STAND. COM. REP. NO. 986 -16

Honolulu, Hawaii
March 4, 2016

RE: H.B. No. 1013
H.D. 3

Honorable Joseph M. Souki
Speaker, House of Representatives
Twenty-Eighth State Legislature
Regular Session of 2016
State of Hawaii

Sir:

Your Committee on Judiciary, to which was referred H.B. No. 1013, H.D. 2, entitled:

"A BILL FOR AN ACT RELATING TO EXPERIMENTAL TREATMENTS,"

begs leave to report as follows:

The purpose of this measure is to authorize a manufacturer of an investigational drug, biological product, or device to make available, and an eligible patient to request, the manufacturer's investigational drug, biologic product, or device.

This measure also:

(1) Prohibits the State from blocking access by an eligible patient to an investigational drug, biologic product, or device;

(2) Grants immunity to manufacturers and other persons involved in providing experimental drugs, products, or devices to consenting patients with terminal illnesses from suit for any harm that results; and

(3) Relieves the heirs of a patient who dies while being treated with an investigational drug, biologic product, or device of any liability for any outstanding debt for the treatment.

The Goldwater Institute testified in support of this measure. The Department of the Attorney General testified in opposition. The Hawaii Medical Service Association provided comments.

Your Committee finds that right to try laws give terminally ill patients, with the recommendation of their treating physician, the opportunity to access investigational new drugs that have passed Phase I of the Federal Food and Drug Administration approval process, if their doctor believes, at this stage of the disease, the drug is the patient's last and best chance. Your Committee notes that clinical trials accept only about three percent of given patients afflicted with the condition for which the therapy is being tested.

Right to try laws are designed for patients who are ineligible or unable to access current clinical trials for the needed investigational new drugs. Your Committee believes this measure may be especially important for residents of Hawaii, who may have great difficulty in their current conditions traveling the long distances to clinical trial locations.

Your Committee has amended this measure to:

(1) Clarify that the patient's estate will be liable for any outstanding debt related to the treatment unless an agreement states otherwise;

(2) Clarify that a licensing board may not sanction a health care provider's licensing or certification based in any way on the provider's recommendation to an eligible patient of an investigational drug, biological product, or device that is being developed to treat the type of terminal illness that afflicts the patient; and

(3) Make technical, nonsubstantive amendments for clarity, consistency, and style.

As affirmed by the record of votes of the members of your Committee on Judiciary that is attached to this report, your Committee is in accord with the intent and purpose of H.B. No. 1013, H.D. 2, as amended herein, and recommends that it pass Third Reading in the form attached hereto as H.B. No. 1013, H.D. 3.

Respectfully submitted on
behalf of the members of the
Committee on Judiciary,

KARL RHOADS, Chair

State of Hawaii
House of Representatives
The Twenty-eighth Legislature

HSCR 986-16

Record of Votes of the Committee on Judiciary

Bill/Resolution No.:	Committee Referral:	Date:
HB 1013, HD2	HLT, CPC, JUD	03/03/16

☐ The committee is reconsidering its previous decision on the measure.

The recommendation is to: ☐ Pass, unamended (as is) ☑ Pass, with amendments (HD) ☐ Hold
☐ Pass short form bill with HD to recommit for future public hearing (recommit)

JUD Members	Ayes	Ayes (WR)	Nays	Excused
1. RHOADS, Karl (C)	✓			
2. SAN BUENAVENTURA, Joy A. (VC)	✓			
3. BELATTI, Della Au	✓			
4. BROWER, Tom	✓			
5. CREAGAN, Richard P.	✓			
6. HASHEM, Mark J.	✓			
7. KAWAKAMI, Derek S.K.	✓			
8. LEE, Chris	✓			
9. MORIKAWA, Dee	✓			
10. NAKASHIMA, Mark M.	✓			
11. TAKAYAMA, Gregg	✓			
12. WOODSON, Justin H.	✓			
13. McDERMOTT, Bob	✓			
14. THIELEN, Cynthia	✓			
TOTAL (14)	14			

The recommendation is: ☑ Adopted ☐ Not Adopted
If joint referral, _____ did not support recommendation.
committee acronym(s)

Vice Chair's or designee's signature: _____

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