2011 Sel DRAFTING REQUEST

Bill

Received: **09/14/2011**

Received By: **tkuczens**

Wanted: **As time permits**

Companion to LRB:

For: **Rich Zipperer (608) 266-9174**

By/Representing: **Lucas Vebber**

May Contact:

Drafter: **tkuczens**

Subject: **Courts - immunity liability**
Courts - torts

Addl. Drafters:

Extra Copies:

Submit via email: **YES**

Requester's email: **Sen.Zipperer@legis.wisconsin.gov**

Carbon copy (CC:) to: **tracy.kuczenski@legis.wisconsin.gov**

Pre Topic:

No specific pre topic given

Topic:

provide immunity from strict liability for drug and medical device manufacturers and sellers

Instructions:

See attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?							
/P1	tkuczens 09/14/2011 tkuczens 09/19/2011	jdyer 09/15/2011 jdyer 09/20/2011	jfrantze 09/15/2011	_____ _____ _____ _____	lparisi 09/15/2011		
/P2			phenry 09/21/2011	_____ _____	ggodwin 09/21/2011		
/1	tkuczens 09/28/2011	jdyer 09/28/2011	rschluet 09/28/2011	_____ _____	lparisi 09/28/2011		

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
	tkuczens 09/28/2011	wjackson 09/28/2011		_____ _____			
/2			jfrantze 09/28/2011	_____ _____	lparisi 09/28/2011	mbarman 10/03/2011	

FE Sent For:

None

<END>

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FE Sent For: 12 WY 9/28 JB 9/28

<END>

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By/Representing: **Lucas Vebber**

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/?	tkuczens	P1 9/15 jld	9/15	R2 9/15			

FE Sent For:

<END>

Kuczenski, Tracy

From: Hurley, Peggy
Sent: Tuesday, September 13, 2011 8:48 AM
To: Kuczenski, Tracy
Subject: FW: Email from LRB Website

FYI

From: Vebber, Lucas
Sent: Monday, September 12, 2011 5:08 PM
To: Hurley, Peggy
Subject: RE: Email from LRB Website

Hi Peggy,

You had mentioned much of this was covered by Act 2.

This legislation would add that for Medical Devices/Pharmaceuticals that have FDA approval, the manufacturer is immune.

Thanks again for your time and assistance,

Lucas Vebber
Office of Senator Rich Zipperer
33rd Senate District
(608) 266-9174

From: Vebber, Lucas
Sent: Thursday, September 08, 2011 4:05 PM
To: Hurley, Peggy
Subject: Email from LRB Website

Please have this drafted as soon as possible.

Related to: Limiting liability for certain drug and medical device manufacturers and sellers under certain circumstances, this bill should state:

1. A manufacturer or seller is immune from civil liability for any claim based on strict liability for a defect in the design of a drug or device if the drug or device was approved for safety and efficacy by the FDA at the time the drug or device left the control of the manufacturer or seller.

2. A manufacturer or seller shall be immune from civil liability for any claim based on the failure to adequately warn of risk of a drug or device if labeling of the drug or device was made available to the consumer or prescribing person and such labeling was in compliance with the FDA's applicable standards at the time the drug or device left the control of the manufacturer or seller.

3. This immunity should not apply if the FDA determined the manufacturer or seller committed a fraud on the FDA with regard to the product at issue in the lawsuit.

4. Approval pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic act shall not be considered approval for safety and efficacy for the purposes of this law. 21 U.S.C. 360

5. Definitions: "Entity" means a individual, corporation, partnership or association having its U.S. corporate H.Q. in Wisconsin, employing more than 200 Wisconsin residents for manufacturing or research and development purposes. "FDA" is the U.S. Food and Drug Administration. "Manufacturer or seller" means any entity engaged in the manufacture, distribution, or sale of drugs or medical devices. "Research and development" is experimental or lab activity for the ultimate purpose of developing new products, improving existing products, or developing new uses for existing products.

how to define drug / device?

State of Wisconsin
2011 - 2012 LEGISLATURE

LRB-2890/P1
TKK:.....

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

9/14/11
Wanted 9/16/11

AN ACT ...; **relating to:** providing immunity from liability to drug and medical device manufacturers and sellers under certain circumstances.

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

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

Analysis by the Legislative Reference Bureau

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

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

History: 2011 a. 2.

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

895.0475 Product liability; drugs and devices. **(1)** DEFINITION. In this section, "manufacturer or seller" means any individual, corporation, partnership, or association that satisfies all of the following:

(a) Has its United States headquarters in this state.

(b) Employs at least 200 residents of this state.

(c) Primarily engages in experimental or laboratory activities with the primary purpose of developing new products, improving existing products, or developing new uses for existing products.

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

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

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

****NOTE: The drafting instructions for this subsection (4) use the phrase "product at issue in the lawsuit" rather than the phrase "drug or device at issue in the lawsuit." Is that intentional?

