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Details:

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WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2007-08

(session year)

Assembly

(Assembly, Senate or Joint)

Committee on ... Public Health
(AC-PH)

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**
- Record of Comm. Proceedings ... **RCP**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

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

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July 13, 2007

PAGE ONE

PILL PUSH

Industry Fights Switch To Generics for Epilepsy

Big Drug Makers Help Patient Groups Lobby; More Attention to States

By SARAH RUBENSTEIN
July 13, 2007

GENERIC DEBATE

- **The Situation:** The Epilepsy Foundation, helped by drug makers, is backing state bills that would make it harder for pharmacists to switch patients to generic epilepsy pills.
- **The Background:** The foundation says switches may be risky. The FDA says it sees little evidence of that.
- **What's at Stake:** Revenue for drug makers. Several popular pills will soon face generic competition.

In state legislatures across the country, the Epilepsy Foundation has been campaigning for bills that would make it harder for pharmacists to switch patients to inexpensive generic epilepsy pills. The effort is getting behind-the-scenes support from drug companies -- a sign of how the industry, long a potent lobbying force in Washington, is increasingly looking to states to achieve its goals.

The foundation, a nonprofit group supported by the drug industry, says switching to generics could cause dangerous seizures. The Food and Drug Administration says it hasn't seen persuasive evidence for that, and it believes each generic is equivalent to the brand-name drug it copies.

Four major brand-name drugs used for epilepsy are expected to lose patent protection and face generic competition between next year and 2010. Those four drugs generated $5 billion in U.S. sales last year, according to IMS Health, meaning the state legislation could have a significant bottom-line impact. Some of the $5 billion figure reflects sales of the drugs for other ailments.

Generic drugs are the centerpiece of efforts to tame growth in America's prescription-drug bill, which topped $270 billion in 2006. When a doctor writes a prescription for a brand-name drug, pharmacists are usually permitted in most states to make an automatic switch to a generic judged equivalent by the FDA.

The epilepsy legislation would carve out an exception to that rule, with many of the bills requiring that doctors explicitly approve such a switch. Tennessee has passed a weaker version that requires doctor notification but not consent. Around 25 other states have considered some form of restriction in the past year.

ON THE TABLE

Model legislation the national Epilepsy

It isn't the only health issue where states have been the central battleground. Earlier this year, **Merck** & Co. drew fire for lobbying states to require that preteen

Foundation has provided to state affiliates to address concerns about epilepsy-drug substitution:

A pharmacist may not interchange an anti-epileptic drug or formulation of an anti-epileptic drug, brand or generic, for the treatment of seizures (epilepsy) without prior notification of and the signed informed consent of such interchange from the prescribing physician and patient, or patient's parent, legal guardian or spouse of such person.

Source: Epilepsy Foundation

girls receive its cervical-cancer vaccine to attend school. Merck stopped its direct lobbying in February, but a group of female state legislators that has received funding from the drug maker continue to push for the laws.

States often move faster than Congress, says Jan Faiks, who runs state policy for the Pharmaceutical Research and Manufacturers of America, or PhRMA, the drug industry's trade group. State legislation can move "from idea, to passage, to governor's signature in 90 days, sometimes faster than that," she says. "So the action is in the states."

Campaign contributions to state candidates by pharmaceutical manufacturers and their employees rose to about $8.8 million for 2006 from about $4.6 million for 2000, according to the National Institute on Money in State Politics. Drug makers spent more than $44 million on state lobbying in 2003 and 2004, the last years for which figures are available, according to the Center for Public Integrity.

In state legislatures, as in Congress, the drug industry often enlists nonprofit health and patient-advocacy groups to advance its agenda. In the epilepsy case, the Epilepsy Foundation's state affiliates, rather than the companies, are taking the most prominent part in the lobbying.

The foundation and its state affiliates receive funding from the epilepsy-drug makers. **GlaxoSmithKline** PLC and UCB SA donated $500,000 to $999,999 each in fiscal 2006 to the national foundation, according to its annual report. **Abbott Laboratories** and a **Johnson & Johnson** unit each contributed $100,000 to $499,999. Representatives of four drug companies sit on the foundation's board, as does PhRMA chief Billy Tauzin.

Top Treatments

U.S. sales of prescription drugs used to treat seizure disorders, in millions:

	2007 (Jan. to April)	2006
Topamax	$656.6	$1,825.4
Lamictal	638.9	1,684.3
Lyrica	306.8	727.8
Keppra	299.7	710.5
Depakote	257.1	770.4

Note: Sales figures include prescriptions for other uses such as migraine prevention (Topamax and Depakote), bipolar disorder (Lamictal and Depakote) and neuropathic pain (Lyrica)

Source: IMS Health

The foundation and its affiliates had about $77 million in revenue in 2005, about $48 million of which came from state and federal grants.

The foundation says its diverse funding base shields it from undue drug-company influence, and the industry executives on its board didn't participate in discussions of the drug-switching issue. Foundation leaders note that the state bills would generally require doctor permission for several kinds of switches, including when a patient goes from a generic to a brand.

"These are people's lives that we're talking about -- nothing about stock options and stock value and how this would affect [companies'] bottom line. That would be insulting to us to have discussions like that," says Sindi Rosales, the head of a foundation affiliate in Texas, one of the states that weighed legislation this year. She says pharmaceutical companies are "fabulous partners" and their help in several areas "has been amazingly tremendous," but the companies leave it to the foundation to call the shots.

For their part, company executives describe their lobbying role as limited and say the bills were primarily an initiative of the foundation, although they acknowledge in certain cases that company officials have gotten directly involved. Executives say the aim of these activities is to protect the health of patients. "Our issue is not selfish toward our individual product," says Richard Denness, a vice president at Belgium-based UCB. "It's a real concern in the minds of prescribers.... All it takes in the scheme of things are one or two patients to have a tragic event."

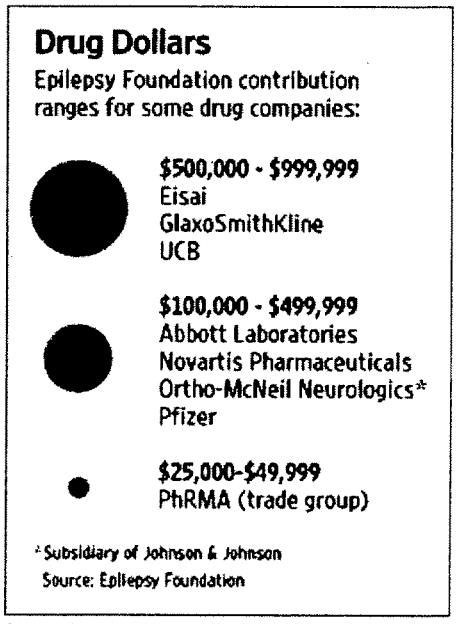
In the late 1990s, the national Epilepsy Foundation, based in Landover, Md., raised concerns about anecdotal reports that some patients experienced seizures and side effects after switching epilepsy drugs. Some of the episodes involved patients who had been switched to a generic from a branded drug. The foundation also worried about cases in which patients were switched from one generic version of a drug to another generic version of the same drug.

