

Transforming Treatment: Psilocybin's Role in Mental Health



SUMMARY

Mental illness has been on the rise in Utah and the United States at large. And yet most psychiatric drugs provide only short-term symptom relief rather than modifying the course of mental illness.¹

Research demonstrates that ancient psychoactive medicines may be an important part of addressing the current mental health crisis. One particular psychedelic, psilocybin, has been shown to be a safe, effective, and long-term way to treat a variety of mental illnesses, most notably treatment-resistant depression and PTSD.

A majority of states have already taken tentative steps towards varying degrees of legalization, in lieu of waiting for action from the Federal government since it may never come .

Utah should take a cautious approach by narrowly legalizing the use of psilocybin in approved therapeutic settings with appropriate medical safeguards, giving Utah patients another option to address their mental illness. This would open the door to veterans, first responders and other mental health patients to a potentially life changing treatment.

Utah needs to move forward with a medicinal psilocybin therapy program instead of waiting for FDA approval

History

Psilocybin is a substance found in over 200 mushroom species worldwide. Humans have been ingesting psychoactive psilocybin mushrooms in ceremonial contexts for millennia.

Neolithic petroglyphs depicting mushrooms have been found in Siberia, the Sahara Desert, and the Americas.² Some evidence even suggests that the iconic white crowns of Egyptian pharaohs were made in homage to the psilocybin mushrooms they used in a medical and religious context.³

Despite their ubiquity and antiquity, Western science only became truly aware of psilocybin mushrooms when Richard Schultes, a Harvard graduate student, collected mushrooms and stories of their ceremonial use in Oaxaca, Mexico, in 1938.⁴

In 1955, mycology hobbyist R. Gordon Wasson traveled to Mexico and participated in a traditional psilocybin ceremony. He published an account of his experience in a 1957 *Life* magazine article, claiming he and his travel companion were “the first white men in recorded history

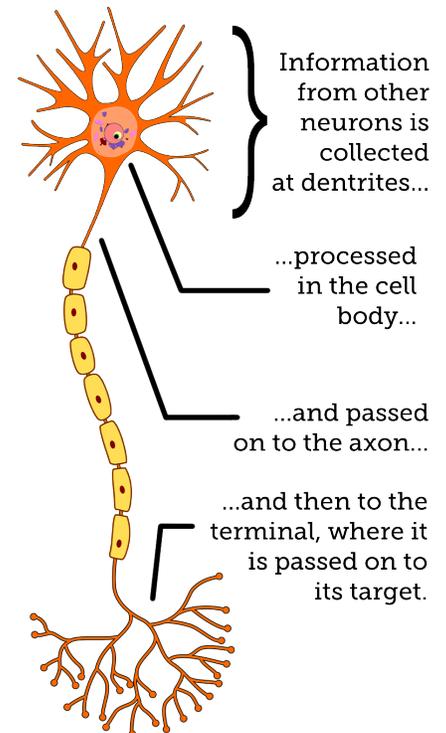
to eat the divine mushrooms.”⁵ In doing so, he was the first to make the American public broadly aware of psilocybin.

Discovery — or reemergence — of psilocybin led to a surge of studies to understand its pharmacology and effects on the mind.⁶ Unfortunately, this legitimate research was undermined by unethical and scientifically dubious experiments conducted by Harvard researcher Timothy Leary.⁷ After being dismissed from Harvard, Leary continued to advocate vociferously for psilocybin and psychedelics more broadly, all while engaging in eccentric and occasionally illegal behavior.

Leary’s antics, combined with use of psilocybin in the counterculture movement of the 1960s, led to psilocybin being listed on Schedule I when the Controlled Substances Act passed in 1970.⁸ This brought psilocybin research to a virtual standstill despite its initial promise.

How Does Psilocybin Work?

