



THE HEALTH LAWYER

June 2022 – Volume 34, Number 5

IN THIS ISSUE

Chair's Column: Challenges, Resiliency and Friendship!, Page 3

By Clay J. Countryman, Breazeale, Sachse & Wilson, LLP, Baton Rouge, LA

Legal Developments in Psychedelic Therapeutics, Page 4

By Karen Luong, Esq., Husch Blackwell, Los Angeles, CA and Kimberly Chew, Esq., Husch Blackwell, Oakland, CA

In WHO's Interest?: Regulating Human Germline Gene Editing, Page 15

By Alex Tritell, JD Candidate 2023, Vanderbilt Law School, Nashville, TN

Will 'Forever Chemicals' be Around Forever? An Analysis and a Proposal Concerning PFAS Contamination and Public Health, Page 52

By Michelle G. Scanlon, JD Candidate 2022, St. John's University School of Law, Jamaica, NY

Refusing to "Play God": Hospital Ethics Committees Can Help Navigate Religious and Moral Accommodations in Assisted Reproductive Technologies, Page 82

By Heather Skrabak, J.D. Candidate 2022, The George Washington University Law School, Washington, D.C.

Editorial Board, **Page 127**

Legal Developments in Psychedelic Therapeutics

By Karen Luong, Esq., Husch Blackwell, Los Angeles, CA and Kimberly Chew, Esq., Husch Blackwell, Oakland, CA

Psychedelic drugs¹ like MDMA, psilocybin (“magic mushrooms”), LSD, and DMT are substances that have psychoactive properties. Their widespread use during the counterculture movement of the 1960s invoked harsh criticism and, ultimately, backlash from the government, earning these substances Schedule I designation as drugs that have “no currently accepted medical use.” However, studies have found many psychedelics administered in a clinical setting with a trained therapist to be effective at treating post-traumatic stress disorder (PTSD), depression, anxiety, and substance abuse disorders.² Increased societal focus on the importance of mental health and wellbeing in recent years has led to a renaissance of scientific and commercial interest in psychedelics and their potential as valuable and effective therapies. With the recognition that there is a significant need for effective therapies to address these mental health issues to which psychedelics may address, this emerging drug market is projected to grow to \$10.75 billion by 2027.³

Efforts are advancing across the United States to reschedule (from Schedule I to less-restrictive schedules), decriminalize, and (in some instances) legalize the use of psychedelics in a therapeutic setting. This article provides a brief overview of the regulatory framework restricting the production, sale, and use of psychedelics; discusses psychedelic drugs which have been approved for limited use; and addresses recent legislative developments in the movement to decriminalize and/or legalize the use of psychedelics.

The Regulatory Framework for Psychedelics: A Brief Introduction

All psychedelic drugs discussed in this article, other than ketamine, are considered Schedule I drugs under the federal Controlled Substances Act (CSA).⁴ They are illegal to produce, possess, distribute, or consume. This does not mean that progress toward legitimization is not occurring.

The U.S. Drug Enforcement Administration’s (DEA) Diversion Control Division manages the registration of applicants seeking to study or otherwise handle Schedule I controlled substances for medical and scientific purposes, clinical research, and religious/indigenous use. A big issue with research of Schedule I drugs is that it can disqualify the facility — like a university — from receiving federal funding even for unrelated projects.⁵ However, in late 2021 the DEA significantly increased the production quota in the manufacturing of the Schedule I substances psilocybin, psilocin, cannabis, and cannabis extract⁶ in the recognition of the need to fulfill research and development requirements and as necessary steps toward potential Food

and Drug Administration (FDA) approval of new drug products for 2022.⁷ The DEA also regulates and enforces the importation of controlled substances, their precursors and analogues. In addition to DEA registration, most states have their own controlled substances laws that require pre-review and authorization or licensure for proposed research projects involving any Schedule I substances.

