(Law): Psychedelic Drugs: Can They Make the "Trip" to the Pharmacy Shelf?

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Goal and Objectives

- Goal: To familiarize pharmacists with the evolving regulatory status of psychedelic drugs in the U.S and their possible role in treating psychiatric disorders.
- Objectives
  1. Review the development of the knowledge of the effects of psychedelic drugs and their potential use in psychiatry, with an emphasis on psilocybin.
  2. Characterize the traditional legal classification of psychedelic drugs and modern reconsideration of their legal status.
  3. Describe efforts at the state level to expand the medical use of psychedelic drugs.

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Disclosure

- Dr. Gianutsos has no relationship with an ineligible company.

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Today's Presentation

- What are psychedelic drugs?
- What is their potential in treating psychiatric disorders?
- How are they regulated by the CSA?
- How are they regulated by states?
- What is the likelihood that pharmacists will be dispensing them?

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https://www.youtube.com/watch?v=HVxy1yd8tv4

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https://synergeticpress.com/blog/consciousness-and-psychedelics/summer-of-love-sale-lsd-1960s-counterculture/

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Psychedelics

- *"Psychedelics may be the oldest class of psychopharmacological agents known to man."* Researcher David Nichols.

Nichols DE. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4813425/

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Psychedelic Drugs

Used for thousands of years for religious, cultural, recreational and medical purposes.

- **Empathogen: increased feeling of empathy and benevolence towards others**
- **Entactogen: touching within**
- **Entheogen: "creating the divine within"**

Natural (plants, fungi, animals) and synthetic

Being explored for clinical use

https://maps.org/images/pdf/history_of_psychedelics.pdf

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Therapeutic Potential

- *"It does not seem to be an exaggeration to say that psychedelics, used responsibly and with proper caution, would be for psychiatry what the microscope is for biology and medicine or the telescope is for astronomy. These tools make it possible to study important processes that under normal circumstances are not available for direct observation"* Czech Psychiatrist Stanislav Grof.

http://cista.net/Grof/Stanislav%20Grof%20-%20Realms%20Of%20The%20Human%20Unconscious%20-%20Observations%20from%20LSD%20Research.pdf

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Primary Drugs of Interest

- **LSD**
- **Psilocybin**
- **3,4-methylenedioxymethamphetamine (MDMA ["Ecstasy"])**
- **Ayahuasca (Dimethyltryptamine [DMT] + harmine)**
- **Mescaline**

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LSD

Effects of psychedelics were largely unknown in West until 1943.

LSD Synthesized by Albert Hofmann (Sandoz) in 1938 in search for respiratory and cardiovascular stimulants.

CNS effects accidentally discovered by Hofmann

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Early Efforts

- By the end of the 1940s there was great interest in the potential use of LSD as a therapeutic agent in psychiatry.
- In 1950s, Sandoz marketed LSD ("Delysid") and psilocybin ("Indocybin)."
- Both drugs underwent clinical testing by psychiatrists.

Belounin SJ. https://www.sciencedirect.com/science/article/pii/S0028390818300753

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Therapeutic Potential

- In 1940s – 1960s, LSD (and others) were touted in the medical literature and popular press as having great promise for the treatment of a variety of serious mental health disorders including anxiety, depression, schizophrenia, war time stress reactions (PTSD), alcoholism and other substance use disorders

Belouin SJ. https://www.sciencedirect.com/science/article/pii/S0028390818300753

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The Washington Post

Panel Finds CIA Broke Law, Defends Record

CIA Infiltrated 17 Area Groups, Gave Out LSD

Suicide Revealed

District the Focus

https://www.ripleys.com/weird-news/project-mkultra/

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50 Years Later

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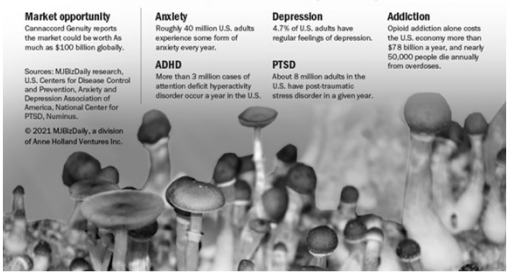
Psychedelic Treatment and Market Opportunities

Some experts say the psychedelics industry could remain medicinal, with heavy regulation and doctor supervision, rather than legalized for recreational use like cannabis. A look at possible treatments for psychedelic drugs.

