

As Amended by House Committee

Session of 2015

HOUSE BILL No. 2004

By Representatives Hildabrand, Kiegerl and McPherson

12-19

1 AN ACT creating the Kansas right to try act.

2

3 *Be it enacted by the Legislature of the State of Kansas:*

4 Section 1. The provisions of sections 1 through 7, and amendments  
5 thereto, shall be known and may be cited as the Kansas right to try act.

6 Sec. 2. (a) The legislature hereby finds and declares that:

7 (1) The process of approval for investigational drugs, biological  
8 products, and devices in the United States protects future patients from  
9 premature, ineffective and unsafe medications and treatments over the long  
10 run, but the process often takes many years;

11 (2) patients who have a terminal illness do not have the luxury of  
12 waiting until an investigational drug, biological product, or device receives  
13 final approval from the United States food and drug administration;

14 (3) patients who have a terminal illness have a fundamental right to  
15 attempt to pursue the preservation of their own lives by accessing available  
16 investigational drugs, biological products, and devices;

17 (4) the use of available investigational drugs, biological products, and  
18 devices is a decision that should be made by the patient with a terminal  
19 illness in consultation with the patient's health care provider and the  
20 patient's health care team, if applicable; and

21 (5) the decision to use an investigational drug, biological product, or  
22 device should be made with full awareness of the potential risks, benefits  
23 and consequences to the patient and the patient's family.

24 (b) It is the intent of the legislature to allow for terminally ill patients  
25 to use potentially life-saving investigational drugs, biological products,  
26 and devices.

27 Sec. 3. As used in sections 1 through 7, and amendments thereto,  
28 unless the context requires otherwise:

29 (a) (1) "Eligible patient" means a person who has:

30 (A) A terminal illness, attested to by the patient's treating physician;

31 (B) carefully considered all other treatment options approved by the  
32 United States food and drug administration;

33 (C) been unable to participate in a clinical trial for the terminal illness  
34 within 100 miles of the patient's home address, or not been accepted to the  
35 clinical trial within one week of completion of the clinical trial application  
36 process;

1 (D) received a recommendation from such patient's treating physician  
2 for an investigational drug, biological product, or device;

3 (E) given written, informed consent for the use of the investigational  
4 drug, biological product, or device, or, if the patient is a minor or lacks the  
5 mental capacity to provide informed consent, a parent or legal guardian  
6 has given written, informed consent on the patient's behalf; and

7 (F) documentation from such patient's treating physician that such  
8 patient meets the requirements of this paragraph.

9 (2) "Eligible patient" does not include a person being treated as an  
10 inpatient in any hospital or ~~ambulatory surgical~~ **recuperation** center, as  
11 those terms are defined in K.S.A. 65-425, and amendments thereto.

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

18 (c) "Terminal illness" means a ~~disease or~~ condition that, without life-  
19 sustaining procedures will ~~soon~~ result in death or a state of permanent  
20 unconsciousness from which recovery is unlikely.

21 (d) "Written, informed consent" means a written document signed by  
22 the patient and attested to by the patient's treating physician and a witness  
23 that, at a minimum:

24 (1) Explains the currently approved products and treatments for the  
25 disease or condition from which the patient suffers;

26 (2) attests to the fact that the patient concurs with the patient's treating  
27 physician in believing that all currently approved and conventionally  
28 recognized treatments are unlikely to prolong the patient's life;

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

31 (4) describes the potentially best and worst outcomes of using the  
32 investigational drug, biological product, or device with a realistic  
33 description of the most likely outcome, including the possibility that new,  
34 unanticipated, different or worse symptoms might result, and that death  
35 could be hastened by the proposed treatment, based on the physician's  
36 knowledge of the proposed treatment in conjunction with an awareness of  
37 the patient's condition;

38 (5) makes clear that the patient's health insurer and provider are not  
39 obligated to pay for any care or treatments consequent to the use of the  
40 investigational drug, biological product, or device;

41 (6) makes clear that the patient's eligibility for hospice care may be  
42 withdrawn if the patient begins curative treatment and care may be  
43 reinstated if the curative treatment ends and the patient meets hospice

1 eligibility requirements;

2 (7) makes clear that in-home health care may be denied if treatment  
3 begins; and

4 (8) states that the patient understands that the patient is liable for all  
5 expenses consequent to the use of the investigational drug, biological  
6 product, or device, and that this liability extends to the patient's estate,  
7 unless a contract between the patient and the manufacturer of the  
8 investigational drug, biological product, or device states otherwise.

