2011 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1053

2011 HOUSE STANDING COMMITTEE MINUTES

House Industry, Business and Labor Committee
Peace Garden Room, State Capitol

HB 1053
January 10, 2011
12701

☐ Conference Committee

Committee Clerk Signature Ellen LeTang

Explanation or reason for introduction of bill/resolution: Workers' compensation benefits for generic drugs.

Minutes:

Chairman Keiser: Opens the hearing on HB 1053.

Jennifer Representative Clark~Legislative Council: Comes from the performance evaluation of narcotic utilization. Recommendation is WSI have the authority to require that generic medicines be dispensed when they are available. WSI may add its discretion allowed medicines be dispensed as written. These medicines as written are an expensive component of current pharmacy expenses. Barring any reasonable and compelling medical reason for a brand medication to be prescribed, such as an adverse reaction to the generic or an ineffective outcome, generic medicine should be used when they are available. This is the recommendation.

Chairman Keiser: Any questions, anyone else here to testify in support.

Tim Wahlin~Chief of Injury Services at WSI. (See attached testimony 1).

Chairman Keiser: Questions for Tim Wahlin?

Representative M Nelson: Your focus is on the narcotics, how are these numbers in psychoactive drugs, does the bill needs to specifically focus on the narcotics? Is that the problem, what are the effects of the other types of drugs?

Tim Wahlin: If you notice on the appended document you have at the end, the very last one takes out the categories that we have, this is WSI data on the dispenses written rates in each of those categories. With the respect of the psychoactive drugs, I'm going to defer to our expert Dr Hanel, but you will notice that some of the rates especially for the non abuse potential medications are exceeding low.

Dr Harvy Hanel~WSI Pharmacy Director: With respect to psychoactive drugs, it depends on what class they come from. There are certain classes of psychoactive drugs that do have some abuse potential and those classes we do see a higher dispenses written rate. For those that have low abuse potential, the rates are much lower with the exception of Prozac. The general statement would be that those that have a higher abuse potential

have tend to have a higher dispenses written rates, those that do not are much more reasonable.

Chairman Keiser: Does 6502-20.1 refer to all drugs, not just listed on the other page.

Tim Wahlin: That's correct.

Chairman Keiser: This is a big hammer we are swinging. We are saying for every drug this is going to apply, not just for the opioids, which you identified as the problem. Why do we want to attack all drugs? Doctors treat patients they best they possible can and now they are being micro manage on every drug.

Tim Wahlin: With the respect to the actual costs of drugs going out and with the companion bill 1054, you will see some of those numbers more clearly. Basically all the dollars arrive in this category; the other categories are going to be unaffected because just so few dispenses written overrides. Secondly, this is the recommendation of out of the performance review.

Chairman Keiser: I understand the performance review, but it applies to all drugs, so now doctors have to be now aware that every time they prescribe a drug, now they have to go generic or not get it paid for at the same rate. Why didn't this bill just address the opioids?

Tim Wahlin: Candidly it could, a broader application was recommended to the extent that the application was narrowed just opioid analgesics and the basic affect would be the same.

Chairman Keiser: I do have a concern, hopefully maintaining our current position and expanding the participation of local doctors. If they are going to have to justify every drug, it's a lot easier just not to take patients. If we have a problem with opioids and we do, let's write legislation that addresses the problem and not create all of this bureaucracy for all the other doctors.

Tim Wahlin: To the extent that the function of the dispense is written override really won't affect the doctors. This takes place when you go to pick up your prescription. It's all on line, all immediate; the pharmacy knows immediately what is going to be paid for, what's not going to be paid for and immediately follow up with a physician to make sure that's clear. This takes place in the pharmacy realm as opposed to physician realm. The only reason we get back to the physician is to clarify whether or not this is one where there would be a documented allergic affect, which would allow that to be over written.

Representative Ruby: The request for the override is not substantial with the other, by saying that that the majority of the prescriptions, are generally prescribing the generics, and nobody is requesting an alternative, except for these?

Tim Wahlin: That's correct, just because of that override pattern essentially will numerically affect that area. That's a 2-3% overrides compared to Human Services overrides which are .2 and .3%. That system has a co-payment of $3.

Chairman Keiser: Just to clarify, currently we don't have this in the law, so if the doctor writes a prescription for X and it's not a generic, you are going to honor it unless you challenge it. This changing the rules, they are not forcing doctor to go to the generic, currently.

Tim Wahlin: There is an administrative rule in place of which case the physician would have to explain why the brand is preferred, but if that explanation comes in, the brand is just paid for. We are set to prescribe generics unless there is a justification why that shouldn't take place. This would change the spectrum in which case, it would set that bar of explanation much higher.

