

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

**Offered By**

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1 AMEND House Committee Substitute for House Bill No. 2372, Page 8, Section 190.246, Line  
2 41, by inserting after said section and line the following:  
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4 "191.455. 1. Sections 191.455 to 191.467 shall be known and may be cited as the "Hope  
5 for Missouri Patients Act".

6 2. As used in sections 191.455 to 191.467, unless the context otherwise requires, the  
7 following terms mean:

8 (1) "Eligible facility", an institution that is operating under a Federalwide Assurance  
9 (FWA) for the Protection of Human Subjects under 42 U.S.C. Section 289(a) and 45 CFR Part  
10 46 and that is subject to the FWA laws, regulations, policies, and guidelines, including renewals  
11 or updates;

12 (2) "Eligible patient", an individual who meets the following conditions:

13 (a) Has considered all other treatment options currently approved by the United States  
14 Food and Drug Administration;

15 (b) Has received a recommendation from his or her physician for an individualized  
16 investigational treatment based on analysis of the patient's genomic sequence; human  
17 chromosomes; deoxyribonucleic acid; ribonucleic acid; genes; gene products, such as enzymes  
18 and other types of proteins; or metabolites;

19 (c) Has a life-threatening or severely debilitating illness, or a serious disease or condition  
20 associated with morbidity that has a substantial impact on day-to-day functioning, as attested to  
21 by the patient's treating physician;

22 (d) Has given written, informed consent for the use of the individualized investigational  
23 drug, biological product, or device; and

24 (e) Has documentation from his or her physician that he or she meets the requirements of  
25 paragraphs (a) to (d) of this subdivision;

26 (3) "Individualized investigational drug, biological product, or device", any drug,  
27 biological product, or device that is unique to and produced exclusively for use for an individual  
28 patient based on the patient's own genetic profile. The term "individualized investigational drug,  
29 biological product, or device":

Action Taken \_\_\_\_\_ Date \_\_\_\_\_

1           (a) Shall include, but not be limited to, individualized gene therapy antisense  
2 oligonucleotides and individualized neoantigen vaccines; and

3           (b) Shall not include any drug, biological product, or device derived from human  
4 primary or secondary embryonic stem cells or cell lines, or tissues or cells derived from abortion,  
5 but shall include any drug, biological product, or device derived from human perinatal tissues,  
6 cells, and secreted factors not obtained from an abortion;

7           (4) "Individualized investigational treatment", treatment with an individualized  
8 investigational drug, biological product, or device;

9           (5) "Life-threatening or severely debilitating illness", any disease or condition that is  
10 life-threatening or severely debilitating, as such terms are defined in 21 CFR 312.81 or any  
11 successor law or regulation, as applicable;

12           (6) "Written, informed consent", a written document that:

13           (a) Is signed by the patient or, if the patient is a minor, signed by any person authorized  
14 to consent under section 431.061;

15           (b) Is attested to by the patient's physician and a witness; and

16           (c) At a minimum, includes all of the following:

17           a. An explanation of the currently approved products and treatments for the illness,  
18 disease, or condition from which the patient suffers;

19           b. An attestation that the patient concurs with his or her physician in believing that all  
20 currently approved and conventionally recognized treatments are unlikely to prolong the patient's  
21 life;

22           c. Clear identification of the specific proposed individualized investigational drug,  
23 biological product, or device that the patient is seeking to use;

24           d. A description of the potentially best and worst outcomes of using the individualized  
25 investigational drug, biological product, or device and a realistic description of the most likely  
26 outcome. The description shall include the possibility that new, unanticipated, different, or  
27 worse symptoms might result and that death could be hastened by the proposed treatment. The  
28 description shall be based on the physician's knowledge of the proposed treatment in conjunction  
29 with an awareness of the patient's condition;

30           e. A statement that the patient's health plan or third-party administrator and provider are  
31 not obligated to pay for any care or treatments consequent to the use of the individualized  
32 investigational drug, biological product, or device unless they are specifically required to do so  
33 by law or contract;

34           f. A statement that the patient's eligibility for hospice care may be withdrawn if the  
35 patient begins curative treatment with the individualized investigational drug, biological product,  
36 or device and that care may be reinstated if this treatment ends and the patient meets hospice  
37 eligibility requirements; and

1           g. A statement that the patient understands that he or she is liable for all expenses  
2 consequent to the use of the individualized investigational drug, biological product, or device  
3 and that this liability extends to the patient's estate unless a contract between the patient and the  
4 manufacturer of the individualized investigational drug, biological product, or device states  
5 otherwise.

