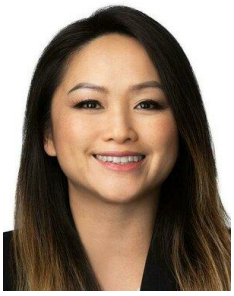
LAW360

Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Psychedelic Sector Can Learn From Cannabis Legal Hurdles

By **Karen Luong and Marshall Custer** (May 5, 2022, 5:09 PM EDT)



Karen Luong

Marshall Custer

Business is booming for companies and institutions developing and researching psychedelic drugs for the treatment of mental health disorders, and the cannabis industry seems like a natural place to look for guidance.

While parallels exist between the movement toward legalization of psychedelics and cannabis, these two industries differ in many ways — but that is not to say that psychedelics hasn't benefited from the path cannabis has helped to clear.

This article examines the psychedelic renaissance, the divergence of the psychedelic and cannabis movements, and how they can learn from one another.

The Psychedelic Renaissance

The mid-20th century saw a high level of research activity directed toward finding therapeutic uses of psychedelics, efforts that were ultimately abandoned largely due to stricter federal regulations, advances in competing small-molecule research and, later, biotechnology and the development of modern antidepressants.

However, as the COVID-19 pandemic has spurred a renewed focus on mental health, we are observing a cultural shift toward destigmatization, if not yet widespread acceptance, of the potential benefits of psychedelics in a therapeutic context.

What were previously seen as recreational and potentially dangerous drugs are now being researched and developed as legitimate and effective treatments for a variety of medicinal uses.

Psychedelic substances, such as MDMA; psilocybin, the active ingredient in magic mushrooms; LSD; and DMT currently remain on Schedule I of the Controlled Substances Act. This means the U.S. Drug Enforcement Administration considers them to have no medical value and a high potential for addiction, and possession and use are federally illegal.

However, recent and ongoing clinical trial results showing real therapeutic benefits are poised to change this, potentially leading to a rescheduling of at least one of these substances in the next few years.

In May 2021, the Multidisciplinary Association for Psychedelic Studies, or MAPS, published its phase 3

results for a clinical trial using MDMA in conjunction with psychotherapy to treat post-traumatic stress disorder. After three treatments, 67% of the participants no longer qualified for a PTSD diagnosis. MAPS is working toward U.S. Food and Drug Administration approval of its protocol in mid-to-late 2023, which could lead to a rescheduling of MDMA.

Multiple other clinical trials are currently underway, run by private companies, nonprofits and academic research institutions to test the effectiveness of psychedelics for the treatment of everything from depression and addiction to chronic pain and traumatic brain injury.

The success of these and future studies stand to reshape drug policy in the U.S. — and, proponents hope, usher in a new era of acceptance and legitimization of these substances for medical use.

Legislative and regulatory developments have progressed concurrently with the scientific research.

In 2020, Oregon passed Measure 109, which established a regulated psilocybin therapy system and formed the Oregon Psilocybin Advisory Board to develop guidelines for implementation in 2023.

Currently, at least 21 states have limited judicial exceptions, pending legislation or completed legislation to decriminalize or legalize psychedelics in some capacity.

In 2021, the DEA twice increased its production quota for research of psilocybin, signaling a growing awareness of possible research and therapeutic uses.

Additionally, the DEA recently granted Cybin a manufacturing license to manufacture Schedule I substances, including psilocybin, within the U.S., at its lab in Boston.

In October 2021 the National Institutes of Health awarded Johns Hopkins University nearly $4 million for the research of psychedelics' potential medical benefits — the first federal grant for this purpose in 50 years.

The scientific, regulatory and legal developments of recent years have led to an influx of psychedelics-based biopharmaceutical companies into the mainstream, including several who have listed on the Nasdaq.

As private industry interest in this space grows and the business case for the development of these drugs becomes clearer, we can expect to see more and more companies and venture capital firms throw their hats into the ring.

Importantly, psychedelic substances have been used sacramentally by Indigenous populations for thousands of years, and developers seeking intellectual property protections in this space should recognize and learn from, not co-opt or exclude, the communities that have practiced entheogenic therapy long before any company took notice.

How the Psychedelic Industry Is Different From Cannabis

It is natural, when thinking about the psychedelic movement, to draw parallels with the cannabis industry. True, both involve Schedule I controlled substances, and the push toward legislative and societal acceptance. However, psychedelic therapeutics differ from the cannabis industry in several key ways.

