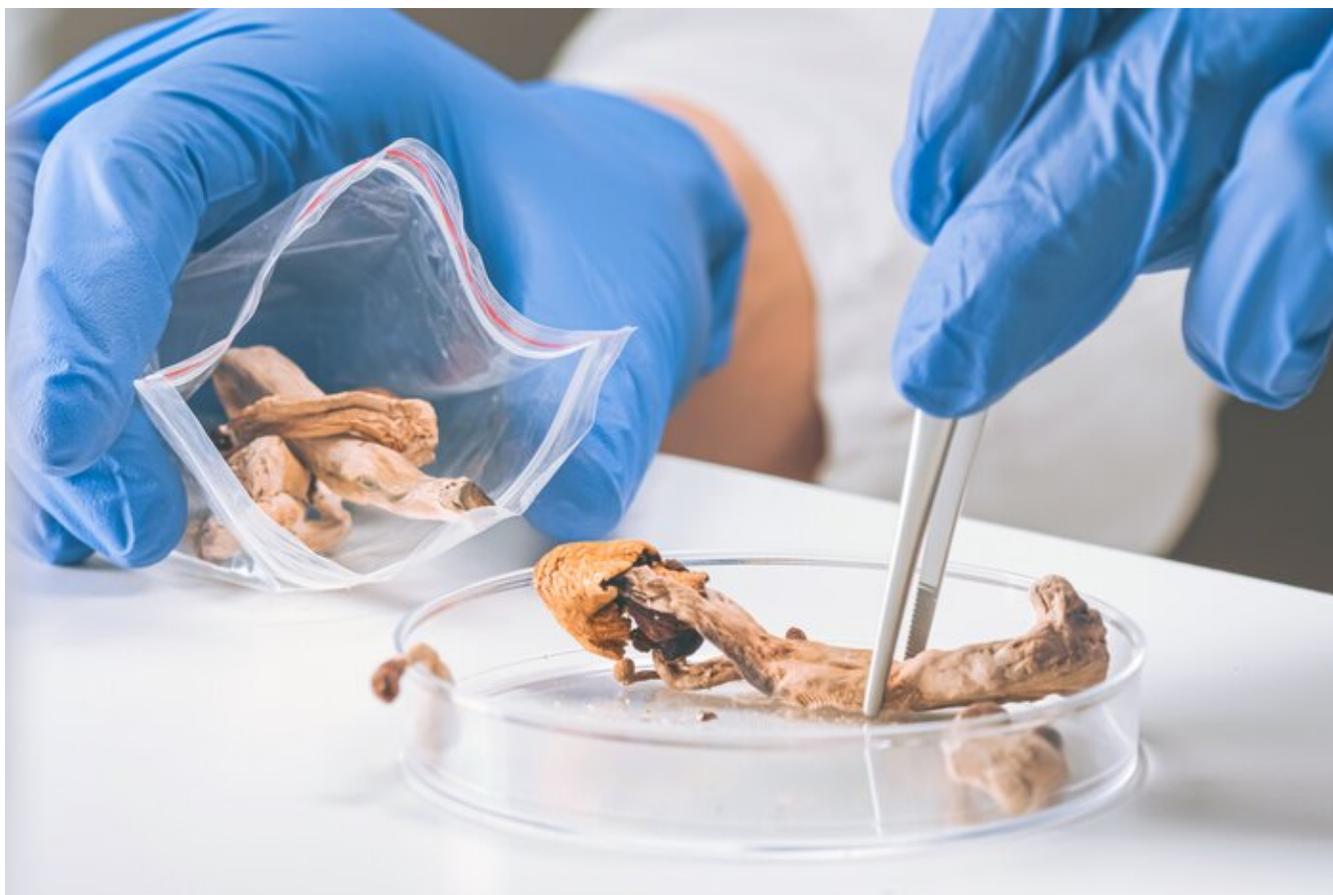


## Insuring Psychedelic Therapy Key To Promising Industry

By **Eli Flesch**

Law360 (August 19, 2022, 9:02 PM EDT) -- For two decades, attorney Ariel Clark was one among the millions of Americans suffering from depression and persistent anxiety. Nightmares afflicted her several times a week. Chronic pain and alcohol-use disorder made her life all the more difficult.

But life started to improve six years ago when she began working with several therapists trained by the Multidisciplinary Association for Psychedelic Studies, a nonprofit that has been closely involved with psychedelic research since 1986.



Research has shown that psychedelics, such as the psilocybin pictured, can treat mental health conditions, but that has not guaranteed that insurers will cover the drugs as mental health treatments. (iStock.com/24K-Production)

"My life was saved," said Clark, who in 2014 co-founded California-based firm Clark Howell LLP, which focuses on clients in both the cannabis and psychedelic industries. "It was me working with those medicines and those therapists and helping hands."

