PMTF Recommendations development

4.1.24

MURAL discussion about clinical vs non-clinical uses of psychedelic medicines

The task force had a discussion on MURAL to evaluate the different legal pathways and potential regulatory factors, as well as a discussion about clinical and non-clinical approaches to psychedelic medicines, and potential regulations under those umbrellas.

Legal pathways to consider

- Administrative exemption to CSA
- Judicial exemption to CSA (the more likely route with the overturning of Chevron)
- Petition US AG for research program (how methadone clinics were started back in the 1970s)
- Expanded Access
- Right to Try
- State-regulated use (medical and adult)
- Decriminalization

Clinical

Facilitators

- Needs to have some sort of training (one option could be a licensed therapist with education on psychedelic training and another facilitator who is trained but not licensed
- MDMA and LSD in medical settings
- Facilitators should be licensed
- For female patients, a male/female pair of facilitators
- In healthcare settings, professionals need to be qualified to administer treatment (either Rx or 'therapy') to the "right" patients. We need to follow this same standard here. E.g., Evidenced based treatments for depression are X, THIS specifically trained professional is qualified to treat depression.
- Tribal models of trained facilitator based on indigenous beliefs and perspectives

Facilities

- All treatment should be through traditional healthcare systems
- My vote is that it is initially all clinical through traditional medical system,
- over reliance on the medical system for access to these substances greatly reduces access to other groups who would benefit and who might not otherwise have access
- Tribal program could regulate intake assessment and follow up
- Facility with resources for medical or psychological emergencies is recommended

- For Tribes due to the lack of resources (professionals) in this field will consider others that can assist and Trained.
- Decriminalizing and Adult use allow more facility options and access, increased flexibility with environment and decreased liability issues
- Allow facilities to specialize in providing assisted 'treatment' outside of a medical setting creates a more inclusive model

Supply

- Medically approved MDMA and LSD
- If possible American based suppliers
- Agreed, medically approved MDMA and LSD
- for synthetic substances, need medical integrity of substances to be assured
- Ban synthetic psilocybin in MN to avoid regulation issues and unethical profiteering by pharmaceutical industry
- Tribal facility, controlled environment, consistency in supply

Individual selection and screening

Safety monitoring

Non-clinical

Facilitators

- Licensing requirement is extremely important even in non-clinical settings, as the abilities to track licensees and threaten to or revoke a license are critical regulatory tools. -Bennett (AG)
- Fewer prerequisites For plant based Intensive courses and personal experience
- Tribal models of trained facilitator based on indigenous beliefs and perspectives
- Plant based non regulated but options to get trained facilitators
- Regulations must be in place for facilitators working with each substance - including contraindications, screening, user safety, some set and setting basics. But providing access in non-clinical environments, facilitated by non-healthcare professionals is important for providing access
- For Veterans: Remove obstacles to therapy. Peer support based healing. Waive license requirements for veteran medical and mental health professionals
- non clinical but trained like Colorado model?
- Multi-tiered program, with different requirements for different license holders.

Facilities

- We need to accept the reality that these substances WILL be used outside of the medical system. So in order to educate the consumer I think it is our duty to provide some recommendations on how/where/when/for whom this is most appropriate.
- Nature/cabin/resort with emergency care available
- Low-barrier facility licensing that generates more access. (Oregon's model has failed in this way.)
- Certify patients who have had a certain number of clinical medicine sessions. Allow certified patients to purchase plant medicine and enjoy expanded access for responsible adult use.

- For Tribes due to the lack of resources (professionals) in this field will consider others that can assist and Trained.
- Decriminalizing and Adult use allow more facility options and access, increased flexibility with environment and decreased liability issues
- Allow facilities to specialize in providing assisted 'treatment' outside of a medical setting creates a more inclusive model

Supply

- allow community cultivation
    - Home growers need safe & verified sources of spores & grow mediums free from contamination. Near-sterile environments are needed for best results & consistency
        - Home grow should be an option.
- For psilocybin, retail availability like for cannabis.
- Fees and license money to help fund program/employes/admin
- Affordable access to safe sterile grow mediums, education & tested spore supplies for home growers of mushrooms, and information on contamination. LSD, MDMA best left to drug manufacturers
- Agree that home grow should be an option, with some guidelines in place
- Growing operations regulated by Dept of Agriculture/labs to test for purity. Violations punishable by heavy fines which can be used to fund low income patients.
- Waive license fees for Veterans and Natives.
- Tribal facility, controlled environment, consistency in supply

Individual selection and screening

Safety monitoring

Recommendations regarding decriminalization

7.1.24

The task force recommends the Minnesota State Legislature decriminalize the use and possession of MDMA.

Strengths

- The data shows that MDMA is statistically the most effective treatment for PTSD. It makes me sad that US military veterans and first responders are unable to access MDMA legally in the US The task force recommends the Minnesota State Legislature decriminalize the use and possession of LSD. The task force recommends the Minnesota State Legislature decriminalize the use and possession of synthetic psilocybin. The task force recommends the Minnesota State Legislature decriminalize the use, possession, and cultivation of natural psilocybin-containing mushrooms.
- Effective for PTSD
- Allows for equity of access.
- It is beneficial for clinic practice
- Low cost and simple to enact for state

- Is consistent with broad public opinion about previous controlled substances
- Increase access
- Removes significant barriers to access for otherwise law abiding clients
- Allows people to access MDMA on their own terms
- Save Public Safety money by not enforcing a drug that isn't a danger to the public
- Would remove criminal penalties for drug that is already broadly used with relative safety today, and has been since 1980s
- Removal of criminal penalties would increase likelihood that users seek care for medical health effects and report abuse, assault, etc. to law enforcement
- Won't displace the community of current sellers.
- Healing can transpire outside the walls of the clinic and Western medicine.
- Criminalization does not has little deterrent effect on "recreational" use.
- Access to valuable/proven treatment.
- Removes collateral consequences associated with drug convictions.

Weaknesses

- Schedule I drug under the Controlled Substances Act
- Decriminalization might not provide a legal framework for patients to access MDMA for PTSD treatment. It might remain "underground."
- Still leaves a legal grey area for medical providers and may risk their licenses to practice if involved in MDMA
- Most relevant for PTSD which is a specific condition that requires properly trained professionals to treat
- Seems unlikely to pass legislative process
- reclassification can be challenge
- Without an active state regulatory body, public education will be sorely lacking and clinicians will have little to no guidance on therapeutic use
- Treatment services should be implemented first prior to decriminalizing the use of the drug
- usage and healing are not the same
- MDMA with Psychotherapy is what is backed by the literature. If decriminalized, then how do we ensure people with trauma/PTSD receive appropriate care? Would need very targeted education around this.
- State agencies won't be able to make any money
- Is there broad public support in the legislature?

Opportunities

- People won't go to jail for possession
- Easier to obtain MDMA for clinical trials
    - This isn't true regarding what drug supply is allowed for clinical trials
- Broad access
- In a clinical setting, gives opportunity for healing
- Additional Training for facilitators/therapist/providers outside of medical system
- opens up for self-medication
- May allow VA to recognize/approve community care for veterans who are receiving care outside of the federal system
- More public education

- The Chevron Deference was overturned last week which limits the decisions federal agencies like DEA/FDA have and enforcement of ambiguous statutes (like the federal RTT act)
- Increased collaboration with physicians and mental health providers.
- Patients can access MDMA on their own terms.
- Could make broad quantitative studies of use easier as people are not afraid to engage in surveys/studies

