Psychedelic Medicine Task Force

Welcome Psychedelic Medicine Task Force members!

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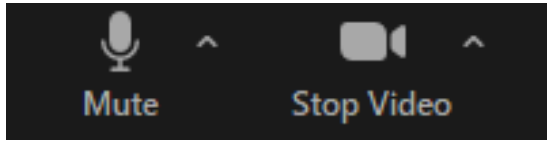
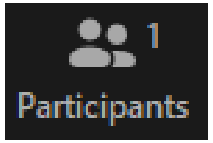
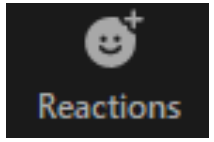
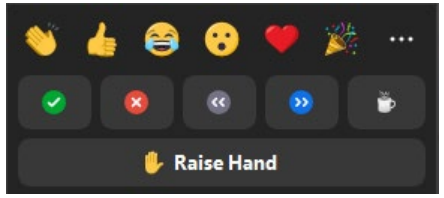








Access **Mural** via the link sent to you in your meeting invitation. Only members have access to this shared workspace. Once on the site, minimize the screen for later use during the meeting.

Task Force staff

MDH staff

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

Task Force leadership

- Dr. Jessica Nielson, Chair
- Bennett Hartz, Vice-Chair
- Paula DeSanto, Work Group Chair

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.

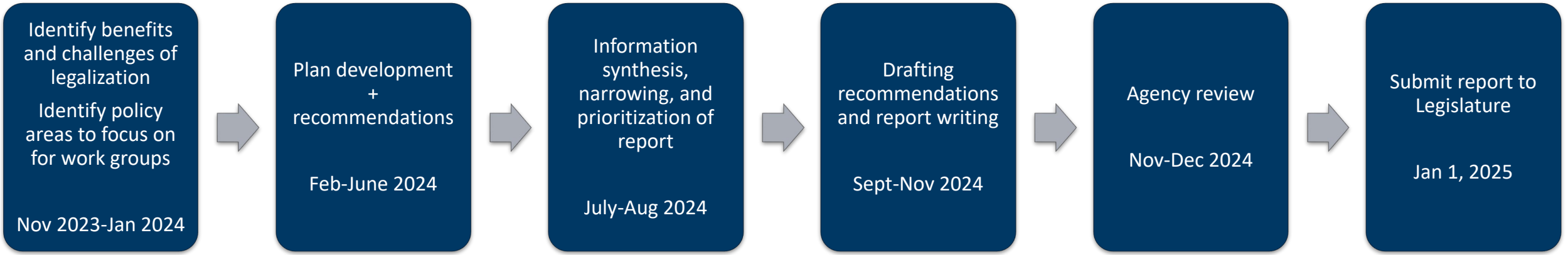
2. state and local regulation of psychedelic medicine

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



Today’s agenda

- Approve July meeting minutes
- Member-collected feedback
- Decision flow chart and decisions to date review
- New recommendations SWOT and gradients of agreement
- Final voting discussion
- Final report production
- Initial discussion on public education requirement