SECTION 3. Initial applicability.

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

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

(END)

D-note

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

P1
LRB-2890/1dn
TKK:...:...
JLd

date

Senator Zipperer:

This bill provides immunity from liability for certain manufacturers and sellers of drugs and devices under certain circumstances. Please review the draft carefully to ensure that it accomplishes your intent and let me know if you wish to make any changes. I have the following questions about the definitions provided for this bill:

bill

1. The drafting instructions provided definitions for "entity" and "research and development." However, because these terms appear only in the definitions, I did not create separate definitions for the terms but instead incorporated the definitional language within the definition for "manufacturer or seller." Okay?

2. "Entity" is defined to include an "individual ... having its United States corporate headquarters in Wisconsin [and] employing more than 200 residents..." Do individuals have corporate headquarters or employ more than 200 residents without forming some sort of business entity within which to operate? Is it your intent that the term, individual, be modified by the material that follows? Or should the word individual be removed from the definition? Also note that the use of the term "individual" without the modifying material could raise other issues related to the illegal manufacturing, selling, or distribution of labeled drugs or devices.

Also, is it appropriate to refer to the headquarters of a partnership or association as a corporate headquarters?

3. Do you wish to provide definitions for "device" or "drug"? See, for example, the definition for "device" and "drug" at s. 450.01 (6) and (10), respectively. Also, the drafting instructions refer to both devices and medical devices. To avoid confusion, I recommend selecting one term and using it consistently throughout the bill. Also, the broad term, product is used several times. Is that intentional? That is, would there be a reason to distinguish between drugs, devices and products in this statutory section governing immunity for drug and device manufacturers or sellers? *

4. The definition provided for manufacturer or seller, when read together with the definition for entity, does not specify that the manufacturer or seller is engaged in the manufacture, distribution, or sale of drugs or devices legitimately or with the approval of the federal Food and Drug Administration. See, for comparison purposes, the

definition for "manufacturer" at s. 450.01 (12). Do you wish to modify the definition for "manufacturer or seller" to address this point?

Tracy K. Kuczenski
Legislative Attorney
Phone: (608) 266-9867
E-mail: tracy.kuczenski@legis.wisconsin.gov

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-2890/P1dn
TKK:jld:jf

September 15, 2011

Senator Zipperer:

This bill provides immunity from liability for certain manufacturers and sellers of drugs and devices under certain circumstances. Please review the bill carefully to ensure that it accomplishes your intent and let me know if you wish to make any changes. I have the following questions about the definitions provided for this bill:

1. The drafting instructions provided definitions for "entity" and "research and development." However, because these terms appear only in the definitions, I did not create separate definitions for the terms but instead incorporated the definitional language within the definition for "manufacturer or seller." Okay?

2. "Entity" is defined to include an "individual ... having its United States corporate headquarters in Wisconsin [and] employing more than 200 residents..." Do individuals have corporate headquarters or employ more than 200 residents without forming some sort of business entity within which to operate? Is it your intent that the term, individual, be modified by the material that follows? Or should the word individual be removed from the definition? Also note that the use of the term "individual" without the modifying material could raise other issues related to the illegal manufacturing, selling, or distribution of labeled drugs or devices.

Also, is it appropriate to refer to the headquarters of a partnership or association as a corporate headquarters?

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4. The definition provided for manufacturer or seller, when read together with the definition for entity, does not specify that the manufacturer or seller is engaged in the manufacture, distribution, or sale of drugs or devices legitimately or with the approval of the federal Food and Drug Administration. See, for comparison purposes, the

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Kuczenski, Tracy

From: Vebber, Lucas
Sent: Friday, September 16, 2011 4:23 PM
To: Kuczenski, Tracy
Subject: Draft Legislation, LRB-2890

Hi Tracy,

To clarify the questions you brought up in the first drafters note, and slightly modify the language of the draft:

1. This is okay, subject to the changes below.

2. Remove the word "individual," and please modify the "corporate headquarters" to account for the headquarters of other business entities as well (i.e., partnerships, associations).

3. The definitions of device and drug as provided in 450.01 (6) and (10) respectively should also apply to the use of those terms in this section. For consistency, please use "device" as opposed to "medical device," as the definition of device in 450.01 (6) is clearly a medical device. For clarity, "product" should not be used.

4. Yes, manufacturer or seller should be defined to ensure that a "manufacturer or seller" is engaged in legitimate business. The definition of manufacturer under 450.01 (12) and manufacturing under 450.01(13) look like they would accomplish this.

Also, can we just say a "manufacturer or seller" is an "entity" (as that term is defined below) engaged in manufacturing, as defined by statute (see #4 above), of a device or drug (as those terms are defined above) – or selling of the same.

Then an "entity" would be a corporation, partnership or association that:

- Has its headquarters in Wisconsin (see #2 above); or
- Has its principal place of research and development or manufacturing in Wisconsin; or
- Employs at least 200 Wisconsinites in research and development or manufacturing in Wisconsin (even if it is not the principal location, or the H.Q.).

