

Honolulu, Hawaii

February 18, 2016

RE: H.B. No. 1013

H.D. 2

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

Sir:

Your Committee on Consumer Protection & Commerce, to which was referred H.B. No. 1013, H.D. 1, 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) Immunizes 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.



Your Committee received comments on this measure from the Department of the Attorney General, HMSA, the Hawaii Association for Justice, and a concerned individual.

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 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 per cent 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 believe 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 by changing the effective date to July 1, 2112, to facilitate further discussion on the measure.

As affirmed by the record of votes of the members of your Committee on Consumer Protection & Commerce that is attached to this report, your Committee is in accord with the intent and purpose of H.B. No. 1013, H.D. 1, as amended herein, and recommends that it be referred to your Committee on Judiciary in the form attached hereto as H.B. No. 1013, H.D. 2.

Respectfully submitted on
behalf of the members of the
Committee on Consumer
Protection & Commerce,



ANGUS L.K. MCKELVEY, Chair



