

SENATE BILL NO. 422

INTRODUCED BY K. BOGNER

A BILL FOR AN ACT ENTITLED: "AN ACT EXPANDING THE RIGHT TO TRY ACT; REMOVING THE RESTRICTION ON PATIENTS WHO ARE ELIGIBLE TO RECEIVE EXPERIMENTAL MEDICATIONS UNDER THE RIGHT TO TRY ACT; EXTENDING GOVERNMENTAL IMMUNITY; AND AMENDING SECTIONS 50-12-102, 50-12-103, 50-12-104, 50-12-105, 50-12-106, 50-12-107, 50-12-108, 50-12-109, AND 50-12-110, MCA.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

**Section 1.** Section 50-12-102, MCA, is amended to read:

**"50-12-102. Definitions.** As used in this part, the following definitions apply:

~~(1) "Eligible patient" means an individual who meets the requirements of 50-12-104.~~

~~(2)~~(1) "Health care facility" has the meaning provided in 50-5-101.

~~(3)~~(2) "Health care provider" means any of the following individuals licensed pursuant to Title 37:

(a) a physician;

(b) an advanced practice registered nurse authorized by the board of nursing to prescribe medicine; and

(c) a physician assistant whose duties and delegation agreement allows the physician assistant to undertake the activities allowed under this part.

~~(4)~~(3) "Investigational drug, biological product, or device" means a drug, biological product, or device that:

(a) has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the United States food and drug administration; and

(b) remains under investigation in a United States food and drug administration-approved clinical trial.

~~(5) "Terminal illness" means a progressive disease or medical or surgical condition that:~~

~~(a) entails significant functional impairment;~~

1 (b) ~~is not considered by a treating health care provider to be reversible even with administration of a~~  
2 ~~treatment currently approved by the United States food and drug administration; and~~

3 ~~(c) without life-sustaining procedures, will result in death.~~

4 ~~(6)(4)~~ "Written informed consent" means a written document that meets the requirements of 50-12-  
5 105."

6

7 **Section 2.** Section 50-12-103, MCA, is amended to read:

8 **"50-12-103. Availability of experimental drugs.** (1) A manufacturer of an investigational drug,  
9 biological product, or device may make the drug, product, or device available to ~~an eligible a~~ patient who has  
10 requested the drug, product, or device pursuant to this part.

11 (2) The manufacturer may:

12 (a) provide an investigational drug, biological product, or device to ~~an eligible a~~ patient without  
13 receiving compensation; or

14 (b) require ~~an eligible a~~ patient to pay the costs of or the costs associated with the manufacture of  
15 the investigational drug, biological product, or device.

16 (3) A manufacturer is not required to make an investigational drug, biological product, or device  
17 available to ~~an eligible a~~ patient."

18

19 **Section 3.** Section 50-12-104, MCA, is amended to read:

20 **"50-12-104. ~~Eligible patient~~ Patient requirements.** A patient is eligible for treatment with an  
21 investigational drug, biological product, or device if the patient has:

22 ~~(1) a terminal illness that is attested to by the patient's treating health care provider;~~

23 ~~(2)(1)~~ considered all other treatment options currently approved by the United States food and drug  
24 administration;

25 ~~(3)(2)~~ received a recommendation from the patient's treating health care provider for an  
26 investigational drug, biological product, or device;

27 ~~(4)(3)~~ given written informed consent for the use of the investigational drug, biological product, or  
28 device; and

1           ~~(5)~~(4) documentation from the treating health care provider that the patient meets the requirements of  
2 this section."

3

4           **Section 4.** Section 50-12-105, MCA, is amended to read:

5           **"50-12-105. Written informed consent required.** (1) A patient or a patient's legal guardian must  
6 provide written informed consent for treatment with an investigational drug, biological product, or device.

7           (2) At a minimum, the written informed consent must include:

8           (a) an explanation of the currently approved products and treatments for the disease or condition  
9 from which the patient suffers;

10           (b) an attestation that the patient concurs with the treating health care provider in believing that all  
11 currently approved and conventionally recognized treatments are unlikely to ~~prolong~~improve the patient's ~~life~~  
12 condition;

13           (c) clear identification of the specific investigational drug, biological product, or device that the  
14 patient is seeking to use;

15           (d) a description of the potentially best and worst outcomes of using the investigational drug,  
16 biological product, or device and a realistic description of the most likely outcome;

17           (e) a statement that the patient's health plan or third-party administrator and provider are not  
18 obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product,  
19 or device unless they are specifically required to do so by law or contract;

20           (f) a statement that the patient's eligibility for hospice care may be withdrawn if the patient begins  
21 curative treatment with the investigational drug, biological product, or device and that hospice care may be  
22 reinstated if the treatment ends and the patient meets hospice eligibility requirements; and

23           (g) a statement that the patient understands that the patient is liable for all expenses related to the  
24 use of the investigational drug, biological product, or device and that the liability for expenses extends to the  
25 patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or  
26 device states otherwise.