On May 19, 2021, Wake Network, Inc. announced the completion of the first legal psilocybin mushroom import into the United States. Wake had successfully applied for and received all required permits from the DEA to import psilocybin from its production facility in Jamaica to its laboratory in California for research purposes. The fact that the DEA has permitted the import of psilocybin signals a marked departure from its previously strict stance. In 2007, the DEA used its discretion to block the importation of a generic version of the FDA-approved drug Marinol® (the manmade version of cannabis), based on the argument that its active ingredient, dronabinol, was a Schedule I substance.⁸ Since that time, other entities have also been licensed by the DEA to allow the importation of psilocybin. In late 2021 the DEA approved Mycrodose Therapeutics for a Schedule I Import & Distribution license that allows the company to import and sell Schedule I compounds. In February 2022 the company acquired a DEA Schedule I Cultivation license to grow psilocybin mushrooms at its San Diego Laboratory facilities.⁹

However, in January 2022 the DEA proposed adding five tryptamine analogues (4-Hydroxy-N,N-diisopropyltryptamine (4-OH-DiPT), 5-Methoxy-alpha-methyltryptamine (5-MeO-AMT), N-Isopropyl-5-Methoxy-N-Methyltryptamine (5-MeO-MiPT), N,N-Diethyl-5-methoxytryptamine (5-MeO-DET), and N,N-Diisopropyltryptamine (DiPT)), to Schedule I of the CSA.¹⁰ The Federal Analogue Act allows any chemical that is “substantially similar” to a listed controlled substance in the CSA to be treated as if it were a Schedule I substance. Psilocybin, DMT, and psilocin are tryptamines, which are a group of alkaloids derived from tryptophan. Because the five tryptamine analogues at issue are chemically similar to these classic psychedelics, the DEA seeks to classify them as Schedule I substances. The research community is challenging this proposed scheduling and Administrative Law Judge Teresa Wallbaum ordered that parties requesting a hearing to file statements and granted a prehearing conference on the matter for May 4, 2022. The DEA is not bound by the judge’s recommendation; however, is it unusual for a hearing to be granted before the agency’s rulemaking is finalized.

Psychedelic Drug Development and FDA Review

The FDA has numerous programs to facilitate and expedite the development and review of new drugs and address unmet medical need in the treatment of serious or life-threatening conditions. These programs include breakthrough therapy designation, fast track designation, accelerated approval, and priority review.¹¹ In addition, the FDA has programs to facilitate the

development of drugs that treat rare diseases (“orphan drug” status) and provide for expanded access, or compassionate use, of experimental drugs. Each of these designations carries its own requirements, and some overlap.¹²

Breakthrough Therapy Designation, Other Expedited Programs, and Clinical Trials Granted to Psychedelic Drugs

Breakthrough therapy designation is one of the ways the FDA seeks to encourage and expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on at least one clinically significant endpoint over available therapy.¹³ Breakthrough therapy designation confers a number of benefits, including eligibility for all fast track designation features and guidance from senior managers at the FDA. Johnson & Johnson obtained the designation for esketamine (a Schedule III substance, now commercialized as Spravato®) in 2013 (for treatment-resistant depression) and 2016 (for major depressive disorder). Of all the drugs colloquially known as “psychedelics,” MDMA is the furthest along on the path to FDA approval, as it received breakthrough therapy designation from the FDA in August 2017. The nonprofit organization Multidisciplinary Association for Psychedelic Studies (MAPS) is currently running Phase 3 clinical trials and is pushing to remove MDMA’s Schedule I classification in 2023.¹⁴

The FDA also granted psilocybin breakthrough therapy designation status for research in October 2018¹⁵ and again in 2019.¹⁶ Psilocybin for the treatment of resistant depression is entering Phase 3 clinical trials. It is also being investigated for behavioral disorders such as smoking cessation, binge eating disorders, clinician depression and burnout, cocaine use, and obsessive-compulsive disorder. Psilocybin clinical trials for SUNHA (short-lasting unilateral neuralgiform headache attacks),¹⁷ cluster headaches, fibromyalgia, and distress in palliative care are also underway.

The FDA has not yet granted breakthrough therapy status for other psychedelics that are currently undergoing research, including LSD, Ibogaine, and DMT. In January 2022 the FDA greenlit a Phase 2b dose-optimization trial for the treatment of anxiety.¹⁸ Small Pharma completed a Phase 1 DMT clinical trial for depressive disorders in February 2022.¹⁹ Ibogaine has been widely researched for the treatment of substance use disorders.²⁰ It will be interesting to see whether research results eventually support these substances’ inclusion for breakthrough therapy designation.

