THE SENATE
THIRTY-SECOND LEGISLATURE, 2023
STATE OF HAWAII

S.C.R. NO. 215

MAR 10 2023

# SENATE CONCURRENT RESOLUTION

REQUESTING THE DEPARTMENT OF HEALTH TO CONVENE A MEDICINAL PSYCHEDELICS RIGHT-TO-TRY TASK FORCE TO EXPLORE THE DEVELOPMENT OF A PROGRAM FOR QUALIFYING TERMINALLY ILL PATIENTS.

WHEREAS, the United States Food and Drug Administration's (FDA) approval process for investigational drugs and biological products protects patients in the United States from premature, ineffective, and unsafe medications and treatments, however, the approval process takes many years from start to final approval; and

WHEREAS, potentially beneficial treatments that have not been granted FDA approval can be unavailable to patients who have been diagnosed with a terminal illness thereby severely restricting their care options; and

WHEREAS, recognizing that terminally ill patients often do not have the time to wait for a potentially lifesaving investigational drug or biological product to obtain final FDA approval, the federal government and forty-one states have enacted "Right-to-Try" legislation that makes available experimental drugs that have not obtained FDA approval to terminally ill patients with no other medication or treatment options; and

WHEREAS, Hawaii has a shortage of mental health professionals and should actively consider nontraditional, innovative, and safe solutions to treat its residents; and

WHEREAS, studies conducted by nationally and internationally recognized medical institutions indicate that psilocybin and psilocin have shown efficacy, tolerability, and safety in the treatment of a variety of mental health conditions, including addiction, depression, anxiety disorders, and end-of-life psychological distress; and

WHEREAS, the FDA has determined that preliminary clinical evidence indicates that psilocybin and psilocin may demonstrate substantial improvement over available therapies for major depressive disorder and severe treatment-resistant depression and has designated psilocybin therapy a breakthrough therapy, which is meant to accelerate the typically sluggish process of drug development and review; and

WHEREAS, it is essential for the Legislature to have information to make an informed decision as to whether the State should enact its own "Right-to-Try" legislation that grants qualifying terminally ill patients access to experimental psychedelic drugs, including psilocybin and psilocin, that have not received final approval from the FDA; now, therefore,

BE IT RESOLVED by the Senate of the Thirty-second Legislature of the State of Hawaii, Regular Session of 2023, the House of Representatives concurring, that the Department of Health is requested to convene a Medicinal Psychedelics Right-to-Try Task Force to explore development of a program that grants qualifying terminally ill patients access to psychedelic drugs, including psilocybin and psilocin, prior to their receiving final approval from the FDA; and

BE IT FURTHER RESOLVED that the Medicinal Psychedelics Right-to-Try Task Force is requested to examine various issues pertaining to allowing qualifying terminally ill patients access to non-FDA-approved psychedelic drugs, including:

(1) Relevant federal and state laws and regulations;

(2) The types of non-FDA-approved psychedelic drugs that may be offered to a qualifying terminally ill patient in this State, including psilocybin and psilocin;

(3) Conditions under which a terminally ill patient may qualify to be granted access to the non-FDA-approved psychedelic drugs, including whether a prescription from a health care provider should be necessary;

(4) Methods by which the non-FDA-approved psychedelic drugs may be distributed to a qualifying terminally ill patient in the State;

(5) Costs of the non-FDA-approved psychedelic drugs to be incurred by the qualifying terminally ill patient;

(6) Health insurance coverage for non-FDA-approved psychedelic drugs; and

(7) Statutory protections that need to be granted to qualifying terminally ill patients who are granted access to non-FDA-approved psychedelic drugs and persons who engage or assist in providing qualifying terminally ill patients access to the non-FDA-approved psychedelic drugs, including health care providers, manufacturers, dispensaries, and persons who transport the drugs, if any; and

BE IT FURTHER RESOLVED that the following individuals, or their respective designees, are requested to serve as members of the Medicinal Psychedelics Right-to-Try Task Force:

(1) The Director of Health, who is requested to serve as chairperson of the task force;

(2) The Attorney General;

(3) Faculty members from the University of Hawaii System with relevant scientific expertise;

(4) The chairpersons of the Senate and House of Representatives Standing Committees whose subject matter purviews include health and the Judiciary;

(5) A clinical practitioner licensed to prescribe psychotropic medication in the State to be invited by the chairperson of the task force;

(6) A representative of the Drug Policy Forum of Hawaii, to be invited by the chairperson of the task force;

(7) A representative of the Clarity Project, to be invited by the chairperson of the task force;

(8) A representative of the Hawaii Psychiatric Medical Association, to be invited by the chairperson of the task force; and

(9) A representative of the public with psychedelics-related industry experience, to be invited by the chairperson of the task force; and

BE IT FURTHER RESOLVED that the chairperson of the Medicinal Psychedelics Right-to-Try Task Force may invite other interested parties with relevant experience to join the task force, provided that the task force does not exceed fifteen members; and

BE IT FURTHER RESOLVED that the Medicinal Psychedelics Right-to-Try Task Force is requested to submit a preliminary report of its findings and recommendations to the Legislature no later than twenty days prior to the convening of the Regular Session of 2024, and a final report of its findings and recommendations, including any proposed legislation, to the Legislature no later than twenty days prior to the convening of the Regular Session of 2025; and

BE IT FURTHER RESOLVED that the Medicinal Psychedelics Right-to-Try Task Force is requested to dissolve on July 1, 2025; and

BE IT FURTHER RESOLVED that certified copies of this Concurrent Resolution be transmitted to the Director of Health, who in turn shall notify the non-governmental organizations represented in the working group; Attorney General; and President of the University of Hawaii.

OFFERED BY: