

MDDCSAM is the Maryland state chapter of the American Society of Addiction Medicine whose members are physicians and other health providers who treat people with substance use disorders.

SB 1009 Task Force on Responsible Use of Natural Psychedelic Substances

SUPPORT WITH AMENDMENTS

Finance Committee March 14, 2024

Dear Chair Beadle and members of the committee,

We have changed our position from 'Oppose' to 'Support with Amendments' for this Senate version. **The amendments below are also proposed by the Maryland Public Health Association (MdPHA).**

We are providing information on risks (1) because risks are often underestimated during enthusiasm for a new therapy, and (2) to illustrate that a **psychedelics Task Force must be unconstrained and free to consider all scenarios, not legally bound to make recommendations regarding changes needed to create a "Maryland Natural Psychedelic Substance Access Program" a priori.**

We share the excitement about expected benefits of psychedelics enumerated by other proponents. Though generally safe, harms have been reported in a minority of those using psychedelics. (Raison). Long-term adverse experiences following psychedelic use **can persist for weeks, months or years.** (Evans) After ingesting psilocybin mushrooms, 2.6% behaved in a physically aggressive or violent manner, **2.7% received medical help**, and of those whose experience occurred more than a year earlier, **7.6% sought treatment for enduring psychological symptoms.** (Carbonaro) Psychedelics have **the potential to be addicting.** (Prekupec) (Flameling). **Hallucinogen-associated ER visits and hospitalizations each increased by over 50%** in California from 2016 to 2022. (Garel). Some individuals believe that their psychedelic use had contributed to **suicidal ideation, aggressive or impulsive behavior and/or misuse of benzodiazepines and opiates.** (Raison) Since 2013 over 4,000 psilocybin-involved exposures among adolescents and young adults, were reported to the National Poison Data System. This number was initially stable, but **tripled from 2019 to 2022 among adolescents and more than doubled among young adults, compared to 2018.** (Farah 2024) The American Psychiatric Association has urged caution in their 2022 Position Statement on psychedelics excerpted below. (APA)

Psychedelic-associated harms have not yet been adequately studied, especially in naturalistic settings. (Raison) (Evans).

MDDCSAM AND MdPHA PROPOSED AMENDMENTS:

Starting at page 3, line 3:

The Task Force shall: (1) study:

- (i) existing laws, policies, and practices relating to the use of natural psychedelic substances;
- (ii) the best available science and data on public benefits of responsible legal access to and use of natural psychedelic substances;

(iii) opportunities to maximize public benefits of if responsible legal access to and use of natural psychedelic substances becomes available.

(iv) the best available data on potential risks of responsible legal access to and use of natural psychedelic substances;

Whether or not potential benefits outweigh potential risks of legal access to and use of natural psychedelic substances, compared to decriminalization of these substances alone; and

(v) opportunities to mitigate potential risks of legal access to and use of natural psychedelic substances; and potential risks and benefits of legal access to and use of natural psychedelic substances limited to Food and Drug Administration (FDA)-approved substances and indications when available vs. legal access to these substances and indications beyond those approved by the FDA.

(vi) barriers health care practitioners and facilitators may encounter relating if legal access to natural psychedelic substances becomes available, including barriers relating to insurance, restrictions by licensing and credentialing entities, zoning, advertising, and financial services

The Task Force shall . . .

(2) make recommendations regarding whether or not a mechanism for legal access to natural psychedelics is advisable, including any changes to State law, policy, and practices that would be needed to create such a mechanism ~~a Maryland Natural Psychedelic Substance Access Program~~ that enables broad, equitable, and affordable access to psychedelic substances, including:

(i) permitting requirements, including requirements regarding education and safety;

(ii) access to treatment and regulated support; and

(iii) production of natural psychedelic substances; restrictions by licensing and credentialing entities, zoning, advertising, and financial services.

RATIONALE:

The FDA's scientific process for establishing drug safety and efficacy has only been bypassed when "medical cannabis" was established (for good reason) by state legislatures as a back-door means of legalizing a substance already widely used illegally. This has reduced devastating legal consequences, but required state legislators to establish pseudo-medical indications (Burnett) without scientific considerations of harms that have resulted (e.g., increases in cannabis use disorder).