Threats

- Unregulated supply could be contaminated with other drugs (e.g. fentanyl)
- What do Law enforcement think?
- Depending on how this is decriminalized, proliferation and exploitation of starting materials may drastically effect certain cultures and/or overall material supply chains. Additionally, knowing there is significant recreational use, this may likely lead to higher levels of abuse.
- Likely increase in unregulated use could lead to increase in harm (overdose, heart problems, harms from cross-use with alcohol and other drugs)
- Unregulated use and the impact on public safety such as impaired driving
- Potential for the narrative to get away from us, as in Oregon, and risk public blowback, political retrenchment, or legal rollback. Nuanced messaging is a must.
- Leave for pharmaceutical company to provide pathway
- I am somewhat concerned that the TF/Minnesota MAY BE Out front in a manner that is premature...given the FDA advisory opinion and the need for more substantive data. My opinion is my own and unvetted with my agency as yet.
- Unregulated use is a threat to public safety - we experienced this with THC
- illegal drug manufacturing contributing to opioid and fentanyl crisis. Could ingredients could creep into manufacturing
- Decriminalizing nature seems like an "easier" path
- Of the four substances we are considering, MDMA is probably the most likely substance to be abused.
- Is there enough evidence to convince the general public that there is an overwhelming need to legalize, and any benefits will outweigh the risks
- Given chaotic drug supply, I worry about contamination with fentanyl and other synthetic opioids,

The task force recommends the Minnesota State Legislature decriminalize the use and possession of LSD.

Strengths

- reduce unnecessary criminal penalty for use/possession
- Equity of access, and puts safety into the hands of consumers.
- Low cost and simple to enact for state
- Opens access for treatment options without high cost for treatment center.
- Allows for equity of access.
- Could put MN in advantageous position as a leading treatment and research state
- lowest risk for federal intervention
- May help with expanding services provided
- Lowers risk for prescribers

- LSD is an excellent tool for addressing substance use disorder. Originally Alcoholics Anonymous included LSD as a step. LSD is less likely to be abused than MDMA. LSD does not have the addictive properties that MDMA has. Decriminalized LSD would allow patients to approach treatment on their own terms. LSD journeys have changed many, many people's lives for the better.
- There seems to have been more testing in this area.
- Removal of criminal penalties would increase likelihood that users seek care for medical health effects and report abuse, assault, etc. to law enforcement
- Few health risks associated with use (e.g. no overdose, addiction, or physical harms)
- LSD is an excellent tool for addressing substance use disorder. Originally Alcoholics Anonymous included LSD as a step. LSD is less likely to be abused than MDMA. LSD does not have the addictive properties that MDMA has. Decriminalized LSD would allow patients to approach treatment on their own terms. LSD journeys have changed many, many people's lives for the better.
- This allows a pathway for education on safe use & for law enforcement and the public
- Few health risks associated with use (e.g. no overdose, addiction, or physical harms)
- Allows people to treat themselves for anxiety/depression and take burden off the healthcare system for these debilitating and expensive conditions
- Healing can transpire outside the walls of the clinic and Western medicine.
- Removes collateral consequences associated with drug convictions.
- Won't displace the community of current sellers.
- Increased autonomy, pleasure for adult users.

Weaknesses

- Schedule I drug under the Controlled Substances Act
- Still leaves a legal grey area for medical providers and may risk their licenses to practice if involved with LSD
- Benefits do not out weigh risk
- Decriminalization should not precede a medical model
- Self-selection use. Not medical application
- Access and sharing could create unknown issues

Opportunities

- There are current training programs preparing clinicians to provide safe, therapeutic use
- People won't go to jail for possession
- Additional facilitator/provider training
- will increase access to LSD
- Sample testing to ensure the LSD supply is pure
- Reduces burden on. medical system
- Could lead to a stepped legalization of clinical use (like cannabis clinics)
- other than clinical settings, may be provided in program structures
- Could make broad quantitative studies of use easier as people are not afraid to engage in surveys/studies
- More effective than traditional therapies for PTSD etc

Threats

- Unregulated supply could be contaminated with other drugs (e.g. fentanyl) or not be LSD at all