When the FDA approves generics, it requires manufacturers to show in human studies that their copycat pills deliver a similar amount of active ingredient to the bloodstream as the brand-name original. However, the agency doesn't require exact equivalence. That would be an impossible bar to clear, because there is always a slight variation in the way people absorb drugs.

The foundation theorized that some generic pills had a meaningful difference from the brands. This difference, it postulated, meant patients were getting more or less of the drug in their blood, causing some of them to have seizures or side effects. Foundation officials floated the idea in a 1999 meeting with the FDA.

The FDA's response: "Show us the data," recalls Sandy Finucane, who oversees state and federal policy for the foundation. The agency, unpersuaded by what it saw, stood firm in its long-held position that the difference was too small to have a tangible impact on patients.

Coming up with the kind of evidence the FDA sought would have required a major clinical trial to demonstrate that the seizures were a direct result of the switches, Ms. Finucane says. The foundation thought it would be difficult to enroll patients for such a trial, and the costs were prohibitive, she says. For years the foundation didn't push the matter, beyond developing policy statements and encouraging patients and doctors to report problems to the FDA.



In early 2006, the issue re-emerged as legislation requiring doctor permission for switches was proposed in Illinois. That's the home state of Abbott Laboratories, which makes Depakote, a leading epilepsy pill that is expected to face generic competition next year. The bill passed, but in watered-down form. An Epilepsy Foundation official in Illinois says Abbott helped fund lobbying for stronger provisions that were considered this year but didn't pass. Abbott said it supports some foundation initiatives but declined to give specifics.

In May 2006, the national Epilepsy Foundation convened a committee of medical experts to examine the question. The committee found a lack of authoritative studies showing that such drug switches cause problems, says its chairman, Steven Schachter, a Harvard Medical School

neurologist. Nonetheless, it recommended that doctors give explicit approval for switches, citing anecdotal reports of seizures and noting that such attacks can be serious.

Last fall, the American Academy of Neurology issued a statement making a similar recommendation. The academy says it receives funding from drug makers for educational programs but not for developing medical guidelines.

At a meeting last September, the national foundation told its local affiliates that if they wanted to push for legislation regulating switches, the foundation would provide model legislation and support, Ms. Finucane says. It also told them to "maintain independence from any company that's going to be interested in this issue," she adds. The 50-plus affiliates operate largely autonomously.

The sponsor of a bill in Georgia, state Rep. Charlice Byrd, says a UCB official was the first person to raise the epilepsy-drug switching issue with her. The Belgian company makes the epilepsy drug Keppra. Ms. Byrd says she was sympathetic because her late mother had epilepsy.

Charlotte Thompson, who joined the foundation's Georgia affiliate as executive director last September, says she became aware of the bill after hearing about it from UCB. "When we realized [Rep. Byrd] was introducing this and looked at it and studied what it was, then we jumped on the bandwagon," Ms. Thompson says. Six lobbyists for three companies joined a committee created by the Epilepsy Foundation to work on the legislative process, she says.

Ms. Byrd says several pharmaceutical-company lobbyists offered their support. Abbott lobbyist Guy Mosier "was extremely helpful working with legislators to help them understand the importance and that this piece of legislation was strictly for patient protection," Ms. Byrd says. Mr. Mosier declined to comment.

Ms. Byrd introduced the bill in the Georgia House in January of this year. At a Feb. 7 hearing of the House's health committee, Lasa Joiner, executive director of the Georgia Psychiatric Physicians Association, testified in support. Ms. Joiner was at the time also a Glaxo lobbyist, which she didn't mention at the hearing. In an interview, she said she didn't raise her tie to Glaxo because the company hadn't asked her to lobby for the bill.

Two days later, epilepsy patients and parents of patients visited lawmakers' offices to ask them to support the bill. The Epilepsy Foundation's Ms. Thompson says drug-company lobbyists accompanied the visitors.

Kimberly Oviedo says her 6-year-old daughter had seizures last year after being switched to a generic version of the epilepsy drug Zonegran. She says she supported the bill because she wouldn't "want any other person to have to go through what we've been through with our kids." Ms. Oviedo also has a son who suffers from epilepsy.

The bill passed the Georgia House in a 161-0 vote on Feb. 28, but it stalled in the Senate after groups representing pharmacists and generic-drug makers mounted heftier opposition to it in that chamber. Pharmacies often earn bigger profit margins on generics than on branded drugs.

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In Texas, two local Epilepsy Foundation affiliates decided to approach an Abbott official after

they resolved to push for a bill, says Ms. Rosales, the head of one of the affiliates. Abbott and other drug makers helped fund the foundation's Texas lobbying, she says.

Ms. Rosales, whose daughter used to have seizures, says she felt deeply about the bill but worried about being perceived as a "mouthpiece for the pharmaceutical industry." She nonetheless hired Santos Alliances, a firm that also represents PhRMA, as her affiliate's lobbyist. Ms. Rosales says it's difficult to find a health-care lobbyist with no drug-maker clients. Frank Santos, head of the lobbying firm, says PhRMA was "absolutely 100% not involved" with the bill.

At a March hearing in the Texas Senate, Ron Hartmann, a lobbyist for a generic-drug maker owned by Novartis AG of Switzerland, testified against the bill. He said he suspected the bill was "less focused on the citizens of Texas than on protecting the market share of a few brand-name drugs that are scheduled to go off-patent in the next few years."

State Sen. Kyle Janek, the bill's sponsor, responded that Mr. Hartmann had "impugned my motivations," and added that, if Mr. Hartmann would "abstain from doing that," then he would abstain from calling Mr. Hartmann a "high-priced shill." Mr. Hartmann apologized. In 2006, Sen. Janek received about $19,000 in campaign contributions from drug makers. He says he sponsored the bill because it was in the best interests of patients.

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Meanwhile, some doctors are pushing harder for a study that would settle the matter. Michel Berg, a neurologist who is chairman of an American Epilepsy Society task force examining the switching issue, has opened discussions with the FDA about what kind of trial would be necessary.

For now, Gary Buehler, the director of the FDA's office of generic drugs, says the agency is skeptical that the drug switches cause seizures. "The only way you can somehow pin this down is to do a good study," says Mr. Buehler.

Write to Sarah Rubenstein at sarah.rubenstein@wsj.com[1]

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Makers Help Patient Groups Lobby; More Attention to States

By Sarah Rubenstein
July 13, 2007
The Wall Street Journal A1

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FORWARD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 11, 2008

Ms. Nicole Schultz
Iowa Pharmacy Association
8515 Douglas Avenue, Suite 16
Des Moines, IA 50322

Dear Ms. Schultz:

This is in reply to your correspondence dated November 6, 2007, directed to Ms. Susan Winckler requesting that the FDA provide a statement regarding generic substitution, particularly with respect to anti-epilepsy drugs. It was forwarded to the Office of Generic Drugs for a reply.

