The Psychedelic Therapy Advisory Working Group **Final Report**

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Legislative Charge

Sec. 1. PSYCHEDELIC THERAPY ADVISORY WORKING GROUP; STUDY

(a) Creation. There is created the Psychedelic Therapy Advisory Working Group for the purpose of reviewing existing research on the cost-benefit profile of the use of psychedelics to improve mental health and to make findings and recommendations regarding the advisability of the establishment of a State program to permit health care providers to administer psychedelics in a therapeutic setting and the impact on public health of allowing individuals to legally access psychedelics under State law.

(b) Membership. The Working Group shall be composed of the following members:

(1) the Dean of the Larner College of Medicine at the University of Vermont or designee;

(2) the President of the Vermont Psychological Association or designee;

(3) the President of the Vermont Psychiatric Association or designee;

(4) the Executive Director of the Vermont Board of Medical Practice or designee;

(5) the Director of the Vermont Office of Professional Regulation or designee;

(6) the Executive Director of the Vermont Medical Society or designee;

(7) the Vermont Commissioner of Health or designee;

(8) the Vermont Commissioner of Mental Health or designee; and

(9) an expert in psychedelic treatment of mental conditions who is affiliated with a Vermont hospital currently providing ketamine therapy appointed by the Vermont Commissioner of Mental Health.

(c) Powers and duties.

(1) The Working Group shall:

(A) review the latest research and evidence of the public health benefits and risks of clinical psychedelic assisted treatments; and

(B) examine the laws and programs of other states that have authorized the use of psychedelics by health care providers in a therapeutic setting and necessary components and resources if Vermont were to pursue such a program.

(2) The Working Group shall seek testimony from Johns Hopkins' Center for Psychedelic and Consciousness Research, in addition to any other entities with an expertise in psychedelics.

(d) Assistance. The Working Group shall have the assistance of the Vermont Department of Mental Health, in collaboration with the Vermont Psychological Association, for purposes of scheduling and staffing meetings and developing and submitting the report required by subsection (e) of this section.

(e) Report. On or before November 15, 2024, the Working Group shall submit a written report to the House and Senate Committees on Judiciary, the House Committee on Health Care, the House Committee on Human Services, and the Senate Committee on Health and Welfare with its findings and any recommendations for legislative action.

(f) Meetings.

(1) The Vermont Department of Mental Health shall call the first meeting of the Working Group to occur on or before July 15, 2024.

(2) The Working Group shall select a chair from among its members at the first meeting.

(3) A majority of the membership shall constitute a quorum.

(4) The Working Group shall cease to exist on January 1, 2025.

Executive Summary

The legislature created the Psychedelic Therapy Advisory Group to study the use of psychedelics to improve mental health. This group was tasked to make findings and recommendations regarding the advisability of the establishment of a State program to permit healthcare providers to administer psychedelics in a therapeutic setting and the impact on public health of allowing individuals to access psychedelics under State law legally.

The Advisory Group convened 5 meetings between July 8, 2024, and October 8, 2024, with presentations from experts in the field of psychedelic research, other state programs set up to facilitate psychedelic experiences, and drug policy related to psychedelic substances. The group also reviewed several meta-analyses on the existing research on psychedelic medicines for a range of conditions from depression, anxiety, addictive disorders, and end-of-life care. Consensus was found among group members that psilocybin-containing mushrooms should be the focus of the recommendations in this report. While other psychedelic substances have been used for centuries or more and have been studied for several decades, the psychedelic compound psilocybin (or psilocin) has the most research to support its use for improving mental health and addictive disorders. Below is a summary of the group's findings and a summary of the group's recommendations. The remainder of the report details the findings that informed the recommendations.

Summary Recommendations

The Psychedelic Advisory Work Group makes the following summary recommendations. These represent only the major points from the full discussion of recommendations found in the report.

- Extend the current working group with the expansion of participants to monitor the evolution of research and programs across the country and to facilitate the ability to research psychedelic therapies in Vermont. Although not the only promising area of application supported by existing science, the group demonstrated general consensus regarding the potential for psilocybin-assisted therapy for depression and anxiety in the context of serious illness & end-of-life care.
- As psilocybin and other psychedelic substance use increases in Vermont and nationally, the group recommends developing and funding harm reduction training and education for health practitioners and the public.

