



Testimony

RAJEEV RAMCHAND

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Strengthening the Evidence Base for and Considering Barriers to Psychedelic-Assisted Therapies

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Improving Treatment Outcomes for Veterans with Mental Health Conditions: Strengthening the Evidence Base for and Considering Barriers to Psychedelic-Assisted Therapies

Testimony of Rajeev Ramchand¹
The RAND Corporation²

Before the Committee on Veterans Affairs
Subcommittee on Health
United States House of Representatives

November 14, 2023

Chairwoman Miller-Meeks, Ranking Member Brownley, and members of the subcommittee, thank you for your invitation to testify today. My name is Dr. Rajeev Ramchand. I am a senior policy researcher at the nonprofit, nonpartisan RAND Corporation. I am an epidemiologist, and my research focuses on improving the mental health of service members and veterans, as well as their families and caregivers. My comments today are based on research conducted within the RAND Drug Policy Research Center and the RAND Epstein Family Veterans Policy Research Institute, where I serve as codirector. I would be remiss not to acknowledge a friend and veteran, Dylan Tete, and a family member, Michael Pollack, who long before it was “in vogue” encouraged me to consider the potential role of psychedelic compounds for assisting those with mental health conditions.

My colleagues on the panel will discuss the potential therapeutic benefits that psychedelics hold for helping veterans with posttraumatic stress disorder (PTSD) and other mental health conditions. My comments will focus on two adjacent yet critical areas for policymakers to consider as we learn more about the benefits and risks associated with these treatments.

¹ The opinions and conclusions expressed in this testimony are the author’s alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

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First, we have a tremendous amount to learn about the potential therapeutic benefits of psychedelic treatment. I will argue that continued federal investment in research and improving scientists' access to psychedelic drugs for research studies are critical for discovering treatment options that reach more veterans and yield greater reductions in their mental health symptoms.

Second, we should be having more conversations like the one we are having here today to develop sound policy solutions that surmount potential barriers to veterans' ability to access psychedelic treatments if and when they become available. In my testimony, I will focus on three components to access that we should be preparing for: (1) how the cost of psychedelic treatment will affect access, (2) whether the U.S. Department of Veterans Affairs (VA) should provide psychedelic treatment directly or outsource such care, and (3) what kinds of safety rails are needed to ensure that veterans receive the highest-quality care.

Research Funding Is Needed to Identify New Treatment Options to Reach More Veterans and Produce Greater Improvements

Let me be clear: There are good treatments currently available for veterans with mental health conditions like PTSD. At the top of that list are prolonged exposure therapy, cognitive processing therapy, and eye movement desensitization and reprocessing, often referred to as EMDR. VA prioritizes these three treatments in its clinical practice guidelines because rigorous research has demonstrated that these treatments yield the best outcomes to date.³ Prioritizing evidence-based treatments may, in part, explain why the clinical quality of mental health care provided in VA is often better than non-VA care.⁴

This does not mean, however, that we should not invest in new, promising treatments. The psychotherapies with the strongest evidence behind them work, but they do not work for everyone. In even the most stringent of experimental settings, between 18 and 30 percent of patients drop out of these three treatments,⁵ and dropout rates may be higher among veterans.⁶ Around one-quarter to one-third of veterans with PTSD who receive these treatments do not

³ U.S. Department of Veterans Affairs and U.S. Department of Defense, *VA/DoD Clinical Practice Guideline for Management of Posttraumatic Stress Disorder and Acute Stress Disorder*, U.S. Government Printing Office, 2023.

⁴ Eric A. Apaydin, Neil M. Paige, Meron M. Begashaw, Jody Larkin, Isomi M. Miake-Lye, and Paul G. Shekelle, "Veterans Health Administration (VA) vs. Non-VA Healthcare Quality: A Systematic Review," *Journal of General Internal Medicine*, Vol. 38, No. 9, July 2023; Claire O'Hanlon, Christina Huang, Elizabeth Sloss, Rebecca Anhang Price, Peter Hussey, Carrie Farmer, and Courtney Gidengil, "Comparing VA and Non-VA Quality of Care: A Systematic Review," *Journal of General Internal Medicine*, Vol. 32, No. 1, January 2017; Amal N. Trivedi, Sierra Matula, Isomi Miake-Lye, Peter A. Glassman, Paul Shekelle, and Steven Asch, "Systematic Review: Comparison of the Quality of Medical Care in Veterans Affairs and Non-Veterans Affairs Settings," *Medical Care*, Vol. 49, No. 1, January 2011.

