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(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

2009-10

(session year)

Senate

(Assembly, Senate or Joint)

Committee on ... Health, Health Insurance, Privacy, Property Tax Relief, and Revenue (SC-HHIPTRR)

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
(**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
(**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

Senate

Record of Committee Proceedings

Committee on Health, Health Insurance, Privacy, Property Tax Relief, and Revenue

Senate Bill 198

Relating to: donating drugs and dispensing donated drugs.

By Senators Robson, Lassa, Lehman, Vinehout, Taylor, Olsen, Harsdorf, Cowles, Carpenter, Darling, Schultz, Miller, Risser and Hansen; cosponsored by Representatives Nygren, Pope-Roberts, Black, Sherman, Smith, Molepske Jr., Van Roy, Suder, Montgomery, Townsend, Vos, Turner, Benedict, Soletski, Tauchen, Kerkman, Petersen, Grigsby, Ripp, Petrowski, Bies, Ballweg, Friske, Gunderson, Kaufert, Knodl, Nass, A. Ott, Spanbauer, Gottlieb and Strachota.

May 07, 2009 Referred to Committee on Health, Health Insurance, Privacy, Property Tax Relief, and Revenue.

August 18, 2009 **PUBLIC HEARING HELD**

Present: (6) Senators Erpenbach, Carpenter, Robson, Lassa, Lazich and Darling.
Absent: (1) Senator Kanavas.

Appearances For

- Judy Robson, Beloit — WI State Senate - 15th District
- Tom Engels, Madison — Pharmacy Society of WI
- Greg Chesmore, Milwaukee — Celgene

Appearances Against

- None.

Appearances for Information Only

- None.

Registrations For

- John Nygren, Marinette — WI State Assembly - 89th District
- Ryan Natzke, Madison — WI Academy of Family Physicians

Registrations Against

- None.

Registrations for Information Only

- Rachel Currans-Sheehan, Madison — Department of Health Services

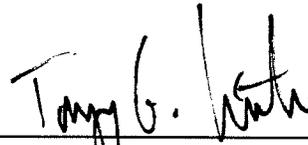
September 17, 2009 **EXECUTIVE SESSION HELD**

Present: (7) Senators Erpenbach, Carpenter, Robson, Lassa,
Lazich, Kanavas and Darling.
Absent: (0) None.

Moved by Senator Robson, seconded by Senator Lassa that **Senate Bill 198** be recommended for passage.

Ayes: (7) Senators Erpenbach, Carpenter, Robson,
Lassa, Lazich, Kanavas and Darling.
Noes: (0) None.

PASSAGE RECOMMENDED, Ayes 7, Noes 0



Tryg Knutson
Committee Clerk

Vote Record
Committee on Health, Health Insurance, Privacy, Property
Tax Relief, and Revenue

Date: 9.17.09

Moved by: SEN. ROBSON

Seconded by: SEN. LASSA

AB _____ SB 198 Clearinghouse Rule _____
 AJR _____ SJR _____ Appointment _____
 AR _____ SR _____ Other _____

A/S Amdt _____
 A/S Amdt _____ to A/S Amdt _____
 A/S Sub Amdt _____
 A/S Amdt _____ to A/S Sub Amdt _____
 A/S Amdt _____ to A/S Amdt _____ to A/S Sub Amdt _____

- Be recommended for:
- Passage Adoption Confirmation Concurrence Indefinite Postponement
 - Introduction Rejection Tabling Nonconcurrency

<u>Committee Member</u>	<u>Aye</u>	<u>No</u>	<u>Absent</u>	<u>Not Voting</u>
Senator Jon Erpenbach, Chair	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Tim Carpenter	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Judith Robson	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Julie Lassa	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Mary Lazich	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Ted Kanavas	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Alberta Darling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Totals:	<u>7</u>	<u>0</u>	_____	_____



WISCONSIN STATE LEGISLATURE





6/17/09 GREG CHESMORE

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Summit, New Jersey 07901
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August 18, 2009

**Testimony of Greg Chesmore, Director of State Government Relations
Supporting Senate Bill 198**

Chairman Erpenbach and members of the Committee on Health, Health Insurance, Privacy, Property Tax Relief and Revenue, I'd like to thank you for the opportunity to share Celgene's support for SB 198.

As a multinational biopharmaceutical company, Celgene seeks to deliver truly innovative and life-changing drugs for our patients, specializing in products for the treatment of cancer and other severe, immune, inflammatory conditions. Specific to the legislation before this committee today, Celgene manufactures the anticancer drugs, Thalomid® (thalidomide) and Revlimid® (lenalidomide), an analog of thalidomide. Because both drugs are unique, extremely active compounds with the potential to cause severe birth defects, the drugs can only be obtained through restricted distribution programs mandated by the federal Food and Drug Administration (FDA).

Our Thalomid® product (through the FDA-approved "System for Thalidomide Education and Prescribing Safety" or S.T.E.P.S.® program) requires comprehensive counseling and regular pregnancy testing for women of child-bearing age, patient surveys and registration, physician-patient agreement forms, prescriber surveys and registration, and unique authorization numbers for each prescription---all of which must be completed before the drug can be dispensed. This program is in place to protect the patient and ensure safe delivery of these medications through contracted pharmacies. Celgene's Revlimid® product has a similar FDA-approved program in place, RevAssist®.