Because current state models, active legislation, and ballot measures are so varied and new in development, advisory group members found it difficult to conclude which model should be pursued in Vermont. Data from existing programs, while promising, are insufficient to inform the public health impact of legalizing the therapeutic use of psilocybin or other psychedelic substances. The group did not reach a consensus, though the majority did not recommend the creation of a state program for psychedelic therapy at this time. Concerns expressed included the practicalities of creating and enforcing standards of care in an environment of federal prohibition or without broad national consensus. There were also concerns about delaying access to this approach with appropriate safeguards given the mental health and addiction crisis in Vermont.

Introduction

Research into the use of psychedelic medicines to treat a variety of mental health conditions and addictive disorders resumed in earnest over the past twenty years after nearly 50 years of dormancy following the passage of the Controlled Substance Act of 1970. Before this time, research on psychedelics for mental disorders flourished between 1950-1970, mostly with LSD or lysergic acid diethylamide for the treatment of alcohol use disorder. The recent resurgence of research on psychedelics, mostly with psilocybin and mostly paired with psychotherapy or psychosocial support, has generated widespread interest in the potential of these substances to address the mental health and substance use disorder crisis in the United States (and globally). According to a 2024 Mental Health America analysis, nearly 25% of US adults experienced a mental illness in the past year. The US also continues to struggle with rising drug death rates (only recently stabilizing or declining in 2023). The rise in optimism around psychedelic research has also fueled changes in state laws and municipalities related to decriminalization and even legalization of some psychedelic drugs with a focus on psilocybin-containing mushrooms. With more and more public awareness and support around the safe and structured use of some psychedelic substances, Vermont is considering potential pathways to allow for the therapeutic use of psychedelics with the involvement of healthcare practitioners and as a matter of public health and safety.

Act 126 of 2024 created the Psychedelic Therapy Advisory Group. This group was comprised of the following:

- Vermont Department of Health (Mark Levine, MD - Commissioner),
- Vermont Department of Mental Health (Kelley Klein, MD - Medical Director),
- Vermont Psychological Association (Rick Barnett, PsyD – Legislative Committee Chair),
- Vermont Board of Medical Practice (Steven J. Runyan, DO),
- Vermont Medical Society (Jessa Barnard, Executive Director),
- UVM Larner College of Medicine (Robert Gramling, MD, DSc – Epidemiologist and Palliative Medicine),

- Brattleboro Retreat (Kurt White, LICSW – Vice President of Community Partnerships),
- Office of Professional Regulation (Emily Tredeau, Staff Attorney),
- Robert Althoff, MD, PhD (Chair of Psychiatry - UVMMC).

Meetings were held via Zoom on July 9, August 13, September 10, October 1, and October 8 from 10:30 am-12:00 pm and a quorum was present at each meeting with public comment in the final 15 minutes. Experts were invited to share their experiences in each of the first three meetings:

- July 9, 2024: Mason Marks, MD, JD from the Petrie-Flom Center at Harvard Law School
- August 13, 2024: Albert Garcia-Romeu, PhD from the Johns Hopkins Center for Psychedelics and Consciousness Research
- September 10, 2024: Angela Albee, Manager of Oregon Psilocybin Service under the Oregon Health Authority, and Heidi Venture, co-owner of Vital Reset Oregon, a licensed psilocybin service center.

The October 1 and October 8, 2024 meetings generated discussion leading to the formulation and review of recommendations based on expert testimony, a review of the research, and each advisory group member's background in the field of healthcare and their understanding of the current research on psychedelic medicine and treatments. A decision was made within the first two meetings to focus recommendations around psilocybin due to its increasing use, the safety profile in and out of therapeutic contexts, and the preponderance of research examining this substance for diverse conditions.

Possible Benefits and Risks of Psychedelic-Assisted Treatments

Overview of Psychedelics in Therapeutic Context

The use of psychedelic drugs in a therapeutic context within clinical trials as well as within the context of ceremony or healing modalities follows three phases: preparation, experience, and integration.[1] Most clinical trials follow some variation of therapeutic support in helping subjects to prepare for a psychedelic experience, curating a safe and calm atmosphere for the experiential part of the overall treatment process, and offering therapeutic support in the hours, days, and weeks following a psychedelic experience. This is referred to in the literature as "set and setting" and is designed to optimize the safety and efficacy of the overall treatment process. Ideally, all three phases of this treatment involve some degree of physical and psychological safety optimization, risk mitigation, careful screening and assessment, exclusion criteria, emergency management procedures, psychoeducation, and psychosocial support with follow-up care as needed.