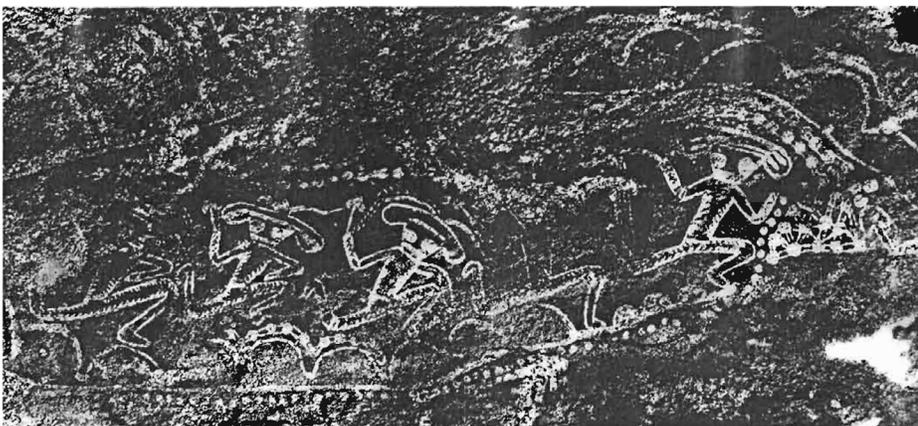
Psilocybin is very similar to serotonin, which regulates mood, self-esteem, happiness, and other biological processes. Psilocybin (known as



psilocin after digestion) seeks out the serotonin-2A receptor specifically in the dendrites of a neuron. This causes dendritic spines, which connect to the dendrites of neighboring neurons, to expand their reach and become more interconnected. Psilocybin also bypasses the normal process the brain uses to interpret sensory information, like sound and sight. Instead of only going through the brain’s gatekeeper, the thalamus, it also sends these sensory signals to areas of the brain outside of its designated function.

Touch gets interpreted by the auditory cortex as well as the somatosensory cortex. Sounds get interpreted in the visual cortex, as well as the auditory cortex. This is why patients who wear eye masks, as the research suggests, can sometimes “see” the music that is played during a session via hallucinations.

The therapeutic effect of psilocybin is caused by the growth of existing and



Tin-Tazarift (Tassili, Algeria) - Dancing masked anthropomorphs holding mushrooms (by Lajoux, 1964)

new dendritic spines. This growth persists long after the effects of ingesting psilocybin have worn off. Studies have shown that patients with depression and anxiety have a markedly reduced number of dendritic spines. These new and augmented pathways of connectivity of the brain are related to a concept called neuroplasticity. Combining therapy with a psilocybin experience allows patients to overcome mental health and addiction issues where no relief has been found in conventional treatment.⁹

Second-Wave Research

In 2000, a group of researchers associated with Johns Hopkins University received regulatory approval to resume research.¹⁰ Since that time, psilocybin research has grown exponentially: over 1,000 scientific papers have been published with psilocybin in the title or abstract.¹¹

Phase 2 clinical trials have demonstrated that psilocybin can lessen symptoms in patients with anorexia, significantly reduce depression scores in those with major depressive disorder,¹³ and decrease the number of heavy drinking days in patients with alcohol use disorder.¹⁴ Follow-up research on subjects who ingested two doses of psilocybin for depression has proven that the benefits of psilocybin treatment are durable: 75 percent of patients still showed a treatment response, and 58 percent were considered to be in continued remission twelve months after ingesting psilocybin.¹⁵

Putting these results in context, researcher Alan Davis said, “The magnitude of the effect we saw was about four times larger than what clinical trials have shown

Stages of Clinical Trials

PHASE 1

Small groups of human subjects are used to see if a substance is safe.

PHASE 2

Studies are designed to test efficacy — whether the substance has a positive impact on treating a condition. Finally, a drug proceeds to...

