

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 center, as those terms are
11 defined in K.S.A. 65-425, and amendments thereto.

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

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

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

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

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

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

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

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

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41 withdrawn if the patient begins curative treatment and care may be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

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

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

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

15 (b) A manufacturer may:

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

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

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

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

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

36 Sec. 5. Notwithstanding any other law to the contrary, the board of
37 healing arts shall not revoke, suspend or otherwise take any action against
38 any individual holding a license issued pursuant to the Kansas healing arts
39 act, K.S.A. 65-2801 et seq., and amendments thereto, based solely on such
40 provider's recommendations to an eligible patient regarding access to or
41 treatment with an investigational drug, biological product, or device, as
42 long as the recommendations are consistent with medical standards of
43 care. Any action against an individual or entity's medicare certification

1 based solely on recommendations that a patient have access to an
2 investigational drug, biological product, or device is prohibited.

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

8 Sec. 7. Nothing in sections 1 through 7, and amendments thereto,
9 shall be construed as creating a private cause of action against a
10 manufacturer of an investigational drug, biological product, or device, or
11 against any other person or entity involved in the care of an eligible patient
12 using an investigational drug, biological product, or device for any injury
13 suffered by the eligible patient resulting from the investigational drug,
14 biological product, or device, so long as the manufacturer or other person
15 or entity acted in accordance with the provisions of sections 1 through 7,
16 and amendments thereto, except when such injury results from a failure to
17 exercise reasonable care.

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