GOV. MSG. NO. 1146

EXECUTIVE CHAMBERS

HONOLULU

DAVID Y. IGE
GOVERNOR

April 29, 2016

The Honorable Ronald D. Kouchi,
President of the Senate
and Members of the Senate
State Capitol, Room 409
Honolulu Hawai'i 96813

The Honorable Joseph M. Souki
Speaker of the House
and Members of the House
State Capitol, Room 431
Honolulu, Hawai'i 96813

Dear President Kouchi, Speaker Souki, and Members of the Legislature:

I am transmitting herewith SB 2181 SD2 HD2, without my approval, and with the statement of objections relating to the measure.

SB 2181 SD2 HD2 RELATING TO ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS.

Sincerely,

David Y. Ige

DAVID Y. IGE
Governor

EXECUTIVE CHAMBERS

HONOLULU

April 29, 2016

STATEMENT OF OBJECTIONS TO SENATE BILL NO. 2181

Honorable Members
Twenty-Eighth Legislature
State of Hawai'i

Pursuant to Section 16 of Article III of the Constitution of the State of Hawaii, I am returning herewith, without my approval, Senate Bill No. 2181, entitled "A Bill for an Act Relating to Access to Treatment for Terminally Ill Patients."

The purpose of this bill is to enable terminally ill patients in Hawai'i to obtain from manufacturers investigational drugs and biological products that have not yet been approved by the United States Food and Drug Administration (FDA) for general use. This bill also shields practitioners who recommend investigational drugs to their patients from liability and the heirs of patients who receive investigational drugs from claims of responsibility for the costs of those drugs in the event of the patient's death.

This bill is objectionable because the FDA's existing "expanded access program" (also known as the "compassionate use program"), which this measure seeks to circumvent, already serves to increase access to investigational drugs for patients under the care of a physician while preserving the approval process, treatment data reporting, and other patient-centered safeguards. The regulations associated with this program were amended in 2009 and should be allowed a chance to be fully implemented and further publicized. While admirably seeking to increase access to potentially life-saving drugs, this measure unreasonably compromises the consumer protections provided by the FDA's expanded access program. The federal system of regulations that govern the sale and distribution of new and investigational drugs is also instrumental in the development of beneficial drug products. Interference with that

system will likely have the unintended consequence of delaying development of those potentially life-saving drugs. Additionally, this measure unreasonably intrudes upon a system of federal law in violation of the Supremacy Clause. Since the sale and distribution of new and investigational drugs will remain federally regulated whether or not this measure becomes law, it is also unclear what actual benefits would accrue to patients in Hawai'i.

For the foregoing reasons, I am returning Senate Bill No. 2181 without my approval.

Respectfully,

DAVID Y. IGE
Governor of Hawaii

THE SENATE
TWENTY-EIGHTH LEGISLATURE, 2016
STATE OF HAWAII

VETO

S.B. NO. 2181 S.D. 2 H.D. 2

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 process of approval for investigational drugs and biological products in the United States protects future patients from premature, ineffective, and unsafe medications and treatments over the long run, but the process often takes many years. Patients who have a terminal illness can be severely restricted in care options until an investigational drug or biological product receives final approval from the United States Food and Drug Administration.

According to the National Conference of State Legislatures, as of the end of 2015, twenty-five states have enacted "right-to-try" legislation that makes available experimental drugs without Food and Drug Administration approval to terminally ill patients with no other medication or treatment options.

The purpose of this Act is to allow for terminally ill patients to use potentially life-saving investigational drugs and biological products.

SECTION 2. Chapter 321, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"§321- Access to investigational drugs and biological products for terminally ill patients. (a) For the purposes of this section:

"Eligible patient" means a person who has:

(1) A terminal illness, attested to by the patient's treating physician;

(2) Considered all other treatment options currently approved by the United States Food and Drug Administration;

(3) Been unable to participate in a clinical trial for the terminal illness within one hundred miles of the patient's home address for the terminal illness, or not been accepted to the clinical trial within one week of completion of the clinical trial application process;

(4) Received a recommendation from the patient's physician for an investigational drug or biological product;

(5) Given written, informed consent for the use of the investigational drug or biological product or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written, informed consent on the patient's behalf; and

(6) Documentation from the patient's physician that the patient meets the requirements of this definition.

"Eligible patient" does not include a person being treated as an inpatient in an institution with an organized medical staff, regulated under section 321-11(10), or a health care facility under chapter 323F.

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

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

"Written, informed consent" means a written document signed by the patient and attested to by the patient's physician and a witness that, at a minimum:

(1) Explains the currently approved products and treatments for the disease or condition from which the patient suffers;

(2) Attests to the fact that the patient concurs with the patient's physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(3) Clearly identifies the specific proposed investigational drug or biological product that the patient is seeking to use;

(4) Describes the potentially best and worst outcomes of using the investigational drug or biological product with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result, and that death could be hastened by the proposed treatment, based on the physician's knowledge

of the proposed treatment in conjunction with an awareness of the patient's condition;

(5) Makes clear that the patient's health insurer and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug or biological product;

(6) Makes clear that the patient's eligibility for hospice care may be withdrawn by the hospice care provider if the patient begins curative treatment and care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements;

(7) Makes clear that in-home health care may be denied if treatment begins; and

(8) States that the patient understands that the patient is liable for all expenses consequent to the use of the investigational drug or biological product, and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug or biological product states otherwise.

(b) Notwithstanding section 328-17, beginning January 1, 2017, a manufacturer of an investigational drug or biological product may make available the manufacturer's investigational drug or biological product to eligible patients pursuant to this section. This section does not require that a manufacturer make available an investigational drug or biological product to an eligible patient. A manufacturer may:

(1) Provide an investigational drug or biological product to an eligible patient without receiving compensation; or

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

(c) A health insurance carrier may, but is not required to, provide coverage for the cost of an investigational drug or biological product.

(d) An insurer may deny coverage to an eligible patient from the time the eligible patient begins use of the investigational drug or biological product through a period not to exceed six months from the time the investigational drug or biological product is no longer used by the eligible patient;

provided that coverage may not be denied for a preexisting condition and for coverage for benefits that commence prior to the time the eligible patient begins use of such investigational drug or biological product.

(e) If a patient dies while being treated by an investigational drug or biological product, the patient's heirs shall not be liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

(f) Notwithstanding any law to the contrary, a licensing board may not revoke, fail to renew, suspend, or take any action against a health care provider's license based on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug or biological product that is being developed to treat the type of terminal illness that afflicts the patient. Action against a health care provider's medicare certification based on the health care provider's recommendation that a patient have access to an investigational drug or biological product that is being developed to treat the type of terminal illness that afflicts the patient is prohibited.

(g) An official, employee, or agent of the State shall not block or attempt to block an eligible patient's access to an investigational drug or biological product. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

(h) This section does not create a private cause of action against a manufacturer of an investigational drug or biological product or against another person or entity involved in the care of an eligible patient using the investigational drug or biological product, for any harm done to the eligible patient resulting from the investigational drug or biological product, so long as the manufacturer or other person or entity is complying in good faith with the terms of this section, unless there was a failure to exercise reasonable care."

SECTION 3. New statutory material is underscored.

SECTION 4. This Act shall take effect upon its approval.

APPROVED this day of , 2016

GOVERNOR OF THE STATE OF HAWAII