ALASKA STATE LEGISLATURE

Session

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Resources Committee

State Affairs Committee

Joint Armed Services Committee

Judiciary Committee

SENATOR BILL WIELECHOWSKI

April 11, 2016

Grant Roderer, MD
Board President
Alaska State Medical Board
333 Willoughby Avenue, 9th Floor
Juneau, AK 99801

Dr. Roderer and Members of the Alaska State Medical Board:

In a letter dated April 7, 2016, the Alaska State Medical Board expressed opposition to Senate Bill 113: New Drugs for the Terminally Ill, also known as "Right to Try" legislation. While I appreciate the Board's attention to this matter, I would like to take this opportunity to address some of the points raised in the letter and perhaps clear up any misunderstanding of the bill.

First, it appears this position is based on version A of the bill. However, an updated version of the bill was adopted by the Senate Health & Social Services Committee on February 24, 2016, which I believe addresses several concerns raised in your letter. A copy of version CSSB 113 ver E (HSS) is attached for your reference. My office did reach out to the Division of Corporations, Business and Professional Licensing prior to the hearing and it is my understanding a representative was in the room when the Committee Substitute was adopted, so my apologies if this information was not received by the State Medical Board.

Second, similar Right to Try legislation has passed in 27 states and is currently pending in 22 others. In the 48 other states where this legislation has been introduced, State Medical Boards have either been supportive or remained neutral. Given this information, the Alaska Board's position has come as a surprise. Therefore, it is my hope to dispel any confusion about my bill in the following point-by-point response.

- **Paragraph 1, line 4 of your letter states that SB 113 would "*prevent hospitals and health facilities from restricting the use of such drugs*…"**

  As was put on the record in the Senate HSS Committee hearing on February 24th, the newest version of the bill removes this language and instead adds Section 4, which clarifies that hospitals and health facilities cannot be required to increase services solely to accommodate physicians prescribing, dispensing or administering investigational drugs to a patient.

- **Paragraph 2, line 1 of your letter states *"the Board determined that the legislation was in conflict with the physician oath to do no harm..."***

  The US Food and Drug Administration (FDA) currently offers an expanded access program called "compassionate use" that allows for the prescription of investigational drugs having passed Phase 1 of the FDA approval process. While SB 113 aims to cut through the red tape of this FDA process, the end result is essentially the same: terminally ill patients, in consultation with their doctor, would gain access to investigational drugs. Therefore, this position statement seems to raise the question as to whether the Alaska State Medical Board views the FDA's existing Compassionate Use Program as being in conflict with the physician oath as well.

  This position also raises the question as to whether the Alaska State Medical Board feels that physicians administering the same experimental drugs in Phase 2 clinical trials are also in conflict with the physician oath to do no harm.

  If this position statement could by clarified by the Board, I would greatly appreciate it.

- **Paragraph 2 of the letter also claims that patients *"currently have the option to participate in clinical trials for such experimental drugs," and that "given the existence of such clinical trials, it was also not clear what problem the bills are attempting to correct."***

  The updated version of Senate Bill 113 addresses concerns around clinical trials, as language was added to clarify that patients must be ineligible or unable to participate in clinical trials before they can turn to investigational treatments. This language serves to protect the integrity of ongoing clinical trials by not siphoning off patients, while still addressing the needs of the 97% of patients who on average do not qualify for clinical trial participation.

- **Paragraph 3, line 1 states *"The Board also expressed concern that such legislation may remove protections to the most vulnerable patients."***

  In fact, Senate Bill 113 includes multiple protections for potentially vulnerable patients. This includes a requirement for written informed consent by the patient, for all FDA approved options to have been previously presented by both the physician and the manufacturer of the drug, and for notices of immunity to have been clearly explained to the patient before consent is received.

  While Section 1 of SB 113 prohibits disciplinary action of physicians by the State Medical Board for prescribing, dispensing or administering investigational drugs, it is important to note this is only limited to the act itself. If the Board has reason to believe a physician is engaging in "deceit, fraud, or intentional misrepresentation while providing professional services," they still have recourse under AS 08.64.326 and AS 08.64.331. I have attached these statutes for your reference.

  Furthermore, please note that Section 2 (page 2, lines 19-20) of the bill also states that immunity is only provided to persons "acting in good faith and with reasonable care."

  As for pharmaceutical companies, federal law 21 U.S.C. § 331 defines prohibited acts that manufacturers cannot engage in, including marketing and selling of unapproved drugs.

Under 21 U.S.C. § 332 (injunctions), § 333 (penalties), and traditional equity authority of federal courts, courts have awarded repayment of profits for violating 21 U.S.C. § 331. *See, e.g., United States v. Rx Depot, Inc.*, 438 F.3d 1052 (10th Cir. 2006),*cert. denied* 549 U.S. 817. While the law does allow for cost recovery by manufacturers, they are not legally permitted to sell an investigational drug for more than it costs to produce.

Further, SB 113 clarifies "investigational drugs" must remain in ongoing FDA clinical trials (Phase 2 or 3). This is another protection to patients. In other words, a company cannot stop trials after Phase I to try and push their drug to desperate people. Remaining in ongoing trials means that the drug is ultimately moving toward approval, results are proving beneficial, and a company is pouring money into the process because they believe it will eventually get to market as a good product.