⁵ Catrin Lewis, Neil P. Roberts, Samuel Gibson, and Jonathan I. Bisson, "Dropout from Psychological Therapies for Post-Traumatic Stress Disorder (PTSD) in Adults: Systemic Review and Meta-Analysis," *European Journal of Psychotraumatology*, Vol. 11, No. 1, 2020.

⁶ Paula P. Schnurr, Kathleen M. Chard, Josef I. Ruzek, Bruce K. Chow, Patricia A. Resick, Edna B. Foa, Brian P. Marx, Matthew J. Friedman, Michelle J. Bovin, Kristina L. Caudle, et al., "Comparison of Prolonged Exposure vs Cognitive Processing Therapy for Treatment of Posttraumatic Stress Disorder Among US Veterans: A Randomized Clinical Trial," *JAMA Network Open*, Vol. 5, No. 1, January 2022.

respond to them, and more than half retain a diagnosis of PTSD even after they complete treatment.⁷

This evidence points to a pressing need for treatments that work for more veterans and that yield better outcomes. Psychedelics are part of the menu of options that may help us reach this potential. They are among a suite of options that are being studied to improve mental health conditions. These options include improved care delivery models (for example, massed treatments that offer therapy sessions more frequently than once per week or that encompass peer support specialists or virtual therapy⁸), new types of psychotherapies (for example, written exposure therapy⁹), novel clinical procedures (for example, stellate ganglion block¹⁰), and other pharmacotherapies (for example, ketamine or riluzole¹¹).

Researchers should not only investigate these treatments in isolation but should consider how they can complement each other to achieve treatment success. Different regimens should be tested under experimental conditions using advances in statistical methods, such as sequential, multiple assignment, randomized trials.¹² These designs replicate real-world conditions and provide mental health practitioners with evidence-based guidance on substituting, augmenting, or complementing one treatment with another. It is critical that providers are empowered with evidence like this to guide the care decisions they are required to make rather than relying on their intuition to make ad hoc decisions on a case-by-case basis.

Continued federal investment in research is necessary to discover treatments that work for more veterans and that yield better outcomes. This includes adequate funding to entities like the National Institute of Mental Health, the National Institute on Drug Abuse, VA, the Department

⁷ Schnurr et al., 2022.

⁸ Alan L. Peterson, Tabatha H. Blount, Edna B. Foa, Lily A. Brown, Carmen P. McLean, Jim Mintz, Richard P. Schobitz, Bryann R. DeBeer, Joseph Mignogna, Brooke A. Fina, et al., “Massed vs Intensive Outpatient Prolonged Exposure for Combat-Related Posttraumatic Stress Disorder: A Randomized Clinical Trial,” *JAMA Network Open*, Vol. 6, No. 1, January 2023; Melba A. Hernandez-Tejada, Wendy Muzzy, Matthew Price, Stephanie Hamski, Stephanie Hart, Edna Foa, and Ron Acierno, “Peer Support During In Vivo Exposure Homework to Reverse Attrition from Prolonged Exposure Therapy for Posttraumatic Stress Disorder (PTSD): Description of a Randomized Controlled Trial,” *Trials*, Vol. 21, 2020.

⁹ Denise M. Sloan, Brian P. Marx, Ronald Acierno, Michael Messina, and Travis A. Cole, “Comparing Written Exposure Therapy to Prolonged Exposure for the Treatment of PTSD in a Veteran Sample: A Non-Inferiority Randomized Design,” *Contemporary Clinical Trials Communications*, Vol. 22, June 2021.

¹⁰ Kristine L. Rae Olmsted, Michael Bartoszek, Sean Mulvaney, Brian McLean, Ali Turabi, Ryan Young, Eugene Kim, Russ Vandermaas-Peeler, Jessica Kelley Morgan, Octav Constantinescu, et al., “Effect of Stellate Ganglion Block Treatment on Posttraumatic Stress Disorder Symptoms: A Randomized Clinical Trial,” *JAMA Psychiatry*, Vol. 77, No. 2, February 2020.

