

**2003 DRAFTING REQUEST**

**Assembly Amendment (AA-AB845)**

Received: **02/25/2004**

Received By: **dkennedy**

Wanted: **As time permits**

Identical to LRB:

For: **Gregg Underheim (608) 266-2254**

By/Representing: **Dick Sweet**

This file may be shown to any legislator: **NO**

Drafter: **dkennedy**

May Contact:

Addl. Drafters:

Subject: **Health - public health**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Underheim@legis.state.wi.us**

Carbon copy (CC:) to:

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**Pre Topic:**

No specific pre topic given

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**Topic:**

Cancer drug or supply manufacturer immunity from liability

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**Instructions:**

See Attached

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**Drafting History:**

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	dkennedy 02/25/2004	wjackson 02/25/2004		_____			
/1			rschluet 02/25/2004	_____	mbarman 02/25/2004	mbarman 02/25/2004	

FE Sent For:

**<END>**

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/?	dkennedy	1 wj 2/25					

FE Sent For:

Handwritten signature and initials, including '225' and '4'.

<END>

Replace subsection 6  
except as provided in paragraph

unless the ~~manufacturer~~ <sup>manufacturer</sup> ~~is~~ <sup>is</sup> ~~found~~ <sup>is</sup> ~~guilty~~ <sup>is</sup> ~~of~~ <sup>is</sup> ~~unprofessional~~ <sup>is</sup> ~~conduct~~ <sup>is</sup> ~~under~~ <sup>is</sup> ~~paragraph~~ <sup>is</sup> ~~(b)~~ <sup>is</sup> ~~does~~ <sup>is</sup> ~~not~~ <sup>is</sup> ~~extend~~ <sup>is</sup> ~~to~~ <sup>is</sup> ~~donation~~ <sup>is</sup> ~~acceptance~~ <sup>is</sup> ~~distribution~~ <sup>is</sup> ~~or~~ <sup>is</sup> ~~dispensation~~ <sup>is</sup> ~~of~~ <sup>is</sup> ~~a~~ <sup>is</sup> ~~cancer~~ <sup>is</sup> ~~drug~~ <sup>is</sup> ~~by~~ <sup>is</sup> ~~a~~ <sup>is</sup> ~~person~~ <sup>is</sup> ~~whose~~ <sup>is</sup> ~~act~~ <sup>is</sup> ~~or~~ <sup>is</sup> ~~omission~~ <sup>is</sup> ~~involves~~ <sup>is</sup> ~~reckless~~ <sup>is</sup> ~~wanton~~ <sup>is</sup> ~~or~~ <sup>is</sup> ~~intentional~~ <sup>is</sup> ~~misconduct~~ <sup>is</sup>

6 (a) A prescription drug manufacturer shall ~~may~~ is not, in the absence of bad faith be subject to criminal or civil liability for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a prescription drug <sup>cancer</sup> manufactured by the ~~prescription drug~~ manufacturer that is donated by any person under the ~~program~~ <sup>section</sup>, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

not not the design or ~~control~~ <sup>control</sup> manufacturer

except as provided in par. (c)

same as (a)

(b) Any person ~~donating~~ <sup>prescription</sup> other than a drug manufacturer, is immune from civil liability for injury to or the death of the individual to whom the cancer drug is dispensed and may not be found guilty of unprofessional conduct for his or her acts or omissions related to donating, accepting, distributing, or dispensing a cancer drug under this section

(c) The immunity or the prohibition on a finding of guilty of unprofessional conduct under par. ~~(b)~~ <sup>(b)</sup> does not extend to donation, acceptance, distribution, or dispensation of a cancer drug by a person whose act or omission involves reckless, wanton, or intentional misconduct

delete (c)

H.B. 898

3

13 entities to be dispensed to persons who meet the eligibility requirements of the program.  
 14 A prescription drug shall be dispensed only pursuant to a prescription issued by a health  
 15 care professional. A pharmacy, hospital, or nonprofit clinic which accepts donated  
 16 prescription drugs shall comply with all applicable federal and state laws dealing with the  
 17 storage and distribution of dangerous drugs and shall inspect all prescription drugs prior  
 18 to dispensing the prescription drugs to determine that they are not adulterated as  
 19 described in section 196.095. The pharmacy, hospital, or nonprofit clinic may charge  
 20 persons receiving donated prescription drugs a handling fee established by rule of the  
 21 department promulgated pursuant to section 196.984. Prescription drugs donated to the  
 22 program shall not be resold.

196.981. 1. The following persons and entities when acting in good faith shall not  
 2 be subject to criminal or civil liability for injury, death, or loss to person or property, or  
 3 professional disciplinary action for matters related to donating, accepting, or dispensing  
 4 prescription drugs under the prescription drug repository program:

- 5 (1) The department of health and senior services;
- 6 (2) The director of the department of health and senior services;
- 7 (3) Any prescription drug manufacturer, governmental entity, or person donating  
 8 prescription drugs to the program;
- 9 (4) Any pharmacy, hospital, nonprofit clinic, or health care professional that  
 10 accepts or dispenses prescription drugs under the program; and
- 11 (5) Any pharmacy, hospital, or nonprofit clinic that employs a health care  
 12 professional who accepts or dispenses prescription drugs under the program.

13 2. A prescription drug manufacturer shall not, in the absence of bad faith, be  
 14 subject to criminal or civil liability for injury, death, or loss to person or property for  
 15 matter related to the donation, acceptance, or dispensing of a prescription drug  
 16 manufactured by the prescription drug manufacturer that is donated by any person under  
 17 the program, including but not limited to liability for failure to transfer or communicate  
 18 product or consumer information or the expiration date of the donated prescription drug.