- Likely increase in unregulated use could lead to increase in harm (harm from use in uncontrolled environments, negative experiences/"bad trips," psychotic triggers)
- Unregulated production and/or supply will effect quality and purity, as we currently see with the illicit market. RC will become more common than they already are.
- Unregulated use and the impact on public safety such as impaired driving
- High potential for abuse
- Schedule I drug
- Is LSD less likely to be adulterated with fentanyl compared with MDMA and other substances?
- All of these are Schedule 1 drugs!
- Potential for the narrative to get away from us, as in Oregon, and risk public blowback, political retrenchment, or legal rollback. Nuanced messaging is a must.
- Unregulated use is a public safety concern
- DEA states that LSD has a high potential for abuse
- Is there enough evidence to convince the general public that there is an overwhelming need to legalize, and any benefits will outweigh the risks

The task force recommends the Minnesota State Legislature decriminalize the use and possession of synthetic psilocybin.

Strengths

- Removes collateral consequences associated with drug convictions.
- Low cost and simple to enact for state
- Allows for therapeutic application and user agency.
- A natural, safe medicine used by humans throughout history.
- Won't displace the community of current sellers.
- reduce unnecessary criminal penalty for use/possession
- Opportunity to be clinically approved through big pharma
- Increased autonomy, pleasure for adult users.
- Few health risks associated with use (e.g. no overdose, addiction, or physical harms)
- Removal of criminal penalties would increase likelihood that users seek care for medical health effects and report abuse, assault, etc. to law enforcement
- Healing can transpire outside the walls of the clinic and Western medicine.

Weaknesses

- Schedule I drug under the Controlled Substances Act
- Doesn't lead to structured access
- Healthcare providers have limited education on medication interactions, risk factors for poor outcomes and affects in youth
- Public education campaigns will be expensive, and decriminalization won't lead to any incoming funds compared to state-regulated production and sales
- Could make broad quantitative studies of use easier as people are not afraid to engage in surveys/studies

Opportunities

- Could make broad quantitative studies of use easier as people are not afraid to engage in surveys/studies
- Decriminalization allows a pathway for education on safe use and benefits. Also allowing breakdown of inaccurate information
- People won't go to jail for possession

Threats

- Synthesis of psilocybin is becoming common. Again, supply chain of inputs would effect the overall cost of MEDS to those who would be prescribed. Illicit production is unregulated and has high potential for adulterants and contaminations
- Likely increase in unregulated use could lead to increase in harm (harm from use in uncontrolled environments, negative experiences/"bad trips," psychotic triggers)
- As seen with countless other compounds, issues arise when concentrating the actives. For instance, salicylic acid is the base to aspirin. It is found in countless plants. Aspirin becomes dangerous because it has been isolated from the other organic compounds, affecting how the body processes the compound. Where consumed dandelions or willow produce zero detrimental effects.
- Involving pharmaceutical companies turns healing objective into a profit driven objective
- Regulation around testing needed

The task force recommends the Minnesota State Legislature decriminalize the use, possession, and cultivation of natural psilocybin-containing mushrooms.

Strengths

- Home cultivation. Low cost meds. Access as needed.
- Safe use education and public information sharing.
- Nature!
- Few health risks associated with use (e.g. no overdose, addiction, or physical harms)
- Low cost and simple to enact for state
- Life-saving medicine. Used by humanity for millennia. Non-toxic (no fatal dose). Non-habit forming, non-addictive. Can be cultivated at home ensuring known product. Decriminalization of nature and natural plant or fungal medicine is a compelling argument for people on all sides of the political spectrum.
- Easy and inexpensive to grow
- Removal of criminal penalties would increase likelihood that users seek care for medical health effects and report abuse, assault, etc. to law enforcement
- safe alternatives with no LD
- Healing through Natural Plant Medicine
- Data show that the effect of "bad trips" is fleeting, ending after 4-6 hours. The benefits of positive journeys can last for months or years.
- reduce unnecessary criminal penalty for use/possession
- Treats adults like grownups who can make their own decision about what non-toxic plants or fungi we can eat.