¹¹ Adriana Feder, Sara Costi, Sarah B. Rutter, Abigail B. Collins, Usha Govindarajulu, Manish K. Jha, Sarah R. Horn, Marin Kautz, Morgan Corniquel, Katherine A. Collins, et al., “A Randomized Controlled Trial of Repeated Ketamine Administration for Chronic Posttraumatic Stress Disorder,” *American Journal of Psychiatry*, Vol. 178, No. 2, February 2021; Patricia T. Spangler, James C. West, Catherine L. Dempsey, Kyle Possemato, Danielle Bartolanzo, Pablo Aliaga, Carlos Zarate, Jr., Meena Vythilingam, and David M. Benedek, “Randomized Controlled Trial of Riluzole Augmentation for Posttraumatic Stress Disorder: Efficacy of a Glutamatergic Modulator for Antidepressant-Resistant Symptoms,” *Journal of Clinical Psychiatry*, Vol. 81, No. 6, 2020.

¹² Kelley M. Kidwell and Daniel Almirall, “Sequential, Multiple Assignment, Randomized Trial Designs,” *JAMA*, Vol. 329, No. 4, January 24/31, 2023.

of Defense, the Congressionally Directed Medical Research Programs, the Agency for Healthcare Research and Quality, and the Patient-Centered Outcomes Research Institute. Research funding for mental health conditions has historically fallen short of the estimated burden attributed to them.¹³ Arguably, the need for treatments has never been greater: Rates of depression and anxiety were increasing even before the coronavirus disease 2019 pandemic,¹⁴ and the United States continues to confront both suicide and overdose crises.¹⁵ Federal investment in treatment for conditions, such as PTSD, that disproportionately affect veterans is even more important because, in many cases, these conditions are attributed directly to traumas experienced in service to the nation.¹⁶ It is also necessary because private funding for novel therapies for mental health conditions is waning.¹⁷ This may be partly because many of the more promising natural psychedelic molecules have been around long enough that some question if they have any patent or profit potential.¹⁸

In addition to investing in research, Congress can expedite this research by making the process for conducting research on psychedelic compounds more efficient. Many of the most promising psychedelic compounds, including MDMA and psilocybin, are classified as Schedule I drugs, requiring researchers to register with the Drug Enforcement Administration for permission to use them and comply with the necessary security regulations. As Director of the National Institute on Drug Abuse Dr. Nora Volkow recently testified, these steps are notoriously time-consuming, confusing, and expensive for researchers,¹⁹ resulting in delays in the evidence we need to maximize the benefits these treatments may offer. In 2021, the White House proposed provisions to facilitate research on Schedule I drugs;²⁰ provisions like these would

¹³ Daniel Arias, Shekhar Saxena, and Stéphane Verguet, “Quantifying the Global Burden of Mental Disorders and Their Economic Value,” *The Lancet*, Vol. 54, December 2022.

¹⁴ A. H. Weinberger, M. Gbedemah, A. M. Martinez, D. Nash, S. Galea, and R. D. Goodwin, “Trends in Depression Prevalence in the USA from 2005 to 2015: Widening Disparities in Vulnerable Groups,” *Psychological Medicine*, Vol. 48, No. 8, June 2018; Renee D. Goodwin, Andrea H. Weinberger, June H. Kim, Melody Wu, and Sandro Galea, “Trends in Anxiety Among Adults in the United States, 2008–2018: Rapid Increases Among Young Adults,” *Journal of Psychiatric Research*, Vol. 130, November 2020.

¹⁵ Mark Olfson, Rajeev Ramchand, and Michael Schoenbaum, “Tempering Optimism Concerning the Recent Decline in US Suicide Deaths,” *JAMA Psychiatry*, Vol. 79, No. 6, June 2022; Centers for Disease Control and Prevention, “Understanding Drug Overdoses and Deaths,” webpage, May 8, 2023, <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

¹⁶ Rajeev Ramchand, Rena Rudavsky, Sean Grant, Terri Tanielian, and Lisa Jaycox, “Prevalence of, Risk Factors for, and Consequences of Posttraumatic Stress Disorder and Other Mental Health Problems in Military Populations Deployed to Iraq and Afghanistan,” *Current Psychiatry Reports*, Vol. 17, No. 5, May 2015.