Market opportunity
Cannacord Genuity reports the market could be worth As much as $100 billion globally.

Sources: MJBizDaily research, U.S. Centers for Disease Control and Prevention, Anxiety and Depression Association of America, National Center for PTSD, Numinus.

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Anxiety
Roughly 40 million U.S. adults experience some form of anxiety every year.

ADHD
More than 3 million cases of attention deficit hyperactivity disorder occur a year in the U.S.

Depression
4.7% of U.S. adults have regular feelings of depression.

PTSD
About 8 million adults in the U.S. have post-traumatic stress disorder in a given year.

Addiction
Opioid addiction alone costs the U.S. economy more than $78 billion a year, and nearly 50,000 people die annually from overdoses.

Smith J. https://mjbizdaily.com/no-hallucination-psychedelics-could-be-next-cannabis-like-boom/

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Potential Clinical Uses

DRUG	SOURCE	POTENTIAL USE	Class
LSD	Synthetic	End-of-life anxiety, substance abuse	Tryptamine
Psilocybin	Psilocybe mushroom	Treatment-resistant depression, anxiety	Tryptamine
MDMA	Synthetic	PTSD, depression	Phenethylamine
DMT/Harmine	Ayahuasca	Depression, anxiety	Tryptamine, MAO-I
Esketamine	Synthetic	Treatment-resistant depression	Dissociative anesthetic
Ibogaine	Iboga	Substance abuse	Mixed
Mescaline	Peyote Cactus	Depression, alcoholism	Phenethylamine

Gianutsos G. https://legacy.freece.com/Home/CECatalogDetails/2911397a-3b68-4afe-9cd5-ef9311ec1d4c

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General Feature of Psychedelics

- Improve depth and speed of psychotherapy
- Likely by encouraging an increased empathy and shared understanding between the patient and therapist, enabling participants to work through and integrate difficult feelings and situations.

Grof S. http://cista.net/Grof/Stanislav%20Grof%20-%20Realms%20Of%20The%20Human%20Unconscious%20-%20Observations%20from%20LSD%20Research.pdf
Sessa B. https://www.rcpsych.ac.uk/docs/default-source/members/sigs/spirituality-spsig/ben-sessa-from-

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Magic Mushrooms

Psilocybe cubensis

https://setasalucinogenas.com/especies/psilocybe-cubensis/

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Psilocybin

- Sacred Aztec magic mushroom *teonanacatl* ("Flesh of God")
- Tryptamine class of psychedelics
- Converted to active metabolite, Psilocin
- Agonist of 5HT2A receptor.

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The tryptamine class of psychedelic drugs (e.g., LSD, psilocybin) produce their psychedelic/therapeutic effects by acting as agonists of a neurotransmitter in the CNS. What is the relevant neurotransmitter system?

A. Serotonin
B. Dopamine
C. Glutamate

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Psilocybin

Clinical research with psilocybin and its active metabolite, psilocyn, has demonstrated rapid and long-lasting possible therapeutic effects in anxiety, treatment-resistant depression, OCD, substance use, and the depression and anxiety associated with cancer, AIDS, or end-of-life suffering.

Psilocybin has some advantages when compared to LSD which potentially makes it a more attractive option for clinical use.

- **Shorter duration of action (an LSD trip may last 8-14 hours, while psilocybin has a duration of action of about 4-5 hours)**
- **Produces less anxiety, fewer panicking and affective disturbances, and milder systemic side effects.**
- **Does not have as strong an association to the 1960's counterculture movement and therefore is less stigmatized than LSD.**

Chi T, Gold JA. *J Neurol Sci*. 2020; 411(April 15):
Carhart-Harris R, *et al. Neuropsychopharmacology.* 2017; 42(11): 2105-2113.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5603818/

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Psilocybin Clinical Trials

The most interest is in the treatment of depression.

A phase II double-blind trial published in 2016 found that that two doses of psilocybin benefited patients with major depression comparable to a six-week course of the SSRI antidepressant escitalopram.

Remission rates were twice as high in the trial arm, and psilocybin had a marginally better safety profile.

Eisenstein M. https://www.nature.com/articles/d41586-022-02872-9

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PSILOCYBIN ON TRIAL

The active ingredient in magic mushrooms has shown intriguing signs of efficacy for treating psychiatric disorders, but the published evidence is limited to a few trials involving small numbers of participants.

