SECOND REGULAR SESSION

HOUSE BILL NO. 2429

101ST GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE DAVIS.

4989H.01I DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal sections 191.480 and 579.015, RSMo, and to enact in lieu thereof two new sections relating to investigational drugs.

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

Section A. Sections 191.480 and 579.015, RSMo, are repealed and two new sections enacted in lieu thereof, to be known as sections 191.480 and 579.015, to read as follows: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 **debilitating, life-threatening, or** 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 **debilitating, life-threatening, or** terminal illness, that has successfully completed phase one of a clinical trial but has not been approved

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.

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) "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. **Notwithstanding any other provision of law, production and distribution of any Schedule I psychedelic drug that qualifies as an investigational drug under subdivision (2) of subsection 1 of this section by a manufacturer and any dispensation of such drug by a physician or pharmacy for use in accordance with this section shall be considered lawful.** 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 **debilitating, life-threatening, or** 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.

579.015. 1. A person commits the offense of possession of a controlled substance if he or she knowingly possesses a controlled substance, except as authorized by this chapter or chapter 195.

2. The offense of possession of any controlled substance except thirty-five grams or less of marijuana **[~~or~~],** any synthetic cannabinoid**, 3,4-methylenedioxymethamphetamine, diethyltryptamine, dimethyltryptamine, 5-methoxy-N,N-diisopropyltryptamine, ibogaine, lysergic acid diethylamide, mescaline, peyote, psilocybin, or psilocyn** is a class D felony.

3. The offense of possession of more than ten grams but thirty-five grams or less of marijuana **[~~or~~],** any synthetic cannabinoid**, 3,4-methylenedioxymethamphetamine, diethyltryptamine, dimethyltryptamine, 5-methoxy-N,N-diisopropyltryptamine, ibogaine, lysergic acid diethylamide, mescaline, peyote, psilocybin, or psilocyn** is a class A misdemeanor**; except that, any such possession shall not be considered an offense if the possession is in accordance with the provisions of section 191.480**.

4. The offense of possession of not more than ten grams of marijuana **[~~or~~],** any synthetic cannabinoid**, 3,4-methylenedioxymethamphetamine, diethyltryptamine, dimethyltryptamine, 5-methoxy-N,N-diisopropyltryptamine, ibogaine, lysergic acid diethylamide, mescaline, peyote, psilocybin, or psilocyn** is a class D misdemeanor**; except that, any such possession shall not be considered an offense if the possession is in accordance with the provisions of section 191.480**. If the defendant has previously been found guilty of any offense of the laws related to controlled substances of this state, or of the United States, or any state, territory, or district, the offense is a class A misdemeanor. Prior findings of guilt shall be pleaded and proven in the same manner as required by section 558.021.

5. In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provision of this chapter or chapter 195, it shall not be

necessary to include any exception, excuse, proviso, or exemption contained in this chapter or chapter 195, and the burden of proof of any such exception, excuse, proviso or exemption shall be upon the defendant.

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