¹⁷ Joshua R. Wortzel, Brandon E. Turner, Brannon T. Weeks, Christopher Fragassi, Virginia Ramos, Thanh Truong, Desiree Li, Omar Sahak, and Hochang Benjamin Lee, “Trends in Mental Health Clinical Research: Characterizing the ClinicalTrials.gov Registry from 2007–2018,” *PLOS One*, Vol. 15, No. 6, 2020.

¹⁸ Sara Reardon, “What’s Next for MDMA in Psychiatry?” *Nature*, Vol. 616, April 20, 2023b.

¹⁹ Nora D. Volkow, “The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances,” testimony before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, National Institute on Drug Abuse, December 2, 2021.

²⁰ White House, “Biden-Harris Administration Provides Recommendations to Congress on Reducing Illicit Fentanyl-Related Substances,” press release, September 2, 2021.

expedite research into psychedelic-assisted therapy and help get novel treatments to veterans struggling with debilitating mental health conditions.

Policy Solutions Are Needed to Address Potential Barriers to Veterans' Ability to Access Psychedelic Treatments If and When They Become Available

Currently, the psychedelic drug closest to receiving approval from the U.S. Food and Drug Administration (FDA) is MDMA, for the treatment of PTSD, so I will focus my comments on access to this treatment. The most recent Phase 3 MDMA treatment protocol entails 15 or more clinical visits over three to four months,²¹ three of which include taking MDMA. The sessions without receiving MDMA are around 90 minutes each. The three visits with MDMA are six to eight hours each and often include an overnight stay. Each of the sessions is led by a psychotherapy pair that includes at least one licensed provider; in addition, one person at the site must be licensed to manage and administer controlled substances.²² Except for the three sessions in which MDMA is administered, the treatment protocol is comparable in treatment duration and session length to that of current evidence-based treatments for PTSD, including prolonged exposure,²³ cognitive processing,²⁴ and EMDR.²⁵

If granted FDA approval, MDMA will have federally recognized medical value. Such recognition presents tremendous opportunities for veterans with PTSD to benefit from this care. But how will they get it? Veterans access mental health treatment from VA or from non-VA community-based providers. It can be paid for by VA, other public or private insurance, philanthropic sources, or veterans themselves. A veteran's eligibility, preferences, and resources dictate where they get care and how they pay for it. This means that U.S. policies need to consider and address all these potential care pathways. And across all care pathways, these policies should consider issues of cost, availability, and quality.

²¹ There were 15 psychotherapy sessions in the most recent Phase 3 clinical trial (Jennifer M. Mitchell, Marcela Ot'olora G., Bessel van der Kolk, Scott Shannon, Michael Bogenschutz, Yevgeniy Gelfand, Casey Paleos, Christopher R. Nicholas, Sylvestre Quevedo, Brooke Balliett, et al., "MDMA-Assisted Therapy for Moderate to Severe PTSD: A Randomized, Placebo-Controlled Phase 3 Trial," *Nature Medicine*, September 14, 2023). The Multidisciplinary Association for Psychedelic Studies (MAPS) website also says that there are 15 sessions (Multidisciplinary Association for Psychedelic Studies, "MDMA-Assisted Therapy for PTSD," webpage, undated, <https://maps.org/mdma/ptsd/>). However, a MAPS consent form for participation in the clinical trial indicates 17 visits (Multidisciplinary Association for Psychedelic Studies, subject information and consent form for study titled "A Test of MDMA-Assisted Psychotherapy in Subjects with Chronic Posttraumatic Stress Disorder (PTSD)," undated, https://maps.org/research-archive/mdma/protocol/ic_070705.html).

²² Mitchell et al., 2023.

²³ National Center for PTSD, "Prolonged Exposure (PE) for PTSD," webpage, U.S. Department of Veterans Affairs, undated, https://www.ptsd.va.gov/understand_tx/prolonged_exposure.asp.

²⁴ National Center for PTSD, "Cognitive Processing Therapy (CPT) for PTSD," webpage, U.S. Department of Veterans Affairs, undated, https://www.ptsd.va.gov/understand_tx/cognitive_processing.asp.

