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Psychedelics

Psychedelics are "psychoactive substances that alter perception and mood and affect numerous cognitive processes."[1] Synthetic psychedelics refers to hallucinogens that are human made, whereas natural psychedelics refer to naturally occurring psychedelics.[2] Some examples of naturally occurring psychedelics include:

- Psilocybin (typically found in psychedelic mushrooms);
- Dimethyltryptamine (DMT);
- Mescaline (peyote cactus);
- Reversible Monoamine Oxidase A-inhibitors; and,
- Muscimol and Iobtenic Acid.[3]

For this report, we will be focusing on the use of natural psychedelics unless stated otherwise.

Clinical Trials

With growing interest and support around the potential uses of psychedelics in recent years, there has been a plethora of new research conducted on the subject. With more studies being undertaken with psychedelics, the U.S. Food and Drug Administration (FDA) has recently released draft guidelines for clinical investigations into psychedelics.[4] Some hurdles and roadblocks can be unique to clinical investigations with psychedelics because, as is laid out in the draft FDA guidelines, psychedelics are extremely potent hallucinogenic substances with potentially harmful short and long-term effects.[5] Due to this, clinical trials must follow stringent safety regulations and controls.

[1] David E. Nichols, "Psychedelics," *Pharmacological Reviews* 68, no. 2 (February 3, 2016): 264–355, https://doi.org/10.1124/pr.115.011478.
[2] Cleveland Clinic, "Addiction & Treatment: PCP, LSD, Psilocybin, Peyote," Cleveland Clinic, April 18, 2023, https://my.clevelandclinic.org/health/articles/6734-hallucinogens-lsd-peyote-psilocybin-and-pcp.
[3] Samane Jahanabadi, Shayan Amiri, Mehdi Karkeh-abadi, and Ali Razmi, "Natural Psychedelics in the Treatment of Depression; a Review Focusing on Neurotransmitters," *Fitoterapia* 169 (September 1, 2023): 105620, https://doi.org/10.1016/j.fitote.2023.105620.
[4] Food and Drug Administration, "Psychedelic Drugs: Considerations for Clinical Investigations Guidance for Industry Draft Guidance," 2023, https://www.fda.gov/media/169694/download.
[5] FDA, "Psychedelic Drugs."

Most psychedelics are listed as Schedule I drugs under the Controlled Substances Act.[6] The Drug Enforcement Administration (DEA), which is charged with creating and enforcing the drug scheduling program, classifies Schedule I drugs as "drugs, substances, or chemicals [that] are defined as drugs with no currently accepted medical use and a high potential for abuse."[7] Schedule I drugs can exclusively be used for research purposes, and all research involving Schedule I drugs must be explicitly approved by the DEA, among other regulations and restrictions.[8]

The psychedelic that has received the most attention in recent years, in both clinical trials and the public consciousness, is psilocybin. Psilocybin is a hallucinogenic compound found in numerous species of mushrooms, which are often collectively referred to as "magic mushrooms."[9] It is worth noting that while psilocybin, psilocin, and magic mushrooms are used interchangeably, they are not the same. Psilocybin, on its own, does not induce hallucinogenic effects in humans. When the psilocybin enters the body, it is stripped of a molecule, which forms a new molecule known as psilocin.[10] The psilocin then induces hallucinogenic effects as it binds with the same receptors as serotonin, the molecule found in the body that regulates things like sleep, nausea, blood pressure, and mood regulation.[11]

Clinical studies have found potential beneficial uses for psilocybin. One area where the potential benefits have been found is in treating depression, especially treatment-resistant depression (TRD). TRD is a severe form of depression that does not respond to antidepressants or therapy and is largely incurable.[12] Studies done into the use of psilocybin for treating TRD have found that it temporarily reduces depression levels in people with TRD, especially at higher doses.[13] Psilocybin has also shown promise in treating addiction. A clinical trial that treated individuals who have alcoholism with psilocybin found that those who had been taking psilocybin had fewer