Today, Thalomid® and Revlimid® are two of the most commonly prescribed drugs for multiple myeloma. Thalomid® is not available at most pharmacies and Revlimid® is not stocked on commercial pharmacy shelves (the drug is commonly drop-shipped directly to patients). This limited distribution environment elevates the risk of pharmacists being unfamiliar with comprehensive restricted distribution programs like S.T.E.P.S.® and RevAssist®.

Without specific legislative language prohibiting the acceptance and redistribution of these drugs within state-run prescription drug repositories---like that which is properly included in SB 198---we are gravely concerned that individuals may access these medications outside of the federally-required restricted distribution process. Currently, Wisconsin's existing Cancer and Chronic Disease Repository does not have specific language in place to ensure that restricted distribution drugs like Thalomid® and Revlimid® are not donated and redistributed. While the Department of Health Services has been willing to take steps to provide information to participating pharmacies about these FDA restricted distribution programs, the

existing program lacks the statutory or regulatory language necessary to protect Wisconsin residents.

Upon learning of this issue and the risk for possible inadvertent exposure through access outside of the FDA-mandated process, many states---including Arizona, Colorado, Montana, Michigan, Kansas, Virginia, Pennsylvania and Nebraska---have specifically exempted these types of drugs from the state's programs dealing with utilization of unused prescription drugs.

In light of the worldwide tragedy that occurred several decades ago, it was once considered unthinkable that thalidomide would ever be marketed in the United States. Yet, Celgene has carefully researched and developed thalidomide as a safe and effective treatment for patients. The restricted distribution programs placed on drugs like Thalomid® and Revlimid® must be respected at all times.

The goal we all share is ensuring that patients have access to the drugs they need---and ensuring patient safety throughout the distribution process.

I applaud Sen. Robson and Rep. Nygren for their foresight in including this important, protective language in this legislation and urge you to support SB 198.

Thank you for your time and consideration.

Greg Chesmore
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Developing Drug Repository Programs Raise Concerns, Boards of Pharmacy Contribute Expertise in Creation of Regulations

Increasing prescription costs continue to raise concerns for those struggling to purchase critical medications. As a possible solution, more states are considering implementation of drug donation or repository programs, which allow certain institutions, and in some cases individuals, to donate unused medications. These donated medications, if confirmed to be unopened, unexpired, and safe for patient use, may eventually be distributed to the medically indigent. Currently, 35 states allow drug repository programs to exist, according to the 2009 *Survey of Pharmacy Law*. Though some states have working programs today, many are still awaiting promulgation of rules in order to make them operational.

In December 2008, NABP surveyed the state boards of pharmacy about recycling unused medications and found that eight of the 19 boards that responded allow drug repository programs to exist or operate, while at least two are awaiting development of rules prior to implementation. The survey was conducted as a follow up to a February 2006 survey on this issue. Of those boards that responded to both the 2006 and the 2008 surveys, five did not allow for drug repository programs to exist or operate in 2006, but now have programs or laws in effect to do so. See the Au-

gust 2006 *NABP Newsletter* article "State Boards' Donation Programs for Unused Prescription Medications Balance Patient Needs, Safety," for details on the results of the February 2006 survey.

In several states, the boards of pharmacy have worked closely with their state legislatures to develop regulations for these programs. In 2007, North Dakota Governor John Hoeven signed House Bill 1256 into law authorizing the state prescription drug repository program. While the program was developed at the request of the American Cancer Society, the North Dakota State Board of Pharmacy was responsible for developing the criteria for the establishment of the program and handling the registration of participants for the receipt and dispensing of the donated items.

Similar to North Dakota, the Pennsylvania State Board of Pharmacy, which specifically allows for a cancer drug repository program, and the Virginia Board of Pharmacy are responsible for promulgating regulations for their states' programs; however, according to the December 2008 survey, neither program is operational yet as both are still in the rule development and approval process.

Safety Concerns

As indicated above, state legislators will often

implement drug repository programs and empower the boards of pharmacy to develop rules and oversee the programs. The boards' expertise in the distribution of safe and effective medications is a necessary component in the development of regulations for such programs as it ensures that the public health and safety remains the top priority. In fact, pharmaceutical manufacturers that produce drugs that must be distributed through restricted distribution programs, including isotretinoin and thalidomide, see the boards of pharmacy as integral to ensuring that all the proper safeguards are in place. According to one biopharmaceutical company representative, "while lawmakers usually exclude controlled substances from the donation programs, oftentimes other higher risk medications are not explicitly prohibited from donation and redistribution."

Food and Drug Administration (FDA) has implemented restricted distribution programs for approximately 15 different drugs that require registration with the manufacturer and patient education. In some cases, these requirements also include registration by the prescriber and dispenser. The number of medications that require special attention by manufacturers and, subsequently, state-run repository programs, is on the rise.

