

THERAPEUTIC PSILOCYBIN FOR HAWAI'I

Expanding Access to Breakthrough Therapeutic Modalities

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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 <u>found on all continents</u> in varying potencies. These mushrooms are both cultivated and found in the wild. <u>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.</u>
- 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.



ONGOING PSYCHEDELIC RENAISSANCE OFFERS ADDITIONAL MODALITIES FOR HEALING

Hawai'i Must Join the Movement for Safe, Therapeutic Access to Psilocybin

Rules governing the use of plant medicines have changed over the centuries, but the therapeutic value of psychedelic medicines - as well as the integrative practice essential to realizing their benefit - has remained a constant.

Psilocybin, a naturally occurring, non-addictive compound found in some mushrooms, has for centuries helped warfighters battle post-traumatic stress. It has aided victims of debilitating trauma struggling to process their suffering. It has facilitated new ways for the ill or dying to consider mortality. The expansive mental health benefits of plant-based medicines such as psilocybin is visceral knowledge deeply embedded in indigenous communities; its value has been understood in these spaces long before fMRI brain mapping studies allowed empirical knowledge to coalesce around psilocybin.

When possession of psilocybin and other plant-based medicines was federally criminalized in 1970, scientific study of these naturally occurring substances became nearly impossible. Mainstream understandings about the therapeutic benefits of safe, guided use of psychedelic medicines like psilocybin faded likewise. This is particularly tragic considering the technological tools that have become ever more available to researchers over the last 51 years.

Over the past two decades, though, driven researchers around the U.S. and beyond have managed to obtain the permissions necessary to build scientific understanding of the effects of plant medicine on the brain and body. Empirical knowledge has slowly begun to blossom. It is this growing body of evidence, arising out of myriad university studies and clinical trials, that has begun to bloom into a psychedelic renaissance.



So it is with increasing certainty that scientists and medical professionals are now working with policymakers to bring plant-based medicines like psilocybin above ground for therapeutic uses. Individual state- and city-level lawmakers now have an essential role to play in the movement toward safe, legal, therapeutic access to psilocybin across the U.S., Canada, and Europe.

In a growing number of places, citizens and lawmakers are electing to permit citizens in need of healing to choose integrated treatment methods that foreground the use of psilocybin in a monitored, therapeutic setting.

We may learn from a successful November, 2020, ballot initiative called Measure 109, which gave the Oregon Health Authority two years to create rules and guidelines for the administration of the psychedelic medicine psilocybin in a therapeutic setting. Or look to Canadian Federal Minister of Health Patty Hajdu, who has since mid-2020 been granting requests from terminally ill patients and therapists seeking to use psilocybin as part of palliative care. On the East Coast, in Washington, D.C., 76% of voters in November, 2020, elected to decriminalize possession of psychedelic substances including psilocybin.

These initiatives have been propelled by clinical research findings in places like the Imperial College of London, John Hopkins University, New York University and Yale University demonstrating the long-term efficacy of psilocybin as an effective treatment for the symptoms of depression.

Positive research findings about psychedelic medicines have led to the creation of entire centers devoted to the study of psychedelic medicine. Centers are being opened on both coasts of the continental United States, including the Center for Psychedelic and Consciousness Research at Johns Hopkins in Baltimore, which opened thanks to \$17 million in philanthropic fundraising in 2020. In September, 2020, the University of California at Berkeley opened the Center for the Science of Psychedelics. In 2021 the Icahn School of Medicine at Mount Sinai launched a Center for Psychedelic Psychotherapy and Trauma Research.

Research and training at these facilities, much of it cross-discipline, empirically demonstrates the great potential of psychedelic medicines including psilocybin - when coupled with the guidance of a trained clinician - for alleviating the mental health crisis tightening its grip on the Western world.

One of five adults in the United States live with a mental illness such as PTSD or depression; it is with this in mind the Clarity Project is actively educating stakeholders in Hawai'i about the last 20 years of mainstream scientific study demonstrating the benefits of psychedelic medicine. We seek also to raise consciousness of public policy initiatives happening across the U.S.

Acting out of a deep sense of service to our community, Clarity Project joins these policy advocates in requesting Hawai'i reconsider its governance of the therapeutic use of plant medicines, starting with psilocybin.