²⁵ National Center for PTSD, "Eye Movement Desensitization and Reprocessing (EMDR) for PTSD," webpage, U.S. Department of Veterans Affairs, undated, https://www.ptsd.va.gov/understand_tx/emdr.asp.

Cost

Cost-effectiveness analyses from 2022 estimate that MDMA-assisted psychotherapy will initially cost at least \$11,500 per patient.²⁶ Relative to the costs that untreated PTSD symptoms pose to individuals and society at large, it is a cost-effective treatment.²⁷

Nonetheless, cost may be a barrier to VA's ability to offer psychedelic-assisted therapy to veterans. The estimated cost is substantially greater than the costs of other psychotherapies that VA currently offers to treat PTSD.²⁸ VA is explicitly permitted to consider cost in making decisions in what it covers and has historically had a more restrictive formulary than other health care organizations.²⁹ On the other hand, VA has begun to make breakthrough treatments more readily available to veterans. For example, in March 2023, VA made available to veterans with Alzheimer's the newly FDA-approved lecanemab, which has an annual list price of \$26,500.³⁰ VA made this decision at a time when the Centers for Medicare and Medicaid Services (CMS) had provided limited coverage for the drug to its Medicare beneficiaries.³¹ (Since then, CMS has expanded eligibility with criteria comparable to VA criteria).³²

Market forces will determine what community-based providers will charge for MDMA-assisted therapy. Price will be determined by at least three conditions: first, the size of the market, which will be guided by state policies that typically dictate licensure and other requirements; second, whether and how much insurers, including VA Community Care and CMS, will pay for this treatment; and third, demand for care that is not restricted to veterans (Approximately 5 percent of American adults have PTSD in a given year.³³). In Oregon, where it is now legal for adults to purchase supervised psychedelic psilocybin services from state-licensed providers, but where these services are not yet covered by insurance, some clinics are charging between \$2,000 and \$3,400 for a six-hour guided psychedelic session that occurs after two

²⁶ Elliot Marseille, Jennifer M. Mitchell, and James G. Kahn, "Updated Cost-Effectiveness of MDMA-Assisted Therapy for the Treatment of Posttraumatic Stress Disorder in the United States: Findings from a Phase 3 Trial," *PLOS One*, Vol. 17, No. 2, 2022.

²⁷ Marseille, Mitchell, and Kahn, 2022.

²⁸ Quang A. Le, Jason N. Doctor, Lori A. Zoellner, and Norah C. Feeny, "Cost-Effectiveness of Prolonged Exposure Therapy Versus Pharmacotherapy and Treatment Choice in Posttraumatic Stress Disorder (the Optimizing PTSD Treatment Trial): A Doubly Randomized Preference Trial," *Journal of Clinical Psychiatry*, Vol. 75, No. 3, March 2014; Ifigeneia Mavranzouli, Odette Megnin-Viggars, Nick Grey, Gita Bhutani, Jonathan Leach, Caitlin Daly, Sofia Dias, Nicky J. Welton, Cornelius Katona, Sharif El-Leithy, et al., "Cost-Effectiveness of Psychological Treatments for Post-Traumatic Stress Disorder in Adults," *PLOS One*, Vol. 15, No. 4, 2020.

²⁹ Milena Sullivan and Ekemini Isaiah, "The VA National Formulary for Top Medical Benefit Drugs Is Narrower Than Current Medicare Part B Drug Coverage," *Avalere*, August 13, 2019.

³⁰ Joshua Cohen, "VA Will Cover Alzheimer's Disease Drug Lecanemab, Provided a Detailed Set of Inclusion and Exclusion Criteria Are Met," *Forbes*, March 15, 2023.

³¹ Cohen, 2023.

³² Centers for Medicare and Medicaid Services, "Statement: Broader Medicare Coverage of Leqembi Available Following FDA Traditional Approval," press release, July 6, 2023.