Year	Subjects	Lead investigator	Indication	Outcome
2011	12	Charles Grob (University of California, Los Angeles)	Cancer-related anxiety (with depression as a component)	Significant improvement in depression-related symptoms after 6 months[a]
2016	12	Robin Carhart-Harris (Imperial College London)	Treatment-resistant depression	58% in remission after 1 week and 42% still in remission after 3 months[b]
2016	29	Stephen Ross (New York University)	Cancer-related anxiety or depression	83% response rate after 7 weeks versus 14% for control arm[c]
2016	51	Roland Griffiths (Johns Hopkins University)	Cancer-related anxiety or depression	78% response rate, 65% in remission after 6 months at high dose[d]
2021	24	Roland Griffiths (Johns Hopkins) and Alan Davis (Ohio State University)	Major depressive disorder	71% response rate with 54% in remission after 4 weeks[e]
2021	59	Robin Carhart-Harris (Imperial College London)	Moderate to severe major depressive disorder	Similar improvement, after 6 weeks, to escitalopram and a higher remission rate (57% against 28%)[f]

Eisenstein M. https://www.nature.com/articles/d41586-022-02872-9

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Clinical Trial Caveats

- Placebo control and study blinding difficult when studying a drug whose vivid cognitive effects are so well known.
- Treatment must be closely coupled with psychiatric care from specially trained medical professionals.
  - No standardized training protocol for psilocybin facilitators.
  - Differences in how procedure is carried out can itself influence study outcome

Eisenstein M. https://www.nature.com/articles/d41586-022-02872-9

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Disadvantages

- Typically, psychedelic therapy for psychiatric disorders is administered within a structured psychotherapeutic setting with considerable therapist input.
- A session may last many hours and there are usually preliminary and follow up sessions with therapists.
  - *Use of psychedelic therapy is time-and resource-intensive.*
- Stringent restrictions and the intensive time and cost commitment for treating and monitoring of patients may dissuade therapists and patients from participating, preferring the simplicity of taking a pill.
- Early studies strongly suggested that psychedelic drugs were not appropriate for patients with well- established psychotic disorders or in those with a risk of developing them, such as a family history of psychosis.
- Insurance?

Nutt D. https://www.cell.com/cell/pdf/S0092-8674(20)30282-8.pdf
Tullis P. https://www.nature.com/articles/d41586-021-00187-9

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A patient considering psilocybin treatment for a psychiatric disorder asks you for advice; he is specifically interested in disadvantages of this type of therapy. What do you tell him?

A. Use of psychedelic therapy is time-and resource-intensive
B. Requires multiple treatments with a slow onset of activity
C. There is a high risk of autonomic side effects and addiction

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MDMA (3,4-methylenedioxymethamphetamine)

- Synthesized by Merck in 1912 in search for anti-coagulants.
- In Phase 3 clinical trails.
- Promising results in PTSD.
  - 2/3 of patients receiving MDMA with assisted therapy no longer met clinical criteria for PTSD.
- Also depression, anxiety, eating disorders, and alcohol and drug use disorders.

Mitchell, JM. https://www.scientificamerican.com/article/a-psychedelic-may-soon-go-to-the-fda-for-approval-to-treat-trauma/

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Pharma Efforts

Recognize shortage of mental health workers.

Trying to discover compounds that produce "empathogenic" effect without hallucinations which would allow shorter and less expensive sessions.

Wirz M. https://www.wsj.com/articles/wall-street-backs-new-class-of-psychedelic-drugs-3c5b9baf?mod=djem10point

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Synthetic

- Methylone
- 3,4-Methylenedioxymethcathinone (methylone) is a designer drug of the phenethylamine class.
- Methylone is a synthetic analog of cathinone with substantial chemical, structural, and pharmacological similarities to 3,4-methylenedioxymethamphetamine (MDMA, ecstasy).
- Schedule I

https://www.deadiversion.usdoj.gov/drug_chem_info/methylone.pdf

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Methylone

Undergoing clinical trials for PTSD and depression.

Milder adverse effects than MDMA and less interaction with SSRI in very preliminary studies.

Critics say manufacturers are trying to create patentable drugs that will be far more costly to purchase than traditional psychedelics without commensurate improvement in outcomes.