196.984. 1. In consultation with the board of pharmacy, the director of the  
 2 department of health and senior services shall adopt and promulgate rules to implement  
 3 the prescription drug repository program. Such rules shall include:

- 4 (1) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and  
 5 dispense donated prescription drugs under the program;
- 6 (2) Standards and procedures for accepting, safely storing, and dispensing donated  
 7 prescription drugs;
- 8 (3) Standards and procedures for inspecting donated prescription drugs to

6(a)

but not  
 the design  
 or manufac  
 #

2003

Date (time) needed

Now

LRBa 2399 / 1

AMENDMENT

DAK:Wlj :

See form AMENDMENTS — COMPONENTS & ITEMS.

4 (A) AMENDMENT



~~TO 2003 A AMENDMENT~~ (LRBa ~~2222~~)

~~TO S A SUBSTITUTE AMENDMENT~~ (LRBs ~~2222~~)

TO 2003 ~~SB~~ ~~SR~~ (AB) ~~AJR~~ ~~AR~~ 845 (LRB ~~2222~~)

At the locations indicated, amend the bill as follows:

(fill ONLY if "engrossed ...." or "as shown by ....." )

#. Page 3, line 21: delete the material beginning with that line and ending with page 4, line 7; and substitute   


~~#. Page . . . . , line . . . . :~~

~~#. Page . . . . , line . . . . :~~

~~#. Page . . . . , line . . . . :~~

~~#. Page . . . . , line . . . . :~~

✓ (b)(a) <sup>(B)</sup>

unless the manufacturer of a cancer drug or supply exercises bad faith, the manufacturer is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a cancer drug or supply manufactured by the manufacturer that is donated by any person under this section, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated cancer drug or supply.

X

ASSEMBLY BILL 845

1 medical facility or pharmacy may charge an individual who receives a cancer drug  
 2 under this subsection a handling fee that may not exceed the amount specified by  
 3 rule by the department. A medical facility or pharmacy that receives a donated  
 4 cancer drug under this subsection may distribute the cancer drug to another eligible  
 5 medical facility or pharmacy for use under the program under this section.

6 (3) A cancer drug may be accepted and dispensed under the program specified  
 7 in sub. (2) only if all of the following requirements are met:

8 (a) The cancer drug is in its original, unopened, sealed, and tamper-evident  
 9 unit dose packaging or, if packaged in single-unit doses, the single-unit-dose  
 10 packaging is unopened.

11 (b) The cancer drug bears an expiration date that is later than 6 months after  
 12 the date that the drug was donated.

13 (c) The cancer drug is not adulterated or misbranded, as determined by a  
 14 pharmacist employed by, or under contract with, the medical facility or pharmacy,  
 15 who shall inspect the drug before the drug is dispensed.

16 (d) The cancer drug is prescribed by a practitioner for use by an eligible  
 17 individual and is dispensed by a pharmacist.

18 (4) No cancer drug that is donated for use under this section may be resold.

19 (5) Nothing in this section requires that a medical facility, pharmacy,  
 20 pharmacist, or practitioner participate in the program under this section.

21 (b) Except as provided in par. (c), any person, including the manufacturer  
 22 of a cancer drug, is immune from civil liability for injury to or the death of the  
 23 individual to whom the cancer drug is dispensed and may not be found guilty of  
 24 unprofessional conduct for his or her acts or omissions related to donating, accepting,  
 25 distributing, or dispensing a cancer drug under this section.

or supply

except



ASSEMBLY BILL 845

1

<sup>c</sup>  
~~(b)~~

The immunity or the prohibition on a finding of guilty of unprofessional  
conduct under par. (a) does not extend to donation, acceptance, distribution, or  
dispensation of a cancer drug by a person whose act or omission involves reckless,  
wanton, or intentional misconduct. ✓/○

5

~~(c) The donation of a cancer drug by the manufacturer of the cancer drug may  
not increase any liability of the manufacturer that would have existed but for the  
donation.~~

8

~~(7) The department shall promulgate all of the following as rules:~~

9

~~(a) Requirements for medical facilities and pharmacies to accept and dispense  
donated cancer drugs under this section, including all of the following:~~

11

~~1. Eligibility criteria.~~

12

~~2. Standards and procedures for accepting, safely storing, and dispensing  
donated cancer drugs.~~

13

14

~~3. Standards and procedures for inspecting donated cancer drugs to determine  
if the cancer drug is in its original, unopened, sealed, and tamper-evident unit dose  
packaging or, if packaged in single-unit doses, the single-unit-dose packaging is  
unopened.~~

18

~~4. Standards and procedures for inspecting donated cancer drugs to determine  
that the cancer drug is not adulterated or misbranded.~~

19

20

~~(b) Eligibility criteria for individuals to receive donated cancer drugs dispensed  
under the program. The standards shall prioritize dispensation to individuals who  
are uninsured or indigent, but will permit dispensation to others if an uninsured or  
indigent individual is unavailable.~~

21

22

23

24

~~(c) A means, such as an identification card, by which an individual who is  
eligible to receive a donated cancer drug may indicate that eligibility.~~

25

(End)

CCC to AAG to AB-845-3894

# Page 2, line 4: delete "par. (a)" and substitute "par. (b)" ⊙

(END)

2/27 WLj



State of Wisconsin  
2003-2004 LEGISLATURE

**CORRECTIONS IN:**

**ASSEMBLY AMENDMENT 6,  
TO 2003 ASSEMBLY BILL 845**

Prepared by the Legislative Reference Bureau  
(February 27, 2004)

1. Page 2, line 4: delete "par. (a)" and substitute "par. (b)".

(END)