THE VARIETIES OF PSYCHEDELIC LAW

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Abstract:

After decades of prohibition, psychedelic substances are generating intense public and private interest. Scientists are researching the therapeutic properties of these substances, and mounting evidence supports their ability to treat a variety of mental health conditions. Meanwhile, cities and states are proposing or enacting psychedelics legislation to promote research, increase therapeutic and non-therapeutic access, and decrease criminal penalties associated with producing, possessing, or consuming psychedelics. This article is the first to generate a typology of state and local psychedelics legislation, which falls into five general categories: decriminalization, supported adult use, medical use, clinical research, and policy analysis. The article defines each category and explains how some jurisdictions create hybrid psychedelic laws that blend categories. Following enactment, government agencies can shift laws from one category to another during the rulemaking process.

1. Introduction

After decades of prohibition, psychedelic substances are generating intense public and private interest. Scientists are researching the therapeutic properties of these substances, and mounting evidence supports their ability to treat a variety of mental health conditions including depression, substance use conditions, and post-traumatic stress disorder (Reiff et al., 2020). Dozens of companies are investing millions to commercialize psychedelic therapies while patenting both the compounds and various means of administering them (Marks and Cohen, 2022). Meanwhile, cities and states are pursuing innovative legal strategies to promote psychedelics research, increase therapeutic and non-therapeutic access, and decrease criminal penalties associated with producing, possessing, or consuming psychedelics.

Much has been written about psychedelics research and commercialization. However, there has been no systematic analysis of state and local psychedelics legislation. This article presents a typology of existing legislation with an emphasis on psilocybin. Of the classic psychedelics, which includes those that strongly stimulate the serotonergic system, psilocybin is arguably the most well-studied and will likely be the first approved by the Food and Drug Administration's (FDA) for therapeutic use. In 2018, the FDA gave

psilocybin its breakthrough therapy designation for addressing treatment-resistant depression. This designation reflects the agency's belief that psilocybin may represent a significant improvement over existing treatments such as selective serotonin reuptake inhibitors (SSRIs) like fluoxetine and paroxetine (Marks, 2020). In 2019, the FDA gave psilocybin breakthrough status for treating major depressive disorder.

Today, numerous clinical trials have been completed to evaluate psilocybin's safety and efficacy in treating a variety of conditions including treatment resistant depression (Carhart-Harris et al., 2021), tobacco use disorder (Johnson, 2022), alcohol use disorder (Bogenschutz et al., 2022), and end of life anxiety (Griffiths et al., 2016). Compass Pathways Limited, which holds patents on two crystalline forms of psilocybin (Marks and Cohen, 2022), recently completed the largest psilocybin trial to date with 233 participants (Willyard, 2022).

Like other classic psychedelics, psilocybin has been used by Indigenous communities for centuries (Badham, 1984), and it appears to exhibit low toxicity and very low potential to produce addiction or dependence (de Veen et al., 2016). Perhaps not surprisingly then, in cities and countries where it has been decriminalized or legalized, psilocybin is believed to pose only minimal public health risks (Amsterdam et al., 2011). For instance, psilocybin-containing fungi are sold over the counter in the Netherlands, and a public health study commissioned by the Dutch Minister of Health concluded that their availability posed little risk to public health or safety (Amsterdam et al., 2011). In 2019, Denver voters approved a ballot initiative requiring the city to deprioritize arrests for possession of psilocybin containing mushrooms. Two years later, the Denver City Council's Psilocybin Mushroom Policy Review Panel, which includes city officials and representatives of law enforcement, published a comprehensive report. The panel concludes that "according to available data, most people use psilocybin in safe and responsible ways," and "no major risks to public health or safety have occurred."

Despite evidence of psilocybin's safety, researchers have published case reports describing adverse events such as worsening or new onset bipolar disorder (Hendin and Penn, 2021). Some hypothesize that psilocybin consumption carries of risk of cardiac valve disease (Thomas, 2022). However, this risk remains theoretical, and no cases of valvular disease have been linked to psilocybin ingestion.

