

June 27, 2024

Hi, Jesse et al.,

I read your open letter about the recent ICER and FDA meetings with interest. As a former VA research psychologist and former call worker for the Veterans Crisis Line, I am all too aware of the epidemic of veteran suicide. These deaths are all the more tragic and infuriating for the fact that a safe and effective treatment, MDMA-AT, has been available since the 1980s (and MDA Assisted Therapy since the 1960s).

However, along with the reasonable critiques, I notice some mischaracterizations and inaccuracies in your open letter. I offer the attached feedback and suggestions in the hope that future critiques are targeted and effective. It's important to represent the arguments of those you disagree with accurately. Mischaracterizing their positions does not contribute to a productive dialogue about the important issues surrounding MDMA-assisted therapy and veteran care.

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Heroic Hearts: "Articles with suspicious origins and strikingly similar narratives raised unfounded and almost laughable rumors, alleging that the 20-plus years of scientific research by the NIH, VA, prominent universities, and researchers were the work of a 'cult.'"

My comment: The straw man fallacy occurs when someone misrepresents their opponent's argument to make it easier to attack. This misrepresents the critics' actual arguments. The critics weren't dismissing all MDMA research as the work of a cult but instead expressing concerns about specific therapy protocols used by one organization.

This characterization is both inaccurate and dismissive. The concerns are based on carefully examining MAPS/Lykos' materials and statements, not unfounded rumors. These concerns are not about preventing MDMA research or denying care to veterans. Instead, they aim to ensure approved therapy is safe and effective for all patients, including veterans and other vulnerable populations.

Heroic Hearts: "No mention was made of the veteran suicide epidemic or the soundness of the clinical trials' results."

My comment: While emotions can be powerful in writing, relying too heavily on them can be a fallacy, especially when used to overshadow logical arguments. While this is a serious issue, it's used here to deflect from specific criticisms of the research methodology.

While the severity of the veteran suicide epidemic is indeed tragic, it is not directly related to assessing the safety and effectiveness of a specific treatment. The committee's role is to evaluate the scientific merits of the proposed therapy, not to make decisions based on the urgency of the problem it aims to address. Furthermore, contrary to your claim, the soundness of the clinical trials' results was discussed in detail during the meeting.

Heroic Hearts: "The question that needs to be asked is: who influenced the Advisory Committee, and why?"

My comment: I can think of two more meaningful and relevant questions: Is the treatment safe? Is the treatment effective?

Heroic Hearts: "This Individual has made it their stated mission to prevent MDMA-AT's FDA approval due to their personal antipathy towards the therapy's sponsor, Lykos."

My comment: Your letter mischaracterizes the position of critics. Far from opposing MDMA research or veteran care, they explicitly state: "While I believe in the therapeutic potential of MDMA, the organization leading this application qualifies as a therapy cult, as I explained in my 17-page comments that I submitted to the FDA." Their goal is not to prevent MDMA-AT approval but to prevent potential harm to vulnerable patients from a specific therapy model.

The main concerns raised are about MAPS/Lykos' specific therapy protocol, not MDMA itself. Critics have highlighted issues with concepts like "inner healing intelligence" and "Self-energy," which form the core of the MAPS/Lykos approach. They explain: "Ultimately, cult indoctrination is a significant iatrogenic risk for a therapy model that introduces totalizing ideologies into a context of pharmacologically induced and heightened suggestibility."

Of particular concern is the touch-based "focused bodywork" technique. As they point out, this practice poses risks, "especially for minorities and survivors of sexual assault." The therapy model's emphasis on therapist intuition over patient articulation of distress is also problematic. As they note, "Continually, therapist intuition of the client's motivations is represented as sacrosanct, I have received many accounts of harm from participants whose perspectives were vetoed by their therapists."

Your letter presents a false dichotomy between supporting MAPS/Lykos' protocol and opposing veteran treatment. In reality, we can support MDMA research and therapy while critically examining specific methodologies to ensure the best outcomes for veterans.

Heroic Hearts: "The motivation of many of the people associated with Psymposia for opposing MDMA-AT lies in their belief that treating veterans suffering from PTSD "perpetuates the logic of white supremacy, capitalism, and imperialism."

Psymposia: "For decades, MAPS and other proponents of psychedelic medicalization have justified their emphasis on treating police and soldiers as a political strategy in service to mainstreaming psychedelic drugs. This strategy perpetuates the logic of white supremacy, capitalism, and imperialism.

My comment: Treating veterans with PTSD is not the same as a political strategy of emphasizing treating police and soldiers that perpetuates the logic of white supremacy. The former is about treatment; the latter is about a political strategy. The former is about veterans; the latter is about police and active duty military. Psymposia's critique is directed at the strategy, not at the treatment of veterans.

Heroic Hearts: "[Psymposia] openly refer to veterans as imperialists, white supremacists, and murderers on their website, in public speeches, and on their social media feeds.

My comment: An ad hominem argument attacks the person making the argument rather than addressing it. This statement attempts to discredit the critics by portraying them as anti-veteran rather than addressing their actual concerns about the therapy protocol.

In the linked article, Psymposia refers to police officers as murderers, not military veterans. They refer to police and the military as institutions that exist to perpetuate white supremacy and imperialism, not to veterans as individuals who are imperialists or white supremacists. This institutional critique does not equate to labeling veterans individually as "imperialists, white supremacists, and murderers."

Heroic Hearts: "Rather than assess the data at hand, the Committee devolved into what one expert called a "dumpster fire." The group strayed from analyzing the safety and efficacy of the treatment to asking bizarre questions about the diversity of the trials, the types of therapy used, and questions regarding whether MDMA-AT would lead to cocaine usage."

Heroic Hearts: "This hateful, anti-veteran rhetoric infiltrated the media and the Advisory Committee's psyches through ICER's draft report, as evidenced by how often committee members raised the issue of a perceived "lack of diversity" in MDMA-AT's Phase 3 clinical trials."

My comment: The diversity of the trials and the type of therapy used are normal subjects for the advisory committee to assess. That is, in fact, a large part of "the data at hand." Contrary to your assertion, the Advisory Committee's questions about diversity were scientifically relevant inquiries necessary for assessing the generalizability of the study results. Diversity in clinical trials is crucial for ensuring that treatments are safe and effective for all populations, including veterans from various backgrounds.

Heroic Hearts assumes that concerns about diversity in the trials were caused by "anti-veteran rhetoric" without evidence of this causal link. Also, Heroic Hearts is conflating two separate issues. ICER committee members asking about the lack of diversity in clinical trials is unrelated to veterans as imperialists, etc. I don't see any way these two data points are connected.

Heroic Hearts: "Moreover, they clung to this narrative despite the fact that over half of confirmatory Phase 3 trial participants self-identified as a race or ethnicity other than white or non-Hispanic Latino."

My comment: The published data contradicts this claim. Mitchell et al. (2021) reported that the MDMA group was 84% White and 89% not Hispanic or Latino. Mitchell et al. (2023) showed improvement, but still not the diversity you claim, with the MDMA group 69% White and 67% not Hispanic or Latino. If there are other confirmatory Phase 3 trials, I am not aware of them.

Heroic Hearts: "Too many lives are at stake for anything other than science to guide the FDA's decision."

My comment: I wholeheartedly agree. This is precisely why the Advisory Committee's thorough examination of the study design, results, and potential risks was necessary and appropriate. Questions about therapy type, participant diversity, and potential for misuse are standard and crucial elements in assessing a new drug's safety and efficacy profile. Rigorous science demands that we critically examine all aspects of a proposed treatment, especially when dealing with a powerful psychoactive substance combined with a novel therapy approach.