THERAPEUTIC PSILOCYBIN FOR MENTAL HEALTHCARE IN HAWAI'I

The Need for Expanding Access to Breakthrough Therapeutic Modalities

Clarion calls for the reconsideration of plant medicines are being sounded by scientists, healthcare professionals, advocates, business leaders, and private citizens across the United States. The Clarity Project is an effort to coalesce the collective wisdoms of these stakeholders and amplify the call for serious consideration and implementation of psilocybin as a revolutionary, life-changing vehicle for use in mental health settings here in Hawai'i.

Hawai'i's medical professionals and outreach programs need access to innovative, effective, and safe tools to continue the work to help heal and support Hawai'i.

Statistics from the National Survey on Drug Use and Health, data incorporated into the national Healthy People 2030 initiative, indicate that just 64.1 percent of adults with serious mental illness receive treatment.





A wide range of diagnosed - and as-yet undiagnosed - mental and psychiatric diagnoses including anxiety, addiction, depression, end-of-life anxiety, and PTSD affect individuals here in the Aloha State. Among goals set in the state's Healthy People 2020 initiative, HP2020, was a reduction in the state's suicide death rate, reduction in the number of adults who experienced major depressive episodes, and an increase the number of adults who experienced major depressive episodes and received treatment. While the state says it has seen an improvement the latter metric, it has failed to reduce - and instead documented increases - in both suicide death rate and the number of adults who experienced major depressive episodes.

Left unaddressed, the effects of untreated depression and anxiety contribute not just to individual suffering - in itself a tragedy - but also to tangibly negative outcomes felt in ripples across our communities: absenteeism, bullying, costs to overburdened healthcare systems, loss of economic opportunity, substance abuse, domestic violence and homelessness, among others.

In 2017, a report from the Lancet Commission on Global Mental Health and Sustainable Development - a consortium on psychiatry, public health, neuroscience and advocacy - estimated that the mental health problems of the world would, unchecked, cost the global economy \$16 trillion by 2030.

Psilocybin is increasingly considered one of the most effective, non-addictive, and safe treatment options for depression and anxiety used in clinical settings. This white paper summarizes the findings of landmark research studies and suggests preliminary recommendations for Hawai'i's action toward expanding access to breakthrough therapies in a safe, controlled and effective manner. Failure to allow Hawai'i citizens a full range of legal treatments for depression, anxiety and PTSD could come at great expense.

Citing this research, groundbreaking initiatives in favor of psilocybin – like passage of Measure 109 in Oregon and Initiative 81 in Washington, D.C. – are occurring at all levels of government, private and public research institutions, and throughout mainstream society. We do not want the citizens of Hawai'i to miss out on this healing modality.





THE CLARITY PROJECT

Expanding Legal Therapeutic Psilocybin Access in Hawai'i

The Clarity Project is a citizen-driven initiative that aims to expand legal patient access to include psilocybin-assisted therapy modalities. Inspired by the decriminalization of psilocybin in Denver, the project was founded in 2019 and comprises doctors, therapists, medical professionals, advocates, and researchers interested in using or currently using psilocybin in Hawai'i.

Through education, advocacy, and legislative action, the Clarity Project aims to create the necessary legal frameworks, regulatory bodies, and associated governmental mechanisms to help expand therapeutic access to psilocybin for those who live in our communities.

We are a part of a growing global movement, connected to those in Colorado, Oregon, and California as well as in countries like Portugal, to pave the way for a sustainable and compassionate approach to healthcare and social equity through legalization of medical psilocybin.

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Groundbreaking US Initiatives

Cities and states across the nation are increasing medical access to psilocybin. Below is a summary of initiatives in all levels of government:

National

The Food and Drug Administration has granted Breakthrough Therapy designation for psilocybin therapy.

- According to the FDA, Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).
- 2018 Clinical trials run by Compass Pathways to research severe treatment-resistant depression; the study will be complete in 2021
 - 2019 Breakthrough Therapy designation was
- granted a second time in 2019 to Usona Institute for phase 2 clinical trials testing psilocybin's efficacy in treating major depressive disorder

In October 2019, **the Department of Defense** acknowledged the potential of psychedelic therapy and announced that the Defense Advanced Research Projects Administration (DARPA) has created a

dedicated program to develop psychedelic drugs for the military.