6           191.457. 1. A manufacturer operating within an eligible facility and in accordance with  
7 all applicable Federalwide Assurance laws and regulations may make available an individualized  
8 investigational drug, biological product, or device and an eligible patient may request an  
9 individualized investigational drug, biological product, or device from an eligible facility or  
10 manufacturer operating within an eligible facility under sections 191.455 to 191.467. Sections  
11 191.455 to 191.467 shall not require that a manufacturer make available an individualized  
12 investigational drug, biological product, or device to an eligible patient.

13           2. An eligible facility or manufacturer operating within an eligible facility may do all of  
14 the following:

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

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

19           191.459. 1. Sections 191.455 to 191.467 shall not expand the coverage required of an  
20 insurer under chapter 376.

21           2. A health plan, third-party administrator, or governmental agency may, but is not  
22 required to, provide coverage for the cost of an individualized investigational drug, biological  
23 product, or device or the cost of services related to the use of an individualized investigational  
24 drug, biological product, or device in accordance with sections 191.455 to 191.467.

25           3. Sections 191.455 to 191.467 shall not require any governmental agency to pay costs  
26 associated with the use of or care or treatment of a patient with an individualized investigational  
27 drug, biological product, or device.

28           4. Sections 191.455 to 191.467 shall not require a hospital or facility licensed by the  
29 department of health and senior services to provide new or additional services unless approved  
30 by the hospital or facility.

31           191.461. If a patient's death is proximately caused by treatment with an individualized  
32 investigational drug, biological product, or device, the patient's estate, heirs, or devisees shall not  
33 be liable for any debt remaining after payment by insurance for charges directly incurred for  
34 such treatment. However, this section shall not provide an exemption to liability for charges for  
35 nonexperimental treatments provided to the patient, including nonexperimental treatments  
36 rendered to the patient due to complications or consequences of the experimental treatment.

37           191.463. 1. A licensing board or disciplinary subcommittee shall not revoke, fail to  
38 renew, suspend, or take any action against a health care provider's license based solely on the

1 health care provider's recommendations to an eligible patient regarding access to or treatment  
2 with an individualized investigational drug, biological product, or device.

3 2. An entity responsible for Medicare certification shall not take action against a health  
4 care provider's Medicare certification based solely on the health care provider's recommendation  
5 that a patient have access to an individualized investigational drug, biological product, or device.

6 191.465. 1. An official, employee, or agent of this state shall not block or attempt to  
7 block an eligible patient's access to an individualized investigational drug, biological product, or  
8 device.

9 2. Counseling, advice, or a recommendation consistent with medical standards of care  
10 from a licensed health care provider shall not be a violation of this section.

11 191.467. 1. Sections 191.455 to 191.467 shall not create a private cause of action  
12 against a manufacturer of an individualized investigational drug, biological product, or device or  
13 against any other person or entity involved in the care of an eligible patient using the  
14 individualized investigational drug, biological product, or device for any harm done to the  
15 eligible patient resulting from the individualized investigational drug, biological product, or  
16 device if the manufacturer or other person or entity has complied in good faith with the terms of  
17 sections 191.455 to 191.467 and has exercised reasonable care.

18 2. Sections 191.455 to 191.467 shall not affect any health care coverage required under  
19 section 376.429 for costs incurred due to participation in clinical trials."; and

20  
21 Further amend said bill by amending the title, enacting clause, and intersectional references  
22 accordingly.