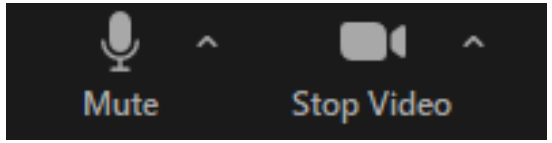
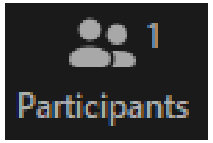
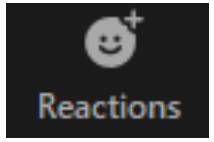
Psychedelic Medicine Task Force

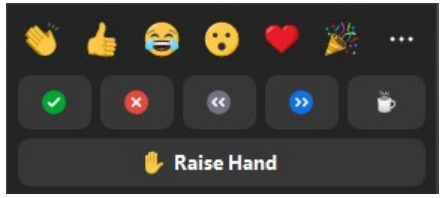
Welcome Psychedelic Medicine Task Force members!

Please use this time to test your Zoom meeting controls located at the bottom of the screen:









Access **Mural** via the link sent to you in your meeting invitation. Only members have access to this shared workspace. Once on the site, minimize the screen for later use during the meeting.

Task Force staff

MDH staff

- **Kari Gloppen**, Epidemiologist Supervisor, Injury and Violence Prevention Section
- **Dr. Caroline Johnson**, Psychedelic Medicine Scientific Researcher

Task Force chair

- Dr. Jessica Nielson

MAD staff

- Jessica Burke, Senior Management Consultant
- Nick Kor, Senior Management Consultant
- Stacy Sjogren, Senior Management Consultant

Welcome meeting observers

Thank you for your interest in the work of the

Psychedelic Medicine Task Force!

This meeting will not be recorded. **Minutes will be posted on the task force's website** along with other materials for this meeting:

https://www.health.state.mn.us/people/psychmed/index.html

health.psychedelicmemedicine@state.mn.us

Legislative charge

The Psychedelic Medicine Task Force was established to advise the legislature on the legal, medical, and policy issues associated with the legalization of psychedelic medicine in the state. For purposes of this work, “psychedelic medicine” means MDMA, psilocybin, and LSD.

Task force duties

as outlined in legislation (Subd. 5.)

Scientific Research

1. Survey existing studies in the scientific literature on the therapeutic **efficacy** of psychedelic medicine in the treatment of mental health conditions, including depression, anxiety, post-traumatic stress disorder, bipolar disorder, and **any other mental health conditions and medical conditions** for which a psychedelic medicine may provide an **effective** treatment option.
2. Compare the efficacy of psychedelic medicine in treating the conditions described [above] with the efficacy of treatments currently used for these conditions.

Duties

Develop a comprehensive plan that covers:

1. statutory changes necessary for the legalization of psychedelic medicine.

2. state and local regulation of psychedelic medicine

3. federal law, policy, and regulation of psychedelic medicine, with a focus on retaining state autonomy to act without conflicting with federal law, including methods to resolve conflicts.

    - Such as seeking an administrative exemption to the federal Controlled Substances Act under United States Code, title 21, section 822(d), and Code of Federal Regulations, title 21, part 1307.03; seeking a judicially created exemption to the federal Controlled Substances Act; petitioning the United States Attorney General to establish a research program under United States Code, title 21, section 872(e); using the Food and Drug Administration's expanded access program; and using authority under the federal Right to Try Act

4. Education of the public on recommendations made to the legislature and others about necessary and appropriate actions related to the legalization of psychedelic medicine in the state.

