

Senate File 40 - Introduced

SENATE FILE 40

BY DANIELSON

A BILL FOR

1 An Act relating to the use of experimental treatments for
2 patients with a terminal illness.

3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 144E.1 Title.

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

4 Sec. 2. NEW SECTION. 144E.2 Definitions.

5 As used in this chapter:

6 1. "*Eligible patient*" means an individual who meets all of
7 the following conditions:

8 a. Has a terminal illness, attested to by the patient's
9 treating physician.

10 b. Has considered and rejected or has tried and failed to
11 respond to all other treatment options approved by the United
12 States food and drug administration.

13 c. Has received a recommendation from the individual's
14 physician for an investigational drug, biological product, or
15 device.

16 d. Has given written informed consent for the use of the
17 investigational drug, biological product, or device.

18 e. Has documentation from the individual's physician that
19 the individual meets the requirements of this subsection.

20 2. "*Investigational drug, biological product, or device*"
21 means a drug, biological product, or device that has
22 successfully completed phase 1 of a United States food and drug
23 administration-approved clinical trial but has not yet been
24 approved for general use by the United States food and drug
25 administration and remains under investigation in a United
26 States food and drug administration-approved clinical trial.

27 3. "*Terminal illness*" means a progressive disease or medical
28 or surgical condition that entails significant functional
29 impairment, that is not considered by a treating physician to
30 be reversible even with administration of treatments approved
31 by the United States food and drug administration, and that,
32 without life-sustaining procedures, will result in death.

33 4. "*Written informed consent*" means a written document that
34 is signed by the patient, a parent of a minor patient, or a
35 legal guardian or other legal representative of the patient and

1 attested to by the patient's treating physician and a witness
2 and that includes all of the following:

3 *a.* An explanation of the products and treatments approved by
4 the United States food and drug administration for the disease
5 or condition from which the patient suffers.

6 *b.* An attestation that the patient concurs with the
7 patient's treating physician in believing that all products
8 and treatments approved by the United States food and drug
9 administration are unlikely to prolong the patient's life.

10 *c.* Clear identification of the specific proposed
11 investigational drug, biological product, or device that the
12 patient is seeking to use.

13 *d.* A description of the best and worst potential outcomes
14 of using the investigational drug, biological product, or
15 device and a realistic description of the most likely outcome.
16 The description shall include the possibility that new,
17 unanticipated, different, or worse symptoms might result
18 and that death could be hastened by use of the proposed
19 investigational drug, biological product, or device. The
20 description shall be based on the treating physician's
21 knowledge of the proposed investigational drug, biological
22 product, or device in conjunction with an awareness of the
23 patient's condition.

24 *e.* A statement that the patient's health plan or third-party
25 administrator and provider are not obligated to pay for any
26 care or treatments consequent to the use of the investigational
27 drug, biological product, or device, unless they are
28 specifically required to do so by law or contract.

29 *f.* A statement that the patient's eligibility for hospice
30 care may be withdrawn if the patient begins curative treatment
31 with the investigational drug, biological product, or device
32 and that care may be reinstated if this treatment ends and the
33 patient meets hospice eligibility requirements.

34 *g.* A statement that the patient understands that the
35 patient is liable for all expenses consequent to the use of

1 the investigational drug, biological product, or device and
2 that this liability extends to the patient's estate unless
3 a contract between the patient and the manufacturer of the
4 investigational drug, biological product, or device states
5 otherwise.

6 Sec. 3. NEW SECTION. **144E.3 Manufacturer rights.**

7 1. A manufacturer of an investigational drug, biological
8 product, or device may make available and an eligible patient
9 may request the manufacturer's investigational drug, biological
10 product, or device under this chapter. This chapter does not
11 require a manufacturer of an investigational drug, biological
12 product, or device to provide or otherwise make available the
13 investigational drug, biological product, or device to an
14 eligible patient.

15 2. A manufacturer described in subsection 1 may do any of
16 the following:

17 a. Provide an investigational drug, biological product, or
18 device to an eligible patient without receiving compensation.

19 b. Require an eligible patient to pay the costs of, or the
20 costs associated with, the manufacture of the investigational
21 drug, biological product, or device.

22 Sec. 4. NEW SECTION. **144E.4 Treatment coverage.**

23 1. This chapter does not expand the coverage required of an
24 insurer under Title XIII, subtitle 1.

25 2. A health plan, third-party administrator, or
26 governmental agency may provide coverage for the cost of an
27 investigational drug, biological product, or device, or the
28 cost of services related to the use of an investigational drug,
29 biological product, or device under this chapter.

