Controversial party drug MDMA poised for FDA approval to treat PTSD

On June 4, the Food and Drug Administration’s advisory committee will meet to discuss the risks and benefits of MDMA therapy. If the committee votes in favor of the drug, it could be approved to treat PTSD this summer. The approval would represent a momentous achievement for proponents of mind-altering drugs, who have been working toward this goal for decades. And it could help pave the way for FDA approval of other illicit drugs like psilocybin. But the details surrounding how these compounds will make the transition from illicit substances to legitimate therapies are still foggy.

Here’s what to know ahead of the upcoming hearing.

What’s the argument for legitimizing MDMA?

Studies suggest the compound can help treat mental-health disorders like PTSD and depression. Lykos, the company that has been developing MDMA as a therapy, looked at efficacy in two clinical trials that included about 200 people with PTSD. Researchers randomly assigned participants to receive psychotherapy with or without MDMA. The group that received MDMA-assisted therapy had a greater reduction in PTSD symptoms.

At the meeting on the 4th, the FDA has asked experts to discuss whether Lykos has demonstrated that MDMA is effective, whether the drug’s effect lasts, and what role psychotherapy plays. The committee will also discuss safety, including the drug’s potential for abuse and the risk posed by the impairment MDMA causes.

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