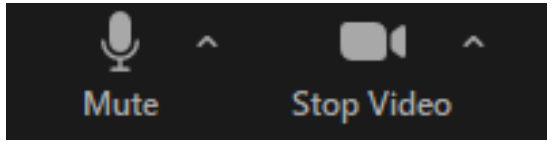
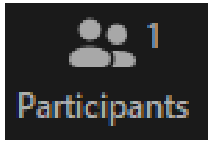
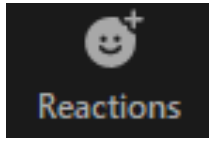
Psychedelic Medicine Task Force

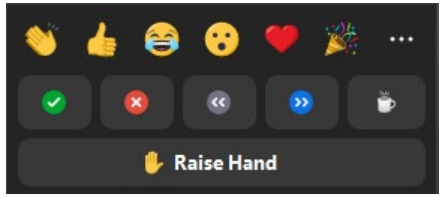
Welcome Psychedelic Medicine Task Force members!

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

- **Dana Farley**, Alcohol & Drug Prevention Policy Director, Drug Overdose Prevention Unit Supervisor
- **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 February meeting minutes
- Membership updates
- Review project tracking tools
- Caveats and realities of existing clinical trials and scientific literature
- **Break**
- State legal and regulatory discussion
- Psychedelic medicine within an Indigenous context
- **Break**
- Work group status reports

Understanding Clinical Trial Results

Dr. Caroline Johnson | Dr. Jessica Nielson

DEPARTMENT OF HEALTH

Overview of section

- Participant population
- Safety
- Generalizability of results
  - Discuss
- Food & Drug Administration (FDA)
  - Discuss
- Clinical trials
  - Discuss

Participant population: Who's in these studies?

- Stringent exclusion criteria
  - No co-occurring psychological, physical, or physiological conditions
- No concomitant medications used to treat condition of interest
  - E.g., no SSRIs
- Lack of demographic diversity

Safety

- Safe for whom?
  - Restrictive study populations
  - Lack of phase IV trials (large-scale safety)
- Case studies

Generalizability of results

- Results extend to the population(s) studied—only
- Lack of phase IV trials
  - Large scale trials for safety, effectiveness

Discussion

- Safety and generalizability of results
- Questions?

The role of FDA

- Products, not practices
  - Therapy aspect not regulated by FDA
- Specificity of New Drug Applications
  - “Off-label”

Updates from FDA about accepted medical use

- Recent recommendation to DEA to place cannabis on schedule III – *unclear if DEA will accept this*
- No successful clinical trials with whole cannabis plant to warrant traditional FDA approval – *synthetic versions of THC and CBD are FDA approved (bifurcated scheduling)*
- Began looking at state medical programs and state adult regulated use
- Low risk in the general population compared to other scheduled drugs (including exempted drugs, like alcohol)
- **State medical programs are now considered as accepted medical use**
- State regulated programs with psychedelics could follow a similar path to change federal policies related to public health and safety for use

Discussion

- FDA
- Questions?

Clinical trial limitations

- Functional unblinding
- Difficulty of true controls
- Placebo/nocebo effects
- Patient expectancy (including media effects)
- Duration of treatments largely unknown
- Conflicts of interest

Discussion

- How does this affect making recommendations?
- Other questions?

Thank You!

MN Psychedelic Medicine Task Force March 4, 2024

Regulatory, Legal & Business Considerations
Presented By Ariel Clark

Six Key Considerations For Successful Psychedelics Law Reform

1) Real Affordability

Run The Numbers

Oregon: $2,000-$3,500 for one (1) psilocybin session

Culturally-Appropriate Accessibility

2) Real Business Viability

Run The Numbers
Taxes, Fees, and Regulatory Costs

California: at least 70% of the cannabis sold is from the illegal market

3) Support Good Actors

Guard Against A Race-To-The-Bottom

Be creative, why more plastic?

