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

H.B. NO. 92

A BILL FOR AN ACT

RELATING TO ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS.

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

SECTION 1. The legislature finds that the United States Food and Drug Administration approval process for investigational drugs, biological products, and devices typically takes many years. This lengthy process often denies potentially life-saving treatment benefits to terminally ill patients because those patients do not have time to wait for final approval of these treatments.

The legislature also finds that terminally ill patients have a fundamental right to access investigational drugs, biological products, and devices, even though the United States Food and Drug Administration has not yet approved their general use, as those patients attempt to extend or improve the quality of their lives. The legislature believes that decisions to access potentially life-saving treatments should be made by a patient after consulting with the patient's treating physician, not the government. Colorado, Missouri, and Louisiana have passed laws that recognize and protect terminally ill patients'

right to access potentially life-saving investigational drugs, biological products, and devices.

The purpose of this Act is to guarantee terminally ill patients access to investigational drugs, biological products, and devices.

SECTION 2. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"CHAPTER

ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR TERMINALLY ILL PATIENTS

§ -1 **Definitions.** As used in this chapter:

"Eligible patient" means a person who has been prescribed by a treating physician an investigational drug, biological product, or device to treat a terminal illness.

"Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a United States Food and Drug Administration approved clinical trial, but has not been approved for general use by the United States Food and Drug

Administration and remains under investigation in a clinical trial.

"Terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

"Treating physician" means a physician or osteopathic physician licensed pursuant to chapter 453 who has examined the eligible patient.

§ -2 Prescribing an investigational drug, biological product, or device; determinations. No treating physician shall prescribe or recommend an investigational drug, biological product, or device to a person unless:

(1) The person is diagnosed with a terminal illness, and the diagnosis has been confirmed by a second independent evaluation by a licensed physician in an appropriate specialty;

(2) No comparable or satisfactory treatment options are available to diagnose, monitor, or treat the person's terminal illness that have been approved for general

use by the United Stated Food and Drug Administration; and

(3) The probable risk to the person from the investigational drug, biological product, or device is not greater than the probable risk from the person's terminal illness.

§ -3 Availability of investigational drugs, biological products, and devices; costs. (a) A manufacturer of an investigational drug, biological product, or device may make an investigational drug, biological product, or device available to eligible patients; provided that a manufacturer may provide an investigational drug, biological product, or device to an eligible patient:

(1) Without charge to the eligible patient; or

(2) Require an eligible patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.

(b) Nothing in this section shall be construed to require a manufacturer to make available any investigational drug, biological product, or device.

(c) No manufacturer shall provide an investigational drug, biological product, or device to an eligible patient without the written consent of the eligible patient, or if the eligible patient is a minor or lacks the mental capacity to provide consent, without the written consent of the eligible patient's parent or legal guardian.

§ -4 Insurance coverage. An insurer may offer coverage for the cost of an investigational drug, biological product, or device, in any policy or contract issued or renewed under chapter 431:10A, 432:1, or 432D; provided that nothing in this section shall be construed to require an insurer to offer coverage for the cost of any investigational drug, biological product, or device.

§ -5 Limitation of liability; physicians. Notwithstanding any provision of law to the contrary, a physician who prescribes an investigational drug, biological product, or device to an eligible patient pursuant to this chapter shall be immune from civil liability, including but not limited to any cause of action arising under chapter 671 for any adverse action, condition, or other outcome resulting from the

patient's use of the investigational drug, biological product, or device.

§ -6 Action against physician license prohibited. Notwithstanding any provision of law to the contrary, the Hawaii medical board shall not revoke, fail to renew, or take any other action against the license of a physician or osteopathic physician issued pursuant to chapter 453 based solely upon the recommendation of the physician or osteopathic physician to an eligible patient regarding, or prescription for, or treatment with, an investigational drug, biological product, or device when the recommendation, prescription, or treatment is undertaken in strict conformance with the provisions of this chapter."

SECTION 3. This Act shall take effect upon its approval.

INTRODUCED BY: Cindy Evans

JAN 21 2015

H.B. NO. 92

Report Title:
Health; Terminal Illness; Investigational Drugs, Biological Products, and Devices

Description:
Provides access for terminally ill patients to receive investigational drugs, biological products, and devices that have not received final FDA approval.

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