The psychedelic renaissance includes private as well as public actors. In October, 2020, the British mental healthcare company Compass Pathways became the first psychedelic medicine company to make an **initial public offering** on the Nasdaq. With offices in London and New York, COMPASS has <u>raised more than \$115</u> million in its efforts to bring to market a psilocybin treatment for depression. In early 2021, Compass announced the <u>creation of a laboratory and treatment</u> center at The Sheppard Pratt Institute for Advanced <u>Diagnostics and Therapeutics in Baltimore, Maryland.</u> The institute is among the largest private, not-for-profit mental healthcare facilities in the U.S.

In December, 2020, the Canadian Federal Health Minister approved more than a dozen healthcare professionals working at a nonprofit patient rights group to possess and use psilocybin for professional training in psilocybin therapy. Among the approved healthcare workers were psychologists, psychiatrists, clinical counselors, social workers, general practitioners, and nurses.



State



Oregon

In November, 2020, Oregon passed a measure to decriminalize psilocybin for use in therapeutic settings. With a clear focus on healthcare, Measure 109 gives the Oregon Health Authority (OHA) two years to create a program for administering psilocybin to individuals aged 21 years or older at designated care centers. The OHA is also tasked with creating regulations. An Oregon Psilocybin Advisory Board (OPAB) will advise the OHA, which is authorized to set guidelines on matters including licensing, training requirements, dosing and packaging rules.



Hawai'i

In January, 2021, four state Senators (Sen. Stanley Chang, Sen. Laura Acasio, Sen. Les Ihara, Jr., Sen. Maile S.S. Shimabukuro) introduced SB738. The measure seeks to remove psilocybin from the list of Schedule 1 substances and require the Department of Health to designate treatment centers for therapeutic administration of psilocybin. The bill requires the Governor's office to convene a review panel to review and assess the effects of measure. The panel would be required to report annually to the state legislature.

The bill was deferred in committee in late February, 2021.

In March, 2020, Senator Les Ihara Jr. and Representative Chris Lee put forward bills in their respective chambers requesting that the state's Department of Health convene a medical psilocybin working group to examine the medicinal and therapeutic effects of the plant-based medicine. The working group would be tasked with creation of a strategic plan to ensure the availability of medicinal psilocybin to patients in need of safe, affordable access. The bills were referred to the Committee on Commerce, Consumer Protection and Health.





Florida

In late January, 2021, a Florida Democrat, Rep. Michael Grieco, <u>filed a bill that</u> if passed would require the Sunshine State's Department of Health to implement regulations to allow people 21 and older to access psilocybin at licensed facilities during therapeutic sessions in a clinical setting. The measure establishes an advisory board to guide the regulatory process, not unlike the successful 2020 ballot initiative in Oregon.



Connecticut

Five Democrats in this Atlantic seaboard state have formally requested the state create a task force to study the health benefits of psilocybin. The measure was introduced in January, 2021. The bill was referred to the legislature's Committee on Public Health.



California

The Covid-19 pandemic stymied citizens' <u>efforts in California</u> to collect enough signatures to put a psilocybin decriminalization measure on the ballot in November, 2020. But several groups are now working in concert and <u>plan to file again in the next election cycle.</u>



Washington

As in California, the pandemic thwarted efforts to gather the signatures necessary to place a psilocybin decimalization measure on the ballot in 2020.

In late November, 2020, a palliative care doctor in Washington submitted an application to the state's Pharmacy Quality Assurance Commission requesting to manufacture psilocybin and administer it to patients, citing the 2017 federal Right To Try Act. The doctor and a collaborating law firm anticipate a legal challenge.





New York

In 2020, Democratic Representative Linda Rosenthal introduced <u>a bill to decriminalize</u> psilocybin. It was referred to the state's Health Committee in May, 2020.



Vermont

In January, 2020, progressive Representative Brian Cina <u>introduced a bill to decriminalize</u> naturally occurring plant-based medicines used "for medicinal, spiritual, religious, or entheogenic purposes." The measure included psilocybin and had three co-sponsors. It was referred to the state's House Committee on Judiciary.



lowa

In February 2021, Republican lawmaker Jeff Shipley proposed <u>a bill in the Iowa House of Representatives</u> to remove psilocybin from the state's list of Schedule 1 substances.