Clark, who is of Odawa Anishinaabe and mixed-European descent, said her experience with psychedelics and a mindfulness of indigenous traditions is helping her better serve clients and run a firm that prizes a respect for the Earth and its beings.

Clark Howell LLP is just one law firm in an ecosystem of activists, scientists and lawmakers supporting the broader use of psychedelic drugs to help treat mental health disorders. The success of this growing movement, experts say, will partly depend on the ability of therapy providers to secure insurance

coverage, even as most psychedelics remain largely illegal and are considered by the U.S. as having no medical use.

As long as the most studied psychedelics remain classified as Schedule I drugs, therapy providers will be deeply challenged to find policies that don't contain the kinds of exclusions that would severely limit coverage in the event of a claim, experts say.

Meanwhile, insurers lacking any significant data about the claims and risks of psychedelic businesses have little incentive to offer affordable coverage; that's also while the U.S. Food and Drug Administration has given "breakthrough" designation to several therapies involving the supervised use of psychedelic drugs in clinical trials.

Ultimately, the issue is one of access and cost: If providers can't secure coverage, running a business or a clinic could become too risky a proposition. That would in turn limit access to a class of drugs that have been recognized for their therapeutic potential in the U.S. at least since the first English language report on LSD was published in 1950.

Even some of Clark's clients who provide cannabis-assisted therapies don't have insurance for their practice, she said. Clark added that she still expects more options to become available for psychedelic treatment providers as the industry grows.

In 2020, an estimated 8.4% of U.S. adults — 21 million — experienced at least one major depressive episode, according to survey data from the National Institute of Mental Health. About 15.9% of adult participants who reported belonging to two or more races said they had a depressive episode, and 29.9% of mixed-race adolescents said the same.

An untold number of depressed individuals may not ever report their condition.

Psychedelic research pioneered by Johns Hopkins University has demonstrated significant and lasting antidepressant effects in individuals administered psilocybin, the psychoactive component in "magic mushrooms." Some patients showed marked improvements that lasted 12 months following psilocybin-assisted therapy, according to a Johns Hopkins study published in February. While the researchers didn't find any serious adverse effects in that period, they noted that little is known about the long-term safety and efficacy of psilocybin treatments on major depressive disorder.

In another Johns Hopkins study from 2016, participants with life-threatening cancers reported lower levels of depression and anxiety following their psilocybin treatment.

It's thought that psychedelic treatments are effective in part because they help relieve patients of fixed patterns of thinking. Researchers from UC San Francisco and Imperial College London in April published a study showing that psilocybin reduced connections in regions of the brain highly associated with depressive thinking. Those changes don't occur in patients taking the most commonly prescribed antidepressants, the study said.

Psychedelics can be used to potentially treat a range of other mental health and behavioral disorders, including addiction, post-traumatic stress disorder, obsessive-compulsive disorder and certain eating disorders, scientists have said. Importantly, much of the research has focused on psilocybin therapies.

But traditional clinical research still often misses underserved populations and marginalized groups, and that's true of the research into psychedelics, said Belinda Tan, a physician and co-founder of People Science, which aims to help expand the research and development of alternative medicines through pathways for FDA approval.

"The data that comes out of clinical research discovery, and thus drug approvals, is based on a tiny fraction of the actual population," Tan said. "These medicines are actually going to do something significant for humanity. So how do we now bring it to this next phase of scaling it, with the rigor of ensuring there's always safety?"

A 2020 review of psychedelic research published in *Neuroscience & Biobehavioral Reviews* examined 34 psychedelic studies and found that researchers should focus on including larger and more diverse samples and use stronger control conditions.

Today's research has helped spur a new psychedelic movement. Michael Pollan's bestseller, "How to

Change Your Mind," is now a Netflix limited series. Lawmakers in New Jersey are considering legislation that would allow the possession and cultivation of psilocybin-containing mushrooms. In California, another bill would have legalized psilocybin and LSD, among other psychoactive drugs like MDMA that don't fall cleanly under the banner of "classic psychedelics." That bill's sponsor withdrew the legislation last week after a committee reduced it to only a study of possible decriminalization.

Oregon's health department in May adopted the first rules regulating the use and production of psilocybin, after voters in 2020 made the state the first in the country to legalize the supervised use of the drug. Under the rules, manufacturers can't produce chemically synthesized versions of psilocybin, which are used in most clinical trials.

There have also been increasing signs of acceptance on the federal level.

