MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

DESCRIPTION

1431

2007 HOUSE HUMAN SERVICES

HB 1431

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1431

House Human Services Committee

☐ Check here for Conference Committee

Hearing Date: January 24, 2007

Recorder Job Number: 1751

Committee Clerk Signature Judy Schock

Minutes:

Chairman Price: calls the committee to order and opens the HB 1431.

Representative Chuck Damschen, District 10: Purpose of this bill is to not substitute generic drugs for treatment to epilepsy and convulsions can result in problems. The pharmacist would not be able to substitute a generic unless he consulted a physician. There are amendments coming down.

Art Taggart, Executive Director of the Epilepsy Foundation South Central Wisconsin: this is an issue we are actually working on in Wisconsin, and that is one of the reasons I ended up here this morning. Because there is no epilepsy foundation in ND we occasionally get calls. We serve a number of clients from ND. See attached testimony, purposed amendments, and epilepsy patient protection attached. The amendments are just to clarify language. It had nothing to do with co pays etc. We assume all generics are alike, they are not. Not that generics are bad, those monitored did not always get the same ingredients every time.

Representative Porter: How many states have been acted similar in legislation to what is being proposed today? The fiscal effect against the state budget for medical services for the Medicaid program is about 300,000 dollars a year. This is their estimate to put this bill in place.

Mr. Taggart: I think there are many states where this legislation is being, at last count something like 20 states now have it and to a large degree epilepsy sponsored bills. Epilepsy is quite unique. These medications work in the brain. It cost the state of Wisconsin nothing.

Dr Shiraz Hyder, Neurologist, Vice President of Medical Affairs, St. Alexis Neuroscience Center: See attached testimony. There are serious side effects even in different generic brands. You need a physicians input. Substituting medications should be with the consent of the physician. The physician knows best what that patient needs. A patient can die from this. They may not have a second chance.

Representative Porter: What happens when patient ends up over the 20 mark for an extended period of time, and what kind of side effects does that have on the rest of the body? Also when you are presented with a patient that has new on set of seizures or one you will be taking over the management of their seizures. How long does it take to get that patient into a therapeutic range and knowing where they are at and than not seeing them and keeping them seizure free?

Dr. Hyder: It can affect the liver, the kidneys, balance, cognation; it can affect their thinking, and concentrating, the higher the levels the more side effects. Everyone is different and it depends on the levels. It could take days and it could take months to get that patient under control.

Chairman Price: When you have a new patient, do you talk about the high costs especially those that have no insurance?

Dr Hyder: Absolutely, we talk about the cost of medication and tests, and what the benefits are.

Dave MacIver, I am representing myself. See attached testimony. I was getting my drugs from the veteran's administration. They wanted to take me off those medications. I left the

VA and went to my regular pharmacist, so I could have medications that I needed. I am scared to death of changing medications. My wife has retired from her job to drive me. The medications I am on now took a long time to get there. I am seizure free now for 7 months. I think it is up to me and my Doctor if there is a change in prescriptions. When I am seizure free, I don't want someone to change my medication. Once you get to the hospital the costs are high trying to find out what causes my seizures. I believe last summer it cost me 70,000 dollars.

Howard Anderson, Executive Director of the ND State Board of Pharmacy: See attached testimony. I am not so much in opposition of this bill, but I think it needs some changes. The physician will have to write on his prescription it is for epileptics, as some meds are also prescribed for other illnesses.

Mark Hardy, from Neche, ND I am a pharmacy student: I was very troubled when I heard about this bell. See attached testimony, along with generic brands.

Representative Kaldor: In your research, how do you account for how patients react from one medication to another, if they are indeed as you say equivalent.

Mr. Hardy: The difference between the two is that narrow margin in all generic products. The variation is in how it is made. The patient is always informed. As a pharmacist I would always try to keep their medication in stock. Yes, patients would like to stay on the same drug. There is a big worry for the patient, that this may not be the same. Typically we like to stay with the same manufacturer of the generic drugs.

Rod St. Aubyn, representing Blue Cross Blue Shield of ND: See attached testimony, Formulary anti convulsive drug list attached.

Dr. Brendan Joyce, Administrator of Pharmacy Services for the Medical Services Division in the Department of Human Services. See attached testimony. Yearly epilepsy totals attached.

Paul Sanderson, attorney in Bismarck with Zuger Kirmis & Smith, I represent Medco Health Solutions, Inc.: See attached testimony. Out position is based on the bill, we have not seen the amendments.

Chairman Price: Any other opposition for HB 1431? If not we will close the hearing on HB 1431.

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1431

House Human Services Committee

☐ Check here for Conference Committee

Hearing Date: January 24, 2007

Recorder Job Number: 1856

Committee Clerk Signature Judy Herock

Minutes:

Chairman Price: take out the HB 1431 on epilepsy.

Representative Weisz: The only things I will say I do believe the pharmacist have a legitimate point when they brought up that same drug can be used for other uses.

Committee discusses: If the Dr. wants to brand name a prescription, that's as far as it goes. The physicians need to be required to write on the prescription for epileptic. Sometimes the pharmacist runs out of inventory, do we run a risk giving them something or do we run a risk to not give anything. The committee discuss some language and what amendments to do.

Representative Weisz moves amendments as changed. **Representative Kaldor** seconds the motion. A verbal vote of all yeas. **Representative Weisz** moves a due pass as amended **Representative Damschen** seconds the motion. The vote was 10 yeas 0 nays and 1 absent. **Representative Damschen** will carry to the floor.

FISCAL NOTE

Requested by Legislative Council
01/29/2007

Amendment to: HB 1431

1A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2005-2007 Biennium		2007-2009 Biennium		2009-2011 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$1,164,498	$0	$1,362,707
Expenditures	$0	$0	$655,926	$1,164,498	$767,188	$1,362,707
Appropriations	$0	$0	$655,926	$1,164,498	$767,188	$1,362,707

1B. **County, city, and school district fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

2005-2007 Biennium			2007-2009 Biennium			2009-2011 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
$0	$0	$0	$0	$0	$0	$0	$0	$0

2A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

The bill would enact a new section 26.1-36 of the NDCC prohibiting a health insurer from imposing penalties for the dispensing of specific drugs for the treatment of epilepsy; and to amend and reenact section 19-02.1-14.1 of the NDCC restricting pharmacists from dispensing substitute epilepsy drugs.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

The fiscal impact was calculated based on the historical expenditure increase of nearly 20% for this class of drugs for the 2007-09 biennium. For the 2009-11 biennium the increase was estimated to be 17%.

The expenditures noted above were calculated based on the 2007-09 projected utilization in the executive budget.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*
   A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

For the 2007-09 biennium $1,164,498 in federal funds would be received.

For the 2009-11 biennium $1,362,707 in federal funds would be received.

B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

For the 2007-09 biennium a total of $1,820,424 would be expended; $655,926 in general funds and $1,164,498 in federal funds.

For the 2009-11 biennium a total of $2,129,895 would be expended; $767,188 in general funds and $1,362,707 in federal funds.

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

For the 2007-2009 biennium the Department would need an appropriation of $1,820,424 of which $655,926 would be general funds and $1,164,498 would be federal funds.

Name:	Debra A. McDermott	**Agency:**	Dept of Human Services
Phone Number:	328-3695	**Date Prepared:**	01/29/2007

FISCAL NOTE

Requested by Legislative Council
01/19/2007

Bill/Resolution No.: HB 1431

1A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2005-2007 Biennium		2007-2009 Biennium		2009-2011 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$1,164,498	$0	$1,362,707
Expenditures	$0	$0	$655,926	$1,164,498	$767,188	$1,362,707
Appropriations	$0	$0	$655,926	$1,164,498	$767,188	$1,362,707

1B. **County, city, and school district fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

2005-2007 Biennium			2007-2009 Biennium			2009-2011 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
$0	$0	$0	$0	$0	$0	$0	$0	$0

2A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

The bill would enact a new section 26.1-36 of the NDCC prohibiting a health insurer from imposing penalties for the dispensing of specific drugs for the treatment of epilepsy; and to amend and reenact section 19-02.1-14.1 of the NDCC restricting pharmacists from dispensing substitute epilepsy drugs.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

The fiscal impact was calculated based on the historical expenditure increase of nearly 20% for this class of drugs for the 2007-09 biennium. For the 2009-11 biennium the increase was estimated to be 17%.

The expenditures noted above were calculated based on the 2007-09 projected utilization in the executive budget.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*
   A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

For the 2007-09 biennium $1,164,498 in federal funds would be received.

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B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

For the 2007-09 biennium a total of $1,820,424 would be expended; $655,926 in general funds and $1,164,498 in federal funds.

For the 2009-11 biennium a total of $2,129,895 would be expended; $767,188 in general funds and $1,362,707 in federal funds.

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

For the 2007-2009 biennium the Department would need an appropriation of $1,820,424 of which $655,926 would be general funds and $1,164,498 would be federal funds.

Name:	Debra A. McDermott	**Agency:**	Dept of Human Services
Phone Number:	328-3695	**Date Prepared:**	01/23/2007

Date: 1/24
Roll Call Vote #: 1

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. "Click here to type Bill/Resolution No."

House HUMAN SERVICES HB 1431 Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Move Amendments as Changed

Motion Made By Rep Weisz Seconded By Rep. Kaldor

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price – Chairman			Kari L Conrad		
Vonnie Pietsch – Vice Chairman			Lee Kaldor		
Chuck Damschen			Louise Potter		
Patrick R. Hatlestad			Jasper Schneider		
Curt Hofstad					
Todd Porter					
Gerry Uglem					
Robin Weisz					

Total (Yes) "Click here to type Yes Vote" 12 No "Click here to type No Vote" 0

Absent 2

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Date: 1/24
Roll Call Vote #: 2

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. "Click here to type Bill/Resolution No."

House HUMAN SERVICES HB 1431 Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass as Amended

Motion Made By Rep Weisz Seconded By Rep Damschen

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price – Chairman	✓		Kari L Conrad		
Vonnie Pietsch – Vice Chairman	✓		Lee Kaldor	✓	
Chuck Damschen	✓		Louise Potter	✓	
Patrick R. Hatlestad	✓		Jasper Schneider		
Curt Hofstad	✓				
Todd Porter	✓				
Gerry Uglem	✓				
Robin Weisz	✓				

Total (Yes) "Click here to type Yes Vote" 14 No "Click here to type No Vote" 0

Absent 2

Floor Assignment Rep. Damschen

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1431: Human Services Committee (Rep. Price, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (10 YEAS, 0 NAYS, 2 ABSENT AND NOT VOTING). HB 1431 was placed on the Sixth order on the calendar.

Page 1, line 1, remove "to create and enact a new section to chapter 26.1-36 of the North Dakota"

Page 1, remove line 2

Page 1, line 3, remove "of specific drugs for the treatment of epilepsy; and"

Page 1, line 12, after "a." insert:

""Anti-epileptic drug" means any drug for the treatment of epilepsy or a drug that is used to treat or prevent seizures. The term does not include an anti-epileptic drug that is used to treat conditions other than epilepsy or to treat or prevent seizures.

b."

Page 1, line 14, overstrike "b." and insert immediately thereafter "c."

Page 1, line 17, overstrike "c." and insert immediately thereafter "d."

Page 1, after line 19, insert:

"e. "Epilepsy" means a neurological condition characterized by recurrent seizures."

Page 1, line 20, overstrike "d." and insert immediately thereafter "f."

Page 1, after line 21, insert:

"g. "Interchange" means the substitution of one version of the same anti-epileptic drug, including a generic version for the prescribed brand, a brand version for the prescribed generic version, a generic version by one manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed anti-epileptic drug, or a different anti-epileptic drug for the anti-epileptic drug originally prescribed."

Page 1, line 22, overstrike "e." and insert immediately thereafter "h."

Page 1, after line 24, insert:

"i. "Seizure" means an acute clinical change secondary to a brief disturbance in the electrical activity of the brain."

Page 2, line 1, overstrike "f." and insert immediately thereafter "j."

Page 2, line 2, overstrike "g." and insert immediately thereafter "k."

Page 4, line 12, replace "dispense a therapeutically equivalent generic name drug" with "interchange an anti-epileptic drug or formulation of an anti-epileptic drug for the treatment of seizures or epilepsy without notification of the prescribing practitioner and

the signed informed consent of the interchange from the patient or the consent of the patient's parent, legal guardian, or spouse"

Page 4, remove lines 13 and 14

Page 4, line 15, remove "issued the prescription and the patient for whom the prescription was prescribed"

Page 4, line 21, after "prescription" insert "and the consent of the patient or the consent of the patient's parent, legal guardian, or spouse"

Page 5, remove lines 9 through 14

Renumber accordingly

2007 HOUSE APPROPRIATIONS

HB 1431

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. **HB 1431**

House Appropriations Committee

☐ Check here for Conference Committee

Hearing Date: 2-8-07

Recorder Job Number: 3164

Committee Clerk Signature Diane Lee

Minutes:

Rep Svedjan: We'll move to HB 1431...it's an engrossed bill with fiscal note dated Jan 29th.

Rep Weisz: Introduced HB 1431. Because of the unique nature of epileptic conditions and seizures and the interactions that the drugs may have, most physicians say that it's very important that you don't switch drug manufacturers without them being aware of it, because even though switching from one generic to another or a brand name to a generic, are essentially the same...there's no question that they meet the FDA guideline, so it's essentially the same drug, but on an individual case by case basis, they can change how the person reacts to the drug and where someone was on brand X of a specific drug, they switch to a generic of the same generic drug...all of a sudden, they're having an epileptic seizure. Obviously, if you have epilepsy, it's imperative to control those seizures...when you haven't had a problem for two years and went to the pharmacy and they tell you they don't have the one you had before, but here's this company's drug. The bill before you merely says that the pharmacies must notify the physician if he's going to substitute the manufacturer. This isn't a carve out, per say, it doesn't say that you can't use generics and it's not brand of generics or generics to brand, it's basically, whatever you're using now to insure that the doctor's notified. It doesn't say you can't switch them and in most cases you can and it won't have an effect, but in some cases there's such a tiny tolerance level between the action of the drug and what it

has on an individual case. I think if you ever pay attention to when FDA does all their test and even the wine that drug companies produce...the drugs produce different effects because of all the different issues on a unique individual. So what this bill says is merely there has to be some notification...so you've got a fiscal note that has a substantial fiscal effect...basically, I think that fiscal note is bogus...this is an identical law that was passed in Wisconsin...I have a copy of their fiscal...absolutely no fiscal effect. That fiscal note is assuming there's going to be a 20% cost increase in that type of drug...obviously, drugs going up 20% so it has to be because we passed this bill. I see absolutely no connection to this and what the price of drugs are going to do in the next biennium...I don't see any relation. The fiscal effect really doesn't take into account, will there be some that stay on brand name that might have switched to generic that's not in the fiscal note and how many just assume the 20% cost increase on the number...and that's what you have in front of you.

Chairman Svedjan: So the assumption is, not only the projected increase in drug prices, but it would also assume that all of these people would be switching?

Rep Weisz: No, what it assumes is that if drug costs go up 20%, that's attributed to the fact that there has to be notification. I would argue that there's absolutely no relationship...this does not say that if you're on a brand name that you can't be put on a generic. This applies from generic to generic or brand to generic or generic to brand...if you're on a generic and the pharmacist is out of that and he hands you a brand name drug that will cost more, it would require the same notification. This isn't about generic or brand name, this is about switching manufacturers and the potential they have to affect that individual whether he may have an epileptic seizure or not...that's why in my opinion (and the committees) the fiscal note did not address what the bill actually did. You'd have to make the assumption that if we didn't have

the bill and switch everybody to generics and they're not going to up 20%, so we wouldn't have had any increased cost.

Rep Carlson: I'm confused as to why we have to do this.

Rep Weisz: We don't have to do this...it's an issue...we had testimony from a lobbyist telling what happened to him when there was a substitution. The reason is and often times a person may not even be aware of it, but he's had a prescription for 9 months and the physician has to fine tune it and they finally have it under control, there's no problem...he hasn't had a seizure, he walks into his pharmacist and he's out of whatever drug you had so here's the same drug, but it's a different company so he grabs the drug and 2 hours later, he has a seizure. The physician had no idea why he had a seizure because there's no requirement to be in communications...this is to insure that the pharmacist doesn't just switch without the physician approving.

Rep Carlson: How prevalent is this...are there a 25 or a 1000 people affected by this? Also, explain to me...I don't understand why if you have to notify somebody that there would be a $665T general fund appropriation...it just doesn't make any sense to me. I agree with you on the fiscal note...where's the cost coming from?

Rep Weisz: I'll try to address the 1st question...I don't know how many, there's no cost effect...but if it's one, why would you want to have a seizure, maybe lose his license...maybe he's driving and has a seizure and he's no longer going to get a license. It has more of an effect of just a health care cost...this can have a tremendous effect...the doctors that testified said they had several, when they switched, either their levels went too high or too low...they caught in and took care of it. So is it prevalent, no, and as far as the fiscal effect...that was my point...the assumption is that everyone's going to switch from generics to brand name and we won't be able to switch and we won't be able to switch anyone from brand name to generics.

Rep Carlson: How many people came in from the public that have this problem and testified that they just had to have this?

Rep Weisz: I believe there were 3 individuals.

Rep Carlson: Were they doctors or were they the actual people taking the medicine?

Rep Weisz: People that were having epileptic seizures plus there were physicians.

Rep Wald: I think the bill is in the title of the bill where a pharmacist can't switch either brand name or generics for this particular ailment...then if you go to page 6, the last section, gives kind of a hold harmless to any practitioner or pharmacist. I still don't understand in relation to question the Rep Carlson asked about...why would this cost money if the pharmacist can't switch without telling the patient...where's the fiscal impact?

Rep Weisz: Again, I'm not defending this fiscal note, because I don't agree with it and if you look it says...was calculated on the historical expenditure increase of nearly 20% for this class of drugs and for the 0911 it was estimated to be 17% so their assumption is that if we pass this bill we will have the 20% increase but then if we don't pass the bill we'll have a 20% increase because that's the historical price...to me that equals 0.

Chairman Svedjan: This 20%, was that applied to our Medicaid drug increases, being that the lobbyist who spoke to you is not on Medicaid so this would only be calculated on the basis of Medicaid patients?

