

United States Senate
Washington, D.C. 20510

August 5, 2024

Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write to you today regarding the U.S. Food and Drug Administration's (FDA) consideration of MDMA-Assisted Therapy (MDMA-AT) as a Post-Traumatic Stress Disorder (PTSD) treatment. Existing treatments and medicines for PTSD, the last of which FDA approved nearly 25 years ago, have not decreased the frequency of suicide within the veteran community. As a nation, we cannot allow our veterans to continue to suffer in silence and must identify treatments proven to drastically decrease the adverse effects of PTSD.

Untreated PTSD can lead to negative consequences, such as homelessness, addiction, depression, and suicide. Our country has a severe veteran suicide and PTSD crisis where 6,000 veterans die by suicide each year, with over 150,000 suicides since 9/11.¹ Advancements in scientific research offer new hope for those suffering from PTSD; MDMA-AT is one of the most promising and available options to provide reprieve for veterans' endless PTSD cycle, which the FDA recognized in 2017 when they designated MDMA-AT as a Breakthrough Therapy.

Seven years have passed, and with several innovative therapies currently under review and more on the horizon, the FDA should remain firmly anchored in scientific evidence and data when evaluating new treatments. The potential for groundbreaking advancements in PTSD treatment is within reach, and we owe it to our veterans and other affected populations to review these potentially transformative therapies based on robust clinical and scientific evidence. The FDA is internationally recognized as the gold standard for drug safety and efficacy review, and we urge the Agency to continue upholding this rigorous standard of safety, quality, and effectiveness, especially for therapies targeting conditions like PTSD, which is alarmingly prevalent among our nation's veterans.

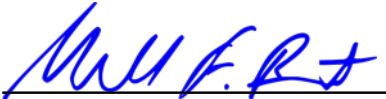
Given the substantial burden of PTSD and the current treatment limitations, the possibility of new, more effective therapies is particularly meaningful. One such promising therapy under consideration is MDMA-assisted therapy (MDMA-AT). If comprehensive evidence demonstrates that MDMA-AT is both effective and safe when administered in appropriate settings, it is our responsibility to ensure that this treatment option is made available to those who could benefit from it. The rigorous, evidence-based review process by the FDA will be

¹ Biertempfel, Maddie. "Veterans Call on FDA to Approve MDMA Treatment." *DC News Now* | Washington, DC, DC News Now | Washington, DC, 10 July 2024, www.dcnewsnow.com/news/veterans-call-on-fda-to-approve-mdma-treatment/.

critical in making informed decisions that could offer a new lease on life for many individuals, including veterans, affected by this condition.

We appreciate your consideration on this critical issue.

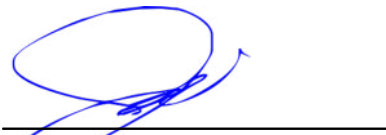
Sincerely,



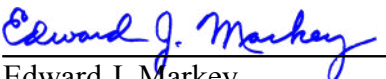
Michael F. Bennet
United States Senator



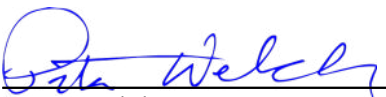
Rand Paul, M.D.
United States Senator



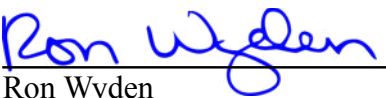
John Fetterman
United States Senator



Edward J. Markey
United States Senator



Peter Welch
United States Senator



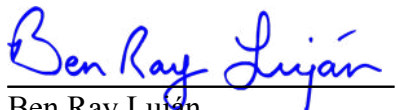
Ron Wyden
United States Senator



Thom Tillis
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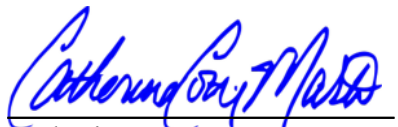
Kyrsten Sinema
United States Senator



Ben Ray Lujan
United States Senator



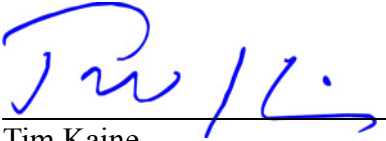
Markwayne Mullin
United States Senator



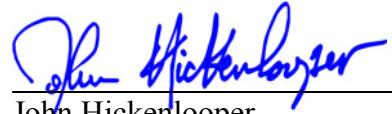
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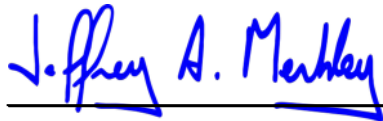
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