The FDA has many years of experience in the review of generic drugs and assures the quality and equivalence of approved generic drug products. FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S., both brand-name and generic, meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires that the proposed generic product is demonstrated to be equivalent to the brand-name drug in both the rate and extent of absorption. As noted in the Preface to the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") (27th Edition),

> FDA classifies as therapeutically equivalent those products that meet the following criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and route of administration, and, (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent; (4) they are adequately labeled; (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.
>
> FDA considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time and other minor aspects of labeling (e.g., the presence of specific pharmacokinetic information) and storage conditions. When such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity. With this limitation, however, FDA believes that products classified as therapeutically equivalent will produce the same clinical effect and safety profile as the prescribed product.

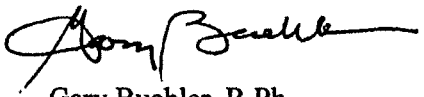
FDA is aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products. To date, we have no scientific evidence that demonstrates a particular problem with this group of products. Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow-up such reports and interact with those concerned.

If FDA has determined a generic to be therapeutically equivalent to the innovator product, FDA continues to believe that:

- Additional clinical tests or examinations by the healthcare provider are not needed when a generic drug product is substituted for the brand-name product or vice-versa.
- Special precautions are not needed when a formulation or manufacturing change occurs for a drug product provided the change is approved according to applicable laws and regulations by the FDA.
- As noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effects whether the products are brand-name or generic.
- It is not necessary for the healthcare provider to approach any one therapeutic class of drug products differently from any other class when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration.

We continue to monitor, take seriously, and, if indicated, investigate reports of potential inequivalence of all generic drugs. The FDA is committed to approving high-quality generic drug products that can be used with confidence by the American public.

Sincerely,



Gary Buehler, R.Ph.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

cc: S. Winckler
C. Jung


FORWARD

Jim Doyle
Governor

Celia M. Jackson
Secretary

WISCONSIN DEPARTMENT OF REGULATION & LICENSING

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Committee on Public Health
Representative J.A. Hines, Chairperson

Statement of Greg Weber, R.Ph., Wisconsin Pharmacy Examining Board
2007 Senate Bill 71: Relating to Substitutions by Pharmacists Dispensing Epilepsy Drugs

Room 328, Northwest, State Capitol, Wednesday, January 30, 2008, 9:00 A.M.

Chairperson Hines and members of the Committee, my name is Greg Weber. I serve as vice chair of the Wisconsin Pharmacy Examining Board. Thank you for the opportunity to appear on behalf of the Board. The Board is opposed to 2007 Senate Bill 71. As noted by the Legislative Reference Bureau, under current Wisconsin law a pharmacist may not substitute a drug product equivalent if a prescription indicates that no such substitution may be made (by the prescribing practitioner).

In a January 11, 2008 letter to the Iowa Pharmacy Association, Gary Buehler, R.Ph., Director of the Food and Drug Administration's Office of Generic Drugs made the following statements:

> "FDA is aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products. To date, we have no scientific evidence that demonstrates a particular problem with this group of products. Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow-up such reports and interact with those concerned."
>
> "If FDA has determined a generic to be therapeutically equivalent to the innovator product, FDA continues to believe that it is not necessary for the healthcare provider to approach any one therapeutic class of drug products differently from any other class when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration."

In summary, the Wisconsin Pharmacy Examining Board opposes 2007 Senate Bill 71 for the following reasons:

1. Current Wisconsin law requires pharmacists to dispense a therapeutically equivalent generic prescription drug if it is lower in cost (Wis. Stats. 450.13(1)).
2. Current Wisconsin law allows prescribing practitioners to prohibit pharmacists from substituting drug product equivalents (generics) (Wis. Stats, 450.13(2)).
3. To date, the FDA has no scientific evidence that there are problems with anti-epileptic drug products and their therapeutic equivalents.
4. If enacted, this legislation will result in higher health care costs for patients, employers, insurers, state and federal government.

Thank you for the opportunity to appear today.


FORWARD

STATE OF WISCONSIN, DEPARTMENT OF VETERANS AFFAIRS

30 West Mifflin Street, P.O. Box 7843, Madison, WI 53707-7843
PHONE: (608) 266-1311 1-800-WIS-VETS (947-8387)
E-MAIL: Headquarters@dva.state.wi.us

WEB SITE: www.dva.state.wi.us
FAX: (608) 267-0403

Jim Doyle, Governor
John A. Scocos, Secretary

January 30, 2008

Dear Legislators:

I am writing in support of SB 71, a bill that proposes to prohibit the substitution of anti-seizure medications with generic equivalents without the approval of the patient and prescribing physician. While current law permits some substitutions by a pharmacist for medications as prescribed, anti-seizure medications often require very careful consideration to meet a very narrow therapeutic range of treatment for patients suffering from seizures – seizures often caused by brain injuries sustained by military service members in a combat zone.

Our armed forces are sustaining attacks by rocket-propelled grenades, improvised explosive devices, and land mines almost daily in Iraq and Afghanistan. Many service members have sustained traumatic brain injury as the result of these attacks. The Defense and Veterans Brain Injury Center (DVBIC) at Walter Reed Army Medical Center recently screened Iraq war veterans who suffered from the effects of a bomb blast. They noted that 61% of all service members injured by bomb blasts also sustained brain injuries, and that brain injuries are the leading cause of epilepsy.

It is important to note that a single breakthrough seizure not only puts a veteran at great physical risk, it also places him or her in financial jeopardy. In Wisconsin, as in many states, a person who experiences a seizure automatically loses his/her drivers license until they can demonstrate that they have been seizure-free for 90 days. As you would expect, this is very disruptive to the veteran, the veteran's employer, and his/her family.

We share the interest of the Epilepsy Foundation and the American Academy of Neurology in preventing the substitution of anti-seizure medications without the approval of the patient and prescribing physician. It is my understanding that Illinois passed a similar law, and that the measure has recently been introduced in twenty other states.

For more information on brain injuries sustained by war veterans, please visit the Defense and Veterans Brain Injury Center's website: www.dvbic.org.

Thank you for your consideration.

Sincerely,
DEPARTMENT OF VETERANS AFFAIRS

JOHN A. SCOCOS
Secretary


FORWARD

Epilepsy Foundation of Western Wisconsin
Kristin Berg
4903 Jeffers Rd. Eau Claire, WI 54703
Lou Kelsey
715 E. Tyler Ave. Eau Claire, WI 54701
Assembly Hearing Testimony for ~~AB150~~ SB 71
January 30, 2008

Case Study #1:
Josh was a male High School student who was very shy and hadn't had any seizures for a 2 year period of time. He was just starting to come out of his shell and socialize with other kids his age when he first had trouble with his medication. When he picked up his meds at the pharmacy he noticed that they looked different but was told that it wasn't a problem – they were just a generic form of his prescribed medication. Within 3 days Josh began having break through seizures to the extent that he had to be hospitalized. His physician put Josh through extensive testing to find out the cause of the seizures because he was not aware of the medication switch by the pharmacy. Josh fell behind in school because of all of the days he had to miss and he had to delay beginning drivers education classes until he was seizure free for the required 90 day period. Through further testing, it has been discovered that Josh must be on the brand name medication to ensure proper seizure control. His parent's insurance will only cover the generic form of Josh's medication, so his parents must pay the full price of his medications out of pocket, which is putting a significant strain on their finances.