Rep Wiesz: This only applies to those on the formulary for the Medicaid...the $655T applied only to the Medicaid population.

Rep Thorson: When you had testimony on this bill on committee, were there representatives from the generic pharmaceuticals industry testifying about this issue?

Rep Weisz: No, there were none.

Rep Monson: I know you've said you don't understand either, but I just don't understand the funding costs...there's no appropriation in here, although the fiscal note says there is. Have we looked at any appropriation anywhere?

Rep Weisz: We did pass prior authorization 03 and that's the reason there's a fiscal not in front of us, it gave the department the ability to manage our Medicaid drug program. What they're saying is that this doesn't give them the ability to do that in this class of drugs and because the drugs go up 20%, all of that would have to be attributed to this bill in this fiscal note.

Rep Gulleson: I have the same concerns as Rep Carlson...I feel like it's within the professional prevue of the pharmacist to always question this on any category of drug...this could cross over into diabetes or whatever...the sensitivity...if we start looking at it and putting it into code (drug by drug) to me it takes away from what we look for just within the profession to protect and make sure we're receiving the appropriate drug for the appropriate condition and work with the physician. Why is this set apart from all the other categories and conditions?

Rep Weisz: I'm assuming you understand the issues better than I do, but again, if I'm taking a cholesterol drug and it's not working 100%...what's the worst that happens in that interim for my cholesterol to get higher? I'm not going to have a seizure while I'm driving and kill someone...it's not going to affect my life and that's why this was singled out, because it is such a fine line and it can have that kind of effect. Often times that's the way it is, we'll take this and if it isn't under control you come back and we'll try something different.

Rep Nelson: I think my question was answered...it was back to the prior authorization aspect of it, so in this regard the department could authorize a generic replacement without a doctor's order? Or do they want that? Is this a condition that they can do that?

Rep Weisz: Yes, they can decide that a generic is a good substitute...now even with prior authorization a doctor can still come and say no, they have to have a brand name and there's a process to go through and they can still get it. This doesn't say you can't take the generic, it just says whatever you're on now...you can't just switch it without at least a physician being part of it, so he knows and can monitor it and if works fine...it's cheaper.

Rep Glassheim: Could we have the Human Service Department explain the fiscal note?

Maggie Anderson, Department of Human Services: The fiscal note was built on factual information from our current expenditures in projecting that out into '07 '09 as well as information about these meds are currently used within the Medicaid population. I'll provide some of those statistics for you. Currently epilepsy medications account for 11% of the North Dakota Medicaid pharmacy expenditure and expenditures for this medication class, so it's not all of our drugs, has growing nearly 20% each year. According to statistics for epilepsy there's a 5% incident of epilepsy in the population, so if you take our population now, it would be roughly about 3,200 individuals in the whole population of North Dakota who may have this. Around 3,550 people on Medicaid are currently on this medication and 90% of that is due to the fact that there used for mood stabilization incidences rather then just strictly epilepsy. One of the reasons why the fiscal note is built the way it is...is this class of drugs is reaching it's maturity, which means that many of the products will coming off of patent in the coming years, so when we build our '07 '09 budget request, we knew that and accounted for a generic mix within this particular drug class as well as our mix of those generic 2 brand names within our other drug class. The bill does talk about notification to the practitioner, but if I could draw your attention to Page 4, Line 25...it says it needs notification of the prescribing practitioner and the signed informed consent of the interchange from the patient or the consent of the patient's parent, legal guardian, or spouse. So in building our fiscal note, we have to take into

consideration whether we believe a significant portion of people will find that consent form and we don't believe that would occur, so we built the fiscal note based on our drug expenditures, our history with those and the way that the bill was drafted indicating there needs to be notification to the practitioner but signed, informed consent of the recipient.

Chairman Svedjan: In building your fiscal note, was it based on the assumption that switches would made from generics to brand name or was that factored in or vice versa?

Maggie Anderson: Yes, there was an assumption that as these items came off of patent, that some individuals would switch to generic and Rep Weisz did speak to the portion of this same section of code that's being proposed to be changed where we have that brand name necessary, or dispense as written...portion in the rule. So if the practitioner indicates on the prescription: "dispense as written" or "brand name necessary" ...then the pharmacist if obligated to dispense that as written or brand name...they have to do that and if they don't the pharmacist exercises their professional judgment in counseling with the client in indicating that there's a therapeutic equivalent in the generic and based on our experience with our Medicaid population and our years of drug expenditures, we know that a percentage of those would go to generic. I also want to point out...in the testimony we provided to House Human Services...we do have the drug utilization review board and in the past interim, as that board has met and that board does include 2 psychologists, we asked if we should have any exemptions from the mandatory generic policy because right now unless "brand name is necessary" is written on the prescription the generic would be distributed and the ?DUR? board member said there should be no exceptions, including the epilepsy medications. It was with all of that that we put our fiscal note together, knowing that they're coming off patent, we figured we'd have a mix of generics...without being able to have that mix it's going to increase the expenditures for the Medicaid program in the drug area.

Chairman Svedjan: So we could put a Do Not Pass on this and that would relieve the notification requirement but things could still happen, where somebody switched from one to another, which could have negative consequences?

Maggie Anderson: That's correct.

Chairman Svedjan: Another would be that we could pass the bill out without any funding in it, which would require notification and then what you're saying is that it would impact your pharmacy budget within Medicaid.

Maggie Anderson: That's also correct.

Chairman Svedjan: Or we could pass it out and put an appropriation with it...that seems to me to be the 3 options here.

Rep Glassheim: On Page 4, it requires notification of the prescribing practitioner and a signed consent form...I'm not sure why a signed consent form is necessary...what if you require the practitioner to agree to the change, because the practitioner knows better...the person taking it doesn't know one way or another, what's good for them in terms of what's in that drug. That would then have many fewer "no signs", because presumably if it's healthy, the practitioner will say, sure, go ahead and if it's not healthy, then we ought to pay what needs to be paid so the person doesn't die or have a seizure. Would you think that would change the fiscal impact significantly if you took out the signed consent form?

Maggie Anderson: I'm not prepared to answer that yes or no, I do believe it would have an impact, but I would want the opportunity to visit with our pharmacy manager and go back and run the numbers, based on our experience with that with other drugs and I can't speak to the part about the pharmacist (I'm not a practicing pharmacist) about how much effort that is and whether they would go through that to have the drug switched to a generic, but I do believe there could be a potential change in the fiscal note. I also can't speak to whether the bill

sponsors and the individuals who have amended this at least once, whether they would support that or not.

Rep Hawken: You read in this bill, you talk about the other people who are on this level or this kind of drug...this is specific, so it's not those other people who are taking it for mood enhancement...this is just epilepsy.

Maggie Anderson: And the convulsive which has me speaking into drug therapy that I'm not at liberty to discuss, but I can check on that.

Rep Svedjan: Do you have any idea why Wisconsin found no fiscal impact.

Maggie Anderson: No I don't, I do know that similar bills are occurring in other states...I know Wyoming and South Dakota have considered this and I could secure their fiscal information as well...they were defeated in those two states.

Rep Wald: On Page 5 of the engrossed bill, starting on Line 11...you're giving the Board of Pharmacy an exemption ...is that characteristic in the Department of Human Service policy that you allow a board to be exempt from a section of the bill?

Maggie Anderson: That's not a new section of the bill and I honestly am not in a position to respond directly to that...I can get back to you.

Rep Svedjan: Any further discussion, we don't have a motion on the floor.

Rep Glassheim: I'm going to try an amendment...delete on Page 4, Lines 25-27, the language...signed informed consent of the interchange from the patient or the consent of the patient's parent, legal guardian, or spouse. Also to delete on Page 5, Line 1...and the consent of the patient or the consent of the patient's parent, legal guardian, or spouse. **I would move that as an amendment.**

Rep Ekstrom: I second it.

Chairman Svedjan: That motion will leave us not for sure what the fiscal effect of that will be. Any discussion, if not, on the motion to amend, taking out the references in the language to the consent form requirements and also on Page 5, the references to consent...that's the tone of the amendment.

Voice Vote

Chairman Svedjan: **Motion Fails** ...what are your wishes?

Rep Thoreson: I would move a **DO NOT PASS**

Rep Carlisle: I second it.

Rep Thoreson: Understanding that this is about the fiscal impact...in discussion with Rep Weisz, the reason I'd asked the question is and this is something I'm working with on a daily basis...now with generic pharmaceuticals...there are very stringent guidelines that the Food and Drug Administration puts forward dealing with bioequivalence and that we necessarily need to be putting these restrictions or these words in our code, because I think they've done a very good job making certain that the generic versus another generic or the innovator brand name drugs are taken care of so for that reason I'm not certain that the bill and fiscal impact are necessary.

Roll Call Vote **Yes 11** **No 13** **Absent 0** **Motion Fails**

Rep Wald: Can we mention that can't be a fiscal impact?

Rep Svedjan: We can pass the bill out and assume that the fiscal impact is incorrect and not put any money in it.

Rep Wald: That's my motion...I will move a **DO PASS motion**

Rep Hawken: I will second it.

Rep Nelson: I agree with the motion but if this bill passes and it shows up, the fiscal impact will be recorded, won't it?

Chairman Svedjan: If there's no money put into it and if the fiscal impact is like what they say it would be, it would impact the pharmacy portion of the Medicaid budget so they would overspend the budget based on how the budget is built.

Roll Call Vote on a DO PASS Motion **Yes 15** **No 9** **Absent 0**

Carrier Rep Damschen

Date: 2/8/07
Roll Call Vote #: 0

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1431

House Appropriations Full Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Amend – delete language re: signed informed consent – p. 4, lines 25-26

Motion Made By Glassheim Seconded By Ekstrom

p.5. line 11: consent

Representatives	Yes	No	Representatives	Yes	No
Chairman Svedjan					
Vice Chairman Kempenich					
Representative Wald			Representative Aarsvold		
Representative Monson			Representative Gulleson		
Representative Hawken					
Representative Klein					
Representative Martinson					
Representative Carlson			Representative Glassheim		
Representative Carlisle			Representative Kroeber		
Representative Skarphol			Representative Williams		
Representative Thoreson					
Representative Pollert			Representative Ekstrom		
Representative Bellew			Representative Kerzman		
Representative Kreidt			Representative Metcalf		
Representative Nelson					
Representative Wieland					

Total (Yes) No

Absent

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Voice Vote – motion failed
remove reference to consent form (p4)
and reference to consent (p5)

Date: 2/8/07
Roll Call Vote #: 2

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1431

House Appropriations Full Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number ———

Action Taken DNP

Motion Made By Thoreson Seconded By Carlisle

Representatives	Yes	No	Representatives	Yes	No
Chairman Svedjan	✓				
Vice Chairman Kempenich	✓				
Representative Wald	✓		Representative Aarsvold		✓
Representative Monson		✓	Representative Gulleson		✓
Representative Hawken		✓			
Representative Klein		✓			
Representative Martinson		✓			
Representative Carlson	✓		Representative Glassheim		✓
Representative Carlisle	✓		Representative Kroeber		✓
Representative Skarphol		✓	Representative Williams	✓	
Representative Thoreson	✓				
Representative Pollert	✓		Representative Ekstrom		✓
Representative Bellew	✓		Representative Kerzman		✓
Representative Kreidt	✓		Representative Metcalf		✓
Representative Nelson		✓			
Representative Wieland	✓				

Total (Yes) 11 No 13

Absent 0

Floor Assignment ———

If the vote is on an amendment, briefly indicate intent:

motion fails

Date: 2/8/07
Roll Call Vote #: 3

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1431

House Appropriations Full Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number —

Action Taken Do Pass

Motion Made By Wald Seconded By Skarphol

Representatives	Yes	No	Representatives	Yes	No
Chairman Svedjan	✓				
Vice Chairman Kempenich		✓			
Representative Wald	✓		Representative Aarsvold	✓	
Representative Monson	✓		Representative Gulleson	✓	
Representative Hawken	✓				
Representative Klein	✓				
Representative Martinson	✓				
Representative Carlson		✓	Representative Glassheim	✓	
Representative Carlisle		✓	Representative Kroeber	✓	
Representative Skarphol	✓		Representative Williams		✓
Representative Thoreson		✓			
Representative Pollert		✓	Representative Ekstrom	✓	
Representative Bellew		✓	Representative Kerzman	✓	
Representative Kreidt		✓	Representative Metcalf	✓	
Representative Nelson	✓				
Representative Wieland		✓			

Total (Yes) 15 No 9

Absent 0

Floor Assignment Dawson

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1431, as engrossed: Appropriations Committee (Rep. Svedjan, Chairman) recommends **DO PASS** (15 YEAS, 9 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1431 was placed on the Eleventh order on the calendar.

2007 SENATE HUMAN SERVICES

HB 1431

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. 1431

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 3-06-07

Recorder Job Number: 4449, 4497

Committee Clerk Signature Veronica Sparling

Minutes:

JOB # 4449

Roll was taken and all members were present.

Senator Erbele, Vice Chairman, opened the public hearing on HB 1431.

Representative Chuck Damschen from District 10 was glad to sign on as a sponsor of this bill. He explained that the tolerances in medications for people with epilepsy are very tight. Substitutions can set off various serious reactions. He said there was a misconception that this bill was an anti-generic drug bill. The intent of the bill is just to make it mandatory that a pharmacist check with a physician before changing a drug.

Senator Lee asked if there was any reason to make this restriction only on drugs for epilepsy.

Representative Damschen said the tolerances for epilepsy drugs are very tight and an adverse reaction could be a seizure. It can be set off by a very minor variation in the medication and can be a threat to their life or the lives of others.

Senator Dever asked if there were problems that had led to this legislation.

Representative Damschen said they would be hearing testimony as such.

Art Taggert, Executive Director of the Epilepsy Foundation of South Central Wisconsin, spoke in favor of the bill. See attachment # 1. He said he has had people from North Dakota contact

him through the internet. He said there is similar legislation being considered in Wisconsin. About a year ago representatives from the Epilepsy Foundation National Office along with the American Epilepsy Society met with the FDA on the subject of substitutions and bio-equivalents for anti-seizure drugs. The FDA can't take any action on it because of lack of data. One reason there is not data available is because physicians and patients don't have any way to know when substitutions are being made. Patients can recognize when a generic has been substituted for a brand name but it's harder to tell when a generic is being substituted for another generic. This bill would require a pharmacist who is making a substitution to get an informed consent of the physician and the patient. If the doctor feels it is important to monitor the patient's blood levels or adjust the doses that can happen. If there is an adverse reaction then an FDA Medwatch Report can be filed and they can contribute to the data bank of information. That might one day lead to the FDA making changes for this class of drugs. Patients work very hard with their doctors to get their seizures under control so their lives can carry on. Doctors and patients don't mind using generics. They just do not feel safe having substitution used without being informed. Mr. Taggert doesn't believe this would raise the cost of medicine. Some of these pressures have come about because of the spiraling cost of healthcare. When a patient suffers therapy failure and has epilepsy, unless you have the seizure in the comfort of your own home you will have ambulance cost and emergency room cost, lab work, facility charges. It is extremely expensive to have therapy failure. Mr. Taggert doesn't think this will open the floodgates for other drugs to require the same. Epilepsy drugs are somewhat unique in that therapy failure results in such a dramatic upheaval of a life. Besides the medical expenses it many times involves loss of work, loss of driving privilege and compromised ability to get to and from work.

Senator Lee asked why this can't just be put in place by the physicians and the pharmacists rather than through legislation. Both the physician and the pharmacist care about the wellbeing of the patient.

Mr. Taggert said as an advocate they become aware of healthcare issues. They have noticed a trend that insurance companies are increasing the co-pays to the point that people are unable to afford it. They also have noticed the trend of substitutions and feel there has to be communication between physician and pharmacist.

Senator Lee said she understands what they are saying but still feels legislating it is not the way to handle it.

Mr. Taggert said if you look at it from an advocate's point of view and a patient's point of view when someone opens a bottle of medication and doesn't recognize their pills, this bill insures there would be some education at the point of sale and reliable communication with the physician. It's a three point process. They hope to utilize pharmacists as one point on that triangle of communication. The prescribing physician and the patient are the other two points. (Audio 17:00) Some state Medicaid plans require use of a less expensive substitute compound if it is available. Mr. Taggert feels that is a way of legislating healthcare and taking it out of the hands of prescribing physicians and making a general rule about how we are going to dispense medications. He understands that not everything can be addressed in law but this is necessary because of the trends in healthcare. He feels there is going to be a need for some legislation until some underlying issues in healthcare are addressed in this country. This one is a matter of patient safety.

Senator Dever asked Mr. Taggert how aware he feels pharmacists are of the critical nature of this issue.

Mr. Taggert feels pharmacists are aware of the issues around Narrow Therapeutic Index (NTI) drugs but in some ways they are hampered by the FDA. When the FDA approves the generic compounds and determines that they are bio-equivalent, they are bio-equivalent within ranges. The range from one generic manufacturer to another is what causes the danger of brittle patients having a break-through seizure if the generic drug is in the low range. One the other hand if a patient gets a generic drug that is in the high range he may experience double vision or slurred speech and stumbling gait. Audio 19:20. They are concerned with the range of the definition of bio-availability for these narrow therapeutic index drugs.

Representative Robin Weisz from District 14 offered support for HB 1431. He mentioned they do legislate healthcare. He said it is important to remember that this is not about prior authorization. It is just about notification, specifically the pharmacist notifying the patient and the physician.

Senator Dever said he understands the bill is not just about Medicaid patients but about all patients. He said we have a law that mandates belonging to PERS for the first biennium. He asked if there was any discussion on that in the House.

Representative Weisz said there was not because he doesn't think this falls under the area Senator Dever is referring to. This isn't a mandate, it's just requiring a notification.

Senator Dever mentioned it has quite a substantial fiscal note.

Representative Weisz said that is correct. Not all of the House members agree with the fiscal note. There is a variance of opinion on what the cost will be because they will many times go from a generic to another generic. There will not be a difference in price necessarily, just a communication between pharmacist and physician.