Given mounting clinical data regarding psilocybin's safety and efficacy, and years of decriminalization without a negative public health impact, it is no coincidence that psilocybin is the only compound included in every piece of state and local psychedelics legislation. Moreover, many states have proposed or enacted psilocybin-specific legislation to regulate its production, sales, and supervised administration. Though cities and states can decriminalize or regulate psychedelics as they see fit, the substances remain illegal at the federal level.

2. Federal Classification of Psychedelics

In 1970, Congress enacted the Controlled Substances Act (CSA) and classified most psychedelics as Schedule I controlled substances. According to the CSA, substances in this category have no currently accepted medical use and a high potential for abuse, even when used under medical supervision (Marks and Cohen, 2021). The CSA restricts the manufacture, distribution, and possession of controlled substances according to their schedule, and Schedule I substances are the most heavily restricted.

Historically, it was burdensome, if not impossible, to obtain DEA registration that permits researchers to work with Schedule I controlled substances (Marks, 2017). The DEA limits their numbers and the quantities of Schedule I substances that can be produced each year (Woodworth, 2011). However, in the 1990s, a small group of researchers gained DEA permission to study psilocybin, ushering in a new era of

psychedelics research, which grew slowly but steadily for the next thirty years. More recently, the DEA increased limits on production in response to increased interest from registered researchers (Jaeger, 2021). Though it remains burdensome and expensive, psychedelics research has increased in recent years, allowing one formulation of psilocybin produced by Compass Pathways Limited to approach FDA approval by completing Phase I and II clinical trials.

Once psychedelics become FDA approved, they will be rescheduled because they no longer meet the definition of a Schedule I controlled substance, which has no currently accepted medical use. However, only the FDA approved formulations and associated treatment protocols will be rescheduled. All other synthetic and naturally occurring forms, such as psilocybin produced by mushrooms, will remain classified in Schedule I. Nevertheless, FDA approved psychedelic therapies are only part of this story.

While FDA approval of psilocybin therapy looms on the horizon, cities and states across the country are introducing a variety of laws to hasten the availability of psychedelics. The following sections analyze and compare existing legislative approaches, which are both complex and diverse. Rather than providing an exhaustive list of proposed laws, many of which are likely to fail in the legislature or at the ballot box, the article defines and compares the general categories that these laws fall into. They include laws that decriminalize psilocybin and other psychedelics, regulate psilocybin's production and supervised administration, allow for medical use in certain patient populations, promote clinical research, or fund psychedelic policy analysis. However, before discussing each category, it will be helpful to explain the differences between legislation enacted through bills versus ballot measures and the difference between enacting legislation and implementing it following its enactment.

3. Bills Versus Ballot Measures

Psychedelic legislation can emerge through two different paths. The legislature of a city or state can pass a bill or ordinance that changes the legal status of a substance. Alternatively, in jurisdictions where ballot initiatives are allowed, activists and voters can pass legislation themselves. Prior to placing a psychedelic initiative on the ballot, activists must obtain a certain number of signatures on their proposed legislation, and the number of required signatures varies by state. Often a certain percentage of the votes cast for governor in the last election is required. In states with large populations, like California and Florida, obtaining the required signatures can require significant funding and highly organized campaigns, putting ballot measures out of reach for many activists and grassroots political organizations. The burden of meeting these requirements can create power asymmetries between grassroots organizers and wealthy special interest groups. These dynamics played out in 2022 when out of state lobbyists placed their initiative on the ballot while Colorado activists failed to obtain the required signatures (Tiney, 2022).

4. Legislation Versus Implementation

Enacting bills or passing ballot measures is only a first step in psychedelics legal reform. After a law is enacted, it must be implemented, a process typically overseen by a governing agency such as a state's department of health. Psychedelic legislation often mandates the creation of a board or task force to study the law and make recommendations to the governing agency during an implementation period. The agency then interprets and implements the text of the law by drafting administrative rules. Depending on the level of detail in a piece of legislation, and the amount of discretion given to the governing agency, the character of the resulting administrative rules may differ significantly from the bill or ballot measure passed by legislators or voters. In other words, boards and agencies can have significant influence over how the resulting regulatory systems take shape. Through the implementation process, boards and agencies can transform a law that started in one category into another, a process I call a regulatory shift. For instance, a

law that is initially promoted as a supported adult use bill could be shifted into a medical use bill or take on qualities of a clinical research bill.