³³ Simon B. Goldberg, Tracy L. Simpson, Keren Lehavot, Jodie G. Katon, Jessica A. Chen, Joseph E. Glass, Paula P. Schnurr, Nina A. Sayer, and John C. Fortney, "Mental Health Treatment Delay: A Comparison Among Civilians and Veterans of Different Service Eras," *Psychiatric Services*, Vol. 70, No. 5, May 2019.

preparatory sessions and one integration session.³⁴ In Australia, where MDMA-assisted therapy recently became available, estimates range from \$10,000 to \$30,000 per patient.³⁵ These harbingers suggest that MDMA-assisted therapy, when offered in the community, will not be cheap—especially in the early years. Cost will likely be a barrier for veterans who want care outside VA’s walls, disproportionately affecting those who have historically faced the greatest cost barriers: those living in poverty, those who are unmarried, and racial and ethnic minorities.³⁶

It is critical to ensure that cost is not a barrier to veterans’ ability to access MDMA-assisted therapy, not only to meet veterans’ preferences for care but also to ensure veterans’ safety. Access barriers to MDMA-assisted therapy in controlled settings may push some veterans to access the drug in illegal markets, where a dose or pill might cost between \$10 and \$50 but there is less control over the drug’s quality and the dose or pill could include adulterants, such as methamphetamine.³⁷ Like all drugs, use of MDMA has also been linked with potential side effects that, if the drug is taken in an unsupervised session, may go unnoticed and untreated and result in severe and even fatal outcomes. And, as discussed later, drugs procured in illegal markets are unlikely to be administered alongside psychotherapy, which many argue is critical for achieving improvements in PTSD symptoms.

Availability

With respect to health care access, the concept of *availability* describes whether health systems have the workforce and resources to provide timely, geographically convenient care that meets patients’ needs. When it comes to VA, a fundamental issue will be whether VA has the workforce and resources to provide MDMA-assisted therapies within its existing behavioral health infrastructure or whether it will be better to pay for this care through the existing Community Care Network or through new partnerships with private-sector or nonprofit providers.

If it offers MDMA-assisted treatment within its own system, VA will need to establish guidance to determine which types of providers should deliver this treatment and what training and certification will be required. The most recent Phase 3 MDMA trial includes a psychotherapy pair that includes one licensed provider, and VA will need to decide whether it too will require a paired approach and, if so, the types of pairs who will provide the care. Amid a

³⁴ EPIC Healing Eugene, homepage, undated, <https://www.epichealingeugene.com/>; Polly Thompson, “It Costs Up to \$3,400 to Experience Magic Mushrooms at the First Legal Psilocybin Center—and Thousands Want to Take a Trip,” *Insider*, September 16, 2023.

³⁵ Gary Nunn, “MDMA: Australia Begins World-First Psychedelic Therapy,” *BBC News*, June 30, 2023.

³⁶ Danielle Kilchenstein, Jim E. Banta, Jisoo Oh, and Albin Grohar, “Cost Barriers to Health Services in U.S. Adults Before and After the Implementation of the Affordable Care Act,” *Cureus*, Vol. 14, No. 2, February 4, 2022.

³⁷ Ariana Eunjung Cha, “Real-Time Testing of Drugs at Music Festivals Shows ‘Molly’ Often Isn’t ‘Molly,’” *Washington Post*, July 11, 2017; Nina Golgowski, “What Is ‘Molly’? Illegal Drug MDMA Sees Rise in Popularity on Street and in Songs,” *Daily News*, last updated January 10, 2019; Jeff Saunders, “Ecstasy Pills Valued at Nearly \$1.35 Million Seized in Portage County Traffic Stop,” *Yahoo! News*, February 6, 2023. The *New York Times* reports that fentanyl has not yet been detected in MDMA, but public health organizations warn that it may be present in pills from illegitimate sources (Rachel Nuwer, MDMA Is One of the Safer Illegal Drugs. But There Are Risks,” *New York Times*, August 18, 2023; APLA Health, “Fentanyl,” webpage, undated, <https://aplahealth.org/fentanyl/>).

national mental health workforce shortage,³⁸ it may need to expand its cadre of mental health professionals to meet veteran demand for psychedelic-assisted therapy. VA has done this in the past: In 2010, it began hiring licensed professional mental health counselors and marriage and family therapists to help meet veterans' demand for timely mental health care.³⁹ Training programs in psychedelic therapy are burgeoning across the country and could provide one avenue for expanding the mental health workforce, but VA will need to consider the merits of these programs, as they have varying eligibility requirements.⁴⁰ In Oregon, for example, licensed psilocybin guides are required to have a high school degree or an equivalent and up to 200 hours of training from an approved program.⁴¹

