



## Executive Summary

While human suffering is as certain as the tides lapping our islands, so too is our never-ending pursuit of relief. Thanks to decades of research and clinical trials, the time is now right to add psilocybin into the raft of therapeutic options legally available to relieve Hawai'i residents suffering from mental health crises.

Studies examining the efficacy of psilocybin and other plant medicines were ongoing in the 1950s and '60s, but when the federal government included psilocybin in its list of Schedule I drugs in the 1970 Controlled Substances Act, research into benefits of this plant-based medicine rapidly decreased.

This classification solidified a negative stigma around psilocybin and other plant medicines, framing them as part of an unsettling countercultural movement.

In the early 1990s, scientists in Europe began studying psychedelic medicine and its impact on humans. These studies led to neuroimaging and psychology studies and in turn to clinical

trials in the United States. Promising results led to additional trials and there presently exists at least 20 years of solid research findings demonstrating the efficacy of psilocybin as a treatment for depression, end-of-life anxiety, alcohol abuse and tobacco cessation. In 2018 and 2019, the FDA designated psilocybin a breakthrough therapy for treatment-resistant depression.

Health policy experts have referenced these findings as they begin to successfully push back against limiting perceptions of psilocybin, an organic substance. Education has led to successful ballot measures in Oregon and Washington D.C. removing regulatory barriers to the use of plant medicines for mental health. Among laypeople, lawmakers and healthcare workers, education has been - and continues to be - necessary to generate greater understanding of psilocybin as one of many tools available to therapists counseling patients in their offices.

The Clarity Project seeks to raise awareness among lawmakers and community leaders as to the value of plant medicines. This White Paper summarizes recent research findings, highlights public health efforts happening elsewhere and includes a spate of links to documents and articles examining the positive mental health benefits of psilocybin.

## Recommendations for Preliminary Legislative Action

Based on a thorough examination of the current socio-political environment and the potential of medical psilocybin, our recommendations for creating a legislative and regulatory framework for legally accessing psilocybin-assisted therapy in Hawai'i include:

- ▶ Developing an advisory, science-based, therapeutic modality for psilocybin that addresses preparation, facilitation, and integration.
- ▶ Providing a nexus for an advisory board of experts from relevant disciplines to assist in the development and management of the program, including risk assessment for contraindications and safety, practice, and ethical standards for trained and competent facilitators.
- ▶ Establishing a process to independently license facilitators, service center operators, and producers of psilocybin mushrooms and products (while building on fundamental lessons learned from the legalization and regulation of medical cannabis in Hawai'i).
- ▶ Supporting public health education programs on the benefits of psilocybin and assisted therapies.
- ▶ An extended development period to protect the successful rollout of the program and encourage the formation of collaborative private-public platforms.

## Therapeutic Psilocybin - Overview

Psilocybin is the main natural ingredient found in more than 200 species of psychoactive mushrooms. Research from major institutions around the world has shown psilocybin to be a promising clinical treatment tool for a wide range of mental and psychiatric diagnoses including anxiety, addiction to alcohol and other drugs, depression, end-of-life anxiety, and post-traumatic stress disorder.

In increasing numbers, medical and mental health professionals are turning to psilocybin as an effective and natural treatment with minimal side effects. These findings have also given rise to a groundswell of interest, study, and use of psilocybin, which has begun to surface in mainstream society through media and art, health, spirituality, and culture. In step with public sentiment, advocates across the U.S. have begun pursuing multi-pronged decriminalization and legalization strategies in an effort to extend the benefits of psilocybin outside of the research setting.

## Fundamental Psilocybin Facts

- ▶ **Natural Fungi** - Psilocybin is a naturally occurring compound found in more than 200 species of mushrooms which collectively can be [found on all continents](#) in varying potencies. These mushrooms are both cultivated and found in the wild. [Cultivated mushrooms tend to be more potent through selective breeding, though some species resist cultivation and require specific conditions found only in complex, natural ecosystems.](#) In clinical studies and psychedelic-assisted therapies, the synthetic version of pure psilocybin is administered to control dosing standards, not the mushroom in its natural or dried form.
- ▶ **Not Addictive** - [Psilocybin does not lead to physical dependence.](#) Studies have found that adolescent use of hallucinogenic drugs, including psilocybin, [does not increase the risk of drug dependence](#) in adulthood (unlike cannabis, cocaine, inhalants, stimulants - all of which were associated with “an excess risk of developing clinical features associated with drug dependence.”).
- ▶ **Safe** - [The toxicity of psilocybin is very low.](#) A person would have to eat nearly one-third of their weight in psilocybin mushrooms to reach a lethal dose. This amount is approximately 1.5 times that of caffeine. Psilocybin also may result in varying effects between people even in proper doses - including negatively perceived reactions, based on differences in the mental state, the personality of the user, and the immediate environment (see “Set & Setting”). In addition to experiencing [peacefulness and connectedness](#), patients may feel distressing emotions and effects such as increased heart rate and blood pressure, anxiety, fear, nausea, impaired coordination, and paranoia. Medical psilocybin is most effective when administered and overseen by a trained healthcare professional who can [guide the patient, understand drug interactions, and screen for known risks such as schizophrenia, bipolar disorder, or other pre-existing mental health diagnoses.](#)
- ▶ **Set & Setting** - Research on psilocybin has shown that the [context of the experience plays a critical role in determining positive outcomes for patients.](#) Overwhelming anecdotal evidence coupled with new research protocol provide guidelines for good practices and a clear roadmap for optimizing patient treatment models. The physical environment (the setting) and the mental space (the mindset) have a fundamental influence in the treatment and outcome of the experience. [In clinical research, patients given psilocybin are provided a safe, comfortable space with trained experts to offer support to participants.](#)