherapy are efficacious in treating Veterans with post-traumatic stress disorder (PTSD), treatment resistant depressive disorder, major depressive disorder and potentially other mental health conditions, such as substance use disorders. VA also continually monitors ongoing psychedelic research outside VA. Based on our assessment of the literature to date, there is still much to learn, and much yet to be understood, about the potential benefits of psychedelic compounds. Our Department is not only focused on finding the best innovative treatments and cures but doing so safely.

While there are several research studies on the use of psychedelic-assisted therapy for the treatment of mental health conditions being conducted at VA facilities, they are funded by outside organizations, not by VA. Medical research with these substances takes place legally through a specific process that involves review of the study protocol by the Food and Drug Administration (FDA) and obtaining a research registration from the Drug Enforcement Administration (DEA). VA complies with all applicable laws in obtaining and using psychedelics in its research studies. While ORD's intramural research program is not currently funding research in this area, the office is closely following the growing research literature and is working with OMHSP determine whether additional studies of psychedelics for Veterans are warranted.

Safety comes first in all of the clinical research conducted within VA. Investigational treatments are delivered in a safe clinical environment using pharmaceutical grade medications under careful quality controls. Potential research participants undergo careful medical and psychiatric screening to make sure it is safe for them to participate. Finally, dosing of psychedelic medication is supported by staff trained in psychedelic-assisted therapy who are knowledgeable to monitor for adverse events and follow clear protocols for using psychotherapy in combination with psychedelic medication.

### *Psychedelic State of the Art Conference*

ORD and OMHSP co-hosted a “State of the Art (SOTA) Conference: Psychedelic Treatments for Mental Health Conditions” in September 2023, to help address two major objectives. The first objective was to better understand the current state of scientific evidence and to identify a strategic framework to consider future psychedelic treatment research for select mental health conditions. The second objective was to determine the necessary next steps for potential VA system-wide clinical implementation for psychedelic compounds for potential future use.

The Psychedelic SOTA Conference took place in two parts. The SOTA virtual seminar occurred September 6-8, 2023, and included speakers from industry, non-VA academia and Veterans’ advocacy groups, as well as attendance from Congressional stakeholders and Federal agencies participating in the SOTA Workshop. These seminars provided a summary of the available data on MDMA and psilocybin, information about current studies, and stakeholder perspectives, as background for the SOTA Workshop discussions. The SOTA Workshop occurred September 27-28, 2023, in Denver, Colorado. Seventy-two (72) participants included key internal VA stakeholders, clinicians, and psychedelic researchers along with representatives from key partner Federal agencies (such as the National Institutes of Health, FDA, Department of Defense (DOD), Substance Abuse and Mental Health Services Administration, and the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Health). SOTA Workshop attendees were broken into four workgroups for intensive discussion and deliberation on four key areas of strategic planning: Pre-Clinical Research, Clinical Research, Clinical Practice Logistics and Implementation, and System Wide Clinical Decision-Making and Scale. The workgroups provided recommendations for future research directions and potential clinical implementation considerations.

### **Research Regarding Therapeutic Potential MDMA for PTSD treatment**

Two phase 3 trials<sup>1</sup> of MDMA treatment for PTSD have shown statistically significant reductions in PTSD symptoms, with the publication of the second trial just

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<sup>1</sup> [MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study | Nature Medicine](#) Mitchell JM et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med. 2021 Jun 27(6):1025-1033.

occurring last month. In that most recently published trial, 87 percent of subjects who received MDMA vs. 69 percent of subjects who received a placebo had a clinically meaningful response. The Bronx VA Medical Center was a recruiting site for both of these trials. Although each study is different, all current psychedelic studies within VA are paired with non-drug treatments (that is, psychotherapy). These treatment protocols involve intensive psychotherapy with at least one licensed clinician. Two clinicians were required for MDMA sessions in the Phase 3 trials cited here: [MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study | Nature Medicine. Based on a recent review of the literature](#), VA and the Department of Defense (DoD) determined the current evidence regarding MDMA as a treatment was insufficient to be included as a recommended treatment in the updated VA/DoD Clinical Practice Guidelines (CPG) for the Management of PTSD and Acute Stress Disorder (ASD); released in June 2023). VA/DoD CPGs follow a rigorous process of reviewing the quality of evidence, the balance of risks and potential benefits, and the feasibility of implementing interventions for PTSD and ASD across health care systems. Primary concerns with the MDMA-assisted psychotherapy data included the small number of Veterans in the trials that had been published (32 Veterans included), and a relatively small number of total participants (176 overall), as well as the use of inactive placebo as a comparison condition. The use of inactive placebo has allowed participants to correctly guess what treatment they received, which can bias results significantly and is a particular problem for a novel treatment with anecdotal support (leading to increased expectation of benefit for the participant). The two studies both used inactive placebos.

One of the key gaps in research identified at the SOTA was the need for more trials conducted with Veterans, specifically with the unique and diverse population of Veterans who receive care through VHA. The issue of needing more rigorous study (such as one that uses an active comparator rather than placebo) in VA patients is important because studies conducted in our population typically show smaller effects than studies conducted outside of VA.

