Quinn Emanuel Cannabis Litigation Practice Alert

New Frontiers in the Law of Psychedelics

The state of the law on psychedelic substances is in flux. Not only are more and more jurisdictions decriminalizing the use of psychedelics for recreational purposes, but it appears that psychedelic substances are the new horizon for the treatment of severe psychological disorders and other ailments. This article provides an overview of the current state of legality of common psychedelic substances, and some of the potential therapeutic uses to which psychedelics may be applied.

The use of psychedelic substances to treat mental illness and physical disorders is known as "psychedelic therapy." In a typical scenario, psychedelic substances would be used in conjunction with psychotherapy sessions to treat disorders for which other medicinal therapies have failed. Patients would participate in therapy sessions to prepare for the use of psychedelics, after which the substances would be administered under the guidance and supervision of trained medical professionals. So far, psychedelics have shown promise in alleviating some of the hardest-to-treat conditions in the world, including, among others: (a) depression, anxiety, and pain associated with terminal illness; (b) addiction to alcohol, cocaine, tobacco and other substances; (c) post-traumatic stress disorder; (d) obsessive compulsive disorder; and (e) cluster headaches.

Psychedelic therapy is not a fringe phenomenon. Many of the world's leading research institutions have been investigating the potential uses of psychedelic therapy, including Johns Hopkins; the University of California-San Francisco (UCSF); Yale University; New York University (NYU); Imperial College London; the University of California-Berkeley; and the Harvard University-affiliated Massachusetts General Hospital. Further, numerous private companies have begun to research psychedelic therapy and develop new pharmaceutical compounds derived from psychedelic substances. These companies not only include new entities that were founded with the primary purpose of conducting medical research on psychedelic therapy, but also established companies like Johnson & Johnson and Abbott Labs. Collectively, private investors have poured billions of dollars into these companies, with more money coming from non-profit organizations.

Some of the most promising substances, and the law applicable to each, are outlined below:

Psilocybin

Psilocybin is a naturally occurring compound produced by over 200 species of mushrooms. Psilocybin is currently categorized as a Schedule I substance under the federal Controlled Substances Act. As such, the use, sale, and possession of psilocybin in the United States is illegal under federal law. However, numerous jurisdictions across the United States have begun to decriminalize the recreational use of psilocybin. Denver, Colorado was the first jurisdiction to decriminalize the use of psilocybin via ballot initiative in May 2019. Since then, several cities and counties have followed suit, including Oakland and Santa Cruz in California; Ann Arbor and Washtenaw County in Michigan; Somerville, Cambridge, and Northampton in Massachusetts; and Washington D.C. On November 3, 2020, Oregon became the first state to decriminalize psilocybin for recreational purposes. As part of the same state-wide initiative, Oregon *legalized* the use of psilocybin for medical purposes. In June 2021, similar measures were passed in Connecticut and Texas, where medical research on psilocybin is now also legal on a

statewide level. Joyce Cutler, *Texas the Latest State to Legalize Psychedelic Medical Research*, BLOOMBERG LAW (June 23, 2021), *available at* https://bit.ly/363GGdD.

Although psilocybin has been recreationally decriminalized in numerous jurisdictions, it appears that psilocybin's most promising application may be for therapeutic purposes. Beginning in 2018, the FDA has started to grant special designations to study the medicinal use of psilocybin via Breakthrough Therapy status. The FDA's Breakthrough Therapy designation is a special status granted to select drugs for which preliminary evidence suggests a substantial improvement over available therapies, and is meant to expedite drug development. *See* Deborah Brauser, *FDA Permits Psilocybin to Be Tested for Refractory Depression*, MEDSCAPE (Oct. 30, 2018), *available at* https://www.medscape.com/viewarticle/904159. In October 2018, the FDA granted the first Breakthrough Therapy designation for psilocybin to a company called COMPASS Pathways, for use in addressing treatment-resistant depression. *Id.* Then, in November 2019, the FDA granted the designation to the nonprofit Usona Institute to study psilocybin's effect on major depressive order, for which clinical trials are currently under way. *See* Usona Institute, *A Study of Psilocybin for Major Depressive Disorder (MDD)*, Clinical Trial ID NCT03866174, *available at* https://clinicaltrials.gov/ct2/show/NCT03866174. In 2020, Canada also began granting legal exemptions for use of psilocybin in medical research, as well as for use by certain doctors and therapists to treat terminally ill patients. Research in North America and beyond indicates that psilocybin may be useful in treating severe depression and anxiety, distress associated with terminal illness, addiction, OCD, cluster headaches, and obesity.

