Utah Mental Illness Psychotherapy Drug Task Force (MIPDT)
Report to the Utah Legislature
Two-Page Summary

Executive Summary

- A comprehensive evidence review was performed by the DRRC at the University of Utah College of Pharmacy using evidence synthesis experts (for detailed methods see Appendix E).
- The report focused on safety and efficacy of methylenedioxymethamphetamine (MDMA) and psilocybin in enhancing psychotherapy for specific psychiatric disorders. The evidence review suggests:
  - Preliminary evidence indicates MDMA-assisted psychotherapy employing the 40-hour MAPS protocol is more effective than placebo or low dose MDMA-assisted psychotherapy in decreasing symptoms of PTSD during acute treatment trials.
  - Psilocybin-assisted psychotherapy may be more effective than placebo-assisted psychotherapy in acute treatment trials for treatment resistant depression (TRD) and in end-of-life care for patients with symptoms of depression and anxiety. However, additional larger confirmatory trials are needed, and the existing evidence is limited by bias threats (e.g., expectancy bias from lack of blinding or unblinding of participants, and possible attrition bias).
  - Safety data for both MDMA and psilocybin is encouraging but incomplete at this time.
  - There was not enough peer reviewed data to make any recommendations about either efficacy or safety for lysergic acid diethylamide (LSD), ayahuasca or ibogaine-assisted psychotherapy.
- Without FDA approval needed government and commercial financing mechanisms that offset patient costs are not available.
- Pathways currently exist for patient access including participation in a clinical trial and compassionate use status.
- Differences between psychedelic compounds and cannabis
  - Psychedelic compounds have two fast-track New Drug Approval applications open
  - FDA approval comes with regulations (manufacturing, administration, storage and safety standards)
  - Associated costs far exceed those of cannabis
- The most rigorous and cost-effective approach to ensuring that the people of Utah have safe access to the most effective programs in psychedelic-assisted psychotherapy would be to wait for the fast-track FDA rulings for MDMA and psilocybin Evidence Review Process.

Indications and Prescribing Practices

- This workgroup reviewed specific recommendations that include appropriate administration and dosage; frequency drug may be used; potential psychotherapeutic modalities with which drug may be used; and any necessary follow-up after an individual takes drug. Recommendations that should be followed are found in steps I-IV, p. 16-17, steps I-III, p. 17-18 and p. 19-21 of the report.

Licensure and Training Needs

- This workgroup reviewed specific recommendations that include any license or credential required; training that may be helpful or should be required; if an additional license or credential is recommended; and procedures for administration of the license or credential. Recommendations that should be followed are found in steps I-V, p. 21-24 in the report.

Patient Safety

- This workgroup reviewed specific recommendations that include any safety requirements regarding a drug; any procedures to appropriately obtain, store and monitor use; and any procedures for data tracking. Recommendations that should be followed are found on p. 24-28 of the report.

Ethical Considerations and Regulation

- This workgroup reviewed specific recommendations that include any organizations that may provide perspective on ethical considerations; any long-term societal impacts on use of a drug; and proposed regulations the Legislature should consider in passing legislation that permits the use of psychotherapy drugs to enhance psychotherapy ahead of FDA approval. Recommendations that should be followed are found on p. 29-32 of the report.

Conclusions and Recommendations for Next Steps

- MDMA and psilocybin are two schedule I controlled substances with a growing body of evidence supporting efficacy and safety as medication adjuncts to facilitate manualized psychotherapy for specific disorders.
- Both substances are under fast-track FDA review and we may see FDA approval for MDMA assisted-psychotherapy for the treatment of PTSD as soon as the end of 2023.
- The MIPDTF recommends Utah **NOT** proceed with the creation of any psychedelic-assisted psychotherapy program ahead of FDA approval. This is the most conservative course of action to ensure the safety of citizens of Utah while minimizing regulatory burdens and cost.
- If this course is not taken and the legislature decides to make these substances available:
  - The extensive manufacturing, safety and regulatory guidelines outlined in the report should be followed.
  - Two prerequisites to any such legislation are recommended by the task force, 1) A fiscal analysis of the one-time and the ongoing costs of developing a statewide program overseeing psychedelic-assisted psychotherapy to the taxpayers of Utah and 2) Development of a risk evaluation and mitigation strategy (REMS) for drug safety to help ensure the benefits of psychedelic-assisted psychotherapy outweigh its risks and an assessment as to what governmental entity should be responsible for managing this part of the regulatory framework.
- Based on the comprehensive nature of the evidence review conducted for this report, no additional evidence review for other schedule I controlled substances is recommended at this time.

This two-page summary was prepared by Cynthia Levinthal, MBA.

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