Several states, including Arizona, Colorado, Kansas, Michigan, and Virginia have explicitly excluded drugs for which FDA has required a restricted distribution program to be in place, notes the company representative. Effective this year, the Kansas State Board of Pharmacy promulgated KAR 68-18-2, which specifies that "a qualifying center or clinic shall not accept or dispense an unused medication that can be dispensed only to a patient or resident registered with the drug manufacturer." Regulations such as this one further assist in protecting the public health and safety. Without safeguards in place, some fear that the medication could be inadvertently redispensed to another patient outside of the FDA-mandated restricted distribution program.

As in Kansas, Arizona proposed rule R4-23-1203, Eligible Prescription Medications, which specifically states:

A prescription medication may be donated to a physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program if the prescription medication . . . is not a . . . drug that can only be dispensed to a patient registered with the drug's manufacturer, because donation could

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nabp newsletter

Drug Donation Programs

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prevent the manufacturer from maintaining required patient registration data.

A few states such as Delaware, Oklahoma, and South Carolina permit, under limited circumstances, pharmacists to "return" or "reuse" medications, but specifically indicate that they do not allow for a drug repository or donation program to exist. According to Delaware regulation 5.11, products under the direct control of a health care professional, that are packaged in manufacturer unit dose or tamper-proof

unopened bulk containers, with the tamper-proof seal intact, including unused multi-dose punch cards, may be redispensed in accordance with expiration dating in the customized patient medication package, but partially used products may not be redispensed. In addition, the regulation prevents medication that potentially has been diverted or adulterated, is not secure, or is expired from being placed back in the distribution system by prohibiting returns or exchanges by any pharmacist or pharmacy after having been taken from the premises where sold, distributed, or dispensed.

Likewise, the Oklahoma State Board of Pharmacy developed a program that, under limited circumstances, allows specific facilities to donate unused medications through its non-central repository program, the Unused Prescription Drug Program for Oklahoma's Medically Indigent. After conducting several trials, the Board developed rules for the program that allow Oklahoma licensed nursing homes, approved Oklahoma licensed assisted living centers, and licensed prescription drug manufacturers to donate unused medications for distribution to indigent patients

as specified in OAC Title 535, Subchapter 12. The state has approximately 36 charitable clinics with pharmacies that are able to receive these unused prescription drugs. In addition to these pharmacies, county-operated pharmacies are allowed to receive and dispense the unused medications. According to the Tulsa County Medical Society, in Tulsa County, a total of 47,878 prescriptions have been filled from the time the program was implemented in November 2004 to February 2009, an average wholesale value of \$4,894,000.

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Safeguarding Patient Safety: NABP to Explore Methods of Medication Repository Programs

Drug donation and repository programs have been implemented in several states; however, hesitations remain. Various factors contribute to these hesitations, including questions of how to ensure the efficacy and safety of a medication, how to regulate the medications and those distributing them, and how to assign liability in situations where medications have left the normal chain of distribution.

In December 2008, NABP convened the Task Force on Medication Collection Programs in Tucson, AZ, to discuss methods of medication

collection and disposal. During this meeting the task force addressed reuse of medications and recommended that NABP work with the boards of pharmacy and appropriate state and federal agencies, such as Food and Drug Administration, to research programs for the reuse of previously dispensed medications. The focus of the research would be to ultimately determine whether safe and legally compliant methods can be utilized.

After reviewing several prescription medication repository programs currently in existence, task force members discussed the societal value of such pro-

grams and why medications should be reused instead of destroyed. They acknowledged that medications in long-term care facilities are maintained within a closed distribution system and, thus, may be appropriate for reuse. However, any programs in the community pharmacy setting would necessitate different requirements, as they raise questions about medications that have left the normal drug distribution channel and their likelihood of having been maintained in a controlled climate and monitored environment. The standards for these medications should be the same as the standards re-

quired of all other medications and must ensure that the medications dispensed are non-adulterated and non-misbranded.

Task force members also agreed that any medication collection programs for reuse must be compliant with all state and federal regulations, including standards of the United States Pharmacopeial Convention, to ensure public safety. The full task force report, which was approved by the NABP Executive Committee at its February 2009 meeting, is available on the NABP Web site at www.nabp.net, under News/Press. ○

The Iowa Prescription Drug Corporation (IPDC), which began operating its repository program in May 2007, voiced the importance of maintaining the quality and effectiveness of medications, stressing that patient safety is of utmost concern at all times as is ensuring in its program that "all [long-term care] medications are under the continuous control of a health care professional . . . verified by a licensed pharmacist for accuracy . . . [and] scrutinized for integrity and proper expiration dating."

Overseen by the Iowa Department of Public Health in cooperation with the Iowa Board of Pharmacy, the IPDC program was established to improve the health of low-income Iowans by authorizing medical facilities and pharmacies to redispense prescription drugs and supplies that would otherwise be destroyed. From March 2007 to December 2007,

the repository received medication donations of almost 319,000 dosage units, valued at an estimated \$292,000. During that same time period, almost 142,000 dosage units of medication, worth an estimated \$150,000, were distributed through the program to indigent patients.