In addition to breakthrough therapy designation, the FDA has other forms of expedited review processes to streamline the development of pharmaceuticals and treatments. For example, the FDA encourages the development of drugs for rare disorders (where the

economic carrot of huge profits from sales does not exist) by offering orphan drug status, which carries various benefits including fee waivers, tax incentives, and a seven-year marketing exclusivity period.²¹ The first psychedelic to achieve orphan drug status was DMT for the prevention of ischemia-reperfusion injury in patients undergoing solid organ transplantation, in April 2021.²²

Compassionate Use

In certain situations, the FDA allows companies to provide their investigational medical products, including drugs, biologics, or medical devices, to people outside of clinical trials. This is referred to as compassionate use or expanded access. Getting access to not-yet-approved drugs through a compassionate use request is a complex process. In late 2019, the FDA agreed to an expanded access program for MDMA for clinical use to treat PTSD, to be run by MAPS under an approved protocol.²³ The expanded access protocol differs from MAPS' ongoing Phase 3 clinical trials in that it is limited to treatment-resistant patients with moderate to severe treatment-resistant PTSD.²⁴

State and Federal Right to Try Legislation

The federal Right to Try Act, signed into law in 2018, allows patients with serious or immediately life-threatening diseases or conditions who are unable to participate in clinical trials to access certain unapproved treatments.²⁵ Eligible investigational drugs under the Right to Try Act must meet certain criteria defined by the FDA, and patients must meet certain criteria to seek Right to Try use; however, the FDA does not review or approve requests for Right to Try Act use — its role is limited to receipt and posting of certain information.²⁶ Since reporting requirements have yet to be standardized, the FDA currently does not report, and it is unknown what drugs or how many patients have applied for and received approval under this statute.

The intersection of the CSA, the federal Right to Try Act, and state right-to-try laws was tested in a case before the 9th Circuit, *AIMS v. DEA*.²⁷ In this case, a group of physicians in Washington State seeking to administer palliative psilocybin therapy to their terminally ill patients to treat end-of-life anxiety approached the DEA for a determination as to whether this was allowable. The DEA stated that there could be no access to this Schedule I substance other than for research, and thus the therapeutic use by the physicians would not be allowed. The physicians petitioned the 9th Circuit via a direct review provision. The petitioners argued that this was a states' right issue and that the federal government's nullification of state law is impermissible and violates long-standing principles of federalism.²⁸ Amicus briefs filed in support of the petitioners include a bipartisan group of attorneys general from eight U.S. states, the American Civil Liberties Union, and leading policy and advocacy groups on both sides of the

political spectrum. Ultimately the panel dismissed the petition for lack of jurisdiction, finding that the DEA's response letter was informational and did not constitute a final agency action. Thus, the court ruled in January 2022 that the advice letter, which recognized that Congress has not yet made an exception to the CSA to allow for legal use of psilocybin for therapeutic purposes, is not a final agency action.²⁹ In February 2022, the petitioners submitted to the DEA a Petition to Reschedule Psilocybin from Schedule I to Schedule II, and a Request for Waiver to enable access to psilocybin pursuant to state and federal Right to Try laws, seeking an agency action sufficiently "final" to enable judicial review. According to the petitioners, the DEA has yet to acknowledge either submission.³⁰ Activists are now calling for demonstrations of civil disobedience in an effort to gain attention to the issue.³¹

Decriminalization and Legalization

Decriminalization is the decision of a governing authority to not enforce criminal laws relating to the use and possession of drugs such as psychedelics. Legalization would allow for regulation and taxation of drugs, and permission for personal use within parameters set by the government.

Movements to decriminalize psychedelics and other drugs in the United States have been underway for decades, but the last three years have seen significant movement in the passing of legislation. In May 2019, Denver, Colorado, became the first city in the United States to decriminalize psilocybin. Similar legislation has passed, both for psilocybin and other entheogenic substances, in Oregon (statewide); Arcata, Oakland, and Santa Cruz, California; Port Townsend and Seattle, Washington; Ann Arbor, Detroit, and Hazel Park, Michigan; Somerville, Cambridge, Easthampton, and Northampton, Massachusetts; and Washington DC.

Oregon's Measure 110 passed in 2020 with a 58 percent vote of the state population and decriminalized the personal possession of all drugs. In June 2021, SB 519, a California bill to decriminalize the possession or sharing of psychedelic drugs, passed all three committees of the state Senate.³² SB 519 has since been paused and is eligible to move forward in 2022.³³ Connecticut,³⁴ Texas,³⁵ and Utah³⁶ have passed laws to form working groups or investigate the medicinal use of psychedelic-mediated therapy.³⁷

On a statewide level, legislation is currently being proposed to decriminalize, investigate, or otherwise ease restrictions on some psychedelics in a growing list of states. Bills are currently active in Colorado, Florida, Georgia, Hawaii, Iowa, Kansas, Maryland, Massachusetts, Missouri, New Jersey, New York, Oklahoma, Rhode Island, Vermont, Virginia, and Washington, and more states no doubt will follow.