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[6] Drug Enforcement Agency, "Controlled Substances by Controlled Substance Code Number," 2023, https://www.deadiversion.usdoj.gov/schedules/orangebook/d_cs_drugcode.pdf.
[7] Drug Enforcement Administration, "Drug Scheduling," July 10, 2018, accessed December 18, 2023, https://www.dea.gov/drug-information/drug-scheduling#:~:text=Schedule%20I%20drugs%2C%20substances%2C%20or,)%2C%20methaqualone%2C%20and%20peyote.
[8] Code of Federal Regulations, 21 U.S.C. § 1301.18 "Research Protocols," accessed December 18, 2023, https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFR0f5a129834f0129/section-1301.18.
[9] Guy M. Goodwin et al., "Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression," *New England Journal of Medicine* 387 (18): 1637–48, 2022, https://doi.org/10.1056/nejmoa2206443.
[10] Ricardo Jorge Dinis-Oliveira,"Metabolism of Psilocybin and Psilocin: Clinical and Forensic Toxicological Relevance," *Drug Metabolism Reviews* 49 (1): 84–91, 2017, https://doi.org/10.1080/03602532.2016.1278228
[11] Martin K. Madsen, Patrick M. Fisher, Daniel Burmester, Agnete Dyssegaard, Dea S. Stenbæk, Sara Kristiansen, Sys S. Johansen, Sczabolz Lehel, Kristian Linnet, Claus Svarer, David Erritzoe, Brice Ozenne & Gitte M. Knudsen, "Psychedelic Effects of Psilocybin Correlate with Serotonin 2A Receptor Occupancy and Plasma Psilocin Levels," *Neuropsychopharmacology* 44 (7): 1328–34, 2019, https://doi.org/10.1038/s41386-019-0324-9.
[12] Goodwin, "Single-dose Psilocybin."
[13] Goodwin, "Single-dose Psilocybin."

days spent drinking heavily than the control group.[14] Another trial found the use of psilocybin was effective in helping individuals quit smoking.[15]

While the results of these clinical trials with psilocybin are promising, some caveats should be noted. First, these trials run anywhere from a month to a year, and thus, the long-term safety and effectiveness of psilocybin treatment are still largely unknown. Additionally, there are side effects from psilocybin. While most side effects experienced while under the influence of psilocybin are minor, such as headaches, nausea and vomiting, and increased heart rate, in rarer instances, there are cases of highly adverse reactions. [16] What is commonly referred to as a "bad trip" is the most infamous adverse reaction to psilocybin. Well-known due to its almost inevitable occurrence among those who frequently use the drug recreationally, a "bad trip" is an experience while under the influence of the drug that causes "significant fear, anxiety, or distress."[17] In a survey of individuals who had experienced a "bad trip," thirty-nine percent rated it among the top five most challenging experiences in their life, and eleven percent reported putting themselves or others at risk of physical harm due to it.[18] The previously mentioned study on the effects of psilocybin on treatment-resistant depression found adverse effects in seventy-seven percent of patients, and most concerningly, suicidal ideation and thoughts of self-harm in a few patients.[19]

Ibogaine is another psychedelic that has seen increased attention in recent years. Like psilocybin, ibogaine is a naturally occurring hallucinogenic compound. Ibogaine is found in the roots of the iboga plant, a shrub-like plant native to Central Africa.[20] For centuries, iboga has been used by certain local tribes in religious and rights-of-passage ceremonies, with its hallucinogenic solid effects believed to take the user closer to higher powers.[21] Unlike psilocybin, which has already been popular throughout the globe as a recreational drug, ibogaine has remained relatively obscure, remaining relegated to clinical trials.

The effects of ibogaine are similar to psilocybin. Like psilocybin, studies have shown the strong potential of ibogaine in combating addiction. A study in which ibogaine was administered to rats

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[14] Michael P. Bogenschutz, Stephen Ross, Snehal Bhatt, Tara Baron, Alyssa A. Forcehimes, Eugene Laska, Sarah E. Mennenga, Kelley O'Donnell, Lindsey T. Owens, Samantha Podrebarac, John Rotrosen, J. Scott Tonigan, and Lindsay Worth, "Percentage of Heavy Drinking Days Following Psilocybin-Assisted Psychotherapy vs Placebo in the Treatment of Adult Patients with Alcohol Use Disorder," *JAMA Psychiatry* 79 (10), 2022, https://doi.org/10.1001/jamapsychiatry.2022.2096.

[15] Matthew W. Johnson, Albert Garcia-Romeu, Mary P. Cosimano, and Roland R. Griffiths, "Pilot Study of the 5-HT2AR Agonist Psilocybin in the Treatment of Tobacco Addiction," *Journal of Psychopharmacology*, September 11, 2014, https://journals.sagepub.com/doi/abs/10.1177/0269881114548296.

[16] Bogenschutz, "Percentage of Heavy Drinking Days."