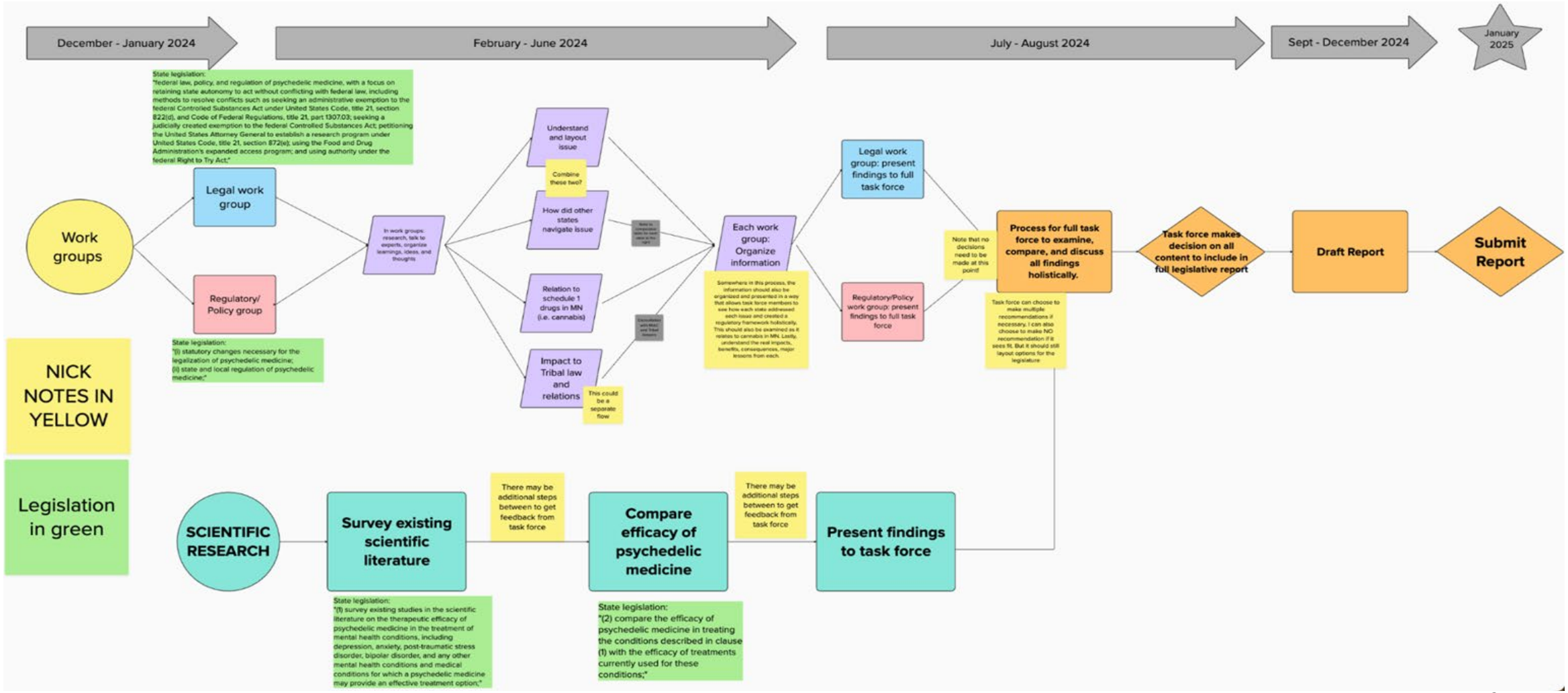
Desired meeting outcomes

- Check in on timeline and discuss decision flow chart
- Review and discuss first round of recommendations
- Discuss additional recommendations
- Overview of final voting process
- Overview of report writing process
- Public education requirement overview

