

Psychedelic Medicine Task Force Meeting Summary

- Participants listed below.
- Meeting documents with presentation slides provide more detail and are available on the task force webpage.

Meeting Summary: June 3, 2023, 9:30 AM – 12:30 PM

Welcome

Facilitator, Stacy Sjogren, with Management Analysis and Development (MAD), called the meeting to order. She reviewed rules of engagement for the meeting, welcomed outside observers, introduced task force staff, and gave reference to the task force webpage to find more information. Stacy also reviewed the legislative charge and task force duties as found on slides 5-7 in the June meeting presentation slides (PDF).

An announcement was made that State Senator Julia Coleman will no longer be serving on the task force due to time commitment constraints. The Minnesota Department of Health (MDH) will be working with legislators to fill the seat.

Roll call was taken, and quorum was secured. See voting log at the bottom of this meeting summary for attendance.

Member-collected feedback

Dr. Jessica Nielson, task force chair, asked task force members to share public feedback collected from their respective constituencies.

Dr. Margaret Gavian shared feedback from two listening sessions with providers who were also patients. There was a desire to have quick and easy access outside the medical system. Individuals said the interventions have been effective in helping people and there was a need to get these medicines to people as soon as possible, as it can be life or death for some people. Another theme provided in the feedback was a need for a public education to ensure proper usage, standards, and safety precautions for both providers and people using outside the medical system.

Donovan Sather shared feedback after talking to tribal providers. Their concerns revolved around public education of the task force and future work about psychedelic medicine in the state. He stated there was not a

lot of knowledge on psychedelics use and encouraged a cohesive message to the public. Donovan stated people are excited to use these medicines for healing but it will take time developing a messaging and doing outreach to gather feedback.

Dr. Ranji Varghese shared feedback from psychiatric and non-psychiatric medical communities. They expressed a need for more public education on psychedelic medicine. He will resend his survey and provide more informed comments at a later date.

Paula DeSanto shared feedback from people who are actively using substances and experiencing mental health issues. She has been receiving of calls from families and loved ones who are needing help. She shared there is a sense of desperation, crisis, and lack of hope she has not experienced in the last 40 years.

Guthrie Capossela shared he reached out to the Minnesota Indian Affairs Council {MIAC} in advance of their meeting, but they didn't want further updates at the time.

Courtney Amundson shared themes from her feedback included affordability, regulation for therapeutic provided services, and regulation around non-therapeutic access.

Approve May meeting summary

A motion was made and seconded to approve the May 2024 meeting summary as written. Motion carried. See voting log for details.

Task force logistical business

Dr. Nielson provided an overview of the agenda and meeting outcomes, found on slides 9-10 of the meeting presentation.

Decision flow chart and timeline discussion

Dr. Nielson provided an overview of the task force timeline found on slide 8 of the meeting presentation and informed task force members that next month they will begin deciding what to include in the recommendations.

Dr. Nielson discussed the task force flow chart, learnings, and next steps found on slides 10-18 of the meeting presentation.

Dr. Nielson expressed her opinion on ensuring affordability, accessibility, and culturally appropriate usage of psychedelic medicine for healing purposes. She shared that programs in other states are coming against the barriers of cost and access. State regulated programs are the most expensive and least accessible. Clinical trials are somewhat accessible. Decriminalization has shown to be the least expensive and most accessible, but least regulated.

Task force members participated in a discussion and an activity on Mural on usage of decision-making tools. Bennet Hartz, task force vice-chair, expressed his opinion on voting based on who is in attendance at the meeting and allowing task force members to vote remotely or by proxy if they cannot attend the meeting.

Bennet provided a summary from his meeting with task force state agency representatives. Generally, state agencies representatives felt the task force had a difficult job and would like to see more concrete proposals before providing input. There is agreement that some recommendations, like rescheduling, may be more straight forward. Some agency representatives felt the proposals to consider adult regulated use of psylocibin was beyond the authority given by the legislature.

Task force members engaged in a Mural activity how to ensure more participation from state agencies.

State Representative Andy Smith shared that state agencies are extremely helpful, but they generally do need more concrete information to examine how they will implement proposals. As the chief author of the legislation, he stated the legislative intent was left vague so the task force could decide which options were best for Minnesota. He recommended the task force give concrete information to state agencies so they can best respond with how it might work. He added that the task force is only making recommendations, it is up to the legislature whether to take up those recommendations.

Bennett asked Rep. Smith whether it would be helpful to have a report that lays out multiple options and/or to have proposals that look out beyond one legislative session. Rep. Smith responded he would personally like the task force to recommend the best model that could and should exist in Minnesota.