The federal government and most of the states in the U.S. have also passed "Right to Try" laws. Right to Try laws permit patients with serious or life-threatening diseases to access drugs that do not yet have government approval. Since May 2014, 41 states have enacted Right to Try laws. In May 2018, the federal Right to Try Act (the "Act") was signed into law. 21 U.S.C. § 360bbb-0a. The Act and its accompanying regulations permit patients with a life-threatening disease or condition to try certain "investigational drugs" if they have exhausted FDA-approved treatment options, and give their physicians informed written consent. *Id*; 21 CFR 312.1-10; 312.80-88; 312.300 et seq. "Investigational drugs" are defined as drugs which are not FDA approved for any purpose, but for which a Phase 1 clinical trial has been completed. 21 U.S.C. § 360bbb-0a(a)(2). The Act makes no mention of the Controlled Substances Act, which is enforced by the U.S. Drug Enforcement Agency ("DEA"). *See id.* Some physicians and therapists have argued that the Right to Try Act permits them to administer psilocybin to terminally ill patients (since studies are well past the Phase 1 stage), but the DEA has met this with resistance given psilocybin's status as a Schedule I drug.

For example, a palliative care physician from Seattle, Washington has petitioned the Ninth Circuit for review of a DEA final agency action which declared that the DEA "has no authority to waive" any requirements of the Controlled Substances Act, including with regard to psilocybin and the Right to Try Act. *AIMS Institute, PLLC. et al. v. U.S. Drug Enforcement Agency et al.*, No. 21-70544 (9th Cir. March 8, 2021). A coalition of state attorneys general, end-of-life groups, researchers, and physicians have filed amicus briefs in support of the petitioning physician, arguing among other things that (1) the DEA's statutory and regulatory interpretations were improper; (2) the DEA's final agency action would improperly restrict states' rights or otherwise upset the balance of federalism; and (3) the DEA's final action is counter to the Right to Try Act's underlying purpose and legislative intent. *See, e.g.*, *Amicus Curiae Brief by State Attorneys General*, 2021 WL 2189172 (May 21, 2021); *Amicus Curiae Brief by End of Life Groups and Physicians,* 2021 WL 2189173 (May 21, 2021); *Amicus Curiae Brief by the ACLU of Washington*, 2021 WL 2189174 (May 21, 2021). Briefing is still under way, with the DEA's responsive brief submitted on June 25, 2021, and the petitioners' reply due July 16, 2021. *See* June 8, 2021 Order, *AIMS Institute et al. v. DEA,*

No. 21-70544, Dkt. 43. Although it is unclear how the appeal will play out, resolution of this case will likely have serious consequences for "Right to Try" efforts throughout the Ninth Circuit and the country at large, including in Oregon where the medical use of psilocybin was legalized on a state-wide level in 2020. As such, entities and individuals with an interest in the therapeutic use of psilocybin should pay close attention to the *AIMS Institute* litigation and its resolution.

Ketamine

Ketamine is a synthetic compound used primarily to induce and maintain anesthesia in clinical settings. Ketamine is currently categorized as a Schedule III substance under the Controlled Substances Act, and is FDA approved for use as an anesthetic. However, outside of the clinical setting, the use, sale, and possession of ketamine is illegal under federal law. Ketamine also remains criminalized on a statewide level in the United States. However, in 2021, legislators in the California State Senate proposed a bill that would decriminalize the use and possession of ketamine, along with other psychedelics, within the state of California. *See* California Senate Bill 519 (last amended May 20, 2021) (proposing to decriminalize psilocybin, DMT, mescaline, LSD, MDMA, ketamine, and other enumerated psychedelics on a statewide level). The bill was approved by the State Senate on June 1, 2021, and was approved by the Assembly's Public Safety Committee on June 29, 2021. It is now set for at least two more rounds of voting by the Assembly's Public Health and Appropriations committees, with the next step being a roll call vote before the entire House.

