

Psychedelics 2021 Year in Review and Looking Ahead to 2022

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An Article providing a high-level survey of 2021 developments on psychedelics. This Article covers certain state, local, and federal activity and anticipated developments for 2022.

History may view 2021 as the year that psychedelics went mainstream. Before then, decriminalization efforts and pharmaceutical developments largely moved at a glacial pace. Now, many states and cities have taken measures to reform their drug policy on these substances, and companies are studying their potential therapeutic benefits. Wall Street has also taken notice of the promising clinical research and multi-billion-dollar psychedelic drug market, which is predicted to nearly double in the next five years. The strong momentum from 2021 is expected to continue this year, with some states considering new legislation on psychedelic drug use, decriminalization, and research.

Moving Toward Legalization

Psychedelics are proceeding toward legalization using the paths of:

- **Pharmaceuticals.** In 2019, the US Food and Drug Administration (FDA) approved Spravato, a ketamine-based nasal spray used for treatment-resistant depression, and studies on other psychedelic drugs are underway (see Drug Trials). Private and public companies are now racing to raise money, develop intellectual property, and capitalize on the tremendous market opportunities associated with government-approved psychedelic drugs.
- **State and local decriminalization and legalization.** Decriminalization already has occurred in cities like Santa Cruz, Denver, and Oakland. States may soon follow. The commercial opportunities associated with decriminalization are less clear. However, many businesses are pushing hard in this area alongside those in the FDA and technology development spaces.

Drug Trials

Before 2021, a couple of psychedelic drugs received a breakthrough therapy designation from the FDA, which means the drugs are intended to treat a serious condition and there is preliminary clinical evidence showing that the drugs may have substantial improvement on at least one clinically significant endpoint over available therapy ([FDA: Fact Sheet: Breakthrough Therapies](#)). The designation provides certain benefits, such as more intensive FDA guidance on the drug development program. Psychedelic drugs that have received the breakthrough therapy designation include:

- **MDMA (3,4-methylenedioxymethamphetamine, also known as ecstasy and molly).** The Multidisciplinary Association for Psychedelics Studies (MAPS) released impressive results in May from the first-ever Phase 3 clinical trial to investigate MDMA-assisted therapy for the treatment of post-traumatic stress disorder (PTSD).
- **Psilocybin.** Compass Pathways released “[breathhtaking](#)” Phase 2b data on its synthesized psilocybin drug, which targets treatment-resistant depression in a talk therapy regime.

MAPS will likely win drug approval in 2022, with commercialization in 2023. Compass Pathways looks to be a few years behind, but the forecast is promising for its drug as well. To that end, a full two-thirds of physicians recently surveyed believe psilocybin therapy has potential therapeutic benefit for patients with treatment-resistant depression.

In addition to the MAPS and Compass FDA studies, by July 2021, a large number of clinical trials were underway for a variety of psychedelic drugs, including psilocybin, MDMA, LSD, ibogaine, mescaline, and 5-MeO-DMT.



Ketamine

Ketamine is currently the only path for US medical providers to generate revenue with psychedelic substances. Although the FDA approved the substance in 1970 as an anesthetic and it is currently being [studied for other uses](#), ketamine infusion therapy has been used [off label](#) at ketamine clinics for psychiatric disorders and the management of chronic pain. Some clinics now also administer Spravato.

The demand for legal services related to ketamine took off in 2021 all across the US. This is despite the fact that for-profit clinics have been around for about a decade. So many ketamine clinics opened in 2021 that it would not be surprising if more opened last year than the total number of clinics that already existed.

State and Local Decriminalization and Legalization

A large number of states and cities have taken steps toward drug policy reform on psychedelics, many of them in 2021. Some highlights from 2021 include:

- **California.** [SB 519](#), legalizing possession of psychedelics, passed the state Senate and two Assembly committees before being tabled for proposed reintroduction in 2022. At the same time, [California Psilocybin Initiative 2022](#), which would fully legalize psilocybin, continues to progress toward 2022 ballot measure placement.
- **Oregon.** The Oregon Psilocybin Advisory Board began work in March on creating the framework for a regulated psilocybin therapy regime, which will launch in January 2022. Measure 110, the [Drug Addiction Treatment and Recovery Act](#), also took effect, decriminalizing possession of all drugs.
- **Maine.** Lawmakers nearly passed a law decriminalizing possession of all drugs. The proposal cleared the House of Representatives and failed narrowly in the Senate by a 14-18 margin.
- **Texas.** Texas enacted a law in June ([HB 1802](#)) to begin studying the therapeutic potential of psilocybin, MDMA, and ketamine, which is impressive considering Texas has failed to progress even on medical marijuana.
- **Seattle.** The City of Seattle decriminalized psychedelics, following the lead of cities like Denver, Oakland, and Washington, DC.
- **New York.** The Empire State introduced medical psilocybin legalization ([AB 8569](#)) in December, which

would “create psilocybin service centers to provide innovative treatment options for ailments such as PTSD, depression, alcohol dependency, anxiety, among others.” This follows a decriminalization proposal for psilocybin mushrooms introduced in March ([AB 6065](#)).

These examples are merely highlights. Many jurisdictions proposed, advanced, or passed legislation, ordinances, or resolutions to improve the treatment of psychedelic substances. There was even the first federal decriminalization proposal, the [Drug Policy Reform Act](#), which would end the threat of incarceration for people caught with possession not only of psychedelics but of all drugs for personal use.

For a sample tracker that covers legalization and decriminalization, see [Psilocybin Alpha: Psychedelic Legalization & Decriminalization Tracker](#).

Investment

Investors have been pouring money into the psychedelic drug sector, with an estimated \$2 billion raised last year. Even though most psychedelics are Schedule I controlled substances under US federal law, there are now 50 psychedelic companies publicly traded on the US exchanges, and nine of them are traded on the Nasdaq or the New York Stock Exchange (NYSE). The bellwether moment was probably MindMed uplisting on the Nasdaq in April, but Atai Life Sciences also went public at a \$2 billion market cap. In addition, Cybin Inc., Field Trip Health, and Small Pharma all had IPOs.

For information on how psychedelic companies are able to be listed in certain stock exchanges despite most psychedelics being controlled substances, see [Harris Bricken: Psychedelics, Cannabis and the Stock Exchanges](#).

Looking Ahead

The outlook for psychedelics, whether it’s drug studies, legalization, or investor interest, looks promising this year.

Besides MDMA and psilocybin (see Drug Trials), there are many other psychedelics being studied in Phase 1 and 2 clinical trials, and others are being evaluated at the preclinical stage. The indications for these drugs cover a wide range of diseases and conditions, including migraines, anxiety, Alzheimer’s disease, opioid use disorder, major depressive disorder, alcohol use disorder, and eating disorders. There may be announcements later

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this year about progress on these different research fronts or about the launch of new clinical trials.

For a sample psychedelic drug development tracker, see [Psilocybin Alpha: Psychedelics Drug Development Tracker](#). For information on how the FDA approves new drugs, see [FDA: The Drug Development Process](#).

It is unlikely that Congress will pass the Drug Policy Reform Act this year, but there will likely be more decriminalization and legalization of psychedelics at the state and local levels. Already this year:

- Washington State legislators filed [SB 5660](#), which would allow individuals at least 21 years old to have psilocybin administered by trained and licensed professionals at licensed service centers “for wellness and personal growth.”
- Virginia is considering legislation that would end felony penalties for possession of psychedelic mushrooms ([HB 898](#)).
- Utah’s [HB 167](#) would create a Mental Illness Psychotherapy Drug Task Force that would study psychedelic drugs that

are currently illegal but have the potential to help those with mental illness.

The US may ultimately end up with a patchwork of state laws on psychedelics, similar to what has happened with marijuana. For more information on state regulation of marijuana, see [Practice Notes, Marijuana State Legal Status Charts: Overview](#) and [State and Local Medical and Recreational Marijuana Laws Chart: Overview](#).

Investor interest in psychedelics is expected to remain strong. The potential of these drugs to treat a myriad of mental health disorders and other diseases makes it an attractive market. More money may funnel into this sector depending on the outcomes of clinical research, whether funded by private companies, wealthy donors, or governments from the US to Australia.

These are exciting and promising times for psychedelics. The shift in public perception of these drugs combined with their potential therapeutic effect will likely keep them in the spotlight in 2022 and for years to come.

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