PHASE 3

Effectiveness and side effects are compared to existing treatments. This phase involves larger groups of subjects.

for traditional antidepressants on the market. Because most other depression treatments take weeks or months to work and may have undesirable effects, this could be a game changer.”¹⁶

Clinical trials have been so positive that Phase 3 trials of psilocybin for depression are underway as are Phase 1 and 2 trials to test its effects on other illnesses including post-traumatic stress disorder, obsessive compulsive disorder, migraines, phantom limb pain, cluster headaches, and binge eating.

But Is It Safe?

Although psilocybin is clearly powerful, it is also very safe. In a 2010 study, members of the Independent Scientific Committee on Drugs scored twenty drugs on sixteen criteria: nine related to the harms a drug produces for an individual and seven related to harm drug users cause others. On a scale of 0–100,

alcohol was the most harmful with a score of 72, and psilocybin was the least harmful with a score of 6.¹⁷

Another way to think about safety is to consider the safety ratio: how many effective doses would a person have to ingest to overdose and die? It is easy to overdose on heroin because the amount it takes to kill you is only six times the amount it takes to get high, giving heroin a safety ratio of six. Alcohol has a safety ratio of ten. By contrast, psilocybin has a safety ratio of 1,000.¹⁸ In other words, it is virtually impossible to ingest enough to die.

Formalized studies have made it possible to systematically examine psilocybin side effects on large groups of people. In the most comprehensive study to date, researchers followed up with one hundred people a year after they ingested psilocybin in a research setting. Researchers “found no indications for subsequent drug abuse, persistent perception disorders, prolonged psychosis or other long-term impairments of functioning in any of our subjects.

Acute adverse reactions (so called ‘bad’ or ‘horror trips’) occurring in a small proportion of subjects in the highest dose conditions, as well as transient emotional instability lasting a few days or weeks in a small number of subjects remain the biggest concerns in psilocybin administration.”¹⁹

When we think of the dangers of drugs, many are concerned about addiction and its host of accompanying ills. However, unlike heroin, cocaine, or alcohol, psilocybin doesn’t increase dopamine levels in the brain and, therefore, doesn’t create chemical dependence.²⁰

Psilocybin was hastily placed on Schedule I — reserved for drugs with no accepted medical use and a high potential for abuse — based on fear of the unknown rather than scientific evidence. Today when new drugs are scheduled, the FDA completes an eight-factor analysis relating to abuse potential:²¹

extraordinary precautions — are also on schedule IV.

By any measure — overdose risk, addiction potential, acute side effects, long-term side effects, or societal harm — psilocybin is safe relative to other medications and illegal drugs as well as in absolute terms.

His wife saw his struggles and suggested he try psilocybin. Never having taken illegal drugs, he was skeptical. However, doing his research convinced him that psilocybin was safe and might offer a path forward.

Due to their illegal status, Eric had to use psilocybin alone, without professional guidance or supervision. Even so, it was a life-changing experience. Here's how Eric described his experience:

“The experience was like hitting a reset button. The gut-wrenching knot of anxiety was gone. The very idea that I had been so anxious now seemed ludicrous. I felt compassion and respect for myself and connected to those around me. It was like my brain had been reprogrammed to think in healthy patterns, rather than the dysfunctional ruts I'd become accustomed to.”

Now, Eric wants other struggling vets to be able to access psilocybin. And he wants them to have the benefit of a therapist to help prepare and guide them through the process.

After psilocybin, Bailey was able to stop taking psychoactive medications, to overcome childhood trauma, and to build a healthier, happier life.

1. Its actual or relative potential for abuse.
2. Scientific evidence of its pharmacological effects, 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 to an already scheduled drug.

A 2018 paper examined the existing psilocybin research as it related to these eight factors. It concluded that abuse potential was so low, psilocybin could not justifiably be placed more restrictively than Schedule IV.²² For perspective, Xanax and Valium — both readily prescribed by physicians for home use without

Eric's Story

Eric grew up watching Hill Air Force jets fly over his home and wanted nothing more than to serve his country in the military when he grew up. After 9/11, he joined the Air Force and served five tours in Afghanistan and Iraq flying C-130s. He loved flying and the camaraderie of the military.