Oregon was the first state to legalize psilocybin therapy in 2020. Ballot measure 109, the Oregon Psilocybin Services Act,³⁸ passed with a 56 percent vote of the state population and will

establish a regulated psilocybin therapy system in Oregon to provide people therapeutic access to psilocybin. Oregon Psilocybin Services (OPS) will be housed within the Oregon Health Authority (OHA) Public Health Division's Center for Health Protection. Measure 109 created the Oregon Psilocybin Advisory Board (OPAB) to make recommendations to the OHA on the requirements, specifications, and guidelines for providing psilocybin services in Oregon. Members of the OPAB are appointed by the state's governor to serve four-year terms.³⁹ OPS is developing the first regulatory framework for psilocybin services in the United States including regulations regarding the manufacture, standards for testing, transportation, delivery, sale, and purchase of psilocybin products and the provision of psilocybin services. Several subcommittees have been formed to advise the OPAB: equity, licensing, products, research, and training. Each subcommittee has been tasked to evaluate and recommend regulations pertaining to different aspects of this new sector, including equity and access to psilocybin treatment, manufacturer standards, facilitator licensing, service center licensing, consumer protection, informed consent, social equity in licensing and laboratory requirements, permissible products, requirements to obtain/renew manufacturing permits, testing protocols, tracking systems, packaging, taxes, safety, efficacy, and production aspects of psilocybin, psilocybin facilitator training, and curriculum development. OPS will be accepting applications for licensure for facilitators, manufacturers, testing labs, and service centers beginning January 2, 2023.⁴⁰

It is impossible to discuss the legalization of psychedelics without drawing parallels to the movement to legalize cannabis; however, the two movements are quite different in their approaches.⁴¹ Unlike the legislation surrounding the decriminalization and legalization of cannabis, the proposed laws on psychedelics do not require individual patients/users to register with a provider or obtain a license (as in the case of medical marijuana licenses). Instead, the burden and responsibility for obtaining the proper licenses and registering with the state falls on providers of psychedelic therapies, such as physicians or clinics seeking to provide the substances for patients. The focus on regulating the providers, not the users, makes enforcement and tracking easier for authorities and reflects the clinical and therapeutic-based approach taken by proponents of psychedelics.

Potency and reality-altering properties of some psychedelic substances may be why the current proposed legislation has largely avoided seeking legalization on a recreational level. Microdosing is an increasingly popular practice in the use of psychedelics like psilocybin and LSD — extremely low doses that are too small to produce perceptible effects, but that proponents claim may nonetheless offer a variety of benefits such as enhanced cognitive abilities, increased energy levels, reduced anxiety, and improved emotional balance.⁴² It remains to be seen whether legislators will eventually push for the legalization of microdoses in a less-regulated setting or without the need for a licensed provider.

Legalization of psychedelics is, as of now, a state-level effort in conflict with federal law. Thus, legislative changes that have taken place at the state level do not change the fact that these substances remain federally illegal. The interplay between states' movements to legalize psychedelics for certain uses and the federal government's control over the same drugs will eventually come to a head. Some policymakers have suggested that the federal government adopt the equivalent of the Cole Memorandum for psychedelics. The Cole Memorandum was a U.S. Department of Justice memorandum issued in 2013 (and repealed in 2018) that instructed state attorneys general to not enforce federal marijuana prohibition in states that had legalized marijuana.⁴³ The purpose was to not waste already scarce federal resources on enforcing laws where states had determined marijuana would be allowed and where the states had established strong regulatory and enforcement mechanisms to enforce those laws. The same argument has been made that state laws legalizing psychedelics should receive similar treatment.⁴⁴

Equity, Inclusion, and Preservation of Indigenous Tradition

Legislative efforts to decriminalize and legalize psychedelic therapeutics have rightly taken into account the traditional use of these substances by indigenous communities. Ayahuasca, mescaline, peyote, and psilocybin, to name a few, have been used for hundreds of years in indigenous ceremonies, and there is growing awareness of the possible effects of legalization. For example, SB519 in California intentionally leaves peyote out of the substances it seeks to legalize, "because of the nearly endangered status of the peyote plant and the special significance peyote holds in Native American spirituality."⁴⁵ The American Indian Religious Freedom Act of 1978 (amended in 1994), codified at 42 U.S.C. 1996-1996a, protects American Indians from penalty, prosecution, or discrimination in public assistance programs for the sacramental use, possession, or transportation of peyote. Ongoing legislative and policy efforts to decriminalize and legalize psychedelics will likely continue to protect their sacramental use by indigenous populations.