4) Ethical Business Models

Nonprofits, PBCs

Colorado: ESG for Psychedelics Companies

5) Consult With Tribes

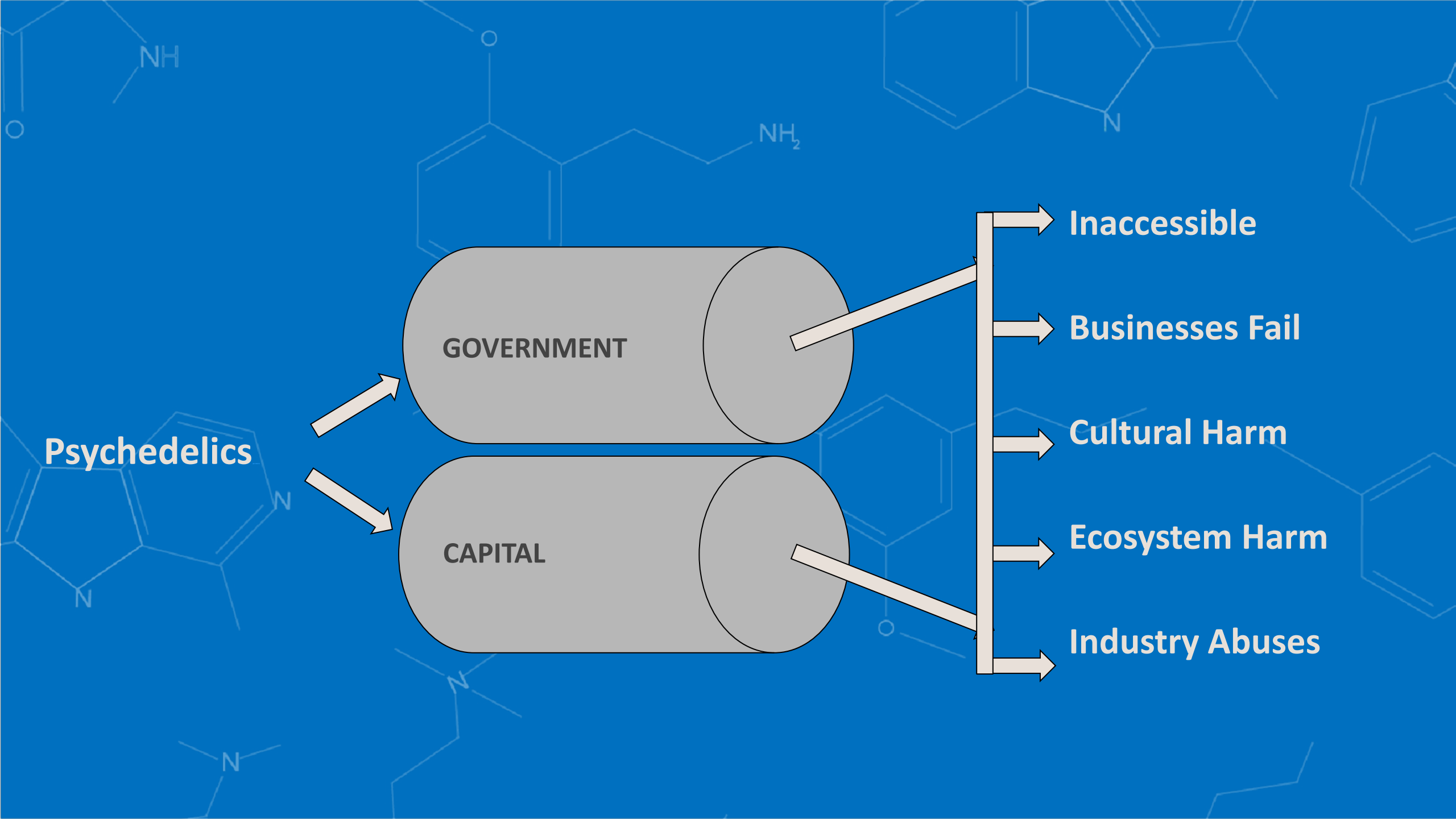
Legally Required

Goal: Mutually-Beneficial Solutions

6) Real Public Education

Informed Constituents = Success

California SB1012: Public Education


Psychedelics
GOVERNMENT
CAPITAL
Inaccessible
Businesses Fail
Cultural Harm
Ecosystem Harm
Industry Abuses

A Values Framework For Drafting & Implementation

1) *Real Affordability*
2) *Real Business Viability*
3) *Support Good Actors*
4) *Ethical Business Models*
5) *Consult With Tribes*
6) *Real Public Education*

Ariel Clark
aclark@clarkhowell.com

Psychedelic medicine within an Indigenous context

Christine McCleave

Work group updates

Work groups updates

- **Upcoming meetings**
  - **Legal:** Thursday, March 7 at 4:00 pm
  - **Regulatory:** Monday, March 11 at 4:00 pm
  - **Policy:** Tuesday, March 19 at 4:00 pm

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, April 1, 2024, 9:30 am – 12:30 pm