29-LS0783\H
Bruce
1/28/16

CS FOR SENATE BILL NO. 113( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-NINTH LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): SENATOR WIELECHOWSKI

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; providing immunity for persons manufacturing, distributing, or providing investigational drugs, biological products, or devices; and relating to licensed health care facility requirements."

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, or providing related treatment, to a patient if the patient

(1) has a terminal illness;

(2) is ineligible or unable to participate in a current clinical trial for the investigational drug, biological product, or device;

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

(4) has given informed consent in writing for the use of the investigational drug, biological product, or device.

(d) 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 and remains in ongoing clinical trials under Phase 2 or Phase 3, 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 or member of the medical team who prescribed, dispensed, or administered the investigational drug, biological product, or device, or provided related treatment, to the patient and, before prescribing, dispensing, or administering the drug, product, or device, or providing related treatment, the physician or member of the medical team

(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).

*** Sec. 4.** AS 47.32.030 is amended by adding a new subsection to read:

(d) The department may not require a licensed entity to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient. In this subsection, "investigational drug, biological product, or device" has the meaning given in AS 08.64.367.