



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Acting Secretary

February 21, 2024

The Honorable Chair Joseline Pena-Melnyk,
Chair, Health and Government Operations Committee
Room 241, House Office Building
Annapolis, MD 21401-1991

RE: House Bill 548-Task Force on Responsible Use of Natural Psychedelic Substances – Letter of Support with Amendments

Dear Chair Pena-Melnyk and Committee Members:

The Maryland Department of Health (the Department) respectfully submits this letter of support for House Bill (HB) 548-Task Force on Responsible Use of Natural Psychedelic Substances.

HB 548 establishes the Task Force on Responsible Use of Natural Psychedelic Substances to study and make recommendations related to the use of natural psychedelic substances and requires the Task Force to submit its findings and recommendations to the Governor and the General Assembly on or before December 15, 2025

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed. FDASIA Section 902 provides for a new designation - Breakthrough Therapy Designation. A breakthrough therapy is a drug:

- intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition and
- preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.¹

The past several years have shown the re-emergence of thoughtful investigations into psychedelics studying the utility of compounds such as 3,4-methylenedioxymethamphetamine (MDMA) and psilocybin, as breakthrough treatments for patients with mood disorders or post-traumatic stress disorder (PTSD) who have already failed multiple interventions.² In fact, MAPS Public Benefit Corp. filed an application in December 2023 with the U.S. Food and Drug Administration to approve MDMA in combination with therapy to treat post-traumatic stress disorder, after two Phase 3 clinical trials.³

¹ United States Food and Drug Administration (2018). Fact Sheet: Breakthrough Therapies. Accessed via the internet on January 31, 2024: <https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fact-sheet-breakthrough-therapies>

² Barber GS, Aaronson ST. The Emerging Field of Psychedelic Psychotherapy. *Curr Psychiatry Rep.* 2022 Oct;24(10):583-590. doi: 10.1007/s11920-022-01363-y. Epub 2022 Sep 21.

³ Multidisciplinary Association for Psychedelic Studies. MDMA-Assisted Therapy for PTSD. Accessed via the internet on January 31, 2024. <https://maps.org/mdma/ptsd/>

This is an emerging field that should be studied for potential risks and benefits in Maryland. The Department is pleased to support this effort with a representative to the Taskforce. However, the Department does not currently have resources or expertise to provide staff to the Task Force.

The Department proposes an amendment to transfer the responsibility for providing staff to the Task Force from the Maryland Department of Health to the Maryland Alcohol, Tobacco and Cannabis Commission (ATC). The ATC houses the Maryland Cannabis Administration (MCA), which is the agency best positioned to support the Task Force due to their experience with cannabis policy in Maryland.

MDH has included proposed amendment language for the Committee's consideration to remove the responsibility to staff the Taskforce from the Maryland Department of Health.

If you have any further questions, please contact Sarah Case-Herron, Director, Office of Governmental Affairs at sarah.case-herron@maryland.gov.

Sincerely,



Laura Herrera Scott, M.D., M.P.H.
Secretary

AMENDMENTS TO HOUSE BILL 548
(First Reading File Bill)

AMENDMENT NO. 1

On page 3, line 9, strike “THE MARYLAND DEPARTMENT OF HEALTH” before “SHALL PROVIDE STAFF FOR THE TASK FORCE.”

Explanation: Remove the Maryland Department of Health from responsibility for providing staff for the Task Force.

AMENDMENT NO. 2

On page 3, line 9, insert “THE MARYLAND ALCOHOL, TOBACCO, AND CANNABIS COMMISSION” before “SHALL PROVIDE STAFF FOR THE TASK FORCE.”

Explanation: Provide necessary staff support for the Task Force from the Maryland Alcohol, Tobacco, and Cannabis Commission, to replace the support removed from the Maryland Department of Health.