



**TESTIMONY IN OPPOSITION TO H.4255
AN ACT RELATIVE TO THE REGULATION AND TAXATION OF NATURAL
PSYCHEDELIC SUBSTANCES
BEFORE THE JOINT COMMITTEE ON INITIATIVE PETITIONS
MARCH 26, 2024**

The Massachusetts Medical Society is a professional association of over 25,000 physicians, residents, and medical students across all clinical disciplines, organizations, and practice settings. The Medical Society is committed to advocating on behalf of patients, to give them a better health care system, and on behalf of physicians, to help them provide the best care possible. The MMS supports decriminalization of personal drug use and possession for personal drug use, enhancing treatment over incarceration, which significantly minimizes risk of harm to those who suffer from substance use disorder. To that end, we support the decriminalization of psychedelic substances. However, we oppose creating a system that characterizes psychedelic therapy as evidence-based when the safety and efficacy of these agents have not been fully reviewed by the United States Food and Drug Administration (FDA), nor have these agents been approved for clinical indication. For these reasons, the Medical Society wishes to be recorded in opposition to **H.4255, *An Act relative to the regulation and taxation of natural psychedelic substances.***

The use of psychedelic substances for psychiatric and other medical indications is currently investigational. Encouraging preliminary research on psychedelics for treating severe and debilitating conditions like treatment-resistant depression (TRD) and posttraumatic stress disorder (PTSD) have sparked increasing interest in the therapeutic possibilities of these substances.¹ In these studies, substances have been given to carefully screened participants within tightly controlled environments.² Typically, they have been paired with structured

¹ American Psychiatric Society. Policy Document. *Position Statement on the Use of Psychedelic and Empathogenic Agents for Mental Health Conditions*. July 2022.
<https://www.psychiatry.org/getattachment/d5c13619-ca1f-491f-a7a8-b7141c800904/Position-Use-of-Psychedelic-Empathogenic-Agents.pdf>

² *ibid.*

psychotherapy protocols proposed by researchers as crucial for attaining maximum therapeutic benefits and safeguarding the safety and well-being of the participant.³

The FDA granted two breakthrough therapy designations for psilocybin in TRD in 2018 and major depressive disorder in 2019, as well as for MDMA for PTSD in 2017.⁴ With breakthrough status, the clinical trials for psilocybin and MDMA have been designed with intensive FDA guidance to expedite the review of these agents. There is a persistent need to advance treatments for complex psychiatric disorders. However, clinical treatments should be dictated by scientific evidence in accordance with appropriate regulatory standards, rather than by popular opinion or commercial interests. There is currently insufficient scientific evidence to support the use of psychedelics in treatment of any psychiatric disorder, except within the confines of approved investigational studies. The MMS therefore supports continued ongoing research and therapeutic exploration into psychedelic agents, conducted with the same scientific rigor, adherence to regulatory standards, and ethical safeguards as other promising therapies in medicine.

Establishing “psychedelic therapy centers” as proposed by H.4255, conveys a message to the public that viable treatment is being offered, yet the regulatory framework proposed lacks scientific and legal standards inherent in health care. Oregon’s example underscores that a significant portion of those seeking psychedelic services will do so for mental health concerns. Contrary to claims that H.4255 will increase access to mental health care, these services will be expensive, will not be covered by insurance, will operate independently from existing treatment frameworks, and will be administered by facilitators who lack appropriate clinical credentials. Until rigorous research establishes their efficacy, portraying psychedelic therapy as evidence-based on a population-wide basis is premature and jeopardize public safety by exposing individuals to the psychological and physical side effects associated with these substances without appropriate clinical oversight.