<u>Testimony was heard</u> on the bill, which Shipley said was written with the intention of enabling use of psilocybin to treat depression, addition and end of life care. The measure was defeated in a subcommittee.

Rep. Jeff Shipley <u>proposed two bills in May 2019</u> to allow state regulators to approve the reclassification of psilocybin to be used in treatment and to remove it from the state's list of banned substances.



Municipal

Denver, CO in May 2019, was the first city to decriminalize the personal use, possession, storage, and cultivation of psychedelic mushrooms.

Denver, CO - Psilocybin Mushroom Decriminalization Initiative

Oakland, CA subsequently became the second city a month later, decriminalizing all entheogenic plants including psychedelic mushrooms.

 Oakland, CA - Resolution supporting entheogenic plant practices and declaring that the investigation and arrest of individuals involved with the adult use of entheogenic plants on the Federal Schedule 1 List be amongst the lowest priority for the city

Chicago, IL city council members introduced a bill in October 2019 expressing support for the decriminalization entheogen plants.

 Chicago, IL - Resolution expressing support for the adult use of entheogenic plants and call for hearings to discuss findings from Department of Public Health on feasibility of use as alternative treatment options

Memphis, TN – Advocacy organization Psilo was founded in October 2019 to increase literacy on the benefits of medicinal mushrooms and push for "common sense psilocybin laws"

Santa Cruz, CA, City Council in February, 2020, became the third city in the United States to direct its law enforcement professionals to give lowest priority to

criminal enforcement of adult possession of entheogens. The City Council <u>unanimously approved a request</u> to decriminalize the adult possession, use and cultivation of plant-based medicines such as mushrooms containing psilocybin.

Ann Arbor, MI, city council in September, 2020, unanimously voted to decriminalize psychedelic plants and fungi. In its resolution, the city council designated as the city's lowest law enforcement priority the investigation or arrest of anyone planting, cultivating, purchasing, transporting, distributing or consuming psychedelic medicines including psilocybin.

Washington, D.C. voters. In November, 2020, overwhelmingly elected to decriminalize entheogens, or psychedelic plants and fungi that contain ibogaine, dimethyltryptamine, mescaline, psilocybin, or psilocyn. The measure passed with 76% approval.

Somerville, MA, in January, 2021, became the first in the Bay State to <u>decriminalize possession</u> of entheogens, or plant-based medicines. Psilocybin is among entheogens. Somerville's City Council approved the proposal unanimously.

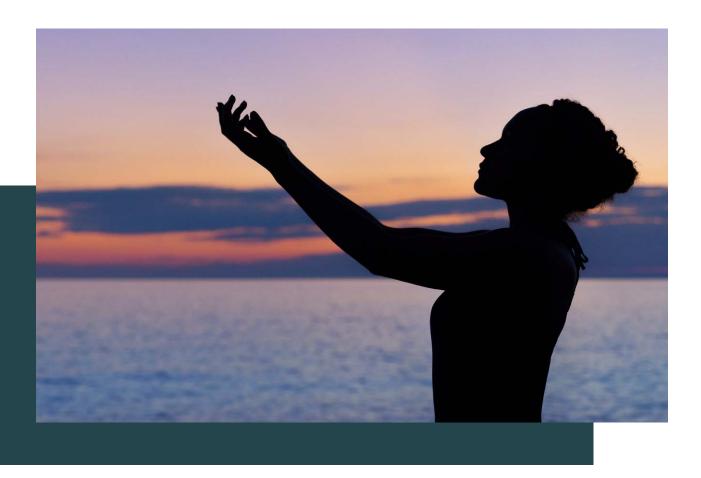
Port Townsend, WA, a local woman requested the town's <u>city council decriminalize</u> possession of all entheogens; the request met with initial support from the Port Townsend City Council's Ad Hoc Committee for Public Safety and Law Enforcement. It was referred in in January, 2021, to a future meeting of full city counsel.