Break

Research update: MDMA

Dr. Caroline Johnson, Psychedelics Medicine Scientific Research at MDH, provided a research update on MDMA found on slides 20-26 of the meeting presentation and in the <u>MDMA Literature Overview</u> of the meeting materials.

Task force members engaged in a discussion and in a Mural activity on whether to recommend MDMA.

Presentation: Lykos Therapeutics

Guest presenters, Ben Everett, Senior Director of Medical Science & Health Outcomes, and Gretchen Shaub, Associate Director of State Government Affairs & Public Policy at Lykos Therapeutics, provided an overview of Lykos' efforts to gain MDMA approval from the U.S. Food and Drug Administration (FDA).

The presenters shared that the FDA has granted them priority review with a potential approval date on August 11. If approval is received, they would go into a rescheduling process with the Drug Enforcement Administration (DEA). Ninety days post potential approval is when they would hear about the rescheduling from Schedule I to an anticipated Schedule II or III. Once federal rescheduling has happened, all 50 states will have their own rescheduling processes. The presenters shared they will be attending an FDA advisory panel meeting, the first for PTSD in 25 years, which will provide recommendations to the FDA.

Task force members engaged in a discussion with Lykos.

Bennett asked what Lykos' plan is if the FDA found its phase 3 trials were insufficient. Gretchen responded if the agency approves the product, the DEA is legally bound to reschedule. If they do not recommend, it will depend

on what information they provide back. Ben added the FDA typically does not just say no, they would send a letter on what to do.

Workgroup update and discussion

Workgroup chair, Paula DeSanto, provided a workgroup update. She mentioned there are 6-7 members who are regularly active which can at times create an echo chamber. Paula extended an invitation for a co-chair, particularly someone from a state agency.

The workgroup has been discussing many issues including decriminalization for psilocybin, regulation and licensing options, community expertise, safety, language, education, supply, political viability, clemency, restorative justice, and tribal considerations.

Task force members engaged in a Mural activity on recommendations for each drug. Generally, there was overwhelming support for more research/clinical trials, large support for decriminalization (except for synthetic psilocybin), mixed support for state regulated medical only models, low support for state regulated non-medical models,

Adjourn

Members of the public were reminded that if they have comments to provide to the task force, they can email health.pyschedelicmedicine@state.mn.us.

Participants

Task force members

Courtney Amundson Helen Bassett Guthrie Capossela Paula DeSanto Jeremy Drucker Dr. Margaret Gavian Bennett Hartz Dave Hoang Arielle McHenry Dr. Jessica Nielson Kit O'Neill Jill Phillips

Ken Sass

Donovan Sather

Rep. Andy Smith

Michael Tabor

Adam Tomczik

Dr. Ranji Varghese

Others

Jessica Burke, MAD
Stacy Sjogren, MAD
Nick Kor, MAD
Kari Gloppen, MDH
Dr. Caroline Johnson, MDH
Ben Everett, Lykos Therapeutics
Gretchen Shaub, Lykos Therapeutics

Next task force meeting

Monday, July 1, 2024, 9:30 a.m. – 12:30 p.m.

Voting log

| Member name | Roll Call | Vote on May 6, 2024, minutes |
|--------------------------|------------|------------------------------|
| | 17 present | Motion: Tomczik |
| | | Second: Hartrz |
| Courtney Amundson | Present | Yes |
| Helen Bassett | Absent | |
| Guthrie Capossela | Present | Abstain |
| Sen. Julia Coleman | | |
| Paula DeSanto | Present | Yes |
| Jeremy Drucker | Present | Yes |
| Stefan Egan | Absent | |
| Dr. Margaret Gavian | Present | Abstain |
| Bennett Hartz | Present | Yes |
| David Hoang (off camera) | Present | Yes |
| Nick Lehnertz | Absent | |
| Arielle "Ari" McHenry | Present | Yes |
| Sen. Kelly Morrison | Absent | |
| Dr. Jessica Nielson | Present | Yes |
| Kit O'Neill | Present | Yes |

| Jill Phillips | Present | Yes |
|--------------------|---------|-----|
| Kenneth Sass | Present | Yes |
| Donovan Sather | Present | Yes |
| Rep. Andy Smith | Present | Yes |
| Michael Tabor | Present | Yes |
| Adam Tomczik | Present | Yes |
| Dr. Ranji Varghese | Present | Yes |
| Rep. Nolan West | Absent | |