Review of Latest Research Findings

Despite being a Schedule I substance, there is a substantial and growing body of research regarding psychedelics. Research using Schedule I substances involves complex approvals at both the FDA and DEA and can be difficult and expensive to pursue.

A review of the latest research findings highlights several themes and can be examined more deeply in the list of references with summary statements at the end of this report. These themes include, with a focus mostly on psilocybin:

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10184717/

- Treatments using psychedelic substances (especially psilocybin) seem to be quite safe and well-tolerated with relatively minor and infrequent adverse events that typically resolve within 24-48 hours.
- Treatments using psilocybin have been shown to be effective in reducing symptoms for a variety of conditions including, but not limited to, major depressive disorder, treatment-resistant depression, end-of-life anxiety and depression, post-traumatic stress disorder, alcohol use disorder, tobacco use disorder, and obsessive-compulsive disorder.
- Most studies have small sample and effect sizes that limit their statistical power and generalizability and may not have long-term outcome data. There are concerns related to functional unblinding in placebo-controlled designs, sampling biases and exclusion criteria, and the influence of psychotherapy on outcomes.
- While the near-term risks of clinical or recreational use of psilocybin appear to be low, studies can improve their adverse events reporting processes to better understand the risks including psychological risks, risk of hallucinogen persisting perceptual disorder (HPPD), interpersonal boundary violations, and risks stemming from using an illegal drug with the fear of legal consequences as well as racial biases.

Legal Landscape: Examining Other States' Programs and the Federal Approval Process

Overview of States with Authorized Psychedelic Use

As of September 2024, only Oregon and Colorado have enacted a statewide process of legal access to one or more psychedelic substances and only Oregon is operational. Oregon enacted Measure 109, the Psilocybin Services Initiative in 2020 with a two-year rule-making process from Jan 1, 2021 – December 31, 2022. Oregon Psilocybin Services Centers began operating under the regulation and licensing of the Oregon Health Authority in May 2023. Nearly 800 people were served in 2023 and it is estimated that over 4000 people have been served as of the writing of this report. According to the OHA officials, there have been over 350 licenses issued for service centers, and over 30 facilitator training programs. As of 9/10/24, there have been 41 complaints, 8 open investigations, 5 final orders, and 4 reports from emergency services. Data collection is being improved and changes to the initiative are currently being considered that would allow healthcare practitioners to be a part of the OHA Psilocybin Program.

Given the complex regulatory realities of providing access to a substance that is still illegal at the federal level and its intersection with professional licensure, Oregon does not refer to this as "therapeutic access" to psilocybin. In Oregon, a facilitator is present to monitor the individual, but the facilitator is prohibited by law from diagnosing or treating medical conditions, cannot make medical claims, and cannot operate in a licensed healthcare facility. There is inconsistent screening for contraindicated conditions. Individuals who participate in the program are referred to as "clients" not "patients" and must sign a waiver that this is not a "treatment." The program costs approximately $1.5 million per year to operate and these costs are largely passed along to clients in the form of $1500-$3500 fees per dose, often up to 3 doses.

In November 2022, Colorado voters approved Proposition 122, known as the Natural Medicine Health Act (NMHA). This legislation legalizes the use of "Natural Medicine" for adults aged 21 and older. The substances considered "Natural Medicine" include dimethyltryptamine (DMT), ibogaine, mescaline (excluding peyote), psilocin, and psilocybin. Immediate legalization applied only to psilocybin; other substances will remain illegal until June 1, 2026. Under the NMHA, personal use and possession of psilocybin are decriminalized, while retail or commercial sales of psilocybin remain prohibited. Furthermore, the NMHA establishes a licensing system for therapeutic psilocybin use. The rule-making is underway for licensed "facilitators" to provide "Natural Medicine Services" at authorized "Healing Centers," as defined by the law. The Colorado Department of Regulatory Agencies (DORA) oversees this framework, with guidance from the newly created Natural Medicine Advisory Board. This program is expected to be up and running in early 2025.

Utah passed a law in March 2024, SB266, a pilot program allowing physicians at two major hospitals in the state to treat patients with either psilocybin or MDMA after careful screening, assessment and preparation. It is not known if any patients have been treated as of this report.

Given factors such as the expense of oversight, costs to patients, and challenges of sourcing, some experts consulted by the workgroup suggested that an alternative to existing state models could be to create a model similar to a safe consumption site where licensed health practitioners can oversee the safe use of psilocybin with legal protections. The cost to set up this kind of system may be significant but could be an avenue for further exploration. There was no consensus on this within the group.