Handling Liability

Though patient safety is the primary concern with repository programs, the issue of liability has also been raised. Several states have included or are attempting to include language in their rules to address this subject. In the December 2008 survey on recycling unused medications, Paul Boisseau, immediate past executive secretary of the New Hampshire Board of Pharmacy, responded that "the Board is currently seeking additional legislation that would include pharmacies and pharmacists participating

in a donation program to be covered under the existing Limited (liability) Immunization section of the law," which currently protects only manufacturers of the donated drugs.

According to Boisseau, the state will need to expand this language to make it applicable to pharmacies and pharmacists in order for the prescription drug program to be viable.

Iowa and South Carolina also address liability in their rules. The Iowa Administrative Code exempts drug manufacturers, as well as others such as pharmacists, acting in good faith, from criminal prosecution, civil liability, and disciplinary action for injury to or the death of an individual to whom a donated prescription drug is dispensed as directed in chapter 641—109.11(135M) Exemption from disciplinary action, civil liability and criminal prosecution. In addition, South Carolina Code of Laws specifies in

its Cancer Drug Donation Program Act in part that "A donor of a cancer drug or supplies, or a participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies . . . are immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to donating, accepting, distributing, or dispensing cancer drugs or supplies pursuant to this article."

Addressing liability issues is just one step in developing and implementing these repository programs. Various concerns remain regarding their ability to maintain and ensure the efficacy of donated medications, and most importantly, their ability to protect the patients who are receiving them. 

Legal Briefs

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respond to the peculiar, if not arbitrary, expectations of the Board."

The appellate court concluded that the licensee complied with the spirit of the Board

order and that the trial court erred in affirming the sanction. Thus, it reversed the trial court holding and remanded the matter back to the Board to vacate the original order.

Under circumstances that dictate potential reentry into practice under speci-

fied conditions, boards of pharmacy are encouraged to examine sanctions intended to ensure public protection, while affording disciplined licensees with an opportunity for reinstatement.

However, boards are encouraged to carefully craft such reinstatement conditions to

ensure a reasonable opportunity for compliance and parameters ascertainable by the board and future boards that may rule on reinstatement requests.

Sutton v State Board of Pharmacy, 2008 WL 5390466 (App Ct OH 2008) 

S.T.E.P.S.® At-A-Glance

Initial Prescription

1. Counsel and perform pregnancy testing (if applicable)
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception. Patients should be instructed to not extensively handle or open THALOMID® (thalidomide) Capsules and to maintain storage of capsules in blister packs until ingestion
3. Complete, print, and sign Patient Registration/Patient-Physician Agreement Form
 - **Males (adults and children)**
 - **Females of childbearing potential include females who have not undergone a natural menopause** for at least 24 months
 - **Adult females not of childbearing potential include females who have had a natural menopause** for more than 24 consecutive months, a hysterectomy, or bilateral oophorectomy
4. Fax Patient Registration/Patient-Physician Agreement Form to 1-888-432-9325
5. Instruct patient to complete phone survey by calling 1-888-423-5436 prior to prescriber obtaining an authorization number
 - **All males:** Patient Registration/Patient-Physician Agreement Form is considered the initial phone survey
 - **All females:** Complete the appropriate phone survey
6. Complete a prescriber phone survey by calling 1-888-423-5436, and obtain a new authorization number for each prescription
 - You will need to enter the following information:
 - Prescriber's DEA number or Social Security number
 - Patient's Social Security number
 - Date and result of patient's last pregnancy test (if applicable); valid only for 7 days
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
7. Write the authorization number on the prescription; prescription and authorization number are valid only for 7 days
8. If drug is not dispensed within 7 days, surveys must be repeated. To cancel authorization number(s), call 1-888-423-5436

Subsequent Prescriptions

1. Perform scheduled pregnancy testing (if applicable)
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception. Patients should be instructed to not extensively handle or open THALOMID® (thalidomide) Capsules and to maintain storage of capsules in blister packs until ingestion
3. Instruct patient to complete surveys **as scheduled**, prior to prescriber obtaining an authorization number and filling prescription
 - Monthly:
 - **Males (adults and children)**
 - **Females of childbearing potential (adults and children), female children not of childbearing potential**
 - Every 6 months:
 - **Adult females not of childbearing potential** (if had **natural menopause** for more than 24 consecutive months, a hysterectomy, or bilateral oophorectomy)
4. Complete a prescriber phone survey, which should be done on the day the prescription is written
 - You will need to enter the following information:
 - Prescriber's DEA number or Social Security number
 - Patient's Social Security number
 - Date and result of patient's last pregnancy test (if applicable); valid only for 7 days
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
5. Obtain authorization number for each new prescription; faxed prescriptions are permissible if state law allows
6. Write the authorization number on the new prescription; prescription and authorization number are valid only for 7 days
7. If drug is not dispensed within 7 days, surveys must be repeated. To cancel authorization number(s), call 1-888-423-5436

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

 **THALOMID**[®]
(thalidomide) Capsules

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State of Wisconsin
Department of Health Services

Jim Doyle, Governor
Karen E. Timberlake, Secretary

Senate Committee on Health
Tuesday, August 18, 2009

Wisconsin Department of Health Services
Rachel Currans-Sheehan, Legislative Liaison

Chairman Erpenbach, Senator Robson, and members of the Health Committee, thank you for the opportunity to present information on Wisconsin's Drug Repository Program.