Dr. Shiraz Hyder, MD explained what epilepsy does and what anti-epilepsy medications do for patients. (Audio 27:00.) See attachment # 2 for a position paper on epilepsy by the American

Academy of Neurology. He doesn't know of any other medical condition that can change someone's life so drastically and so suddenly as epilepsy can. (Audio 29:00). He feels epilepsy is a very unique situation because the level of drugs is so critical. The medication stabilizes the brain cell membrane where the electrical current in the brain generates. It decreases the irritability of the brain cells but it needs a very specific drug level to achieve that. Every patient is unique and meds need to be adjusted for each person. It may take 200 mg of one drug as compared with 300 mg of a different drug to achieve seizure free status. It may even take a combination of a few drugs. There are so many variables to consider. It can take a long time to get a patient to where they are stable and can lead a normal life. Once the right drug level has been reached, then what happens when a drug is changed? (Audio 32:50). Every drug is different and every patient responds differently. With that change the patient is very likely to have a seizure. Rocking the boat on a patient who is finally under control on epilepsy medication is very risky. (Audio 34:20) The issue is not generic to generic or generic to brand name. The issue is do not change the medication without the input of the physician. It is the responsibility of the physician to care for the patient. He is the one who has taken the history of the patient, etc. He emphasized the cost of the correct medication will be much less than the cost of hospital stays etc. caused by changing medications on patients who had finally become stable.

Senator Lee asked if Dr. Hyder has had a lot of problems with this particular issue.

Dr. Hyder said the "dispense as written" on the prescription is used less than 5% of the time by the physicians. If we were to use something that was more effective we should put "substitution permitted". It almost becomes a double positive. Well, if the physician writing a prescription that means he wants that. It seems you also have to write "dispense as written".

Senator Lee asked if that was a hardship to write that. If you write it on the prescription are you having trouble with the pharmacists following your directions?

Dr. Hyder responded that a patient can be well regulated on a generic and then an incentive comes along and a pharmacist switches the patient to another generic without checking with the doctor. The levels of anti-epileptic medicine may vary enough to cause a patient to have a break-through seizure. He feels the pharmacists mean well but it is not best for the patient. He feels the use "substitution permitted" would be a more effective communication.

Senator Heckaman asked if generics are required to have the same active ingredient at the same level as the brand name it substitutes for.

Dr. Hyder said it is not exactly the same because it may absorb differently.

Senator Heckaman asked where the breakdown is. Is it in the physician in writing it or the pharmacist in filling it or in the pharmacist communicating it to the patient?

Dr. Hyder said the trouble is in the differences between how someone responds to the medications and there is no "play" for some of the brittle epileptics. The pharmacists don't recognize the difference but the patient's blood level knows the difference.

Senator Heckaman asked about blood levels changing with stress, diet and illness.

Dr. Hyder said with all of that fluctuation which is unavoidable, it seems even more important to not change drugs and cause further fluctuation.

Rebecca Boyce of Bismarck submitted written testimony in favor of HB 1431. See attachment # 3.

Senator Heckaman asked if she had a medication change that caused her seizure.

Rebecca said no, it was just a breakthrough seizure. She would not want to go through the long process of getting her medication adjusted, regain her license and then have a pharmacist change something on her. She explained how time consuming the process of

getting the medication levels correct is. She addressed the aspect of cost effectiveness in mentioning that there are "hidden costs" with seizure disorders such as poor self esteem leading to a tendency to isolate themselves and even the cost of injuries to themselves from the seizures. If seizures can be avoided by not switching medications it would save money in the long run.

Senator Dever asked if Rebecca has found she needs to be assertive with her pharmacist to get the right medications.

Rebecca said she has a good rapport with her pharmacist because she sees a lot of him. She also knows what her medication looks like and she double checks that she gets the right one.

Dave MacIver spoke in favor of HB 1431. He is an epileptic since 1995 and said his first seizure was the most terrifying experience of his life. He spoke of his personal experiences with epilepsy, the need to change medications gradually and the fact that he is a Vietnam veteran so he can get his medications through the veterans association. He doesn't want to change his medication because of the risk of seizures. He spoke of how much seizures can change someone's life. If he has a 5% drop in medication level he has a good chance of having a seizure.

Senator Warner asked if they measure the level of a certain chemical in their blood.

Dave said that is correct.

Opposition:

Bob Treitline, a registered pharmacist from Dickinson, ND urged a NO vote on HB 1431. See attachment # 4. He isn't so sure this bill would solve anything. In his store and as per statute the pharmacist makes the patient aware if a substitute is being dispensed. Any change made is indicated to the patient. He said there is less variance in levels in the drugs that have a

narrow therapeutic level. The policy he uses in his store is if he wouldn't give it to his family, he wouldn't give it to a patient.

Opposition:

Jim Carlson, CEO and Co-Founder of PRACS Institute in Fargo, spoke strongly in opposition to HB 1431. See attachment # 5. He pointed out that diet is absolutely critical for epileptics. Other factors are exercise and levels of stress and proper rest, so it's not just the drug. Dr. Carlson said PRACS has no financial interest in the failure or passage of this bill. His input is purely from a scientific standpoint.

Senator Lee asked Dr. Carlson to explain what they do at PRACS.

Dr. Carlson said in Fargo and Grand Forks they have research facilities. Combined, these two facilities have 900 beds. They have more research beds than any other drug research company in the world. They are the leader in generic drug evaluations. They research how drugs are absorbed, metabolized and eliminated. It is a very controlled environment and in 24 years they have never had the FDA disagree with their findings on a drug.

Opposition:

Ron Hartman, a pharmacist and Director of Government Affairs for Sandoz Pharmaceuticals, spoke in opposition to HB 1431. See attachment #6. Sandoz has three major concerns with HB 1431.

The first issue is that it is not really needed. Physicians in ND can mandate by a simple notation on the prescription blank, "dispense as written." Pharmacists in ND are mandated to dispense the exact prescription.

The second issue is that there is no difference between the brand name and the generic drug. He said Dr. Carlson had explained this well and the FDA had also done two studies in the 1990's to test the integrity of the substitution drugs. There was a 3.5% difference in one study

and a 3.25% difference in the other one. The FDA said there is no more difference found than the variances found in different lots of the very same medication.

The third issue is that there are no documented examples of a generic product that could not be used for a brand name product.

He said this legislation is less focused on the citizens of North Dakota and more focused on protecting the market share of a few brand name drugs that are scheduled to lose patent protection in the next few years. The suspicion was increased because there are 21 states that currently have legislation identical to what is proposed in ND that would basically protect the brand name drugs from competition. This legislation was already defeated in SD, WY, and UT, It has been held up in NE and NM. MN tried to get a bill out but no one would sponsor it. Mr. Hartman is under the impression that it was defeated last year in Wisconsin. The reasons it was defeated are two-fold. Legislators have realized the anti-competitive nature of this legislation and also because of the high fiscal impact. In SD just the Medicaid part could have cost the state 1.1 million dollars per year. In Wisconsin the fiscal impact would have been 21 million dollars per year. In ND the impact would be approximately $750, 000 per year. These numbers are just for Medicaid. It would be a lot more if you considered consumers and patients within the state. These amounts would also be higher in subsequent years because of the patents due to expire on brand name drugs.

Howard Anderson, Executive Director of the Board of Pharmacy, spoke in opposition to the bill. See attachment # 7. He feels this bill would be hard to interpret. Line 9 says an "anti-epileptic drug" means any drug for the treatment of epilepsy or a drug that is used to treat or prevent seizures. It continues on line 10 "The term does not include an anti-epileptic drug that is used to treat conditions other than epilepsy or to treat or prevent seizures." He said many drugs that are used to treat epilepsy are also used to treat other conditions so there would be confusion

about what this bill would cover. In addition to that, the pharmacists do not always know what the patient's diagnosis is. How would he know if the medicine is being prescribed because the patient has seizures or some other illness? There may be even a greater fiscal impact than the estimates because the pharmacists wouldn't know when the meds are being prescribed for seizures and when they aren't. When in doubt they would have to avoid substitutions, causing an even greater fiscal impact.

Kyle Schwandt, a Pharm D student from the NDSU College of Pharmacy, spoke in opposition to the bill. See attachment # 8.

Paul Sanderson, an attorney with Zuger Kirmis and Smith, spoke on behalf of Medco Health Solutions in opposition to the bill. See attachment # 9. He mentioned that the legislation has also been killed in the state of Washington in addition to the states that were previously listed. He also distributed testimony from Robert Harms on behalf of Caremark, Rx Inc. See attachment # 10.

Neutral:

Maggie Anderson with the Medical Services Division and the Department of Human Services provided information on HB 1431 along with information on the fiscal note. Epilepsy medications account for nearly 11% of the ND Medicaid pharmacy expenditures. Expenditures for this drug classification have grown nearly 20% per year. See attachment #11. 90% of the epilepsy drugs that are dispensed are not to control seizures. The 1.8 million dollars that was in the fiscal note was based on the use of generic drugs when available. There was a comparison of a Wisconsin fiscal note to our fiscal note. The Wisconsin fiscal note estimated a zero fiscal impact and ours estimated a 1.8 million dollar fiscal impact. Wisconsin did not check with Medicaid in estimating the fiscal impact and they also didn't consider drug costs in their fiscal note. It is an apples to grapefruit comparison.

Chairman Judy Lee closed the public hearing on HB 1431.

JOB # 4497

Vice Chairman Erbele opened discussion on HB 1431.

There was discussion about the testing done at PRACS and the comparison of the responses to generic and to brand name drugs. They discussed whether the testing of healthy people in a very controlled environment is adequate to test the effectiveness of a medication that will be used for people who are not healthy and are not in a controlled environment.

Senator Dever said from the testimony he has heard the doctors are saying don't change my medicine, the pharmacists are saying write "brand necessary" or "dispense as written" and we won't, and PRACS is saying it doesn't make any difference.

Senator Erbele said pharmacists make a lot more money on generics than they do on brand names. He questioned whether the legislators are getting caught in a turf war.

Senator Heckaman related a personal experience of a pharmacist substituting a different generic for her neurofibromyalgia medicine until she spoke up and asked him not to do the substitution. She feels the patient has some responsibility.

There was discussion about whether Medicaid would allow a patient to refuse to be switched to a (cheaper) substitute drug. Some people also don't have the wherewithal to take the responsibility for their medicines like Senator Heckaman did in the experience she related.

Senator Dever said it seemed the effect of this bill would be that pharmacists wouldn't call the doctor, he would just dispense it as it is written so the expense would be higher.

How much of this bill is being driven by the fact that some drugs are coming off a patent?

Senator Dever said the testimony led them to believe that this had become law in Wisconsin. He checked and it is not law in Wisconsin.

Senator Erbele said he would lean more toward what the doctors said today. He feels a pharmacist is just a dispenser whereas the doctors are the ones who make the diagnosis based on test results.

See attachment # 12 for other testimony for the record.

There were no amendments offered.

Vice Chairman Erbele closed the discussion on HB 1431.

The committee will act on this bill at a later date.

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. 1431

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 3-12-07

Recorder Job Number: 4868

Committee Clerk Signature Veronica Spurling

Minutes:

JOB # 4868

Chairman Judy Lee opened discussion on HB 1431.

Chairman Lee mentioned that the epilepsy drugs are used to treat many other conditions. She had asked a doctor in Fargo to comment on the possible ramifications of this bill. His first impression was that it was an effort of special interests to circumvent the FDA since one of the responsibilities of the FDA is to insure that generic drugs are bioequivalent to the brand name drug. The FDA gives drugs an A or B rating. If a physician and a pharmacist have to get in touch with each other there is additional cost to the patient. Using fewer generics will cause insurance companies to raise their co-pays which results in another increase in cost to the patient. With the restrictions of Medicare Part D a patient may be solely responsible for the cost of their medicines. It is true that pharmacists get a higher dispensing fee for generics, but she doesn't feel they are dispensing generics because of that.

Senator Heckaman agreed there is a higher dispensing fee for generics but she said it is only minimally higher. It is $4.60 for brand name and $5.60 for a generic, just a $1.00 difference.

Senator Warner asked if a doctor's orders "dispense as written" can override a drug company's formularies.

Brendan Joyce, Medicaid Pharmacy Administrator, spoke about Medicare Part D. If a doctor writes "brand name necessary" for a drug that only the generic is on the formulary, the Part D Plan will deny the claim. The Medicare recipient would have to do an appeals process through Medicare to try to get them to cover the brand name drug. They may or may not win the appeal. If the brand name is on the formulary they are just going to have a higher co-pay.

Senator Warner asked if we can pass state law that governs the way Part D... *(I couldn't hear the tape).*

Mr. Joyce said he doesn't think Part D can be affected by state laws. He is basing this on testimony he has heard in similar bills this session.

Senator Lee asked if he would tell the committee that same scenario but submitting it to Blue Cross/ Blue Sheild instead of Medicare.

Mr. Joyce said with BC/BS the cost would still be covered but would just have a higher co-pay. Additionally ff the patient wants to appeal this higher co-pay they can appeal and may get BC/BS to pay it at a better rate.

With Medicare any time a doctor prescribes a medication and writes "dispense as written," he is required to fill out a one page form to say why it must be dispensed as written.

Senator Heckaman asked about how many medications this bill would affect.

Mr. Joyce said about 20. Three of them account for 53% of their drug spend in this category. Those 3 are going to be losing their patent in the next two years. He doesn't feel that is a coincidence with the timing of this bill. There is one more that will be losing its patent as well and that accounts for about another 12%.

Senator Heckaman asked how many of the anti-epilepsy drugs are prescribed for other conditions.

Mr. Joyce said 100%.

Senator Lee mentioned that this doesn't just affect Medicare. It affects all other prescribing entities as well.

Senator Dever said it seems the doctors are saying don't change my medication, the pharmacists are saying write "dispense as written" and we won't, and PRACS said it doesn't make any difference. A neurologist sent an email that said sometimes the medication is prescribed by a specialist and the refills are done by the primary care physician who probably doesn't register the importance so it just doesn't happen. It's all a matter of communication along the whole chain.

Mr. Joyce agreed it is a communication issue and feels there is already a mechanism in place to make sure the right medication is dispensed. They just need to utilize it. He feels the communication is realistically a problem not just with epilepsy medication but with others as well such as medications that treat irregular heartbeat.

Senator Lee referred to testimony given by James Carlson from PRACS. She read the summary that starts on the bottom of page 2 in attachment # 5 from the 3-06-07 testimony. She reminded the committee that he has nothing to gain by the passage or defeat of this bill. This is strictly scientific.

Senator Heckaman said her friend with epilepsy has many factors other than her medication: stress management, diet, overall health, etc. She said she gets a little nervous about this bill. She doesn't want to say that the committee doesn't care about the health of people.

Senator Lee said she does care about the health of people but she doesn't care much about this bill.

Dr. Ted Kleimen from Fargo related that they were always told to avoid using generic thyroid, to always use Synthroid. Four or five years ago there was a study in the New England Journal that showed the generic is more potent and is a better drug. The problem is there are several

generics and there are subtle differences between generics. If you stay on the same generic, it shouldn't be a problem. The evidence is clear that substituting generics is totally appropriate.

Senator Lee reminded the committee that Mr. Carlson from PRACS said there is no more variation from one generic to another than there is between two lots of the very same drug.

Senator Heckaman asked what the House vote was and what testimony they had. She also gave personal testimony of her experience with receiving generic medications.

Senator Heckaman made a do not pass motion.

Senator Erbele seconded the motion.

Roll Call Vote: Yes 5 No 1 Absent 0

Carrier: Judy Lee

Date: 3-12-07

Roll Call Vote #: 1

2007 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. HB 1431

Senate **HUMAN SERVICES** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Not Pass

Motion Made By Sen. Heckaman Seconded By Sen. Erbele

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee, Chairman	✓		Senator Joan Heckaman (2)	✓	
Senator Robert Erbele, V. Chair (2)	✓		Senator Jim Pomeroy	✓	
Senator Dick Dever	✓		Senator John M. Warner	·	✓

Total (Yes) 5 No 1

Absent 0

Floor Assignment Senator Lee

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1431, as engrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO NOT PASS** (5 YEAS, 1 NAY, 0 ABSENT AND NOT VOTING). Engrossed HB 1431 was placed on the Fourteenth order on the calendar.

2007 TESTIMONY

HB 1431

Testimony on Behalf of HB 1431
Arthur J Taggart
Executive Director
Epilepsy Foundation South Central Wisconsin

Chairwoman Price and members of the committee, my name is Art Taggart. I have been executive director of the Epilepsy Foundation South Central Wisconsin for the past 15 years and I'm here today in support of HB 1431, which the Epilepsy Foundation initiated in your state. I'll briefly describe this bill, outline the rationale and provide some supporting evidence for the need for this legislation.

HB 1431 prohibits a pharmacist from substituting an anti-epileptic drug, brand or generic, for the treatment of epilepsy unless the pharmacist obtains and documents the consent of the prescribing practitioner and the patient. Also, if a pharmacist is dispensing a refill of an epilepsy drug, the bill insures the pharmacist dispenses the same brand or generic drug product, from the same manufacturer that was previously dispensed, unless the pharmacist obtains and documents the consent of the prescribing practitioner.

The Epilepsy Foundation is seriously concerned about substitution of generic anti-epileptic drugs without knowledge or consent of the patient and treating physician. Generic formulations of a number of widely used anti-epileptic drugs have recently become available and present the opportunity to reduce costs. Some states and some health plans have mandated that the pharmacist fill a prescription with the least expensive available drug. This cost-containment strategy is safe and effective in most medical instances. However, with epilepsy this approach is not safe and could very well result in increased medical costs to the provider as well as to the patient.

- **"The FDA guidelines allow for a therapeutic range that is too broad to ensure that each individual will receive the same amount of AED (Anti-Epileptic Drug) when switching from brand name to generic or from one generic to another." (Epilepsy Foundation of America, 2005)**

A generic formulation of an innovator drug is said to be bioequivalent if the amount of drug absorbed and the rate of absorption falls between 80 percent and 125 percent of the innovator drug 90 percent of the time. In addition, there is significant variation in response to Anti-Epileptic Drugs among epilepsy patients

Epilepsy drugs have narrow therapeutic indices and some epilepsy patients are extremely susceptible to any blood level fluctuations of epilepsy medications. This means they can require very specific blood levels in order to remain seizure free and free from side effects.

If a pharmacy changes suppliers of an epilepsy drug a patient could experience unnecessary therapy failure. Even where state law provides for "Dispense As Written" by a prescriber, the prescription may inadvertently be refilled with a generic, or a different

generic than what was originally dispensed. To ensure that patients are protected, there must be a continuity of supply to avoid repeated, uncontrolled brand to generic and generic-generic switching.

In North Dakota, an epilepsy patient risks the loss of driving privileges, a compromised ability to maintain employment, costly and unnecessary ambulance calls and emergency room visits, and risk to their personal safety and public safety if a formulation change results in therapy failure. Finding the proper blood levels and the right medication or combination of medications to control seizures is a trial and error process, unfortunately. It can take a physician and a patient months or even years to attain control.

Patients and physicians have a right and should be clearly informed of a switch between different makes of Anti-Epileptic Drugs. This is not a "do not use generics" initiative. This is a measure to ensure that there is continuity of supply by sticking with the same manufacturer's product to protect patients from the serious consequences of breakthrough seizures.

HB 1431 simply states that before a pharmacist in North Dakota substitutes any formulation of an anti-epileptic medication, he will obtain consent of the prescribing physician and the patient. This will insure that substitutions are made safely, that everyone is aware of the change in formulation, and that the prescribing physician will have an opportunity to adjust the dose accordingly.

This legislation conforms to a 20 year-old position paper endorsed by the Epilepsy Foundation national office; it conforms to established guidelines of the American Academy of Neurology, and is in agreement with a monograph presented at the American Epilepsy Society annual conference in 2006.

We strongly believe that, due to the high direct medical costs and the high indirect costs that epilepsy patients must bear due to therapy failure, that medical treatment and dosing strategies need to be in the hands of the prescribing physician and their patients.

Every one of us applauds and supports efforts to minimize the high costs and hyper-inflation of our health care system. Patients who suffer from epilepsy know well the high costs associated with treating their disorder, but drug therapy substitutions have not proven to be effective at lowering their costs. The small savings in drug costs are gobbled up quickly by increased doctor visits, facility charges, and indirect costs. I'd like to underscore this point with an illustration from a study published in ***Contemporary Therapies*** that compares the cost of treatment for epilepsy patients taking name brand medications versus generics. SHOW FIGURE 2 CHART.

On behalf of over 10,000 North Dakota residents with epilepsy thank you, Madam Chairwoman and committee members, for your time and consideration of this important bill. I'd like to thank our sponsors for their support of this bill. I hope the committee will recommend an overwhelming "Do Pass" for this legislation, and I'm happy to answer any questions.

Proposed Amendments to House Bill 1431
Mark Up Version

Page 1, line 1 change the Bill title to read:

A BILL ~~for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to prohibiting a health insurer from imposing penalties for the dispensing of specific drugs for the treatment of epilepsy; and~~ to amend and reenact section 19-02.1-14.1 of the North Dakota Century Code, relating to restricting pharmacists from dispensing substitute epilepsy drugs.

Page 2, add the following definitions:

h. "Anti-epileptic drug" means: (1) any drug prescribed for the treatment of epilepsy or (2) a drug used to treat or prevent seizures. Anti-epileptic drugs being used to treat conditions other than epilepsy or to treat or prevent seizures are not subject to the provisions of this section.

i. "Epilepsy" means a neurological condition characterized by recurrent seizures.

j. "Seizure" means an acute clinical change secondary to a brief disturbance in the electrical activity of the brain.

k. "Interchange" means the substitution of one version of the same anti-epileptic therapeutic product, including a generic version for the prescribed brand, a brand version for the prescribed generic version, a generic version by one manufacturer for a generic version by different manufacturer, a different formulation of the prescribed anti-epileptic drug or a different anti-epileptic therapeutic drug product for the anti-epileptic product originally prescribed

Page 4, line 12, strikeover and insert language to read:

6. Notwithstanding any other provision of this section or other provision of law, a pharmacist may not ~~dispense a therapeutically equivalent generic name drug product for the treatment of epilepsy or the treatment or prevention of convulsions unless the pharmacist obtains and documents the consent of the practitioner who issued the prescription and the patient for whom the prescription was prescribed.~~ "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 practitioner and patient, or patient's parent, legal guardian or spouse of such person." If a pharmacist dispenses a refill of a prescription drug for epilepsy or for the treatment or prevention of convulsions upon the expiration of a prescription order for the same epilepsy drug, the pharmacist shall dispense the same prescription drug product from the same manufacturer that was last dispensed, unless the pharmacist obtains and documents the consent of the practitioner

who issued the prescription "and patient, or patient's parent, legal guardian or spouse of such person."

Page 5, remove lines 9-14

~~**SECTION 2.** A new section to chapter 26.1-36 of the North Dakota Century Code is created and enacted as follows: **Epilepsy drug prescriptions - Nondiscrimination.** An insurance company, nonprofit, health service corporation, or health maintenance organization may not penalize a practitioner for prescribing, a pharmacist for dispensing or a covered individual for requesting a specific drug for the treatment of epilepsy or convulsions.~~

HB 1431
Epilepsy Patient Protection

Why Legislation is Necessary

- "The FDA guidelines allow for a therapeutic range that is too broad to ensure that each individual will receive the same amount of AED (Anti-Epileptic Drug) when switching from brand name to generic or from one generic to another." (Epilepsy Foundation of America, 2005)
  - Generics are required to demonstrate bioavailability vs. brand only (Range is 80% to 125% of innovator product)

- Epilepsy is a serious neurological condition where minor fluctuations in blood concentrations can lead to:
  - loss of seizure control
  - Increase in side effects
  - Increase in serious adverse events

- Loss of seizure control can lead to:
  - More severe, treatment-resistant seizures
  - Lost driving privileges
  - Lost employment
  - Serious physical injury
  - Death

- There is significant variation in response to AEDs amongst epilepsy patients.

- Even where state law provides for "DAW" by a prescriber, the prescription may inadvertently be refilled with a generic, or a different generic than what was originally dispensed.

- To ensure that patients are protected, there must be a continuity of supply to avoid repeated, uncontrolled brand to generic and generic-generic switching.

- Patients and physicians have a right and should be clearly informed and give documented consent to a switch between different makes of AEDs.

- "Loss of Seizure Control" may occur when medication is switched between different manufacturers' versions of the same anticonvulsant due to differences in bioavailability. (MIMS April 2005)

- **This is not a "do not use generics" initiative.** This is a measure to ensure that there is continuity of supply by sticking with the same manufacturer's product to protect patients from the serious consequences of breakthrough seizures.

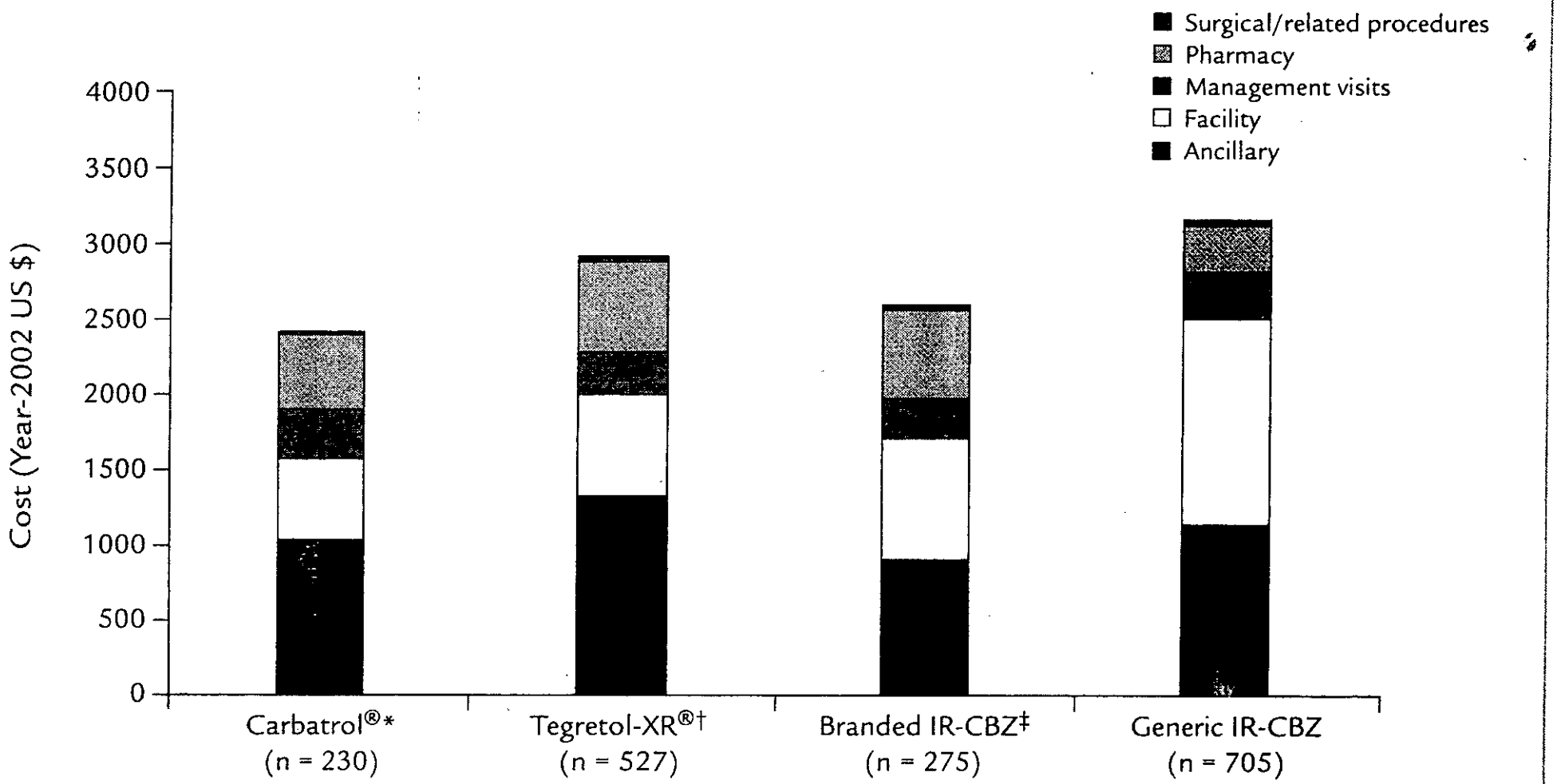

Figure 2. Annual epilepsy-related health care costs among patients with epilepsy from 61 US health plans who initiated therapy with carbamazepine (CBZ) between July 1999 and June 2001. IR = immediate release. *Trademark of Shire US Inc., Wayne, Pennsylvania; †Trademark of Novartis Pharmaceuticals Corporation, East Hanover, New Jersey; ‡Trademark: Tegretol® (Novartis Pharmaceuticals Corporation).

AMERICAN ACADEMY OF NEUROLOGY
POSITION STATEMENT ON THE COVERAGE OF ANTICONVULSANT DRUGS FOR THE TREATMENT OF EPILEPSY
NOVEMBER 2006

Presented by Dr. Shiraz Hyder, MD
Neurologist, Vice President of Medical Affairs,
St. Alexius Neuroscience Center
On Behalf of HB 1431

The American Academy of Neurology (AAN), representing over 19,000 neurologists and neuroscience professionals, has taken an active interest in the clinical, ethical and policy considerations concerning the coverage of anticonvulsant drugs for people with epilepsy. The AAN has developed evidence-based guidelines which strongly support complete physician autonomy in determining the appropriate use of anticonvulsants for their patients with epilepsy. Based on this evidence, the AAN has adopted the following principles concerning coverage of anticonvulsants for adults and children with epilepsy.

The AAN opposes generic substitution of anticonvulsant drugs for the treatment of epilepsy without the attending physician's approval. The FDA has allowed for significant differences between name-brand and generic drugs. This variation can be highly problematic for patients with epilepsy. Even minor differences in the composition of generic and name-brand anticonvulsant drugs for the treatment of epilepsy can result in breakthrough seizures.

• Anticonvulsant drugs for the treatment of epilepsy differ from other classes of drugs in several ways that make generic substitution problematic.

• For anticonvulsant drugs, small variations in concentrations between namebrands and their generic equivalents can cause toxic effects and/or seizures when taken by patents with epilepsy.

• The AAN opposes all state and federal legislation that would impede the ability of physicians to determine which anticonvulsant drugs to prescribe for the treatment of patients with epilepsy.

• The AAN believes that formulary policies should recognize and should support complete physician autonomy in prescribing, and patients in accessing, the full range of anticonvulsants for epilepsy.

• The AAN opposes policies that would result in arbitrary switching among anticonvulsants. Therefore, the AAN opposes generic substitution of anticonvulsants for patients with epilepsy at the point of sale (e.g., in the pharmacy), without prior consent of the physician and the patient.

Testimony of Dave MacIver
HB 1431
January 24, 2007

Good morning Madam chair and committee members. My name is Dave MacIver and I am here this morning representing myself. Thank you for the opportunity to come before you in Support of HB 1431. I only have a few comments for you this morning.

I am epileptic and I don't think any of you can understand how terrifying it is to stand before you knowing that at anytime I could fall and have a seizure in front of you. In addition to the serious danger and physical pain they cause, it would be very embarrassing. I make my living speaking, whether it's in front of a legislative committee or another audience, so control of these seizures is very important to me.

I receive my medications through the VA. In those cases where they won't give me the name brand drug prescribed by my doctor I have chosen to go to my regular pharmacist at a much higher cost to me. I don't dare change any prescription I take, not even my blood pressure medication. Even if there was only a 1% difference in them, in my mind I could run the risk of another seizure. I am not willing to take that chance. Would you? If you were an epileptic and standing up to give a floor speech would you take that chance? For these reasons I would ask that the committee give HB 1431 a DO PASS.

BOARD OF PHARMACY
State of North Dakota

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Sure to given to Senate Human Service

HOUSE BILL No. 1431 – EPILEPSY DRUGS
8:30 AM -WEDNESDAY – JANUARY 24TH, 2007
House Human Services Committee – Fort Union Room

Chairman Price, members of the House Human Services Committee, for the record I am Howard C. Anderson, Jr, R.Ph, Executive Director of the North Dakota State Board of Pharmacy. Thank you for the opportunity to speak with you today.

When you pass laws and rules, we expect our pharmacists to follow them. There are a *long* list of drugs, which have a specific FDA indication for epilepsy. There is also another long list of drugs, which are sometimes prescribed by physicians for off-label use in treating epilepsy, or a seizure disorder of one type or another.

If you are going to pass a law which says that a pharmacist *cannot* dispense a therapeutically equivalent generic drug for epilepsy, then you also need to pass a law which says the physician needs to include the diagnoses on the prescription.

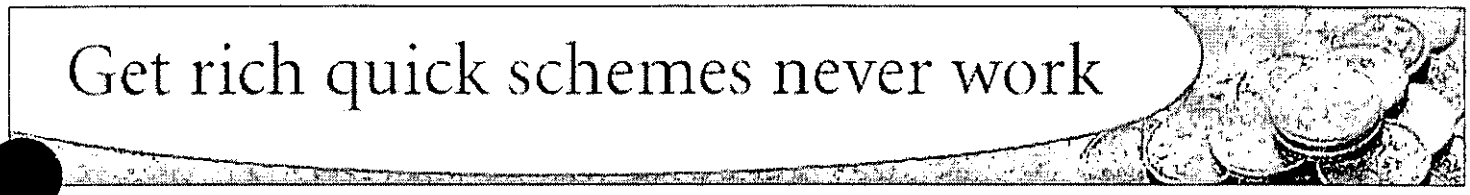
As an example, Neurontin, generic name Gabapentin, has been and is very often used for off-label uses. In fact, Pfizer paid 430 million dollars to settle charges that they were marketing Neurontin for off-label uses. When you get FDA approval for a drug, you are allowed to market it for the approved indications. Physicians may prescribe it for off-label uses based on research they read in their journals, but, the manufacturer is not allowed to market it for off-label uses until they have demonstrated it's effectiveness for that use.

Also, you need to solve the issue of *who* is going to pay for that brand name drug, when the prescription is written for the brand name, the pharmacist *cannot* dispense a generic and the patient's payer, insurance – Medicaid or whatever - will not pay for the drug. This means you are sticking the patient with a large bill or a return trip to the physician to try and resolve the difference in the price, which can often be several hundred dollars.

A drug such as Gabapentin, is marketed in different strengths. But, for example, a 300 mg strength might be prescribed, then the physician may adjusted that dosage, so the patient might be taking up to 2,400 mg a day, or 8 capsules. The physician adjusts the dose to obtain the proper patient response. Should this generic vary by 1% or 10%, which does not happen, from the brand name drug, the physician can then adjust the dosage of that generic drug to get the proper response.

It is a fallacy to assume that we give one pill, of one strength and this solves all the patient's problems, the patient and the physician work together to adjust their dosage to an effective level.

Therefore, I would respectfully ask for a do not pass on this bill.



Forbes.com

Pharmaceuticals

Pfizer's New Blockbuster Drug

Matthew Herper, 01.22.07, 10:35 AM ET

For the first time in almost a decade, Pfizer can boast that it has launched a new blockbuster drug.

Lyrica, a treatment for pain caused by nerve damage that was launched in the middle of 2005, looks like a surprise hit, bringing in $1.2 billion in 2006. But the drug's success highlights how difficult it is for pharmaceutical firms to invent new medicines.

The news came as the world's largest drug firm announced fourth-quarter earnings of $9.45 billion, or $1.35 per share, on sales of $12.6 billion. When $7.9 billion in profit from the sale of Pfizer's consumer business to Listerine are discounted, per-share earnings dropped 12% to 45 cents. Later today, Pfizer will outline its plans for the future; the drug maker is expected to cut thousands of jobs.

Lyrica, an improved version of the off-patent Neurontin, was initially delayed for several years at the U.S. Food and Drug Administration. When it was finally approved on Dec. 30, 2004, there was another delay, as the U.S. Drug Enforcement Agency took months more to decide what special restrictions needed to be placed on the medicine.