Although ketamine is an FDA approved anesthetic with a long history of use in the clinical setting, it appears that ketamine may have uses beyond anesthetizing patients. For example, ketamine is widely used as a third-line drug for treating opioid-resistant pain in patients dealing with cancer, life-threating disease, and other intractable chronic pain disorders. Further, like with psilocybin, the FDA has issued a Breakthrough Therapy designation for use of ketamine to treat severe depression. In August 2016, the FDA granted the Breakthrough Therapy designation for use of esketamine, a nasal spray derived from ketamine and aimed at addressing severe forms of depression. *See* Press Release, Johnson & Johnson, *Esketamine Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration* (Aug. 16, 2016), *available at* https://bit.ly/35IsuGS. Since then, "ketamine clinics" have proliferated throughout the U.S., where patients are legally administered ketamine for treatment of mental illness and severe pain. *See* Kristin O'Connor, *The Proliferation of Ketamine Infusion Clinics*, LEGITSCRIPT (Oct. 30, 2019), *available at* https://www.legitscript.com/blog/2019/10/the-proliferation-of-ketamine-infusion-clinics-presents-opportunities-and-uncertainty/. In March 2019, the FDA issued a final approval for the use of esketamine to address treatment-resistant depression. *See* FDA New Drug Application Approval, NDA 211243, (March 5, 2019). In July 2020, the FDA also approved esketamine for the short-term treatment of suicidal thoughts. *See* NDA 211243, Supplement 4 (July 31, 2020). Today, it is sold under the brand name SPRAVATO, and is prescribed by doctors throughout the United States.

MDMA

MDMA, also called "ecstasy" or "molly," is a psychoactive drug primarily used for recreational purposes. MDMA is currently categorized as a Schedule I substance under the Controlled Substances Act, and is therefore illegal to use, sell, and possess under federal law. However, in November 2020, voters in Oregon approved a ballot initiative that lowered the penalties for personal use of MDMA, LSD, and all other recreational drugs, and for which the penalty is now similar to a simple parking ticket. *See* Oregon Ballot Measure 110 (2020). Further,

as with ketamine and other enumerated psychedelics, MDMA would be decriminalized throughout California if proposed Senate Bill 519 is signed into law.

Although MDMA is traditionally a party drug used at raves and other social gatherings, it appears that MDMA may have significant therapeutic applications as well. Recent research suggests that MDMA may be useful for treating disorders such as PTSD, alcohol use disorder, and anorexia. For example, in August 2017, the FDA granted a Breakthrough Therapy designation for using MDMA to treat PTSD. *See* Janet Burns, *FDA Designates MDMA As 'Breakthrough Therapy' For Post-Traumatic Stress,* FORBES (August 28, 2017), *available at* https://bit.ly/3gM9X2Q. Subsequent studies on MDMA have shown a highly significant therapeutic effect on PTSD symptoms and subjective wellbeing in PTSD patients—including studies published in some of the world's most prestigious peer-reviewed journals, like Nature. *See* Jennifer M. Mitchell, *MDMA-Assisted Therapy For Severe PTSD: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study,* 27 NATURE MEDICINE 1025-1033 (May 10, 2021). Although research on MDMA continues, it appears that MDMA may no longer be the pure party drug that it was once considered to be.

LSD

Lysergic acid diethylamide (LSD), also known as "acid," is a synthetic compound which is derived from a fungus and created through a series of chemical reactions. It produces hallucinogenic effects in users. LSD is currently categorized as a Schedule I substance under the Controlled Substances Act, and it is therefore illegal to use, sell, and possess LSD on a federal level. While several large cities such as Denver, Oakland, and Washington D.C. have decriminalized naturally occurring psychedelics like psilocybin, synthetic compounds like LSD have not been given the same treatment. If California Senate Bill 519 is signed into law, however, LSD would be decriminalized throughout the entire state along with other psychedelics. *See* California Senate Bill 519 (last amended May 20, 2021). Further, as part of the same Oregon ballot initiative that reduced the penalties for personal use of recreational drugs like MDMA in November 2020, the personal use of LSD is now a mere infraction in the State of Oregon.

Although LSD may have once been considered a fringe recreational drug, it now appears to have legitimate therapeutic uses. For example, a U.S.-based company has begun to study a combination therapy that blends LSD and MDMA in different amounts to treat various forms of mental illness and other ailments, such as mood disorders, existential anxiety, and cluster headaches. *See* Will Yakowicz, *Drug Development Company To Launch First LSD-MDMA Combination Clinical Trial* , FORBES (August 31, 2020), *available at* https://bit.ly/3d1o9m1. Although the trials are being conducted in Switzerland, this study may be an important step for convincing the FDA to grant Breakthrough Therapy status to LSD in the U.S., whether alone or in combination with other substances.