Case Study #2:
Joe is a 52 year old single male who receives Governmental Assistance because of his epilepsy. He recently had his medications switched to a generic and has had considerable negative side effects. Joe has had to reduce his work hours because of a lack of stamina. He is also extremely tired all of the time and has sleep and emotional problems. Because Joe is on a limited income, he cannot afford to pay for the brand name of his medication, even though he knows it would improve his whole situation. Governmental Assistance will only pay for the generic form of Joe's medication, so that is what he continues to take, despite all of the side effects.

Case Study #3:
Kristi is a mother of two who has had epilepsy for over 10 years. She picked up her medication, which had been switched to a generic form, and within days began having increased seizure activity and unpredictable mood swings. Family members who were gravely concerned about the change in her behavior contacted the Epilepsy Foundation for help. At her family's urging, Kristi contacted her physician. She was put through a complete series of tests, including blood levels, and it was determined that the level of medication in her blood stream was very low. Kristi's physician stated that she must stay on the brand name of her medication in order to keep her blood levels in an acceptable range. It was only after Kristi had many terrible seizures and mood swings and went through a full battery of medical tests that her insurance company would cover the cost of the brand name medication.

ANTICONVULSANTS — NONSPECIALTY RANK 7

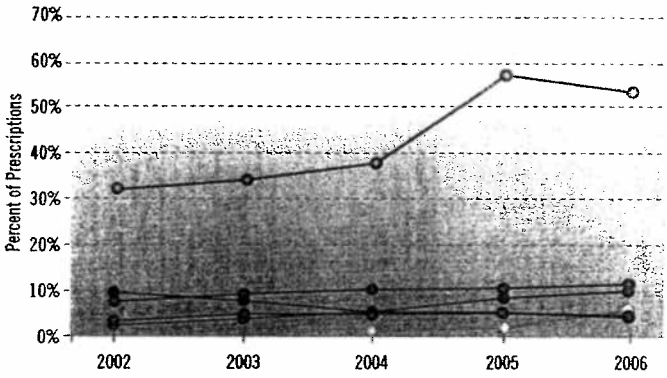
COMPONENTS OF TREND 2005 TO 2006

Cost per Prescription		**5.5%**
Price	0.6%	
Units per Prescription	-0.3%	
Brand/Generic Mix	-1.6%	
Therapeutic Mix	6.9%	
Utilization		**7.9%**
Prevalence	9.2%	
Intensity	-1.2%	
New Drugs		**0**
TOTAL		**13.8%**

KEY FACTS 2006

Cost PMPY: $24.60
 # Rx PMPY: 0.25
Prevalence of Use: 3.4%
Average Cost/Rx: $97.80
 # Rx/User/Year: 7.31

Anticonvulsants Market-Share Trend



- Trend in this category increased from 3.4% in 2005 to 13.8% in 2006. While utilization trend for anticonvulsants is not much higher than the previous year's trend, the cost component rebounded in 2006 as the impact of generics to gabapentin declined.
- Utilization of Lyrica® increased in 2006, mostly due to a new FDA-approved indication for the treatment of nerve pain associated with diabetes.
- Off-label use continues to expand this market because anticonvulsants are often used for conditions such as bipolar disorder, neuropathic pain and migraine prophylaxis.

Drug	Indication	Pipeline or Patent Expiration	Anticipated Availability
Xilep® (rufinamide)	Epilepsy	Pipeline	2008
Trileptal® (oxcarbazepine)	Epilepsy	Patent Expiration	2007
Depakote®/Depakote ER (divalproex/divalproex extended release)	Epilepsy/ Migraine	Patent Expiration	07/29/2008*

**Litigation*

Warren La Duke
210 S. Academy St
Stoughton, WI 53589

I am here to share my experience with generic medications that were substituted to me through my regular prescription for seizure control without my knowledge or consent.

In January 2006, while taking Keppra and Zonigran my seizures were well controlled. Beginning with my February monthly refills, and continuing for four months, the Zonigran prescription was substituted with a generic version unbeknown to me. Within a week of taking these generic prescription there was a noticeable change in my seizure activities.

Ultimately this change resulted in my having complex partial seizures again, and I had to voluntarily hand in my driver's license until my seizures were once again under control. As a result of appointments with my neurologist and an understanding pharmacist willing to work with me I was able to get back on the medication that was prescribed and get my seizures under control once again.

I consider myself one of the lucky ones because of the excellent health benefits provided to me through my work. I'm able to get some extra time off to make the necessary appointments to see my doctor when the time is available, to get the brand name medications, and find ways to get around the temporary limitations created when I lose my drivers license.

Unfortunately, many people who have epilepsy as a pre-existing condition often struggle with their health coverage and are not provided the cooperation from their work. Because of cost, or their health coverage, they end up taking the generic brands. When pharmacies switch the generic brands from manufactures so often, as they did with myself, problems similar to mine will continue and a person may never get their seizures under control just because of the constant change. It's almost like taking a new medication with every switch in manufacture brand.

Therapy failure for epilepsy means either a breakthrough seizure if your blood level gets low or toxicity if it goes too high. With generics the difference is enough to make such a difference. By informing both the patient and the prescribing physician, we can help avoid any unnecessary therapy failure, unnecessary expense and difficulty maintaining health at work or school.


FORWARD

EPILEPSY FOUNDATION

SOUTH CENTRAL WISCONSIN

1302 MENDOTA STREET #100
MADISON, WI 53714-1024

Committee on Public Health
January 30, 2008

Testimony on SB 71

Honorable committee members:

My name is Art Taggart, I have been Executive Director with the Epilepsy Foundation South Central Wisconsin for the last 17 years. The Epilepsy Foundation provides direct client services for people and families with epilepsy, as well as public health education programs and advocacy.

The Epilepsy Foundation would like to draw your attention to a disturbing trend in patient care we have experienced over the past several years. Our agency has received an increasing number of calls from consumers who, upon arriving home from the pharmacy, open their pill bottles, and do not recognize the pills they have been dispensed. Some of these patients have brand necessary orders from their physicians but receive generic refills; others are already taking generic medications but their pharmacy has changed suppliers and the pills look different. In several cases, generic formulations from two different manufacturers have been used to fill a single prescription.

We are concerned about patients who have difficult seizure disorders or fragile therapeutic windows suffering unnecessary and expensive therapy failure, not to mention high indirect costs such as loss of driving privilege and lost wages.

