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Outside Counsel

Psychedelic Startups Set To Capitalize On Evolving Regulatory Landscape

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In 2019, Dr. Katherine MacLean and Brett Greene coined the term "corporadelic" to describe the corporate commodification of the psychedelic "landscape." And they couldn't have been more on point. There has been an explosion of renewed interest in the psychedelic space, specifically in the medical application of psychedelic substances as a therapeutic treatment for mental and emotional disorder. This has caught the eye of some of the largest names in private equity, and investor enthusiasm is not going unnoticed.

Industry reporting has tracked some of these cutting-edge psychedelic biotechs through a series of highly successful funding rounds, which have culminated in initial public offerings. For example, in June 2021 Peter Thiel-backed Atai raised $225 million in its first day of trading on the New York Stock Exchange. Now valued at $2.3 billion dollars, the German biotech firm is developing therapeutic treatment for addiction and mental illness using psilocybin, LSD, and methylenedioxymethamphetamine, or MDMA. Atai's subsidiary, Perception Neuroscience, has received an unprecedented FDA approval to conduct a clinical trial on the effects of a nonpsychedelic form of Ketamine on depression.

There are now over 30 companies focused on psychedelics and other mind altering drugs that are publicly traded in the US, including COMPASS Pathways, MindMed and Field Trip to name a few.

The interest in psychedelics is not limited to those in the private sector hoping to see returns from investment in psychedelic research and development. State and local governments are rethinking the way psychedelic substance use is perceived and handled within the criminal justice system. Oregon has broadly legalized the possession and consumption of Schedule 1 substances, and dedicated resources previously used to lock day-trippers up towards creating state-funded substance abuse rehabilitation programs. New York is considering legislation that would authorize psychedelic therapy treatments for patients upon recommendation from state Department of Health licensed practitioners. Washington, D.C., and local governments in Oakland, Denver and Detroit are also following suit, with voter approved ballot initiatives that have decriminalized possession and use.

However, psychedelics remain categorized as Schedule 1 substances under the United States Controlled Substances Act. This designation, which declares that there is no medically accepted use for the listed substance, makes it virtually impossible to broadly research all the benefits that could be available to the public from relaxed regulation or even recreational use. At this stage, the hope should be that once Congress or the FDA or both realize the incredible social (and revenue)

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implications of introducing these substances into the stream of commerce, they'll realize what they are missing out on and embark on a course of decriminalization and deregulation similar to that which we saw following statewide legalization of marijuana. But, before we get there, maybe we should tune in, drop out, and remember how we got here, in the first place.

The current system of drug regulation in the United States traces back to the 1961 United Nations Single Convention on Narcotic Drugs, an international treaty designed to combat drug trafficking and limit the production, distribution and possession of illicit drugs to medical and scientific purposes. This was followed by the 1971 United Nations Convention on Psychotropic Substances and the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropics.

The United States Comprehensive Drug Abuse Prevention and Control Act of 1970 (also known as the Controlled Substances Act or CSA) brought the United States into compliance with the United Nations Single Convention and created the precursors to the five schedules of controlled substances we recognize today. The United States Psychotropic Substances Act (the PSA) of 1978 amended the CSA to capture psychotropic substances within the CSA's classification framework. Ever since the enactment of the PSA, psychotropic drugs have remained listed as Schedule 1 substances that have a high risk of abuse while serving no legitimate medical purpose.

The New York State Controlled Substances Act mirrors the CSA and also creates a scheduling system where drugs are classified according to their perceived risk of abuse and potential medical application—or lack thereof. As with the CSA, the NY Controlled Substances Act classifies psilocybin, LSD, and other psychedelics as Schedule I substances.

Substances may only be removed from the CSA or modified into another Schedule through Congressional legislation or administrative rule-making. Despite the glacial pace and current uncertainty surrounding proactive Congressional action, legitimizing psychedelic substances and introducing them into the marketplace may be closer to a reality than it seems. Another Schedule I substance, marijuana, benefitted greatly from a shift in public perception, and a rapid wave of legalization and decriminalization at the state level soon followed.

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By 2010, 14 states had legalized medical marijuana programs as more and more attention was drawn to the therapeutic properties that the marijuana plant and its derivatives, such as CBD, possessed. The sudden prevalence of these compassionate care programs arguably softened the public's opinion on marijuana, and conversations began to turn to the revenue-generating potential that could arise from the legalization of adult recreational usage.