The Wisconsin Drug Repository Program has been operating in Wisconsin for four years with 28 pharmacies volunteering to participate in this program.¹

A recent survey of participating pharmacies found that in 2008, on average, a pharmacy received 9.75 donated prescriptions and dispensed approximately 5.83 of these prescriptions. Using these averages, it can be estimated that 163 prescriptions were dispensed through the Drug Repository Program in 2008.

The purpose of the drug repository is to provide access to medications for patients who have cancer or chronic diseases and valid prescriptions from their physicians, but do not have the means to pay for the medication. Pharmacies accept donated medications which meet specified qualifications, and dispense these medications to qualified persons who inquire at the pharmacy.²

Given that the statutory definition of "chronic disease" is fairly expansive, most pharmacies participating in the program accept many types of medications, excluding controlled substances or drugs on FDA-mandated restricted distribution programs.

The Department of Health Services implements the program by providing the guidelines for pharmacies, donors, and recipients' participation in the program.

¹ There are approximately 1,100 pharmacies in the state of Wisconsin.

² Additional information on the Drug Repository Program can be found online at <http://dhs.wisconsin.gov/bqaconsumer/cancerdrugreposy.htm>.

The Department monitors pharmacies compliance with these guidelines and the FDA-mandated restricted distribution program.

A recent survey of participating pharmacists found that there are many tangible examples illustrating the benefits of the program.

- Patients are able to obtain access to medication they would not have access to otherwise,
- Donors are pleased to have a way to dispose of unused medications, and
- Participating pharmacies are connected to the community and have a means to help those that need essential medication.

While there are benefits to the program, DHS and pharmacies face barriers to operate a robust and efficient program.

- A recent survey of 15 participating pharmacies showed that up to half of drugs donated were either unused or disposed of.
- Recipients, pharmacists and donors lack knowledge of the program; the Department lacks resources to market the program.
- Wisconsin does not have a coordinated registry system which means participating pharmacies cannot search for medications and supplies available at other repository sites. The Department lacks resources to create a coordinated registry system.
- Pharmacists lack information on what to do with the disposal of unused drugs; this barrier is not unique to the drug repository program.
- Medications included in the repository program are most often excluded not because of the type of disease they treat (ie: cancer, chronic disease), but due to the requirement that medications must be in “original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened” and the expiration date must be 6 months from date of donation. It is more cost-efficient for pharmacies to package medications in prescription pill bottles than to package medications in tamper-evident unit dose packing.

SB 198 addresses the challenge that the pool of qualified medications is small due to “expiration date standards.” Changing the expiration date standards from 6 months to 90 days will expand the number of medications eligible for the program because medications with expiration dates earlier than 6 months, but less than 90 days from date of donation will now be accepted in the program.

SB 198 expands the drug repository program to include additional medications by removing the type of disease (“cancer” and “chronic disease”) to define accepted medications. This is laudable and will ease the public understanding of accepted

and available medications for donation to the program; however, the benefits may not be as far-reaching as intended without additional resources to implement a robust registry program.

Using existing resources, DHS will be able to provide guidance to pharmacists and providers on the expansion of the program through online provider updates and will work to expand the number of participating pharmacies. DHS' ability to market the program to a wider audience to ensure people are fully utilizing the program will remain limited without additional resources.

Thank you for the opportunity to testify today on SB 198. I would be happy to take any questions you may have.





**PHARMACY
SOCIETY OF
WISCONSIN**

*"Leading Our Profession
in a Changing
Health Care Environment"*

Tom Engels, Vice President of Public Affairs, Pharmacy Society of Wisconsin

**Testimony before the Senate committee on Health, Health Insurance, Privacy,
Property Tax Relief and Revenue in Support of Senate Bill 198**

Tuesday, August 18, 2009

Thank you chairman Erpenbach and members of the Senate committee on Health, Health Insurance, Privacy, Property Tax Relief and Revenue for this opportunity to testify in support of Senate Bill 198. I would also like to Senator Judy Robson, author of Senate Bill 198 and Representative John Nygren, author of the companion bill AB 272 for their support.

The changes recommended by this legislation will amend current Wisconsin laws related to the operations of the cancer and chronic disease prescription drug repository programs. These changes are based on the experiences of Wisconsin pharmacists that are involved in free health clinics located in Senator Robson's and Representative Nygren's legislative districts that see patients in need of medications, but are limited by the programs restrictions. We believe this legislation will expand the options available to patients and health care providers.

Cancer and Chronic Disease Drug Repository Programs

The current drug repository programs were started in 2005 and have experienced only moderate success. There are fewer than 30 pharmacies or medical facilities registered with the Department of Health Services to participate in the programs. (List attached)

Under these programs, any person may donate an unused prescription drug used to treat cancer or the side effects of cancer or a chronic disease. The legislation defines chronic diseases as any illness, impairment or other physical condition, other than cancer, that requires health care and treatment over a prolonged period and, although amenable to treatment, frequently progresses to increasing disability or death.