SB 71 insures informed consent of the patient and the prescribing physician before a pharmacist dispenses a product different from what has been working for a patient with epilepsy. This will enable physicians to follow and monitor these patients, as well as report adverse incidents to the FDA MedWatch system. Currently, physicians have no mechanism by which to find out when substitute formulations are dispensed, so the MedWatch system has only scant data. Both the American Academy of Neurology and the American Epilepsy Society have charged their members to take the extra time to file these reports.

Consent is only necessary when the product being dispensed is different from what the patient has been taking. Dispense as written rules only serve to indicate that a generic substitution is not permitted. If this is the only method available to physicians to insure continuity of supply, then physicians will have to write more brand name necessary prescriptions, an unintended consequence of current substitution policies and practices.

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www.epilepsyfoundation.org/socentralwisc

SB 71 allows patients with epilepsy to take advantage of lower cost generics safely and with confidence because they and their doctors will be informed any time a different formulation is being dispensed.

SB 71 keeps prescribers informed

Currently, the prescriber only has the authority to order name brand drugs. A physician has no control over which manufactured version of a generic is dispensed from one month to the next. There are 17 different generic manufacturers of one particular epilepsy medication, zonisamide. Physicians have absolutely no comparative information about these products. If a physician attempts to use generics he has no guarantee that his patient will have a continuous supply of the medication that is maintaining control and no method to follow and report incidents caused by formulation differences.

SB 71 removes barriers to access to generic drugs

Patients who have experienced problems when they have been on generic drugs are motivated to spend money out of pocket for more expensive brand name drugs. The FDA and the AMA support generic substitution and the Epilepsy Foundation supports the use of lower cost generic drugs. We believe that SB 71 establishes a best practice of patient education and pharmacist-physician partnership that will help epilepsy patients take full advantage of lower cost alternatives safely and with confidence.

Furthermore, pharmacies will not have to wait until their patients are standing at the counter to obtain consent. When they know they will be changing suppliers they can begin this process at their leisure for prescriptions that they have on file. Some have complained that there are many off label uses for these medications. Consent is only required for those being treated for epilepsy. A pharmacist needs to know the diagnosis anyway, because the information dispensed at the point of sale is different if a medication is being used for the control of seizures as opposed to migraine or other indications.

Mandates

This bill is being called a mandate in the pejorative sense, but people with epilepsy are familiar with mandates. When they experience lost or altered consciousness or involuntary muscle movement they are mandated to surrender their driving privilege for 90 days. It's costly, it's inconvenient, and it doesn't matter why it happened. There are no exceptions. It's a mandate that is intended to insure public safety. SB 71 insures the safety of patients with epilepsy who require unique and individual medication levels to control their seizures.

The FDA and the AMA

The FDA rates a generic as bioequivalent when the absorption rate and bioavailability is between 80 to 125% of the innovator drug with 90% assurance. Bioequivalence is tested on healthy volunteers under very controlled circumstances. People with difficult seizure disorders spend a great deal of energy and effort eliminating variables that might cause breakthrough seizures. The

avoid alcohol, they take their medications at the same times every day and even with the same foods so their bodies absorb the medicine the same way every day. There is such a wealth of anecdotal evidence that small formulation changes add to problems that the FDA has recently agreed to accept experiential data from physicians treating people with epilepsy.

The AMA's Council on Science and Public Health concluded that when a prescription for a generic product is refilled, changing the manufacturer should be discouraged whenever possible to avoid confusion for the patient. They go on to stipulate that for many drugs, especially those with narrow therapeutic indices, drug concentration or pharmacodynamic monitoring is necessary to assure the desired clinical response. This monitoring can be costly and time consuming but is increasingly necessary because of product interchanges. They go on to conclude that patients must receive adequate education to be able to fully understand the nature and proper use of their medications. SB 71 establishes a best practice for patients with epilepsy consistent with each of these important conclusions.

Veterans groups support SB 71

Veteran's organizations have fully supported SB 71. Over 50% of the returning injured Iraqi war veterans have traumatic brain injuries. These veterans are at increased risk of post-traumatic epilepsy as a result of their service injuries. Recently the United States Senate passed a measure that will establish six regional centers of excellence in epilepsy to serve returning vets and we are very hopeful that these centers will be fully funded and that Middleton VA Hospital in Madison will be chosen as one of the sites.

Many of these returning veterans will rehabilitate, go back to work, and participate in the same health plans as you and I. SB 71 insures that they have continuous access to the medications that work for them, or sufficient information to maintain their seizure control despite the vagaries of the marketplace or health policy that puts profits ahead of patients.

Thank you for giving a hearing to this important bill.

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www.epilepsyfoundation.org

EPILEPSY FOUNDATION®
Not another moment lost to seizures™

EPILEPSY MESSAGE

Epilepsy is a serious public health problem that can have a devastating impact on people with the disorder and their families. Studies tell us that the impact of seizures on quality of life is comparable to the impact of arthritis, heart problems and cancer. We need additional funding for epilepsy services to help those suffering from seizure disorders.

The Epilepsy Foundation of Central and Northeast Wisconsin,
The Epilepsy Foundation of South Central Wisconsin,
The Epilepsy Foundation of Southeast Wisconsin,
The Epilepsy Foundation of Southern Wisconsin,
The Epilepsy Foundation of Western Wisconsin support:

The passage of SB71 and AB150 to help prevent costly breakthrough seizures by eliminating mandatory generic substitution without physician consultation

An increase in the amount of money set aside in the state budget to serve people with seizure disorders. The current amount, $150,000 has been the same since the statute was put in place in 1989. The number of people served has grown significantly since that time. The dollars need to be increased by $150,000 to $300,000.


FORWARD

Testimony from the Pharmacy Society of Wisconsin
Before the Assembly Committee on Public Health

Senate Bill 71

Tom Engels, Vice President of Public Affairs

Wednesday, January 30, 2008

PHARMACY SOCIETY OF WISCONSIN

"Leading Our Profession in a Changing Health Care Environment"

The Pharmacy Society of Wisconsin opposes the passage of Senate Bill 71 because this legislation will not offer the protections to people with epilepsy that are implied by the bill. Pharmacists fully respect the right of people with epilepsy to obtain medications that offers them the best treatment. That exists today.

But the reality is, their treatment is not solely up to them. It is not up to pharmacists, it is not up to their physicians, it is up to the pharmacy benefit manager that is responsible for managing the prescription drug claims for their health insurer.

This legislation is similar to legislation that has been introduced in approximately 16 other states and has been financially supported by pharmaceutical manufacturers.

This legislation has been introduced at the request of the Epilepsy Foundation that would prohibit the substitution of prescription medications used for the treatment of epilepsy. This legislation is similar, but not identical, to a proposal that was introduced in the last Wisconsin legislative session. To date, no state has enacted this type of policy.