So when he was diagnosed with Meneire's disease, an incurable inner ear disorder which causes vertigo and loss of balance, he was devastated. He would never fly again. In one fell swoop, he lost his military community and his career as a pilot.

Adjusting to civilian life was hard. Eric felt disconnected from people and like he constantly needed to be on guard. He was diagnosed with PTSD and generalized anxiety disorder. He started to take daily medications and participate in counseling. However, he felt like he was putting on a Band-aid without treating the underlying infection.

Bailey's Story

Bailey had a chaotic upbringing. Her mom struggled with alcohol and drug addictions, which led her to be absent a lot of the time. When her mom was home, she was verbally and physically abusive. Not surprisingly, this impacted Bailey's well-being. By age eleven, she had been diagnosed with obsessive compulsive disorder, anxiety, and depression. She was given huge doses of psychotropic drugs, none of which addressed the underlying issues Bailey was coping with.

When Bailey turned eighteen, she moved out and started to build a healthier life for herself. She went to college, got a job, and was in a healthy relationship. And yet everything she had lived through as a child still impacted her mental health. Simple social interactions like running into someone at the grocery store made her so anxious she would become physically ill. Irrational obsessions like having to put all the light switches in the same position made her late to work. Sometimes she wanted to go to sleep and never wake up.

Then Bailey tried psilocybin. It was able to do what antidepressants never had. She felt a lightness and happiness that had eluded her for her entire life. Her obsession with perfection subsided, and she was able to rationally control her response to things like mismatched light switches. Best of all, rather than dreading social interactions, she loves them and can connect with people without fearing that something she says or does won't be good enough.

After psilocybin, Bailey was able to stop taking psychoactive medications, to overcome childhood trauma, and to build a healthier, happier life. She wants other people to be able to take back control of their lives as she has, rather than having poor mental health call the shots.

The Landscape of Legalization

Given that small-scale trials have proven psilocybin to be both safe and effective plus the need for additional options, it's little wonder that some jurisdictions are moving toward legalization. Internationally, the Czech

Republic, Jamaica, Portugal, Spain, and Uruguay have decriminalized possession of user quantities of all drugs, including psilocybin. However Australia — where drugs have not been generally decriminalized — has taken an approach that recognizes the medical value of psilocybin. In 2023, it became the first country to allow psilocybin to be legally prescribed for treatment-resistant depression.²³

Closer to home, Oregon passed two ballot measures in 2020. Measure 109 decriminalized possession of user amounts of all drugs while Measure 110 created a framework for the legal administration of psilocybin in a therapeutic context. Psilocybin services are overseen by Oregon Psilocybin Services (OPS) and include licensed growers, laboratories, administration facilities, and facilitators.²⁴ OPS began taking applications and issuing licenses in January 2023, and it is anticipated that patients will be able to access supported psilocybin services in mid-2023.

In November 2022, Colorado passed Ballot Measure 122 which legalized possession, growing, and gifting psilocybin mushrooms as well as a regulated therapeutic use. Colorado's framework has not yet been fully developed through the rulemaking process but will include trained facilitators and healing centers which are subject to government oversight.²⁵

Maryland became the first state to legalize psilocybin legislatively — rather than through ballot measure — on a limited basis in 2022. Its approach was unique in that it created a fund to research alternative therapies, including psilocybin,

and to provide them cost-free to veterans with PTSD and traumatic brain injuries.²⁶

Cities lack legal authority to legalize or decriminalize psilocybin in contravention of state law. However, a wave of cities have passed ordinances making enforcement of drug laws targeting psilocybin and other selected hallucinogens the lowest priority for law enforcement, accomplishing nearly the same results as decriminalization. Denver was the first city to do so with the passage of Initiative 301 in 2019.²⁷ At the same time, Denver created the Denver Psilocybin Mushroom Policy Review Panel to assess the impact of Initiative 301 in terms of crime, hospitalizations, and user experience. Two and a half years after passage, the Panel reported that decriminalization “has not presented any measurable public health or community safety risks.”

