FDA Issues First Ever Guidance for Research of Psychedelics

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By Darren Grady on August 3, 2023

Earlier this summer, the Food & Drug Administration (FDA) issued draft guidance for those researching the use of psychedelics to treat certain serious medical conditions including major depressive disorder, PTSD, and substance use disorders. This is the very first time the FDA has provided guidance to the ever growing list of entities conducting research on these controlled substances for the purpose of setting up clinical trials.

The FDA has recognized and acknowledged the scientific community's increasing interest in the potential therapeutic benefits of psychedelic compounds. It has also recognized, however, the challenges in developing clinical studies focusing on the safety and effectiveness of this family of drugs. Dr. Tiffany Farchione, the director of the Division of Psychiatry in the FDA's Center for Drug Evaluation and Research has commented on the initial promise of the use of psychedelics, but also qualified that promise by stressing that these are still "investigational products." In publishing this guidance, the FDA has set forth what it sees as the varied challenges in establishing psychedelic drug programs and has provided a framework on how to take on these challenges. Dr. Farchione stated that "the goal is to help researchers design studies that will yield interpretable results that will be capable of supporting future drug applications."

This guidance is a necessary response to the growing public support of the use of psychedelics to treat medical conditions and disorders, as well as the medical community's increasing interest in seeking out treatment methods that involve psychedelics. As we reported back in January, there is legitimate scientific evidence (including studies, approvals, and press releases from the FDA) demonstrating that psychedelic / entheogenic treatments can be offered in a safe and controlled environment, with an excellent success rate. Studies have shown that such treatments have been successful for patients suffering from a wide array of ailments including addiction, traumatic brain injury, depression, and PTSD. The term psychedelic is used in the recent FDA guidance as shorthand to include so called "classic" psychedelics, typically psilocybin and lysergic acid diethylamide (LSD), as well as entactogens or empathogens such as methylenedioxymethamphetamine (MDMA).

While ketamine (an FDA approved *anesthetic*) is also becoming popular among clinicians for combatting depression, it is not FDA approved for the treatment of any psychiatric disorder and is not addressed in the recently released guidance. However, a specific derivative of ketamine, which is known as Spravato (esketamine), is a Schedule III controlled substance that was approved by FDA in 2019 as a nasal spray for treatment-resistant depression in adults and adults with major depressive disorder with acute suicidal ideation or behavior, in conjunction with an oral antidepressant.

Psilocybin continues to gain popularity in the research setting to treat neurological and mental health conditions. About a year ago, the FDA approved an investigational new drug application which would allow for clinical testing of psilocybin for those suffering from anorexia. More and more state and local governments are also addressing the use of psychedelics In May of 2019, Denver, Colorado decriminalized psilocybin. Ann Arbor, Michigan, Somerville, Massachusetts, Washington D.C., Seattle, Washington, and Cambridge, Massachusetts have also decriminalized the possession, use, and propagation of psychedelic mushrooms. Oregon, with the passage of 2020's Ballot Measure 109, was the first state to formally decriminalize psilocybin *and* legalize its use in a therapeutic setting. Colorado passed similar legislation in 2022. In January of this year, an Illinois lawmaker proposed legislation would set up a state governmental agency that would advise and make recommendations regarding the provision of psilocybin services, set up licensing to manufacture or test psilocybin products, operate service centers, and effectively decriminalize psilocybin.

The formal FDA guidance is yet another step forward in the ever changing landscape of public and legislative acceptance of the benefits of psychedelic / entheogenic based therapies for patients searching for more profound and effective treatments. The FDA currently has an open comment period (ending on August 25, 2023) and those in the industry should make their voices heard. While encouraging progress continues, these substances remain illegal under federal law and psilocybin, LSD, and MDMA are considered a Schedule I substances under the Controlled Substances Act (defined as a substance which has a high potential for abuse and no currently accepted medical use).

Companies who wish to conduct psychedelics research must be careful to do so in a manner that does not run afoul of any state or federal law. For these Schedule I controlled substances, the FDA notes that activities in this area must comply with applicable DEA regulatory requirements. This is where trusted legal counsel can be a valuable asset. Those interested in following the FDA guidance to develop clinical trials should seek the advice of counsel who have experience in working with the DEA and state agencies to secure licensure for this research.