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# A BILL FOR AN ACT

RELATING TO EXPERIMENTAL TREATMENTS.

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

1           SECTION 1. The Hawaii Revised Statutes is amended by  
2 adding a new chapter to be appropriately designated and to read  
3 as follows:

4   "CHAPTER

5   RIGHT TO TRY ACT

6           § -1 Title. This chapter shall be known and may be  
7 cited as the "Right to Try Act".

8           § -2 Definitions. As used in this chapter, and unless  
9 the context otherwise requires:

10           "Eligible patient" means an individual who meets all of the  
11 following conditions:

12           (1) Has a terminal illness, attested to by the patient's  
13               treating physician;

14           (2) Has considered all other treatment options currently  
15               approved by the United States Food and Drug

16               Administration;



1           (3) Has received a recommendation from the individual's  
2           physician for an investigational drug, biological  
3           product, or device;

4           (4) Has given written, informed consent for the use of the  
5           investigational drug, biological product, or device;  
6           and

7           (5) Has documentation from the individual's physician that  
8           the individual meets the requirements of this chapter.

9           "Health care provider" means a health care professional  
10          listed under section 451D-2.

11          "Investigational drug, biological product, or device" means  
12          a drug, biological product, or device that has successfully  
13          completed phase one of a clinical trial but has not yet been  
14          approved for general use by the United States Food and Drug  
15          Administration and remains under investigation in a United  
16          States Food and Drug Administration-approved clinical trial.

17          "Terminal illness" means a progressive disease or medical  
18          or surgical condition that entails significant functional  
19          impairment, that is not considered by a treating physician to be  
20          reversible even with the administration of current federal drug



1 administration-approved and available treatments, and that,  
2 without life-sustaining procedures, will soon result in death.

3 "Written, informed consent" means a written document that  
4 is signed by: the patient; the patient's parent, if the patient  
5 is a minor; or the patient's legal guardian, and attested to by  
6 the patient's physician and a witness and that, at a minimum,  
7 includes all of the following:

8 (1) An explanation of the currently approved products and  
9 treatments for the disease or condition from which the  
10 patient suffers;

11 (2) An attestation that the patient concurs with the  
12 patient's physician in believing that all currently  
13 approved and conventionally recognized treatments are  
14 unlikely to prolong the patient's life;

15 (3) Clear identification of the specific proposed  
16 investigational drug, biological product, or device  
17 that the patient is seeking to use;

18 (4) A description of the potentially best and worst  
19 outcomes of using the investigational drug, biological  
20 product, or device and a realistic description of the



1 most likely outcome. The description shall include  
2 the possibility that new, unanticipated, different, or  
3 worse symptoms might result and that death could be  
4 hastened by the proposed treatment. The description  
5 shall be based on the physician's knowledge of the  
6 proposed treatment in conjunction with an awareness of  
7 the patient's condition;

8 (5) A statement that the patient's health plan or third  
9 party administrator and provider are not obligated to  
10 pay for any care or treatments consequent to the use  
11 of the investigational drug, biological product, or  
12 device, unless they are specifically required to do so  
13 by law or contract;

14 (6) A statement that the patient's eligibility for hospice  
15 care may be withdrawn if the patient begins curative  
16 treatment with the investigational drug, biological  
17 product, or device and that care may be reinstated if  
18 the treatment ends and the patient meets hospice  
19 eligibility requirements; and



1           (7) A statement that the patient understands that the  
2           patient is liable for all expenses consequent to the  
3           use of the investigational drug, biological product,  
4           or device unless a contract between the patient and  
5           the manufacturer of the drug, biological product, or  
6           device states otherwise.

7           § -3 **Manufacturer responsibilities.** (a) A manufacturer  
8           of an investigational drug, biological product, or device may  
9           make available and an eligible patient may request the  
10          manufacturer's investigational drug, biological product, or  
11          device under this chapter; provided that a manufacturer shall  
12          not be required to make available an investigational drug,  
13          biological product, or device to an eligible patient.

14          (b) A manufacturer may do any of the following:

15          (1) Provide an investigational drug, biological product,  
16          or device to an eligible patient without receiving  
17          compensation; or

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



1           §   -4   **Applicability to other laws.**   This chapter shall  
2 not be construed to:

3           (1)   Expand the coverage required of an insurer under  
4                article 10A of chapter 431, article 1 of chapter 432,  
5                or chapter 432D;

6           (2)   Require a health plan, third party administrator, or  
7                governmental agency to provide coverage for the cost  
8                of an investigational drug, biological product, or  
9                device, or the cost of services related to the use of  
10               an investigational drug, biological product, or device  
11               under this chapter;

12          (3)   Require any governmental agency to pay costs  
13                associated with the use, care, or treatment of a  
14                patient with an investigational drug, biological  
15                product, or device; or

16          (4)   Require the provision of new or additional services by  
17                hospital that is licensed under by the department of  
18                health under section 321-14.5, unless approved by the  
19                hospital or facility.



1           §   -5   **Claims against the patient's estate.**  If a patient  
2 dies while being treated with an investigational drug,  
3 biological product, or device, the patient's heirs are not  
4 liable for any outstanding debt related to the treatment or lack  
5 of insurance due to the treatment.

6           §   -6   **Licensing and certification sanctions against**  
7 **health care providers.**  (a)  A licensing board shall not revoke,  
8 fail to renew, suspend, or take any action against a health care  
9 provider, based solely upon the health care provider's  
10 recommendations to an eligible patient regarding access to, or  
11 treatment with, an investigational drug, biological product, or  
12 device.

13           (b)  No entity responsible for medicare certification shall  
14 take action against a health care provider's medicare  
15 certification based solely upon the health care provider's  
16 recommendation that a patient have access to an investigational  
17 drug, biological product, or device.

18           §   -7   **State intervention prohibited.**  No official,  
19 employee, or agent of the State shall block or attempt to block  
20 an eligible patient's access to an investigational drug,



1 biological product, or device. Any counseling, advice, or  
2 recommendation consistent with medical standards of care from a  
3 licensed health care provider shall not constitute a violation  
4 of this chapter.

5 § -8 Private causes of action. This chapter shall not  
6 create a private cause of action against a manufacturer of an  
7 investigational drug, biological product, or device or against  
8 any other person or entity involved in the care of an eligible  
9 patient using the investigational drug, biological product, or  
10 device for any harm done to the eligible patient resulting from  
11 the investigational drug, biological product, or device, if the  
12 manufacturer or other person or entity complies in good faith  
13 with the terms of this chapter and has exercised reasonable  
14 care."

15 SECTION 2. This Act does not affect rights and duties that  
16 matured, penalties that were incurred, and proceedings that were  
17 begun before its effective date.

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

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INTRODUCED BY:

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JAN 27 2015



# H.B. NO. 1013

**Report Title:**

Experimental Treatments; Protections

**Description:**

Exempts from liability and sanctions persons who are involved in a patient's participation in experimental treatments for a terminal illness.

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

