

1 S.258

2 Introduced by Senator McCormack

3 Referred to Committee on

4 Date:

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

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

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

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

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

15 CHAPTER 112. ACCESS TO TREATMENTS FOR PATIENTS WITH
16 A TERMINAL ILLNESS

17 § 5271. SHORT TITLE

18 This chapter shall be known and may be cited as the “Right to Try Act.”

19 § 5272. DEFINITIONS

20 As used in this chapter:

1 (1) “Eligible patient” means an individual who:

2 (A) has a terminal illness;

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

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

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

8 (E) has given written, informed consent for the use of the
9 investigational drug, biological product, or device or, if the patient is a minor
10 or lacks the mental capacity to provide informed consent, a parent or legal
11 guardian has given written, informed consent on the patient’s behalf; and

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

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

19 (3) “Investigational drug, biological product, or device” means a drug,
20 biological product, or device that has successfully completed Phase I of a

1 clinical trial but has not yet been approved for general use by the U.S. Food
2 and Drug Administration and remains under investigation in a clinical trial.

3 (4) “Terminal illness” means a disease that without life-sustaining
4 procedures will result in death in the near future or a state of permanent
5 unconsciousness from which recovery is unlikely.

6 (5) “Written, informed consent” means a written document that is signed
7 by the patient and attested to by the patient’s physician and a witness that, at a
8 minimum:

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

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

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

16 (D) describes the best and worst potential outcomes of using the
17 investigational drug, biological product, or device and a realistic description of
18 the most likely outcome, which shall include the possibility that new,
19 unanticipated, different, or worse symptoms might result and that death could
20 be hastened by the proposed treatment, and which shall be based on the

1 physician's knowledge of the proposed treatment in conjunction with an
2 awareness of the patient's condition;

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

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

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

15 § 5273. AVAILABILITY OF INVESTIGATIONAL DRUGS, BIOLOGICAL

16 PRODUCTS, AND DEVICES; COSTS; INSURANCE COVERAGE

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

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

3 (b) A manufacturer may:

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

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

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

10 (2) This subsection shall not be construed to limit or otherwise affect
11 any required coverage for participation in a cancer clinical trial pursuant to
12 8 V.S.A. § 4088b.

13 § 5274. LIMITATIONS ON LIABILITY

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

19 (b) Notwithstanding any provision of law to the contrary, no State agency
20 or regulatory board shall revoke, fail to renew, or take any other action against
21 the license of a physician issued pursuant to 26 V.S.A. chapter 31 based solely

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

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

8 § 5275. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL
9 PRODUCTS, AND DEVICES

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

14 § 5276. NO PRIVATE CAUSE OF ACTION

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

1 Sec. 2. EFFECTIVE DATE

2 This act shall take effect on passage.