When Lyrica was finally launched in 2005, analyst expectations were fairly low, forecasting sales of $500 million a year in 2006. There were big reasons to doubt Lyrica. In September 2004, the FDA had rejected Pfizer's claim that Lyrica could be used to treat anxiety as well as epilepsy and nerve pain. And there was a cloud over its predecessor as well. In 2004, Pfizer paid $430 million to settle allegations that it had marketed Neurontin for unapproved uses.

But Lyrica became a big seller anyway at a time when new blockbusters--generally defined as medicines that bring in more than $1 billion a year--are few and far between. Pfizer is hoping to further increase sales of the pill. Late last year, it submitted a new drug application to the FDA, hoping to market Lyrica as a treatment for fibromyalgia, a chronic, widespread pain that Pfizer says afflicts tens of millions of people.

Neuropathic pain, which results when nerves are damaged and send constant pain signals to the brain, can result from diabetes, chemotherapy or injury. It also affects tens of millions of people.

Most of Pfizer's big sellers are aging, with many losing patent protection, causing sales to crumble. The most recent blockbuster drugs it launched were Celebrex and Viagra, both approved by the FDA in 1998. Xalatan, a glaucoma drug approved in 1996, crossed the $1 billion mark in 2005.

Norvasc, a $5 billion blood pressure pill, loses patent protection in September. Top seller Lipitor, which generated almost $13 billion last year, was approved in 1996, and loses patent protection as early as 2010. How hard will it be to replace? Lipitor, the best-selling drug in the world, is as big as the next two best-selling pills combined.

Pfizer is hoping that a few more big sellers are on the way, but all of them face major hurdles. Sutent, a targeted cancer pill, could become a big drug if ongoing studies in breast cancer prove effective. A second cancer pill, meant to be similar to **Genentech**'s Avastin, is being tested against thyroid cancer. An obesity drug, similar to Accomplia from Sanofi-Aventis, also just entered Phase 3 trials.

Right now it seems unlikely that these new medicines will make up for the losses ahead. Pfizer's analyst meeting, where new strategies and cost cuts will be unveiled, begins at 1 p.m.

Chairman Price and the members of the House Human Services Committee, for the record I am Mark Hardy from Neche, ND. Thank you for the opportunity to speak with you today.

I am here to testify as a professional pharmacy student currently in my last year at NDSU and as a future pharmacist in Rural North Dakota. When I heard about this bill I was troubled by it. I am here to support a DO NOT PASS vote today of HB 1431.

When I read through this bill the drugs in concern are those to treat epilepsy. I have attached a list of these drugs. Epilepsy is a brain disorder in which clusters of nerve cells, or neurons, in the brain sometimes signal abnormally. In epilepsy, the normal pattern of neuronal activity becomes disturbed, causing strange sensations, emotions, and behavior or sometimes convulsions, muscle spasms, and loss of consciousness. Only when a person has had two or more seizures is he or she considered to have epilepsy. It is a very serious and scary condition.

In researching through the Orange book, which is the standard at rating generic drug's equivalence to its brand drug, I found that all generic epilepsy drugs are therapeutically or pharmaceutically equivalent to its branded counterpart. When determining bioequivalence researchers look at pharmacokinetic studies, pharmacodynamic studies, clinical trials and in vitro studies between the brand and generic drug. In other words they are determined to be the same drug with the same active ingredient.

If a physician would like to have a patient use a brand named drug, all that physician needs to do is write BRAND NECESSARY on that prescription, by doing this the pharmacist is to dispense only the branded drug. If the patient would like to have the brand drug he/she can request this and the pharmacist will fill the prescription with the brand drug. Otherwise the prescription would be filled with a cheaper generic drug if available.

Another big concern with this bill is the fact that there is numerous uses for these drugs. For example Neurontin can be use to treat epilepsy, but can also be used to treat postherpetic neuralgia. If HB 1431 passed, the doctor would have to write a diagnosis on each prescription so the pharmacist would know if he/she could substitute a generic drug if applicable.

There is always talk about the rising cost of health care and how to control it, using generic drugs is important in controlling this cost. If a patient wants to use a branded drug instead of a generic when all clinical evidence points toward them being equivalent, that patient should, in my opinion, pay a higher price. I will leave you with one example in the difference in price for a common epilepsy drug Neurontin. For 90 capsules of brand name Neurontin 300mg it costs a little more than $155. The generic Gabapentin 300mg 90 capsules costs a little less that $80. That is a difference of about $75, which I hope you agree is quite substantial. Thank you

List of Antiepileptic Drugs Approved in US – Brand (Generic)

Tegretol (Carbamazepine)
Dilantin (Phenytoin)
Cerebyx (Fosphenytoin)
Trileptal (Oxcarbazepine)
Lamictal (Lamotrigine)
Zonegran (Zonisamide)
Ativan (Lorazepam)
Valium (Diazepam)
Klonopin (Clonazepam)
Luminal (Phenobarbital)
Mysoline (Primidone)
Gabatril (Tiagabine)
Neurontin (Gabapentin)
Lyrica (Pregabalin)
Depacon (Valproate)
Depakote (Valproic acid)
Felbatol (Felbamate)
Topamax (Topiramate)
Keppra (Levetiracetam)

Testimony on HB 1431
House Human Services Committee
January 24, 2007

Madam Chair and Committee members, for the record I am Rod St. Aubyn, representing Blue Cross Blue Shield of North Dakota. We are opposed to this bill, specifically to Section 2 of the bill. This section will, in effect, create just what it wants to prevent for the interest group pushing this legislation – that is discrimination. This bill will create a special situation for this one condition that is not afforded to all other conditions. In effect, it will mandate that any drug used in the treatment of epilepsy or convulsions must be made formulary for every health insurance company doing business in ND. I must clarify this though, because it will only apply to fully insured plans. This law will not apply to self-funded plans because they are exempt based on ERISA. It will also not apply to Medicare Part D plans, because that program is generally exempt from state laws and regulation.

Health plans develop formularies (a list of approved drugs). For our company, the formulary is reviewed for every formulary class at least once a year. Our formulary Committee is comprised of ND physicians and ND pharmacists. They determine which drugs are added to our formulary and which are deleted. Should this bill pass, it will take away the formulary committee's authority to establish a formulary for any drug prescribed for epilepsy, and it is important to note that that would not be limited to just anticonvulsant drugs. As an example, I have been informed that at times we have seen Valium prescribed for patients with epilepsy. That is not in that anticonvulsant category, so managing this process would be very difficult for a health plan. A member can appeal that their specific drug is not on the formulary and they need a specific drug for their medical condition. This appeal process can approve a non-formulary drug being made formulary for that member. This same process is allowed under Medicare Part D plans as well.

There exists in the Century Code protections and mechanisms to assist the consumer, such as dispense as written (brand necessary). If a specific drug is necessary for a patient, the physician can simply write "brand necessary" on the prescription and no substitution is allowed without that physician's permission.

If this bill should pass, it will likely increase health care costs and will result in higher health insurance premiums. To what extent I do not know. The other problem with this bill, it will establish a precedent that will be repeated by other interest groups for other specific medical conditions. In short, I will predict that this will be the start of the erosion of any formulary, which will result in higher pharmaceutical costs for health plans and thus higher premiums for the consumers. For all the reasons noted, we would urge that you defeat this bill. I would attempt to answer any questions the committee may have. Thank you.

$ meloxicam
$ naproxen IR, DR
$ naproxen sodium, NF = ER
$ piroxicam
$ sulindac
$$ diclofenac sodium DR, ER
$$ indomethacin, NF = ER
celecoxib
$$$$ CELEBREX
adalimumab [PA]
$$$$$ HUMIRA [PA]
anakinra [PA]
$$$$$ KINERET [PA]
auranofin
$$$$$ RIDAURA
etanercept [PA]
$$$$$ ENBREL [PA]
rituximab [PA]
$$$$$ RITUXAN [PA]

10.4 Migraine Products

$ acetaminophen/ isometheptene/ dichloralphenazone
$$$$$ dihydroergotamine inj
$$$$$ MIGRANAL
divalproex sodium ER
$$$$ DEPAKOTE ER
sumatriptan
$$$$$ IMITREX inj, nasal, tabs
zolmitriptan
$$$$$ ZOMIG nasal, tabs
$$$$$ ZOMIG ZMT

10.5 Gout

$ allopurinol
$ colchicine
$$ probenecid
$$$ probenecid/colchicine

CHAPTER 11. NEUROMUSCULAR DRUGS

11.1 Anticonvulsant

$ clonazepam, NF = orally disintegrating tabs
$$ phenytoin susp
$$ phenytoin sodium extended
$$$ DILANTIN
phenytoin sodium prompt
$$ PHENYTOIN SODIUM PROMPT
$ carbamazepine
$$$$ TEGRETOL-XR
$$$$ CARBATROL
divalproex sodium DR
$$$$$ DEPAKOTE
$$$ primidone
$$$$ ethosuximide
oxcarbazepine
$$$$ TRILEPTAL
$$$$ valproic acid
$$$$ zonisamide
diazepam rectal gel
$$$$$ DIASTAT
$$$$ gabapentin
$$$$ NEURONTIN soln
$$$$$ lamotrigine chew tabs
$$$$$ LAMICTAL chew tabs, 2 mg; tabs
levetiracetam
$$$$$ KEPPRA
topiramate
$$$$$ TOPAMAX

11.2 Antiparkinson

$ benztropine
$ trihexyphenidyl
$$ selegiline
$$$ carbidopa/levodopa IR, ER
$$$$ PARCOPA
$$$$ bromocriptine
apomorphine [PA]
$$$$$ APOKYN [PA]
entacapone
$$$$$ COMTAN
$$$$$ pergolide
pramipexole
$$$$$ MIRAPEX
ropinirole
$$$$$ REQUIP

11.3 Neuromuscular Agents

riluzole
$$$$$ RILUTEK

11.4 Musculoskeletal Therapy Agents

$ cyclobenzaprine
$$ baclofen
$$ methocarbamol
$$ orphenadrine ER
$$ orphenadrine/aspirin/caffeine
$$$$ dantrolene

11.5 Antimyasthenic agents

$$$$ pyridostigmine
$$ MESTINON TIMESPAN
$$$ MESTINON syrup

CHAPTER 12. NUTRITIONAL PRODUCTS

12.1 Vitamins

$ phytonadione inj, 1 mg/0.5 mL
$ PHYTONADIONE inj, 10 mg/mL
$ MEPHYTON
$$ ergocalciferol
$$$ calcitriol

12.2 Multivitamins

$ pediatric multivitamins/fluoride
$ pediatric multivitamins/fluoride/iron
$ pediatric vitamins ADC/fluoride
$ pediatric vitamins ADC/fluoride/iron
$ prenatal multivitamins/1 mg folic acid

12.3 Minerals & Electrolytes

$ potassium phosphate/sodium phosphates
$ potassium chloride IR, ER
$ sodium fluoride
$ SODIUM FLUORIDE soln, 0.55 mg/drop; tabs, 1.1 mg
potassium phosphate monobasic
$$ K-PHOS
potassium/sodium phosphates
$$$ URO-KP-NEUTRAL

CHAPTER 13. HEMATOLOGICAL AGENTS

13.1 Hematopoietic Agents

$ cyanocobalamin inj
$ folic acid 1 mg
darbepoetin alfa
$$$$$ ARANESP
epoetin alfa
$$$$$ PROCRIT
filgrastim
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Testimony
House Bill 1431 – Department of Human Services
House Human Services Committee
Representative Clara Sue Price, Chairperson
January 24, 2007

Chairman Price, members of the committee, I am Dr. Brendan Joyce, Administrator of Pharmacy Services for the Medical Services Division in the Department of Human Services. I appear before you to provide testimony in opposition of House Bill number 1431.

Epilepsy medications (anticonvulsants) account for roughly 11 percent of the North Dakota Medicaid pharmacy expenditure (October 2006 expenditures of $2.6 million, of which $296,000 were for anticonvulsants). Expenditures for this medication class has been growing nearly 20 percent per year (see Attachment A).

According to national statistics, epilepsy has an incidence of roughly 0.5%; therefore, it is likely that North Dakota has roughly 3,200 individuals diagnosed with epilepsy. Around 3,550 Medicaid recipients are currently on a medication in this category. This is due to the fact that nearly 90 percent of the use of these medications in Medicaid is for mood stabilization, not epilepsy. Since this bill is specific to the medications and not the patients, the impact will be much broader than one may anticipate given the use of these medications outside of epilepsy.

This class of medications is reaching maturity, meaning many of the products will be coming off of patent in the coming years. As this happens in a typical free market, the growth in costs slows and actually begins to decline. This maturation is accounted for in the inflation rates

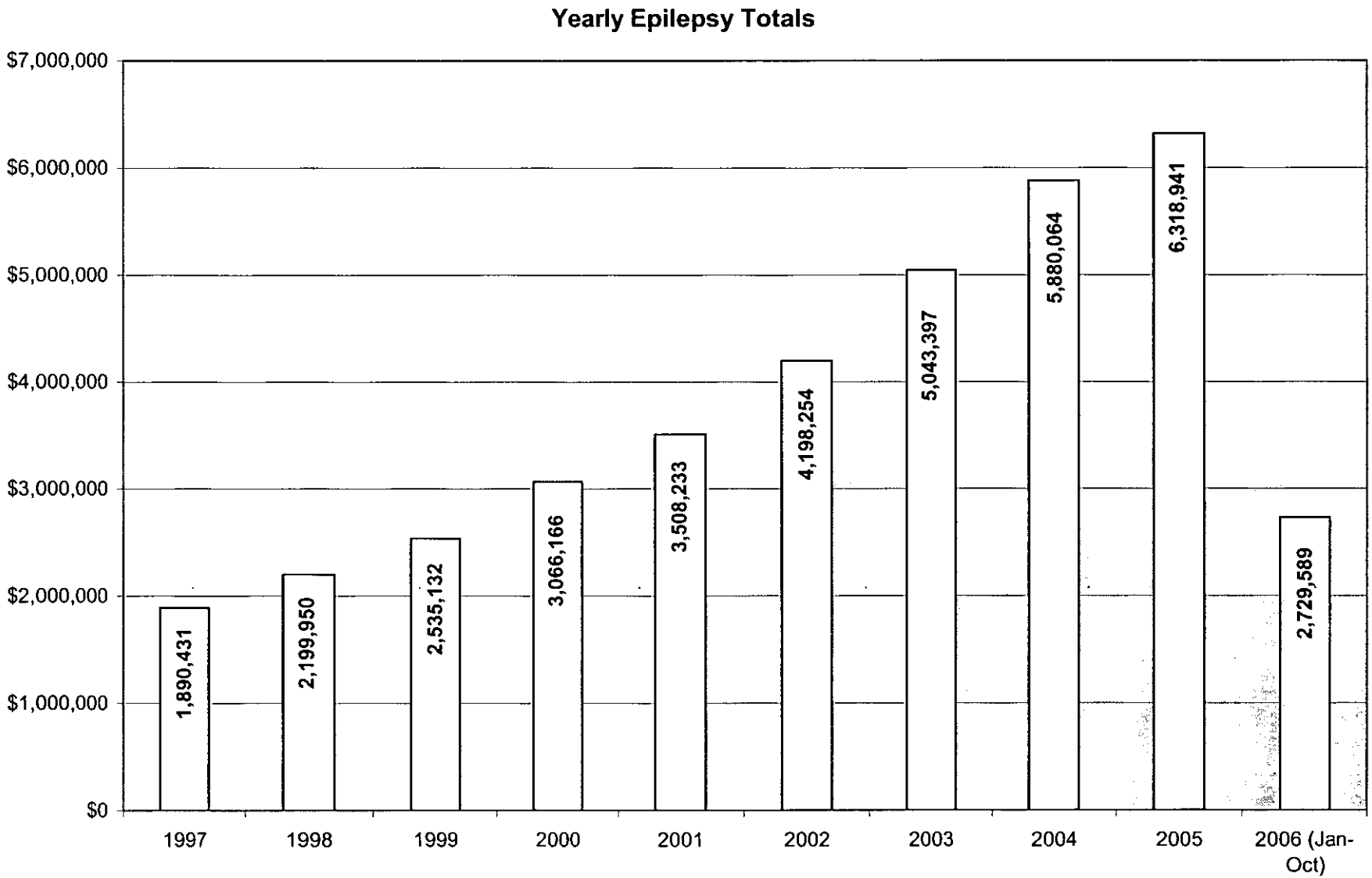
factored into our budget for the upcoming biennium. If this bill passes, this natural maturation will not occur, and the inflation will continue upward at a potentially higher rate given the typical pharmaceutical company practice of increasing the drug cost at a higher rate once generics are released. The projected impact is $1.8 million in total funds.

Tools are already in place to allow physicians to request brand name necessary medication for their patients. Also, the Food and Drug Administration (FDA) approves all generics through a stringent process – to assume a product will not succeed for a patient simply because it is generic overlooks the FDA expertise.

Also, during the past interim, ND Medicaid asked the physicians (which includes two psychologists) and pharmacists on the Drug Utilization Review (DUR) Board to recommend exemptions for the mandatory generic policy (requiring a generic be used instead of a brand if that brand has a generic), and the DUR Board members said that there should be no exemptions, including epilepsy medications.

I would be happy to answer any questions the committee would have.

Attachment A



TESTIMONY OF PAUL SANDERSON IN OPPOSITION TO HB 1431

HOUSE HUMAN SERVICES COMMITTEE
JANUARY 24, 2007

Madam Chair and Members of the House Human Services Committee, my name is Paul Sanderson. I am an attorney in the Bismarck law firm of Zuger Kirmis & Smith. I represent Medco Health Solutions, Inc., a pharmacy benefits management company, in opposition to HB 1431 because this legislation would reduce patient access to prescription drugs as well as escalate costs.

Medco is a leading provider of comprehensive, high-quality, affordable prescription drug care in the United States. We work with patients, pharmacists, physicians and health plan sponsors to improve the quality of pharmaceutical care provided to patients, while helping to control the growth in drug costs. We work under contract with health plan clients throughout the country that are providing prescription drug benefits for their members and employees, totaling more than 60 million covered lives. Our clients include:

- Fortune 500 corporations and smaller employers
- local, state and federal employee and retiree groups
- Blue Cross/Blue Shield plans
- unions, and
- insurance carriers and managed care plans.

