

**Senate File 2323 - Introduced**

SENATE FILE 2323  
BY COMMITTEE ON TECHNOLOGY

(SUCCESSOR TO SSB 3170)

(COMPANION TO HF 2290)

**A BILL FOR**

1 An Act relating to the right to try Act.

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

1 Section 1. Section 144E.2, Code 2024, is amended to read as  
2 follows:

3 **144E.2 Definitions.**

4 As used in [this chapter](#):

5 1. "Eligible facility" means an institution operating under  
6 a federalwide assurance for the protection of human subjects  
7 pursuant to 42 U.S.C. §289(a) and 45 C.F.R. pt. 46, and  
8 subject to the federalwide assurance laws, rules, policies, and  
9 guidelines including renewals and updates.

10 ~~1.~~ 2. "Eligible patient" means an individual who meets all  
11 of the following conditions specified under paragraph "a" or  
12 "b":

13 a. (1) Has a terminal illness, attested to by the patient's  
14 treating physician.

15 ~~b.~~ (2) Has considered and rejected or has tried and failed  
16 to respond to all other treatment options approved by the  
17 United States food and drug administration.

18 ~~c.~~ (3) Has received a recommendation from the individual's  
19 physician for an investigational drug, biological product, or  
20 device.

21 ~~d.~~ (4) Has given written informed consent for the use of  
22 the investigational drug, biological product, or device.

23 ~~e.~~ (5) Has documentation from the individual's physician  
24 that the individual meets the requirements of this subsection  
25 paragraph "a".

26 b. (1) Has a life-threatening or severely debilitating  
27 illness, attested to by the patient's treating physician.

28 (2) Has considered all other treatment options currently  
29 approved by the United States food and drug administration.

30 (3) Has received a recommendation from the individual's  
31 physician for an individualized investigational treatment,  
32 based on an analysis of the patient's genomic sequence, human  
33 chromosomes, deoxyribonucleic acid, ribonucleic acid, genes,  
34 gene products such as enzymes and other types of proteins, or  
35 metabolites.

1     (4) Has given written informed consent for the use of the  
2 individualized investigational treatment.

3     (5) Has documentation from the individual's physician that  
4 the individual meets the requirements of this paragraph "b".

5     3. "Individualized investigational treatment" means a drug,  
6 biological product, or device that is unique to, and produced  
7 exclusively for use by, an individual patient, based on the  
8 individual patient's own genetic profile. "Individualized  
9 investigational treatment" includes but is not limited to  
10 individualized gene therapy, antisense oligonucleotides, and  
11 individualized neoantigen vaccines.

12     ~~2.~~ 4. "Investigational drug, biological product, or  
13 device" means a drug, biological product, or device that has  
14 successfully completed phase 1 of a United States food and drug  
15 administration-approved clinical trial but has not yet been  
16 approved for general use by the United States food and drug  
17 administration and remains under investigation in a United  
18 States food and drug administration-approved clinical trial.

19     ~~3.~~ 5. "Terminal illness" means a progressive disease  
20 or medical or surgical condition that entails significant  
21 functional impairment, that is not considered by a treating  
22 physician to be reversible even with administration of  
23 treatments approved by the United States food and drug  
24 administration, and that, without life-sustaining procedures,  
25 will result in death.

26     ~~4.~~ 6. "Written informed consent" means a written document  
27 that is signed by the patient, a parent of a minor patient, or a  
28 legal guardian or other legal representative of the patient and  
29 attested to by the patient's treating physician and a witness  
30 and that includes, at a minimum, all of the following:

31     a. If the patient is an eligible patient as specified in  
32 subsection 2, paragraph "a":

33     (1) An explanation of the products and treatments approved  
34 by the United States food and drug administration for the  
35 disease or condition from which the patient suffers.

1 ~~b.~~ (2) An attestation that the patient concurs with the  
2 patient's treating physician in believing that all products  
3 and treatments approved by the United States food and drug  
4 administration are unlikely to prolong the patient's life.

5 ~~c.~~ (3) Clear identification of the specific proposed  
6 investigational drug, biological product, or device that the  
7 patient is seeking to use.

8 ~~d.~~ (4) A description of the best and worst potential  
9 outcomes of using the investigational drug, biological product,  
10 or device and a realistic description of the most likely  
11 outcome. The description shall include the possibility that  
12 new, unanticipated, different, or worse symptoms might result  
13 and that death could be hastened by use of the proposed  
14 investigational drug, biological product, or device. The  
15 description shall be based on the treating physician's  
16 knowledge of the proposed investigational drug, biological  
17 product, or device in conjunction with an awareness of the  
18 patient's condition.

19 ~~e.~~ (5) A statement that the patient's health plan or  
20 third-party administrator and provider are not obligated to  
21 pay for any care or treatments consequent to the use of the  
22 investigational drug, biological product, or device, unless  
23 they are specifically required to do so by law or contract.

24 ~~f.~~ (6) A statement that the patient's eligibility for  
25 hospice care may be withdrawn if the patient begins curative  
26 treatment with the investigational drug, biological product,  
27 or device and that hospice care may be reinstated if this  
28 treatment ends and the patient meets hospice eligibility  
29 requirements.

30 ~~g.~~ (7) A statement that the patient understands that the  
31 patient is liable for all expenses consequent to the use of  
32 the investigational drug, biological product, or device and  
33 that this liability extends to the patient's estate unless  
34 a contract between the patient and the manufacturer of the  
35 investigational drug, biological product, or device states

1 otherwise.

2 b. If the patient is an eligible patient as specified in  
3 subsection 2, paragraph "b":

4 (1) An explanation of the currently approved products and  
5 treatments for the disease or condition from which the patient  
6 suffers.

7 (2) An attestation that the patient concurs with the  
8 patient's treating physician in believing that all currently  
9 approved and conventionally recognized products and treatments  
10 are unlikely to prolong the patient's life.

11 (3) Clear identification of the specific proposed  
12 individualized investigational treatment that the patient is  
13 seeking to use.

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

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

29 (6) A statement that the patient's eligibility for hospice  
30 care may be withdrawn if the patient begins curative treatment  
31 with the individualized investigational treatment and that  
32 hospice care may be reinstated if this treatment ends and the  
33 patient meets hospice eligibility requirements.

34 (7) A statement that the patient understands that the  
35 patient is liable for all expenses consequent to the use of

1 the individualized investigational treatment and that this  
2 liability extends to the patient's estate, unless a contract  
3 between the patient and the manufacturer of the individualized  
4 investigational treatment states otherwise.

5 Sec. 2. Section 144E.3, Code 2024, is amended to read as  
6 follows:

7 **144E.3 Manufacturer and eligible facility rights.**

8 1. A manufacturer of an investigational drug, biological  
9 product, or device or a manufacturer operating within, and in  
10 compliance with all requirements applicable to, an eligible  
11 facility may make available, and an eligible patient, as  
12 applicable under section 144.1, subsection 2, paragraph "a"  
13 or "b", may request from a manufacturer of an investigational  
14 drug, biological product, or device, or a manufacturer  
15 operating within, and in compliance with all requirements  
16 applicable to, an eligible facility, the manufacturer's  
17 investigational drug, biological product, or device, or the  
18 manufacturer's individualized investigational treatment under  
19 this chapter. This chapter does not require a manufacturer  
20 of an investigational drug, biological product, or device, or  
21 of an individualized investigational treatment to provide or  
22 otherwise make available the investigational drug, biological  
23 product, or device, or the individualized investigational  
24 treatment to an eligible patient.

25 2. A An eligible facility, or a manufacturer described  
26 in [subsection 1](#), that is in compliance with all applicable  
27 requirements, may do any of the following:

28 a. Provide an investigational drug, biological product, or  
29 device, or an individualized investigational treatment to an  
30 eligible patient, as applicable under section 144.1, subsection  
31 2, paragraph "a" or "b", without receiving compensation.

32 b. Require an eligible patient, as applicable under section  
33 144.1, subsection 2, paragraph "a" or "b", to pay the costs  
34 of, or the costs associated with, the manufacture of the  
35 investigational drug, biological product, or device, or the

1 individualized investigational treatment.

2 Sec. 3. Section 144E.4, Code 2024, is amended to read as  
3 follows:

4 **144E.4 Treatment coverage.**

5 1. **This chapter** does not expand the coverage required of an  
6 insurer under **Title XIII, subtitle 1.**

7 2. A health plan, third-party administrator, or  
8 governmental agency may, but is not required to, provide  
9 coverage for the cost of an investigational drug,  
10 biological product, or device, the cost of an individualized  
11 investigational treatment, or the cost of services related to  
12 the use of an investigational drug, biological product, or  
13 device, or an individualized investigational treatment under  
14 this chapter.

15 3. **This chapter** does not require any governmental agency  
16 to pay costs associated with the use, care, or treatment of a  
17 patient with an investigational drug, biological product, or  
18 device, or an individualized investigational treatment.

19 4. **This chapter** does not require a hospital licensed under  
20 chapter 135B or other health care facility to provide new or  
21 additional services, unless approved by the hospital or other  
22 health care facility.

