HOUSE BILL NO. 215

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-NINTH LEGISLATURE - SECOND SESSION

BY REPRESENTATIVES KAWASAKI, Drummond, Gruenberg, Gara

Introduced: 1/19/16
Referred: Health and Social Services, Judiciary

A BILL

FOR AN ACT ENTITLED

"An Act relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill; and providing immunity for persons manufacturing, distributing, or providing investigational drugs, biological products, or devices."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** AS 08.64.367 is amended by adding new subsections to read:

(c) A physician may not be subject to disciplinary action by the board for prescribing, dispensing, or administering an investigational drug, biological product, or device to a patient if the patient has

(1) a terminal illness;

(2) considered, after consultation with the physician, all other treatment options currently approved by the United States Food and Drug Administration; and

(3) given informed consent in writing for the use of the investigational

drug, biological product, or device.

(d) A hospital or health facility may not interfere with the physician-patient relationship by restricting or forbidding the use of investigational drugs, biological products, or devices when prescribed, dispensed, or administered by a physician under (c) of this section.

(e) In this section,

(1) "investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed Phase 1 studies of clinical trials for investigation, but has not been approved for general use by the United States Food and Drug Administration;

(2) "terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

*** Sec. 2.** AS 09.65 is amended by adding a new section to read:

Sec. 09.65.325. Immunity relating to use of investigational drugs, biological products, and devices. (a) A person is not liable in an action for damages for the injury or death of a patient with a terminal illness resulting from the patient's use of an investigational drug, biological product, or device if the person acting in good faith and with reasonable care is a

(1) physician who prescribed, dispensed, or administered the investigational drug, biological product, or device to the patient and, before prescribing, dispensing, or administering the drug, product, or device, the physician

(A) obtained the informed consent of the patient in writing after presenting to the patient all treatment options currently approved by the United States Food and Drug Administration for treatment of the patient's terminal illness; and

(B) provided written notice of the immunity provided under this section to the patient; or

(2) manufacturer, importer, or distributor of the investigational drug, biological product, or device and, before providing the drug, product, or device to the patient's physician, presented to the physician all treatment options currently approved

by the United States Food and Drug Administration for treatment of the patient's terminal illness and provided written notice of the immunity provided under this section to the patient.

(b) In this section, "investigational drug, biological product, or device" and "terminal illness" have the meanings given in AS 08.64.367.

*** Sec. 3.** AS 17.20.110 is amended by adding a new subsection to read:

(b) This section does not apply to a physician who prescribes or administers a new drug in accordance with the conditions set out in AS 08.64.367(c).