Vice Chairman Kasper: You statement say that the real basis behind the bill is to attempt to minimize the illegal diversion of these dangerous medications to the general North Dakota population, what evidence do you have you show that this is being done or is it opinion?

Tim Wahlin: To the extent that facts are ascertainable in an area where you have illegal drug trade, there will always be suspects of criticism of how accurate they are. Antidotally, we will see from time to time, when there is a drug bust that takes place, we will be able to go back and pick up a name and look through the file and see that if may have been our meds. That an antidotal, that's not necessarily factually driven, numerically driven or be able to be accessed by us. Discussions with VCI, seem to indicate that there is a significant diversion issue and we are basically relying on those as well.

Vice Chairman Kasper: Let me ask in a different way, in the last year, if there is a drug bust, is WSI is notified is any of your claimants have been involved in what they suspect is a illegal diversion and if so, in the last year how many numbers can you identify?

Tim Wahlin: No we are not asked but once in a while we will see a name in the paper.

Vice Chairman Kasper: You have no evidence about your worker's doing the illegal diversion; it's a supposition on your part as it might be happening in the general population.

Tim Wahlin: Yes.

Vice Chairman Kasper: I want to get to the handout on the selective dispensement of written rates, Dr. Hanel on these charts, percentages look really bad, however do you have date that show the numbers of employees in each category the number of dollar amounts that have been dispensed in the brand compared to what it would have been in the generics so that we can see a bottom line result of these drugs your are showing. What are the actual costs to WSI?

Dr Harvey: I do have this information. These percentages are not based off the dollar amount because that would skew the information. These are based on number of prescriptions written.

Vice Chairman Kasper: I understand that, what I'm getting to is dollar amounts paid by WSI compared to if you had to dispense the generic. I'm trying to get a handle on the dollar problem not the percentage problem.

Chairman Keiser: That's in the fiscal note.

Vice Chairman Kasper: As far as getting to the area of other drugs besides the opiaids, my doctor told me never to take generic. I do get concerned that we are going into an area that isn't a problem.

Representative Nathe: In regards to the fiscal note, I see the proposed legislation will serve to reduce medical prescription costs by approximately 350,000 per year, how much is based on the opioid category or all categories going generic?

Dr Hanel: All categories which the contribute 66% of that.

Tim Wahlin: Our internal numbers for injured worker fraud cases, currently about 25% of all those cases have to do with the diversion of narcotics, so that's an all time high.

Chairman Keiser: Anyone here to testify here in support to HB 1053?

Bill Shalhoob~North Dakota Department of Commerce. (see attached testimony 2).

Mike Schwab~Executive Vice President of the North Dakota Pharmacists: (see attached testimony 3).

Representative Ruby: Earlier there was testimony about generally more of a pharmaceutical issue than it is a doctor-patient issue. Is it pretty common if the patient tells the doctor the brand they want, he isn't going to argue with them?

Mike Schwab: Maybe someone from the medical association could answer from the terms of the physician-patient relationship, but typically when the patient comes into the pharmacy and that claim is going to be adjudicated, it's my understanding, they pharmacist will be able to tell that patient if its covered or not covered.

Representative Ruby: Do pharmacist get into argument with patient with the credibility of the generic?

Mike Schwab: Once in a while it might happen, but typically from the public perspective, we seen generic utilization trends continue to increase year after year. Public is open to the idea.

Representative Clark: When I went to the drug store to pick up my normal prescription, I noticed a switch change; I asked the pharmacist, why did you change this prescription? He said BCBS won't pay for that brand name drug, so at a substantial cost reduction I take the generic. Doesn't BCBS already mandate what this bill says or is there an override for that?

Mike Schwab: I believe there is representation from BCBS, I don't know if they want to speak to that question. It's my understanding, that the formulary that BCBS had under your plan had changed and that no longer covered. We are seeing more generics enter the market.

Representative M Nelson: You mentioned that there is a lot of generic programs that are coming out. Are you familiar with any that are working well, that maybe are not quite harsh as this bill?

Mike Schwab: You see a wide range of generic first programs. Some of them might be actually tailored to actual employer and a group of his employees based on what they might need.

Chairman Keiser: Anyone here in support, in opposition HB 1053?

