HOUSE OF REPRESENTATIVES
TWENTY-EIGHTH LEGISLATURE, 2015
STATE OF HAWAII

H.B. NO. 882

A BILL FOR AN ACT

RELATING TO ACCESS TO EXPERIMENTAL MEDICAL TREATMENTS FOR TERMINALLY ILL PATIENTS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that terminally ill patients have the right to try to preserve their own lives by accessing investigational drugs, biological products, and devices that are available to patients in clinical trials. The legislature further finds that the United States Food and Drug Administration's approval process for investigational drugs, biological products, and devices may take years. While there are more than twenty thousand drugs deemed safe by the Federal Drug Administration (FDA) that are waiting to complete the approval process, only three per cent of the sickest patients are eligible for clinical trials.

The value of allowing terminally ill patients to access investigational drugs is particularly evident in the 2014 Ebola virus epidemic. The 2014 Ebola outbreak is the largest Ebola outbreak in history, with the Centers for Disease Control and Prevention (CDC) estimating that the total number of cases

exceeds three thousand. To date, there are no FDA-approved vaccines or drugs to prevent or treat the Ebola virus.

When two American workers were infected with the deadly Ebola virus in 2014, they were given the experimental drug "ZMapp" and showed dramatic improvements to their condition within one hour. The experimental drug was made available through the FDA's expanded access, or "compassionate use" regulation, which allows access to investigational drugs outside of clinical trials to treat a patient with a serious or immediate life-threatening disease or condition who has no comparable or satisfactory alternative treatment options.

FDA regulations allow access to investigational drugs for treatment purposes on a case-by-case basis for an individual patient, or for intermediate-size groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial. In order for a patient to qualify for expanded access to an investigational drug, FDA requirements state that the manufacturer of the investigational drug and the patient's doctor make special arrangements to obtain the drug for the patient, and that the arrangements must be authorized by the FDA.

It is the intent of the legislature to allow all terminally ill patients to seek out and use potentially life-saving investigational drugs, biological products, and devices that are currently available only through enrollment in clinical trials, and to eliminate any additional barriers at the state-level that would inhibit a patient's right to try to preserve their own life through experimental medical treatments. However, the patient's decision to use an investigational drug, biological product, or device is a decision that:

(1) Should be made in consultation with the patient's health care provider and the patient's health care team, if applicable; and

(2) Should be made with full awareness of the potential risks, benefits, and consequences to the patient and the patient's family.

SECTION 2. Chapter 328, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§ 328- Experimental medical treatments; access and eligibility.** (a) Notwithstanding the provisions of section 328-17 or any other law to the contrary, a manufacturer of an

experimental medical treatment, including investigational drugs, biological products, or devices, may make available the manufacturer's experimental treatment to eligible patients pursuant to this section. This section does not require a manufacturer to make available an experimental treatment to an eligible patient.

(b) A manufacturer may:

(1) Provide an experimental treatment to an eligible patient without receiving compensation; or

(2) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the experimental treatment.

(c) A health carrier may, but is not required to, provide coverage for the cost of an experimental treatment.

(d) A health carrier may deny coverage to an eligible patient from the time the eligible patient begins use of the experimental treatment through a period not to exceed six months from the time the experimental treatment is no longer used by the eligible patient; except that coverage shall not be denied for a preexisting condition and for coverage for benefits which

commenced prior to the time the eligible patient begins use of the experimental treatment.

(e) An official, employee, or agent of the State shall not block or attempt to block an eligible patient's access to an experimental treatment. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed practitioner is not a violation of this section.

(f) Notwithstanding any other law to the contrary, a State regulatory board shall not revoke, fail to renew, or take any other action against a physician's license based solely on a physician's recommendation to an eligible patient regarding the use of an investigational drug, biological product, or device under this section.

(g) Notwithstanding any other law to the contrary, a State agency shall not take any action against a health care institution's license based solely on the institution's participation in any treatment involving use of an investigational drug, biological product, or device under this section.

(h) This section shall not create a private cause of action against a manufacturer of an investigational drug,

biological product, or device, or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, from any harm done to the eligible patient resulting from the investigational drug, biological product, or device, provided that the manufacturer or other person or entity has acted in good faith and in accordance with the prevailing standard of care in their respective industries or professions.

(i) For the purposes of this section:

"Eligible patient" means a person who has:

(1) A terminal illness, as certified by the patient's treating physician;

(2) Considered all other treatment options currently approved by the United States Food and Drug Administration;

(3) Been unable to participate in a clinical trial for the terminal illness within miles of the patient's home address for the terminal illness, or not been accepted to the clinical trial within one week of completion of the clinical trial application process;

(4) Received a recommendation from his or her physician for an investigational drug, biological product, or device;

(5) Given written, informed consent for the use of the investigational drug, biological product, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written, informed consent on the patient's behalf; and

(6) Documentation from his or her physician that he or she meets the requirements of this section.

"Experimental treatment" means an investigational drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

"Health carrier" has the same meaning as in section 432E-1.

"Terminal illness" means an illness or physical condition which can reasonably be expected to result in death in twenty-four months or less."

SECTION 3. The director of health shall adopt rules, pursuant to chapter 91, necessary for the purpose of this chapter.

SECTION 4. New statutory material is underscored.

SECTION 5. This Act shall take effect on July 1, 2015.

INTRODUCED BY: _____

JAN 26 2015

H.B. NO. 882

Report Title:
Experimental Medical Treatments; Investigational Drugs; Terminal Illness

Description:
Allows terminally ill patients to seek access and to use potentially life-saving investigational drugs, biological products, and devices that are currently only accessible to patients enrolled in clinical trials.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.