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The program includes strict criterion for donated medications to ensure their integrity and for the safety of patients receiving the medications.

- Participation is voluntary by a pharmacy or a medical facility. Even if a pharmacy chooses to participate in the program(s) they can refuse to accept a donated prescription drug if they question its integrity.
- Both programs require the pharmacy or medical facility to perform an inspection of all donated items. The cancer drug or chronic disease drug or supplies must be in their original, unopened, sealed and tamper-evident unit dose packaging. If the drug is packaged in single-unit doses, then the single unit dose must be unopened.
- The donated drugs or supplies are not adulterated or misbranded as determined by a pharmacist. The drug's expiration date must be at least six months later than the date the drug was donated.
- Additionally, donated prescription medications can not be a registered DEA controlled substance.

From the beginning, PSW raised conceptual concerns with the programs but supported their creation with reservations. Here are a few of the problems identified by pharmacy providers with the current repository programs.

- Soon after the enactment of the law creating these programs, individuals would come into pharmacies with medications expecting to be able to donate the items even though the pharmacy had not opted to participate in the repository programs.
- People came into the pharmacy with bags of unused medications expecting to be able to donate the medications. However, of the medications brought to pharmacies; most did not qualify because they were dispensed in vials or were controlled substances.
- In many cases, individuals would simply leave the unused medications at the pharmacy which required the pharmacy to make arrangements for their disposal.
- Most people cannot identify whether or not a medication is a controlled substance, furthermore they are not aware of the federal law that prohibits pharmacies from accepting these medications.
- Pharmacies participating in the program are unable to track available medications for qualified patients, other pharmacies or prescribing practitioners. This inability to track medications results in many donated items later being disposed of because they are not used.

I would like to emphasize that the Pharmacy Society of Wisconsin supports these programs but believes they must be amended. Senate Bill 198 makes some of those changes by allowing for more medications to be made available for donation.

Unfortunately, the changes recommended by this legislation won't go far enough to address the problems with the current programs. For instance, due to limited financial resources, SB 198 will not have a tracking system which lists the available donated medications and where they can be obtained. The Pharmacy Society of Wisconsin hopes that someday the Wisconsin repository programs can incorporate a tracking system that is similar to that used in the neighboring State of Iowa.

Although this legislation is not perfect it is a step in the right direction and we urge you to support SB 198.

Name of Pharmacy or Medical Facility	Address	City	Zip	Phone	Contact
Bohman Drugstore, Inc.	1028 Wisconsin Ave	Boscobel	53805	608-375-4466	Michelle Farrell
Dennis L. Hunt Pharmacy, Inc. DBA Omro Pharmacy	109 E. Main St.	Omro	54963	920-685-5041	Kenneth A. Bressers
Stoxen Professional Pharmacy	2251 North Shore Dr.	Rhinelander	54501	715-361-4770	Corlis Stoxen
Larson-Mayer Pharmacy	3535- 30 Avenue #103	Kenosha	53144	262-658-8124	Raymond E. Larson
Family Health Center Pharmacy	200 East Upham St.	Marshfield	54449	715-389-7474	Nadra Havican
Marshfield Clinic Pharmacy	1000 N Oak Avenue	Marshfield	54449	715-387-9100	Sue Wilhelm
Marshfield Clinic Pharmacy	1000 N Oak Avenue	Marshfield	54449	715-389-3891	Janet Schoenherr, R.Ph.
Marshfield Clinic Pharmacy-Rice Lake Center	1700 West Stout St	Rice Lake	54868	715-236-8103	Marni Britton
Marshfield Clinic Pharmacy Minoqua Center	9601 Townline Rd.	Minoqua	54548	715-358-1216	Blain Nyberg
Marshfield Clinic Pharmacy Ladysmith Center	906 College Avenue West	Ladysmith	54848	715-532-2323	David Werner
Marshfield Clinic Pharmacy Wausau Center	2727 Plaza Drive	Wausau	54401	715-847-3302	Nikki Tieman
Marshfield Clinic Pharmacy Eau Claire Center	2116 Craig Road	Eau Claire	54701	715-858-4811	Bruce Bergmann
Marshfield Clinic Pharmacy Central Avenue	630 South Central Avenue, Suite #106	Marshfield	54449	715-389-5900	Richard Gritt
Marshfield Clinic Pharmacy Merrill Center	1205 O'Day Street	Merrill	54452	715-539-0118	Dale Hugo
Marshfield Clinic Pharmacy Chippewa Center	2655 County Hwy I	Chippewa Falls	54729	715-726-4177	Steve Bartig
Marshfield Clinic Pharmacy Oakwood Center	3501 Golf Raod	Eau Claire	54701	715-858-4224	Dana Whittlinger
Marshfield Clinic Pharmacy Riverview Center	1000 Starr Avenue	Eau Claire	54703	715-858-4366	Justin Slominsky
Marshfield Clinic Pharmacy Weston Center	3501 Cranberry Boulevard	Weston	54476	715-393-1040	Eric Paulson
Marshfield Clinic Pharmacy Mosinee Center	390 Orbiting Dr.	Mosinee	54455	715-693-9181	Holly Dillenbeck
Marshfield Clinic Pharmacy Lake Hallie Center	12961 27th Avenue	Chippewa Falls	54729	715-738-3710	Dana Whittlinger
Wheaton Franciscan Pharmacy	5000 W. Chambers St.	Milwaukee	53210	414-447-2585	Jessica Giombi
Wheaton Franciscan Pharmacy	19333 W North Ave	Brookfield	53045	262-780-4430	Uche Dike
Wheaton Franciscan Pharmacy	3237 S. 16th St. Room 121	Milwaukee	53215	414-647-5300	Jennifer York
All Saints Cancer Center	3809 Spring St.	Racine	53405	262-687-5000	David Fucile
Kmart Pharmacy #3541	103 Oak	Menomonie	54751	715-237-6770	Brenda Maloney
Gundersen Lutheran East Pharmacy	724 Denton Street	La Crosse	54601	608-775-1000	Jim Lukas
Community Pharmacy	341 State Street	Madison	53703	608-251-4454	Richard Kilmer
Healthnet of Janesville	23 West Milwaukee St	Janesville	53548	608-531-0015	Michael J. Dow