23 Sec. 4. Section 144E.5, Code 2024, is amended to read as  
24 follows:

25 **144E.5 Heirs not liable for treatment debts.**

26 If a patient dies while being treated ~~by~~ with an  
27 investigational drug, biological product, or device, or  
28 an individualized investigational treatment, the patient's  
29 heirs are not liable for any outstanding debt related to the  
30 treatment or lack of insurance due to the treatment, ~~unless~~  
31 ~~otherwise required by law.~~

32 Sec. 5. Section 144E.6, Code 2024, is amended to read as  
33 follows:

34 **144E.6 Provider recourse.**

35 1. To the extent consistent with state law, the board of

1 medicine created under [chapter 147](#) shall not revoke, fail  
2 to renew, suspend, or take any action against a physician's  
3 license based solely on the physician's recommendations to  
4 an eligible patient regarding access to or treatment with an  
5 investigational drug, biological product, or device, or an  
6 individualized investigational treatment.

7 2. To the extent consistent with federal law, an entity  
8 responsible for Medicare certification shall not take action  
9 against a physician's Medicare certification based solely on  
10 the physician's recommendation that a patient have access to  
11 an investigational drug, biological product, or device, or an  
12 individualized investigational treatment.

13 Sec. 6. Section 144E.7, Code 2024, is amended to read as  
14 follows:

15 **144E.7 State interference.**

16 An official, employee, or agent of this state shall not  
17 block or attempt to block an eligible patient's access to an  
18 investigational drug, biological product, or device, or to an  
19 individualized investigational treatment. Counseling, advice,  
20 or a recommendation consistent with medical standards of care  
21 from a licensed physician is not a violation of [this section](#).

22 Sec. 7. Section 144E.8, Code 2024, is amended to read as  
23 follows:

24 **144E.8 Private cause of action.**

25 1. [This chapter](#) shall not create a private cause of action  
26 against a manufacturer of an investigational drug, biological  
27 product, or device or an individualized investigational  
28 treatment, against an eligible facility, or against any other  
29 person or entity involved in the care of an eligible patient  
30 using the investigational drug, biological product, or device,  
31 or the individualized investigational treatment for any harm  
32 done to the eligible patient resulting from the investigational  
33 drug, biological product, or device, or the individualized  
34 investigational treatment, if the manufacturer, eligible  
35 facility, or other person or entity is complying in good faith



1 with the terms of **this chapter** and has exercised reasonable  
2 care.

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

6 EXPLANATION

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

9 This bill relates to Code chapter 144E, the right to try Act.  
10 Under current law, an "eligible patient" under the Code  
11 chapter is, in part, a person who has a terminal illness.  
12 Under the bill, an "eligible patient" also includes, in part,  
13 a person who has a life-threatening or severely debilitating  
14 illness.

15 Under current law, the Code chapter applies to an  
16 "investigational drug, biological product, or device",  
17 meaning a drug, biological product, or device that has  
18 successfully completed phase I of a United States food and  
19 drug administration (FDA)-approved clinical trial but has not  
20 yet been approved for general use by the FDA and that remains  
21 under investigation in an FDA-approved clinical trial. Under  
22 the bill, the Code chapter also applies to an "individualized  
23 investigational treatment", meaning a drug, biological product,  
24 or device that is unique to and produced exclusively for use  
25 by an individual patient based on the individual patient's  
26 own genetic profile and includes individualized gene therapy,  
27 antisense oligonucleotides, and individualized neoantigen  
28 vaccines.

29 The bill amends the definition under the Code chapter for  
30 "written informed consent" to reflect the changes made to  
31 "eligible patient" and the application of the Code chapter to  
32 individualized investigational treatments.

33 The bill provides a definition of "eligible facility" to  
34 mean an institution that is operating under a federalwide  
35 assurance for the protection of human subjects pursuant

1 to federal law. The bill amends provisions relating to a  
2 manufacturer's rights under the Code chapter to also apply to  
3 eligible facilities. The bill provides that a manufacturer  
4 of an investigational drug, biological product, or device  
5 or a manufacturer operating within, and in compliance with  
6 all requirements applicable to, an eligible facility may  
7 make available, and an eligible patient may request from a  
8 manufacturer of an investigational drug, biological product, or  
9 device, or a manufacturer operating within, and in compliance  
10 with all requirements applicable to, an eligible facility, the  
11 manufacturer's investigational drug, biological product, or  
12 device, or the manufacturer's individualized investigational  
13 treatment. However, the Code chapter does not require a  
14 manufacturer of an individualized investigational treatment  
15 to provide or otherwise make available the individualized  
16 investigational treatment to an eligible patient. The bill  
17 provides that an eligible facility or a manufacturer that is  
18 in compliance with all applicable requirements may provide  
19 an individualized investigational treatment to an eligible  
20 patient without receiving compensation, or require an eligible  
21 patient to pay the costs of, or the costs associated with, the  
22 manufacture of the individualized investigational treatment.

23 The bill makes conforming changes in the Code chapter to  
24 reflect the bill's provisions.

25 The bill does not amend Code section 144E.9, which  
26 provides that the Code chapter shall not be construed to  
27 allow a patient's treating physician to assist the patient in  
28 committing or attempting to commit suicide.