Kelmendi B. https://www.anncaserep.com/open-access/clinical-evidence-for-the-use-of-methylone-in-the-treatment-8922.pdf
https://www.wsj.com/articles/wall-street-backs-new-class-of-psychedelic-drugs-3c5b9baf?mod=djem10point

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Regulatory Overreaction?

In the 1960s, psychedelic substances were characterized as problematic largely due to misinformation, politicization, and irrational fear by many in society.

Political leadership on both sides of the aisle took action, resulting in the near banning of clinical research with these substances.

States also took action

- **California and Nevada enacted bills imposing fines of as much as $1000 and prison sentences of up to one year for possession of LSD.**

Belouin S. https://www.sciencedirect.com/science/article/pii/S0028390818300753

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Banned

Drug Abuse Control Amendments (1965) restricted the medical use of psychedelic drugs.

Amendments were aimed specifically at controlling three classes of products: barbiturates, stimulants and, hallucinogens.

The act authorized the Secretary of Health, Education, and Welfare to designate certain hallucinogenic drugs as controlled, requiring licensing for sales and distribution and hallucinogens were essentially banned. and the

Licenses were required to manufacture chemicals needed for research any research projects could no longer acquire psychedelics.

https://www.govinfo.gov/content/pkg/STATUTE-79/pdf/STATUTE-79-Pg226.pdf#page=1
https://maps.org/images/pdf/history_of_psychedelics.pdf

34

https://prezi.com/g5ioxdqbdn8u/controlled-substance-act-of-1970/

35

Problem

- Psilocybin, like most psychedelics, is a Schedule I Drug

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Which feature distinguishes a C-I drug from other controlled substances?

A. High potential for abuse, especially among hi-riskpopulations
B. Lack of accepted safety for use under medical supervision
C. No currently accepted medical use in treatment in the United States

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Schedule I

- Schedule I under the Controlled Substances Act.
  - High potential for abuse
  - Lack of accepted safety for use under medical supervision
  - *No currently accepted medical use in treatment in the United States*

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How Does a Drug Become Scheduled/Re-Scheduled?

- Anyone can request.
- Evaluation by FDA.
- 8 factor test.

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

https://www.dea.gov/drug-information/csa

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Application

- Five tryptamine analogs in 2021.
- "Data show that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT have been encountered by law enforcement (Factor 5)."
- "Based on published case reports in the medical literature and anecdotal reports (Factor 4), HHS states that these substances are being abused for their hallucinogenic properties."
- "HHS has determined that consumption of these five tryptamines due to their hallucinogenic properties poses a safety hazard to the public health." (Factor 6).
- "Abuse of 5-MeO-AMT and 5-MeO-MiPT has been associated with hospital emergency room admissions."

https://www.regulations.gov/document/DEA-2022-0001-0005

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Application

- "Tryptamine hallucinogens are believed to produce their characteristic effects primarily through stimulation of the 2A subtype of serotonin (5-HT) receptors (5-HT2A) ... (which) has also been shown to mediate the in vivo behavioral effects and discriminative stimulus effects of the three classes of classic hallucinogens, ergotamines (e.g., LSD), phenethylamines (e.g., DOM), and tryptamines (e.g., DMT)." Factor 2.
- "After consideration of the above eight factors determinative of control of a substance (21 U.S.C. 811(c)), and a review of the scientific and medical evaluations and scheduling recommendations provided by HHS, DEA finds that 4-OH-DiPT, 5-MeO-AMT, 5- MeO-MiPT, 5-MeO-DET, and DiPT *meet the … criteria for placement in schedule I of the CSA.*"

https://www.regulations.gov/document/DEA-2022-0001-0005

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Why There Could Be A Change

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Overreaction?

- Today, generally agreed that psychedelics are not "addictive" and the potential for harm was exaggerated (media, political).

https://maps.org/images/pdf/history_of_psychedelics.pdf

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Precedence?

- **Cannabidiol (CBD) formulated as Epidiolex®**
- **Approved 2018 for rare, serious seizure disorders in infants and children.**
  - **"recognized use"**
- **Placed in C-V, acknowledging medical use.**
- **De-Scheduled in 2020**

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Movement

In 2018, the FDA designated psilocybin a "breakthrough therapy" as a treatment for severe depression.

