

The VA Is Quietly Fast-Tracking MDMA Therapy for Veterans

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A member of the Air Force climbs a ladder during training. Photo: U.S. Department of Defense. The appearance of U.S. Department of Defense (DoD) visual information does not imply or constitute DoD endorsement.

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By Mattha Busby, originally published by $\underline{\text{The Intercept}}$ with funding from A-Mark Foundation.

Veterans of U.S. wars with post-traumatic stress disorder may soon be able to undergo MDMA-assisted therapy through their health care plans. The Department of Veterans Affairs is working on making the care possible ahead of the potential Food and Drug Administration approval of the drug, commonly known as ecstasy, for therapeutic uses.

The Veterans Health Administration, the largest integrated health care system in the U.S., with more than 150 medical centers, recently launched an internal "Psychedelic Charter" to devise a comprehensive strategy for the deployment of FDA-approved psychedelic treatments for mental health disorders, according to a document reviewed by The Intercept and two sources with knowledge of the plan who asked for anonymity.

In March, the VA <u>opened</u> a center in Portland, Oregon, to stage a group MDMA trial for veterans, one of 13 psychedelic studies <u>it is funding</u>. Ketamine-assisted therapy and esketamine treatments have also <u>recently</u> been rolled out to a few dozen centers.

The moves on psychedelic mental heath therapy from the VA comes amid a growing veterans' suicide crisis. The U.S. saw an average of 18 veteran suicides a day in 2021, more than 70 percent higher than national rates, according to a recent Government Accountability Office report. Some estimates hold that the number is as high as 40 former service members taking their own lives per day. The VA dispenses \$18 billion a year on disability compensation to 1 million veterans with PTSD, with the runaway costs straining the department's budget.

Many are struggling on their current treatments, and the VA has faced criticisms for only taking significant steps now, with approval of psychedelic therapies on the horizon.

"It's a relief to now see VA leadership stepping up with some important proactive measures to help those who are struggling and in need of new tools," said Brett Waters, the executive director of advocacy group Reason for Hope, which pushes for the public policy changes to allow wider access to psychedelic therapies.

The document circulated within the VA outlines the responsibilities of the "Psychedelic Medicine Integrated Project Team," including regular tasks for the team like advising the VA Under Secretary for Health Shereef Elnahal. The team "will provide strategic direction for the deployment of psychedelic medicine for mental health treatment in VHA," says the internal paper, which was reviewed by The Intercept. (The VA declined to comment.)

An FDA advisory committee will meet on June 4 for a public hearing as part of the fast-tracked path toward potential approval of MDMA-assisted therapy for PTSD, reportedly to review a potential new treatment for the chronic condition for the first time in 25 years.

Pressure on the VA

On May 10, Elnahal, the VA under secretary, told a psychedelic conference in New York that there is an "unstoppable narrative" in support of legalizing psychedelic medicine. The VA, he said, must be prepared for the "overwhelming demand" upon the approval of MDMA-assisted therapy, which could come as soon as August.

 $"The \, reason \, l'm \, here \, is \, that \, the \, data \, and \, results, \, the \, stories \, that \, l \, have \, heard \, from \, veterans \, who \, have \, gone \, through \, these \, studies, \, descriptions and \, results \, and \, resul$

these therapies, speak for themselves," Elnahal <u>said</u>. "The evidence-based therapies that we have, while they help, pale in comparison if we are able to replicate the scale seen in the preliminary results we have seen in psychedelics, especially MDMA for PTSD, and increasingly psilocybin for treatment-resistant depression."

"We're proving the case that the federal government is no longer unwilling to engage with this. It took some work to get there," he said. "But we're there."

The plan from the VA follows pressure to act from <u>Congress</u> and the <u>American Legion</u> National Executive Committee, a veterans organization. In a letter to Elnahal on April 23, nine members of Congress <u>wrote</u>, "We're concerned that if VA is not prepared to implement emerging psychedelic-assisted therapies when they become available, veterans will be left to navigate providers outside VA who may not have the specialized expertise in addressing their unique needs and the relevant military context of their trauma."

A VA insider echoed those concerns, even while welcoming a potentially "monumental shift" in attitude toward medical treatment with scheduled drugs. "There is simply no way that the VA will be anywhere near ready, even on a small scale, to begin building meaningful infrastructure within the next couple of months," said the VA official, who asked for anonymity because they weren't authorized to speak publicly. "I worry that we won't be able to meet the needs of veterans — with so many struggling with unmet needs and ineffective treatments in a timely fashion."

In June 2022, a letter on behalf of the Health and Human Services secretary said President Joe Biden's administration anticipated the approval of MDMA-assisted therapy within two years. The letter said that the potential of psychedelic-assisted therapies "must be explored" to address the twin mental health and drug misuse crisis, which kill thousands every week.

Since then, the FDA has received further advanced trial data showing the efficacy of MDMA-assisted therapy in <u>significantly</u> reducing PTSD symptoms. The regulator will rule on whether the evidence is sufficient to grant approval in August. The FDA blessing would be a landmark moment for the psychedelics movement, and it would help provide safer settings for psychedelic therapies — with hundreds of veterans going abroad each year to unregulated centers.

"Implementing these treatments in the VA will be no easy task, but is necessary to ensure those who selflessly served our country can receive the best available care," said retired Lt. Gen. Martin Steele, the president of the Veteran Mental Health Leadership Coalition. "I hope the VA continues to proceed thoughtfully and with the urgency that the moment requires."

"As a multi-generation survivor of suicide loss," said Waters, of Reasons for Hope, whose mother died by suicide in 2018, "I empathize with the many veterans who have been wondering why it's taking the federal government so long to take even small common-sense steps like funding research into breakthrough therapies for PTSD and depression."

There are concerns that the advanced-stage trial data for MDMA-assisted therapy only studied the effects of the drug on less than 1,000 people, and a recent report <u>suggested</u> that there remained "uncertainty" about the treatment. Scrutiny of the Multidisciplinary Association for Psychedelic Studies, or MAPS, which was behind the MDMA studies, is also <u>growing</u>. There is also likely to be criticism of the rollout of MDMA therapy to veterans from some psychedelic therapy advocates, who <u>question</u> the focus on former soldiers getting first access to fully-funded legal psychedelic treatments.

MAPS founder Rick Doblin welcomed the move but lamented how he first spoke to the VA about the benefits of MDMA-assisted therapy back in 1995 — almost three decades ago. "Just think of all the veteran suicides that happened in that period of time," he said. "Now the VA is trying to become a leader, and they deserve enormous support for that. The next big question is when will the Department of Defense adopt [in-house MDMA-assisted therapy]?"

Dr. Aaron Wolfgang, an army psychiatrist and service chief at Walter Reed National Military Medical Center — who in 2019 was the first in the Defense Department official to be trained to provide MDMA-assisted therapy, albeit in a personal capacity — expressed hope that the Pentagon would follow suit.

"It looks like the DoD is closely behind in terms of just monitoring the landscape and hopefully preparing where we can be," he said. On the use of psychedelic therapy for active duty personnel, he said, "There's no guarantee that this might even be appropriate for active duty folks. It's critically important for us to do the studies to clarify these open questions."

The data, he said, show that MDMA-assisted the rapy for PTSD could be "in a class of its own in terms of potential efficacy."

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