FIRST REGULAR SESSION

HOUSE BILL NO. 1072

98TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE NEELY.

2357H.01I D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal section 191.480, RSMo, and to enact in lieu thereof one new section relating to investigational drug trials, with penalty provisions.

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Section A. Section 191.480, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 191.480, to read as follows: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 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 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 illness, that has successfully completed phase one of a clinical trial but has not been approved for general use by the United

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

States Food and Drug Administration and remains under investigation in a clinical trial. The term shall not include Schedule I controlled substances;

(3) "Terminal illness", a disease 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. **A manufacturer or prescribing physician of an investigational drug, biological product, or device may market the investigational drug, biological product, or device to eligible patients under this section who are considering informed consent for a label-expansion, placebo-controlled trial. A manufacturer or physician seeking informed consent for a label-expansion, placebo-controlled trial from eligible patients shall:**

(1) Make the investigational drug, biological product, or device available to the eligible patient outside a placebo-controlled trial; or

(2) Present the eligible patient with the name, address, telephone number, and any other identifying information provided by physicians who are willing to prescribe the investigational drug, biological product, or device to the eligible patient outside the placebo-controlled trial.

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

[5.**]** **6.** 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.**] 7.** 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.**] 8.** 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.**] 9.** 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 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.

10. Any manufacturer that violates the provisions of subsection 3 of this section shall be assessed a fine of one hundred thousand dollars per patient.

11. (1) There is hereby created in the state treasury the "Investigational Drug Fund", which shall consist of moneys collected under subsection 10 of this section and any punitive damages awarded or settlements reached as a result of lawsuits filed by the attorney general for the off-label marketing of investigational drugs, biological products, or devices. The state treasurer shall be custodian of the fund. In accordance with sections 30.170 and 30.180, the state treasurer may approve disbursements. The fund shall be a dedicated fund and, upon appropriation, moneys in the fund shall be used solely to cover the costs of eligible patients under subsection 3 of this section whose health care coverage does not cover off-label use of the investigational drug, biological product, or device.

(2) Notwithstanding the provisions of section 33.080, to the contrary, any moneys remaining in the fund at the end of the biennium shall not revert to the credit of the general revenue fund.

(3) The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any interest and moneys earned on such investments shall be credited to the fund.

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