**OHIO STATE MEDICAL ASSOCIATION HOUSE OF DELEGATES**

**Resolution No. 28 – 2021**

**Introduced by:** Medical Student Section

**Subject:** Acknowledging and Supporting Psychiatric Research Involving Psychedelic Substances

**Referred to:** Resolutions Committee #3

**- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -**

**WHEREAS**, From 2013–2017, the annual average prevalence of past-year Major Depressive Episode (MDE) in Ohio was 12.5% (or 112,000), of which only an annual average of 47.9% (or 53,000) received depression care1; and

**WHEREAS**, From 2014–2017, the annual average prevalence of past-year tobacco use among people aged 12 years or older in Ohio was 34.2% (or 3,329,000), which is higher than the national average (28.9%)1; and

**WHEREAS**, From 2014–2017, the annual average prevalence of past-year alcohol use disorder in Ohio was 6.1% (or 594,000), which is higher than the national average (5.8%)1; and

**WHEREAS**, There is a shortage of access to treatment for patients suffering from addiction and mental disease2-3; and

**WHEREAS**, In research conducted over the last decade, compounds with psychedelic effects have shown promise in the treatment of treatment-resistant depression,4 PTSD,5-7 tobacco,8-9 and alcohol,10 addiction, and end-of-life anxiety and depression in cancer patients;11-13; and

**WHEREAS**, The Food and Drug Administration has granted breakthrough therapy status to three separate indications involving psychedelic compounds: psilocybin for treatment resistant depression, psilocybin for treatment of Major Depressive Disorder, and MDMA for treatment of Post-Traumatic Stress Disorder;14-15; and

**WHEREAS**, Given the completion of FDA Phase III trials for the clinical use of MDMA for treatment of Post-Traumatic Stress Disorder, these substance-assisted therapies have the potential for regulatory approval as early as 202116; and

**WHEREAS**, Clinical use of Psilocybin for treatment of Major Depressive Disorder is undergoing several FDA Phase II trials in 2020-202;17-18; and

**WHEREAS**, Current State of Ohio law does not prohibit research utilizing controlled substances conducted under the auspices of an accredited medical school involving an approved investigational new drug (IND) in conformance with approval granted by an accredited institutional review board;20; **therefore be it**

**RESOLVED,** The OSMA supports further rigorous, controlled, longitudinal studies of psilocybin and MDMA therapy in patients who have mental health conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease; and, **be it further**

**RESOLVED**, Our OSMA acknowledges that the status of psilocybin and MDMA as federal schedule I22 controlled substances must be reviewed in light of evidence in contradiction with the standard definition of schedule I, with the goal of facilitating the conduct of clinical research and development of psilocybin- and MDMA-based therapies; and, **be it further**

**RESOLVED,** Our OSMA recognizes that further scientific evidence on the therapeutic uses of psilocybin and MDMA is needed to meet the current standards for a prescription drug product before the implementation of state-based medical psilocybin and MDMA programs.

**Fiscal Note:** $ (Sponsor)

$ 500 (Staff)

**References**

1. Substance Abuse and Mental Health Services Administration. Behavioral Health Barometer: Ohio, Volume 5: Indicators as measured through the 2017 National Survey on Drug Use and Health and the National Survey of Substance Abuse Treatment Services. HHS Publication No. SMA-19-Baro-17-OH. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019.
2. STAT Overzealous use of the CDC’s prescribing guideline is harming patients by Kate M. Nicholson, Diane E. Hoffman, and Chad D. Kollas December 6, 2018
3. With Opioids, Government Is the Problem, Not the Solution by Jeffrey A. Singer CATO Institute. Article in USA Today July 31, 2017
4. Carhart-Harris, R. L. et al. Psilocybin with psychological support for treatment-resistant depression: an open-label feasibility study. Lancet Psychiatry **3**, 619–627 (2016).
5. Mithoefer, M. C. et al. 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for post-traumatic stress disorder in military veterans, firefighters, and police officers: a randomised, double-blind, dose-response, phase 2 clinical trial. Lancet Psychiatry **5**, 486–497 (2018).
6. Mithoefer, M. C. et al. MDMA-assisted psychotherapy for treatment of PTSD: study design and rationale for phase 3 trials based on pooled analysis of six phase 2 randomized controlled trials. Psychopharmacology (Berl.) **236**, 2735–2745 (2019).
7. Mithoefer, M. C., Wagner, M. T., Mithoefer, A. T., Jerome, L. & Doblin, R. The safety and efficacy of ±3,4-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder: the first randomized controlled pilot study. J. Psychopharmacol. (Oxf.) **25**, 439–452 (2011).
8. Johnson, M. W., Garcia-Romeu, A., Cosimano, M. P. & Griffiths, R. R. Pilot study of the 5-HT2AR agonist psilocybin in the treatment of tobacco addiction. J. Psychopharmacol. (Oxf.) **28**, 983–992 (2014).
9. Johnson, M. W., Garcia-Romeu, A. & Griffiths, R. R. Long-term follow-up of psilocybin-facilitated smoking cessation. Am. J. Drug Alcohol Abuse **43**, 55–60 (2017).
10. Bogenschutz, M. P. et al. Psilocybin-assisted treatment for alcohol dependence: A proof-of-concept study. J. Psychopharmacol. (Oxf.) **29**, 289–299 (2015).
11. Griffiths, R. R. et al. Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. J. Psychopharmacol. Oxf. Engl. **30**, 1181–1197 (2016).
12. Ross, S. et al. Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial. J. Psychopharmacol. Oxf. Engl. **30**, 1165–1180 (2016).
13. Grob, C. S. et al. Pilot Study of Psilocybin Treatment for Anxiety in Patients With Advanced-Stage Cancer. Arch. Gen. Psychiatry **68**, 71–78 (2011).
14. "COMPASS Pathways Receives FDA Breakthrough Therapy Designation for Psilocybin Therapy for Treatment-resistant Depression – COMPASS". compasspathways.com. Retrieved 2020-11-03.
15. "FDA grants Breakthrough Therapy Designation to Usona Institute's psilocybin program for major depressive disorder". www.businesswire.com. 2019-11-22. Retrieved 2020-11-03.
16. Mithoefer, M., & MAPS Public Benefit Corp. (2018, May 5 - 2020, October 25th). A Multi-Site Phase 3 Study of MDMA-Assisted Psychotherapy for PTSD (MAPP1). Identifier NCT03537014. https://clinicaltrials.gov/ct2/show/NCT03537014
17. Johns Hopkins University (U.S.). (2017, August - 2020, December). Effects of Psilocybin in Major Depressive Disorder. Identifier NCT03181529. https://clinicaltrials.gov/ct2/show/NCT03181529
18. Usona Institute (U.S.). (2019, October - 2021, February). A Randomized, Double-Blind, Support-of-Concept Phase 2 Study of Single-Dose Psilocybin for Major Depressive Disorder (MDD). Identifier NCT03866174. https://clinicaltrials.gov/ct2/show/NCT03866174
19. “Public Law No: 115-176 (05/30/2018)” [www.congress.gov](http://www.congress.gov). Retrieved 2020-11-29

## “4731-11-07. Research Utilizing Controlled Substances” www.codes.ohio.gov. Retrieved 2020-11-29

## “4729:9-1-01. Schedule I Controlled Substances” www.codes.ohio.gov. Retrieved 2020-11-03

1. Drug Scheduling. DEA.gov. Accessed November 4, 2020. <https://www.dea.gov/drug-scheduling>