- Even more than the other synthetic substances, I think the public thinks we should not outlaw plants that grow naturally
- Reduces burden of anxiety/depression care management off of medical system
- Lacks the of contamination that comes with synthetic drugs

Weaknesses

- Schedule I drug under the Controlled Substances Act
- could create public confusion over what's legal with synthetic and plant based
- No official regulated process regarding cultivation or therapeutic use. I'd prefer legalization and adult regulated use similar to cannabis.
- Unknown factors, educational resources
- Could make broad quantitative studies of use easier as people are not afraid to engage in surveys/studies

Opportunities

- Broad Access
- Could make broad quantitative studies of use easier as people are not afraid to engage in surveys/studies
- allows for ceremonial integration
- Giving people agency over how they care for themselves, less dependent on medical system/pharm
- Education materials for providers on how to guide their clients/patients if they choose to use
- Adults can use mushrooms as they deem appropriate. Could be conventional psychotherapy, Native ceremonies, other non-Western spiritual traditions. The adults get to decide on how to approach mushrooms.
- Could allow more broad use and protection for ceremonial and religious uses (e.g. via a state RFRA)
- People won't go to jail for possession
- Opportunity for integrative and/or collaborative care in medicine.
- Access and Cultivation possibilities
- Could reduce the overall costs of treatment and disability payments for veterans with PTSD

Threats

- Likely increase in unregulated use could lead to increase in harm (harm from use in uncontrolled environments, negative experiences/"bad trips," psychotic triggers)
- Reckless use
- Many different mushroom species, some are very potent and smaller in weight
- Unknown variable in dosage when used
- Unregulated use increase risk of harm for the public in general

Recommendations regarding research and clinical trials

The task force recommends the Minnesota State Legislature allocate funding for more research and clinical trials on using MDMA to treat mental health and other health conditions.

Strengths (duplicates are duplicates, unclear if by accident or intentionally copied to echo idea)

- Will provide more safety and efficacy data for more conditions
- May lead to greater number of FDA approved drugs
- Data typically provides additional information on safe use
- Low risk for healthcare providers to be openly involved
- Absolutely, benefit of more data and for more conditions
- Absolutely, benefit of more data and for more conditions
- Simple law for state to enact
- Clinical trials will be 100% legal and comply with DEA rules.
- This is important. It seems a likely and good next step.

Weaknesses

- Clinical trials are science experiments, not healthcare/therapy
- Would lead to delay in Minnesotans accessing MDMA.
    - Curious how?
- Trials would have to meet FDA's quality standards to be used in consideration of new drugs
    - These would only be for pharmaceutical products that have an IND with the FDA
- Cost: would require funding allocation from State
- Expense
- expense

Opportunities

- Broader training/resources for providers
- Additional research could diversify the participate pool for more accurate and reflective data.
- Gives more people access to MDMA in a controlled setting that is legal
- Gives more people access to MDMA in a controlled setting that is legal
- More evidence!
- Several pharma companies with eligible products

Threats

- Supply issues if Lykos is the only supplier and they are bogged down with navigating a potential rejection of approval by FDA
- Potential delays in treatment due to waiting for research findings

The task force recommends the Minnesota State Legislature allocate funding for more research and clinical trials on using LSD to treat mental health and other health conditions.

Strengths

- Simple law for state to enact
- More data to support medical use for specific conditions
- Will provide more safety and efficacy data for more conditions
- Data typically provides additional information on safe use
- The earliest data on LSD is from 1950s and 1960s before modern ethical review board processes. It would be good to get new data and complies with contemporary concerns.
- More data to support medical use for specific conditions
- Clinical trials will be 100% legal and comply with DEA rules.

Weaknesses

- Cost: would require funding allocation from State
- Clinical trials are science experiments, not healthcare/therapy
- Cost
- Expense

Opportunities

- Gives more people access to LSD in a controlled setting that is legal
- Several pharma companies with eligible products
- Additional research could diversify the participate pool for more accurate and reflective data.