[17] Theresa M Carbonaro, Matthew P Bradstreet, Frederick S Barrett, Katherine A MacLean, Robert Jesse, Matthew W Johnson, and Roland R Griffiths, "Survey Study of Challenging Experiences after Ingesting Psilocybin Mushrooms: Acute and Enduring Positive and Negative Consequences," *Journal of Psychopharmacology* 30 (12): 1268–78, 2016, https://doi.org/10.1177/0269881116662634.

[18] Carbonaro, "Survey Study of Challenging Experiences."

[19] Goodwin, "Single-dose Psilocybin."

[20] Harrison G. Pope, "Tabernanthe Iboga: An African Narcotic Plant of Social Importance," *Economic Botany* 23 (2): 174–84, 1969, https://www.jstor.org/stable/4253038?seq=1.

[21] Pope, "Tabernanthe Iboga."

found that it significantly reduced cocaine and heroin consumption.[22] Another study conducted on humans who have an opioid addiction in New Zealand (one of the few places ibogaine is legal) found that almost all participants severely cut back on or completely stopped using opioids.[23]

While the evidence of ibogaine as an anti-addiction treatment is promising, there are serious safety concerns. Heart complications from the consumption of ibogaine have shown to be much more frequent than in other psychedelics, and a study of the properties of ibogaine found it to be conducive to causing cardiac arrhythmia, which can be fatal.[24] In the previously mentioned New Zealand study, one of the participants died during the study, in what was likely related to the consumption of ibogaine.[25]

It is worth noting that while the research and clinical trials of different psychedelics have shown promise in their ability to combat addiction and depression, many experts are concerned the legalization movement is getting ahead of the research.[26] The American Psychiatric Association, for example, has advocated against legalization until more studies can be conducted.[27]

Pilot Programs

Another way the information regarding psychedelics is expanding is through states' establishment of pilot programs. A pilot program is a study where a temporary exemption is given—in this case, the legality of psychedelic use—to collect data for evaluating alternatives to existing regulations and legislation, all while ensuring that specific safety measures are met.[28] In the context of psychedelics, these pilot programs have been established to evaluate the benefits and disadvantages of psychedelic use.

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[22] Steven I. Dworkin, Suzanne Gleeson, Domenico Meloni, Timothy R. Koves, and Thomas J. Martin, "Effects of Ibogaine on Responding Maintained by Food, Cocaine and Heroin Reinforcement in Rats," *Psychopharmacology*, March 1995, https://www.researchgate.net/publication/15427793_Effects_of_ibogaine_on_responding_maintained_by_food_cocaine_and_heroin_reinforcement_in_rats.

[23] Geoffrey E. Noller, Chris M. Frampton, and Berra Yazar-Klosinski, "Ibogaine Treatment Outcomes for Opioid Dependence from a Twelve-Month Follow-up Observational Study," *The American Journal of Drug and Alcohol Abuse* 44 (1): 37–46, https://www.tandfonline.com/doi/full/10.1080/00952990.2017.1310218 .

[24] Xaver Koenig, and Karlheinz Hilber, "The Anti-Addiction Drug Ibogaine and the Heart: A Delicate Relation," *Molecules* 20 (2): 2208–28, 2015, https://doi.org/10.3390/molecules20022208.

[25] Noller, "Ibogaine Treatment Outcomes."

[26] Mike Baker, "A New Era of Psychedelics in Oregon," *The New York Times*, October 23, 2023, https://www.nytimes.com/2023/10/23/us/oregon-psychedelic-mushrooms.html.

[27] American Psychiatric Association, "Position Statement on the Use of Psychedelic and Empathogenic Agents for Mental Health Conditions," *American Psychiatric Association*, 2022, https://www.psychiatry.org/getattachment/d5c13619-ca1f-491f-a7a8-b7141c800904/Position-Use-of-Psychedelic-Empathogenic-Agents.pdf.

[28] Legal Information Institute, "49 CFR § 381.400 - What Is a Pilot Program?" n.d., accessed December 18, 2023, https://www.law.cornell.edu/cfr/text/49/381.400 .

Connecticut

One state that has developed a pilot program for the testing of psychedelics is Connecticut. The bill establishing this program was passed during the February 2022 session and labeled Substitute HB No. 5396, "An Act Increasing Access to Mental Health Medication."[29] This bill established the Psychedelic-Assisted Therapy Pilot Program to be carried out within Connecticut's Department of Mental Health and Addiction Services (DMHAS).[30] This pilot program became effective as of July 1st, 2022, and is expected to run until the US Drug Enforcement Agency (DEA) approves synthetic and natural psychedelics for medical use.[31] The bill establishes the qualifications for patients, an outline of the funding and cost of the program, as well as expectations for the program itself.

