S.37

Introduced by Senators McCormack, Collamore, Degree, and Flory

Referred to Committee on

Date:

Subject: Health; prescription drugs; terminal illness; right to try

Statement of purpose of bill as introduced: This bill proposes to provide access to experimental medical treatment for patients with a terminal illness. It would allow manufacturers to provide access to, and health insurers to provide coverage for, investigational drugs, biological products, and devices to eligible patients. The bill would also provide immunity for physicians who prescribe or recommend experimental treatments.

An act relating to access to treatment for patients with a terminal illness

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. chapter 112 is added to read:

CHAPTER 112. ACCESS TO TREATMENT FOR PATIENTS WITH A TERMINAL ILLNESS

§ 5271. SHORT TITLE

This chapter shall be known and may be cited as the "Right to Try Act."

§ 5272. DEFINITIONS

As used in this chapter:

(1) "Eligible patient" means an individual who:

(A) has a terminal illness;

(B) has considered all other treatment options currently approved by the U.S. Food and Drug Administration;

(C) is ineligible to qualify for or unable to get into a clinical trial;

(D) has received a prescription or recommendation from his or her physician for an investigational drug, biological product, or device;

(E) has given written, informed consent for the use of the investigational drug, biological product, or device 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

(F) has documentation from his or her physician that he or she meets the requirements of subdivisions (A) through (E) of this subdivision (1).

(2) "Health insurer" shall have the same meaning as in section 9402 of this title, and for purposes of this chapter shall include the State of Vermont and any agent or instrumentality of the State that offers, administers, or provides financial support to State government, including Medicaid or any other public health care assistance program.

(3) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the U.S. Food and Drug Administration and remains under investigation in a clinical trial.

(4) "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.

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

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

(B) attests to the fact that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(C) clearly identifies the specific proposed investigational drug, biological product, or device that the patient is seeking to use;

(D) describes the best and worst potential outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome, which shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could

be hastened by the proposed treatment, and which shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(E) makes clear that the patient's health insurer or third party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless they are specifically required to do so by law or contract;

(F) makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and that care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements; and

(G) includes a statement that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

§ 5273. AVAILABILITY OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES; COSTS; INSURANCE COVERAGE

(a) A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients in accordance with this chapter; provided, however, that nothing in this chapter shall be construed to require a

manufacturer to make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may:

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

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

(c)(1) A health insurer may, but shall not be required to, provide coverage for the cost of an investigational drug, biological product, or device.

(2) This subsection shall not be construed to limit or otherwise affect any required coverage for participation in a cancer clinical trial pursuant to 8 V.S.A. § 4088b.

§ 5274. LIMITATIONS ON LIABILITY

(a) Notwithstanding any provision of law to the contrary, a physician who prescribes or recommends an investigational drug, biological product, or device to an eligible patient pursuant to this chapter shall be immune from civil liability for any adverse action, condition, or other outcome resulting from the patient's use of the investigational drug, biological product, or device.

(b) Notwithstanding any provision of law to the contrary, no State agency or regulatory board shall revoke, fail to renew, or take any other action against the license of a physician issued pursuant to 26 V.S.A. chapter 23 or 33 based

solely on the physician's recommendation to an eligible patient regarding a prescription for, or treatment with, an investigational drug, biological product, or device.

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

§ 5275. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES

An official, employee, or agent of this State shall not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care shall not be considered a violation of this section.

§ 5276. NO PRIVATE CAUSE OF ACTION

This chapter does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, as long as the manufacturer or other person or entity complies in good faith with the provisions of this chapter and has exercised reasonable care.

Sec. 2. EFFECTIVE DATE

This act shall take effect on passage.