Beginning in 2012, Colorado and Washington became the first states in the nation to legalize recreational marijuana consumption. Ten years later, legalization initiatives in New York, Virginia, New Mexico and Connecticut have now brought the total number of states that have legalized recreational marijuana to 18. Medical programs have continued to grow, with 36 states and four territories now having some form of medical marijuana program.

No doubt that more states will soon follow, especially considering how those states that have legalized recreational marijuana have seen significant revenue growth (the Tax Foundation reported that in 2020 alone states with legalized and licensed marijuana marketplaces collected $1.7 billion dollars in state level excise taxes).

It requires no great inferential leap to conclude that the interest in marijuana's medical applications likely opened the door for a resurgence in the interest of the therapeutic properties of psychedelic substances. And the wellness applications of psychedelics look just as, if not more, promising than those associated with marijuana. Recent studies have examined the correlation between using psychedelics and a decrease in psychological distress; others hypothesize a link between consistent usage of hallucinogens and a decreased likelihood of developing mental disorders.

The potential has prompted many of the more storied medical institutions in the country to create centers to explore psychiatric treatment through psychedelics. In early 2021, New York University's Langone Health Department of Psychiatry established the Center for Psychedelic Medicine with over $10 million in philanthropic funding; the Icahn School of Medicine at Mount Sinai launched the Center for Psychedelic Psychotherapy and Trauma Research at roughly the same time.

And, happily, interest no longer appears to be limited to private institutions with private funding. The federal government is more actively supporting the exploration of psychedelic treatments. In October 2021, Johns Hopkins Medicine received a grant of nearly $4 million from the National Institute of Health to explore the impacts of psilocybin on tobacco addiction.

On Aug. 16, 2017, the Food and Drug Administration granted Breakthrough Therapy Designation to the Multidisciplinary Association for Psychedelic Studies (MAPS) use of MDMA in clinical trials. Currently, MAPS is using this accelerated development and review status to work in partnership with the United States Department of Veteran Affairs and the James J. Peters VA Medical Center, conducting a trial that explores the effects of multiple doses of MDMA on up to 60 United States veterans suffering from moderate to severe Posttraumatic Stress Disorder. And yet, despite these developments and the swelling interest in both the private and public sectors, psychedelics remain a Schedule I substance.

And so, as with marijuana, the states are now leading the way in decriminalization, deregulation and legalization. On Nov. 3, 2020, voters in Oregon approved ballot Measure 110, which authorized the use of psilocybin for medical purposes under state law.

The measure also reduces penalties for drug possession and makes Oregon the first state to decriminalize the personal possession of illegal drugs. For possession of smaller amounts of controlled substances, Measure 110 reduces the penalty from the criminal misdemeanor level to a new, Class E violation, punishable by a $100 fine. In lieu of a fine, a person charged with a violation may instead complete a health assessment at an Addiction Recovery Center.

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Measure 110 also removes penalty enhancements for possession of smaller amounts of controlled substances where the individual has a previous felony conviction or multiple previous convictions for possession. Oregon will dedicate anticipated savings from the current cost of enforcing drug possession penalties to the establishment of grants to fund drug addiction treatment and rehabilitation centers.

Oregon is not alone. In December 2021 New York Assemblyman Pat Burke introduced Assembly Bill A08569, which seeks to "… create psilocybin service centers to provide innovative treatment options for ailments such as PTSD, depression, alcohol dependency [and] anxiety, among others." Although the bill includes a specific list of maladies that could qualify a patient for psilocybin treatment, it also allows therapist practitioners to make recommendations for "any other condition" to be treated with psilocybin therapy.

New York's Department of Health (NYDOH) will be responsible for creating a training program to qualify therapists interested in recommending the treatment for patients. NYDOH would also be responsible for licensing psilocybin service centers, cultivators, processors, testing facilities and scientists interested in continuing research on fungi properties.

States and localities are wise to begin reconsidering their positions on the regulation of psychedelic substances. One need only look to the financial performance of the recreational marijuana industry and the resultant impact on state and local revenues for an example of the potential financial windfall that deregulation could bring about. According to a recent study, "U.S. Psychedelic Drugs Market—Industry Trends and Forecast to 2027," by Data Bridge Market Research, the potential market in psychedelics is estimated to be as much as $7 billion by 2027. And that's a trip we would all be crazy to pass up.