Growing Grassroots Support

With the passing of the Oakland resolution, <u>Decriminalize Nature</u>, the group behind that effort, has become a pillar in the psychedelics and psilocybin advocacy communities. Activists from <u>more than half the states</u> in the country have already reached out to the organization expressing interest and pursuing a similar model in their own municipalities. <u>As of June 2019, 55 cities across 30 states were actively seeking guidance on reforming psychedelics laws</u>. Several months later, in late November, 2019, <u>more than 100 cities</u> were actively seeking guidance for consideration of reforming psychedelics laws. Hawai'i is prominently listed on their "<u>Advocacy Leaderboard</u>", tied for fifth place with San Francisco (CA), Sacramento (CA), Santa Barbara (CA), Seattle (WA), Ann Arbor (MI), Denver (CO), Boulder (CO), Baltimore (MD), and Marquette (MI).

The wave is coming, whether this state is prepared or not. Now is the time to assess the possibilities of working with the undercurrents and tides of society, instead of fighting against them.





Research Institutions Studying Psilocybin

United States

- Johns Hopkins Medicine Center for Psychedelic and Consciousness Research
- Icahn School of Medicine at Mount Sinai <u>Center</u> for Psychedelic Psychotherapy and Trauma Research
- New York University Psychiatry
- Harbor-UCLA Medical Center
- University of California San Francisco
- University of California at Berkeley <u>Center for</u> <u>Science of Psychedelics</u>
- Yale University
- Purdue University

- University of Alabama at Birmingham
- University of Wisconsin Madison
- University of Arizona College of Medicine
- Heffter Research Institute
- Usona Institute
- Compass Pathways
- Multidisciplinary Association for Psychedelic Studies
- Segal Institute for Clinical Trials
- Great Lakes Clinical Trials

International

- Imperial College London Centre for Psychedelic Research (UK)
- University of Oxford Psychiatry (UK)
- Beckley Foundation (UK)
- University of Toronto Mississauga Psychedelics Studies Research Program (CA)
- University of British Columbia Vancouver BC (CA)

- Maastricht University Psychopharmacology (Netherlands)
- Leiden University Psychology (Netherlands)
- Silo Wellness (US/Jamaica)
- Monash University (Australia)



THE SCIENCE OF PSILOCYBIN

Below are findings from landmark research studies that demonstrate the potential of psilocybin treatment. More information on these studies and others can be found at the end of this document.

Landmark Research Studies - Key Findings

<u>Psilocybin Decreases Existential Distress (Depression/Anxiety of Life Threatening Cancer)</u>

Griffiths, Roland R et al. "Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial."

Journal of psychopharmacology (Oxford, England) vol. 30,12 (2016): 1181-1197.

doi:10.1177/0269881116675513

The effects of psilocybin were studied in 51 cancer patients with life-threatening diagnoses and symptoms of depression and/or anxiety. The study found that when administered under psychologically supportive, double-blind conditions, a single dose of psilocybin produced substantial and enduring decreases in depressed mood and anxiety along with increases in quality of life and decreases in death anxiety in patients with a life-threatening cancer diagnosis. The overall rate of clinical response at 6 months on clinician-rated depression and anxiety was 78% and 83%, respectively.



Johnson, Matthew W, and Roland R Griffiths. "Potential Therapeutic Effects of Psilocybin." Neurotherapeutics: the Journal of the American Society for Experimental NeuroTherapeutics vol. 14,3 (2017): 734-740. doi:10.1007/s13311-017-0542-y The current state of modern research suggests considerable therapeutic promise for psilocybin. This research is most advanced regarding the treatment of cancer-related psychiatric distress, with three randomized, placebo-controlled trials showing promising results for psilocybin. Two of these trials involved a moderate number of participants and administered relatively large doses of psilocybin. These two studies, in particular, provide strong evidence showing substantial decreases in depressive and anxious symptoms that appear to persist for at least 6 months after a single active treatment.

Psilocybin Decreases Obsessive-Compulsive Disorder Symptoms

Moreno FA, Wiegand CB, Taitano EK, Delgado PL. Safety, tolerability, and efficacy of psilocybin in 9 patients with obsessive-compulsive disorder. J Clin Psychiatry. 2006; 67 11: 1735- 40. PubMed PMID: 17196053

In a controlled clinical environment and modified double-blind study, psilocybin was safely used in subjects with OCD and was associated with acute reductions in core OCD symptoms. Nine subjects with OCD were administered a total of 29 psilocybin doses. Marked decreases in OCD symptoms of variable degrees were observed in all subjects during 1 or more testing sessions.