President Joe Biden's administration expects the FDA to stamp its approval of psilocybin and MDMA treatments within 24 months, per a letter from Assistant Secretary of Health and Human Services Miriam Delphin-Rittmon sent to a lawmaker in May.

Franklin G. Snyder, a Texas A&M law professor with experience in the marijuana legalization movement, said that if the FDA were to find a medical use for a Schedule I drug and if those drugs were to go through the agency's approval processes, the drug would then be subject to FDA regulations with the permission of the Drug Enforcement Agency.

"If they suddenly decided that LSD had medical use and they wanted to start prescribing it, the drug enforcers would tend to get out of the way of those people using it legally because they wouldn't be breaking the law," Snyder told Law360. "If you're using a cannabis drug approved by the FDA, you're not in possession of illegal marijuana."

In many respects, Snyder said, the business considerations for a company in the cannabis industry are like any other, but with added difficulties like banking and credit limitations. Insurance policies issued to businesses in the cannabis industry come loaded with "nasty" provisions, like limitations on plants and illegal activities, he added.

Experts have said that the same could be true of psilocybin-containing mushrooms.

"If you don't know what you're doing, you could pay money for a policy and have the insurance company do what insurance companies love to do, which is say, 'Sorry!'" Snyder said. "Insurance companies don't make money by paying you money, right?"

Rae Guyse, an associate at Carrington Coleman Sloman & Blumenthal LLP, said standard insurance forms that include illegality and federal law exclusions could prevent psychedelic therapy providers from being able to secure coverage on their claims.

"If you have any broad exclusions related to health hazards, claims arising out of a violation of federal law or exclusions barring coverage for criminal acts, the fact that these substances are Schedule I may very well compromise the policy," she said.

Legal experts also warn that the possibility of a 'bad trip' or other possible adverse reaction to psychedelic therapies could potentially lead to lawsuits against providers of psychedelic therapies. That could be true even if a patient gave their informed consent and received treatment by competent doctors, said Michael H. Sampson, an insurance coverage lawyer who co-leads Leech Tishman Fuscaldo & Lampl's cannabis practice.

The cost of defending those kinds of suits could be enormous to therapy providers, even if they eventually prevail at some point in the litigation process, Sampson said.

"It may not be, for example, that having a general liability policy is sufficient," he said. "If you're a clinic provider engaged in some sort of treatment involving psychedelics, you may well need to have some sort of professional liability or errors and omissions policy."

Contraband exclusions in property policies could also be implicated, experts say.

Jodi Green, an attorney with Miller Nash LLP who has experience in cannabis and psychedelics, said she has not yet seen any policies specifically tailored to psychedelic businesses. Insurers also might try to

limit their risks with high deductibles, she said. Still, Green noted that the psychedelic industry has grown despite the challenges.

"There's lots of investing activity going on," Green told Law360. "A lot of Canadian companies in particular that have started various stages of clinical operations using several different psychedelic compounds — psilocybin, LSD, DMT, MDMA."

To meet the needs of businesses and providers, there do exist brokerages dealing in psychedelics.

Eric Rahn, managing director of the brokerage Rahn & Associates, which focuses on hard-to-place coverages, said his business has recently dealt with licensed trainers, guides and psychedelic retreats both in the U.S. and abroad. He said his clients need protection against risks like sexual misconduct and health care privacy breaches.

As for the type of clients, big or small: "It runs the gamut," Rahn told Law360. "We wrap pretty much a professional medical [errors and omissions policy] around you."

It's important, Rahn said, that psychedelic businesses find trustworthy advisers.

"They have to have a good lawyer, a good accountant, good insurance and a bank," Rahn said. "And from there, you can build a foundation of any business."

What a fully developed psychedelic industry might look like remains to be seen. But experts say issues of social justice should be prioritized, given the long history of psychedelic substances outside of Western medicine and a legal system that still punishes marginalized communities disproportionately for drug use and possession.

Evidence shows that psychedelic compounds in mushrooms have been used by indigenous peoples in spiritual and religious contexts for hundreds, if not thousands, of years. These lineages and uses of psychedelics need to be considered along with questions of social equity as the psychedelic industry develops, Ariel Clark said.

Businesses could be set up as public benefit corporations, she said. Those kinds of companies are often subject to stronger transparency and reporting requirements, and they have legally defined social goals to achieve, as well as profit considerations.

"You've got psychedelic drug companies who are filing patents on psychedelics, and different forms of psychedelics, and different delivery methods, and therapies that are the cultural property of indigenous people," she said. "Do we really want the same sort of driver to be trying to maximize profits for shareholders? That is dangerous, actually."

--Editing by Emma Brauer.