WISCONSIN LEGISLATIVE COUNCIL
ACT MEMO

2017 Wisconsin Act 165 [2017 Senate Bill 84]	Right to Try

2017 Wisconsin Act 165 creates a method by which an eligible patient may gain access to an investigational drug, device, or biological product, as defined in the Act, under certain circumstances.

Under the Act, a person qualifies as an eligible patient if the person satisfies all of the following criteria:

- Has been diagnosed with a life-threatening disease or condition.
- Has exhausted approved treatment options and is unable to participate in a clinical trial involving the investigational drug, device, or biological product.
- Has received a recommendation or prescription order from the individual's treating physician for an investigational drug, device, or biological product.
- Has given written informed consent to use the investigational drug, device, or biological product. The content of the written informed consent provided by the patient must be consistent with and at least as comprehensive as the consent used in clinical trials for the investigational drug, device, or biological product.
- Is aware of the potential costs that may be associated with or otherwise result from the use of the investigational drug, device, or biological product under this section.
- Possesses a written verification executed by the individual's treating physician attesting that the individual meets the above conditions, and that the physician is not compensated directly by the manufacturer of the investigational drug, device, or biological product for making that attestation.

In the case of any eligible patient, the Act authorizes, but does not require, a manufacturer of an investigational drug, device, or biological product to make it available to the patient under

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certain specified conditions. The Act also 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 Act limits liability for any manufacturer, distributor, pharmacist, practitioner, health care facility, or other person who makes the investigational drug, device, or biological product available under conditions specified in the Act. Additionally, the Act immunizes a physician from civil or criminal liability or professional discipline based solely on a recommendation of an experimental treatment to an eligible patient to treat the patient's terminal illness, if the patient has given informed consent.

The Act also 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, and provides that the obligations of an eligible patient's insurer under the contract of insurance or applicable law are not altered by the Act.

Effective date: March 30, 2018

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