Threats

- *None noted*

The task force recommends the Minnesota State Legislature allocate funding for more research and clinical trials on using synthetic psilocybin to treat mental health and other health conditions.

Strengths

- Simple law for state to enact
- Will provide more safety and efficacy data for more conditions
- Data typically provides additional information on safe use
- Clinical trials will be 100% legal and comply with DEA rules.

Weaknesses

- Cost: would require funding allocation from State
- Clinical trials are science experiments, not healthcare/therapy
- Expense

Opportunities

- It would be very interesting to determine the difference between synthetic psilocybin and whole mushrooms that have more chemicals beyond psilocybin.
- Additional research could diversify the participate pool for more accurate and refletive data.
- Gives more people access to psilocybin in a controlled setting that is legal
- Several pharma companies with eligible products

Threats

- *None noted*

The task force recommends the Minnesota State Legislature allocate funding for more research and clinical trials on using natural, psilocybin-containing mushrooms to treat mental health and other health conditions.

Strengths

- Simple law for state to enact
- Simple law for state to enact
- Helps to prove the safety and efficacy of organic
- Seems like more support around natural products
- Will provide more safety and efficacy data for more conditions
- Clinical trials will be 100% legal and comply with DEA rules.

Weaknesses

- Hopefully lower cost
- Expense
- Clinical trials are science experiments, not healthcare/therapy
- Cost: would require funding allocation from State

Opportunities

- Data and Access
- Gives more people access to mushrooms in a controlled setting that is legal
- There are two companies now that have a natural product that has received IND from FDA for use in clinical trials

Threats

- *None noted*

Recommendations regarding a medical model

The task force recommends the Minnesota State Legislature establish a state-regulated medical program for MDMA, similar to the state's medical cannabis program.

Strengths

- Help for MN Veterans
- If FDA reschedules MDMA to Schedule 3 in August 2024, such a program would be fully legal at federal and state level
- Strong supporter. State program would alleviate concerns about adulteration. Could be combined with the psychotherapy as proposed by Lykos. MDMA is very effective for PTSD.
- Access to healing
- Gives people medical access without having to wait for the slog of FDA approval and DEA rescheduling
- Could bring in more out of state clients and generate revenue for state of MN
- There are trained professionals to provide the care
- Better oversight than decriminalization
- great option for controlled access, focuses on healing
- Therapeutic application vs prescription model (integrative)
- Low risk of contamination or administration to youth
- Addresses public safety concerns, such as access by children, driving, and adulteration. Of all substances, MDMA is most susceptible to abuse or addiction, but State-regulated process will address those concerns.
- Access in health care setting
- Access! Access! Access! Data! Data!

Weaknesses

- Unknown regulations
- Much of the risk of federal intervention, or lack thereof, will be dependent on FDA rescheduling decision in August 2024
- Potentially limited access.
- Uncertainty about whether FDA will approve, if DEA will reschedule, and if it will stay on schedule 1 except for the approve pharmaceutical product.
- Expense
- cost will restrict access. How will health insurance respond
- Probably few risks if done in well regulated settings
- Uncertainty about whether to pursue prescribed medical model or non-prescribed therapeutic model
- Medical licenses may be at risk regardless of state legalization, could lead to lack of providers willing to help patients and drive up waiting lists and costs

- Low potential to generate income, unlikely to be reimbursed by Insurance
- May cause federally funded programs to pull out their dollars, forcing isolated MDMA clinics to be the only providers
- Could be expensive for both providers and clients
- Slow bureaucratic process to get this established
- Cost

Opportunities

- Opportunity to obtain more long term data and identify other use potential.
- Yes, more data and healing
- Increased participant diversity in research resulting in accurate, reflective data.
- Regulated and effective treatment for veterans, law enforcement, and first responders who suffer the mental and spiritual scars of keeping the public safe.
- People can access MDMA with healthcare professional in a supervised setting
- Tracing of outcomes regarding the treatments themselves as well as the oversight/tracking of "providers"
- Improved safety due to increase in oversight
- More safety monitoring in place
    - Agree
- Expanded addiction recovery services in the state
- Regulated supply

