



State of Wisconsin
2015 - 2016 LEGISLATURE

LRB-1795/1
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2015 BILL

1 **AN ACT** *to create* 450.135 of the statutes; **relating to:** access to investigational
2 drugs, devices, and biological products and limitations on liability related to
3 their use.

Analysis by the Legislative Reference Bureau

Under this bill, a manufacturer of an investigational drug, device, or biological product may make the investigational drug, device, or biological product available to an eligible patient. Under the bill, an investigational drug, device, or biological product is one that has not yet been approved for general use by the federal Food and Drug Administration, but, among other requirements, has successfully completed a phase one clinical trial and remains under investigation or is pending approval by the federal food and drug administration for general use. A patient is eligible under the bill if, among other things, the patient has considered all treatment options approved for general use, has received a treating physician's recommendation or prescription order for an investigational drug, device, or biological product, and has given written informed consent for use of the investigational drug, device, or biological product.

The bill provides a limitation of liability under state law for a manufacturer, distributor, pharmacist, physician or other practitioner, or other person who makes available, delivers, distributes, prescribes, dispenses, or administers an investigational drug, device, or biological product to an eligible patient consistent with the bill's provisions, and who in doing so exercises reasonable care.

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Finally, the bill prohibits an official, employee, or agent of the state from blocking or attempting to block an eligible patient's access to an investigational drug, device, or biological product.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 450.135 of the statutes is created to read:

2 **450.135 Access to investigational drugs, devices, and biological**
3 **products for terminally ill patients. (1) DEFINITIONS.** In this section:

4 (a) “Eligible patient” means a patient who is eligible under sub. (2).

5 (b) “Investigational drug, device, or biological product” means a drug, device,
6 or biological product that has not been approved for general use by the federal food
7 and drug administration and meets all of the following conditions:

8 1. Has successfully completed a phase one clinical trial approved by the federal
9 food and drug administration.

10 2. Remains under investigation in a phase 2 or 3 clinical trial approved by the
11 federal food and drug administration or has completed a phase 3 clinical trial and
12 is pending approval by the federal food and drug administration for general use.

13 3. Is not the subject of a clinical trial that was closed due to the toxicity or lack
14 of efficacy of the drug, device, or biological product.

15 (c) “Terminal illness” means a disease that, without life-sustaining procedures,
16 will soon result in death or a state of permanent unconsciousness from which
17 recovery is unlikely.

18 **(2) ELIGIBILITY.** An individual is an eligible patient for purposes of this section
19 if the individual meets all of the following conditions:

20 (a) Has a terminal illness.

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1 (b) Has considered all treatment options approved by the federal food and drug
2 administration for general use.

3 (c) Has received a recommendation or prescription order from the individual's
4 treating physician for an investigational drug, device, or biological product.

5 (d) Has given written informed consent to use the investigational drug, device,
6 or biological product. The content of the written informed consent provided by the
7 patient shall be consistent with and at least as comprehensive as the consent used
8 in clinical trials for the investigational drug, device, or biological product.

9 (e) Possesses a written verification executed by the individual's treating
10 physician attesting that the individual meets the conditions under pars. (a) to (d).

11 **(3) MANUFACTURERS.** A manufacturer of an investigational drug, device, or
12 biological product may, but is not required to, make that investigational drug, device,
13 or biological product available to an eligible patient. If the manufacturer charges an
14 eligible patient for an investigational drug, device, or biological product, the
15 manufacturer may not charge more than an amount that is equal to the
16 manufacturer's actual cost to manufacture the investigational drug, device, or
17 biological product provided to the eligible patient.

18 **(4) LIMITATIONS OF LIABILITY.** (a) A physician is immune from civil or criminal
19 liability or professional discipline based solely on the physician's recommendation to
20 an eligible patient for the use of an investigational drug, device, or biological product
21 to treat the patient's terminal illness if the eligible patient gives written informed
22 consent that satisfies sub. (2) (d) and s. 448.30.

23 (b) Any manufacturer, distributor, pharmacist, practitioner, or other person
24 who lawfully makes available, delivers, distributes, prescribes, dispenses, or
25 administers an investigational drug, device, or biological product to an eligible

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1 patient consistent with this section, and who in doing so exercises reasonable care,
2 may not be held liable in any action under state law for any loss, damage, or injury
3 arising out of, relating to, or resulting from any of the following:

4 1. The design, development, clinical testing, investigation, manufacture,
5 labeling, distribution, sale, purchase, donation, dispensing, prescribing,
6 administration, or use of the investigational drug, device, or biological product.

7 2. The lack of safety or effectiveness of the investigational drug, device, or
8 biological product.

9 **(5) STATE OFFICIALS.** No official, employee, or agent of this state may block or
10 attempt to block an eligible patient's access to an investigational drug, device, or
11 biological product. Any counseling, advice, or recommendation of a practitioner that
12 is consistent with the applicable standard of care for the practitioner is not a
13 violation of this subsection.

14 **(6) INSURANCE.** Nothing in this section alters the obligations of an eligible
15 patient's insurer under the contract of insurance and applicable law.

16 **(END)**