- **Paragraph 4 of the letter suggests that this legislation should be amended to only allow the use of investigational treatments that have passed Phase 3 of the FDA approval process, rather than Phase 1.**

  We fear making this change would result in very little benefit to terminally ill patients fighting to survive. It can take years for treatments to pass Phase 3 of the FDA approval process, which is the final phase. Even more concerning is that such an amendment would in fact make SB 113 even more restrictive than the FDA's existing Compassionate Use Program.

  Thus, making this change would completely defeat the purpose of Senate Bill 113, which is to help terminally ill patients who have exhausted all other options the chance to fight the clock and attempt to save their own lives.

Thank you for taking the time to consider the information provided above. Please do not hesitate to contact me with any questions you may have. I look forward to working with the Alaska State Medical Board to review and perhaps received updated comments on Senate Bill 113.

Cordially,

Bill Wielechowski

Senator Bill Wielechowski

CC: Representative Scott Kawasaki

CS FOR SENATE BILL NO. 113(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-NINTH LEGISLATURE - SECOND SESSION

BY THE SENATE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered: 4/1/16
Referred: Judiciary

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.

Sec. 08.64.326. Grounds for imposition of disciplinary sanctions.

(a) The board may impose a sanction if the board finds after a hearing that a licensee

(1) secured a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation while providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted, including conviction based on a guilty plea or plea of nolo contendere, of

(A) a class A or unclassified felony or a crime in another jurisdiction with elements similar to a class A or unclassified felony in this jurisdiction;

(B) a class B or class C felony or a crime in another jurisdiction with elements similar to a class B or class C felony in this jurisdiction if the felony or other crime is substantially related to the qualifications, functions, or duties of the licensee; or

(C) a crime involving the unlawful procurement, sale, prescription, or dispensing of drugs;

(5) has procured, sold, prescribed, or dispensed drugs in violation of a law regardless of whether there has been a criminal action;

(6) intentionally or negligently permitted the performance of patient care by persons under the licensee's supervision that does not conform to minimum professional standards even if the patient was not injured;

(7) failed to comply with this chapter, a regulation adopted under this chapter, or an order of the board;

(8) has demonstrated

(A) professional incompetence, gross negligence, or repeated negligent conduct; the board may not base a finding of professional incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrable physical harm to a patient;

(B) addiction to, severe dependency on, or habitual overuse of alcohol or other drugs that impairs the licensee's ability to practice safely;

(C) unfitness because of physical or mental disability;

(9) engaged in unprofessional conduct, in sexual misconduct, or in lewd or immoral conduct in connection with the delivery of professional services to patients; in this paragraph, "sexual misconduct" includes sexual contact, as defined by the board in regulations adopted under this chapter, or attempted sexual contact with a patient outside the scope of generally accepted methods of examination or treatment of the patient, regardless of the patient's consent or lack of consent, during the term of the physician-patient relationship, as defined by the board in regulations adopted under this chapter, unless the patient was the licensee's spouse at the time of the contact or, immediately preceding the physician-patient relationship, was in a dating, courtship, or engagement relationship with the licensee;

(10) has violated AS 18.16.010;

(11) has violated any code of ethics adopted by regulation by the board;

(12) has denied care or treatment to a patient or person seeking assistance from the physician if the only reason for the denial is the failure or refusal of the patient to agree to arbitrate as provided in AS 09.55.535(a); or

(13) has had a license or certificate to practice medicine in another state or territory of the United States, or a province or territory of Canada, denied, suspended, revoked, surrendered while under investigation for an alleged violation, restricted, limited, conditioned, or placed on probation unless the denial, suspension, revocation, or other action was caused by the failure of the licensee to pay fees to that state, territory, or province.

(b) In a case involving (a)(13) of this section, the final findings of fact, conclusions of law and order of the authority that suspended or revoked a license or certificate constitutes a prima facie case that the license or certificate was suspended or revoked and the grounds under which the suspension or revocation was granted.

Sec. 08.64.331. Disciplinary sanctions.

(a) If the board finds that a licensee has committed an act set out in AS 08.64.326(a), the board may

(1) permanently revoke a license to practice;

(2) suspend a license for a determinate period of time;

(3) censure a licensee;

(4) issue a letter of reprimand;

(5) place a licensee on probationary status and require the licensee to

(A) report regularly to the board on matters involving the basis of probation;

(B) limit practice to those areas prescribed;

(C) continue professional education until a satisfactory degree of skill has been attained in those areas determined by the board to need improvement;

(6) impose limitations or conditions on the practice of a licensee;

(7) impose a civil fine of not more than $25,000; or

(8) impose one or more of the sanctions set out in (1) - (7) of this subsection.

(b) The board may end the probation of a licensee if it finds that the deficiencies which required this sanction have been remedied.

(c) The board may summarily suspend a license before final hearing or during the appeals process if the board finds that the licensee poses a clear and immediate danger to the public health and safety if the licensee continues to practice. A person whose license is suspended under this section is entitled to a hearing conducted by the office of administrative

hearings (AS 44.64.010) not later than seven days after the effective date of the order, and the person may appeal the suspension after a hearing to a court of competent jurisdiction.

(d) The board may reinstate a license that has been suspended or revoked if the board finds after a hearing that the applicant is able to practice with reasonable skill and safety.

(e) The board may suspend a license upon receipt of a certified copy of evidence that a license to practice medicine in another state or territory of the United States or province of Canada has been suspended or revoked. The suspension remains in effect until a hearing can be held by the board.

(f) The board shall be consistent in the application of disciplinary sanctions. A significant departure from earlier decisions of the board involving similar situations must be explained in findings of fact or orders made by the board.