By requiring both physician and patient consent before dispensing a generic product for any treatment of epilepsy or convulsions, HB 1431 will make it harder for patients to access affordable care. At the same time, by preventing Employers or Health Plan Sponsors from designating different co-pay amounts for specific drugs, this bill will also inhibit competition, encourage plans to shift a greater share of the cost to

the patient, and/or reduce the plan's ability to maintain meaningful coverage of prescription drugs.

A. HB 1431 Will Make it Harder for Patients to Obtain Lower Cost Therapies for Seizures.

This legislation likely stems from concerns in the past when manufacturers could not produce reliable generic versions of epilepsy medication. However, currently and for the past ten years, many generic seizure drugs have come on the market and have been given an "A" rating by the FDA, and are interchangeable with the brand name drugs. Requiring consent from prescribers and patients before dispensing a generic medication creates an administrative burden that would deter patients from using lower-cost therapies that would have the same efficacy as their brand name counterparts.

B. The Solution Lies with the Pharmacist, Not the Legislature

Notifying the patient of medication changes should be a responsibility of the pharmacist and should be an issue of professional practice, not legislation. Because a change from one name brand medication to another name brand medication made by a different manufacturer can make a huge therapeutic difference for patients just as easily as a change from a name brand to a generic can, it should be the responsibility of pharmacists to tell patients and physicians when they make a change in the medications they dispense. There is no rational basis for discriminating against generic drugs in this instance.

C. Employers Struggle With Health Care Costs, Yet HB 1431 Prohibits The Use Of Cost-Management Tools.

In a time of rapidly escalating drug costs, policymakers should be focused on encouraging the use of innovative and effective cost control techniques rather than discouraging them. HB 1431 would prohibit plans from implementing formulary management programs that promote generics and lower cost branded drugs. The FTC has previously determined that pharmacy benefits management companies use formulary management programs to drive price competition among manufacturers. As part of their plan design, PBMs create formularies or drug lists that indicate which drugs (both brand and generic) they will cover. They incentivize generics as lower cost options. A-rated generics are available to be listed on the formularies they create. HB 1431 will prohibit PBMs from utilizing lower cost options to provide necessary care and treatment to their patients.

We strongly urge you to recommend a Do Not Pass on HB 1431.

#1

Testimony on Behalf of HB 1431
Arthur J Taggart
Executive Director
Epilepsy Foundation South Central Wisconsin

Madam chair and members of the committee, my name is Art Taggart. I have been executive director of the Epilepsy Foundation South Central Wisconsin for the past 15 years and I'm here today in support of HB 1431, which the Epilepsy Foundation initiated in your state. I'll briefly describe this bill, outline the rationale and provide some supporting evidence for the need for this legislation.

HB 1431 insures that a pharmacist substituting an anti-epileptic drug, brand or generic, for the treatment of epilepsy, obtains and documents the consent of the prescribing practitioner and the patient. Also, if a pharmacist is dispensing a refill of an epilepsy drug, the bill insures the pharmacist dispenses the same brand or generic drug product, from the same manufacturer that was previously dispensed, unless the pharmacist obtains and documents the consent of the prescribing practitioner.

The Epilepsy Foundation is seriously concerned about substitution of generic anti-epileptic drugs without knowledge or consent of the patient and treating physician. Generic formulations of a number of widely used anti-epileptic drugs have recently become available and present the opportunity to reduce costs. Some states and some health plans have mandated that the pharmacist fill a prescription with the least expensive available drug. This cost-containment strategy is safe and effective in most medical instances. However, with epilepsy this approach may not be safe and could very well result in increased medical costs to the provider as well as to the patient.

"The FDA guidelines allow for a therapeutic range that is too broad to ensure that each individual will receive the same amount of AED (Anti-Epileptic Drug) when switching from brand name to generic or from one generic to another." (Epilepsy Foundation of America, 2005)

A generic formulation of an innovator drug is said to be bioequivalent if the amount of drug absorbed and the rate of absorption falls between 80 percent and 125 percent of the innovator drug 90 percent of the time. In addition, there is significant variation in response to Anti-Epileptic Drugs among epilepsy patients.

Epilepsy drugs have narrow therapeutic indices and some epilepsy patients are extremely susceptible to any blood level fluctuations of epilepsy medications. This means they can require very specific blood levels in order to remain seizure free and free from intolerable side effects.

If a pharmacy changes suppliers of an epilepsy drug a patient could experience unnecessary therapy failure. Even where state law provides for "Dispense As Written" by a prescriber, the prescription may inadvertently be refilled with a generic, or a different generic than what was originally dispensed. We believe that informed consent is the

simplest and most cost-effective method to ensure that patients are protected when substitutions become necessary or when generic suppliers are changed.

In North Dakota, an epilepsy patient risks the loss of driving privileges, a compromised ability to maintain employment, costly and unnecessary ambulance calls and emergency room visits, and risk to their personal safety and public safety if a formulation change results in therapy failure. Finding the proper blood levels and the right medication or combination of medications to control seizures is a trial and error process, unfortunately. It can take a physician and a patient months or even years to attain control.

HB 1431 simply states that before a pharmacist in North Dakota substitutes any formulation of an anti-epileptic medication, he will obtain consent of the prescribing physician and the patient. This will insure that substitutions are made safely, that everyone is aware of the change in formulation, and that the prescribing physician will have an opportunity to adjust the dose accordingly.

Patients and physicians have a right and should be clearly informed of a switch between different makes of anti-epileptic drugs. This is not a "do not use generics" initiative. This is a measure to ensure that patients and their physicians are aware of any changes in formulation and can monitor blood levels if necessary, monitor patients and report any adverse events through the FDA Medwatch program.

This legislation conforms to a 20 year-old position paper endorsed by the Epilepsy Foundation national office; it conforms to established guidelines of the American Academy of Neurology, and is in agreement with a monograph presented at the American Epilepsy Society annual conference in December of 2006.

We strongly believe that, due to the high direct medical costs and the high indirect costs that epilepsy patients must bear due to therapy failure, that medical treatment and dosing strategies need to be in the hands of the prescribing physician and their patients.

Every one of us applauds and supports efforts to minimize the high costs and hyper-inflation of our health care system. Patients who suffer from epilepsy know well the high costs associated with treating their disorder, but drug therapy substitutions may have devastating and expensive consequences if therapy fails. The small savings in drug costs are gobbled up quickly by increased doctor consultations, emergency room charges, ambulance rides, and the indirect costs of lost work.

On behalf of 10,000 North Dakota residents with epilepsy, thank you Chairwoman Lee and committee members, for your time and consideration of this important bill. I'd like to thank our sponsors for their support of this bill. I hope the committee will recommend an overwhelming "Do Pass" for this legislation, and I'm happy to answer any questions.

#2

AMERICAN ACADEMY OF NEUROLOGY
POSITION STATEMENT ON THE COVERAGE OF ANTICONVULSANT DRUGS FOR THE TREATMENT OF EPILEPSY
NOVEMBER 2006

Presented by Dr. Shiraz Hyder, MD
Neurologist, Vice President of Medical Affairs,
St. Alexius Neuroscience Center
On Behalf of HB 1431

The American Academy of Neurology (AAN), representing over 19,000 neurologists and neuroscience professionals, has taken an active interest in the clinical, ethical and policy considerations concerning the coverage of anticonvulsant drugs for people with epilepsy. The AAN has developed evidence-based guidelines which strongly support complete physician autonomy in determining the appropriate use of anticonvulsants for their patients with epilepsy. Based on this evidence, the AAN has adopted the following principles concerning coverage of anticonvulsants for adults and children with epilepsy.

The AAN opposes generic substitution of anticonvulsant drugs for the treatment of epilepsy without the attending physician's approval. The FDA has allowed for significant differences between name-brand and generic drugs. This variation can be highly problematic for patients with epilepsy. Even minor differences in the composition of generic and name-brand anticonvulsant drugs for the treatment of epilepsy can result in breakthrough seizures.

- Anticonvulsant drugs for the treatment of epilepsy differ from other classes of drugs in several ways that make generic substitution problematic.

- For anticonvulsant drugs, small variations in concentrations between namebrands and their generic equivalents can cause toxic effects and/or seizures when taken by patents with epilepsy.

- The AAN opposes all state and federal legislation that would impede the ability of physicians to determine which anticonvulsant drugs to prescribe for the treatment of patients with epilepsy.

- The AAN believes that formulary policies should recognize and should support complete physician autonomy in prescribing, and patients in accessing, the full range of anticonvulsants for epilepsy.

- The AAN opposes policies that would result in arbitrary switching among anticonvulsants. Therefore, the AAN opposes generic substitution of anticonvulsants for patients with epilepsy at the point of sale (e.g., in the pharmacy), without prior consent of the physician and the patient.

#3

Rebecca Boyce
Testimony on Behalf of HB 1431

My name is Rebecca Boyce. I've lived in Bismarck for about 10 years. I moved here with my parents and two brothers from Chicago in 1997. I have had a seizure disorder for most of my life – it was first diagnosed in fourth grade.

I'm here today to urge you to pass HB 1431.

Over the years I've taken many different medications. I have more experience than I'd like to have working with different medications. Getting the right combination of meds and doses is a very touchy and time consuming process. The fact that all of the work and time invested in achieving effective seizure control with medications could be undone or affected by a pharmacist making a substitution that wasn't approved by me and my doctor is very troublesome to me.

There is a definite difference between drugs and between brand name and generic drugs. In college I experienced therapy failure triggered by taking a generic version of a brand name drug I was using. This wasn't because of my unknowing. My doctor and I decided to try the generic to saving money. It did have an adverse affect and caused me to have seizures. The FDA says these medications are bioequivalent but I can attest that there is a difference between the name-brand and the generic drug and that difference can be enough to make people with seizure disorders lose seizure control.

It might seem like a lot to ask that people with my condition be treated differently than those who suffer from other ailments, but I think when it comes to controlling seizures there is a difference. Seizures affect a person's entire life. I had to get a ride here this morning because my driver's license is suspended. Currently I'm in a job where driving is required and I was very worried I was going to lose my job. I am working with medications to regain seizure control and get my license back. If you used me as an example, an unauthorized substitution of meds that caused me to lose seizure control would set me back many months. I don't think it's fair or responsible or even very sensible to allow that to happen.

Maintaining control of seizures is the most cost-affective approach to treating people with seizure disorders long term, whether by enabling people to be more self sufficient, being injury free, staying out of the doctor's office or just being a happier person. I know my parents, who have two children with seizure disorders, would agree.

If I am prescribed a drug to control my seizures then I feel I should receive that medication unless both my doctor and I authorize a change. I urge you to pass HB 1431.

#4

3-6-2007

Re: HB1431

Robert Treitline RPH
Dickinson, ND

I am here today to urge a NO vote on HB1431.

HB1431 only targets the drug class for epilepsy ?????????
I believe this bill may be an anti-generic bill. I must clarify pharmacies position of generic vs brand name. In North Dakota, prescriptions can only be substituted with an AB rated generic for brand name drugs. Physicians in North Dakota can request Brand Necessary or Dispense as Written on the prescription if they want the brand name only to be dispensed. Most, if not all , insurance companies do impose a differential co-pay or deductible for brand name vs generic drugs. This differential co-pay is an incentive to use the generic version of the drug.
I serve on the DUR Board for the Department of Human Services and I can tell you there will be a dramatic cost increase to the State if we do not maximize the utilization of generic drugs. The current cost difference for average generic vs brand name at NDM is generic $22.00 per Rx vs. brand name $138.00 per Rx. This bill would have a huge impact on our NDM budget. Does the incentive or differential co-pay work? The answer is yes. In North Dakota, the Dept. of Human Services , about 5 years ago imposed a $3.00 co-pay for all brand name drugs and zero $ for generic. The generic utilization went from 45% up to the current utilization of 68% . As stated before there is a difference on average of $116.00 per prescription filled, this is big money.

North Dakota Medicaid

One other issue with the bill is this class of drug is often used for other conditions and treatment protocols. An example of this would be Nero-pain control. With more than one indication for this class of drug we would have to get the diagnoses from the Physician for every prescription we fill in this class.
Even though this bill only deals with epilepsy type drugs, I would bet in the next legislative session there will be more classes and the question is will it benefit anyone or only cost all of us more. I believe the answer is increased cost with no benefit.
Thank you for your time and consideration. I again urge a NO vote on HB1431. I would be happy to answer any questions the committee may have.

ndpharm treitline

From: "Dawn Pruitt" <ddtline@ndsupernet.com>
To: <ndpharmacy@ndsupernet.com>
Sent: Monday, March 05, 2007 6:33 PM

Pharmacy Times - August 2006

A Message from Kathleen Jaeger: The Resurgence of Drug Misinformation Campaigns

Many state governments have promoted the use of generic medicines through adoption of generic substitution and other laws. These policies are designed to ensure that a state's citizens receive the highest quality of care at the most affordable price. Consequently, increases in generic utilization have saved consumers and taxpayers billions of dollars in prescription drug costs. A recent resurgence in efforts by special interest groups to "carve out" or exempt certain therapeutic classes of medicine from generic substitution requirements (such as prior authorization and preferred drug lists), however, may significantly influence prescribing practices and spur needless increases in US health care costs.

Today, as with narrow therapeutic index (NTI) drugs in the mid-to-late 1990s, some brand manufacturers are arguing that certain classes of drugs are not safe for generic substitution. As lucrative patents expire on brand drugs, special interest groups representing brand manufacturers have renewed their efforts to maintain market share by waging misinformation campaigns throughout the country. By July 2005, over 20 states had passed legislation, and more are considering legislative proposals that would prevent the substitution of generic medicine for patients with conditions such as epilepsy, mental health disorders, and HIV/AIDS. (eg, see NC GEN. STAT. § 90-85.28, [exempting conditions such as "HIV/AIDS (and) mental illnesses" from generic substitution requirements]). A 2006 bill in Tennessee suggested that all prescribers and pharmacists "remain aware of the potential public safety and healthcare implications that generic? drug product[s] may have on persons with epilepsy." Deliberately misleading scare tactics such as this are intended to create a public perception of generic medicines as being poor-quality and unsafe substitutes for brand drugs. This could not be further from the truth.

The term *NTI drug* refers to a drug that could yield significantly different results when its quality or potency varies only slightly. The past controversy surrounding NTI drugs was based on the misconception promoted by some brand manufacturers that an approved generic drug could vary beyond a safe and effective range of potency of its brand counterpart and still be placed on the market.

In 1998, the FDA responded to the NTI controversy, stating that "products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is a brand name or generic drug product." True to its mission to advance public health by making medicines more affordable, the FDA has steadfastly supported its determination that a generic medicine is interchangeable with its brand counterpart. The same policy remains today.

In order to gain approval, generic drugs must undergo rigorous testing to demonstrate their equivalence to the branded counterpart. The FDA requires that a generic drug contain

identical amounts of the same active ingredient as the brand name product, and that the generic drug meet the same high standards for identity, quality, and purity. The FDA has stated that its strict bioequivalence standards account for precise degrees of variation between products, so that additional testing or monitoring is unnecessary when a patient is switched from a brand to a generic—in the FDA's words, "the goalposts would always be scaled to the variability of the [brand drug]." In one survey covering more than 400 samples of 24 marketed brand and generic drugs, all products were found to meet the established criteria for purity and quality. Regardless of whether the drug is prescribed for treating epilepsy, mental health disorders, HIV/AIDS, or any other medical condition, a generic substitute is equally as safe and effective as the brand drug.

It is important to note that, when a brand manufacturer alters a manufacturing process or makes changes to a formulation, it may be required to demonstrate equivalence between the new product and the old product to ensure that the drug has the same safety and effectiveness. In these instances, brand companies rely on exactly the same testing procedures as those used by generic manufacturers to demonstrate equivalence between the generic product and its brand counterpart. The FDA has stated that, if a generic drug is substituted for a brand, "the physician, pharmacist, and patient have the FDA's assurance that the physician should see the same clinical results and safety profile?any differences that could exist should be no greater than one would expect if one lot of the innovator's product was substituted for another."

In light of the FDA's long-standing policy, the recent campaigns waged by some brand manufacturers to carve out entire therapeutic classes from generic substitution laws are not only misleading, they are misguided and needless. Carve-outs will result in patients who suffer from epilepsy, mental health disorders, or whatever particular medical condition is the subject of the carve-out having less access to affordable generic medicine. More broadly, carve-outs will needlessly increase the cost of prescription drugs for consumers and taxpayers.

Pharmacists, physicians, policy makers, and patients alike should be aware of the facts about generic substitution, so that the influences of special interests are not allowed to put profits before public health.

Kathleen Jaeger, GPhA president and chief executive officer

Sheryl Treitline

From: "Lorri Giddings" <giddings@nodakpharmacy.com>
To: "Bob Treitline" <treit@ndsupernet.com>
Sent: Monday, March 05, 2007 4:01 PM
Subject: FW: [NDPhA-District 8] HB 1431

Lorri Giddings
North Dakota Pharmacists Association
North Dakota Society of Health-System Pharmacists
North Dakota Pharmacy Service Corporation
1661 Capitol Way Ste 102
Bismarck ND 58501-5600
Ph: 701-258-4968 or 701-258-4922
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email: ndpha@nodakpharmacy.net
email2: lgiddings@nodakpharmacy.net

"Life may not be the party we hoped for... but while we are here we might as well dance!"

If you no longer want to receive information from us, send an email to ndpha@nodakpharmacy.net stating your wish to be removed from our mailing list.

From: Melbye, Rick [mailto:Rick.Melbye@pfizer.com]
Sent: Friday, March 02, 2007 10:06 AM
To: lgiddings@nodakpharmacy.net
Subject: RE: [NDPhA-District 8] HB 1431

Lori,

Thanks for the update. Just briefly, my situation/position as you might know is with Pfizer, Inc. as a CEM. I live in MN, but cover ND, SD, and MT. Although Pfizer manufactures Lyrica for epilepsy, I totally agree with your/our professional position on this one. Due to the fact I live in MN, I'm not certain what type of influence I may have with ND legislators? But, if I can be of help with this in any way, please give me a ring, I'd be more than happy to testify if need be, and if there is an opportunity.

Good Luck!