- Designed to expedite the development and review of drugs that are intended to treat a serious condition
- Breakthrough designation is used for drugs that in early clinical trials demonstrate substantial improvement over existing treatments on a clinically significant endpoint.

In 2019, psilocybin received breakthrough designation for drug-assisted therapy for treatment-resistant depression

https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/07/15/more-states-may-legalize-psychedelic-mushrooms
Fingerstein M https://www.nature.com/articles/d41586-022-03073-9

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Coming Soon?

Letter from SAMHSA Assistant Secretary (May 2022):

Preparing for approval of psychedelics.

- "(A)nticipated approval by the Food and Drug Administration (FDA) of 3,4-methylenedioxymethamphetamine (MDMA) for the treatment of Post-Traumatic Stress Disorder and psilocybin for the treatment of depression within approximately 24 months."
- SAMHSA ... is exploring the prospect of establishing a Federal Task Force to monitor and address the numerous complex issues associated with emerging substances. The Task Force may establish and oversee the functions of a public-private partnership that can broadly focus on addressing numerous complex issues associated with psychedelic (psilocybin) and entactogenic (MDMA) medicines but whose risks to public health may require harm reduction, risk mitigation, and safety monitoring."

https://www.documentcloud.org/documents/22121426-exhibit-3-response-to-rep-dean-et-al
Busby M. https://theintercept.com/2022/07/26/mdma-psilocybin-fda-ptsd/

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The FDA granted "breakthrough therapy" designation to psilocybin for treatment of a specific condition. What condition is it?

A. Schizophrenia
B. Treatment resistant depression
C. Post traumatic stress disorder

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Experience with Ketamine Raises Red Flags

- Can be prescribed for depression.
- Patients needed face-to-face meeting with prescriber and treatment was mostly limited to infusions in clinics.
- In 2020, in response to COVID pandemic, rules were relaxed to make it easier to treat patients by telemedicine, and to remotely prescribe controlled substances.
- The shift away from clinics led many patients to take the drug more frequently and for longer periods of time.
- While many patients benefitted, it broadened debates over the proper balance between availability and safety.

Hamby C. https://www.nytimes.com/2023/02/20/us/ketamine-telemedicine.html

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Ketamine

- Some patients said they concealed problems from their telehealth providers for fear of losing access to the only treatment that had ever helped, while others acknowledged abusing their prescriptions, taking too much and in some cases dissolving and injecting the drug.

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States

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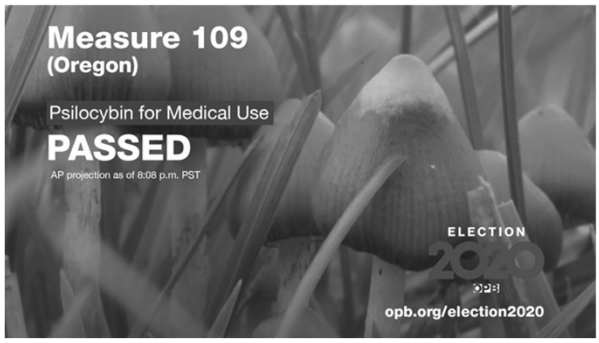

https://www.opb.org/article/2020/11/04/oregon-measure-109-psilocybin/

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Oregon

Oregon became the first state in the nation to allow the therapeutic use of psilocybin.

The measure does not decriminalize psilocybin.

It directs the Oregon Health Authority to create a state-licensed, psilocybin-assisted therapy program and determine how psilocybin would be regulated.

https://www.opb.org/article/2020/11/04/oregon-measure-109-psilocybin/

52

Oregon

The measure will allow therapists to use psilocybin to treat chronic mental health issues

https://www.opb.org/article/2020/11/04/oregon-measure-109-psilocybin/

53

Oregon

- Psilocybin will not be available for purchase in stores.
- It will only be available through an extensive, three-session therapy system provided in a state-licensed clinic.
- The Oregon Psychiatric Physicians Association came out against the measure calling it "unsafe."
  - A former drug policy advisor for Presidents Bill Clinton, George W. Bush and Barack Obama (Kevin Sabet), said the measure treats Oregonians like "lab rats".
  - Said psilocybin should be subject to the rigors of science, not a popular vote.

https://www.opb.org/article/2020/11/04/oregon-measure-109-psilocybin/

54

Oregon

- It will not be legal to consume psilocybin without guidance or oversight.
- The measure sets up a screening system so individuals suffering from psychiatric disorders like schizophrenia, would not be permitted to receive psilocybin.

https://www.opb.org/article/2020/09/30/election-preview-measure-109-allows-therapy-using-the-active-ingredient-in-hallucinogenic-mushrooms/

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In Oregon where medical use of psilocybin was first approved, which of the following statements describes its availability?