### **VA Immersive: Virtual Reality for Physical and Mental Well-Being**

VA is leveraging immersive technology to test a non-pharmaceutical approach to help Veterans address the day-to-day challenges related to physical and mental well-being. VA recognizes that immersive technology—like virtual reality (VR) and augmented reality (AR)—has the ability to transform care delivery and experience, and VA is focused on efforts to expand its application and evidence-based implementation. Immersive technology leverages the senses of sight, sound and touch to bring a new level of engagement and sense of presence to each Veteran’s health care experience. Immersive technology also expands the footprint of the health care system, increasing access by offering Veterans opportunities to receive care at medical care facilities and from the comfort of their home. This technology, when used to supplement care provides a more immersive, engaging experience than traditional telehealth or care by creating more enjoyable therapeutic environments, gamifying the approach, or by transporting the patient to environments otherwise difficult to access in the presence of

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a clinician. Additionally, it can also provide a means for standardized assessment and metric completion in-device to be shared with the clinician decreasing interrater variability in some instances and allowing VA to better capture Veteran impact. One example of this effort is the potential implementation of VR to aid chronic pain management. Multiple VR-based programs are being evaluated, which have received preliminary approval, and are now being evaluated for higher level approval. One of the VR-based programs is being co-developed with VA and another FDA-authorized treatment for chronic low back pain. Given that experiencing pain is a significant risk factor for suicide among Veterans, this is being pursued as part of VA suicide prevention efforts.

Eliminating Veteran suicide is a top VA priority, and we continue to work diligently across the Department and with Federal, tribal, state and local governments to advance a public health approach to suicide prevention. The VA suicide prevention strategy is guided by the National Strategy for Preventing Veteran Suicide 2018-2028 and is in alignment with the President's 2021 National Strategy for Reducing Military and Veteran Suicide. Part of VA's suicide prevention strategy is to fund innovation through demonstration and special projects to inform promising and best practices with measurable outcomes. Projects are prioritized for their ability to reach specific high-risk/vulnerable Veteran populations. Results from these projects inform potential wider dissemination and implementation of interventions. VA has a robust process in evaluation of these projects. Proposed demonstration project proposals must be time limited (typically 1-2 fiscal years), provide specific background justification including literature review, provide clear and measurable outcomes to evaluate return on investment, include an implementation and evaluation plan, must be aligned with national internal and external suicide prevention strategies and provide a detailed budget for each fiscal year (FY). The project must be used to pilot potential long-term solutions to improve outcomes for Veteran wellness and suicide prevention.

Innovative projects are critical to advance suicide prevention with regards to complex risks associated with suicide, such as pain. Recent data indicates that about 9% of Americans who have died by suicide had chronic pain. Furthermore, people with moderate or severe pain are three times more likely to have suicidal ideation, and two to three times more likely to die by suicide than people without pain. Emerging research exists regarding the use of VR to treat a variety of physical and mental health conditions.<sup>2</sup> Ongoing study is needed. Systematic reviews and meta-analysis studies evaluating the evidence for VR-based treatment of acute and chronic pain management and PTSD have returned mixed evidence for treatment and indicate the need for more

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<sup>2</sup> Baker, N. A., Polhemus, A. H., Ospina, E. H., Feller, H., Zenni, M., Deacon, M., DeGrado, G., Basnet, S., & Driscoll, M. (2022). The state of science in the use of virtual reality in the treatment of acute and chronic pain: A systematic scoping review. *Clinical Journal of Pain*, 38(6), 424-41. <https://doi.org/10.1097/AJP.0000000000001029>;

Cieslik, B., Mazurek, J., Rutkowski, S., Kiper, P., Turolla, A., & Szczepanska-Gieracha, J. (2020). Virtual reality in psychiatric disorders: A systematic review of reviews. *Complementary Therapies in Medicine*, 52, 102480. <https://doi.org/10.1016/j.ctim.2020.102480>;

Dellazizzo, L., Potvin, S., Luigi, M., & Dumais, A. (2020). Evidence on virtual reality-based therapies for psychiatric disorders: Meta-review of meta-analyses. *Journal of Medical Internet Research*, 22(8), e20889. <https://doi.org/10.2196/20889>;

research in this area (Langener et al., 2021; Wu et al., 2022; Baker et al., 2022; Knaust et al., 2022).

OMHSP and the Office of Health Care Innovation and Learning partnered at the beginning of FY 2023 to develop a pilot program that addresses intersections of suicide as it relates to pain. Specifically, VA established a 60-site pilot that has deployed 300 VR headsets to mental health and non-mental health providers to VAs across the country. This pilot leverages software that is being evaluated for use as a tool to help clinical care teams address chronic pain and or suicidality. This pilot also includes utilization of positive environments to distract from negative stressors and to build positive coping mechanisms and resilience related to chronic pain and mental health diagnoses like development of VR applications to support breathing exercises, sequential muscle relaxation, or other evidence-based complimentary modalities. In addition, it includes co-development of multiple in-vivo exposure environments, like a restaurant or grocery store, to supplement treatment for trauma-related triggers or phobias as Veterans transition into civilian life. This will include data collected regarding ease of use and experience in addition to patient reported outcomes for pain, anxiety, suicidality, pain interference, depression and mood. As of October 2023, over 450 VR sessions have been completed with over 200 unique Veterans being served through this pilot.

## **Conclusion**

When it comes to improving veteran mental health, VA will continue to fully implement the current evidence-based interventions we know works to move forward treatment of mental health concerns, while we simultaneously encourage ongoing innovation paired with strong program evaluation and research to assess for new effective interventions. Our Department is not only focused on finding the best innovative treatments and cures but doing so safely. We appreciate the Committee's continued support in this shared mission. Nothing is more important to VA than supporting the health and well-being of the Nation's Veterans and their families. My colleagues and I are prepared to respond to any questions you may have.