Work cadence

Identify benefits and challenges of legalization **Identify policy areas to focus on for work groups** *barriers TBD as group work and research continue*		**Plan development + recommendations** *continual review through work group updates, SME presentations, and TF collaborative decision-making*					**Information synthesis, narrowing, and prioritization of report** *research and workgroup(s) continue if needed*		**Drafting of recommendations** *continue information synthesis, narrowing, and prioritization of report as draft takes shape*			**Submit Report Jan 1, 2025**
Dec 12/4/23	**Jan** 1/8/24 **Determine initial subgroups** **Draft initial legislative report due Feb 1**	**Feb** 2/5/24	**March** 3/4/24	**April** 4/1/24	**May** 5/6/24	**June** 6/3/24	**July** 7/1/24	**Aug** 8/5/24 **Begin outlining** Determine potential cost of implementation, needed investments, sustainable supports, etc.	**Sept** 9/9/24	**Oct** 10/7/24	**Nov** 11/4/24	**Dec** 12/2/24	**Jan 1** **TF ends** Report includes comprehensive plan, scientific research, and any other additional materials members find necessary to share.

Today's agenda

- Approve April meeting minutes
- Member-collected feedback
- Elect vice chair and work group chairs
- Subject matter expert panel
- **Break**
- Research update: psilocybin
- Work group updates and discussion: adult regulated use of natural mushrooms (including a **break**)

Desired meeting outcomes

- Choose a task force vice chair and chairs for the legal and regulatory work group
- Subject matter expert panel: regulating for equity
- Research update – psilocybin results and discussion
- Work group updates and discussion: Members stay abreast of small group work sequencing and have an opportunity to weigh in to keep process moving. We will be discussing adult regulated use of natural mushrooms.

Regulating for equity: subject matter expert panel

Dominique Mendiola, Senior Director, Marijuana Enforcement Division & Natural Medicine Division, Colorado; Jason Ortiz, Last Prisoner Project; Dr. Mason Marks, Visiting Professor of Law, Harvard Law School; Florida Bar Health Law Section Professor, Florida State University; Visiting Fellow, Yale Law School Information Society Project; and Emma Knighton, Washington task force and measure 109 in Oregon

DEPARTMENT OF HEALTH

Psilocybin Literature Review

Dr. Caroline Johnson

DEPARTMENT OF HEALTH

Overview of section

- Health Conditions
- Mood & Anxiety Disorders
- Risks
- Discussion/Mural Activity

Health conditions

- Mood & Anxiety Disorders
  - Major Depressive Disorder (including treatment-resistant depression)
  - Bipolar Type 2 Disorder
- Substance Use Disorders
  - Alcohol Use Disorder
  - ~~Tobacco Use Disorder~~
- ~~Obsessive-Compulsive Disorder~~
- Cluster Headache, ~~Migraine~~
- ~~Anorexia Nervosa~~

Mood & Anxiety Disorders: Clinical Trials

- 9 randomized controlled trials (RCTs) (+ 4 further publications)
- Major depressive disorder (MDD), including treatment-resistant depression (TRD), bipolar 2 disorders, anxiety disorders
- 1, 2, or 3 facilitated sessions
  - Psychotherapy before/after
- Doses
  - 1-3 milligrams (mg) (active control)
  - 10-30 mg experimental dose
- 597 participants
  - 518 got any dose
  - 370 received experimental dose
- **All studies indicated a beneficial effect of psilocybin on measures of depression & anxiety**
  - **Including response & remission rates**

Mood & Anxiety Disorders: Clinical Trials

- Psilocybin vs control[1]
  - Depression: g=0.83 (large)
  - Anxiety: g=0.82 (large)
- Psilocybin only, baseline vs end[1]
  - Depression: g=1.47 (very large)
  - Anxiety: g=1.38 (very large)
- Response (depression)[2]:
  - 57% psilocybin
  - 22% control
- Remission (depression)[2]:
  - 45% psilocybin
  - 14% control

1) Goldberg et al., 2020, Psychiatry Research; 2) Haikazian et al., 2023, Psychiatry Research

Mood & Anxiety Disorders: Direct Comparison of Efficacy

- Carhart-Harris et al., 2021[3]
- Direct comparison of psilocybin and escitalopram, phase 2 study
  - 59 participants; psilocybin (25mg) vs escitalopram (10-20mg)
  - 2 drug sessions, psychotherapy over 6 weeks
- **Depression scores decreased similarly in both groups**
- **Response**: **70%** of psilocybin group, **48%** of escitalopram group
- **Remission**: **57%** of psilocybin group, **28%** of escitalopram group