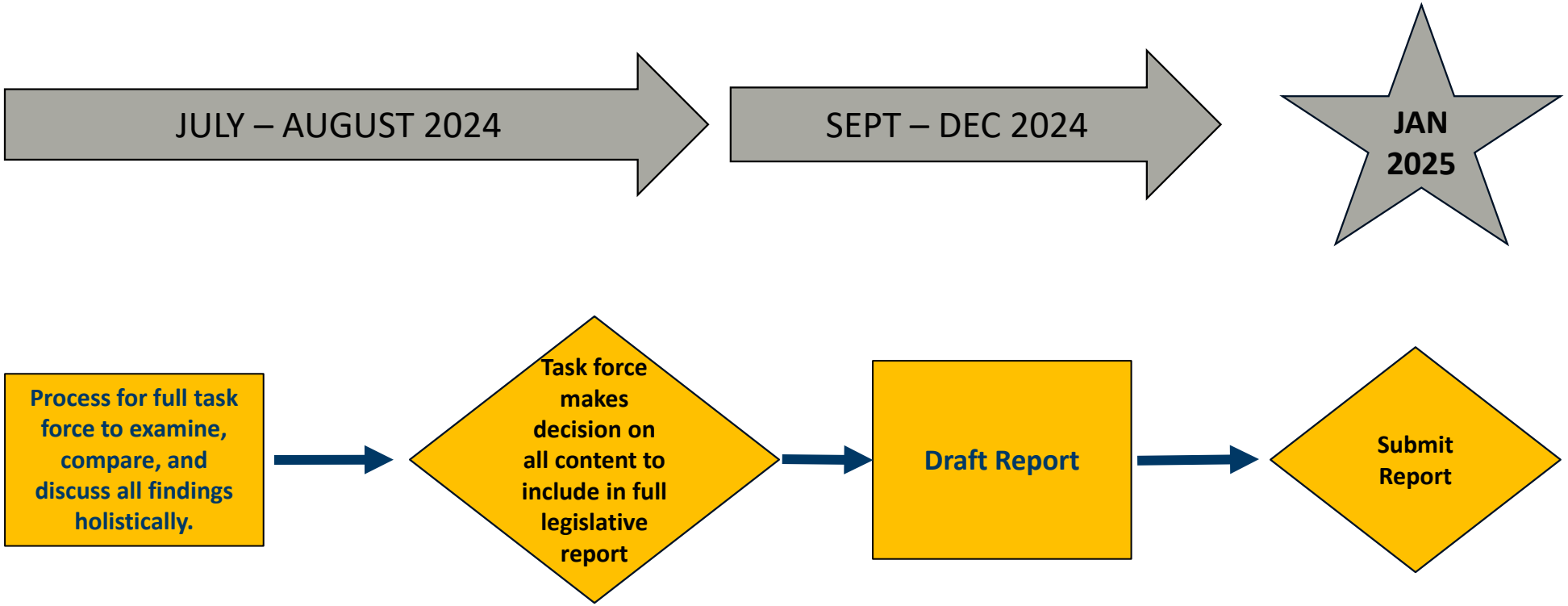
Task Force Status Update – August 2024

Dr. Jessica Nielson | Task Force Chair

Timeline: decision flow chart



Timeline: decision flow chart



Summary of what we've learned

- December – brief introduction to clinical trials and how the Food and Drug Administration (FDA) approves new drugs, and special considerations for psychedelic clinical trials.
- January – learned from Robert Rush and Ismail Ali about the history of drug prohibition, the controlled substances act, "states as labs"
- February – learned from Mason Marks about federal laws and how what Oregon and Colorado are doing could run afoul of certain federal laws regarding data privacy and blending services with schedule 1 drugs into federally supported healthcare systems, noting that decriminalization is the simplest option to implement (e.g. legally, financially), with funding more clinical trials and education programs for the public are the most legal option under current federal law.
- March – learned about cultural genocide of plant medicines and practices from Christine Diindiisi McCleave and Tribal consultation, and ethical guidelines for businesses with psychedelics (lessons learned from Cannabis) from Ariel Clark.

Summary of what we've learned

- April – we learned from Shane Pennington about how state regulated medical programs may help build support for the US Department of Health & Human Services (HHS) to recommend federally rescheduling psilocybin but may delay/limit access for Minnesota; and Caroline Johnson presented clinical trial results with LSD.

- May – we learned from a panel (Mason Marks, Jason Ortiz, Emma Knighton, Dominque Mendiola) about regulating for equity, criminal justice reform, community investment, and economic opportunity, decriminalization must come before/along with legalization (not after), lessons learned and growing pains out of Oregon and Colorado, including involving state licensing boards from the beginning, having more flexibility for allowed facilitation locations to help with accessibility and costs (e.g. home, outdoor use), barriers to access regarding cost for both facilitators (startup fees, tax code complications, licenses) and clients (limited accessibility, payment out of pocket, creates a tourist industry), and requiring the program to fund itself through licensing fees drives up implementation costs across the board; and Caroline Johnson presented clinical trial results with synthetic psilocybin.

- June – we learned from representatives from Lykos Therapeutics about the development of MDMA-AT and what the roll out might look like if FDA approved in August; and Caroline Johnson presented clinical trial results with MDMA.

Noteworthy updates that impact our work

- HHS modified the way they consider "accepted medical use" when making rescheduling recommendations to the Drug Enforcement Administration (DEA) - *recommended rescheduling cannabis to schedule III due to accepted medical use across many states, not because of FDA approval of a specific product.*

- Unfavorable review from external advisory panel for FDA regarding MDMA-AT for PTSD (voted against FDA approval) - *this is a recommendation and FDA isn't bound by their decision. FDA will make their final decision on August 11, 2024.*

- The Chevron Accord was overturned by the Supreme Court, which *may* enable more successful litigation of cases with the DEA around Right to Try (RTT) or religious use (RFRA) access for psychedelic medicines - *previous attempts for Controlled Substances Act (CSA) exemptions to access psilocybin under the RTT have been rejected due to deference to the DEA on whether RTT applies to schedule 1 drugs (they say no). Many churches have also been denied exemptions for similar restrictions with the CSA (with some successes).*

Bringing it together – what is legal?

Review of 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***.

- Seeking an administrative exemption to the federal CSA 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 FDA's expanded access program
- Using authority under the federal Right to Try Act
- *State-approved medical and/or adult regulated use*
- *Decriminalization*

Legal research

- **Seeking an administrative exemption to the federal CSA under United States Code, title 21, section 822(d), and Code of Federal Regulations, title 21, part 1307.03 - federally legal**
  - This would involve submitting a request to the DEA to allow the use of specific controlled substances for some compelling reason (up to the discretion of the agency to decide whether to grant an exemption)..This might be the process for obtaining a schedule 1 license for research (need to check that) for conducting research or developing new drugs, also the way a church/religious organization would ask for an exemption from the CSA (e.g. invoking RFRA), as under the broad part 1307 umbrella that refers to the Native America Church use of peyote (§ 1307.31)
- **Seeking a judicially created exemption to the federal CSA – federally legal**
  - This might be another way to get religious exemption, for example, with the Supreme Court or a district court. Several psychedelic churches have attempted this route with mixed success. The most recent is the Church of the Eagle and the Condor, the third group to be granted exemption (after they sued the US Attorney General, the Department of Homeland Security, the DEA, and US Customs and Border Protection in the US District Court of Arizona, following seizure of ayahuasca, their sacrament; and they settled to allow them to import and store, use, and dispense ayahuasca). However, other groups have also tried this route, and been denied or had the cases thrown out on a technicality (e.g. wrong jurisdiction).
  - This could happen for Minnesota if we, for example, tried to give people in the state access under our own RTT, and if the DEA were to get involved, we could take them to court and ask for an exemption ~ *courtesy of SME Mason Marks, MD, JD*