John Nygren

WISCONSIN STATE REPRESENTATIVE ★ 89TH ASSEMBLY DISTRICT

Testimony

Senate Bill 198 – Drug Repository Program

Representative John Nygren

August 18, 2009

Thank you Chair Erpenbach and members of the Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief, and Revenue for holding a public hearing on Senate Bill 198 today. I apologize for not appearing in person, but please don't hesitate to contact my office if I can be of any assistance.

In April 2004, Governor Doyle signed Nick's Law or AB 845 into law creating a cancer drug repository program. Nick's Law was named after Nick Scavone who battled cancer for 20 years. After Scavone's death his wife Barbara, tried to donate his unused medications and supplies – worth \$2,000 by her estimation. Though the drugs and supplies were sealed in their original packaging, she was told to dispose of the medication and throw the supplies away. She later joined forces with the American Cancer Society to pass "Nick's Law."

The following year in July of 2005, Governor Doyle signed AB 197 into law, expanding the Cancer Drug Repository Program to include Prescription Drugs and Supplies for Chronic Diseases.

Currently, cancer and chronic disease patients may donate unused medications and supplies to a participating pharmacy or medical facility. Those items are then recertified and given to individuals with cancer or chronic disease that do not have insurance or are underinsured. At present, 28 Pharmacies and Medical facilities participate in the program.

The idea for this legislation arose from suggestions from a constituent of mine, Bill Clement, who owns and operates three pharmacies and is on the board of directors of the Twin Counties Free Clinic of Marinette, WI and Mr. Mike Dow, a Pharmacist and President of Janesville's Healthnet. Mr. Clement and Mr. Dow, as pharmacists, indicated the need to expand the current Cancer and Chronic Disease Drug Repository Program to include other prescription drugs, to help assist free clinics and their patients. With the help of Bill, Mike, Tom Engles of

the Pharmacy Society, and Senator Robson I drafted this legislation to expand the current Drug Repository Program to help maximize participation and assist more low income individuals.

At present, Free Clinics dispense a combination of physician samples and drugs donated by manufacturers to patients who do not have any form of health coverage. However, the supply of these drugs is not sufficient enough to meet increasing demand. Free clinics have pharmacists, like Bill and Mike, who handle drug utilization review and dispensing. Free clinics, under law, can not accept, store, or dispense controlled substances.

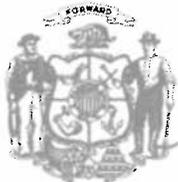
This bill would expand the program to allow for the donation of all drugs and supplies, with certain limited exceptions, to pharmacies and medical facilities. Common sense protections continue to be in place under this bill so only qualified individuals can dispense the drugs and supplies. Protections to ensure no expired or tampered drugs are accepted under the program are in place as well.

When drugs are no longer useful to a patient, it is better to reuse them for the benefit of needy patients than to flush them or send them to a landfill. The drug repository program and the changes included in this bill assist our neediest citizens at a time when they are in need of medical care.

Governor Doyle stated in a news release when he signed AB 197 into law on July 5, 2005, *"I'm pleased to sign a bill that will further our efforts to provide access to quality health care for all citizens in Wisconsin... The cancer drug repository will help families who can least afford it to get the life-saving drugs that they need. It is an innovative effort but it can only work if people know about it, people donate to it, and people use it. I'm calling on pharmacists, physicians, families, and patients to donate unused drugs and participate in this program."*

Today, I am echoing Governor Doyle's call to help families who can least afford it to help them get the drugs they need. I encourage you to support Senate Bill 198 for passage. If you have any questions, please don't hesitate to contact me I. Thank you!





