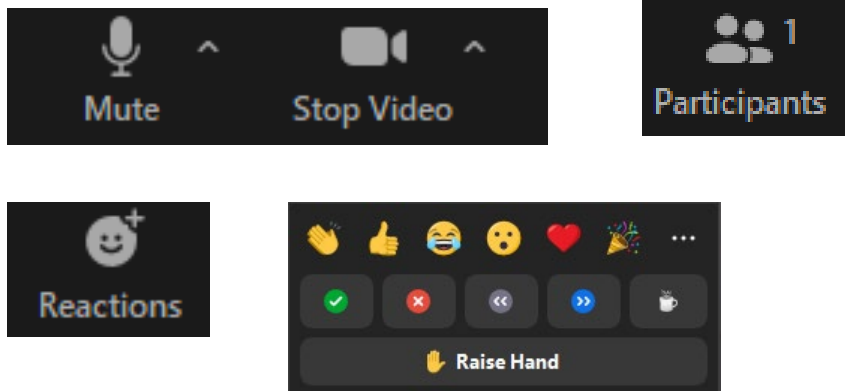




# Psychedelic Medicine Task Force

# 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.

## 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.psychedelicismedicine@state.mn.us](mailto:health.psychedelicismedicine@state.mn.us)

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.

## 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.

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

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

# 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

- 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

- Safety and generalizability of results
- Questions?

- 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

- 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

- 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***



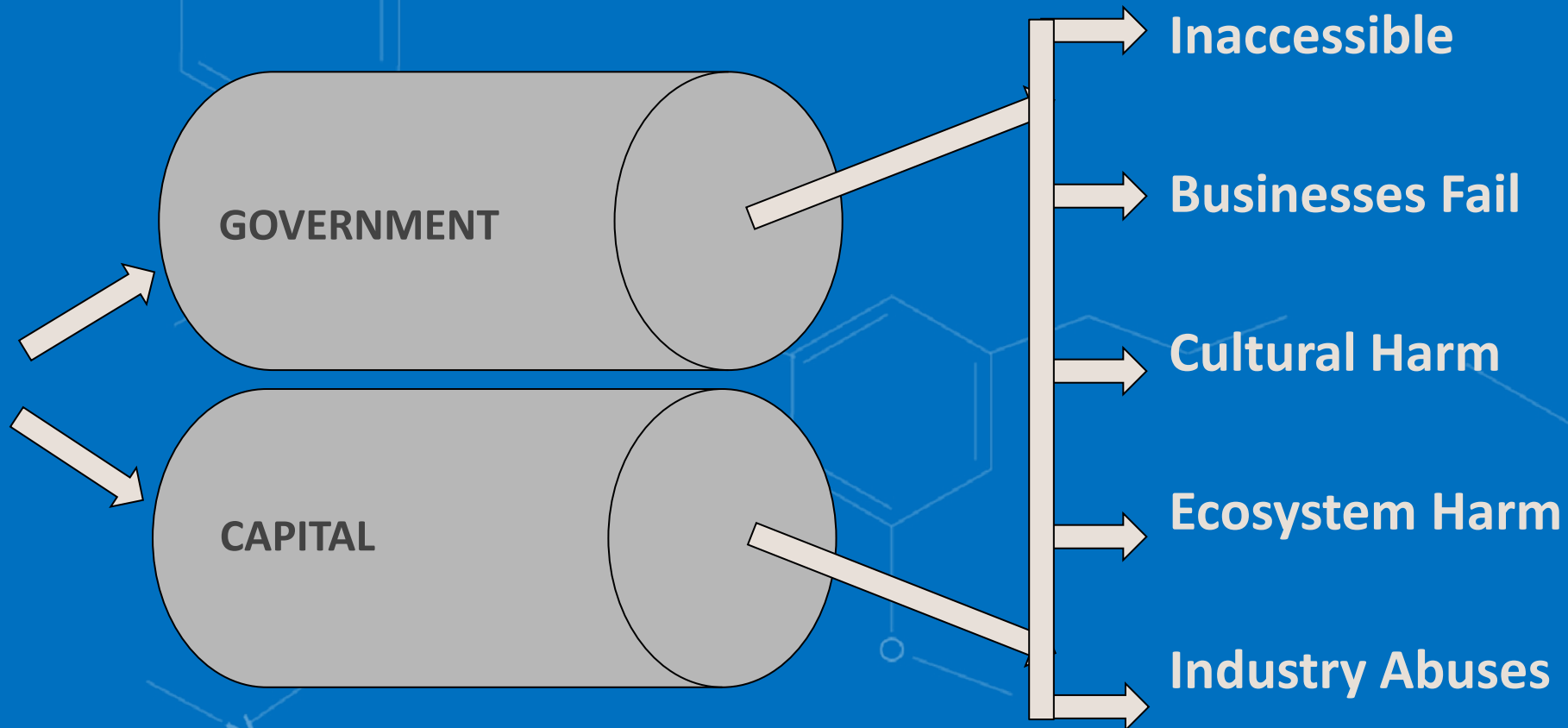
## ***6) Real Public Education***

***Informed Constituents = Success***

***California SB1012: Public Education***



# Psychedelics



## ***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](mailto:aclark@clarkhowell.com)





# Psychedelic medicine within an Indigenous context

Christine McCleave

# Work group 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](mailto:jessica.burke@state.mn.us))
- **Next meeting:** Monday, April 1, 2024, 9:30 am – 12:30 pm