VA will also need to adapt its scheduling processes to incorporate a new protocol that will require three eight-hour sessions supervised by two providers and potentially an overnight stay. VA has had to flex to accommodate treatments that might better suit veterans' preferences in the past,⁴² and it could do so again. But it may face challenges meeting expectations to provide care to veterans in a timely manner, given recent and ongoing difficulties meeting existing demand for mental health care. Meeting these expectations will require balancing demand for psychedelic-assisted therapy while ensuring that timely care is still available for other veterans who want or need other types of therapies.

Given these logistical hurdles, the government may conclude that relying on community-based partners to provide MDMA-assisted therapy makes intuitive sense. There are, however, at least four hurdles with VA outsourcing this care. First, the market may become volatile: VA employed an outsourcing model to provide ketamine infusion therapy for treatment-resistant depression,⁴³ but less than a year later, a chain it partnered with closed, leaving veterans who had been receiving the treatment in peril.⁴⁴ Second, there is no evidence that care provided in the community will be more readily available to veterans than care provided in VA. Although the expansion of community-based care for veterans originated from a demand for more-timely care, the VA is the only health care system in the United States that publicly reports appointment wait times; thus, whether expanded community care offerings have reduced veteran wait times

³⁸ Nathaniel Counts, "Understanding the U.S. Behavioral Health Workforce Shortage," Commonwealth Fund, May 18, 2023.

³⁹ U.S. Government Accountability Office, *Veterans Health Care: Efforts to Hire Licensed Professional Mental Health Counselors and Marriage and Family Therapists*, GAO-22-104696, March 2022.

⁴⁰ Danica Jefferies, "Psychedelic Therapies Are on the Horizon, but Who Will Administer the Drugs?" NBC News, December 26, 2022.

⁴¹ Oregon Health Authority, "Oregon Psilocybin Services - Training Programs with Approved Curriculum," webpage, undated, <https://www.oregon.gov/oha/ph/preventionwellness/pages/psilocybin-training-programs-approved-curriculum.aspx>.

⁴² Cynthia Yamokoski, Heather Flores, Vanessa Facemire, Kelly Maieritsch, Sara Perez, and Ashley Fedynic, "Feasibility of an Intensive Outpatient Treatment Program for Posttraumatic Stress Disorder Within the Veterans Health Care Administration," *Psychological Services*, Vol. 20, No. 3, August 2023.

⁴³ Rachel Nostrant, "VA Community Clinics Expand Ketamine Treatment Options for Depression," *MilitaryTimes*, September 29, 2022.

⁴⁴ Melissa Chan, "Abrupt Closure of Ketamine Clinic Chain Blindsides Veterans and Others with Severe Depression and Chronic Pain," NBC News, updated March 24, 2023.

remains an open question.⁴⁵ Furthermore, licensing and credentialing providers for MDMA-assisted therapy will vary by state, and cost of this care will depend on regional market forces. These factors may require VA to establish and monitor multiple contracts to accommodate state-level variation in the cost and regulation of this care.

Quality

As with any care provided to U.S. veterans, the government has an obligation to ensure that the care is safe and of high quality. Some of the points I have already raised relate also to quality of care. For example, it will be critical to ensure that providers who deliver and oversee administration of psychedelic treatment are adequately trained and have met all licensing requirements established across states. However, it will be equally critical to determine which veterans will be eligible for treatment based on individual medical history, what treatment protocol will be required, and how quality of care will be monitored.