Conclusion

The landscape is changing fast around psychedelic drug development, legislation, and research. Phase 3b clinical trials of MDMA-mediated therapy for the treatment of PTSD are anticipated to conclude in 2022, which points to a possible approval of this new modality of treatment in 2023. There are a dizzying number of moving parts to the puzzle, and what holds true today may change tomorrow. As the movement to legitimize psychedelic therapy progresses, one thing is certain: we are entering uncharted waters, and what a trip it will be.

Kimberly Chew is co-founder and co-lead of Husch Blackwell's [Psychedellic and Emerging Therapies](#) practice group. She is a former research scientist with a broad range of litigation and regulatory experience, representing and advising business owners of closely held entities, individual manufacturing facilities, educational institutions, and Fortune 500 companies in product liability, environmental tort, and controlled substance-related matters. She may be reached at Kimberly.Chew@huschblackwell.com.

Karen Luong is a senior counsel at Husch Blackwell LLP, and co-lead of the firm's Psychedelics and Emerging Therapies practice group. She has a background in commercial litigation and cannabis law, and has represented some of the largest corporations in the United States in product liability litigation matters. She may be reached at Karen.Luong@huschblackwell.com.

¹ 3,4-Methylenedioxymethamphetamine (MDMA), commonly known as ecstasy, is a psychoactive drug developed in 1912 by Merck, which was used in psychotherapy in the 1970s and became popular as a club drug in the 1980s. Lysergic acid diethylamide (LSD), also known as acid, is a hallucinogenic drug first made in 1938. N,N-Dimethyltryptamine (DMT) is a chemical substance that occurs in many plants and animals. It is used and prepared by various cultures and religions for ritual purposes. It is also used recreationally.

² Modern medical research into the potential utility of psychedelic therapies aligns centuries' old folk remedies practiced by indigenous cultures.

³ Psychedelic Drugs Market, By Drugs (LSD, Ecstasy, Phencyclidine, GHB, Ketamine, Ayahuasca, Psilocybin), Route of Administration (Oral, Injectable, Inhalation), Distribution Channel, End-Users, Application and Geography - Global Forecast to 2026, (December 2020). *See*

https://www.researchandmarkets.com/reports/5240207/psychedelic-drugs-market-by-drugs-isd-ecstasy?utm_source=GNOM&utm_medium=PressRelease&utm_code=894w6r&utm_campaign=1513085+-+Global+Psychedelic+Drugs+Market+Report+2020%3a+Market+Size+is+Projected+to+Reach+%2410.75+Billion+by+2027&utm_exec=chdo54prd.

⁴ Psilocybin was designated Schedule I in 1968; as was LSD. MDMA was designated Schedule I in 1985; Ketamine was designated Schedule III in 1999.

⁵ In 2019, U.S. Representative Alexandria Ocasio-Cortez introduced an amendment to a bill with the goal of making it easier to study psilocybin and other Schedule I substances by eliminating a rider that has been attached to federal spending bills since 1996 prohibiting any federal spending for "any activity that promotes the legalization of any drug or other substance in Schedule I." She attempted re-introduction of the amendment in 2021. *See* <https://edmontonjournal.com/cannabis-news/psychedelics/undeterred-aoc-again-introduces-amendment-to-facilitate-psychedelics-research/wcm/6cee5798-9710-49d9-b110-e2a2ae3e8a9e/amp/>.

⁶ <https://www.federalregister.gov/documents/2021/10/18/2021-22624/proposed-aggregate-production-quotas-for-schedule-i-and-ii-controlled-substances-and-assessment-of>.

⁷ Section 306 of the Controlled Substances Act (CSA) ([21 U.S.C. 826](#)) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II.

⁸ *John Doe v. Drug Enforcement Administration*, 484 F.3d 561 (DC Cir. 2007), *available at* <https://caselaw.findlaw.com/us-dc-circuit/1349273.html>.

⁹ <https://mycrodosether.com/>.

¹⁰ <https://www.federalregister.gov/documents/2022/01/14/2022-00713/schedules-of-controlled-substances-placement-of-4-hydroxy-nn>.

¹¹ <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review>.

¹² For further analysis of the FDA drug approval process and clinical trials of psychedelics, *see* related article, Sumner, N, *The Trials and Tribulations of Psychedelic Research* (Apr. 22, 2022), <https://microdose.buzz/news/the-trials-and-tribulations-of-psychedelic-research-natasha-sumner/>.