In Oregon, the first state to pass psilocybin-specific legislation, passage of ballot Measure 109 triggered a two-year implementation period. During this period, a governor-appointed advisory board, and officials from the Oregon Health Authority, drafted rules for implementing Measure 109. Because the ballot initiative tasked the agency with filling in details of the emerging psilocybin industry, the agency could shift certain aspects of the law and shape the nature of the industry.

Many subsequently proposed psilocybin laws follow this example, tasking advisory boards and state agencies with drafting many details of psychedelics regulation. In Colorado, Proposition 122 gave the governing agency, the Department of Regulatory Agencies, far more discretion to shape the state's psychedelics industry than Measure 109 gave the Oregon Health Authority.

A. Decriminalization

Before states enacted psychedelics legislation, cities across the country adopted local resolutions and ordinances to decrease criminal penalties associated with psychedelics. While ordinances are more permanent and have the force of law, resolutions are statements of policy that lack the force of law and could be more easily ignored or reversed.

There are many shades of psychedelic decriminalization. On one end of the spectrum, a city might adopt a resolution stating that enforcing laws criminalizing psychedelics should be its "lowest law enforcement priority," which is sometimes called deprioritization. At the other extreme, a city could abolish criminal penalties associated with psychedelics across the board, which would constitute true decriminalization, at least at the local level. Somewhere in between, a city might prohibit spending money and other resources on enforcement of certain offenses like psilocybin possession, but not others, such as production or sales. Due to these gradations, all but the most comprehensive decriminalization laws might best be described as shades of partial decriminalization.

In 2019, Denver, Colorado became the first U.S. jurisdiction to enact psychedelics legislation when voters approved Ordinance 301, the Denver Psilocybin Mushroom Initiative (Chavez and Prior, 2019). Through this ordinance, voters prohibited the city from spending resources to arrest or prosecute people for possessing or using psilocybin producing mushrooms.

Oakland (Kennedy, 2019) and Santa Cruz, California (Kaur, 2020) quickly followed Denver's example by partially decriminalizing psilocybin producing fungi while also partially decriminalizing certain psychedelic plants such as iboga (which contains the psychedelic ibogaine) and ayahuasca (a combination of the shrub *Psychotria viridis*, which contains the psychedelic N,N-Dimethyltryptamine (DMT), and the vine *Banisteriopsis caapi*, which contains monoamine oxidase inhibitors (MAOIs) that increase the bioavailability of orally consumed DMT).

Today, over a dozen U.S. cities have partially decriminalized psilocybin producing fungi and various psychedelic plants. They include large cities like Washington, D.C. and Seattle, Washington. States are also proposing or enacting psychedelic decriminalization bills. On November 3, 2020, Oregon voters passed Measure 110, a ballot initiative that partially decriminalized psilocybin and other common psychedelics, reducing possession of small amounts of each substance from a misdemeanor to a civil penalty, punishable by a $100 fine (Selsky, 2021). Measure 110 also eliminated criminal penalties associated with small amounts of other controlled substances such as cocaine and heroin. The initiative was supposed to divert

money raised from the state cannabis industry to fund substance use treatment programs. However, two years later, critics claim the funds have not reached service providers (Green, 2022).

Until recently, it looked as though California or Washington might be the next states to decriminalize psilocybin and other psychedelics. However, ballot measures in Washington and Colorado failed to gather enough signatures to make the 2022 ballot. In California, State Senator Scott Wiener sponsored Senate Bill 519, an ambitious attempt to decriminalize possession and sharing of small amounts of several psychedelics, including synthetic substances like lysergic acid diethylamide (LSD) and 3,4-Methylenedioxymethamphetamine (MDMA). However, on August 11, 2022, the California's Assembly Appropriations Committee gutted the bill, reducing it to a mandate to study potential psychedelics policy reforms (Symon, 2022). Weiner quickly pulled the bill from consideration and vowed to reintroduce it in 2023.