Other municipalities or cities in states like Washington, Michigan, Minnesota, Massachusetts, Maine, California, and Washington DC have decriminalized psilocybin. A ballot initiative will be voted on in November of 2024 in Massachusetts called Question 4: Legalization and Regulation of Psychedelic Substances Initiative. If approved, a taxed and regulated legal system for accessing some psychedelic substances by persons aged 21 and older will be established.

FDA Approval Status

Phase III clinical trials are the last step for new drug approval through the Food and Drug Administration (FDA). In August 2024, despite two positive Phase III clinical trial results using MDMA (ecstasy) combined with psychotherapy for Post-Traumatic Stress Disorder, the FDA rejected the application for MDMA-Assisted Psychotherapy, requesting another Phase III clinical trial be conducted. This may take another 2-3 years. However, two companies are in Phase III clinical trials for their pharmaceutical version of psilocybin for the treatment of Major Depression Disorder (USONA) and Treatment Resistant Depression (Compass Pathways). When these trials are completed, a new drug application will be submitted to the FDA for approval. There is speculation that a pharmaceutical version of psilocybin could be approved in 2027 or later. While not the focus of this workgroup, for context, ketamine is a Schedule III controlled substance that is FDA-approved for induction and maintenance of general anesthesia. A racemic version of ketamine is available in troches, as well as nasal spray and an injectable form, as well as in an isomeric, inhaled esketamine (Spravato). Spravato has FDA indications for treatment-resistant major depressive disorder and major depression with active suicidality. Although racemic ketamine is not approved for the treatment of conditions such as depression or chronic pain, there has been increased use of racemic ketamine for these types of conditions, and prescribed “off label” for purposes other than those approved by the FDA.

Some members of the PTAG insisted that FDA approval is important to establish safe indications and guidelines for new medicines and suggested that Vermont should not take any further action on access to psychedelics without FDA approval. However, some members stated Vermont should remain open to regulatory change happening sooner given the mental health crisis, current good evidence for psilocybin in particular, and to facilitate safe access to this approach.

Recommendation

Extend the current working group with the expansion of participants to monitor the evolution of research and programs across the country and to facilitate the ability to research psychedelic therapies in Vermont. Although not the only promising area of application supported by existing science, the

group demonstrated general consensus regarding the potential for psilocybin-assisted therapy for depression and anxiety in the context of serious illness & end-of-life care.

Medical or Personal Use of Psilocybin

Specific to Vermont, members of the group did not reach a consensus on the use of psilocybin in a medical model or setting, or the use of psilocybin in non-medical settings such as at home, in community ceremonies, or with friends or facilitators. Regardless of any regulatory change pursued by the legislature, there was widespread agreement that it would be beneficial to develop education for the public and training for practitioners to reduce risk for those who choose to use psilocybin outside of a legalized system. This recognizes that there are limitations to what licensing boards can develop if use is not legal.

Impact on Public Health of Legal Access to Psychedelics

The PTAG refrained from commenting and discussing at length topics related to the decriminalization or the legalization of psilocybin (or other psychedelics). The group often referenced the process Vermont experienced related to medical marijuana followed by a personal grow, use, and share model, and then to the current taxed and regulated system of cannabis legalization. Comparing cannabis to psilocybin seemed useful at times but it also seemed unclear if the comparison was helpful. Further exploration of decriminalization would require input from experts in a broader range of fields including law enforcement, the judiciary, and substance misuse prevention. This seemed beyond the scope of this workgroup. Some members of the group favored further discussion around a model of decriminalization of psilocybin specifically.

Recommendation

As psilocybin and other psychedelic substance use increases in Vermont and nationally, the group recommends developing and funding harm reduction training and education for health practitioners and the public.

Summary and Conclusion

The Psychedelic Therapy Advisory Group, through a careful examination of current research, state programs, and expert insights, has outlined the potential for Vermont to explore structured and safe avenues for psilocybin use within therapeutic contexts. The recommendations in this report are:

1) Extend the current working group with the expansion of participants to monitor the evolution of research and programs across the country and to facilitate the ability to research psychedelic therapies in Vermont. Although not the only promising area of application supported by existing science, the group demonstrated general consensus regarding the potential for psilocybin-assisted therapy for depression and anxiety in the context of serious illness & end-of-life care.

2) As psilocybin and other psychedelic substance use increases in Vermont and nationally, the group recommends developing and funding harm reduction training and education for health practitioners and the public.