Legal research

- **Petitioning the United States Attorney General to establish a research program under United States Code, title 21, section 872(e) - federally legal**
  - This is a suggested path by SME Shane Pennington on the state working with the federal government to implement a new research program with a controlled substance that functions more like a clinical trial to protect patient confidentiality. This is how methadone clinics were started, where patients were classified as research participants in this program. The state could create a medical program under this umbrella, and it wouldn't run afoul of the federal government.
- **Using the FDA's expanded access program – federally legal**
  - This is essentially the same as a clinical trial and depends on a pharmaceutical company being willing to authorize a physician to give the drug to a patient. It's decided on a case-by-case basis, and not all pharmaceutical companies offer an expanded access program. Expanded Access trials must be approved by the FDA and registered on clinicaltrials.gov
- **Using authority under the federal Right to Try Act – federally legal**
  - In theory, this should be a right for everyone in the US to be able to access experimental medications currently showing promise in clinical trials, and thus a decision between a physician and their patient that shouldn't involve asking the government for permission. However, when it comes to schedule 1 drugs, such as psychedelic medicines, the DEA has rejected requests for access under RTT. This may be another pathway that becomes more accessible after the overturning of Chevron#.

https://www.scotusblog.com/2024/06/supreme-court-strikes-down-chevron-curtailing-power-of-federal-agencies/

Legal research

- **State regulated medical program (like Oregon and Colorado) - not federally legal**
  - States have done this for medical cannabis regarding existing legal pathways for such a program to exist, but with the added factor that medical programs with psychedelics are also including facilitation by another person(s) that also needs to be regulated. This has a chance of running afoul with the FDA if clinics are advertising services and making medical claims (e.g. psilocybin treats depression) when FDA has not approved of that. Oregon's program is sort of doing this but keeping licensed professionals from using their skills due to potential federal conflicts of licensing boards. Colorado will be blending with their healthcare system, but at this time they are not up and running.
  - The most federally legal way to implement a medical program might be the options we're supposed to explore about petitioning the US AG to establish a research program under United States Code, title 21, section 872(e)
- **State regulated adult use program (like Colorado) - not federally legal**
  - This is already being done with cannabis for many years across many states, however psychedelics like psilocybin mushrooms may not have the widespread public approval as cannabis does, with too many unknowns regarding public safety with wider access. We can look to population statistics from psychedelic users, as well as data from other countries, such as the Netherlands, where psilocybin is sold in stores and consumed, mostly by tourists.
  - The legal framework exists for states to have such a program, thanks to cannabis precedent, however psychedelics also involve (for some) facilitation for people while intoxicated on them, and ensuring there are ample public safety parameters in place (public education and first responder training, dedicated spaces that are safe for experiences) for people to consume them, if not confined to specific facilities (not recommended by Oregon where this was attempted).

Legal research

- **Decriminalization – N/A**
  - This option only requires states to not enforce the federal CSA, as is the right of states under the 10th amendment of the US Constitution. It doesn't mean people can't be punished or held accountable for committing crimes related to psychedelic medicines (e.g. drunk driving is a crime even though alcohol is legal), however the state can decide whether to remove criminal penalties for things such as possession, use, sharing, etc.; while still having accountability for public safety of related behaviors (e.g. facilitation, cultivation/manufacturing, education programs, etc.).
- **Religious use - should be federally legal under RFRA, states can adopt additional protections**
  - This type of access/use should be protected as a religious freedom. Many churches have popped up over the years using different psychedelic medicines as sacraments, so long as criminalizing the use and sharing of those sacraments doesn't constitute a "compelling government interest" that may override religious protections

Legal research

- **Tribal Sovereignty**
  - There are 11 Tribal nations within the state of Minnesota, where all but 2 of them (Red Lake and Bois Forte) are subject to Public Law 280, which allows state and local law enforcement to have jurisdiction over criminal activity on tribal lands. Tribes are allowed to make decisions/enforcement of civil matters, but state and county can intervene on criminal matters. For Red Lake and Bois Forte, only the federal government can intervene on criminal activity.
  - Ongoing consultation with Tribal governments and the Minnesota Indian Affairs Council (MIAC) as new legislation is explored and implemented to ensure proper language and protections of Tribal Sovereignty.

Statutory changes needed

- Decriminalization – change state statute for the controlled substances act (CSA, Ch. 152) for psychedelic medicines (LSD, MDMA, psilocybin) - https://www.revisor.mn.gov/statutes/cite/152
    - Remove criminal penalties for certain behaviors (e.g. use, possession, cultivation, sharing) and/or remove them from the state CSA entirely (descheduling).
- More research/clinical trials – no changes in state statute needed. Already happening in Minnesota, just needs more funding.
- State medical program – change state statute to allow for medical use under the state CSA (Ch. 152), adopting statutory language from medical cannabis program (Ch. 152.21-37)
    - May also explore the option to partner with the US AG to create a new research program for psychedelic medicine (federally legal, but only used to establish methadone clinics (https://www.law.cornell.edu/uscode/text/21/872)
    - Amend the state RTT act to broaden to palliative care (not just end of life/hospice) and to include the use of S1 substances on state CSA (Chapter 151.375, https://www.revisor.mn.gov/statutes/cite/151.375)
- Adult regulated use – change state statute to allow for adult regulated use under the state CSA (Ch. 152), adopting statutory language from the office of medical cannabis (Chapter 342).