Compared to cannabis, psychedelics are used illegally by far fewer people. Also, serious legal consequences can and should be addressed by decriminalization now, possibly with a system of state-licensed retailers. **The need for the state to determine approval of substances, indications and precautions, bypassing the FDA process at this time, is not clear and should be determined by the Task Force.**

Unlike cannabis, FDA approval of psychedelics appears imminent with several phase II and phase III clinical trials completed or underway. Compass Pathways, Ltd. and Usona Institute, have received FDA “breakthrough” designation for psilocybin to treat depression. Half-a-dozen ongoing clinical trials are listed on the ClinicalTrials.gov website.

Unlike state legislatures, the FDA has the expertise to weigh scientific evidence for safety and efficacy. Unlike state legislatures, the FDA is **far less susceptible to ongoing commercial and political influence that tends to grow as commercial interests expand**. Several companies, some valued at over a billion dollars, have emerged to compete in the psychedelics market. (Raison). Alcohol and tobacco corporations continue to exert influence over laws and regulations. (Barry) (WHO) **Legalized cannabis, along with its important benefits, will lead to a powerful consolidated market, and has already led to a small army of cannabis providers promoting and initiating long-term treatment for various conditions without evidence of effectiveness, likely to result in harms to some patients**. Patients get much or most of their medical cannabis advice from dispensary staff (“budtenders”) with no expertise and an incentive to make sales. A study of dispensaries found that nearly 70% recommended cannabis products to manage nausea in the first trimester of pregnancy contrary to medical society recommendations. (Dickson)

We strongly support all of the bill’s decriminalization provisions, which can and should be enacted now.

With these amendments, we urge a favorable report.

Respectfully,

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REFERENCES:

- APA (American Psychiatric Association) 2022 Position Statement on the Use of Psychedelic and Empathogenic Agents for Mental Health Conditions Excerpt:
“...given growing public interest and commercial interest, ... there is the risk that use of psychedelics for purported clinical goals may outpace evidence-based research and regulatory approval.

“There is currently inadequate scientific evidence for endorsing the use of psychedelics to treat any psychiatric disorder except within the context of approved investigational studies. APA supports continued research and therapeutic discovery into psychedelic agents with the same scientific integrity and regulatory standards applied to other promising therapies in medicine...”

<https://www.psychiatry.org/getattachment/d5c13619-ca1f-491f-a7a8-b7141c800904/Position-Use-of-Psychedelic-Empathogenic-Agents.pdf>

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- Burnett GM, et. al. Policy Ahead of the Science Medical Cannabis Laws Versus Scientific Evidence. Psychiatr Clin N Am 45 (2022) 347–373.
- Carbonaro TM, et. al. Survey study of challenging experiences after ingesting psilocybin mushrooms: Acute and enduring positive and negative consequences. Journal of Psychopharmacology 2016, Vol. 30(12) 1268–1278
- Dickson B,, et. al. Recommendations From Cannabis Dispensaries About First-Trimester Cannabis Use. Obstet Gynecol. 2018;131(6):1031-1038.
- Evans J, et al. Extended difficulties following the use of psychedelic drugs: A mixed methods study. 2023. PLoS One;18(10):e0293349.
- Farah R, et. al. Psilocybin Exposures Reported to US Poison Centers: National Trends Over a Decade. Journal of Adolescent Health xxx (2024) 1-4
- Flaming J. et. al. Not too quick on “Debunking the myth of ‘Blue Mondays’”. J Psychopharmacol. 2022 Aug; 36(8): 1001–1004.
- Garel N, et al. Trends in hallucinogen-associated emergency department visits and hospitalizations in California, USA, from 2016 to 2022. Addiction. 11 January 2024.
- Raison CL, et. al. Effects of Naturalistic Psychedelic Use on Depression, Anxiety, and Well-Being: Associations With Patterns of Use, Reported Harms, and Transformative Mental States. March 2022. Frontiers in Psychiatry. Vol. 13:831092.
- WHO (World Health Organization) Framework Convention on Tobacco Control. 2003 free: <https://www.paho.org/en/documents/who-framework-convention-tobacco-control#:~:text=The%20WHO%20Framework%20Convention%20on,the%20highest%20standard%20of%20health.>