Under the provisions of this bill, a pharmacist would be prohibited from substituting an equivalent generic medication for its brand counterpart and from substituting a generic medication from one manufacturer for an equivalent generic medication made by another manufacturer, for all prescription products used in the treatment of epilepsy. A substitution would only be allowed with the consent and authorization of both the prescribing practitioner and the patient (or the patient's spouse, parent or legal guardian). Patients who have been diagnosed with epilepsy should have their condition carefully monitored and they should not have their treatment options inappropriately limited by insurance company policies.

Generic Substitution in Wisconsin

As it relates to interchange of prescription drug products, Wisconsin has taken a common and conservative approach that relies upon a sophisticated therapeutic equivalency testing process of the Food and Drug Administration (FDA). In Wisconsin, medications available for substitution only include those that meet the most rigorous equivalency tests and that receive the FDA's A/B rating.

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Wisconsin pharmacists work everyday to help patients in their medical treatments and help to reduce the cost of prescription medications by dispensing lower cost generic medications. In fact, Wisconsin law requires pharmacies to dispense a therapeutically equivalent generic prescription drug if it is lower in cost. This practice has been proven to help lower the cost of health care while maintaining the quality of treatment.
There are some instances where a prescribing practitioner will request that a specific medication be dispensed to a patient. In that case the prescribing practitioners will indicate that directive by writing "dispense as written" (DAW) on the prescription order. Most insurers and health plans provide a system for such a product to be considered for approval, dispensing and reimbursement.

Related Information
In the co-sponsorship memo that was circulated to legislators there was a reference to injured Iraq war military personnel who suffered severe head injuries. Ironically, active duty military personnel can receive any prescription drug they are prescribed — the United States Department of Defense (DoD) doesn't have a prescription drug formulary (a selected list of drugs that can be dispensed). However, when a member of the armed services leaves active status he or she becomes eligible for medical care, including prescription drugs, from the Veterans Administration (VA). Although the VA pharmacy system does employ a prescription drug formulary, VA pharmacies are not subject to Wisconsin pharmacy laws and regulations, including the provisions of this bill, should it become law.

Unintended Consequences
Some medications are prescribed for multiple symptoms, including epilepsy. The legislation would prohibit substitution of these medications if they are used in the treatment of epilepsy, but not if they are used for other conditions.

Patients receiving a generic epilepsy medication may find it difficult to receive treatment when the pharmacy provider selects an alternate generic manufacturer of the epilepsy product. It is common for a pharmacy or the pharmacy's wholesale distributor to change sources of generic products based upon the availability of the product and pricing advantages from one manufacturer over another. Changes in generic supply can change literally every month. It is possible that a patient would be unable to locate a pharmacy that stocks the very same generic manufacturer's product. Patients would also be set-up for failure as they are admitted or discharged from a hospital that may stock a different generic manufactured product than what the patient had received from a community pharmacy. Further, generic medications cost about ¼ of the brand-name medication cost, on average, although the difference varies from medication to medication. If enacted, this legislation will result in higher health care costs — for epilepsy patients, businesses and insurers alike.

Proponents Raise Concerns with the Bioequivalence of Substituted Products
The major concerns raised by proponents of this legislation are problems that may arise with the substitution of any medication used in the treatment of epilepsy. They argue that patients who have epilepsy should be allowed to maintain access to the same medication by the same manufacturer in order to minimize the potential of a seizure due to therapeutic differences between products. To illustrate this point, advocates reference the bioequivalence of generic medications not only from their brand name counter-parts but also from generic to generic.

The United States Food and Drug Administration states, "a generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance and intended use. The FDA bases evaluations of substitutability or "therapeutic equivalence" of generic drugs by requiring and testing that the drug product contains identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product."

Bioequivalence of different versions of a drug can vary by up to 20% (80-120%), because for most drugs, such variation does not noticeably alter effectiveness or safety. However, actual differences between FDA-approved generic and trade-name drugs are generally much smaller than the allowable 20%. The FDA reports that actual differences are 3.5% on average and rarely exceed 10% in any single study of bioequivalence.

PSW recognizes that sometimes generic substitution is not appropriate. For example, some generic versions cannot be determined to be bioequivalent to the original drug because no standards for comparison have been established. These versions should not, and in Wisconsin may not, be interchanged for the original drug.

PSW Recommended Action
While the intent of the proponents of this legislation is understandable, the negative consequences associated with its passage are clear. PSW recommends that the legislation be rejected. PSW further recommends that the Office of the Insurance Commissioner ensure that patients with epilepsy are not inappropriately denied access to necessary therapies by their insurer or health plan.


FORWARD

Legislative Fiscal Bureau
One East Main, Suite 301 • Madison, WI 53703 • (608) 266-3847 • Fax: (608) 267-6873

February 18, 2008

TO: Representative J.A. Hines
Room 10 West, State Capitol

FROM: Charles Morgan and Art Zimmerman

SUBJECT: Fiscal Effect of Senate Bill 71: Epilepsy Drugs

In response to your request, this memorandum provides information on the fiscal effect of Senate Bill 71 on the state's medical assistance and SeniorCare programs, as well as the cost of providing health care benefits to state employees.

Summary of Bill

Under current law, a pharmacist must dispense every prescription using either the drug product prescribed, or its drug product equivalent, if its drug product equivalent is lower in price to the consumer than the drug product prescribed. The pharmacist must inform the consumer of the options available in dispensing the prescription. A "drug product equivalent" is defined in statute as a drug product that is designated the therapeutic equivalent of another drug product by the U.S. Food and Drug Administration.

However, a prescriber may indicate, in writing on the face of the prescription order, or with respect to the prescription order submitted electronically, by designating in electronic format the phrase "No substitutions" or words of similar meaning, or the initials "N.S.," that the pharmacist may not substitute the drug specified in the prescription. The face of any prescription may not include a preprinted statement regarding drug product substitution.

Senate Bill 71 would prohibit a pharmacist that dispenses an epilepsy drug (a drug prescribed for the treatment of epilepsy or a drug used to treat or prevent seizures), from dispensing the drug product equivalent to the prescribed epilepsy drug unless the pharmacist obtains and documents the consent of the practitioner who issued the prescription order and the consent of the patient for whom the drug product is prescribed or the patient's parent, spouse, or legal guardian.

Fiscal Effect on MA and SeniorCare Benefits Costs

In calendar year 2007, the MA and SeniorCare program paid pharmacies approximately $22.4 million for four drugs that are commonly used by persons with epilepsy, including Lamotrigne (Lamictal), Levetiracetam (Keppra), Topiramate (Topamax), and Valproic Acid/ Valproex Sodium (Depakote and Depakote ER). However, since the state received approximately $8.9 million in rebates for these drugs, the net cost to the state of providing these drugs was approximately $13.5 million (all funds).