Psilocybin Helps Treat Major Depressive Disorder

Carhart-Harris, R L et al. "Psilocybin with psychological support for treatment-resistant depression: six-month follow-up."
Psychopharmacology vol. 235,2 (2018): 399-408.
doi:10.1007/s00213-017-4771-x

In this study, Twenty patients (six females) with (mostly) severe, unipolar, treatment-resistant major depression received two oral doses of psilocybin (10 and 25 mg, 7 days apart) in a supportive setting. Treatment was generally well tolerated. Overall results suggest that psilocybin represents a promising paradigm for unresponsive depression that warrants further research in double-blind randomised control trials.



Resources

Carhart-Harris, Robin. "Big Pharma Is About to Tune Into The Potential of Psychedelics." Wired Magazine, 1 January, 2021.

www.wired.co.uk/article/psychedelics-big-pharma.

Tulles, Paul. "How Ecstasy and Psilocybin Are Shaking Up Psychiatry." Nature, 27 January, 2021. www.nature.com/articles/d41586-021-0 0187-9#ref-CR1

Lim, Austin. "Psychedelics as Antidepressants." Scientific American. 30 January, 2021.

www.scientificamerican.com/article/psy chedelics-as-antidepressants.

Dr. Robin Carhart-Harris heads the Centre for Psychedelic Research at Imperial College London. He uses brain imaging to assess how psychedelic compounds work in the brain and explores therapeutic uses of these medicines. In this opinion piece he posits that psychedelic will cross over into the mental health mainstream during 2021. He points to a boom in clinical research and cites an increase in nonprofit fundraising spurring research and policy initiatives alike. He also points to increased interest coming from the pharmaceutical and, tangentially, technology sectors.

In this news analysis piece published in a weekly journal of science, a patient successfully uses psilocybin to overcome treatment-resistant depression in the U.K. The article also presents a useful overview of the psychedelic renaissance including an overview of recent research, a brief explanation of how psychedelics work in the brain, and concerns about psychedelic medicines including the difficulties of standardizing experiences for patients. A useful chart depicts the increasing number of clinical trials testing psychedelics such as psilocybin and MDMA and analysis raises some important challenges of conducting trials, such as obvious placebo treatments.

Dr. Lim, a professor of neuroscience at DePaul University, contrasts psychedelic medicines with selective serotonin reuptake inhibitors, or SSRIs, which he calls the gold standard in medication for depression. He posits that psychedelic medicines take effect more quickly and have a longer-lasting effect. He writes, "It is still unclear how much these treatments will cost, but one study predicts that psychedelic therapy for post-traumatic stress disorder could save each patient \$100,000 over a 30-year window."



Joiner, Whitney. "Who Will Benefit From Psychedelic Medicine?" The Washington Post, 21 September 2020,

www.washingtonpost.com/magazine/20 20/09/21/psychedelic-medicine-will-it-b e-accessible-to-all/?arc404=true Reporting on the inaugural Psychedelic Medicine & Cultural Trauma Workshop, one of approximately 20 conferences held in 2019-20 in the United States examining medicinal uses for and policies governing psychedelic medicine, this workmanlike article gives an overview of the last 50 years of U.S. drug policy involving psychedelic substances as well as recent scientific study findings.

It also examines difficult questions of equitable access to psychedelic medicines in a therapeutic setting and examines the history of racially biased enforcement of drug laws and how this history has shaped attitudes toward psychedelic medicines in various socio-economic communities, particularly in black communities.

Heacock, Craig. "What psychedelics taught me about healing trauma." CNN, 20 December 2020,

www.cnn.com/2020/12/20/opinions/psy chedelics-trauma-healing-this-is-life-he acock/index.html.

In this opinion piece for CNN, the adolescent and adult psychiatrist and addiction specialist Dr. Craig Heacock of Colorado shares his evolved perspective on the benefits of psychedelic medicines. Dr. Heacock is a co-therapist in the Phase 3 trial of the psychedelic medicine MDMA. He observed patients "being able to mentally return to the source of the trauma and begin to rework and reframe their experience without fear. Using pharmaceutical-grade doses of MDMA alongside psychotherapy sessions, they were able to process what happened with the warm light of compassion, pushing away the toxic sludge of shame that surrounded the trauma."

