

House \_\_\_\_\_ Amendment NO. \_\_\_\_\_

Offered By

1 AMEND Senate Bill No. 717, Page 1, Section A, Line 2, by inserting immediately after said line the  
2 following:

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

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

6 (a) Has a terminal illness;

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

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

11 (d) Has given written informed consent for the use of the investigational drug, biological  
12 product, or device or, if the patient is a minor or lacks the mental capacity to provide informed  
13 consent, a parent or legal guardian has given written informed consent on the patient's behalf; and

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

16 (2) "Investigational drug, biological product, or device", a drug, biological product, or  
17 device that has successfully completed phase one of a clinical trial but has not been approved for  
18 general use by the United States Food and Drug Administration and remains under investigation in a  
19 clinical trial. The term does not include Schedule I controlled substances;

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

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

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

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

30 3. This section does not require a health care insurer or the Missouri Department of  
31 Corrections to provide coverage for the cost of any investigational drug, biological product, or

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1 device. A health care insurer may provide coverage for an investigational drug, biological product,  
2 or device.

3 4. Notwithstanding any other provision of law to the contrary, no state agency or regulatory  
4 board shall revoke, fail to renew, or take any other action against a physician's license issued under  
5 chapter 334 based solely on the physician's recommendation to an eligible patient regarding  
6 prescription for or treatment with an investigational drug, biological product, or device.

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

10 6. If a provision of this section or its application to any person or circumstance is held  
11 invalid, the invalidity does not affect other provisions or applications of this section that can be given  
12 effect without the invalid provision or application, and to this end the provisions of this section are  
13 severable."; and

14 Further amend said bill by amending the title, enacting clause, and intersectional references  
15 accordingly.  
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