

STAND. COM. REP. NO.

1047

Honolulu, Hawaii

MAR 03

, 2023

RE: H.B. No. 1340
H.D. 2

Honorable Scott K. Saiki
Speaker, House of Representatives
Thirty-Second State Legislature
Regular Session of 2023
State of Hawaii

Sir:

Your Committee on Consumer Protection & Commerce, to which was referred H.B. No. 1340, H.D. 1, entitled:

"A BILL FOR AN ACT RELATING TO MENTAL HEALTH,"

begs leave to report as follows:

The purpose of this measure is to establish the Beneficial Treatments Advisory Council to:

- (1) Review, evaluate, and recommend new medicinal treatments for mental health; and
- (2) Develop a long-term strategic plan to ensure the availability of therapeutic psilocybin and 3,4-methylenedioxymethamphetamine.

Your Committee received testimony in support of this measure from the Office of Wellness and Resilience, Malama Mushrooms, Hawai'i Psychological Association, Beyond Mental Health, Clarity Project, Dawn Patrol Assessments, SoundMind Institute, and numerous individuals. Your Committee received comments on this measure from the Department of Health.

Your Committee finds that the breakthrough therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and

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preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. Your Committee further finds that actions on the breakthrough therapy designations for psilocybin and 3,4-methylenedioxymethamphetamine (MDMA) are imminent. As such, efforts for evaluating potentially beneficial treatments should be focused on future breakthrough therapy designations, rather than on the existing designations for psilocybin and MDMA.

Accordingly, your Committee has amended this measure by:

- (1) Authorizing the Director of Health to establish a temporary Breakthrough Therapy Designation Advisory Council within three months of a breakthrough therapy designation approval by the United States Food and Drug Administration, rather than establishing a Beneficial Treatments Advisory Council;
- (2) Specifying the composition, duties, reporting requirements, and duration of the Breakthrough Therapy Designation Advisory Council; and
- (3) Making technical, nonsubstantive amendments for the purposes of clarity, consistency, and style.

As affirmed by the record of votes of the members of your Committee on Consumer Protection & Commerce that is attached to this report, your Committee is in accord with the intent and purpose of H.B. No. 1340, H.D. 1, as amended herein, and recommends that it pass Third Reading in the form attached hereto as H.B. No. 1340, H.D. 2.

Respectfully submitted on
behalf of the members of the
Committee on Consumer
Protection & Commerce,



MARK M. NAKASHIMA, Chair