Threats

- Seems like risk of federal involvements gets less and less
- FDA is going to issue decision on rescheduling in August 2024, and may decide against rescheduling MDMA to Schedule III
- The FDA ruling on this drug
- Labs synthesizing this could be in the crosshairs of the DEA, FDA, and FTC
- Unknown Financial burden to client

The task force recommends the Minnesota State Legislature establish a state-regulated medical program for LSD, similar to the state's medical cannabis program.

Strengths

- Access to data.
- Equity for diverse settings.
- I like the idea of deeper analysis and presumably deeper data availability in a controlled environment
- Gives people medical access without having to wait for the slog of FDA approval and DEA rescheduling
- LSD began in the 1950s and 1960s as a medical program. Single doses were found to cure alcoholism. Nixon criminalized LSD in 1970 to punish rivals who opposed the Vietnam War. A regulated process led by the State would ensure quality product and proper handling.

- A state run program would drastically reduce any potential facilitator abuse of clients (as opposed to non-state program)
- Provides data of the medical approach that includes therapy...Inclusivity in medicine.
- Better training & monitoring of providers/facilitators
- Non-addictive, non-habit forming, no known lethal dose.
- Would create safe and controlled oversight of use, which is especially important for LSD
- Non-toxic, no lethal dose.
- Entering Phase 3 of FDA trials.
- Addresses public safety concerns, such as access by children, driving, and adulteration.
- Would instantly put MN as a top mental health and substance abuse treatment state in the nation

Weaknesses

- FDA not currently considering rescheduling LSD, so will necessarily create conflicts with federal law
- If resources are limited I would prefer to focus on MDMA over LSD
- Uncertainty about whether FDA will approve (currently in phase III for generalized anxiety disorder), if DEA will reschedule, and if it will stay on schedule 1 except for the approve pharmaceutical product.
- Medical licenses may be at risk regardless of state legalization, could lead to lack of providers willing to help patients and drive up waiting lists and costs
- Could be expensive for both providers and clients
- State HLB's such as medical board and psychology are missing from this group and their licenses could be at risk regardless of state legislation
- Limited and poor data on efficacy
- Reduces access to some extent
- Slow bureaucratic process to get this established
- Length of "trip" makes it harder to work with than MDMA/Psy.
    - ...which leads to greater expense of treatment, despite having similar effects as psilocybin

Opportunities

- A regulated LSD process could help with our current epidemic of substance abuse.
- Increase diversity in research participant for accurate data.
- People can access LSD with healthcare professional in a supervised setting
- People can access LSD with healthcare professional in a supervised setting
- Regulated supply

Threats

- Labs synthesizing this could be in the crosshairs of the DEA, FDA, and FTC
- Is there enough research to show effectiveness?
- Labs synthesizing this could be in the crosshairs of the DEA, FDA, and FTC
- Administrators and centers could be targets of FDA/DEA
- Of the three agents, LSD appears to have the least amount of data
- Are there Implications for native communities who do have histories and years of self report

The task force recommends the Minnesota State Legislature establish a state-regulated medical program for synthetic psilocybin, similar to the state's medical cannabis program.

Strengths

- Access to long term data.
- Strong supporter. State program addresses concerns about adulteration and access to children and driving concerns. Synthetic product is much more predictable in effect than naturally-grown mushrooms. Journey lasts 4-6 hours which is a good amount of time for healthcare personnel staffing issues.
- Strong supporter. State program addresses concerns about adulteration and access to children and driving concerns. Synthetic product is much more predictable in effect than naturally-grown mushrooms. Journey lasts 4-6 hours which is a good amount of time for healthcare personnel staffing issues.
- Better quality control and monitoring
- Gives providers some process to move through/refer to for guidance
- Gives people medical access without having to wait for the slog of FDA approval and DEA rescheduling
- Addresses public safety concerns, such as access by children, driving, and adulteration.
- Easier on patients to consume than whole mushroom products
- Consistent supply
- Non-addictive, non-habit forming, no known lethal dose.
- Would create safe and controlled oversight of use, which is especially important for psilocybin
- allows for better monitoring of dosing