The patents for all of these brand name drugs will expire in 2008-09: (a) Lamictal, in July, 2008; (b) Depakote and Depakote ER in July, 2008; (c) Keppra in November, 2008; and (d) Topamax in March, 2009. Following the expiration of the patents for each drug, generic versions of these drugs will become available, which will be less expensive than the current brand-name drugs. Based on DHFS estimates of the average difference in the cost of brand name and generic drugs, it is assumed that the cost of the generic equivalents of these drugs would be approximately 40% of the current cost of the brand-name drugs. Further, it is assumed that once the generic drugs become available, approximately 95% of the prescriptions written for these medications would be filled by using generic drugs. (This reflects the current rate of generic use for drugs that have a generic equivalent under the MA program.)

Based on the assumptions described above, and, assuming no change in the number of prescriptions written for these medications, it is estimated that the bill could increase MA and SeniorCare costs by approximately $4.1 million (all funds) annually, compared to current law. However, since federal matching funds support approximately 59% of the costs of most MA-eligible services, including drugs, the state's share of these costs would be approximately $1.7 million annually.

The estimated cost of the proposal represents savings that would not be realized if the bill were enacted. Information regarding expiring patents for drugs covered under the MA and SeniorCare programs is not explicitly used in projecting drug costs for these programs. However, by using historical information on changes in drug utilization (costs per user), together with projected changes in caseload, the budget projections implicitly reflect an assumed continuation of the practice of generic substitution as drug patents expire.

State Employee Health Plan Costs

The Department of Employee Trust Funds (ETF), under the authority of the Group Insurance Board, administers health insurance coverage plans for state employees and offers a health insurance coverage plan to municipal employers under the Wisconsin Public Employers' Group Health Insurance Program. Departmental officials indicate that, because ETF was not directed to produce a fiscal note for the bill, it has not had their consulting actuary analyze the potential costs of the proposal. However, in informal discussion with the consulting actuary, ETF has concluded that drug cost savings that are anticipated under current law would not be realized

under the bill. While a precise estimate cannot be made without a complete actuarial analysis, departmental officials indicate that lost cost savings could range from $1.0 million to $2.0 million (all funds) annually.

According to ETF, the projected reduction in state cost savings would result because drug product equivalent alternatives to prescribed drugs would be less likely to be utilized under the bill's provisions. The class of drugs specified in the bill (those prescribed to treat epilepsy or to treat or prevent seizures) are also commonly prescribed for the treatment of other conditions such as headaches and depression. Therefore, this class of drugs is widely prescribed under the state's health insurance coverage plans. ETF indicates that the Department's prescription drug program currently expends approximately $8.5 million annually for this class of drugs (unadjusted for copayments). For some of the drugs in this class, generic alternatives are due to be available in the near future (discussed above). When this occurs, state savings would be anticipated. Typically, when a drug product equivalent alternative becomes available, the ETF prescription drug program experiences cost savings in the range 40% to 90% for the affected drug.

The bill would make drug product equivalent substitutions more difficult by requiring pharmacists to document the consent of the practitioner and the patient for the drug product equivalent substitution to be made. ETF officials believe the requirements under the bill would reduce the number of future drug product equivalent substitutions that would occur under current law provisions. This situation would result in higher prescription drug costs for the health insurance coverage plans administered by ETF.

If ETF is directed to produce a fiscal note for SB 71, a more thorough analysis by the Department's consulting actuary would be made.

Please contact us if you require additional information on this matter.

CM/AZ/sas


FORWARD

Legislative Fiscal Bureau
One East Main, Suite 301 • Madison, WI 53703 • (608) 266-3847 • Fax: (608) 267-6873

February 19, 2008

TO: Representative J.A. Hines
Room 10 West, State Capitol

FROM: Charles Morgan and Art Zimmerman

SUBJECT: Assembly Amendment (LRB 1259/1) to 2007 Senate Bill 71: Epilepsy Drugs

In response to your request, this memorandum provides a summary of an Assembly amendment to Senate Bill 71 (LRB 1259/1) and discusses the fiscal effect of the bill, as amended by LRB 1259/1.

Summary of Amendment

Senate Bill 71, as introduced, would prohibit a pharmacist from substituting a drug product equivalent for a drug prescribed for treating epilepsy or for treating convulsions, unless the pharmacist obtains and documents the consent of the prescribing practitioner and the patient, or the patient's parent, spouse, or legal guardian.

The amendment would delete the requirement that the pharmacist obtain and document the consent of the prescribing practitioner and the patient or the patient's parent, spouse, or legal guardian. Instead, the pharmacist would be required to notify both the prescribing practitioner and the patient or the patient's parent, spouse or legal guardian.

Fiscal Effect of the Bill, as Amended

It is difficult to determine what effect, if any, the amendment would have on the cost of providing epilepsy drugs under the medical assistance (MA) and SeniorCare programs, and to state employees under the state health plans because it is not clear how pharmacies or the Pharmacy Examining Board (PEB) would interpret the new requirements in the amendment.

One interpretation of the amendment would be that, prior to dispensing a drug product equivalent, the pharmacist would be required to notify the physician and the person for whom the

drug was prescribed. Alternatively, the requirement could be interpreted to mean that pharmacies could notify the prescribing physician after dispensing the drug product equivalent and the patient at the time that the drug is delivered.

In addition, the form of this notification is not specified in the amendment. For example, it is not clear whether the pharmacist would need to notify the prescriber each time the pharmacist dispenses a drug product equivalent, or whether the pharmacist could comply with the requirement by simply indicating to all physicians whose prescriptions are filled by the pharmacist that the pharmacist will provide a drug product equivalent whenever a drug product equivalent is available, unless the physician specifically instructs the pharmacist to fill the prescription as written. It would be the role of the PEB to interpret these provisions and to determine the manner in which pharmacies would comply with them.

Finally, if, due to the enactment of the bill, patients receive more explicit notification of the pharmacy's substitution of a drug product equivalent, it is possible that patients will more frequently request that their physicians prescribe brand-name drugs due to their belief that these drugs are superior to the drug product equivalents that they would otherwise receive. While it is not known how physicians would respond to these requests, it is possible that physicians would increase the percentage of prescriptions they write with the "no substitutions" designation.

In summary, the amendment, as drafted, leaves some uncertainty regarding the manner in which pharmacies would administer these provisions and could limit, to some extent, the acceptability of a drug product equivalent substitution. However, generally, the amendment (requiring notification of the physician and patient for any substitution) may be viewed as a lesser change to current law than the original bill (which would require the consent of the physician and patient for any substitution). Therefore, the extent to which drug product equivalents are substituted for branded drugs would likely be greater under the amendment than under the original bill. A higher level of substitution would allow for greater savings for the MA and Senior-Care programs and the health insurance plans covering state employees. While the amendment would be expected to allow for greater savings than the original bill, the extent of these savings cannot be quantified.

Please contact us if you require additional information on this matter.