These recommendations reflect a proactive approach to harnessing the benefits of psychedelics while prioritizing public health and safety. However, it is essential to recognize that it may be difficult to move forward with these initiatives until federal regulatory and legal frameworks are established and more information is gathered from existing programs in other states. As the state navigates this evolving landscape, it is crucial to remain flexible and responsive to new data and trends in psychedelic research and regulation.

In discussion, the committee weighed the desirability and feasibility of many possible approaches and recommendations, including:

- Adopting a model similar to other states, which would allow use in specific sites with trained facilitators
- Recommending consideration of the decriminalization of psilocybin with public health, safety, and education initiatives,
- creating a statewide training program for healthcare practitioners to assist patients with harm reduction, prevention/integration practices and to reduce risk
- creating practice guidelines for therapeutic integration for medical and mental health professions

- recommending that the State support a “right to try” framework, using existing FDA pathways for medications not yet approved by the FDA
- creating a specific pathway for life-threatening illness/end of life to have a facilitated psilocybin experience
- recommending further exploration and study of psychedelics other than psilocybin in future work.

While each of these possibilities had support from some members, there was not a clear consensus among the group for moving forward with most of these measures at this time, with concerns about efficacy, safety, and practicalities cited as barriers. The Psychedelic Therapy Advisory Group attests to the curiosity and hope for the potential strong application of the research on psychedelics as medicines and therapy, and that a segment of the population may benefit from these applications in the future.

Appendix

Meta-Analyses with Abstracts/Conclusions

Efficacy & Safety

1) Yao Y, Guo D, Lu TS, Liu FL, Huang SH, Diao MQ, Li SX, Zhang XJ, Kosten TR, Shi J, Bao YP, Lu L, Han Y. Efficacy and safety of psychedelics for the treatment of mental disorders: A systematic review and meta-analysis. *Psychiatry Res*. 2024 May;335:115886.

ABSTRACT: "We aim to systematically review and meta-analyze the effectiveness and safety of psychedelics [psilocybin, ayahuasca (active component DMT), LSD and MDMA] in treating symptoms of various mental disorders. Web of Science, Embase, EBSCO, and PubMed were searched up to February 2024 and 126 articles were finally included. Results showed that psilocybin has the largest number of articles on treating mood disorders (N = 28), followed by ayahuasca (N = 7) and LSD (N = 6). Overall, psychedelics have therapeutic effects on mental disorders such as depression and anxiety. Specifically, psilocybin (Hedges' g = -1.49, 95% CI [-1.67, -1.30]) showed the strongest therapeutic effect among four psychedelics, followed by ayahuasca (Hedges' g = -1.34, 95% CI [-1.86, -0.82]), MDMA (Hedges' g = -0.83, 95% CI [-1.33, -0.32]), and LSD (Hedges' g = -0.65, 95% CI [-1.03, -0.27]). A small amount of evidence also supports psychedelics improving tobacco addiction, eating disorders, sleep disorders, borderline personality disorder, obsessive-compulsive disorder, and body dysmorphic disorder. The most common adverse event with psychedelics was headache. Nearly a third of the articles reported that no participants reported lasting adverse effects. Our analyses suggest that psychedelics reduce negative mood, and have potential efficacy in other mental disorders, such as substance-use disorders and PTSD."

2) [depression specific] Hsu TW, Tsai CK, Kao YC, Thompson T, Carvalho AF, Yang FC, Tseng PT, Hsu CW, Yu CL, Tu YK, Liang CS. Comparative oral monotherapy of psilocybin, lysergic acid diethylamide, 3,4-methylenedioxymethamphetamine, ayahuasca, and escitalopram for depressive symptoms: systematic review and Bayesian network meta-analysis. BMJ. 2024 Aug 21;386:e078607.

ABSTRACT: "**Results:** Placebo response in psychedelic trials was lower than that in antidepression trials of escitalopram (mean difference −3.90 (95% credible interval −7.10 to −0.96)). Although most psychedelics were better than placebo in psychedelic trials, only high dose psilocybin was better than placebo in antidepression trials of escitalopram (mean difference 6.45 (3.19 to 9.41)). However, the effect size (standardised mean difference) of high dose psilocybin decreased from large (0.88) to small (0.31) when the reference arm changed from placebo response in the psychedelic trials to antidepressant trials. The relative effect of high dose psilocybin was larger than escitalopram at 10 mg (4.66 (95% credible interval 1.36 to 7.74)) and 20 mg (4.69 (1.64 to 7.54)). None of the interventions was associated with higher all cause discontinuation or severe adverse events than the placebo.