Judith B. Robson
Wisconsin State Senator

Testimony
SB 198 – Expansion of the Drug Repository Program

August 18, 2009

Thank you Chair Erpenbach and committee members for holding this hearing today on Senate Bill 198 to enhance Wisconsin's drug repository law.

The Department of Health Services administers the drug repository program that is now limited to cancer drugs and prescription drugs and supplies for chronic illness. These unused medications help the uninsured and indigent receive needed, but costly, prescription drugs.

This bill expands the program to allow the donation of all drugs and supplies with certain exceptions, such as controlled substances. The bill provides safety requirements and protections for these prescription drugs to be re-cycled. Only qualified individuals can dispense these donated drugs and supplies. Expired drugs are not accepted under the program and the drugs must be in their original, sealed, tamper-proof packaging.

When medications are no longer needed by a patient, it is cost-effective to re-dispense them for the benefit of patients without access to health care coverage to pay for these medications. Without this program, these drugs would be destroyed or sent to the landfill.

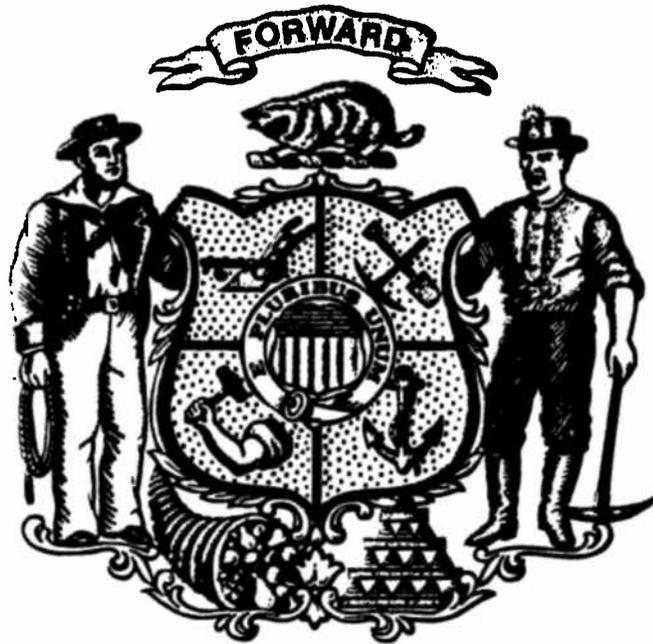
The idea for this program came from Mike Dow, a pharmacist and volunteer at the Janesville's HealthNet, a free clinic in my district. He noted that pharmacies get a lot of prescription returns from nursing facilities and they are unable to credit them for the returns. They have already billed for those prescriptions and many private insurance companies do not have a mechanism to issue credits for them. Consequently, the pharmacy cannot resell these medications because that would be fraud. Therefore, according to law they must dispose of them.

However, under the proposed new bill, they could donate these medications to free clinics, like HealthNet.

This is a safe source of drugs because each tablet or capsule has its own place in the package and each package has been filled and initialed by a pharmacist and pharmacy technician. The package also includes the name and strength of the drug, the lot number and the expiration date.

There is currently shortage of medications. While free clinics can dispense physician samples and drugs donated by manufacturers, the supply is not sufficient to meet increasing demand. This bill would help fill that gap.

I urge the committee to support SB 198 and its companion, AB 272, introduced by Rep. John Nygren. Thank you.



58 198

Chairman Erpenbach and Committee Members,

Hello! My name is Bill Clement and I own three pharmacies in Northeast Wisconsin. One pharmacy is called Peshtigo Pharmacy and the second is Oconto Pharmacy. The third one, Peshtigo Pharmacy Health Care Services, is a long term care pharmacy that services area nursing facilities. I am also on the Board of Directors for the Twin County Free Clinic in Marinette, WI. We provide free physician care and prescriptions to poor and needy people. When we have our meetings, a large concern of ours is the high cost of medications. We have fourteen people on our board and I always feel like I should be doing more to reduce pharmacy costs since I am a pharmacist. We get a lot of prescription returns from facilities and are unable to credit them for the returns. We have already billed these prescriptions out and many private insurance companies do not have a mechanism to issue a credit for them. Consequently, we cannot resell these medications because it would be fraud, and they must be disposed of, according to the law. However, under the proposed new bill we could donate these medications to the "free clinic".

Medications are sent to the nursing facilities in thirty-one day supply bubble packages. Each tablet or capsule has its own individual place in the package and each package has been filled and initialed on the back by a pharmacist and a pharmacy technician. The package back also includes the name and strength of the drug, lot number and expiration date.

These medications come back to us from the nursing facilities for many reasons. The doctor may change the drug or the strength, the patient may suffer a drug reaction or interaction, or the patient may pass away. The medications left in the package are perfectly good and, since each tablet or capsule is enclosed in an individual bubble, they are untouched.

I talked to Mr John Nygren, our state representative, regarding my concern about this excessive waste and the lack of funds for medications at our free clinic. He was very concerned and suggested enacting a law to correct the waste. In conclusion I hope you will strongly support this bill sponsored by Mr. Nygren.

Sincerely,

R. William Clement, R. Ph..