¹³ The criteria, as stated on the FDA’s website, is “substantial improvement over available therapy on a clinically significant endpoint.” Substantial improvement “is a matter of judgment and depends on both the magnitude of the treatment effect, which could include duration of the effect, and the importance of the observed clinical outcome. In general, the preliminary clinical evidence should show a clear advantage over available therapy.” See <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy>.

¹⁴ <https://maps.org/news/media/9122-maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd>.

¹⁵ <https://compasspathways.com/compass-pathways-receives-fda-breakthrough-therapy-designation-for-psilocybin-therapy-for-treatment-resistant-depression/>.

¹⁶ Brooks, M., *FDA Grants Psilocybin Second Breakthrough Therapy Designation for Resistant Depression*, Medscape (Nov. 25, 2019), <https://www.medscape.com/viewarticle/921789>.

¹⁷ Phase 1b results are expected by September 30, 2022. See <https://clinicaltrials.gov/ct2/show/NCT04905121>

¹⁸ <https://fortune.com/2022/01/26/fda-clears-ld-based-drug-clinical-trials/>.

¹⁹ <https://www.globenewswire.com/news-release/2022/02/22/2389340/0/en/World-s-First-Clinical-Trial-for-DMT-Assisted-Therapy-in-Major-Depressive-Disorder-Shows-Consistent-Quality-of-Psychedelic-Response-in-Phase-I.html>.

²⁰ <https://www.sciencedirect.com/science/article/pii/S0740547221004438>.

²¹ For a detailed analysis of current and anticipated intellectual property and trademark issues related to psychedelic drug and ancillary products, see related article, Chew, K.I., Gamson, E.P., PhD, & Kamps, M.M., *Protecting the Science and Innovation of Psychedelics* (Jan. 7, 2022), <https://microdose.buzz/news/protecting-the-science-and-innovation-of-psychedelics/>.

²² <https://www.yahoo.com/now/pharmadrug-announces-first-fda-orphan-120300545.html>.

²³ <https://maps.org/news/media/8008-press-release-fda-agrees-to-expanded-access-program-for-mdma-assisted-psychotherapy-for-ptsd>.

²⁴ <https://maps.org/mdma/ptsd/expanded-access/>.

²⁵ Pub. L. 115-176.

²⁶ Companies who develop and make therapies can provide information about whether their drug or biologic is considered an eligible investigational drug under Right to Try and if they are able to provide it to individuals under the Right to Try Act.

²⁷ *AIMS et. al v DEA*, No. 21-70544 (9th Cir. 2021).

²⁸ The Supreme Court ruled in *Gonzales v. Oregon* that the state, not the federal government, is the regulator of the practice of medicine in cases of terminally ill patients, and the CSA does not allow the federal government to prohibit doctors from prescribing regulated drugs to these patients when state law permits it. *Gonzales v. Oregon*, 126 S.Ct. 904 (2006).

²⁹ <https://fingfx.thomsonreuters.com/gfx/legaldocs/xmvjjojygpr/AIMS%20v%20US%20DEA%209th%20Cir.pdf>.

³⁰ https://righttotrypsilocybin.com/wp-content/uploads/2022/04/2022_4_13_Letter_to_Milgram.pdf.

³¹ <https://righttotrypsilocybin.com/>.

³² https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB519.

³³ <https://www.courthousenews.com/california-psychedelics-bill-put-on-back-burner-until-2022/>.

³⁴

https://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=SB01083&which_year=2021.

³⁵ <https://capitol.texas.gov/BillLookup/History.aspx?LegSess=87R&Bill=HB1802>.

³⁶ <https://le.utah.gov/~2022/bills/static/HB0167.html>.

³⁷

https://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=SB01083&which_year=2021.

³⁸ <http://oregonvotes.org/irr/2020/034text.pdf>.

³⁹ <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Advisory-Board-Meetings.aspx>.

⁴⁰ <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Oregon-Psilocybin-Services.aspx>.

⁴¹ In May 2021, the House reintroduced the Marijuana Opportunity Reinvestment and Expungement Act of 2021, (the “MORE Act”), a bill to decriminalize marijuana and strike it from the list of controlled substances. The Senate is unlikely to approve the bill.

⁴² <https://sitn.hms.harvard.edu/flash/2020/can-microdosing-psychedelics-improve-your-mental-health/>.

⁴³ <https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

⁴⁴ <https://scholarship.law.vanderbilt.edu/faculty-publications/1201/>.

⁴⁵ https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB519.