30 3. This chapter does not require any governmental agency
31 to pay costs associated with the use, care, or treatment of a
32 patient with an investigational drug, biological product, or
33 device.

34 4. This chapter does not require a hospital licensed under
35 chapter 135B or other health care facility to provide new or

1 additional services.

2 Sec. 5. NEW SECTION. 144E.5 Heirs not liable for treatment
3 debts.

4 If a patient dies while being treated by an investigational
5 drug, biological product, or device, the patient's heirs are
6 not liable for any outstanding debt related to the treatment
7 or lack of insurance due to the treatment, unless otherwise
8 required by law.

9 Sec. 6. NEW SECTION. 144E.6 Provider recourse.

10 1. To the extent consistent with state law, the board of
11 medicine created under chapter 147 shall not revoke, fail
12 to renew, suspend, or take any action against a physician's
13 license based solely on the physician's recommendations to
14 an eligible patient regarding access to or treatment with an
15 investigational drug, biological product, or device.

16 2. To the extent consistent with federal law, an entity
17 responsible for Medicare certification shall not take action
18 against a physician's Medicare certification based solely on
19 the physician's recommendation that a patient have access to an
20 investigational drug, biological product, or device.

21 Sec. 7. NEW SECTION. 144E.7 State interference.

22 An official, employee, or agent of this state shall not
23 block or attempt to block an eligible patient's access to
24 an investigational drug, biological product, or device.
25 Counseling, advice, or a recommendation consistent with medical
26 standards of care from a licensed physician is not a violation
27 of this section.

28 Sec. 8. NEW SECTION. 144E.8 Private cause of action.

29 1. This chapter shall not create a private cause of
30 action against a manufacturer of an investigational drug,
31 biological product, or device or against any other person
32 or entity involved in the care of an eligible patient using
33 the investigational drug, biological product, or device
34 for any harm done to the eligible patient resulting from
35 the investigational drug, biological product, or device, if

1 the manufacturer or other person or entity is complying in
2 good faith with the terms of this chapter and has exercised
3 reasonable care.

4 2. This chapter shall not affect any mandatory health care
5 coverage for participation in clinical trials under Title XIII,
6 subtitle 1.

7 EXPLANATION

8 The inclusion of this explanation does not constitute agreement with
9 the explanation's substance by the members of the general assembly.

10 This bill, titled the "Right to Try Act", permits
11 manufacturers of investigational drugs, biological products, or
12 devices to make available, and eligible patients with terminal
13 illnesses to attempt treatment with, an investigational
14 drug, biological product, or device as long as they provided
15 written informed consent. The bill defines the terms "eligible
16 patient", "terminal illness", "investigational drug, biological
17 product, or device", and "written informed consent".

18 Under the bill, an eligible patient's physician must
19 acknowledge that the patient's illness is terminal and
20 recommend the patient try an investigational drug, biological
21 product, or device. The patient's written informed consent
22 must acknowledge that treatments currently approved by the
23 United States food and drug administration are unlikely to
24 prolong the patient's life. It must identify the specific
25 treatment sought and the potential best, worst, and expected
26 results from the treatment. It must acknowledge that the
27 patient's insurance is not required to pay for the treatment
28 and that any hospice service may refuse to accept the patient
29 after receiving the treatment. It must also acknowledge
30 that expenses will be credited to the patient, including the
31 patient's estate, unless an agreement with the manufacturer of
32 an investigational drug, biological product, or device states
33 otherwise. If the patient dies during treatment, the patient's
34 heirs are not liable for any remaining debts unless otherwise
35 required by law.

1 The manufacturer of an investigational drug, biological
2 product, or device may charge an eligible patient or provide
3 the treatment free of charge. Governmental entities are
4 not required to pay costs associated with the use, care, or
5 treatment of a patient with an investigational drug, biological
6 product, or device. The bill does not require hospitals
7 licensed under chapter 135B or other health care facilities to
8 provide new or additional services.

9 Consistent with existing law, the board of medicine shall
10 not take an adverse action against a physician's license solely
11 for recommending an investigational drug, biological product,
12 or device for the physician's eligible patient. The bill does
13 not create a new private cause of action against any person or
14 entity involved in the care of an eligible patient using the
15 investigational drug, biological product, or device for any
16 harm done to the patient resulting from the treatment if the
17 person or entity is complying in good faith with the terms of
18 the bill and has exercised reasonable care.