

FDA asked to consider party drug MDMA as treatment for PTSD

December 13 2023, by Robin Foster



A California company has asked the U.S. Food and Drug Administration to approve MDMA, the active ingredient in party drugs like molly and ecstasy, as a treatment for post-traumatic stress disorder (PTSD).

When announcing the new [drug](#) application (NDA) filing on Tuesday, MAPS Public Benefit Corp. noted it has been studying the drug for this use for years. The FDA has 60 days to decide whether whether MDMA will be accepted for review and whether it will be fast-tracked through the approval process, the company said. The drug would be given in concert with talk therapy.

"The filing of our NDA is the culmination of more than 30 years of clinical research, advocacy, collaboration and dedication to bring a potential new option to adults living with PTSD, a patient group that has experienced little innovation in decades," MAPS CEO [Amy Emerson](#) said in a company [news release](#). "If approved, MDMA-assisted therapy would be the first psychedelic-assisted therapy, which we hope will drive additional investment into new research in mental health."

MDMA belongs to a class of psychoactive drugs that produce experiences of emotional connection, relatedness and emotional openness.

Meanwhile, roughly 13 million Americans suffer from PTSD each year, the company said. The symptoms can be debilitating, and patients can also suffer anxiety, depression and substance use disorder. That doesn't include the [economic burden](#) of treating PTSD, which reaches over \$200 billion a year.

On top of that, "there are high treatment discontinuation rates... underscoring the urgent need for novel and effective PTSD therapies," the company said.

Back in 2017, the FDA granted MDMA-assisted therapy a breakthrough therapy designation, which speeds the development and review of drugs used to treat a serious condition that early evidence suggests might be a substantial improvement over available therapies.

The MDMA application included data on two studies, with 90 and 104 participants respectively, that showed MDMA significantly reduced symptoms and impairment associated with PTSD when compared with a placebo. MAPS added that it has now completed a total of six late-stage [clinical trials](#) testing MDMA for PTSD.

For now, treating PTSD includes antidepressants and some specialized forms of cognitive behavioral therapy, *CNN* reported.

If the FDA approves MDMA for this purpose, it would need to be rescheduled, MAPS noted, because it is a schedule I drug under the Controlled Substances Act, which the U.S. Drug Enforcement Administration defines as having no accepted medical use.

More information: Mount Sinai has more on [MDMA as a mental health treatment](#).

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