Surveys of Denver residents who used psilocybin after passage of the initiative found that 90 percent felt the experience created a positive change in well-being or life satisfaction and 34 percent rated it among the top most insightful experiences of their lives.

Other cities have followed Denver's example. Oakland, California, decriminalized entheogenic plants and fungi a few months after Denver. Santa Cruz, California; Ann Arbor, Michigan; and Washington, DC, followed in 2020.²⁸ Somerville and Cambridge, Massachusetts; Arcata, California; Seattle and Port Townsend Washington; and Detroit and Hazel Park, Michigan decriminalized psilocybin in 2021.²⁹

Making psilocybin legally available to patients is a widespread trend. Although only three states and a handful of cities have legalized or decriminalized psilocybin, twenty-two states (California,³⁰ Connecticut,³¹ Florida³², Illinois,³³ Iowa,³⁴ Kansas,³⁵ Maine,³⁶ Massachusetts,³⁷ Michigan,³⁸ Missouri,³⁹ Montana,⁴⁰ Nevada,⁴¹ New Hampshire,⁴² New Jersey,⁴³ New York,⁴⁴ North Carolina,⁴⁵ Oklahoma,⁴⁶ Rhode Island,⁴⁷ Utah,⁴⁸ Vermont,⁴⁹ Virginia,⁵⁰ and Washington⁵¹) have introduced legislation to legalize psilocybin.

An additional seven states have introduced or passed legislation to study psilocybin with an eye towards possible future legalization (Hawaii,⁵² New Mexico,⁵³ Arizona,⁵⁴ Georgia,⁵⁵ Minnesota,⁵⁶ Pennsylvania,⁵⁷ and Texas⁵⁸). In other words, two-thirds of states are already on the path toward some form of psilocybin legalization.

Federal Legalization Efforts

Psilocybin is currently on Schedule I at both the federal and state level meaning that doctors cannot prescribe it. Currently, the only path to legal use is through clinical trials,

which accept only a small number of patients who meet study criteria. Broader, federally legal access will require psilocybin to be moved to a more permissive schedule. Although the DEA has occasionally rescheduled derivatives of Schedule I drugs, such as when it rescheduled the cannabis extract Epidiolex to Schedule V,⁵⁹ it has never rescheduled the whole form of a Schedule I substance.

There are only two paths to rescheduling: Congress can pass a law, or it can be rescheduled through the executive rulemaking process.

Legislative change is straightforward: sponsor a bill and garner enough votes to pass it. Unfortunately, straightforward doesn't mean easy or likely. Like psilocybin, cannabis has been a Schedule I substance since 1970. Every Congress since 1995 has proposed at least one bill to reschedule cannabis. None have passed.

Under the executive route, the Secretary for Health and Human Services or an outside party may file a petition with the Attorney General to reschedule, or the Attorney General may initiate the process. The FDA is then tasked with reviewing the

scientific evidence regarding the drug's effects, dependence liability, and public health risks before making a recommendation to the Attorney General. The Attorney General is to consider this recommendation and, if there is substantial evidence to justify a schedule change, initiate the rulemaking process to do so.⁶⁰

Again, the history of cannabis is instructive. A 2014 Phase 3 FDA-approved clinical trial — the highest level of trial used by the FDA when deciding whether to approve a drug — demonstrated the efficacy of treating neuropathic pain from spinal injuries with cannabis nearly a decade ago.⁶¹ Despite this evidence, the DEA, the responsible agency under the Attorney General, denied a 2016 petition to reschedule cannabis.⁶²

The history of attempts to reschedule MDMA, another psychedelic with potential to improve mental health, is also instructive. MDMA received FDA Breakthrough Designation in 2017, which is intended to accelerate the approval process. Phase 3 clinical trials completed in 2020 showed that MDMA significantly decreased PTSD and depressive symptoms and that these results were better



than other PTSD medications on the market. And yet MDMA is still a Schedule I substance, and patients have no way to legally access it. Although the federal drug scheduling is supposed to be grounded in science, it is ultimately a political process.