First, to be considered a qualified patient, one must be a resident of Connecticut "(A) a veteran, (B) a retired first responder, (C) a direct care healthcare worker, or (D) from a historically underserved community, and who has a serious of life-threatening mental or behavioral health disorder and without access to effective mental or behavioral health medication."[32]

This program is funded through a Qualified Patients for Approved Treatment Sites Fund, also called a "PAT Fund."[33] The PAT fund is responsible for allocating the money to fund and maintain this program. For Fiscal Year 2023 (FY '23), the state allocated three million dollars to DMHAS.[34] The funds are allocated, at the discretion of the DMHAS, to qualified applicants to provide either MDMA-assisted or psilocybin-assisted therapy to qualified patients.[35] A "qualified applicant" refers to "a provider of mental or behavioral health services that [have] received approval from the federal Food and Drug Administration as an approved treatment site with an expanded access protocol that allows the provider access to an investigational drug for treatment use."[36] For this pilot program up to three of the qualified applicants will be selected as approved treatment site which means that these locations have the authority to distribute psilocybin or MDMA.[37] Additionally, these locations will be responsible for collecting and submitting data to DMHAS surrounding protocols, training, facilitation of treatment, implementation, and strategies for patients.[38]

[29] Connecticut General Assembly, "An Act Increasing Access to Mental Health Medication," March 31, 2022, https://www.cga.ct.gov/2022/fc/pdf/2022HB-05396-R000237-FC.PDF.
[30] Connecticut General Assembly, "OLR Bill Analysis: SHB 5396: An Act Increasing Access to Mental Health Medication," 3AD, 1, accessed December 18, 2023, https://www.cga.ct.gov/2022/ba/pdf/2022HB-05396-R000237-BA.pdf.
[31] Connecticut General Assembly, "OLR Bill Analysis: SHB 5396: An Act Increasing Access to Mental Health Medication."
[32] Connecticut General Assembly, "An Act Increasing Access to Mental Health Medication."
[33] Connecticut General Assembly, "An Act Increasing Access to Mental Health Medication."
[34] Connecticut General Assembly, "OLR Bill Analysis: SHB 5396: An Act Increasing Access to Mental Health Medication."
[35] Connecticut General Assembly, "An Act Increasing Access to Mental Health Medication."
[36] Connecticut General Assembly, "An Act Increasing Access to Mental Health Medication."
[37] Connecticut General Assembly, "An Act Increasing Access to Mental Health Medication."
[38] Connecticut General Assembly, "An Act Increasing Access to Mental Health Medication."

This bill also establishes an eleven-member Connecticut Public Treatment Advisory Board within DMHAS, advising the department on various issues under the pilot program.[39] This board is made up of

> (1) two members appointed by the speaker of the House of Representatives; (2) two appointed by the president pro tempore of the Senate; (3) one appointed by the minority leader of the House of Representatives; (4) one appointed by the minority leader of the Senate; (5) two appointed by the Office of the Governor; (6) one appointed by the Commissioner of Mental Health and Addiction Services; (7) one appointed by the Commissioner of Public Health; and (8) one appointed by the Commissioner of Consumer Protection. The board shall include members with experience or expertise in psychedelic research, psychedelic-assisted therapy, public health, access to mental and behavioral health care in underserved communities, veterans mental and behavioral health care, harm reduction, and sacramental use of psychedelic substances.[40]

Another critical responsibility of this group is to review the data and develop a long-term plan to improve mental health care.

Washington

Washington is another state that has recently established a psychedelic pilot program. The Bill is called SB 5263, 'Psilocybin Services – Task Force Pilot Program,' passed by both the Washington Senate and House of Representatives.[41] The final bill comprises fourteen sections; however, the Governor vetoed several of the sections.[42] The remaining sections establish the guidelines for the pilot program.