Ayahuasca (DMT)

Ayahuasca is a psychoactive tea brewed from certain vines and shrubs that are native to the Amazon rainforest. The primary psychoactive component of ayahuasca is DMT, which is a naturally occurring chemical produced in many species of plants and animals. DMT is currently categorized as a Schedule I substance under the Controlled Substances Act, and is therefore illegal to use, sell, and possess under federal law. However, like psilocybin, ayahuasca has been recently decriminalized in numerous cities across the United States, including Santa Cruz, Oakland, Ann Arbor, and Washington D.C. Further, as with ketamine and other enumerated psychedelics, ayahuasca would be decriminalized statewide if California Senate Bill 519 is signed into law.

Ayahuasca has been used by indigenous peoples of the Amazon basin as a traditional medicine in religious and spiritual ceremonies for hundreds of years.[1] Like with other psychedelics, however, it appears that ayahuasca and its main psychoactive component (DMT) have a therapeutic application that goes well beyond traditional use by indigenous peoples. For example, in early 2021, a Canadian company announced a clinical research program for treatment of stroke using a compound derived from DMT named AP-188, for which the company is seeking a Breakthrough Therapy designation from the FDA. *See* Mark Zipkin, *FDA to Consider Allowing Trials for Algernon's Psychedelic DMT*, BIOSPACE (March 17, 2021), *available at* https://www.biospace.com/article/fda-to-consider-allowing-trials-for-algernon-s-psychedelic-dmt/. Further, regulators in the United Kingdom recently approved clinical trials for studying use of DMT to treat severe depression, for which trials commenced in February 2021. *See* Rachel Schraer, *Psychedelic therapy could 'reset' depressed brain*, BBC NEWS (March 15, 2021), *available at* https://www.bbc.com/news/health-56373202. New research in Australia suggests that DMT might also be useful for treating PTSD, and a study in Spain found that DMT promotes formation of new brain cells, which may be crucial for treating Alzheimer's and Parkinson's disease. *See* Jose A. Morales-Garcia et al., *N,N-dimethyltryptamine compound found in the hallucinogenic tea ayahuasca, regulates adult neurogenesis in vitro and in vivo*, 10 NATURE - TRANSLATIONAL PSYCHIATRY 331 (Sept. 28, 2020). It remains to be seen whether ayahuasca and DMT may be useful for treating other disorders and ailments.

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As more research is being conducted on the therapeutic applications of psychedelic compounds, it appears that psychedelics may be the "new wave" in treating mental illnesses and other disorders. Although long-stigmatized and neglected by society—and criminalized by the law—it now seems that psychedelic compounds may hold the secret to treating certain diseases and disorders that were once considered intractable. Although it is unclear how the legal issues identified above will play out, the law is moving in the direction of being more accepting of psychedelics, especially in the clinical setting. Entities and individuals with an interest is psychedelics should pay close attention to the resolution of these legal issues, as these substances and their accompanying medical applications may shape-up into an extremely active and lucrative market in the years to come.

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[1] Given the traditional use of ayahuasca in religious ceremonies, some courts in the United States have even granted limited exemptions for legal use of ayahuasca pursuant to the Religious Freedom Restoration Act. *E.g.*, *Church of the Holy Light of the Queen v. Mukasey*, 615 F. Supp. 2d 1210, 1221 (D. Or. 2009) (Church in Oregon granted exemption for variety of ayahuasca called Daime tea); *O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 282 F. Supp. 2d 1236, 1270 (D.N.M. 2002) (same; religious group in New Mexico granted exemption for ayahuasca).

If you have any questions about the issues addressed in this Client Alert, or if you would like a copy of any of the materials we reference, please do not hesitate to contact us:

Robert Becher
Email: robertbecher@quinnemanuel.com
Phone: 213-443-3182

Jomaire A. Crawford
Email: jomairecrawford@quinnemanuel.com
Phone: 212-849-7581

Leonidas Angelakos
Email: leonidasangelakos@quinnemanuel.com
Phone: 650-801-5073