A. Psilocybin can be purchased at retail outlets including pharmacies
B. Psilocybin is available from any therapist throughout the state
C. Psilocybin is only available in state licensed clinics

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Oregon

Measure includes a process through which cities and counties can opt out.

Local officials can decide to refer to voters either a two-year moratorium or an outright ban on psilocybin services.

In November 2022 election, nearly two-thirds of the state opted out of allowing psilocybin centers and manufacturing, mostly in rural areas.

https://oregoncapitalchronicle.com/2022/08/08/many-oregon-voters-will-have-to-decide-again-on-a-psilocybin-program/
https://www.oregonlive.com/politics/2022/11/137-oregon-towns-and-counties-vote-to-opt-out-of-psilocybin-services.html

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Other States Contemplating Medical Use

- Colorado became second state in 2022
- Connecticut
- Texas
- Utah
- Washington
- New Jersey
- Maryland
- Maine, Virginia Rejected

https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/07/15/more-states-may-legalize-psychedelic-mushrooms
https://psychedelicalpha.com/data/psychedelic-laws

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Connecticut

Signed into law in 2022as part of budget bill

Established a psychedelic-assisted therapy pilot program to provide qualified patients with the funding necessary to receive MDMA-assisted or psilocybin-assisted therapy

"Qualified patient" means a resident of the state who is (A) a veteran, (B) a retired first responder, or (C) a direct care health care worker

https://www.cga.ct.gov/2022/ACT/PA/PDF/2022PA-00118-R00HB-05506-PA.PDF

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Related Developments

- Many states and cities have decriminalized the use of “entheogens” for personal use.

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More Signs of Easing?

DEA proposed adding five tryptamine analogues in January 2022.

In July, DEA announced it was suspending the enactment of the ban, at least temporarily, in response to pushback.

They will also submit a request for an updated scientific review of the tryptamines from the US Department of Health and Human Services (HHS).

Jaeger K. https://filtermag.org/dea-cancels-psychedelics-ban/

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Congressional Actions

A bipartisan bill (co-sponsored by Sens. Cory Booker, D-N.J., and Rand Paul, R-Ky.) introduced to force the DEA to stop barring terminally ill patients from trying controlled drugs which have passed early trials. (July 2022)

Would amend Right to Try Act.

https://www.booker.senate.gov/news/press/booker-paul-introduce-bipartisan-legislation-to-amend-the-right-to-try-act-to-assist-terminally-ill-patients
https://theintercept.com/2022/07/26/mdma-psilocybin-fda-ptsd/

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Patients

DEA is also being sued by patients seeking access to psilocybin under the Right-To-Try Act.

Suit asserts that DEA is unlawfully misinterpreting and misapplying Right to Try statute and should allow terminally ill patients to access Schedule I investigational drugs like psilocybin.

Jaeger K. https://www.marijuanamoment.net/dea-sued-again-over-refusal-to-allow-psilocybin-access-for-patients-despite-federal-law/

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Model of Possible Outcome

One solution proposed by psychedelic researchers at John Hopkins would place drugs (specifically psilocybin) in Schedule IV along with a legally binding REMS plan which would incorporate limits on dosing for an individual patient, administration in a clinic setting with psychological support by specially trained staff, restrictions on distribution, and post marketing surveillance.

Could require pharmacists working in this area to have special certification.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6791528/
https://www.scientificamerican.com/article/a-strategy-for-rescheduling-psilocybin/

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Take Home Points

- Psychedelics drugs are moving from objects of opprobrium to potential therapies in psychiatry.
- Clinical trials have shown rapid onset and efficacy in psychiatric conditions, including treatment-resistant disorders.
- A growing number of states have enacted laws permitting medical (and personal) use of psychedelics.
- Federal agencies are showing signs of willingness to remove most restrictions on their use.
- What will this mean for pharmacists?

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