Chief among these differences is the fact that the modality of proposed treatments often include a mandatory psychotherapy component, referred to as integration sessions. The addition of a therapy component carries its own breed of potential professional liability, insurance issues and ethical concerns, especially in conjunction with mind-altering and inhibition-reducing substances.

Another distinction is that the nature of psychedelic molecules and innovations related to their administration lend them more readily to patent protection.

Drug companies are already rushing to patent a panoply of formulations in this space and are already seeing IP disputes as companies compete with one another, as well as a push by nonprofit organizations that support a patent-less system allowing for psychedelics to be made accessible to those who need it most.

In addition, the potent and reality-bending nature of some psychedelics do not lend themselves to recreational use as readily as cannabis — and unlike cannabis, the movement toward legalization for psychedelics has remained focused on their medical and therapeutic potential.

Due to the rigorous clinical trial work on MDMA-assisted therapy, it may receive FDA approval and DEA rescheduling before cannabis gets descheduled.

Indeed, cannabis is having somewhat of an identity crisis at the moment. Most of the current industry is focused on adult-use, which requires descheduling; however, cannabis got its first step toward legitimization pushing a medical use policy, typically accomplished by rescheduling. Harmonizing these two competing use cases complicates the process for comprehensive federal legislation.

As with psychedelics, pharmaceutical companies want their piece of what could be a very big pie. While there is precedent in the DEA disallowing generics of FDA-approved, brand-name formulations of cannabis — see: Marinol and dronabinol — it remains to be seen whether the DEA will take a similar approach to psychedelics.

Learning From the Cannabis Industry

Colorado was the first state to pass and implement a comprehensive medical marijuana licensing program in 2010. Adult-use marijuana followed, with Colorado's first retail stores opening in 2014.

Across the country the pattern repeats itself: Medical marijuana passes first, followed by adult-use in a few years. The reason for the pattern is simple — it works, because the public is inherently aware of the medical potential for cannabis products and is more likely to accept medical marijuana legislation as a first step.

For those of us that support regulated adult-use cannabis, this legislative strategy has been very successful. However, the downside has been that it has detracted from the medical marijuana movement, at least as a state-regulated phenomenon, stunting its development. Rigorous medical research involving cannabinoids remains in its infancy, and in many ways lags the current state of psychedelic medical research.

Much like early marijuana legislation efforts, the discussion surrounding psychedelics revolves around its incredible medical potential. However, it would be a mistake to use medical psychedelics legislation as a

quick jump to state-sanctioned adult use. Such a tactic is likely to impede continued research as resources are drawn into the fast returns promised by an adult-use market.

More importantly, polling suggests the public is much more wary of recreational psychedelics, though we all know how fast public opinion can swing the more it is exposed to an issue.

If the psychedelic industry is to progress as quickly as it can, it should fully embrace and fulfill the public's perception of its medical potential. This means continuing to push for federal rescheduling and FDA oversight.

We would add that decriminalization efforts and restoring the rights of Indigenous people are actually more important — but then you might forget we are heartless big firm attorneys.

There are several other more practical lessons the psychedelic industry can learn from the cannabis industry. To traditional companies and practitioners, these are obvious, but remember: There are a large number of people from the early cannabis industry that have started new psychedelic companies in the past three to four years.

First, this is not the handshake, bootstrap world of early cannabis. You need contracts, you need sound legal advice at every stage, and there are far fewer problems that you will be able to fix later if you ignore them now. If the goal is to one day commercialize a new therapy or sell to a larger pharmaceutical company, there is little to no room for error when it comes to documenting and locking down intellectual property.

Second, don't worry so much about Internal Revenue Code Section 280e, the tax code that prohibits a business involved in federally illegal activity from deducting ordinary business expenses.

If you have an adviser telling you to create a spiderweb of affiliated entities, get a second opinion. If you are extremely worried about Section 280e, you likely have a bigger problem with your business model or financing plan than you do your corporate structure.

Finally, pretend the FDA already regulates your industry. Unlike cannabis, the psychedelic industry has the opportunity to skip over much of the legislative mess involved with inventing a new industry. Instead, there is a relatively straightforward path open for quick rescheduling and FDA oversight.

Early-stage psychedelic companies would be wise to pretend applicable FDA regulations and processes already apply to their activities, as it will save a great deal of time and money down the line.

Karen Luong is senior counsel at Husch Blackwell LLP and co-leader of the firm's psychedelic and emerging therapies practice group.

Marshall Custer is a partner at the firm and head of its cannabis practice group.

Disclosure: MAPS is a client of Husch Blackwell.