27           (3) The description of potential outcomes required under subsection (2)(d) must:

28           (a) include the possibility that new, unanticipated, different, or worse symptoms might result ~~and~~

- 1 ~~that the proposed treatment could hasten death; and~~
- 2 (b) be based on the treating health care provider's knowledge of the proposed treatment in
- 3 conjunction with an awareness of the patient's condition.
- 4 (4) The written informed consent must be:
- 5 (a) signed by:
- 6 (i) the patient;
- 7 (ii) a parent or legal guardian, if the patient is a minor; or
- 8 (iii) a legal guardian, if a guardian has been appointed pursuant to Title 72, chapter 5; and
- 9 (b) attested to by the patient's treating health care provider and a witness."

10

11 **Section 5.** Section 50-12-106, MCA, is amended to read:

12 **"50-12-106. Effect on insurance coverage and health care services.** (1) This part does not:

- 13 (a) expand the coverage required of an insurer under Title 33 or of the state or a local government
- 14 under Title 2 or Title 53;
- 15 (b) affect the requirements for insurance coverage of routine patient costs for patients involved in
- 16 approved cancer clinical trials pursuant to 2-18-704, 33-22-101, 33-22-153, 33-31-111, 33-35-306, 53-4-1005,
- 17 or 53-6-101;
- 18 (c) require a health plan, third-party administrator, or governmental agency to pay costs associated
- 19 with the use, care, or treatment of ~~an eligible~~ a patient with an investigational drug, biological product, or device;
- 20 or
- 21 (d) require a health care facility to provide new or additional services.
- 22 (2) A health plan, third-party administrator, or governmental agency may provide coverage for the
- 23 cost of an investigational drug, biological product, or device or the cost of services related to the use of an
- 24 investigational drug, biological product, or device under this part.
- 25 (3) A health care facility may approve the use of an investigational drug, biological product, or
- 26 device in the health care facility."

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28 **Section 6.** Section 50-12-107, MCA, is amended to read:

1           **"50-12-107. Heirs not liable for payments.** If ~~an eligible a~~ patient dies while being treated with an  
 2 investigational drug, biological product, or device, the patient's heirs are not liable for any outstanding debt  
 3 related to the treatment or to a lack of insurance as a result of the treatment."  
 4

5           **Section 7.** Section 50-12-108, MCA, is amended to read:

6           **"50-12-108. Disciplinary action prohibited.** (1) A licensing board may not revoke, fail to renew,  
 7 suspend, or take any action against a license issued under Title 37 to a health care provider based solely on  
 8 the health care provider's recommendations to ~~an eligible a~~ patient regarding access to or treatment with an  
 9 investigational drug, biological product, or device.

10           (2) The department of public health and human services may not take action against a health care  
 11 provider's medicare certification based solely on the health care provider's recommendation that a patient have  
 12 access to an investigational drug, biological product, or device."  
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14           **Section 8.** Section 50-12-109, MCA, is amended to read:

15           **"50-12-109. State action prohibited.** (1) An official, employee, or agent of the state of Montana may  
 16 not block or attempt to block ~~an eligible a~~ patient's access to an investigational drug, biological product, or  
 17 device.

18           (2) Counseling, advice, or a recommendation consistent with medical standards of care from a  
 19 licensed health care provider is not a violation of this section."  
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21           **Section 9.** Section 50-12-110, MCA, is amended to read:

22           **"50-12-110. Immunity from suit.** A manufacturer of an investigational drug, biological product, or  
 23 device, a pharmacist, a health care facility, a health care provider, or a person or entity involved in the care of  
 24 ~~an eligible a~~ patient using an investigational drug, biological product, or device is immune from suit for any harm  
 25 done to the ~~eligible~~ patient resulting from the investigational drug, biological product, or device if the  
 26 manufacturer, pharmacist, health care facility, health care provider, or other person or entity is complying in  
 27 good faith with the terms of this act and has exercised reasonable care."  
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