The bill established three different groups. First, the "Psilocybin Advisory Board (Board within the Department of Health (DOH) to provide advice and recommendations to the DOH, the Liquor and Cannabis Board (LCB), and the Washington Department of Agriculture (WSAD)."[43] The board should consist of expert and agency officials appointed by the Governor.[44] The second group is called the Interagency Psilocybin Work Group, which is a part of the DOH, the LCB, and the WSDA and has the task of providing recommendations and updates regarding "a regulatory framework for a regulated psilocybin system…reviewing indigenous practices with psilocybin, clinical psilocybin trials, and [their] findings."[45] Finally, the bill establishes a Psilocybin Task Force, which must provide a report on psilocybin services. "The Task Force must also include:

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[39] Connecticut General Assembly, "OLR Bill Analysis: SHB 5396: An Act Increasing Access to Mental Health Medication."
[40] Connecticut General Assembly, "An Act Increasing Access to Mental Health Medication."
[41] Connecticut General Assembly, "Certification of Enrollment Second Substitute Senate Bill 5263," July 23, 2023, https://lawfilesext.leg.wa.gov/biennium/2023-24/Pdf/Bills/Session%20Laws/Senate/5263-S2.SL.pdf?q=20231107111751.
[42] Connecticut General Assembly, "Certification of Enrollment Second Substitute Senate Bill 5263,"
[43] State of Washington, "House Bill Report 2sSB 5263," July 23, 2023, https://lawfilesext.leg.wa.gov/biennium/2023-24/Pdf/Bill%20Reports/House/5263-S2%20HBR%20APP%2023.pdf?q=20230410123438.
[44] State of Washington, "House Bill Report 2sSB 5263."
[45] State of Washington, "House Bill Report 2sSB 5263"

- The Secretary of the DOH and the Director of the LCB or their designees; and
- The following individuals, as appointed by the Director of the HCA or their designee:
    - A military veteran or representative of an organization that advocates on behalf of military veterans with knowledge of psilocybin;
    - Up to two recognized indigenous practitioners with knowledge of the use of psilocybin in their communities;
    - An individual with expertise in disability rights advocacy;
    - A public health practitioner;
    - Two psychologists, two physicians, and two mental health counselors, marriage and family therapists, or social workers with knowledge of psilocybin, experience in mental and behavioral health, or experience in palliative care;
      a health researcher with expertise in health equity or researching psilocybin;
    - A pharmacologist with expertise in psychopharmacology;
    - A representative of the cannabis industry with knowledge of the regulation of medical cannabis;
    - An advocate from the LGBTQIA+ community;
    - A member of the Psychedelic Medicine Alliance of Washington; and
    - Up to two members with lived experience of utilizing psilocybin."[46]

The University of Washington's Department of Psychiatry and Behavioral Sciences will administer the pilot program by January 1st, 2025.[47] The pilot program focuses on first responder and veteran populations who are over the age of twenty-one and are experiencing post-traumatic stress disorder (PTSD), mood disorders, or substance use disorders.[48] "The Pilot Program must:

- Offer psilocybin therapy services through pathways approved by the federal Food and Drug Administration (FDA) to populations including first responders and veterans who are 21 years of age or older and experiencing posttraumatic stress disorder, mood disorders, or substance use disorders;
- Offer psilocybin therapy services facilitated by certain types of health care professionals;
- Ensure psilocybin therapy services are safe, accessible, and affordable;
- Require an initial assessment before a participant receives psilocybin therapy services and an integration session after a participant gets psilocybin therapy services; and,
- Use outreach and engagement strategies to include participants from communities or demographic groups more likely to be historically marginalized and less likely to be included in research and clinical trials." [49]

Vermont

In Vermont, there are currently no pilot programs for psychedelics. Legislation has been introduced in the House of Representatives and the Senate. The bill was read for the first time on February 24th, 2023, and as of November 2023, and referred to the Committee on Judiciary. As

[46] State of Washington, "House Bill Report 2sSB 5263"
[47] State of Washington, "House Bill Report 2sSB 5263"."
[48] State of Washington, "House Bill Report 2sSB 5263"
[49] State of Washington, "House Bill Report 2sSB 5263"

of November 2023, the bill (H.371) is still in committee.[50] This bill aims to make findings that depict the therapeutic benefits of psilocybin.[51] Additionally, the bill wants to establish a "Psychedelic Therapy Advisory Working Group" to examine the use of psychedelics to improve physical and mental health and to make recommendations regarding the establishment of a state program…to permit health care providers to administer psychedelics in a therapeutic setting."[52] In the Senate, a similar bill has been proposed (S.114). It was read for the first time on March 3rd, 2023, and referred to the Committee on Health and Welfare.[53] As of November 2023, the bill has not left the Senate committee. The proponents of this bill mirror the one proposed in the House of Representatives.[54]