3) Carhart-Harris et al., 2021, New England Journal of Medicine

Mood & Anxiety Disorders: Other Comparisons of Efficacy

- Current standard treatments
  - Antidepressants, anti-anxiety medications, psychotherapy (cognitive behavior therapy (CBT))
- Antidepressants vs placebo: Medium to low effect size[4]
- Psychotherapy with antidepressants: Medium effect size[5]
- Psychotherapy alone: Low effect size[5]
- Psilocybin vs control[1]
  - Depression: Large effect size
  - Anxiety: Large effect size
- Psilocybin only, baseline vs end[1]
  - Depression: Very large effect size
  - Anxiety: Very large effect size

1) Goldberg et al., 2020, Psychiatry Research; 4) Cipriani et al., 2009, Lancet; 5) Karyotaki et al., 2016, Journal of Affective Disorders

Risks

- Mild-to-moderate adverse effects, dose-dependent
  - Headache, nausea, dizziness, fatigue[6]
  - Migraine, paranoia
- Increases in blood pressure, heart rate
  - Escitalopram pre-treatment reduces many negative psilocybin effects[7]
- Other things to think about:
  - Drug-drug interactions
  - Low abuse potential, low potential for toxicity
  - Individuals with treatment-resistant depression

Most adverse effects occur following use of outside of the clinical environment

6) Yerubandi et al., 2024, JAMA Network Open; 7) Becker et al., 2022, Clinical Pharmacology & Therapeutics

Psilocybin Discussion

- Recommend psilocybin?
  - If so, in what capacity?

References

1) Goldberget al. (2020). The experimental effects of psilocybin on symptoms of anxiety and depression: A meta-analysis. Psychiatry research, 284, 112749.
2) Haikazian, S., Chen-Li, D. C., Johnson, D. E., Fancy, F., Levinta, A., Husain, M. I., ... & Rosenblat, J. D. (2023). Psilocybin-assisted therapy for depression: A systematic review and meta-analysis. Psychiatry Research, 115531.
3) Carhart-Harris, R., Giribaldi, B., Watts, R., Baker-Jones, M., Murphy-Beiner, A., Murphy, R., ... & Nutt, D. J. (2021). Trial of psilocybin versus escitalopram for depression. New England Journal of Medicine, 384(15), 1402-1411.
4) Cipriani, A., Furukawa, T. A., Salanti, G., Geddes, J. R., Higgins, J. P., Churchill, R., ... & Barbui, C. (2009). Comparative efficacy and acceptability of 12 new-generation antidepressants: a multiple-treatments meta-analysis. The Lancet, 373(9665), 746-758.
5) Karyotaki, E., Smit, Y., Henningsen, K. H., Huibers, M. J. H., Robays, J., De Beurs, D., & Cuijpers, P. (2016). Combining pharmacotherapy and psychotherapy or monotherapy for major depression? A meta-analysis on the long-term effects. Journal of Affective Disorders, 194, 144-152.
6) Yerubandi, A., Thomas, J. E., Bhuiya, N. M. A., Harrington, C., Zapata, L. V., & Caballero, J. (2024). Acute Adverse Effects of Therapeutic Doses of Psilocybin: A Systematic Review and Meta-Analysis. JAMA Network Open, 7(4), e245960-e245960.
7) Becker, A. M., Holze, F., Grandinetti, T., Klaiber, A., Toedtli, V. E., Kolaczynska, K. E., ... & Liechti, M. E. (2022). Acute effects of psilocybin after escitalopram or placebo pretreatment in a randomized, double-blind, placebo-controlled, crossover study in healthy subjects. Clinical Pharmacology & Therapeutics, 111(4), 886-895.

Work groups updates

- **Upcoming meetings**
  - **Legal:** Thursday, May 9 at 4:00 pm
  - **Regulatory:** Monday, May 13 at 4:00 pm
  - Additional meetings TBD

Next steps and adjournment

- **Opportunity for member feedback:** please leave your feedback in Mural.
- **Questions between meetings:** contact Jess Burke (jessica.burke@state.mn.us)
- Next meeting: Monday, May 6, 2024, 9:30 am – 12:30 pm