Shostak, Seth and Bentley, Molly. "Skeptic Check: Shroom with a View" SETI Institute, 3 December, 2020,

Radio.seti.org/episodes/skeptic-check-s hroom-with-a-view. This hour-long radio show utilizes smart and humorous storytelling in an exploration of the psychedelic renaissance and its focus on clinical trials demonstrating efficacious treatments for depression and neurodegenerative diseases. Guests include John Hopkins University School of Medicine professor Albert Garcia-Romeu as well as biologist and author Merlin Sheldrake. The podcast also includes a section on archeology, examining past and present uses of psychedelic drugs among indigenous people.



Carey, Benedict. "Johns Hopkins Opens New Center for Psychedelic Research." The New York Times, The New York Times, 4 Sept. 2019,

www.nytimes.com/2019/09/04/science/psychedelic-drugs-hopkins-depression.html.

In September, Johns Hopkins University opened the Center for Psychedelic and Consciousness Research, the first of its kind dedicated to the study of psychedelic compounds as treatment for mental illnesses. This initiative was funded by private donors and a foundation. Given the long history of psychedelic misuse, researchers are excited to bring to light how/if these compounds can be used responsibly. The article also outlines how human trials will take place and under what precautions but ends on a positive and hopeful note, describing the experience of someone who has benefitted from participating in a trial.

Pollan, Michael. "Michael Pollan: Not So Fast on Psychedelic Mushrooms." The New York Times, The New York Times, 10 May 2019,

www.nytimes.com/2019/05/10/opinion/denver-mushrooms-psilocybin.html.

In this opinion piece, Michael Pollan warns against getting too excited about the legalization of psilocybin. While he acknowledges its potential, he also emphasizes the need for more rigorous studies and the dangers psychedelics can have with other drug interactions and certain mental illnesses such as schizophrenia. Pollan also expresses concern about using ballot initiatives as the pathway to legalization, citing past political backlash that hampered research on psychedelics in the 1960s.

Pollan, Michael. The New Science of Psychedelics. Michael Pollan, 3 May 2019,

www.michaelpollan.com/articles-archive/the-new-science-of-psychedelics/

This article summarizes overall findings on psychedelics and their clinical implications. Pollan provides a history of psychedelic therapy, describing the deficiencies in past studies. Pollan describes a Johns Hopkins study regarding psychedelic therapy and smoking addiction. Pollan then goes into great detail about a study at Imperial College explaining the default mode network, its reduced activity when on psychedelics, and the relationship between ego and mental illness.



Resources - Legislative Initiatives

Zdinjak, Nina. "California Activists Fight To Decriminalize Psilocybin Mushrooms." MSN, 1 Oct. 2019,

www.msn.com/en-us/finance/news/calif ornia-activists-fight-to-decriminalize-psil ocybin-mushrooms/ar-AAl7usL An activist group in California called "Decriminalize California" is aiming to decriminalize psychedelic mushrooms in California by submitting a citizen's initiative to be placed on the November 2020 ballot.

Warner, Gary. "Magic Mushrooms May Be on the 2020 Ballot." The Bulletin, The Bulletin, 17 Aug. 2019,

www.bendbulletin.com/localstate/73663 55-151/magic-mushrooms-may-be-on-t he-2020-ballot.

McCormick-Cavanagh, Conor. "How Psilocybin Advocates Grew Denver's Trippiest Ballot Initiative." Westword, 4, 21 June 2019,

www.westword.com/news/how-psilocyb in-advocates-grew-denvers-trippiest-bal lot-initiative-11308625.

Hughes, Trevor. "Denver Decriminalizes 'Magic Mushrooms' in Historic Vote." USA Today, Gannett Satellite Information Network, 10 May 2019,

www.usatoday.com/story/news/nation/2 019/05/08/denver-decriminalizes-magic -mushrooms-historic-vote/1147857001/.

