Panel rejects psychedelic drug MDMA as a PTSD treatment in possible setback for advocates

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In this photo made with a long exposure, a man is silhouetted against lights reflected in the waters off Cape Neddick in Maine on Dec. 11, 2017. Federal health advisers are considering the first request to approve the mind-altering club drug MDMA as a treatment for PTSD. The advisers to the Food and Drug Administration are scheduled to vote on the drug's safety and effectiveness Tuesday, June 4, 2024, potentially setting the stage for federal approval later this

year. Credit: AP Photo/Robert F. Bukaty, File

A first-of-a-kind proposal to begin using the mind-altering drug MDMA as a treatment for PTSD was roundly criticized Tuesday—a potentially major setback to psychedelic advocates who hope to win a landmark federal approval and bring the banned drugs into the medical mainstream.

A panel of advisers to the Food and Drug Administration voted 10-1 against the overall benefits of MDMA when used to treat post-traumatic stress disorder. They cited flawed study data, questionable research conduct and significant drug risks, including the potential for heart problems, injury and abuse.

"It seems like there are so many problems with the data—each one alone might be OK, but when you pile them on top of each other … there's just a lot of questions I would have about how effective the treatment is," said Dr. Melissa Decker Barone, a psychologist with the Department of Veterans Affairs.

The FDA is not required to follow the group's advice and is expected to make its final decision by August, but the negative opinion could strengthen FDA's rationale for rejecting the treatment.

MDMA is the first in a series of psychedelics—including LSD and psilocybin—that are expected to come before the FDA for review in the next few years as part of a resurgence of interest into the drugs' medical potential, which advocates claim could transform the treatment of mental health disorders.

But FDA advisers spent most of Tuesday's meeting leveling pointed

questions and criticisms at the research submitted on MDMA, which is sometimes called ecstasy or molly. Panelists pointed to flawed studies that could have skewed the results, missing follow-up data on patient outcomes and a lack of diversity among participants. The vast majority of patients studied were white, with only five Black patients receiving MDMA, raising questions about the generalizability of the results.

"The fact that this study has so many white participants is problematic because I don't want something to roll out that only helps this one group," said Elizabeth Joniak-Grant, the group's patient representative.

The FDA advisers also drew attention to allegations of misconduct in the trials that have recently surfaced in news stories and a report by the nonprofit Institute for Clinical and Economic Review, which evaluates experimental drug treatments. The incidents include a 2018 report of apparent sexual misconduct by a therapist interacting with a patient.

Lykos Therapeutics, the company behind the study, said it previously reported the incident to the FDA and regulators in Canada, where the therapist is based. Lykos is essentially a corporate spinoff of the nation's leading psychedelic advocacy group, the Multidisciplinary Association for Psychedelic Studies, or MAPS, which funded the studies. The group was founded in 1986 to promote the benefits of MDMA and other mind-altering substances.

Lykos and MAPS did not immediately respond to requests for comment Tuesday evening.

The negative panel ruling could further derail financial investments in the fledgling psychedelic industry, which has mainly been funded by a small number of wealthy backers. Dozens of startup companies have launched in recent years seeking to study psilocybin, ketamine and other drugs for conditions like depression and addiction, though many have

struggled to raise money.

MDMA's main effect is triggering feelings of intimacy, connection and euphoria. When used to enhance talk therapy, the drug appears to help patients process their trauma and let go of disturbing thoughts and memories.

But the panel struggled with the reliability of those results, given the difficulties of objectively testing psychedelic drugs.

Because MDMA causes intense psychological experiences, almost all patients in two key studies of the drug were able to guess whether they had received the MDMA or a dummy pill. That's the opposite of the approach generally required for high-quality drug research, in which bias is minimized by "blinding" patients and researchers to whether they received the drug under investigation.

"I'm not convinced at all that this drug is effective based on the data I saw," said Dr. Rajesh Narendran, a University of Pittsburgh psychiatrist who chaired the panel.

Panelists also noted the difficulty of knowing how much of patients' improvement came from MDMA versus simply undergoing the extensive therapy, which totaled more than 80 hours for many patients. Results were further marred by other complicating factors, including a large number of patients who had previously used MDMA or other psychedelic drugs recreationally.

Nearly three dozen public speakers addressed the panel, including veterans who said they benefitted from MDMA therapy, medical professionals who advised against its use and journalists and independent researchers who reiterated the allegations of misconduct in the trials.

The meeting concluded with several experts encouraging Lykos and the FDA to continue studying psychedelics for PTSD, citing the field's potential to help patients.

"I think this is a really exciting treatment and I'm encouraged by the results to date," said Dr. Paul Holtzheimer of the VA's National Center for PTSD, "but from a safety and efficacy standpoint I feel it's still premature."