Thank you, and please call me with any questions.

Lucas Vebber
Office of Senator Rich Zipperer
33rd Senate District
(608) 266-9174

9/27/11 Per Lucas – remove " at the time the drug or device was made available to consumer"

9/28/11 Per Lucas - Change definition of "entity" to mean " a corporation, partnership, or association." Make same change to CRB – 3016/1

State of Wisconsin
2011 - 2012 LEGISLATURE

LRB-2890/P1 12
TKK:jld:jf
Insert

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

9/19/11
wanted 9/21

Regen

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

Insert analysis

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

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

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

Insert 2-3

895.0475 Product liability; drugs and devices. (1) DEFINITION. In this section, "manufacturer or seller" means any individual, corporation, partnership, or association that satisfies all of the following:

(a) Has its United States headquarters in this state.

(b) Employs at least 200 residents of this state.

(c) Primarily engages in experimental or laboratory activities with the primary purpose of developing new products, improving existing products, or developing new uses for existing products.

INS 2-10

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

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Insert after 2-25

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

(END)

Insert analysis

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, 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 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; [redacted] any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other conditions in persons or other animals; [redacted] 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 [redacted] any substance intended for use as a component of any article specified in pars. (a) to (c) 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 that satisfies one of the following: (a) has its headquarters in Wisconsin; (b) employs at least 200 Wisconsin residents to engage in research and development or manufacturing activities in this state; or (c) has its principal place of research and development or manufacturing activities in this state.

Insert 2-3

(a) "Device" has the meaning given in s. 450.01 (6).

(b) "Drug" has the meaning given in s. 450.01 (10).

items 1) to 3), above,

(c) NO

Insert 2-10

(d) "Manufacturer" means an entity licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidances implementing the federal prescription drug marketing act.

Insert after 2-25

****NOTE: I added the clause "at the time the drug or device was made available to the consumer" after "if labeling for the drug or device was made available to the consumer." Okay?

State of Wisconsin
2011 - 2012 LEGISLATURE

LRB-2890/P2
TKK:jld:ph
RMR

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

9/28/11 Today

companion to 3016/1

X Regen

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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, 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 that satisfies one of the following: (a) has its headquarters in Wisconsin; (b) employs at least 200 Wisconsin residents to engage in research and development or manufacturing activities in this state; or (c) has its principal place of research and development or manufacturing activities in this state.

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

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

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

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

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

(a) "Device" has the meaning given in s. 450.01 (6).

(b) "Drug" has the meaning given in s. 450.01 (10).

(c) "Entity" means any corporation, partnership, or association that satisfies at least one of the following:

1. Has its headquarters in this state.

2. Employs at least 200 residents of this state who are engaged in research and development or manufacturing activities in this state.

3. Has its principal place of research and development or manufacturing activities in this state.

(d) "Manufacturer" means an entity licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidances implementing the federal Prescription Drug Marketing Act.

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

(3) LIABILITY OF MANUFACTURER OR SELLER; FAILURE TO WARN. Except as provided in sub. (4), a manufacturer or a seller of a drug or device is immune from civil liability for any claim based on the failure to adequately warn of risk of a drug or device if labeling for the drug or device was made available to the consumer or to the person

who prescribed the drug or device to the consumer at the time the drug or device was made available to the consumer and the labeling was in compliance with the federal food and drug administration's applicable standards for labeling at the time the drug or device left the control of the manufacturer or seller.

****NOTE: I added the clause "at the time the drug or device was made available to the consumer" after "if labeling for the drug or device was made available to the consumer." Okay?

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

SECTION 3. Initial applicability.

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

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

(END)

State of Wisconsin
2011 - 2012 LEGISLATURE

LRB-2890/1 2
TKK:jld:rs

2011 BILL

2/28/11
TODAY
conform to
LRB-3016/2

Rejen

AN ACT ***to amend*** 895.047 (1) (intro.); and ***to create*** 895.0475 of the statutes; **relating to:** providing immunity from liability to drug and device 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.

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

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

(a) "Device" has the meaning given in s. 450.01 (6).

(b) "Drug" has the meaning given in s. 450.01 (10).

(c) "Entity" means any corporation, partnership, or association that satisfies at least one of the following:

1. Has its headquarters in this state.

2. Employs at least 200 residents of this state who are engaged in research and development or manufacturing activities in this state.

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

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

(END)

Barman, Mike

From: Vebber, Lucas
Sent: Monday, October 03, 2011 9:50 AM
To: LRB.Legal
Subject: Special Session Jacket Request - 11-2890/2

Please Jacket LRB 11-2890/2 as a SPECIAL SESSION BILL for the SENATE.

Thanks,

Lucas Vebber
Office of Senator Rich Zipperer
33rd Senate District
(608) 266-9174