

Congress of the United States
Washington, DC 20515

August 2, 2024

The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, D.C. 20500

Dear President Biden:

We write today to express our sense of urgency to address the post-traumatic stress disorder (PTSD) and suicide epidemic among Veterans and servicemembers, and the grave need for new and better treatment options like MDMA-assisted therapy.

As you know, between 17 and 44 Veterans take their lives each and every day, and nearly 150,000 have done so since 9/11 – more than 21 times as many American lives lost in warzones over that same time. PTSD and suicide have been exponentially more lethal for those who served in uniform than combat.

Despite billions of federal dollars spent on addressing PTSD and mental health, the number of Veteran lives lost to suicide has not decreased. This is due in part to the fact that the FDA has not approved any new treatments for PTSD in nearly 25 years. This astounding lack of innovation has undoubtedly contributed to our rising Veteran suicide rates over the past two decades.

Fortunately, hope is on the horizon. Promising new treatments like MDMA-assisted therapy (MDMA-AT) have the clinically proven potential to bring Veterans who have long suffered with PTSD a treatment that works. MDMA-AT has shown enormous promise in privately funded research for decades and was officially designated a “Breakthrough Therapy” by the FDA in 2017.

Under this designation, the FDA has worked closely with the drug’s sponsor to design clinical trials that included strategies to ensure the study’s validity and safety, and which ultimately proved MDMA-AT’s remarkable efficacy.

In Phase three confirmatory trials, 71.2% of participants no longer qualified for a PTSD diagnosis after three eight-hour sessions of MDMA-AT. Moreover, 86.5% of participants experienced “clinically significant” improvements in their PTSD symptoms. These results are nearly double those of existing PTSD treatments, rendering MDMA-AT the most effective PTSD treatment ever developed.

We understand that the FDA has a statutory obligation to carefully weigh both the risks and benefits of any new drug application. This duty is undoubtedly more complicated when dealing with a novel treatment like MDMA-assisted therapy, which calls on the FDA to consider not only the risks and benefits of a novel drug, but also the unique combination of a pharmaceutical when combined with psychotherapy interventions.

It is not our intent to urge the FDA in any direction related to its decision, which must be based solely on the data and evidence. However, we are aware that as this application has made its way through the regulatory review process, certain groups and individuals have voiced criticism of the application. It is our understanding that while these critics may be well-intentioned, their criticism is not necessarily reflective of the science, but rather their personal ideological beliefs and biases related to the medicalization of substances like MDMA.

While all Americans are free to voice their views on this and other topics of public interest, scientific evidence should not be ignored in favor of those who have been on a mission to discredit this promising treatment at all costs – especially when that would come at the cost of our servicemembers and Veterans.

Thousands of Veterans suffering from PTSD continue to take their lives each year. Current treatments clearly are not working well enough, and our Veterans can no longer wait.

If the data and evidence show that MDMA-AT is safe and effective at relieving the suffering that many Veterans face, then we owe it to them and the millions of others who are living with PTSD to make this treatment option available to them.

We appreciate your consideration of our views on this matter and look forward to the FDA's decision on this application.

Sincerely,



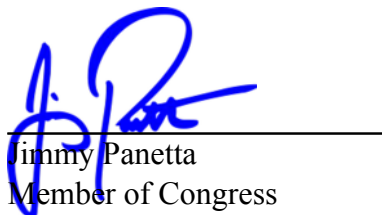
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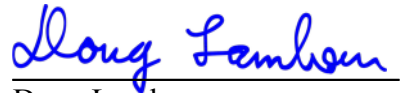
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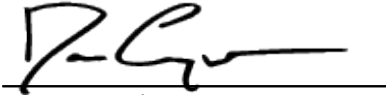
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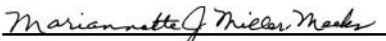
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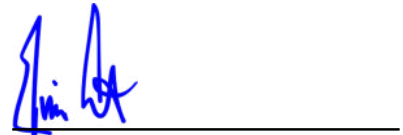
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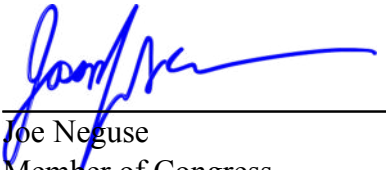
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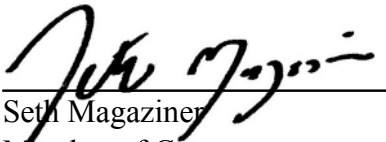
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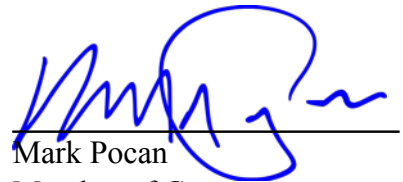
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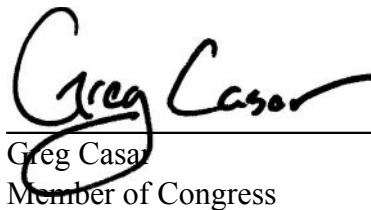
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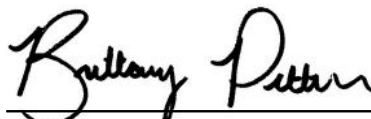
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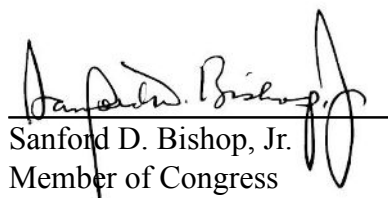
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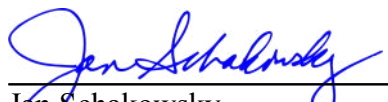
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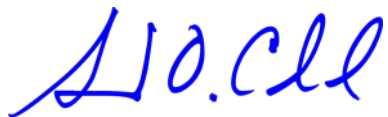
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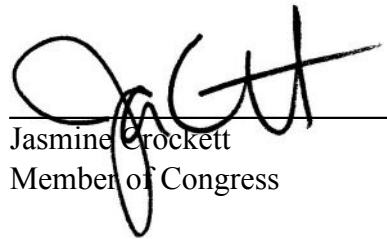
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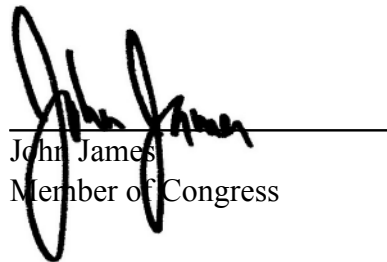
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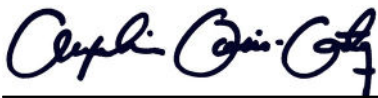
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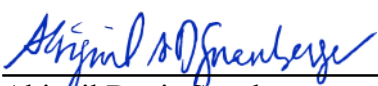
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Robert J. Menendez
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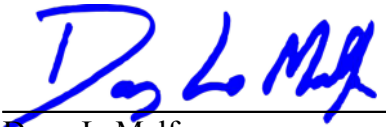
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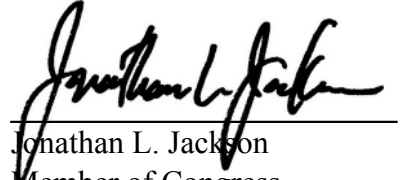
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CC:

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