State and local regulation

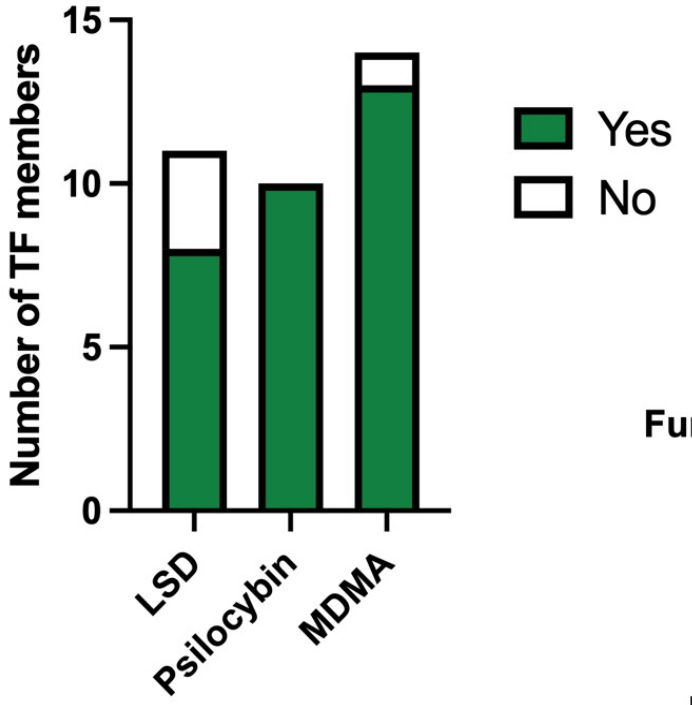
- Decriminalization – public safety/education, first responder education/training, regulations to prevent commercial manufacturing and sales (existing drug laws).
- More research/clinical trials – creating or adding to existing grant programs (e.g. through the Minnesota Department of Health [MDH]) and allocating funding for eligible investigator-initiated clinical trials (credentialed professionals who secure FDA, Institutional Review Board (IRB), DEA approval), or allocating funding to help with sites participating in phase III industry-sponsored trials (e.g. COMPASS at the University of Minnesota).
- State medical program – need to work on dual licensure for licensed professionals, regulations of psychedelic medicine supply, training and licensing of facilitators, safety monitoring and adverse event reporting, incentives for equity licenses and business startup to reduce barriers to entry.
- Adult regulated use – allowing for legacy (e.g. existing underground) market to move into a state-legal regulated space, incentives for equity licenses and business startup to reduce barriers to entry.
- Religious use – explore intersection with "compelling government interests" for enforcing state CSA and religious freedom protected under the 1st amendment of the US constitution and RFRA.