Bruce Levi~North Dakota Medical Association. The discussion we had with the NDMA has been on the original bill with the language regarding life threatening side affect, I think in the realm of the medical with physicians, we work with the board of medical examiners on issues. If this bill is about drug diversion or inappropriate care provided by physicians, we work with the board of medical examiners. We don't support bad doctors; we just make sure they have a fair hearing within the board of medical examiner process. The point was made bill doesn't affect physicians; I think that if you look at legislation, it's a payment rule. Physicians are not paid for prescription drugs per say, so apparently the notion here is that the injured worker would pressure the physician, to put more focus on generic because otherwise the injured worker will pay for the difference. Right now there has been things raised about the current process, if pharmacist do have the ability to dispense as written is written on a prescription to do a substitution to work with patient. Typically the standard is therapeutic equivalency between the generic and brand name drug. If we have a dispense as written situation, we look at it as an ethical issue. The physician determines that a particular drug is the best drug for this patient and circumstances, they have the ability to write "dispense as written" on the prescription. The pharmacist does not have the ability to substitute a therapeutic equivalent. That's the process in place right now and we have had some fights with WSI over the years about dispense as written. We went through a process in 2006 prior authorizing all dispenses written. They were moving forward with that, we lost in the administrative rules committee, 8 to 7. That isn't in the administrative code as I could find it. What we are looking at the 2 to 3%, is the 2 to 3% a problem, I don't know? I don't know if comparing it to the department of Human Services statics is comparing apples to apples. We do have different populations, and that should be looked at. If we have a problem with the 2 to 3% or if we have problems with any particular physician as an outl-lier, then there are other methods to work with those particular physicians rather than developing a rule. I don't see the connection between this particular payment rule, opioid discussion that has been raised and how this is all going to work.

Vice Chairman Kasper: Is there a potential liability for a doctor, WSI or pharmacist, if the doctors writes dispense as written and it is not the drug given in the end?

Bruce Levi: I don't see any perceived medical liability on the part of the physician if they write, dispense as written. The law we have right now is if the dispensed as written is not

written, the brand name isn't written, dispensed as written, then we do have the statue that allows the substitution. From that standpoint the pharmacist has statutory cover in terms of being allowed to do that.

Chairman Keiser: Could we make an amendment on line 8, where we would strike "create a life-threatening side effect" and place that with a "produce a verifiable allergic reaction"? The only problem with that is that you don't know if there is an allergic reaction until after you take the drug.

Bruce Levi: I agree with that, how do you verify it at this point? What we are doing here is providing the brand name drug. All the agency is saying here is that you are providing the brand name drug, we may never know whether there may be an allergic reaction, but we are just going to pay you the generic rate if it's less.

Chairman Keiser: Have you had a board discussion on whether or not this would impact a number of physicians willing to participate in WSI program?

Bruce Levi: We have had several discussions at the board level and at the legislative committee. The generic argument about participating or not participating comes up in all these bills. The issue with the process that is being proposed in the next bill is also a concern, it's just another reason not to participate.

Chairman Keiser: In introduction 6502-20.1, where this is for all pharmaceutical dispensing, if it were limited to the opioids, would you have less of a problem?

Bruce Levi: I still believe this particular tool that is being proposed in relating to payment, I still don't understand fully how it will impact the current 2 to 3%. It doesn't have a direct impact on physicians except that there may be some discussion if the injured worker is stuck with the difference between the generic and the brand name I still don't see this as an effective tool going back to the issue of what is medically neces or not necessary. If we have a problem with a particular physicians, then work with those particular physicians within the WSI process and or work with the board of medical examiners.

Chairman Keiser: BCBS currently have a program where it is a generic substitution unless the physician goes through some additional intervention. When we say BCBS, what percent of your physicians are not participating BCBS versus not participating in WSI.

Bruce Levi: I don't know the WSI number. I suspect there maybe one physician. I'm sure it's 99.9% on the BCBS side.

Representative Ruby: It's going to be the standard for the most part rather than the rule, I would wonder why you would think that doctors would be less likely to participate because WSI did this when it's pretty much be the standard.

Bruce Levi: I think from the perspective of brand names, I'm not sure how BCBS works, I know when a brand name and we have a process to look at any these situations. I don't know if our board members have seen these legislations. I think there are other ways of

looking at this issue, the payment as it's laid out in the bill, will address the problem. Need to work with the physicians and finding a way to do this. We don't see the connection.

Chairman Keiser: Further questions for Bruce? Seeing none, is there any one in opposition to HB 1053?

Dave Kemnitz: (see attached testimony 4).

Representative Ruby: I understand your opposition to lines 10-11, you were the one giving opposition to the life threading side effects and we forwarded this on asking that this be considered as a change of language if WSI could come up with a better term. Do you feel better with the term they came up with in their amendment?

Dave Kemnitz: Thank you for addressing an earlier term. A duck in any other name is still a duck. That term is exactly poignant about this particular legislation is. The guinea pig is the claimant; the insurance could make the decision. How do you resolve that before you become a guinea pig?