Rick Melbye, Pharm. D.
Clinical Education Manager
Managed Markets
High Plains Region
Office: 218 236-5000
Cell: 952 237-6788

From: district8-owner@nodakpharmacy.net [mailto:district8-owner@nodakpharmacy.net] **On Behalf Of** Lorri

#5

PRACS Institute, Ltd.
Clinical Research, Bioanalytical & Statistical Services

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February 06, 2007

Senate Members
Health and Human Services Advisory Committee

Re: HB 1431 Non-substitution of Epilepsy Drugs

From: James Carlson, Pharm.D.
CEO and Co-Founder PRACS Institute, Ltd.

Alan Copa, Pharm.D.
President, PRACS Institute, Ltd.

Anthony Godfrey, Pharm.D.
Director of Clinical Research, PRACS Institute, Ltd.

Honored Senate Members:

HB 1431:

HB 1431 states therapeutically equivalent generic drugs may not be substituted for innovator drugs in the treatment of epilepsy. There is no scientific basis for this law revision. This requested change in the law is a clear attempt by the innovator drug manufacturers group to block generic substitution by attaching this provision to a medical disorder which is sometimes poorly understood by lay persons and sometimes feared by the public. There is no economic or scientific foundation for this change in law.

Background:

Economic: According to my recent discussion with Bob Treitline, R.Ph., a Dickinson pharmacist / pharmacy owner and former President of the North Dakota Pharmaceutical Association, the use of generic drugs in 2001 was about 45% of all prescriptions. In his recent discussion with the Health and Human Services Department, generic prescription use in North Dakota has increased from 45 to 68%

in 2006. This represents excellent attention to prescription cost containment by North Dakotans. Another tidbit reported was the states recent average generic prescription cost of about $22.00 versus innovator drug prescription cost of about $138 dollars. Those prices include all generic and all innovator drugs and not a single therapeutic area such as epilepsy. Therefore, on average, innovator prescription drugs cost about $111 per prescription more than generic prescriptions – again, on average. I do not have any information on individual anti-epilepsy prescription costs.

Medical Science: PRACS Institute, Ltd, is a North Dakota based human drug research company with 24 years of experience. By federal law enforced by the U.S. Food and Drug Administration (FDA), both innovator and generic drug studies must meet the same criteria to be marketed in the U.S. Therefore, both innovator and generics must demonstrate the same level of drug purity, and the same reproducibility from lot to lot and the same level of drug integrity. By federal law, no generic drug can be any better or any worse than an innovator company drug. By federal law, each lot of innovator product can only vary within very tight margins. The same applies to generic products. PRACS is contracted by both the innovator and generic companies to provide an unbiased assessment of their product(s) and determine if the product meets today's FDA requirements.

PRACS has evaluated many anti-epileptic medications over the past several years. We selected 5 different anti-epilepsy drugs representing 60 studies over the past ~5-6 years. Only 41 of the 60 studies passed FDA requirements, which are reasonably typical for all drug classes when comparing either product from Lot A versus Lot B, changes in manufacturing equipment, changes in chemical sources, as well as generic versus innovator products.

The criterion the FDA requires for generic drugs is rather simple. No generic product may be better (or worse) than the innovator in any of the evaluation categories. If there is a mismatch during the evaluation process, then the product must be reformulated so all categories of evaluation match within FDA standards. In our 24 year experience and understanding the drug formulation process has progressed tremendously in the past 10-15 years, there are many instances where the generic must back down on a product so as not to out perform the innovator. Remember, a generic drug should be 'the same as' the innovator and not better or worse.

To finalize this discussion, we have prepared random graphs from some of the 41 passing studies which meet all requirements of the FDA. The average data presented clearly indicate the innovator and generic products are comparable as defined by the FDA. The statistical analysis supports the visual observations of the attached graphs.

Summary:

In summary, based on our 24 years of experience in comparing generic versus innovators, we have no scientific data to support why innovator (branded drugs) cannot be substituted with generic drugs in the treatment of epilepsy. Our proprietary

scientific evidence clearly demonstrates those generic vs. innovator drug studies meeting FDA criteria and submitted to the FDA for approval can substitute the generic for the innovator product and achieve comparable blood levels and the therapeutic response necessary for the suppression of seizure activity in epileptic patients.

Recommendation:

Based on our data from 41 studies over ~5-6 years as well as our scientific expertise and 24 years of PRACS experience, **we strongly recommend the Senate membership deny passage of HB 1431**.

We regret not having the data collated to present this information to the North Dakota House of Representative or their advisory committee members.

Qualifications:

PRACS Institute, Ltd. has no financial interest in HB 1431. The successful passage or failure of the bill will have no impact on PRACS financial past or future nor will it financially impact the experts submitting this position paper.

PRACS Institute, Ltd. is a 24 year old drug research company founded in Fargo North Dakota by James Carlson, Pharm.D. and Albert Dietz, MD, Ph.D.. PRACS is a North American leader in evaluating both generic and innovator drug products to answer the variety of questions posed by drug manufacturers as well as the FDA when evaluating new and old drugs. In the past 24 years, PRACS has completed over 3,000 studies which has involved over 110,000 study participants and has collected over 3,800,000 blood samples for drug content analysis at the request of 120-150 different drug companies (US and international). The Fargo, ND and East Grand Forks, MN sites have a combined bed capacity for ~900 study participants while employing ~500 local staff. Although the company was founded in Fargo in 1983, the recent addition of investors has created a new company, Cetero Research, and added a 520 bed facility in St. Louis MO and additional sample analysis capacity in Houston TX and Toronto, Canada. The new total bed capacity of ~1,400 has created Cetero Research, the largest clinical research facility of its type in the world.

James Carlson, Pharm.D., CEO and Co-Founder of PRACS Institute, Ltd., is a graduate of the University of Iowa and University of Michigan Colleges of Pharmacy and former faculty at the NDSU College of Pharmacy. He began his generic / innovator drug research career in 1978 at NDSU. Dr. Copa, President of PRACS Institute, received his pharmacy degrees from the University of Minnesota and is also a past faculty of NDSU College of Pharmacy. Dr. Copa has been actively involved in drug research since ~1988 and at PRACS for the past ~15 years. Dr. Godfrey received his pharmacy education from NDSU and, after a few years in retail pharmacy, has been employed by PRACS Institute for ~8 years. Dr. Godfrey currently manages the largest scientific research department at PRACS.

#6

Written Testimony of Sandoz Inc.

Before the Human Services Committee

On North Dakota House Bill 1431

Tuesday, March 6, 2007

Sandoz Pharmaceuticals is pleased to have this important opportunity to share the views of the generic pharmaceutical industry with North Dakota lawmakers.

Today I would like to address "carve out" laws being considered by many state legislatures, including North Dakota's, which would restrict generic substitution. These laws are based on the mistaken belief that switching a patient from a brand drug to its generic equivalent involves a risk to patient safety. Allow me to clear up the apparent confusion surrounding the safety and appropriateness of generic drug substitution for certain classes of drugs. Over the years, the Federal Food and Drug Administration (FDA) has held a longstanding policy that if one therapeutically equivalent drug is substituted for another, the physician, pharmacist, and patient have FDA's assurance that the drug will have the same clinical results and safety profile. FDA has stated that any differences that could exist should be no greater than one would expect if one lot of the brand's product was substituted for another. The FDA stands behind the quality of generic drugs.

In order for a generic drug to be approved, it must undergo many rigorous tests and procedures to prove that it is interchangeable with the brand drug under all approved indications and conditions of use. Because state carve-out rules apply to particular classes of drugs, I want to emphasize that the interchangeability of a generic drug and its brand counterpart applies to all drugs, including those prescribed for treating mental illness, HIV/AIDS, and epilepsy. There are no documented examples of any generic drug manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand drug.

In the mid to late 1990s, many States initiated carve-out legislation for "narrow therapeutic index (NTI) drugs," an informal term referring to those drugs that could yield significantly different results when the quality or potency varies only slightly. At that time, FDA notified the public and state Boards of Pharmacy that after thoroughly examining the issue, the agency found no evidence to suggest the need for changes in the bioequivalence standards applied to generic drugs. Thus, FDA advised state health agencies, prescribers and pharmacists that generic substitution was within the public's interest and helped to foster containment of health care costs. FDA's affirmation of the interchangeability of a brand drug and

its generic therapeutic equivalent helped to counter much of the misinformation upon which state carve-out legislation had been founded. FDA stated that "products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is a brand name or generic product."[1] The agency's policy has not changed.

Despite FDA's assurances that the substitution of a therapeutic equivalent drug, generic or otherwise, is equally as safe and effective as a brand, the misconception that generic substitution may be unsafe in some instances appears to be lingering. This ongoing misconception is indicated by the recent upswing in carve-out laws initiated by numerous state legislatures, as it has here in North Dakota, for conditions such as mental illness, epilepsy, HIV/AIDS and others. It is critical for the public to understand that FDA's generic drug approval process is reliable, and that its scientific determinations of therapeutic equivalence apply to all classes of drugs.

Generic drugs generally provide a less costly alternative to brand name products. States are able to significantly reduce health care costs by raising generic utilization rates. Sandoz hopes that North Dakota's policy makers will recognize this, and protect the interests of public health and consumers over the profits of the brand industry.

Thank you for your time and attention.

Ron Hartmann, R.Ph.
Director of Government Affairs
Sandoz Inc.

[1] See Stuart L. Nightingale, M.D., FDA Associate Commissioner for Health Affairs, "Therapeutic Equivalence of Generic Drugs," Letter to Health Practitioners, January 28, 1998, accessible at http://www.fda.gov/cder/news/nightgenlett.htm

GPhA

GENERIC PHARMACEUTICAL ASSOCIATION

OPPOSITION TO HB 1431

1. **HB 1431, which restricts generic usage of epileptic drugs, will dramatically increase costs for the consumer, the state of North Dakota, the Medicaid budget, physicians, and pharmacists.**

   Average brand name prescription price: $101.71
   Average generic prescription price: $29.82(1)

2. **There are no differences between brand name and generic drugs**

   "The FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product." (2)

   "If one therapeutically equivalent drug is substituted for another, the physician, pharmacist, and patient have FDA's assurance that the physician should see the same clinical results and safety profile. Any differences that could exist should be no greater than one would expect if one lot of the innovator's product was substituted for another."(3)

3. **The FDA has found no examples of generic drug failures**

   "For both brand-name and generic drugs, FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S. meet specifications for identity, strength, quality, purity, and potency.....To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug."(4)

4. **Even the American Medical Association has recognized the value of generic drugs:**

   "One of the primary ways physicians can practice cost-effective prescribing is by offering patients a generic medicine when one is available."

5. **The physician can already mandate the use of the brand-name drug with a simple notation on the prescription blank: "Dispense as written"**

(1) National Association of Chain Drug Stores, 2005, NACDS web site
(2) Approved Drug Products with Therapeutic Equivalence Evaluations, 27th Edition, 2007. Preface Section 1.2
(3) FDA letter to the National Association Boards of Pharmacy, April 16, 1997
(4) FDA Letter to Health Practitioners, Jan. 28, 1998

#8

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
P O Box 1354
Bismarck ND 58502-1354
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Howard C. Anderson, Jr, R.Ph.
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Bonnie J. Thom, R.Ph.
Granville, President
Gary W. Dewhirst, R.Ph.
Hettinger, Senior Member
Dewey Schlittenhard, MBA, R.Ph.
Bismarck
Rick L. Detwiller, R.Ph.
Bismarck
Laurel Haroldson, R.Ph.
Jamestown
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

HOUSE BILL No. 1431 – EPILEPSY DRUGS
9:00 AM -TUESDAY – MARCH 6th, 2007
Senate Human Services Committee – Red River Room

Chairman Lee, members of the Senate Human Services Committee, for the record I am Kyle Schwandt a Pharm D student from the NDSU College of Pharmacy. Thank you for the opportunity to speak with you today.

Many anti-epilepsy medications are not just used for epilepsy, but are commonly used to treat other indications such as pain or anxiety. This would result in confusion when pharmacies dispense drugs such as valium or phenobarbital, which are indicated for a variety of disease states.

There are already means available for the doctor to use to continue with the same manufactured drug. If he would like to use a brand drug the doctor just has to write brand necessary on the prescription. In addition, doctors have a tendency to write brand names for many prescriptions not intending them to be brand necessary because they assume the pharmacy will dispense the cheapest available product.

This means you are sticking the patient with a large bill or a return trip to the physician to try and resolve the difference in the price, which can often be several hundred dollars, since many insurance plans – Medicaid or whatever - will not pay for the drug

Therefore, I would respectfully ask for a do not pass on this bill.

#9

TESTIMONY OF PAUL SANDERSON IN OPPOSITION TO HB 1431

SENATE HUMAN SERVICES COMMITTEE
MARCH 6, 2007

Madam Chair and Members of the Senate Human Services Committee, my name is Paul Sanderson. I am an attorney in the Bismarck law firm of Zuger Kirmis & Smith. I represent Medco Health Solutions, Inc., a pharmacy benefits management company, in opposition to HB 1431 because this legislation would reduce patient access to prescription drugs as well as escalate health care costs.

Medco is a leading provider of comprehensive, high-quality, affordable prescription drug care in the United States. We work with patients, pharmacists, physicians and health plan sponsors to improve the quality of pharmaceutical care provided to patients, while helping to control the growth in drug costs. We work under contract with health plan clients throughout the country that are providing prescription drug benefits for their members and employees, totaling more than 60 million covered lives. Our clients include:

- Fortune 500 corporations and smaller employers
- local, state and federal employee and retiree groups
- Blue Cross/Blue Shield plans
- unions, and
- insurance carriers and managed care plans.

Regardless of how the sponsors choose to characterize this bill, HB 1431 is a nationwide PhRMA-backed initiative to stall generic substitutions of name brand drugs. By requiring both physician and patient consent before dispensing a generic product for any treatment of epilepsy or convulsions, HB 1431 will make it harder for patients to access affordable care. At the same time, by preventing Employers or Health Plan

Sponsors from designating different co-pay amounts for specific drugs, this bill will also inhibit competition, encourage plans to shift a greater share of the cost to the patient, and/or reduce the plan's ability to maintain meaningful coverage of prescription drugs.

A. HB 1431 Will Make it Harder for Patients to Obtain Lower Cost Therapies for Seizures.

This legislation likely stems from concerns in the past when manufacturers could not produce reliable generic versions of epilepsy medication. However, currently and for the past ten years, many generic seizure drugs have come on the market and have been given an "A" rating by the FDA, and are interchangeable with the brand name drugs. Requiring consent from prescribers and patients before dispensing a generic medication creates an administrative burden that would deter patients from using lower-cost therapies that would have the same efficacy as their brand name counterparts.

B. The Solution Lies with the Physician and Pharmacist, Not the Legislature

If there is a concern over substitutions of certain epilepsy drugs, the physician may designate on the prescription that no substitution is allowed. Requiring the notification of the physician and the signed consent of the patient is an unreasonable burden when the physician has the power to ensure there are no changes in the medication if that is the physician's wish. Notifying the patient of medication changes should be a responsibility of the pharmacist and should be an issue of professional practice, not legislation.

C. **Employers Struggle With Health Care Costs, Yet HB 1431 Prohibits The Use Of Cost-Management Tools.**

In a time of rapidly escalating drug costs, policymakers should be focused on encouraging the use of innovative and effective cost control techniques rather than discouraging them. HB 1431 would prohibit plans from implementing formulary management programs that promote generics and lower cost branded drugs. The FTC has previously determined that pharmacy benefits management companies use formulary management programs to drive price competition among manufacturers. As part of their plan design, PBMs create formularies or drug lists that indicate which drugs (both brand and generic) they will cover. They incentivize generics as lower cost options. A-rated generics are available to be listed on the formularies they create. HB 1431 will prohibit PBMs from utilizing lower cost options to provide necessary care and treatment to their patients.

We strongly urge you to recommend a Do Not Pass on HB 1431.

#10

Human Services Committee
North Dakota Senate
March 6, 2007

HB 1431 (Epileptic drug interchange/ pharmacists limited)

Madam Chair and members of the committee, for the record I am Robert W. Harms on behalf of Caremark, Rx Inc., a national pharmaceutical services company that provides PBM services nationwide.

-14,000 employees; 1,300 licenses pharmacists in 39 states.

-Contracts with 60,000 pharmacies nationwide

-2,000 health plan sponsors

-Processes 550 million prescriptions annually; 86% of prescriptions in the US are still filled by retail pharmacists.

Caremark Opposes HB 1431.

HB 1431 restricts the ability of pharmacists to interchange drugs for epilepsy by requiring the consent of the attending physician and the consumer (who is not trained in pharmacology, or medicine) but is put in a position to dictate decisions that may not be in his/her own health interest, and as a matter of public policy is likely to raise the costs of prescription drugs in North Dakota. Cost increases are likely because the premise of HB 1431 runs counter to basic principles employed by PBMs to save North Dakota citizens tens of millions of dollars each year—through the use of innovative and effective cost control techniques, including the use of generics and lower cost brand names. (*See Price Waterhouse Study; 2005).* HB 1431 impedes the ability to use those techniques while still maintaining patient health. Finally, if a patient requires a certain brand or specific drug, North Dakota law allows the treating physician to direct the prescription to be designated: "dispense as written" which prevents the prescription from being altered without the doctor's approval.

For these reasons we oppose the bill and request a DO NOT PASS recommendation on HB 1431.

#11

Testimony
House Bill 1431 – Department of Human Services
Senate Human Services Committee
Senator Judy Lee, Chairperson
March 6, 2007

Chairman Lee, members of the Senate Human Services committee, I am Maggie Anderson, Director of Medical Services in the Department of Human Services. I appear before you to provide information on House Bill number 1431.

Epilepsy medications (anticonvulsants) account for roughly 11 percent of the North Dakota Medicaid pharmacy expenditure (October 2006 expenditures of $2.6 million, of which $296,000 were for anticonvulsants). Expenditures for this medication class has grown nearly 20 percent per year (see Attachment A).

