WISCONSIN LEGISLATIVE COUNCIL
AMENDMENT MEMO

2017 Senate Bill 84	Senate Substitute Amendment 1
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2017 SENATE BILL 84

Senate Bill 84 creates a method by which an eligible patient may gain access to an investigational drug, device, or biological product under certain circumstances. The bill includes definitions for the terms "eligible patient" and "investigational drug, device, or biological product."

In the case of any eligible patient, the bill authorizes, but does not require, a manufacturer of an investigational drug, device, or biological product to make it available to the patient under certain conditions specified in the bill. The bill limits liability for any manufacturer, distributor, pharmacist, practitioner, or other person who makes the investigational drug, device, or biological product available under the conditions specified in the bill.

Additionally, a physician is immune from civil or criminal liability or professional discipline based solely on a recommendation of an investigational drug, device, or biological product to an eligible patient to treat the patient's terminal illness, if the patient has given informed consent as provided under the bill.

The bill also prohibits an official, employee, or agent of the state from blocking or attempting to block an eligible patient's access to an experimental treatment covered under the bill, and provides the obligations of an eligible patient's insurer under the contract of insurance or applicable law are not altered by the bill.

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SENATE SUBSTITUTE AMENDMENT 1

The substitute amendment differs from the bill in the following respects:

- The substitute amendment makes various modifications governing who is considered to be an "eligible patient," by 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.
    - 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.
    - The treating physician attest that he or she is not compensated directly by the manufacturer of the investigational drug, device, or biological product.
    - 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.
- 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.
- The substitute amendment makes a change to the definition of "investigational drug, device, or biological product," specifying that the active development or production of the drug, device, or biological product must be ongoing and has not been discontinued by the manufacturer or placed on clinical hold.
- The substitute amendment adds a reference to health care facilities in the list of persons entitled to immunity under the substitute amendment.

BILL HISTORY

Senator Moulton offered Senate Substitute Amendment 1 on January 29, 2018. On February 6, 2018, the Senate Committee on Health and Human Services recommended adoption of the amendment, and passage of the bill, as amended, on votes of Ayes, 5; Noes, 0.

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