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## 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:**

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

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



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

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

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

9 "CHAPTER

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

12 § -1 Definitions. As used in this chapter:

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

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



1 Administration and remains under investigation in a clinical  
2 trial.

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

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

10 § -2 Prescribing an investigational drug, biological  
11 product, or device; determinations. No treating physician shall  
12 prescribe or recommend an investigational drug, biological  
13 product, or device to a person unless:

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

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



1 use by the United States Food and Drug Administration;  
2 and

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

7 § -3 Availability of investigational drugs, biological  
8 products, and devices; costs. (a) A manufacturer of an  
9 investigational drug, biological product, or device may make an  
10 investigational drug, biological product, or device available to  
11 eligible patients; provided that a manufacturer may provide an  
12 investigational drug, biological product, or device to an  
13 eligible patient:

14 (1) Without charge to the eligible patient; or

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

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



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

7           §   -4 Insurance coverage. An insurer may offer coverage  
8 for the cost of an investigational drug, biological product, or  
9 device, in any policy or contract issued or renewed under  
10 chapter 431:10A, 432:1, or 432D; provided that nothing in this  
11 section shall be construed to require an insurer to offer  
12 coverage for the cost of any investigational drug, biological  
13 product, or device.

14           §   -5 Limitation of liability; physicians.  
15 Notwithstanding any provision of law to the contrary, a  
16 physician who prescribes an investigational drug, biological  
17 product, or device to an eligible patient pursuant to this  
18 chapter shall be immune from civil liability, including but not  
19 limited to any cause of action arising under chapter 671 for any  
20 adverse action, condition, or other outcome resulting from the



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

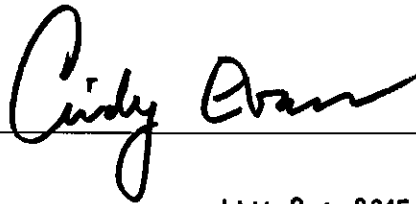
3 § -6 Action against physician license prohibited.

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

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

15

INTRODUCED BY:



JAN 21 2015



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**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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