SECOND REGULAR SESSION

SENATE BILL NO. 1454

103RD GENERAL ASSEMBLY

INTRODUCED BY SENATOR BROWN (16).

6202S.02I KRISTINA MARTIN, Secretary

AN ACT

To repeal section 191.480, RSMo, and to enact in lieu thereof one new section relating to alternative therapies.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Section 191.480, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 191.480, to read as follows:

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

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

(a) Has a terminal **condition or illness, a life-threatening condition or illness, or a severely debilitating condition or** illness;

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

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

(d) Has given written informed consent which shall be at least as comprehensive as the consent used in clinical trials for the use of the investigational drug, biological

EXPLANATION-Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

product, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written informed consent on the patient's behalf; and

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

(2) "Investigational drug, biological product, or device", a drug, biological product, or device, any of which are used to treat the patient's terminal **condition or illness, life-threatening condition or illness, or severely debilitating condition or** illness, that has successfully completed phase one of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial**[**. The term shall not include Schedule I controlled substances**]**;

(3) **"Life-threatening condition or illness", a disease or condition:**

(a) Where the likelihood of death is high unless the course of the disease or condition is interrupted; and

(b) With potentially fatal outcomes, where the end point of clinical trial analysis is survival;

(4) "Severely debilitating condition or illness", a disease or condition that causes major irreversible morbidity;

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

2. A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or

device to eligible patients under this section. This section does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient. A manufacturer may:

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

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

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

4. This section does not require the department of corrections to provide coverage for the cost of any investigational drug, biological product, or device.

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

6. If a provision of this section or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications

of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable.

7. If the clinical trial is closed due to lack of efficacy or toxicity, the drug shall not be offered. If notice is given on a drug, product, or device taken by a patient outside of a clinical trial, the pharmaceutical company or patient's physician shall notify the patient of the information from the safety committee of the clinical trial.

8. Except in the case of gross negligence or willful misconduct, any person who manufactures, imports, distributes, prescribes, dispenses, or administers an investigational drug or device to an eligible patient with a terminal **condition or illness, a life-threatening condition or illness, or a severely debilitating condition or** illness in accordance with this section shall not be liable in any action under state law for any loss, damage, or injury arising out of, relating to, or resulting from:

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

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

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