So even though the FDA has granted psilocybin breakthrough status multiple times beginning in 2018,⁶³ and even though trials have demonstrated both safety and efficacy, it does not follow that federal legalization will happen soon or at all.

What Can States Do?

In the face of federal inaction and increasing rates of mental illness, states have several options to make psilocybin available to their citizens.

Rescheduling: Most states also have drug schedules which mirror federal law. States could simply remove psilocybin from any schedule, making possession and distribution legal. This approach is simple and requires no state resources to implement. However, it does not address minor access to psilocybin. It also leaves medical providers in a legal gray area. Prescribing controlled substances

is a privilege governed by both federal and state law.⁶⁴ Practitioners who recommend psilocybin or supervise patient use risk not only federal criminal prosecution, but may also have their prescription privileges revoked. Without explicit state approval giving political cover, most medical practitioners are likely to be wary of supervising patient use of psilocybin.

Right to Try: Federal and state right-to-try laws give patients access to non-approved drugs in limited circumstances, typically when a patient has a life-threatening condition which has not responded to available treatments. Since most states already have right-to-try frameworks in place, it would require only minor modifications to accommodate non-terminal patients. Implementation would be inexpensive since states would not be required to create expensive new oversight mechanisms. And given that right to try is familiar at the state and federal levels, providers are likely to feel more comfortable recommending treatment and supervising patient use, despite federal prohibition.

Therapeutic Programs: Some states have considered and sponsored a regulated therapeutic model with

licensing for producers, laboratories, facilitators, and the facilities where patients ingest psilocybin. Extensive rules protect minors, protect product purity, and ensure that patients are adequately prepared and supervised. The downside of such a program could be the cost to patients and the state, but these programs need not be overly expensive to protect patients and the community. In 2023, Utah proposed a medical psilocybin program which would largely track its medical cannabis program. Utah's cannabis program consistently generates revenue: In 2022, the Center for Medical Cannabis — housed in the Department of Health and Human Services and tasked with overseeing Utah's cannabis program — had a \$1.7 million surplus.⁶⁷ A medical psilocybin program could use much of the cannabis regulatory infrastructure, which has already proven to be cost effective.

Therapeutic programs offer the greatest ability to protect the public while also providing a safe product and competent oversight for patients. However, such programs must be carefully constructed or they can become so expensive that patients can't access treatment or are driven to use less-safe, black-market alternatives.

Endnotes

1. S Nassir Ghaemi, "Symptomatic Versus Disease-modifying Effects of Psychiatric Drugs," *Acta Psychiatrica Scandinavica* 146, no.3 (June 2, 2022): 251-57, <https://doi.org/10.1111/acps.13459>.
2. Giorgio Samorini, "The Oldest Representations of Hallucinogenic Mushrooms in the world (Sahara Desert, 9000-7000 B.P.)," *Integration Journal of Mind-moving Plants and Culture*, no.2/3 (1992).
3. Stephen Berlant, The entheomycological origin of Egyptian crowns and the esoteric underpinnings of Egyptian religion, image, Scientific Figure on ResearchGate, Accessed December 14, 2022, 2023. https://www.researchgate.net/figure/Left-Glyphs-of-mushroom-crowned-humanoids-on-cliffs-in-Chukchi-region-of-Russia_fig4_7566286.
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For the remainder of the endnotes, please visit [Libertas.org/transformingtreatment](https://libertas.org/transformingtreatment)

PUBLIC POLICY BRIEF

Transforming Treatment: Psilocybin's Role in Mental Health



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UTAH CONSTITUTION
ARTICLE I, SEC 27