Recent Policy Changes

Overview

Beginning with Oregon in 2020, states have begun to enact or consider policies relating to psychedelics.[55] According to the authors of an article published in *JAMA Psychiatry*, the number of psychedelic reform bills reached a peak last year in 2022, with 36 bills considered across the United States; in 2019, the number was far lower, with only five bills being considered that year.[56] A large majority of these bills reform the status of natural medicines such as psilocybin, with an emphasis on decriminalization as opposed to legalization.[57]

Oregon

Originating from a ballot measure, The Oregon Psilocybin Services Act (Codified as ORS 475A) began the progressive legalization of the usage of psilocybin within controlled settings in Oregon.[58] The Act does not permit recreational use and prohibits the sale of psilocybin for that purpose. People seeking administration of psilocybin must go to licensed individuals who are certified to administer the drug through a process the act calls "Psilocybin Services."[59] The

[50] Vermont Legislature "Bill Status H.371," https://legislature.vermont.gov/bill/status/2024/H.371.
[51] Vermont Legislature, "Bill as Introduced," https://legislature.vermont.gov/Documents/2024/Docs/BILLS/H-0371/H-0371%20As%20Introduced.pdf.
[52] Vermont Legislature, "Bill as Introduced."
[53] Vermont Legislature, "Bill Status S.114," legislature.vermont.gov, accessed November 23, 2023, https://legislature.vermont.gaov/bill/status/2024/S.114.
[54] Vermont Legislature, "Bill as Introduced S.114," 2023, https://legislature.vermont.gov/Documents/2024/Docs/BILLS/S-0114/S-0114%20As%20Introduced.pdf.
[55] Joshua Siegel, James Daily, Demetrius Perry, Ginger Nicole, "Psychedelics Drug Legislative Reform and Legalization in the US," *JAMA Psychiatry* 80, no. 1 (Jan 2023): 77-83, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10069558/.
[56] Siegel, Daily, Perry, Nicole, "Psychedelics," 77-83.
[57] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10069558/
[58] State of Oregon, "Oregon Psilocybin Services Overview," Prevention and Wellness, https://www.oregon.gov/oha/ph/preventionwellness/pages/oregon-psilocybin-services.aspx
[59] State of Oregon, "Chapter 457A-Psilocybin Regulation," bills/laws, 2021, https://www.oregonlegislature.gov/bills_laws/ors/ors475A.html

Oregon Health Authority (OHA) regulates the entire process with advice from the Oregon Psilocybin Team housed within the OHA.[60]

Licenses and Regulation: In Oregon, a person can obtain four license types relating to psilocybin services: a manufacturer license, a testing laboratory license, a service center license, and a facilitator license. A manufacturer's license is required to produce psilocybin within regulation and generate psilocybin products for transfer to licensed service centers for use in psilocybin services. The only form of psilocybin that is admissible to cultivate with this license is *psilocybe cubensis* mushrooms.[61] These mushrooms can be harvested and made into various products, such as extracts, dried mushrooms, and edible products. As part of the licensing process, the mushroom growing facility must be inspected and comply with local land use and zoning codes.[62] Once the product is cataloged in a products database, the psilocybin products go to a licensed lab for testing.[63]

A testing laboratory license is required to test psilocybin products from the licensed manufacturer for potency and to confirm the presence of *psilocybe cubensis.* To receive this license, labs must be accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP).[64] Once products are tested, the results are entered into the product tracking system, and the manufacturer can transfer or sell the product to a licensed service center.[65]

A service center license is required to host clients for psilocybin services. Licensed service centers can be of any size if they comply with regulations present in administrative rules and statutes.[66] The location must be inspected as part of the licensure process, and the property must comply with state and local ordinances.[67] Service centers must track their psilocybin product in the product tracking system as well.[68]

A facilitator license is required to administer psilocybin services to a person at a licensed service center.[69] To become a licensed facilitator of psilocybin services, a person will need to meet the following OHA requirements before being able to provide psilocybin services to clients:[70]

- Prove they are 21 years of age or older;