Weaknesses

- Not enough data to support efficacy of synthetics vs organic. Cannabis has shown value in entourage.
- Leaves decision making to governing boards, reducing access and putting care in hands of govt/capitalism/big pharm
- Chance of bio-piracy
- Allowing that MindMed is in Phase III trials, FDA not currently considering rescheduling psilocybin, so will necessarily create conflicts with federal law
- Could be expensive for both providers and clients
- Uncertainty about whether FDA will approve (currently in phase III for generalized anxiety disorder), if DEA will reschedule, and if it will stay on schedule 1 except for the approve pharmaceutical product.
- Uncertainty about whether FDA will approve (currently in phase III for generalized anxiety disorder), if DEA will reschedule, and if it will stay on schedule 1 except for the approve pharmaceutical product.
- Medical licenses may be at risk regardless of state legalization, could lead to lack of providers willing to help patients and drive up waiting lists and costs
- We have heard from Oregon that expense of treatment is currently a major barrier
- Cost and complexity of creating state regulations and regulatory body
- Weakened version of psilocybin

Opportunities

- Access through programming
- People can access psilocybin with healthcare professional in a supervised setting
- Regulated supply

Threats

- Invites lobbying and profit driven motives from pharma. creating ethical dilemmas
- Cost is a known barrier
- Cost to clients
- Administrators and centers could be targets of FDA/DEA

The task force recommends the Minnesota State Legislature establish a state-regulated medical program for natural, psilocybin-containing mushrooms, similar to the state's medical cannabis program.

Strengths

- Using the natural source accessible by the public.
- The entire mushroom might bring the entourage effect from many different chemicals affecting neurology. Remains non-toxic with no fatal dose. Some evidence that entire mushrooms helps with repairing nerve damage, including paralysis and tinnitus.
- Better screenings for at-risk patients, more data on drug interactions
- State regulation would provide patients with known amounts of active ingredients. More predictability than decriminalization alone.
- Addresses public safety concerns, such as access by children, driving, and adulteration.
- Non-addictive, non-habit forming, no known lethal dose.
- Would create safe and controlled oversight of use, which is especially important for psilocybin
- Higher chance of a strong public education campaign, potential for income generation
- Access to healing
- Gives people medical access without having to wait for the slog of FDA approval and DEA rescheduling
- Guided facilitation can be beneficial for people to experience

Weaknesses

- Naturally-grown mushrooms have greater variability than synthetic psilocybin in concentration of effective ingredients.
- FDA not currently considering rescheduling naturally grown psilocybin, so will necessarily create conflicts with federal law
- Less equitable. Drives costs up creating a situation where wealthy facilitators work with wealthy clients.
- Could be expensive for both providers and clients
- No RCTs for efficacy with natural mushroom products
- We have heard from Oregon that expense of treatment is currently a major barrier
- Cost and complexity of creating state regulations and regulatory body
- State Regulation

- State regulation would drive up costs in an already affordable and low-risk market

Opportunities

- Access in regulated system
- People can access mushrooms with healthcare professional in a supervised setting
- Regulated supply
- Access to a regulated system
- Access to experience
- Improved data on drug-drug interactions, outcomes for under-studied patient populations
- Could tap the legacy market for expertise in growing and facilitation

Threats

- Administrators and centers could be targets of FDA/DEA
- Cost to client
- Safety and expertise of mushroom growing supply
- A state program would invite inevitable over-regulation
- State-controlled process has the danger of "one-size-fits-all" without concern for Native ceremonies, other non-Western approaches to this medicine, or alternative approaches to these mushrooms that have been used for millennia. It's important to not lose the sacred aspect of mushrooms.