Recommendations presentation and discussion

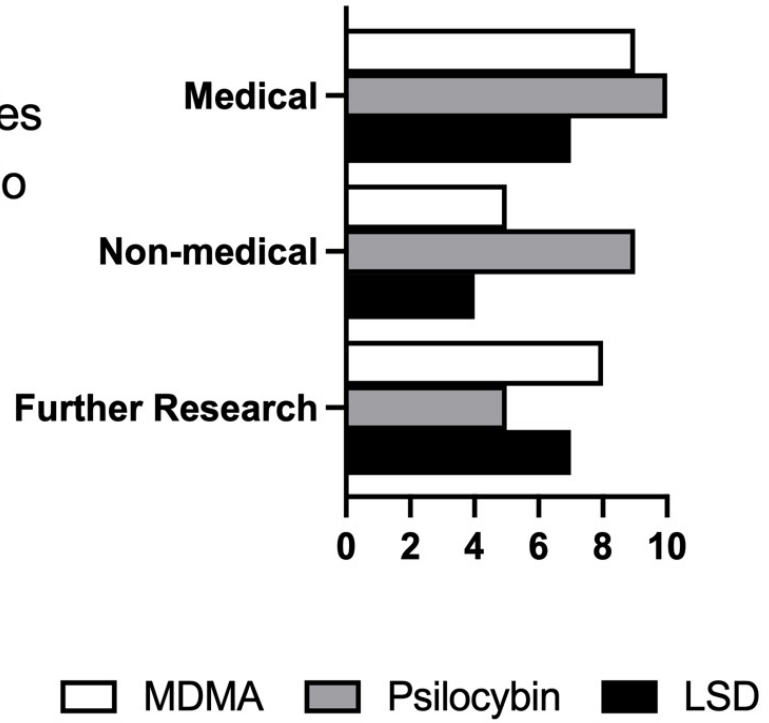
DEPARTMENT OF HEALTH

Summary of Clinical Trial MURAL Activity

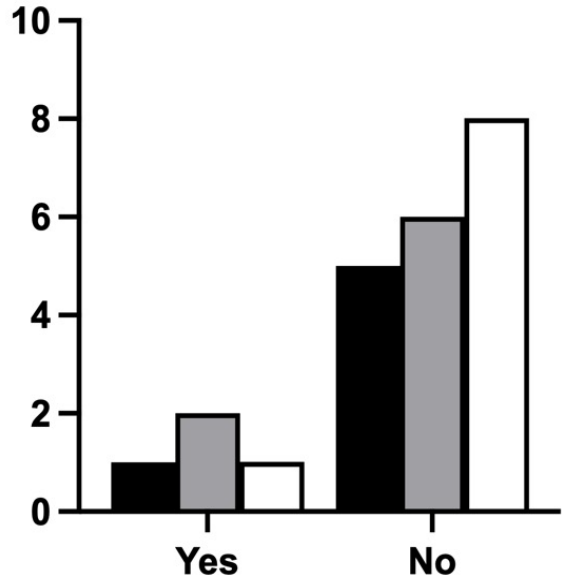
Research MURAL Activity: Recommend?



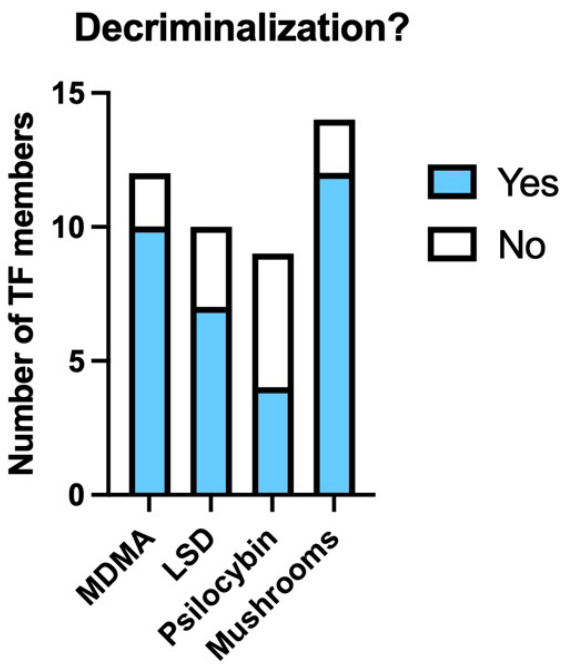
Research MURAL Activity: Context?

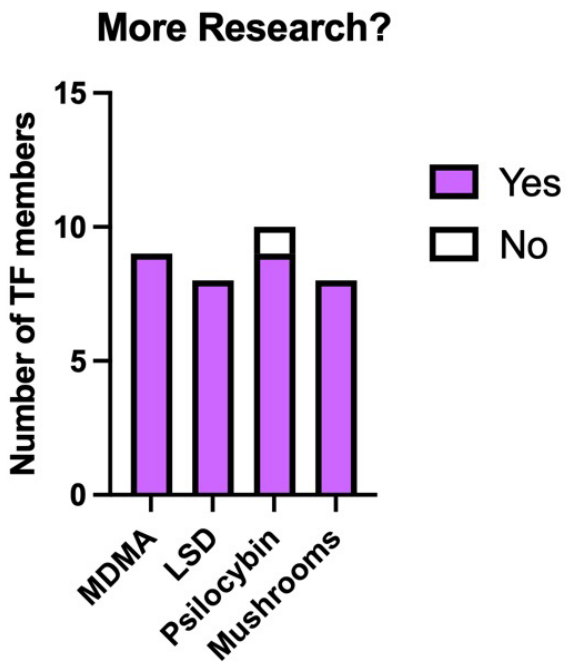


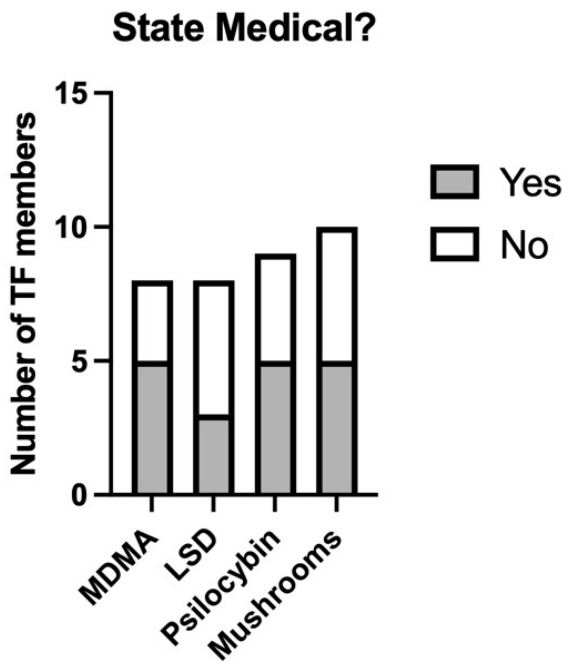
Research MURAL Activity: Restricted Medical Conditions?