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[60] State of Oregon, "Chapter 457A-Psilocybin Regulation."
[61] Oregon Health Authority, "How to Become a Licensed Psilocybin Manufacturer in Oregon," Oregon Psilocybin Services, https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Manufacturer-License-Fact-Sheet.pdf
[62] Oregon Health Authority, "Manufacturer in Oregon."
[63] Oregon Health Authority, "Manufacturer in Oregon."
[64] Oregon Health Authority, "Laboratory in Oregon."
[65] Oregon Health Authority, "Laboratory in Oregon."
[66] Oregon Health Authority, "How to Become a Licensed Psilocybin Service Center in Oregon," Oregon Psilocybin Services, https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Service-Center-License-Fact-Sheet.pdf.
[67] Oregon Health Authority, "Service Centers in Oregon."
[68] Oregon Health Authority, "Service Centers in Oregon."
[69] State of Oregon, "Chapter 457A-Psilocybin Regulation."
[70] Oregon Health Authority, "How to Become a Licensed Psilocybin Facilitator in Oregon," Oregon Psilocybin Services, https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Facilitator-License-Fact-Sheet.pdf.

- Have a high school diploma;
- Be an Oregon resident;
- Pass a criminal background check;
- Have taken an OHA-approved education course and training prescribed by the OHA; and,
- Complete an examination administered by the Oregon Psilocybin Services.

The OHA can revoke the license for any reason it deems worthy of revocation, including, but not limited to, negligence, abuse of substances (alcohol, marijuana, etc.), or receiving a felony charge while the license is in effect.[71]

The OHA manages the product tracking system for all parts of this process to regulate the production, distribution, and use of psilocybin in the state. This is done to prevent products from passing to other states, ensure the safety of the products, and make sure stock is accounted for, among other things.[72] Manufacturers, testing labs, and service centers must have a psilocybin tracking administrator to regulate psilocybin movement.[73]

Psilocybin Services: Psilocybin service facilitators are responsible for all aspects of the direct administration of the drug to people. They can only administer psilocybin products after they earn a facilitator license. For unlicensed citizens to obtain psilocybin services, they will need to go to a licensed facilitator at a psilocybin service center who is certified by the Oregon Health Authority to administer the drug.[74]

The act details three distinct parts of the psilocybin services process that are required of the facilitator:

- A preparation session. This is a meeting between the client and the psilocybin service facilitator, either at the administering location or remotely. Upon completing this, the facilitator must record that the client completed it according to OHA regulations.[75]
- An administration session. This session can only happen after the client completes the preparation session and fills out the required client information forms. The drugs are administered, and the client is to be supervised throughout the session. Upon completing an administration session by OHA regulation, it must be certified that it was completed. The administration sessions must be held at a psilocybin service center.[76]
- An integration session. This is a session that takes place after the administration of the drug. The facilitator has to offer it, but it is optional for the client to partake in this session. This session can be done outside the facility itself. Upon completing an integration session by the OHA regulation, it must be certified that it was completed.[77]

[71] State of Oregon, "Chapter 457A-Psilocybin Regulation."
[72] Oregon Health Authority, "Psilocybin – Chapter 333," Public Health Division, https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=7102.
[73] Oregon Health Authority, "Psilocybin – Chapter 333"
[74] State of Oregon, "Chapter 457A-Psilocybin Regulation."
[75] State of Oregon, "Chapter 457A-Psilocybin Regulation."
[76] State of Oregon, "Chapter 457A-Psilocybin Regulation."
[77] State of Oregon, "Chapter 457A-Psilocybin Regulation."

Colorado

Much like Oregon's ORS 475A, Colorado's first natural psychedelic reform legislation came from a ballot measure in 2022. The act passed by the people of Colorado, known as the Natural Medicine Health Act of 2022 (Article 107, Title 12), sets up the framework for adults over 21 to access "natural medicine." The act defines "natural medicine" as "dimethyltryptamine; ibogaine; mescaline (excluding Lophophora williamsii ("peyote")); psilocybin; or psilocyn." Till June 1, 2026, "natural medicines" will only include psilocybin and psilocin.[78] After that date, the other substances mentioned can be added to the legislation with the recommendation of the newly established Natural Medicine Advisory Board.[79]

The Natural Medicine Advisory Board was established by "SB 23-290: Natural Medicine Legalization and Regulation" and is an advisory board for other regulatory departments and agencies to assist in implementing these laws.

This Act lays the framework for two primary things:

- It begins legalizing access to natural medicine for people 21 or older within state-regulated facilities administered by trained and state-licensed facilitators.
- It decriminalizes the personal use of natural medicines for people 21 years or older.