Conclusions: Of the available psychedelic treatments for depressive symptoms, patients treated with high dose psilocybin showed better responses than those treated with placebo in the antidepressant trials, but the effect size was small.

3) [specific to life-threatening illness contexts] Schipper S, Nigam K, Schmid Y, Piechotta V, Ljuslin M, Beaussant Y, Schwarzer G, Boehlke C. Psychedelic-assisted therapy for treating anxiety, depression, and existential distress in people with life-threatening diseases. Cochrane Database Syst Rev. 2024 Sep 12;9(9):CD015383.

"Authors' conclusions: Implications for practice Psychedelic-assisted therapy with classical psychedelics (psilocybin, LSD) may be effective for treating anxiety, depression, and possibly existential distress, in people facing a life-threatening disease. Psychedelic-assisted therapy seemed to be well tolerated, with no treatment-emergent serious adverse events reported in the studies included in this review. However, the certainty of evidence is low to very low, which means that we cannot be sure about these results, and they might be changed by future research. At the time of this review (2024), psychedelic drugs are illegal in many countries. Implications for research The risk of bias due to 'unblinding' (participants being aware of which intervention they are receiving) could be reduced by measuring expectation bias, checking blinding has been maintained before cross-over, and using active placebos. More studies with larger sample sizes are needed to reduce imprecision. As the US Drug Enforcement Administration (DEA) currently classifies psychedelics as Schedule I substances (i.e. having no

accepted medical use and a high potential for abuse), research involving these drugs is restricted, but is steadily increasing."

4) Erritzoe, D. et al. Effect of psilocybin versus escitalopram on depression symptom severity in patients with moderate-to-severe major depressive disorder: observational 6-month follow-up of a phase 2, double-blind, randomised, controlled trial. *The Lancet,* 2024 Sep 21.

"**Interpretation**: Six-week intensive treatments with either psilocybin or escitalopram (with psychological support) for MDD were associated with long-term improvements in depressive symptom severity. The greater degree of improvement in the psilocybin therapy arm at follow-up on psychosocial functioning, meaning in life, and psychological connectedness warrants future research."

Adverse Events

5) Yerubandi A, Thomas JE, Bhuiya NMMA, Harrington C, Villa Zapata L, Caballero J. Acute Adverse Effects of Therapeutic Doses of Psilocybin: A Systematic Review and Meta-Analysis. *JAMA Netw Open*. 2024 Apr 1;7(4):e245960.

"Conclusions and Relevance: In this meta-analysis, the acute adverse effect profile of therapeutic single-dose psilocybin appeared to be tolerable and resolved within 48 hours. However, future studies need to more actively evaluate the appropriate management of adverse effects."

6) Hinkle JT, Graziosi M, Nayak SM, Yaden DB. Adverse Events in Studies of Classic Psychedelics: A Systematic Review and Meta-Analysis. *JAMA Psychiatry*. 2024 Sep 4:e242546.

"Conclusions and Relevance: In this systematic review and meta-analysis, classic psychedelics were generally well tolerated in clinical or research settings according to the existing literature, although SAEs did occur. These results provide estimates of common AE frequencies and indicate that certain catastrophic events reported in recreational or nonclinical contexts have yet to be reported in contemporary trial participants. Careful, ongoing, and improved pharmacovigilance is required to understand the risk and benefit profiles of these substances and to communicate such risks to prospective study participants and the public."

Canadian Model

7) de la Salle S, Kettner H, Thibault Lévesque J, Garel N, Dames S, Patchett-Marble R, Rej S, Gloeckler S, Erritzoe D, Carhart-Harris R, Greenway KT. Longitudinal experiences of Canadians receiving compassionate access to psilocybin-assisted psychotherapy. Sci Rep. 2024 Jul 17;14(1):16524.

ABSTRACT (edited): “Significant improvements in anxiety and depression symptoms, pain, fear of COVID-19, quality of life, and spiritual well-being were observed. Attitudes towards death, medical assistance in dying, and desire for hastened death remained unchanged. While most participants found the psilocybin sessions highly meaningful, if challenging, one reported a substantial decrease in well-being due to the experience. These preliminary data are amongst the first to suggest that psilocybin-assisted psychotherapy can produce psychiatric benefits in real-world patients akin to those observed in clinical trials.”