



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.

HB 548. Task Force on Responsible Use of Natural Psychedelic Substances

OPPOSED Health and Government Operations Committee February 21, 2024

Society is understandably impatient to make new therapies available. Justifiable excitement has been generated over the past decade by surveys showing therapeutic benefit from self-medication with psychedelics (Raison) and a handful of controlled clinical trials reporting that psychedelics in clinical settings with extensive psychotherapeutic support—produce **rapid, robust, and sustained improvements in a variety of psychiatric conditions including addictions.** (Lowe)).

Although use of psychedelics is 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, and **are relatively unexplored in psychedelic research.** (Evans). Among approximately 2,000 individuals who had ingested 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 emergency department visits and hospitalizations increased by 54% and 55%, respectively, in California from 2016 to 2022. (Garel). Some individuals believe that their psychedelic use had contributed to suicidal ideation, aggressive/impulsive behavior and/or misuse of benzodiazepines and opiates. (Raison) In unsafe and un-monitored settings, psychedelics have rarely been associated with suicide (a preliminary finding due to the limited nature of the evidence). (Zeifman). **Information on psychedelic-associated harms is incomplete; this area has not yet been adequately studied, especially in naturalistic settings.** (Raison)

A scientific process by the Federal Drug Administration (FDA) has been the standard for establishing drug safety and effectiveness, and safeguarding the public, for over a hundred years. This process has only been bypassed, for understandable reasons, when “medical cannabis” was established 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 without a scientific process (Burnett) that resulted in some harms (e.g., increases in cannabis use disorder). Why re-create this environment with psychedelics?

There is no need to apply the medical cannabis model to psychedelics. **Psychedelics are used illegally by far fewer people.** Also, serious legal consequences can and should be addressed by decriminalization and/or legalization of psychedelics now, possibly with a system of state-licensed retailers, without the need to set-up pseudo-medical approval for health indications by state legislatures.

Also, **unlike cannabis, psychedelics are already in the FDA’s drug development pipeline, with several phase II and phase III controlled clinical trials completed or underway.**

FDA-approved psychedelic medications to treat depression, anxiety, and a substance use disorders are likely to be available soon. Two entities, Compass Pathways, Ltd. and Usona Institute, have received FDA “breakthrough” designation for psilocybin to treat depression. Half-a-dozen ongoing clinical trials with psychedelic-assisted psychotherapy are listed on the ClinicalTrials.gov website. **In the case of psychedelics, there is no pressing need to take the almost unprecedented step of bypassing the FDA approval process.**

The FDA process serves the critical purpose of weighing scientific evidence for drug safety and efficacy. Unlike state legislatures, it has the necessary expertise, and **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)

A Task Force could be re-visited in the future after more information is available on possible risks, complications, needed precautions, and appropriate dosage and indications in the unlikely event that the FDA process becomes protracted or inadequate.

We strongly support all of the bill’s decriminalization provisions, which can and should be enacted now, without the establishment of a Task Force biased toward a pre-established goal of state regulation of therapeutic psychedelics.

The bill would establish a Task Force that “shall... make recommendations regarding any changes to state law, policy, and practices **needed to create a Maryland Natural Psychedelic Substance Access Program.**” Throughout the description of the Task Force’s mandate, **it will be legally required to lead to a natural psychedelic substance access program, prohibited from determining whether or not such a program should be established.**

If a Task Force is ever contemplated in the future, it should be given the flexibility to examine all of the evidence, including pros and cons of such an access program.

Our position is consistent with that of the American Psychiatric Association's 2022 Position Statement on the Use of Psychedelic and Empathogenic Agents for Mental Health Conditions:

Excerpt:

"...given growing public interest and commercial interest, and the ever-compelling need to advance treatments for challenging psychiatric conditions, 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. Clinical treatments should be determined by scientific evidence in accordance with applicable regulatory standards and not by ballot initiatives or popular opinion."

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

Respectfully,

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