

SENATE SUBSTITUTE
FOR
HOUSE COMMITTEE SUBSTITUTE
FOR
HOUSE BILL NO. 1685

AN ACT

To amend chapter 191, RSMo, by adding thereto one new section relating to the use of investigational drugs, with a penalty provision.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI,
AS FOLLOWS:

1 Section A. Chapter 191, RSMo, is amended by adding thereto
2 one new section, to be known as section 191.480, to read as
3 follows:

4 191.480. 1. For purposes of this section, the following
5 terms shall mean:

6 (1) "Eligible patient", a person who meets all of the
7 following:

8 (a) Has a terminal illness or irreversibly debilitating
9 disease or condition;

10 (b) Has considered all other treatment options currently
11 approved by the United States Food and Drug Administration and
12 all relevant clinical trials conducted in this state;

13 (c) Has received a prescription or recommendation from the
14 person's physician for an investigational drug, biological
15 product, or device;

16 (d) Has given written informed consent which shall be at

1 least as comprehensive as the consent used in clinical trials for
2 the use of the investigational drug, biological product, or
3 device or, if the patient is a minor or lacks the mental capacity
4 to provide informed consent, a parent or legal guardian has given
5 written informed consent on the patient's behalf; and

6 (e) Has documentation from the person's physician that the
7 person has met the requirements of this subdivision;

8 (2) "Investigational drug, biological product, or device",
9 a drug, biological product, or device, any of which are used to
10 treat the patient's terminal illness or irreversibly debilitating
11 disease or condition, that has successfully completed phase one
12 of a clinical trial but has not been approved for general use by
13 the United States Food and Drug Administration and remains under
14 investigation in a clinical trial. The term shall not include
15 Schedule I controlled substances;

16 (3) "Terminal illness", a disease that without life-
17 sustaining procedures will result in death in the near future or
18 a state of permanent unconsciousness from which recovery is
19 unlikely.

20 2. A manufacturer of an investigational drug, biological
21 product, or device may make available the manufacturer's
22 investigational drug, biological product, or device to eligible
23 patients under this section. This section does not require that
24 a manufacturer make available an investigational drug, biological
25 product, or device to an eligible patient. A manufacturer may:

26 (1) Provide an investigational drug, biological product, or
27 device to an eligible patient without receiving compensation; or

28 (2) Require an eligible patient to pay the costs of or

1 associated with the manufacture of the investigational drug,
2 biological product, or device.

3 3. This section does not require a health care insurer to
4 provide coverage for the cost of any investigational drug,
5 biological product, or device. A health care insurer may provide
6 coverage for an investigational drug, biological product, or
7 device.

8 4. Notwithstanding any other provision of law to the
9 contrary, no state agency or regulatory board shall revoke, fail
10 to renew, or take any other action against a physician's license
11 issued under chapter 334 based solely on the physician's
12 recommendation to an eligible patient regarding prescription for
13 or treatment with an investigational drug, biological product, or
14 device. Action against a health care provider's Medicare
15 certification based solely on the health care provider's
16 recommendation that a patient have access to an investigational
17 drug, biological product, or device is prohibited.

18 5. Any official, employee, or agent of this state who
19 blocks or attempts to block access of an eligible patient to an
20 investigational drug, biological product, or device is guilty of
21 a class A misdemeanor.

22 6. If a provision of this section or its application to any
23 person or circumstance is held invalid, the invalidity does not
24 affect other provisions or applications of this section that can
25 be given effect without the invalid provision or application, and
26 to this end the provisions of this section are severable.

27 7. If the clinical trial is closed due to lack of efficacy
28 or toxicity, the drug shall not be offered. If notice is given

1 on a drug, product, or device taken by a patient outside of a
2 clinical trial, the pharmaceutical company or patient's physician
3 shall notify the patient of the information from the safety
4 committee of the clinical trial.

5 8. Except in the case of gross negligence or willful
6 misconduct, any person who manufactures, imports, distributes,
7 prescribes, dispenses, or administers an investigational drug or
8 device in accordance with this section shall not be liable in any
9 action under state law for any loss, damage, or injury arising
10 out of, relating to, or resulting from:

11 (1) The design, development, clinical testing and
12 investigation, manufacturing, labeling, distribution, sale,
13 purchase, donation, dispensing, prescription, administration, or
14 use of the drug or device; or

15 (2) The safety or effectiveness of the drug or device.
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