B. Supported Adult Use

On November 3, 2020, in addition to partially decriminalizing psilocybin through Measure 110, Oregon voters approved a new type of psilocybin legislation called *supported adult use* (Marks, 2021). Instead of partially decriminalizing psilocybin, the Oregon Psilocybin Services Act (Measure 109), established a regulated system for its production, sale, and administration. Supported adult use is a variation of *adult use*, which describes retail sales of cannabis that do not require a medical diagnosis or physician's recommendation. Like adult use cannabis, Measure 109's supported adult use model allows people to access psilocybin for any reason, such as personal or spiritual growth and the promotion of physical and mental wellness. However, unlike adult use cannabis, Measure 109's supported adult use model requires a trained and licensed facilitator to administer psilocybin.

Instead of selling psilocybin at retail dispensaries, businesses licensed under Measure 109 will dispense psilocybin only under supervision at licensed facilities called service centers. The requirement that people travel to service centers has raised concerns regarding access for people with disabilities and those in hospice who may have limited mobility. Accordingly, a proposed Washington State bill called the Washington Psilocybin Wellness and Opportunity Act (Senate Bill 5660), includes an option for home administration for people medically unable to travel to service centers (Marks, 2022).

In keeping with the non-medical nature of these bills, psilocybin facilitators need only complete training programs approved by the public health agency of each state. Oregon's education and licensing requirements illustrate the potential for regulatory drift. When Measure 109 was announced, it was hailed as a democratic bill that would allow anyone with a high school diploma or its equivalent to enter the emerging field of psilocybin facilitation (Oregon Health Authority, 2022). However, in practice, it appears that many approved training programs require students to have prior experience as healthcare professionals. Consequently, though the legislation promised to make the industry accessible to aspiring facilitators without college degrees or prior professional licensure, the implementation process raised barriers to entry for those individuals. Training programs led by healthcare professionals could become gatekeepers for Oregon's emerging psilocybin industry, shifting Measure 109 in the direction of medical use legislation.

C. Medical Use

While Oregon's Measure 109 and Washington State's SB 5660 ostensibly create non-medical systems for the supported adult use of psilocybin, some states take a traditional medical approach from the outset. Their proposed legislation would make licensed healthcare providers the sole providers of psilocybin therapy and, in some cases, create access only for certain patient populations. The bills proposed separately by New York Assemblymembers Pat Burke and Linda Rosenthal are two examples. For instance, Burke's bill would

allow medical professionals to administer psilocybin to "certified patients" with a "life threatening or disrupting condition certified by a facilitator," who must be a licensed healthcare professional.

Some might view medical psilocybin bills as means of circumventing the FDA's regulatory authority and providing untested medicines before they have been fully evaluated for safety and efficacy. A bill enacted by the Connecticut Legislature in 2022 addresses this concern by limiting services to clinical sites that the FDA has authorized to provide investigational drugs like psilocybin under expanded access protocols (Lekhtman, 2022).

Other bills blend elements of supported adult use with medical use, blurring the line between categories. Colorado's Natural Medicine Health Act (Proposition 122) borrows heavily from Oregon's Psilocybin Services Act (Colorado Natural Medicine Health Act, 2022). However, unlike Oregon's law, which specifies that no medical diagnosis or prescription can be required to access psilocybin services, the Colorado Act lacks this limitation. Consequently, during the implementation period, DORA, the agency tasked with implementing the Natural Medicine Health Act, could decide to require a medical diagnosis and prescription, shifting Proposition 122 into the medical category. Some aspects of Proposition 122 make it a clinical research bill, which is the fourth category of psychedelic legislation.

D. Clinical Research

In 2021, Texas became the first state to enact a psychedelic research bill. With political support from former Governor Rick Perry, the state is funding a trial that will administer psilocybin to veterans with post-traumatic stress disorder at Baylor College of Medicine and the Veterans Affairs Medical Center of Houston. In 2021, Pennsylvania legislators introduced a bill to fund psychedelics research in their state. However, the Public Health Benefits of Psilocybin Act has not progressed beyond consideration in a House health committee.