³ *ibid.*

⁴ Heal DJ, Smith SL, Belouin SJ, Henningfield JE. Psychedelics: Threshold of a Therapeutic Revolution. *Neuropharmacology*. 2023 Sep 15;236:109610. doi: 10.1016/j.neuropharm.2023.109610. Epub 2023 May 27. Meisner JA, Wilcox SR, Richards JB. Ibogaine-associated cardiac arrest and death: case report and review of the literature. *Ther Adv Psychopharmacol*. 2016 Apr;6(2):95-8. doi: 10.1177/2045125315626073. Epub 2016 Jan 13. PMID: 27141291; PMCID: PMC4837967. PMID: 37247807. <https://pubmed.ncbi.nlm.nih.gov/37247807/>

The MMS is particularly concerned about the dangerous inclusion of ibogaine in H.4255. Ibogaine has known risks for inducing arrhythmia, which can lead to fatal cardiac arrest.⁵ Clinical guidelines created by ibogaine treatment providers recommend ibogaine administration exclusively within a health care facility and under the supervision of trained professionals.⁶ This supervision should entail, at a minimum, a review of medications, laboratory tests, and an electrocardiogram (EKG), owing to the genuine risk of cardiac arrest.⁷ Until further research is conducted, ibogaine should only be accessible within tightly controlled research settings.

Additionally, the inclusion of ibogaine and Dimethyltryptamine (DMT) in H.4255 poses a significant risk of serious, and potentially fatal, Drug-drug interactions (DDI). H.4255 fails to incorporate safeguards ensuring that the “licensed facilitators” overseeing psychedelic substance administration in “natural psychedelic service” sessions possess the requisite clinical expertise to identify potentially serious DDIs between commonly prescribed medications and the psychedelic substances ibogaine and DMT. Several of these medications have the potential to inhibit the liver's Cytochrome P450 2D6 enzyme, leading to a slowdown in the metabolism of ibogaine.⁸ This can lead to potentially dangerous accumulations of ibogaine in the body, sometimes resulting in fatal consequences. Among these medications are antidepressants, antiretroviral drugs, cardiac medications, cannabidiol, and antifungal medications. Moreover, DMT has the potential to interact with certain antidepressants containing serotonin, increasing the risk of life-threatening serotonin syndrome.⁹

Furthermore, H.4255 has the potential to increase the risk of psychotic disorders and mania on a population-wide basis. Individuals with pre-existing psychotic disorders and bipolar disorders, and those with high genetic susceptibility to psychotic or bipolar disorders, would be particularly vulnerable. Psilocybin/psilocin, ibogaine, mescaline and DMT have been

⁵ Meisner JA, Wilcox SR, Richards JB. Ibogaine-associated cardiac arrest and death: case report and review of the literature. *Ther Adv Psychopharmacol*. 2016 Apr;6(2):95-8. doi: 10.1177/2045125315626073. Epub 2016 Jan 13. PMID: 27141291; PMCID: PMC4837967. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4837967/>

⁶ Global Ibogaine Therapy Alliance. *Clinical Guidelines for Ibogaine-Assisted Detoxification*, 1st edition. Version 1.1. [Internet]. 2015. Available from: <https://ibogaineguidelines.com/>

⁷ *ibid*.

⁸ Litjens RP, Brunt TM. How toxic is ibogaine? *Clin Toxicol (Phila)*. 2016;54(4):297-302. doi: 10.3109/15563650.2016.1138226. Epub 2016 Jan 25. PMID: 26807959. <https://pubmed.ncbi.nlm.nih.gov/26807959/>

⁹ Perez A. Everything you need to know about DMT. *Medical News Today*. January 10, 2023. <https://www.medicalnewstoday.com/articles/306889>

documented to cause psychosis (both new onset psychosis and exacerbation of psychotic symptoms), mania, and new on-set mania in persons with no previous history of bipolar disorder, and mental health symptoms that may be long-lasting after ingestion of the psychedelic substance.

While psychedelic substances hold promise for future mental health treatments, this proposal is premature and not suitable for implementing what are still experimental therapies on a population-wide scale. Furthermore, H.4255 disregards the potential risk of fatalities and public safety by treating all natural psychedelic substances, such as ibogaine and DMT, as if they present identical risks and benefits, which is not the case. For these reasons, the Medical Society respectfully urges further study on H.4255, *An Act relative to the regulation and taxation of natural psychedelic substances*.