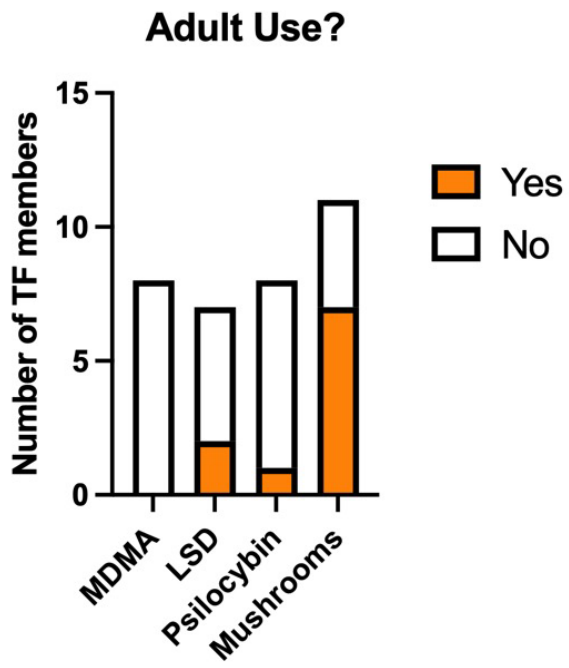


Summary of June Recommendation Test



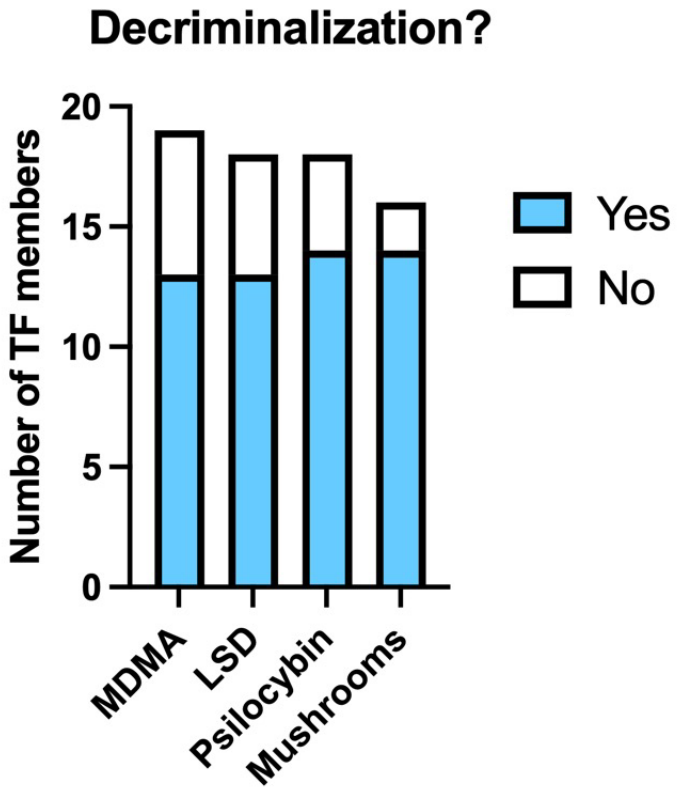


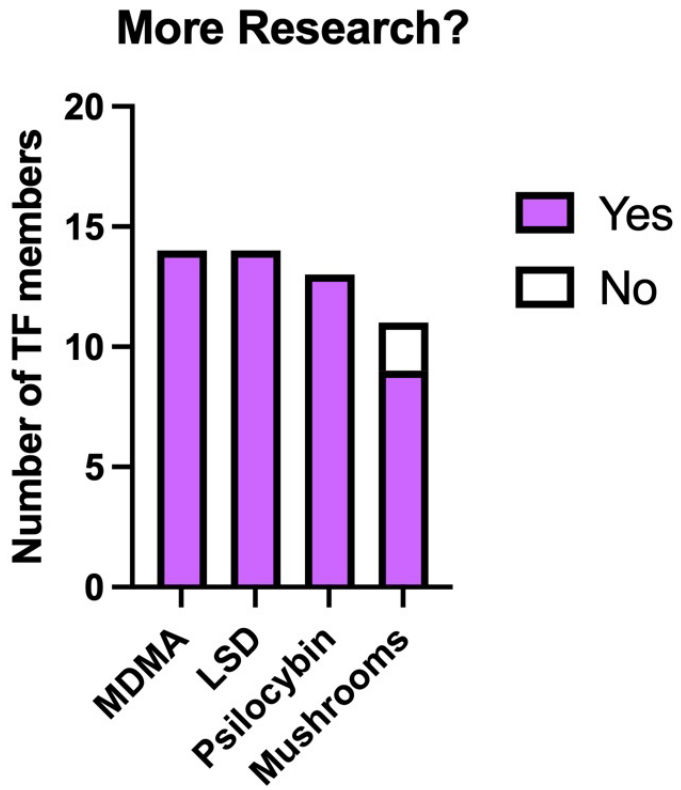


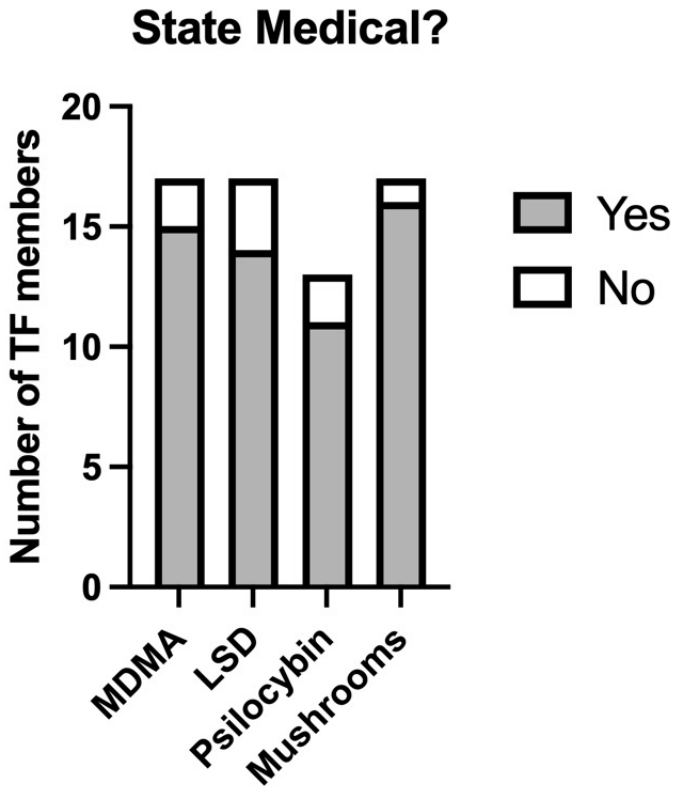


- **Yes = Green + circles from Mural, indicating support**
- **No = Red x circles from Mural, indicating no support**

Summary of July recommendation gradients of agreement







- **Yes = love it, like it, live with it**
- **No = leery of it, loathe it**

Adult regulated use – psilocybin mushrooms

- The task force recommends the Minnesota State Legislature establish a state-regulated adult-use program for natural, psilocybin-containing mushrooms

Final Voting Discussion

Jess Burke | Senior Management Consultant (MAD)

Final voting on recommendations

- The task force is scheduled to conduct a final vote on recommendations in the September 9, 2024, meeting.
- Recommendations will pass with a supermajority vote of members (yes, no, or abstain). We ask that all members attend the meeting. If you won’t be able to attend, we ask that you let the planning team know as soon as possible, so we can consider alternate voting options (Microsoft Forms, email, etc.).

Final voting

- There may be additional recommendations that come up in the report-writing process. If that happens, the task force will have an opportunity to vote on them.
- If you have a constituency to report back to (state agency, other communities), please ensure you have gotten any input you require before the September task force meeting.

Report Writing Discussion

Dr. Caroline Johnson | Psychedelic Medicine Scientific Researcher

Timeline

	August	September	October	November	December
At the meeting	Continue drafting and finalizing recommendations	Decide upon high-level recommendations to be included in final report	Discuss the draft, suggest edits, discuss additional recommendations	Discuss draft, edits, recommendations. Approve version to be submitted to MDH	Discuss any returned edits
Rest of month	Review recommendations, discuss with State agencies	Draft comprehensive version of the final report	Continue drafting and polishing report	Submit report to MDH for review of formatting, accessibility. Continue writing	Make final edits