Compared to medical and supported adult use legislation, clinical research bills may have greater potential to generate useful scientific insights because they tend to use standardized treatment protocols and include more narrowly defined patient populations. Colorado's Proposition 122 requires the governing agency to collect and analyze outcomes data from clients in the state's psilocybin program. However, this data may be of limited utility and expose Colorado clients to social, professional, and legal risks.

Because supported adult use programs likely lie outside the healthcare system, potentially skirting federal drug regulations and research standards, clients may lack protections of the federal Common Rule, which defines basic requirements for obtaining informed consent and ensuring research protocols comply with ethical standards. Moreover, psychedelic client data is unlikely to be covered by the Health Insurance Portability and Accountability Act (HIPAA). Instead, client data could be subject only to agreements between clients and psychedelic businesses, a scenario that more closely resembles commercial data practices than HIPAA-compliant healthcare delivery or federally funded clinical research, which could expose clients to legal, safety, and privacy risks (Marks, 2022).

During the implementation of Oregon's Measure 109, some members of the psilocybin advisory board advocated for adding a research focus to the state's psilocybin program by implementing mandatory data collection from clients, which would allow client information to be shared with third parties outside psilocybin service centers (Marks, 2022). That would have shifted Oregon's program into the clinical research category. However, Measure 109 contains protections for client confidentiality that preclude mandatory data collection. These safeguards apply to all forms of information, regardless of whether data has been stripped of personal identifiers, a process called "de-identification" or "anonymization." Accordingly, the advisory board voted to give clients control over their information and the right to share

information outside a psilocybin service center or participate in research without jeopardizing their ability to receive psilocybin (Marks, 2022). Nevertheless, in draft rules published in September and November of 2022, the Oregon Health Authority overruled its advisory board, requiring clients to consent to share de-identified data "for research and other purposes." In addition to shifting Measure 109 into the research category, such broad language could allow client data to be used for any purpose, including commercial exploitation.

E. Policy Analysis

Instead of funding research or expanding access to psychedelic substances, the fifth category of legislation merely creates task forces or work groups to study the feasibility of decriminalizing or regulating psychedelics. When the Washington State Legislature failed to pass SB 5660 in early 2022, the bill's sponsors pivoted to a policy analysis bill that established the Washington State Psilocybin Work Group (Jaeger, 2022). Funded by $200,000, this committee will meet for one year before producing a final report with recommendations for the state legislature on improving and implementing SB 5660. Other states including Hawaii (Hawaii Psilocybin Working Group, 2022) and Utah (Utah Psychotherapy Drug Task Force, 2022) have enacted similar psychedelic policy analysis legislation as a cautious first step toward more substantive drug policy reform.

5. Conclusion

This article has defined five varieties of state and local psychedelics legislation and several variations within those categories. A detailed study and comparison of these legislative variants is beyond the scope of the article. However, future articles may offer deeper analysis and policy recommendations. Soon, more categories and subcategories of psychedelics legislation are likely to emerge. We may also see additional hybrid bills that incorporate elements from several different categories. Alternatively, as states copy and paste material from existing legislation, psychedelic laws may increasingly converge. For laws that create regulated systems, implementation periods can significantly shape the resulting industries, potentially shifting systems from one category to another. Increased transparency and accountability during implementation are necessary to ensure safe and ethical psychedelic programs that remain true to what voters or legislators approved. It remains unclear whether legal categories such as decriminalization and supported adult use will persist or be shifted into or subsumed by medical and clinical research bills. Regardless, aside from potential allocations of research funding, comprehensive federal legislation remains unlikely, and most legislative activity will remain at the state level for the foreseeable future.

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Conflicts Statement:

Mason Marks is a member of the Psychedelic Bar Association. He serves on the boards of non-profit organizations in the psychedelic space such as the Psychedelic Medicine Coalition and the Plant Medicine Healing Alliance. As an unpaid volunteer, Marks chaired the Licensing Subcommittee of the Oregon Psilocybin Advisory Board before moving out of state to serve as the Florida Bar Health Law Section Professor at Florida State University.

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