



State of Wisconsin
2017 - 2018 LEGISLATURE

LRBs0117/1
MED:emw

**SENATE SUBSTITUTE AMENDMENT 1,
TO SENATE BILL 84**

January 29, 2018 - Offered by Senator MOULTON.

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

This substitute amendment differs from 2017 Senate Bill 84 in the following respects:

1. The substitute amendment makes various modifications governing who is considered to be an eligible patient, including:

a. Requiring that, instead of having a terminal illness, an individual have a life-threatening disease or condition, as defined under federal Food and Drug Administration regulations governing Investigational New Drug Applications.

b. Requiring that, instead of having considered all other available treatment options, the individual exhaust approved treatment options and be unable to participate in a clinical trial involving the investigational drug, device, or biological product.

c. Requiring that the treating physician attest that he or she is not compensated directly by the manufacturer of the investigational drug, device, or biological product.

d. Requiring that the individual be aware of the potential costs that may be associated with or otherwise result from the use of the investigational drug, device, or biological product.

2. The substitute amendment requires the manufacturer or sponsor of an investigational drug, device, or biological product that makes it available to a patient in this state to submit to the federal Food and Drug Administration an annual summary of the use of the drug, device, or biological product containing certain information.

3. The substitute amendment makes various changes to the definition of investigational drug, device, or biological product.

4. The substitute amendment adds a reference to health care facilities in the list of persons entitled to immunity under the substitute amendment.

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 or licensed for use by the federal food
7 and drug administration and meets all of the following conditions:

8 1. The drug, device, or biological product has successfully completed a phase
9 one clinical trial approved by the federal food and drug administration.

10 2. The drug, device, or biological product remains under investigation in a
11 phase 2 or 3 clinical trial approved by the federal food and drug administration or
12 has completed a phase 3 clinical trial and is pending approval or licensure by the
13 federal food and drug administration.

14 3. The active development or production of the drug, device, or biological
15 product is ongoing and has not been discontinued by the manufacturer or placed on
16 clinical hold under 21 USC 355 (i).

1 (c) “Life-threatening disease or condition” means a disease or condition that
2 is life-threatening, as defined in 21 CFR 312.81 (a).

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

5 (a) Has been diagnosed with a life-threatening disease or condition.

6 (b) Has exhausted approved treatment options and is unable to participate in
7 a clinical trial involving the investigational drug, device, or biological product.

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

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

14 (e) Is aware of the potential costs that may be associated with or otherwise
15 result from the use of the investigational drug, device, or biological product under
16 this section.

17 (f) Possesses a written verification executed by the individual’s treating
18 physician attesting that the individual meets the conditions under pars. (a) to (e),
19 and that the physician is not compensated directly by the manufacturer of the
20 investigational drug, device, or biological product for making that attestation.

21 **(3) MANUFACTURERS.** A manufacturer of an investigational drug, device, or
22 biological product may, but is not required to, make that investigational drug, device,
23 or biological product available to an eligible patient. If the manufacturer charges an
24 eligible patient for an investigational drug, device, or biological product, the
25 manufacturer may not charge more than an amount that is equal to the

1 manufacturer's actual cost to manufacture the investigational drug, device, or
2 biological product provided to the eligible patient.

3 (4) LIMITATIONS OF LIABILITY. (a) A physician is immune from civil or criminal
4 liability or from professional discipline under s. 448.02 based solely on the
5 physician's recommendation to an eligible patient for the use of an investigational
6 drug, device, or biological product to treat the patient's life-threatening disease or
7 condition if the eligible patient gives written informed consent that satisfies sub. (2)
8 (d) and s. 448.30.

9 (b) Any manufacturer, distributor, pharmacist, practitioner, health care
10 facility, or other person who lawfully makes available, delivers, distributes,
11 prescribes, dispenses, or administers an investigational drug, device, or biological
12 product to an eligible patient consistent with this section, and who in doing so
13 exercises reasonable care, may not be held liable in any action under state law for
14 any loss, damage, or injury arising out of, relating to, or resulting from any of the
15 following:

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

19 2. The lack of safety or effectiveness of the investigational drug, device, or
20 biological product.

21 (5) REPORTING. The manufacturer or sponsor of an investigational drug, device,
22 or biological product that makes the investigational drug, device, or biological
23 product available to a patient in this state shall submit to the federal food and drug
24 administration an annual summary of the use of the investigational drug, device, or
25 biological product. The summary shall include the number of doses supplied, the

1 number of patients treated, the uses for which it was made available, and any known
2 serious adverse events.

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

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

10 **(END)**