Initial draft

- On Teams:
  - General → Report development → Final report: “PMTF Legislative Report_Working Draft”
- Placeholders
- Currently italic text is notes/comments/context
- Can comment on document
- Start thinking about other data to include

- Table of Contents
  - Cover letter
  - Acknowledgements
  - Glossary
  - Executive summary
  - Legislation
  - Introduction
  - Scientific literature review
  - Community research review
  - Legal pathways
  - Recommendations
  - Tribal nation sovereignty
  - Public education
  - Appendices

Personal anecdotes

- Possibility for an appendix of personal anecdotes, experiences regarding psychedelic medicine
- Paragraph or so finished by mid-September

Writing process/Q&A

- Volunteers for writing? Reviewing?
- Pivot current working group to a writing group after deciding upon recommendations?
- Other questions, comments

Public education discussion

DEPARTMENT OF HEALTH

Plans for public education

Education about the task force recommendations, which may include the following:

- Providing funding for education campaigns from community organizations
- First responder training (law enforcement, EMTs, firefighters, ER personnel) and managing psychedelic crisis (akin to trainings on trauma-informed care)
- Legal education about federal scheduling and status of clinical trials and FDA approval process
- Education about what is legally protected religious use of psychedelic medicines
- Education for clinicians from all sectors (physicians, nurses, social workers, chaplains, psychologists, integrative medicine practitioners, and other professions that may become facilitators or have clients using psychedelic medicines)
- Education on the culture and history of psychedelic medicines, including Indigenous uses, community use, and religious use

Work groups updates

- **Upcoming meetings**
  - Second and fourth Thursdays of each month, 4:00-5:00 pm
  - Additional, ad hoc meetings possible, if members want or need to meet to discuss recommendations and/or writing.

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, September 9, 2024, 9:30 am – 12:30 pm