



**AMERICAN
PSYCHOLOGICAL
ASSOCIATION**
SERVICES, INC.

June 3, 2024

Joyce Frimpong, PharmD
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
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Email: PDAC@fda.hhs.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 Dr. Frimpong and Members of the Advisory Committee,

We are writing on behalf of the American Psychological Association Services, Inc. (APASI) to provide comments for consideration for the upcoming decision about drug application 215455, for the use of MDMA- assisted psychotherapy for post-traumatic stress disorder (PTSD). The American Psychological Association Services, Inc. is the companion organization of the American Psychological Association (APA), which is the nation’s largest scientific and professional nonprofit organization representing the discipline and profession of psychology, as well as over 157,000 members and affiliates who are clinicians, researchers, educators, consultants, and students in psychological science.

Recently, a multidisciplinary panel of experts, including psychology, psychiatry, social work, nursing, and patient members met to update APA’s (2017) *Clinical Practice Guideline for the Treatment of PTSD in Adults*. This updated guideline draft will be released soon for public comment. However, given the urgency and timing of the upcoming hearing on MDMA- assisted psychotherapy, we write to address this specific topic.

APA’s guideline update panel reviewed the literature on MDMA-assisted psychotherapy and determined that there is insufficient evidence for the panel to be able to recommend MDMA-assisted psychotherapy for patients with PTSD. This conclusion is based on research studies with comparisons to both inactive placebo and active placebo.

APA’s panels make decisions about recommendation based on four factors: the overall quality of the evidence, the balance of benefits to potential harms, applicability (generalizability), and patients’ values and preferences. For MDMA-assisted psychotherapy, the panel noted concerns that benefits in the included literature may be overstated and that participants who did not receive MDMA may have known their group assignments which may have reduced expectations. There was also concern about the few available studies

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and heterogeneity with different and inconsistent comparisons. The panel also noted concerns about various potential harms and burdens (e.g., side effects, 8-hour multiple day commitment of MDMA-assisted psychotherapy).

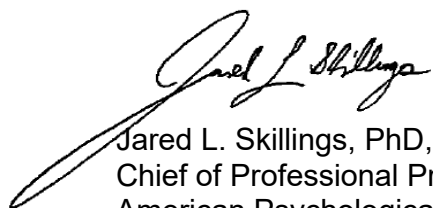
Given all these concerns, the panel was unable to determine the balance of benefits to harms/burdens between MDMA-assisted psychotherapy and inactive placebo and between MDMA-assisted psychotherapy and active placebo. The panel acknowledged the community interest in MDMA-assisted psychotherapy and emphasized the importance of informed consent and ethical practices given that patients are incapacitated during MDMA-assisted psychotherapy. The panel noted potential challenges of using this in outpatient settings and private practices though acknowledged that some patients may find processing the trauma easier with MDMA. Finally, the panel also noted concerns about applicability of the existing research evidence to a broader population of patients.

Thus, overall, the panel determined that there was insufficient evidence at this time for the panel to be able to recommend for or against MDMA-assisted psychotherapy. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources. Additional high-quality research is needed on MDMA-assisted psychotherapy to clarify the balance of potential benefits versus potential harms.

We encourage the FDA to consider the findings of APA's panel of experts in its deliberations about MDMA-assisted psychotherapy for PTSD, and to ensure that its decisions on this treatment are firmly based on strong scientific evidence. The FDA is encouraged to proceed with caution given the number of identified concerns and the small body of empirical studies. Caution may be especially necessary given the high rates of addiction among both males and females with PTSD.

For more information on this issue, please contact APA staff member Raquel Halfond, PhD at rhalfond@apa.org.

Sincerely,



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