This class of medications is reaching maturity, meaning many (Depakote®, Topamax®, and Lamictal® to name a few) of the products will be coming off of patent in the next two years. These three products account for 53 percent of our drug spend in this drug class. As this happens in a typical free market, the growth in costs slows and actually begins to decline. This maturation is accounted for in the inflation rates factored into our budget for the upcoming biennium. If this bill passes, this natural maturation will not occur, and the inflation will continue upward at a potentially higher rate given the typical pharmaceutical company practice of increasing the drug cost at a higher rate once generics are released. The projected impact is $1.8 million in total funds.

Tools are already in place to allow physicians to request brand name necessary medication for their patients. Also, the Food and Drug Administration (FDA) approves all generics through a stringent process – to assume a product will not succeed for a patient simply because it is generic overlooks the FDA expertise.

A bill with the same purpose has been introduced this year in a number of other states including South Dakota and Wyoming. It has been defeated in South Dakota and Wyoming. Wisconsin has been quoted as another state that considered this bill, which they did during their 2005 Assembly. It was also defeated in Wisconsin.

Finally, nearly 20 percent of ND Medicaid pharmacy claims are billed after 4 pm or on the weekend. The requirement for notification of the physician may cause delays in patients receiving medications as the physicians are not typically available at these times.

I would be happy to answer any questions the committee would have.

#12

NDLA, S HMS

From: Lee, Judy E.
Sent: Friday, March 02, 2007 12:20 PM
To: NDLA, S HMS
Subject: FW: HB1431

Mary -
Please make copies for our notebooks.

From: Velva Drug [mailto:velvadrug@stellarnet.com]
Sent: Thursday, March 01, 2007 5:53 PM
To: Lee, Judy E.
Cc: Erbele, Robert S.; Dever, Dick D.; Heckaman, Joan M.; Pomeroy, Jim R.; Warner, John M.; Taylor, Ryan M.
Subject: HB1431

Senator, re: HB1431 (bill restricting pharmacists from dispensing substitute epilepsy drugs in ND). I'm not sure if this bill is the same # in the Senate. I would urge a **do NOT pass** of this bill.
Currently ND has a provision in place allowing doctors to write 'Brand Necessary" on the face of the prescription if they deem it necessary --- and this is rarely done.
As many of the epilepsy medications are also used for other indications, unless the MD is writing the diagnosis on the prescription, I will not know whether it is being used for epilepsy or something else ---- and having to follow up with MD will delay this process for my patients.
Currently there are only a few of the epilepsy medications available generically, and the patients that we have receiving them have not had problems with their therapy. The generic medications are required to pass rigorous testing to ensure that they are bioavailability and effectiveness is equivalent to that of the brand product.
Based on the above, I believe that passing this piece of legislation would NOT improve patient care and WOULD INCREASE the COST of MEDICATION to this group of patients (as the generic is more cost effective than the brand and is as effective) (as well as increasing cost to the state for those patients who qualify for Medicaid).

Thank You

Bonnie Thom, RPH
Velva Drug Co
PO Box 10
Velva, ND 58790
701-338-2911

NDLA, S HMS

From: Lee, Judy E.
Sent: Friday, March 02, 2007 2:06 PM
To: NDLA, S HMS
Subject: FW: hb1431

Mary -
Copies, please, for everyone.

From: DOLIG@aol.com [mailto:DOLIG@aol.com]
Sent: Friday, March 02, 2007 8:56 AM
To: Lee, Judy E.
Subject: hb1431

Judy,
I'm asking you for a do not pass on hb 1431.The bill that deals with the inability to substitute generics for certain medications. It appears to be turf protection for the pharmaceutical manufacturers of these drugs. As I'm sure you already know the generic medications used are FDA approved to be bioequivalent as well as the same drug and strength. This bill only puts another road block in the way of sound, safe and financially responsible health care.

I'm planning to come out Wed. 4/13 to testify in favor of 1433 & 1432, (PERS diabetes patient education bill). We have talked about this concept for years. These bills will finally give us chance to put together a pilot that will show the true benefits of disease state management and patient focused education programs.
. Dave Olig

NDLA, S HMS

From: Lee, Judy E.
Sent: Friday, March 02, 2007 11:35 AM
To: NDLA, S HMS
Subject: FW: HB1431

Mary - Please make copies for our binders.

From: Spencer Clairmont [mailto:rxshop@utma.com]
Sent: Thursday, March 01, 2007 11:11 PM
To: Lee, Judy E.
Subject: HB1431

Senator Judy Lee
Chair
Senate Human Services Committee

Dear Senator Lee:

I own a pharmacy in Walhalla,ND and am quite concerned about the fact that HB1431 seems to have a chance of passing & becoming law. The state pharmacy association has sent talking points to try and convince you and your colleagues that this is a bad idea. I am sure that you will get all the talking points many times, and I believe that all of them are true.

However, the primary point I would like to make is that if this law is passed, your constituents will have to pay dramatically more for their medications, and they will not be any more healthy than if they were using the less expensive generic form of the same drug. The safeguards in place already prevent problems with the use of generics. Lab work is required to maintain appropriate doses & if the physician feels strongly that the brand must be used he can specify "Brand Necessary" to require this & state and federal law then require the use of the brand.

Please give a don't pass to this law as it would be a great disservice to your constituents who deserve the best medical care at a fair price. The drug manufacturers are disseminating misinformation to convince people to take the patient right of choice away from them. In my pharmacy practice, I offer generics to patients when they are available. If the patient doesn't want to take a generic, I don't force it on them as it is their money and their decision.

Thank you for your consideration
Spencer Clairmont R.Ph.
Walhalla Prescription Shop
701-549-2661

NDLA, S HMS

From: Lee, Judy E.
Sent: Friday, March 02, 2007 2:07 PM
To: NDLA, S HMS
Subject: FW: HB 1431

Mary -
copies, please

From: Tim Carlson [mailto:tcar@min.midco.net]
Sent: Friday, March 02, 2007 7:33 AM
To: Lee, Judy E.
Subject: HB 1431

Dear Sen. Lee: I am a pharmacist writing to you concerning HB 1431, regarding dispensing BRAND anti epilepsy medications. I am urging a DO NOT PASS vote on this bill. Brand drug manufacturers have long tried to protect their own interests by forcing patients to use their more expensive products. As generics become available, they represent a cost effective, therapeutically efficient way to treat patients. Using scare tactics and misinformation, they try to maintain market share of their costly name brand products. Below are some points about this bill along with an internet reference to an article in Pharmacy Times dealing with this topic:

1. Many of these anti-epilepsy medications are not just used for epilepsy, but also to treat other indications like pain or anxiety.

2. There are already means available for the MD to use to continue with the same manufactured drug. It he would like to use a brand drug the doctor just has to write BRAND NECESSARY on the face of the prescription.

3. Doctors have a tendency to write brand names for all prescriptions assuming the pharmacy will dispense the least costly generic equivalent. This will cause increases in health care costs.

4. If a pharmacy runs out of a specific manufacturer of a drug, the pharmacy would need a doctor's approval to dispense a therapeutically equivalent drug. Generics could not be substituted.

5. It appears that drug companies, through legislation, want to carve out specific drug classes, like anti-seizure medications, so that their higher priced branded products are used again.

6. Many PBMs today do not even recognize a DAW 1 when it is submitted, so we are at risk of having MAC pricing applied to a brand name drug, causing US to lose money! We must not let this happen.

7. There is absolutely no evidence to support some of the claims saying that bioavailability and effectiveness of generics is less than that of brand name drugs.

8. It appears that drug companies, through legislation, want to carve out specific drug classes, like epilepsy, so that their higher price Branded products are used again.
http://www.pharmacytimes.com/article.cfm?ID=3756

I appreciate your consideration of this issue and again urge a DO NOT PASS on HB 1431.

Thank you.

NDLA, S HMS

From: Lee, Judy E.
Sent: Monday, March 05, 2007 8:42 AM
To: NDLA, S HMS
Subject: FW: HB1431

Copies, please.

From: Patricia Churchill [mailto:patchurchill@bis.midco.net]
Sent: Monday, March 05, 2007 12:07 AM
To: Lee, Judy E.; Erbele, Robert S.; Dever, Dick D.; Heckaman, Joan M.; Pomeroy, Jim R.; Warner, John M.; Kilzer, Ralph L.; dcook@nf.gov
Cc: patchurchill@bis.midco.net
Subject: HB1431

Dear Senator,

As a pharmacist I am asking you to please vote no on HB1431. This bill would require all prescriptions written in ND for a brand name anti-seizure medication only be dispensed as brand unless pharmacies had permission from the physician and patient. As the law now stands, a pharmacist may substitute a less expensive generic medication unless the physician writes Brand Necessary on the script. The FDA requires that a generic drug contain identical amounts of the same active ingredienct as the branded counterpart. They have stated that, if a generic drug is substituted for a brand. "the physician, pharmacist, and patient have the FDA's assurance the the physician should see the same clinical results and safety profile. Any differences that could exist should be no greater than one would expect if one lot of the innovator's product was substituted for another."

Our pharmacy services HIT group homes and 2 ISLA homes in Mandan. Many of these patients are on anti-seizure medications. All but 2 patients are on generics. We all respond differently to different drugs regardless of the disease state!

I have served on the states DUR board for several years. This boards responsibility is to ensure that medicaid recipients receive the highest quality of care at the most affordable price. The use of generics has saved consumers and taxpayers bilions of dollars in prescription drug costs. The pharmaceutical companies are facing the loss of patents and therefore loss of revenue. It appears these companies, through legislation, want to carve out specific drug classes, like epilepsy, so that their higher priced Branded products are used again.

The physician will also have to list the diagnosis on the prescription, as many of these medications are used for other disease states beside epilepsy. Depakote ER, Topamax and Neurontin are all effective in migraine prophylaxis
Tegretol and Depakene are effective in bipolar disorder
Tegretol and Neurontin are effective in neuropathic pain treatment

This requirement could be very cumbersone for the physician especially considering all the Medicare Part D and other insurance demands. It will mean delays for the patients, etc. It would be much easier to leave the law as it stands!

NDLA, S HMS

From: Lee, Judy E.
Sent: Monday, March 05, 2007 1:02 PM
To: NDLA, S HMS
Subject: FW: Opposition to HB 1431

Senator Judy Lee
North Dakota State Legislature
State Capitol
Bismarck, ND

Honorable Senator Lee:

Sandoz Pharmaceuticals would like to express our concerns with recent legislation, HB 1431, that is scheduled to be heard in the Senate Human Services Committee this Tuesday. This legislation would severely limit the ability of pharmacists to substitute a number of prescription drugs that are currently almost universally dispensed generically. This, in turn, would greatly increase the financial burden on patients and on the state of North Dakota through its Medicaid program.

This legislation basically prohibits the pharmacist from substituting a generic drug for a brand-name epileptic drug without the written permission of the physician. This bill would greatly increase the bureaucracy, time, and paperwork needed for both the pharmacist and the physician and will ultimately mean higher costs for the patient.

As you may be aware, the FDA has addressed bioequivalency and has, in fact, conducted two studies involving hundreds of drugs that demonstrated the mean difference of AUC(area under the curve) between the brand drug and its generic counterpart averaged only 3.5% in one study and only 3.25% in the other study. The FDA further noted in a letter to health care providers this statement:

"If one therapeutically equivalent drug is substituted for another, the physician, pharmacist, and patient have FDA's assurance that the physician should see the same clinical results and safety profile. Any differences that could exist should be no greater than one would expect if one lot of the innovator's product was substituted for another."

It appears that a brand-name drug company has encouraged this type of legislation simultaneously in a number of states conveniently missing the fact that a physician can mandate the dispensing of the branded drug by merely writing on the prescription "dispense as written". It's almost the situation where we have a solution in search of a problem.

It has been my experience that many pharmacies only carry limited quantities of the branded versions of the common epilepsy drugs since the generic substitutes have been shown to be just as efficacious with substantial cost savings to the patient. Obviously there are a number of additional epileptic drugs on the market with no generic substitute but as patents expire, these drugs also will be available generically with the same efficacy but at lower prices.

I urge you to oppose this legislation particularly when the physician, as you are aware, can still mandate the brand-name drug by noting on the prescription blank "dispense as written".

Please feel free to contact me if I can provide any additional information.

Sincerely,

Ron Hartmann, R.Ph.

NDLA, S HMS

From: Lee, Judy E.
Sent: Sunday, March 04, 2007 3:16 PM
To: NDLA, S HMS
Subject: FW: HB1431

Mary -
Please put copies in our notebooks. ✓

From: Alan Copa - Cetero Research [mailto:alan.copa@pracs.com]
Sent: Sunday, March 04, 2007 2:04 PM
To: Lee, Judy E.; Erbele, Robert S.; Dever, Dick D.; Heckaman, Joan M.; Pomeroy, Jim R.; Warner, John M.
Cc: James Carlson - Cetero Research
Subject: HB1431

Dear Representatives.

It would be a sad state of affairs if this bill HB1431 were to pass. Generic drugs undergo very rigorous and stringent testing and review by the FDA. There is no wiggle room or its close enough for a generic drug product, the criterion for equivalence has been dictated and if the criteria are not met the generic product is not approved. Based on this, to meet the required criteria the generic drug product must be no more variable than the current reference listed drug and in most cases is less variable. This of course then translates into equivalence between the generic product and the reference listed product and for all intent and purpose the two are interchangeable.

In following this path the state of North Dakota is in essence stating the state knows more about these drug products than the Food and Drug Administration (FDA) that reviewed and approved the currently available drug products. At the least I would suggest that all the data from the brand name products and the generic products be submitted to an expert review panel for evaluation prior to making such a hasty decision. Based on the testing required for the generic products, these products are equivalent to the brand name product and in cases display less variability than the brand name product. I can name a handful of brand name products that the manufacturer would be hard pressed to prove that its drug product is bioequivalent from lot to lot.

If the state chooses this path, where does it stop? Based on the increased expenditures quoted and the relatively small population base it appears this one decision will cost each citizen in the state approximately $1000.00 annually. I would be very interested in reviewing the scientific evidence which supports this bill. I have not noticed the FDA or PMA companies sending out alerts regarding the potential dangers.

It is my business and the business of PRACS Institute, Ltd. for the past 24 plus years to test for bioequivalence between generic and brand name drug products. The generic drug is not approved unless it is determined to be equivalent to the brand name product. There are no exceptions regardless of the safety profile of the medication. To the best of my knowledge, none of the generic products that have been tested by PRACS Institute Ltd. and have been approved by the FDA have been pulled from the market for being an inferior product. The most recent recalls have been for safety concerns with innovator products i.e. Viox. If the innovators or branded companies are concerned regarding epilepsy patients and generic medications why not match the price of the generic products available? In any other free market, the innovator would have to match the price of its competitors to stay in the market. In this case the innovators are trying to use legislation to maintain their market share and price mark-up. This tactic with respect to epilepsy was soundly defeated in South Dakota, Iowa, and Nebraska.

Other states are stepping up the pace to embrace generic products to help defray rising healthcare costs. This is the theme in countless publications across the nation. Our federal government currently is reviewing multiple legislative initiatives to increase generic drug competition and prevent the big pharmaceutical companies from stifling generic drug entry to the market place. Please do not be submissive to the estimated 3000 lobbyists of the big Pharmaceutical Companies and the 300 to 500 million dollars they spend to hinder generic competition. If you elect be submissive, North Dakota's response is to hinder generic drug competition. This is how the state will be perceived by the rest of the nation. If this bill is successful, the flood gates will open, the increased healthcare

costs to the state will become millions of dollars and North Dakota will be looking for funding for increased health care costs. Some how I do not think the feds will be willing to help the state of North Dakota. I also believe the citizens of the state will ask if their representatives are working for the citizens of North Dakota or for the big pharmaceutical companies.

Concerned Citizen,

Alan Copa, Pharm.D.
President
PRACS Institute, Ltd. - Cetero Research
4801 Amber Valley Parkway
Fargo, ND 58104
(701) 461-8229 Fax (701) 239-4955
alan.copa@pracs.com

Effective October 17, 2006, PRACS Institute, Ltd. is a founding member of Cetero Research, one of the world's leading providers of early stage clinical trials and bioanalytical research services to the pharmaceutical industry.

NDLA, S HMS

From: Lee, Judy E.
Sent: Friday, March 02, 2007 3:34 PM
To: NDLA, S HMS
Subject: FW: HB 1431

Importance: High

Copies, please.

-----Original Message-----
From: Weippert, Tim [mailto:TWeippert@ThriftyWhite.com]
Sent: Friday, March 02, 2007 2:45 PM
To: Lee, Judy E.
Subject: HB 1431
Importance: High

Hi Senator Lee,
As a resident of West Fargo and pharmacist in North Dakota and resident of the district you serve and represent, I am writing to ask you to vote NO on HB 1431. I know you chair the Senate Human Service Committee that will be hearing this next week and I want you to know this bill will doing nothing more than contraindicate what we as health professionals try to do today, work with our patients to give them the best and most affordable healthcare availabe This bill, if passed, will do nothing more than INCREASE cost of medications to the patient, increase costs to the employer's that maybe paying for part or all of them through an insurance plan and INCREASE cost to the state if it is medicaid prescription. The only way to change it is for the physcian and the patient to allow us to use a less cost costly, EQUIVALENT generic medication through permission from both. Today, physicians have that ability already, by writing the verbage "Brand Necessary" across the prescription, otherwise, we as pharmacist's work directly with the patient and ask and let them know there are cheaper, EQUIVALENT products available.

This is nothing more than a ploy by the drug manufacturer's to keep their product in the forefront at the EXPENSE of the patient, not in the BEST interest of the patient. These drugs for epilepsy are also used for other indications such as pain and anxiety too and again, their are generic alternatives to use.

Some manufacturer's and others might say, well pharmacy is just protecting their pocket book because we make a little more profit on generic medicaitons. I want you to know that our profession is not predicated on just making money too, but is predicated on the HEALTH and WELFARE of the patient. I dare say I do not believe that to be the case always of the drug manufacturer. They raise the question of the bioavailability and effectiveness of the generics. Well I do believe we have one of the most sophisticated means of that not happening through all the FDA testing and approvals that are necessary before a drug is released for patient consumption.

So please consider the vote of NO on HB 1431.

Thank you

Tim Weippert, RPh
1817 Princeton Lane
West Fargo, ND

701-492-7902
tweippert@thriftywhite.com