9 **(e) "Physician" means a person licensed to practice medicine and**  
10 **surgery by the board of healing arts.**

11 Sec. 4. (a) A manufacturer of an investigational drug, biological  
12 product, or device may make available the manufacturer's investigational  
13 drug, biological product, or device to eligible patients pursuant to sections  
14 1 through 7, and amendments thereto. Nothing in sections 1 through 7, and  
15 amendments thereto, shall be construed to require that a manufacturer  
16 make available an investigational drug, biological product, or device to an  
17 eligible patient.

18 ~~(b)—A manufacturer may:~~

19 ~~(1) Provide an investigational drug, biological product, or device to~~  
20 ~~an eligible patient without receiving compensation therefor; or~~

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

24 ~~(e) (1) A health insurance carrier may, but shall not be required to,~~  
25 ~~provide coverage for the cost of an investigational drug, biological~~  
26 ~~product, or device.~~

27 (2) An insurer may deny coverage to an eligible patient from the time  
28 the eligible patient begins use of the investigational drug, biological  
29 product, or device through a period not to exceed six months from the time  
30 the investigational drug, biological product, or device is no longer used by  
31 the eligible patient, except coverage may not be denied for a pre-existing  
32 condition and for coverage for benefits which commenced prior to the time  
33 the eligible patient begins use of such investigational drug, biological  
34 product, or device.

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

39 Sec. 5. (a) **No physician who in good faith recommends or**  
40 **participates in the use of an investigational drug, biological product,**  
41 **or device pursuant to the provisions of this act shall be subject to any**  
42 **criminal or civil liability, nor shall such physician be found to have**  
43 **committed an act of unprofessional conduct pursuant to K.S.A. 65-**

1 **2837, and amendments thereto.**

2 (b) Notwithstanding any other law to the contrary, the board of  
3 healing arts shall not revoke, suspend or otherwise take any action against  
4 any individual holding a license issued pursuant to the Kansas healing arts  
5 act, K.S.A. 65-2801 et seq., and amendments thereto, based solely on such  
6 provider's recommendations to an eligible patient regarding access to or  
7 treatment with an investigational drug, biological product, or device, ~~as  
8 long as the recommendations are consistent with medical standards of  
9 care.~~ Any action against an individual or entity's medicare certification  
10 based solely on recommendations that a patient have access to an  
11 investigational drug, biological product, or device is prohibited.

12 Sec. 6. No state officer, employee or agent thereof shall block or  
13 attempt to block an eligible patient's access to an investigational drug,  
14 biological product, or device. Counseling, advice or a recommendation  
15 ~~consistent with medical standards of care~~ from a licensed health care  
16 provider is not a violation of this section.

17 Sec. 7. Nothing in sections 1 through 7, and amendments thereto,  
18 shall be construed as creating a private cause of action against a  
19 manufacturer of an investigational drug, biological product, or device, or  
20 against any other person or entity involved in the care of an eligible patient  
21 using an investigational drug, biological product, or device for any injury  
22 suffered by the eligible patient resulting from the investigational drug,  
23 biological product, or device, so long as the manufacturer or other person  
24 or entity acted in accordance with the provisions of sections 1 through 7,  
25 and amendments thereto, ~~except when such injury results from a failure to  
26 exercise reasonable care.~~

27 Sec. 8. This act shall take effect and be in force from and after its  
28 publication in the statute book.