

Wounded Warrior Project

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May 23, 2024

Psychopharmacologic Drug Advisory Committee
c/o Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

**RE: Docket No. FDA-2024-N-1938
Psychopharmacologic Drugs Advisory Committee; Notice of Meeting;
Establishment of a Public Docket; Request for Comments – midomafetamine
(MDMA) capsules**

Dear Psychopharmacologic Drug Advisory Committee Members,

On behalf of Wounded Warrior Project (WWP), thank you for the opportunity to provide public comments related to new drug application 215455 (Lykos Therapeutics’ submission for MDMA capsules for the treatment of post-traumatic stress disorder (PTSD)), the overall benefit-risk profile of MDMA, and the potential public health impact of the proposed treatment modality. Our perspective is informed by over 20 years of direct service to wounded, ill, and injured veterans and Service members who served on or after September 11, 2001.

Wounded Warrior Project was founded in 2003 with a mission to honor and empower wounded warriors. Today we serve more than 200,000 warriors and offer more than a dozen direct service programs spanning mental, physical, and financial health and wellness to create a 360-degree model of care and support. This holistic approach empowers warriors to create a life worth living and helps them build resilience, coping skills, and connection to peers.

The depth and scale of our programming has matured alongside those we serve, and today our largest programming investments are in mental health. Approximately 3 in 4 warriors (76%) responding to our 2022 Annual Warrior Survey warriors self-reported PTSD. Those reporting PTSD often had moderate to severe symptoms (48.2% of men and 50.7% of women) and were less likely to have physical or mental health quality of life scores above the median of the general U.S. population. The results suggest that PTSD has a negative impact on WWP warriors’ quality of life. These results are consistent with other studies with post-9/11 veterans, highlighting the associations between mental and physical health on a veteran’s well-being.ⁱ

Unfortunately, these trends are not unique to the post-9/11 veteran community but have been felt across the wider veteran community. Regardless of the era they served, our veterans deserve access to the highest quality, cutting-edge, and evidence-based treatment. Several

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effective treatments for PTSD are available. Cognitive processing therapy, prolonged exposure, and eye movement desensitization and reprocessing (EMDR) are among the most widely deployed evidence-based treatments. While effective for many, others – particularly veterans – can struggle to commit to a full course of treatment. Some veteran patients view prescription medications skeptically due to a range of factors including side effects, dependency concerns, and perceived ineffectiveness.

Emerging treatment modalities for PTSD, such as psychedelic assisted therapies, have the potential to advance PTSD treatment from a “one-size fits all approach” – which has been proven to not be effective for all – to an individualized model of care where the treatment plan is tailored to needs of each unique veteran and augmented based on symptomology and responsiveness to treatment. MDMA-assisted psychotherapy for PTSD in particular has shown great promise in multiple studies and is safe when used in clinical trials.

Although the recent announcement from the Department of Veterans Affairs (VA) to fund MDMA assisted therapy research is unquestionably positive, the field still has fundamental questions to answer. Based on multiple factors like veteran demand, provider availability, and cost, the Veterans Health Administration (VHA) will not be able to provide care to all who seek MDMA assisted therapy for all who seek it after FDA approval. While several VA locations are primed to provide this modality of treatment on a limited basis as potential psychedelic treatment centers, we know the need for treatment has the potential to overwhelm the system, further straining capacity. As such, we are committed to helping advance further research to help identify

Our work to date is best illustrated by our work with community partners. We are actively funding innovative research into cutting edge treatments for veterans through WWP’s Warrior Care Network. As an example, we have funded an Emory Healthcare Veterans Program study MDMA in combination with exposure therapy (PE) for veterans with PTSD, contributing to and expanding our understanding of the therapeutic potential of MDMA in the context of veteran mental health. WWP will continue to urge investment in further research. Studies to help determine clinical indications for appropriateness of MDMA-assisted therapy versus existing evidence-based PTSD treatment would help organizations like ours educate and guide veterans toward care. We should also strive to understand how to best incorporate MDMA-assisted therapy into the culture care delivery model and how to scale treatment to meet large numbers of veterans who need PTSD treatment. The long-term impact of MDMA-assisted therapy and the need for tailored follow-on care are also natural areas to explore.

Finally, we stress the need to work with the manufacturing community, clinical providers, and the Veteran Service Organization community to ensure that veterans have access to clear and reliable information as other “psychedelic” drugs and therapies come to the treatment market. While we have discussed MDMA here, dozens of companies are developing drugs using psilocybin, LSD, ibogaine, and other substances and are progressing through various stages of development. Broad discussion of psychedelic assisted therapy should be careful to differentiate these various products and their myriad health impacts and delivery methods. In this same context we stress the need be transparent about the impact that therapies of this variety can have

on employment and encourage Congress and federal agencies to protect veterans from adverse administrative actions if participating in a reputable and well-governed research or clinical trial.

In closing, we thank the Advisory Committee for the opportunity to provide comments intended to promote our shared goal of providing safe, effective, and well-researched methods of treatment for PTSD to the veteran community. We hope these comments have helped to better inform the Committee regarding the potential veteran health impact of MDMA-based PTSD treatments. We look forward to continuing to be of assistance in any way we can.

¹ For a detailed discussion of this analysis, please consider reviewing WWP's 2022 Annual Warrior Survey. A full copy of the report can be viewed at <https://www.woundedwarriorproject.org/mission/annual-warrior-survey>.