In Oregon, advocates of the "Oregon Psilocybin Serves Act" are calling for an initiative to decriminalize psychedelic mushrooms on the 2020 ballot. More specifically, chief petitioners Thomas Ecker and Sheri Ecker seek the opportunity to allow therapists to legally integrate guided hallucinogenic treatments into their practice. This initiative is distinctive from other state and local efforts as it is target towards the Oregon Health Authority and the monitored and controlled use of psychedelic substances.

The story behind Initiative 301 in Denver, or the decriminalization of psychedelic mushrooms. The article highlights the story of Kevin Matthews, the man behind the ballot initiative and Tyler Williams, a drug-policy reform activist who informally started the campaign. Since the beginning of the campaign in 2017, it took many separate attempts to get the initiative on the ballot and a significant amount of collaboration.

Denver decriminalizes psychedelic mushrooms by slim margins. In this case, decriminalization means the enforcement of drug laws against mushroom users will be the lowest priority for police.



Sells, Toby. "New Group Pushes for Reforms on 'Magic Mushrooms'." Memphis Flyer, Memphis Flyer, 8 Oct. 2019,

www.memphisflyer.com/NewsBlog/archiv es/2019/10/07/new-group-pushes-for-ref orms-on-magic-mushrooms.

A new nonprofit organization in Memphis called Psilo is working on grassroots education focused on psilocybin treatment.

Weise, Elizabeth, and Marco della Cava. "Oakland in California Decriminalizes Magic Mushrooms and Peyote." USA Today, Gannett Satellite Information Network, 5 June 2019,

www.usatoday.com/story/news/2019/06/05/oakland-california-legalizes-magic-mushrooms-and-peyote/1347888001/.

Oakland officially decriminalized natural hallucinogens about a month after Denver. Like the initiative in Denver, this vote directs law enforcement to cease the investigation and prosecution of individuals for using or possessing drugs sourced from plants, cacti, and mushrooms. Several amendments were added to ensure safe usage.

Jaeger, Kyle. "GOP Lawmaker's Bill Would Legalize Psychedelic Mushrooms And MDMA For Medical Use." Marijuana Moment, 7 Feb. 2019,

www.marijuanamoment.net/gop-lawma kers-bill-would-legalize-psychedelic-mu shrooms-and-mdma-for-medical-use/.

Norcia, Alex, and Hunter. "People Are Hungry for Shroom Legalization, and the Money to Fund It Is Growing." Vice, 4 Aug. 2019,

www.vice.com/en_asia/article/8xw4av/what-comes-after-shroom-decriminalization-in-denver.

A freshman republican lowa lawmaker made several proposals to legalize psychedelics. Rep. Jeff Shipley proposed several bills that would allow state regulators to approve the reclassification of psilocybin, MDMA, and ibogaine to be used in treatment. Shipley sees psychedelic treatment as "paramount to solving the healthcare crisis". This move was especially notable given that he is a member of the Republican Party, which has historically been opposed to drug policy reform.

Discusses the coalitions working to decriminalize and legislate psychedelics after the win in Denver. Notably, Denver's campaign manager Kevin Matthews is in the process of creating a new non-profit called the Society for Psychedelic Outreach, Reform, and Education (SPORE) which seeks to advocate for psychedelics in general. This is overall perceived as an attempt to bolster or create a lobbying arm on the psilocybin and hallucinogenic front. The article also covers the money making potential of psychedelics that is already taking off in the form of micro-dosed coffee



CONCLUSION

The time is right for Hawai'i to allow safe, legal access to psilocybin.

Already designated as a breakthrough therapy for treatment-resistant depression by the FDA, psilocybin can also provide relief for end-of-life anxiety and PTSD. Administered in a therapist's office or other safe, regulated setting, this non-addictive plant medicine can help patients reframe the way they consider past events or harmful thought patterns.

Across the U.S., citizens in cities like Washington D.C., Denver and Santa Cruz are electing to remove regulatory barriers to accessing plant medicines for mental health. In November, 2020, voters in the state of Oregon approved Measure 109, which gives the state's health authority a two-year quiet period to create rules and guidelines for administering psilocybin in a therapeutic setting.

Thanks to empirical data collected by scientists, the visceral knowledge held for centuries of the efficacy of plant medicines like psilocybin for alleviating human suffering is being actualized. It is now the role of citizens and lawmakers to wisely choose a legal way forward to expand access to this healing modality.