Not all veterans may have immediate access to psychedelic-assisted therapies. For example, the Phase 3 trial for MDMA-assisted therapy excluded those with some comorbid mental health conditions, those who were acutely suicidal, those with a recent history of ecstasy use, and those with unmanaged cardiovascular conditions.⁴⁶ Given the treatment's projected cost and intensity, VA and others paying for care may consider whether the treatment should be eligible to any veteran with PTSD or to only those who have tried and not benefited from another evidence-based treatment. However, if veterans are required to have undergone past treatment and are prescribed one or more psychiatric medications, these drugs may need to be discontinued before psychedelic-assisted therapy is commenced, as they were for participants in the Phase 3 trial.⁴⁷ This process needs to be monitored closely, as withdrawal symptoms from even common antidepressants can be severe and persist for long periods of time.⁴⁸

MDMA-assisted treatment for PTSD occurs in the context of a course of psychotherapy treatment, which is deemed a critical component of the treatment by the Multidisciplinary Association for Psychedelic Studies and by providers and veterans who have been part of clinical trials.⁴⁹ However, the FDA typically does not regulate psychotherapy,⁵⁰ leaving monitoring to such entities as VA, states, or other insurers. If VA were to provide MDMA-assisted treatment, it would need to decide how closely it would adhere to the FDA-approved protocol and how, in

⁴⁵ Carrie M. Farmer, "Wait Times for Veterans Scheduling Health Care Appointments: Challenges with Available Data on the Timeliness and Quality of VA Community Care," testimony before the U.S. Senate Committee on Veterans' Affairs, RAND Corporation, CT-A2291-1, September 21, 2022, <https://www.rand.org/pubs/testimonies/CTA2291-1.html>.

⁴⁶ Mitchell et al., 2023.

⁴⁷ Mitchell et al., 2023.

⁴⁸ James Davies and John Read, "A Systematic Review into the Incidence, Severity and Duration of Antidepressant Withdrawal Effects: Are Guidelines Evidence-Based?" *Addictive Behaviors*, Vol. 97, October 2019.

⁴⁹ Sara Reardon, "US Could Soon Approve MDMA Therapy—Opening an Era of Psychedelic Medicine," *Nature*, April 19, 2023a; Hans Petersen, "Exploring Psychedelics for the Treatment of Veterans," VA News, September 26, 2023.

⁵⁰ Reardon, 2023a.

practice, it would monitor providers' adherence to this protocol. VA currently does not have a process for monitoring quality of care that it pays for and that is delivered in the community, creating yet another hurdle to outsourcing psychedelic-assisted therapy in a newly emerging marketplace.

Finally, whether or not VA decides to provide and/or cover psychedelic-assisted therapy, a marketplace is already forming, and we should expect it to grow. Increasing numbers of states and municipalities are making psychedelic therapies available to residents, including veterans, in the communities they govern. Services will be targeted to veterans, and veterans will be curious about these treatments. VA should provide guidance to prepare its providers to talk to their patients, who may be considering accessing this treatment outside of VA, like they did in 2017 for marijuana-assisted therapy.⁵¹ In addition, VA should encourage veterans to speak with their providers about their interest in these treatments without fear of losing VA benefits.

Conclusion

Mental health conditions, such as PTSD, can be debilitating and cost the United States hundreds of billions of dollars each year.⁵² Although existing treatments are good, the U.S. government can improve the way it cares for individuals with PTSD, including veterans, whose conditions often arise from their service to the country. Psychedelic-assisted therapies hold great promise, but their full benefits will be realized only with continued investment in research, improvements in access to these compounds for research purposes, and careful planning for how this care can be offered to ensure that all veterans who need and want these treatments can benefit from them. Ensuring veterans' equitable access to psychedelic-assisted therapies will require attention to the potential barriers that I have outlined today: addressing psychedelic treatment costs, determining where and how psychedelic treatment is made available to veterans, and ensuring that veterans who receive this treatment do so safely.

⁵¹ Bryce Pardo, Beau Kilmer, Rajeev Ramchand, and Carrie M. Farmer, *Psychedelics and Veterans' Mental Health*, RAND Corporation, PE-A1363-6, December 2022, <https://www.rand.org/pubs/perspectives/PEA1363-6.html>; U.S. Department of Veterans Affairs, "VHA Publications: Directives," webpage, last updated October 6, 2023, <https://www.va.gov/vhapublications/publications.cfm?pub=1>.

⁵² Lori L. Davis, Jeff Schein, Martin Cloutier, Patrick Gagnon-Sanschagrin, Jessica Maitland, Annette Urganus, Annie Guerin, Patrick Lefebvre, and Christy R. Houle, "The Economic Burden of Posttraumatic Stress Disorder in the United States from a Societal Perspective," *Journal of Clinical Psychiatry*, Vol. 83, No. 3, May–June 2022.