CM/AZ/sas


FORWARD

Wisconsin State Assembly
70th Assembly District

Serving Wood, Marathon
& Portage Counties

AMY SUE VRUWINK
STATE REPRESENTATIVE

February 19, 2008

Representative J.A. Hines, Chairman
Committee on Public Health
Room 10 West
Hand Delivered

Dear Representative Hines,

I would like to take this opportunity to request that Senate Bill 71 (SB 71), relating to substitutions by pharmacists dispensing epilepsy drugs, be given an executive hearing in the Assembly Committee on Public Health.

As you know, SB 71 was passed out of the Senate unanimously and has broad bi-partisan support in the Assembly. Notifying physicians of substantial prescription changes is crucial in determining the most effective long-term treatment for epilepsy patients. This bill will help to protect Wisconsin citizens who suffer from epilepsy and ensure that they receive the best possible health care.

My district, like many districts throughout our state, has a large rural population. If prescription changes have an adverse effect on epilepsy patients in these areas, it is often difficult if not impossible to get them to a hospital for immediate care and monitoring. Breakthrough seizures are a very serious medical emergency and can have lasting effects not only on the health of the individual, but also on their ability to retain their job, driver's license, and dignity. I would respectfully request that you and the members of the Committee on Public Health pass this bill and allow it to come before the full Assembly for a vote.

Thank you very much for your time and consideration. If you have any further questions, please do not hesitate to contact me personally.

Sincerely,

Amy Sue Vruwink
State Representative
70th Assembly District

ASV:amp

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TOLL-FREE: 1-888-534-0070 • **E-MAIL:** Rep.Vruwink@legis.state.wi.us • **DISTRICT PHONE:** (715) 652-2909


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EPILEPSY FOUNDATION
CENTRAL AND NORTHEAST WISCONSIN
Not another moment lost to seizures

Headquarters
1004 First Street • Stevens Point, WI 54481-2627

Cynthia Piotrowski
Executive Director
Epilepsy Foundation Central & Northeast Wisconsin
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- We see health care trends in the problem calls we receive from clients
- Clients are calling when they get home and they don't recognize the medications that have been dispensed
- The Epilepsy Foundations in Wisconsin would like to enlist pharmacists as an important treatment partner and insure that before any kind of substitution is made at the point of sale the patient and the physician are in the loop
- The American Academy of Neurology & the American Epilepsy Society have charged their members with filing Food & Drug Administration Medwatch reports about adverse incidents. A recent poll suggests that only 13% of neurologists have done so, but this is because neurologists currently have no way of knowing when these substitutions are made
- 5871 ~~AB 150~~ insures that physicians will be able to adjust doses, order blood levels or monitor their patients as necessary when substitutions are made
- EF clients want cheaper co-pays and they want medications that are affordable – just like everyone else
- 5871 ~~AB 150~~ insures that they can have confidence in generics and that their physicians will take steps when their formulation changes due to inconsistency of supply
- EF stresses that this is not anti-generic and we are not asking for pharmacists to absorb any costs. What we are doing is asking that they help make sure all parties involved are informed when changes are made by keeping in mind that epilepsy patients often have a very narrow therapeutic range.

On November 14th, my staff was notified by my doctor's office that on the 15th of November, the insurance company was no longer going to cover my Trileptal, but instead put me on Oxcarbazepine (a generic of Trileptal) due to cost. Within 24 hours, I had a seizure. I had been seizure free before that since July. Over the next nine days, I had 19 seizures.

I have had trouble with generic medications in the past and I feel that insurance companies should not be able to change medications from brand names to generics without consulting the patient first.

Once the seizures started, my doctor's office, the pharmacy, my staff and I all contacted the insurance company to let them know what was happening. The insurance company representative told my staff that I had to try two different generics and fail on both of them before they would put me back on the Trileptal. It felt to me like the insurance company did not care that I was suffering because of their decision.

On November 22nd, Thanksgiving Day, I was on a home visit and had a seizure. I had actually stopped breathing and my skin was a bluish/purple color. I was so wiped out that I had to go back to the group home early. The seizures are very, very hard on me. They leave me weak, confused and extremely tired.

My opinion is that the insurance company wasn't concerned with me as a person but was more interested in saving a few bucks at my expense.

Kyle Glamann
617 Hamilton St
Wausau WI 54403


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EPILEPSY FOUNDATION®
Not another moment lost to seizures™

Please Support the

"Epilepsy Patient Protection Act" (Senate Bill 71)

The Bill

The bill ensures that before a pharmacist substitutes any drug product for treating epilepsy the pharmacist obtains the consent of the prescribing practitioner and the patient. **It does not prohibit substitutions.** Also, if a pharmacist dispenses a refill, he must also obtain consent from the patient and treating physician before substituting a different drug than the one previously dispensed.

Fact Sheet

- Supporters of SB 71: Wisconsin Epilepsy Foundation, American Academy of Neurology (AAN), Wisconsin Medical Society, State of Wisconsin Department of Veterans Affairs, Polish Legion of American Veterans (P.L.A.V.), Wisconsin Paralyzed Veterans of America (PVA), American Ex-Prisoners of War, County Veterans Service Officers (CVSO), Catholic War Veterans

- **This bill has no cost to the state**, according to the fiscal note, and **no cost to pharmacists**, according to Legislative Council. A November 7 memo from the Legislative Council clarified that "Senate Bill 71 does not require pharmacists to make up the difference between the cost of the brand-name drug and what the patient's health insurance plan (if any) will pay for the drug."

- **More than 50 percent of injured soldiers returning from Iraq have traumatic brain injuries.** Traumatic brain injury is the leading known cause of epilepsy. This bill is supported by the Wisconsin Dept. of Veterans Affairs.

- **Wal-Mart, Walgreen's & CVS change suppliers of generic drugs at an alarming rate.** This bill puts the treating physician and the patient on notice when one generic is substituted for another so that the patient can be more closely monitored and a breakthrough seizure prevented.

- Epilepsy advocates in Wisconsin and several other states are asking their state legislatures to **close a loophole in the "Dispense as Written" law**. Those suffering from epilepsy report at an increasing rate of having their medications switched to a different supplier, which can have dangerous or deadly consequences. The "Dispense as Written" safety net does not prevent this in situations in which a person is taking a generic.

- **Some drugs for the treatment of epilepsy are narrow therapeutic index drugs** and some epilepsy patients have even narrower therapeutic ranges and require very dose-specific blood levels. **There can be formulation differences from one generic drug product to another or from a name brand to a generic.** This means that if a pharmacy changes suppliers, a patient could experience unnecessary therapy failure.

- Unlike other health conditions, by law in Wisconsin, **epilepsy patients who experience therapy failure and a seizure lose their driving privileges for at least 90 days**. They also are subject to costly and unnecessary ambulance calls and emergency room visits, and can risk problems maintaining employment and personal safety if a dosage change results in therapy failure.

For more information:

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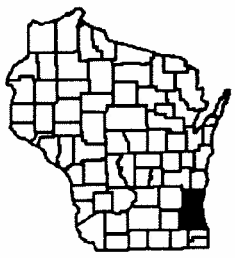

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