Healing centers: Healing centers are licensed locations to transport, grow, process, supply, or sell natural medicine. A healing center can also administer natural medication to clients at a price. Much like ORS 475A, a licensed "facilitator" carries out the administration process. No later than December 31, 2024, facilitator licenses will be available, and the requirements to attain a permit will be finalized. Generally, though, the act defines a facilitator as someone with the "necessary qualifications, training, experience, and knowledge…to perform and supervise natural medicine services for a participant."[80] Regulation has been called to allow facilitators to administer natural medicine to people in their private residences and health care clinics, allowing natural treatment to reach those who cannot or decide not to go to a healing center.[81]

The Division of Professions and Occupations is tasked with creating rules regarding the administration process. The director oversees the regulation and the issuing of licenses to facilitators, establishing the parameters for the various administration stages, approving educational material for training programs, and creating other rules necessary for regulating natural medicine, natural medicine products, and natural medicine businesses.[82]

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[78] Colorado General Assembly, "Senate Bill 23-290," Senate, https://leg.colorado.gov/sites/default/files/2023a_290_signed.pdf.
[79] Division of Professions and Occupations, "Natural Medicine Act – DORA Implementation Timeframe," State of Colorado, https://dpo.colorado.gov/NaturalMedicine/Implementation.
[80] Colorado General Assembly, "Senate Bill 23-290."
[81] Colorado General Assembly, "Senate Bill 23-290."
[82] Colorado General Assembly, "2023 Legislative Update, SB 23-290: Natural Medicine Legalization and Regulation," https://leg.colorado.gov/bills/sb23-290.

The administration process mirrors Oregon's process detailed in ORS 475A. Colorado's administration consists of a Preparation, administration, and integration session. [83]

The NMHA decriminalizes possession and permits people to grow natural medicine in their private residences.[84] While home growing is permitted, doing it for profit is not permissible. Only healing centers are allowed to profit from the sale of natural medicines. The act provides for the transfer of natural medicines between people, but no funds can be involved.[85] Homegrown natural medicines must be grown privately in a location without residents under 21 years of age. Otherwise, they must be grown in a location where underage individuals are not able to access them.[86]

Washington D.C.

D.C. Law 23-268, the "Entheogenic Plant and Fungus Policy Act of 2020", was passed by the people of DC through a ballot initiative during an election in December 2020. For its use in the legal text, the law defines "entheogenic plant and fungus" as "any plant or fungus of any species in which there is naturally occurring any of the following substances in any form, which would cause such plant or fungus to be described in § 48-902.04(3): ibogaine, dimethyltryptamine, mescaline, psilocybin, or psilocyn."[87]

D.C. Law 23-268 caused two significant changes in DC relating to natural psychedelics:

- First, it makes arresting and investigating people ages eighteen or older for crimes relating to entheogenic plants and fungi the lowest law enforcement priority for the Metropolitan police. These crimes include Non-commercial planting, purchasing, transporting, distributing, engaging in practice with, and/or processing entheogenic plants and fungi.[88]
- Second, the Attorney General of the District of Columbia is ordered to cease prosecution of D.C. residents for Non-commercial planting, purchasing, transporting, distributing, engaging in practice with, and/or processing entheogenic plants and fungi.[89]

Conclusion

Overall, clinical research, pilot programs, and legislation involving psychedelic use and legalization have significantly expanded in recent years. Clinical research has shown that certain psychedelics show promise in treating different types of addiction and depression. As for pilot programs, states have been able to effectively implement guidelines and criteria to allow for successful testing of psychedelic use within the respective states. States and cities across America have begun to adopt a regulatory framework to allow psychedelics to be administered to

[83] Colorado, "Article 170," Initiatives, https://www.sos.state.co.us/pubs/elections/Initiatives/titleBoard/filings/2021-2022/58Final.pdf.
[84] Colorado, "Senate Bill 23-290."
[85] Colorado, "Senate Bill 23-290."
[86] Colorado, "Senate Bill 23-290."
[87] Council of the District of Columbia, "D.C. Law 23-268, Entheogenic Plant And Fungus Policy Act of 2020," Law Information, https://code.dccouncil.gov/us/dc/council/laws/23-268.
[88] Council of D.C., "D.C. Law 23-268."
[89] Council of D.C., "D.C. Law 23-268."

those who live there. Through a gradually increasing number of participating states and locations, psychedelic decriminalization has worked to change the stigma associated with psychedelics.

This report was completed on December 18, 2023 by Morgan Ambrose, Nate Biscotti, and Luke McDermott under the supervision of VLRS Director, Professor Anthony "Jack" Gierzynski in response to a request from Representative Brian Cina.

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