



State of Wisconsin
2011 – 2012 LEGISLATURE



LRB-2890/2
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2011 BILL

1 AN ACT *to amend* 895.047 (1) (intro.); and *to create* 895.0475 of the statutes;
2 relating to: providing immunity from liability to drug and device
3 manufacturers and sellers under certain circumstances.

Analysis by the Legislative Reference Bureau

This bill provides immunity from liability to a manufacturer or a seller of a drug or device for any claim based on strict liability for a defect in the drug or device if the drug or device was approved by the federal Food and Drug Administration (FDA) at the time the drug or device left the control of the manufacturer or seller. The bill also provides immunity from liability to a manufacturer or seller of a drug or device for any claim based on the failure to warn of the risk of the drug or device if labeling for the drug or device was made available to the consumer or the person who prescribed the drug or device and the labeling was in compliance with applicable standards established by the FDA at the time the drug or device left the control of the manufacturer or seller.

The bill defines a “device” as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part, or accessory, which does not achieve any of its principal intended purposes through chemical action within or on the body of a person or other animal, is not dependent upon being metabolized for the achievement of any of its principal intended purposes, and is: (a) recognized by the U.S. pharmacopoeia and national formulary or official homeopathic pharmacopoeia of the United States, or any supplement to either of them; (b) intended for use in the diagnosis, cure,

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mitigation, treatment, or prevention of disease or other conditions in persons or other animals; or (c) intended to affect the structure or any function of the body of persons or other animals. The bill defines a “drug” as: 1) any substance recognized as a drug in the official U.S. pharmacopoeia and national formulary or official homeopathic pharmacopoeia of the United States or any supplement to either of them; 2) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other conditions in persons or other animals; 3) any substance other than a device or food intended to affect the structure or any function of the body of persons or other animals; or 4) any substance intended for use as a component of any article specified in items 1) to 3), above, but does not include gases or devices or articles intended for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes. The bill defines a “manufacturer” as an entity licensed or approved by the FDA to engage in the manufacture of drugs or devices. The bill defines an “entity” as a corporation, partnership, or association.

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

1 **SECTION 1.** 895.047 (1) (intro.) of the statutes, as created by 2011 Wisconsin Act
2 2, is amended to read:

3 895.047 **(1)** LIABILITY OF MANUFACTURER. (intro.) ~~In~~ Except as provided in s.
4 895.0475, in an action for damages caused by a manufactured product based on a
5 claim of strict liability, a manufacturer is liable to a claimant if the claimant
6 establishes all of the following by a preponderance of the evidence:

7 **SECTION 2.** 895.0475 of the statutes is created to read:

8 **895.0475 Product liability; drugs and devices. (1) DEFINITIONS.** In this
9 section:

10 (a) “Device” has the meaning given in s. 450.01 (6).

11 (b) “Drug” has the meaning given in s. 450.01 (10).

12 (c) “Entity” means a corporation, partnership, or association.

13 (d) “Manufacturer” means an entity licensed or approved by the federal food
14 and drug administration to engage in the manufacture of drugs or devices, consistent

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1 with the definition of “manufacturer” under the federal food and drug
2 administration’s regulations and interpreted guidances implementing the federal
3 Prescription Drug Marketing Act.

4 **(2) LIABILITY OF MANUFACTURER OR SELLER; STRICT LIABILITY.** Except as provided
5 in sub. (4), a manufacturer or a seller of a drug or device is immune from civil liability
6 for any claim based on strict liability for a defect in the design of a drug or device if
7 the drug or device was approved for safety and efficacy by the federal food and drug
8 administration at the time the drug or device left the control of the manufacturer or
9 seller. A drug or device approved pursuant to the procedures under section 510 (k)
10 of the federal Food, Drug and Cosmetic Act, 21 USC 360, shall not be considered
11 approved for safety and efficacy by the federal food and drug administration for the
12 purposes of this subsection.

13 **(3) LIABILITY OF MANUFACTURER OR SELLER; FAILURE TO WARN.** Except as provided
14 in sub. (4), a manufacturer or a seller of a drug or device is immune from civil liability
15 for any claim based on the failure to adequately warn of risk of a drug or device if
16 labeling for the drug or device was made available to the consumer or to the person
17 who prescribed the drug or device to the consumer and the labeling was in
18 compliance with the federal food and drug administration’s applicable standards for
19 labeling at the time the drug or device left the control of the manufacturer or seller.

20 **(4) EXCEPTION; FRAUD.** Immunity under subs. (2) and (3) shall not extend to a
21 claim brought against a manufacturer or a seller of a drug or device if the federal food
22 and drug administration determines that the manufacturer or seller committed a
23 fraud against the federal food and drug administration with regard to the product
24 at issue in the claim.

25 **SECTION 3. Initial applicability.**

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1 (1) The treatment of section 895.0475 (2) of the statutes first applies to a claim
2 based on strict liability commenced on the effective date of this subsection.

3 (2) The treatment of section 895.0475 (3) of the statutes first applies to a claim
4 based on failure to warn of risk commenced on the effective date of this subsection.

5 (END)