Chairman Keiser: Anyone here in opposition HB 1053?

LeRoy Volk~I'm an injured worker: Explains his situation with how the HB 1053 will affect him.

Chairman Keiser: Anyone here to testify opposition, in neutral.

Chairman Keiser: Closes the HB of 1053, what are the wishes of the committee?

Representative Ruby: I move the amendment of proposed by WSI which would strike "create a life threatening side effect" and replace that language with "produce a verifiable allergic reaction".

Representative Gruchalla: Second.

Voice vote taken on amendment, motion carried.

Chairman Keiser: May voice would be for WSI to redrafting some language section to the opoids and give it a two year try. This affects every medication. This will affect physicians on whether or not they will take on WSI cases.

Vice Chairman Kasper: I agree, I don't even know that I like the bill even after the amendment. I certainly hope that we would move to limit it and put a sunset on it.

Chairman Keiser: Further discussion? Seeing none, Representative Gruchalla, you have this bill, would you be willing to work with WSI and see if we can find an amendment that would be directed at those two concerns and present it back to the committee.

Representative Nathe: Regarding the sunset, would a reporting a requirement to the interim committee?

Chairman Keiser: Yes, a report to the interim WSI committee as part of that amendment.

2011 HOUSE STANDING COMMITTEE MINUTES

House Industry, Business and Labor Committee
Peace Garden Room, State Capitol

HB 1053
January 12, 2011
12813

☐ Conference Committee

Committee Clerk Signature Ellen LeTang

Explanation or reason for introduction of bill/resolution:
Workers' compensation benefits for generic drugs.

Committee Work Minutes:

Chairman Keiser: Opens the work committee session on HB 1053

Representative Gruchalla: Goes over the amendment (see attachment).

Chairman Keiser: Any questions on the amendments for Representative Gruchalla?

Representative N Johnson: Is the addition of the expiration date just a sunset so it gets revisited?

Representative Gruchalla: Correct, I believe that was the intent.

Chairman Keiser: Can you remind us what we are doing with this bill as it appeared and now with the amendment?

Representative Gruchalla: This was a bill to address the problem with the drugs that are getting...

Chairman Keiser: This is a bill that would allow the agency basically to pay only amount for a bioequivalent drug or generic drugs? Is that correct?

Representative Gruchalla: Yes.

Chairman Keiser: Then we said "providing that treatment would not create not a verifiable allergic reaction".

Representative Gruchalla: Correct.

Chairman Keiser: Then they went further to substitute, again the problem they identified I believe, one the opioid group of drugs, the first amendment in terms of these controlled substances, get us to the opioids, primarily?

Representative Gruchalla: Yes, those are the ones listed in section 19.

Chairman Keiser: That we would be limited there and we put a sunset on it and required a report to see what impact this has had on utilization. Does this suming up the bill?

Representative Gruchalla: Yes.

Chairman Keiser: What are the wishes of the amendment?

Representative Clark: This bill is originally written included other drugs and opioids and I few that as a cost saving measure. I have no problem supporting the bill as originally written. I'm going to oppose this amendment.

Representative Ruby: It was broad to all generics, however, the vast majority of the ones getting the request for dispense as written, are generally those. The other ones, nobody is requesting name brand types of medications they may on. This is getting basically at the root at what they want. The other issues went a problem, they weren't getting the dispensed as requests, so this is narrower but still their main focus.

Representative Ruby: Moves a Do Pass for the amendment.

Representative Gruchalla: Second.

Chairman Keiser: Further discussion on the amendment.

Representative Kreun: In reference to the representative's comments, if it's not a problem and they are using them, why wouldn't require to a cost saving measure?

Representative Boe: My notes indicate what we amended this bill already, are my notes wrong?

Chairman Keiser: This would be a second amendment.

Representative Boe: Would our amendments be right for how we already amended it?

Representative N Johnson: (inaudible). What would happen is this would over ride that which would do the same thing.

Chairman Keiser: Good point, further discussion on adoption of the amendment?

Representative Gruchalla: The other point, the opposition that we had to the bill was that they opposed substituting the other drugs that we now are not going to change. I think the amendments took their opposition to the bill.

Chairman Keiser: I think it reduces it, absolutely.

Voice vote to adopt the amendment, motion carried.

Chairman Keiser: We have HB 1053 before us, what are the wishes of the committee?

Chairman Keiser: Talks about his indirect observation of opioids.

Representative Ruby: I move a Do Pass as Amended.

Representative Vigesaa: Second

Roll call was taken for a Do Pass as Amended on HB 1053 with 6 yea's, 8 nay's, 0 absent and Representative Gruchalla is the carrier.

Chairman Keiser: Motion failed. Given the failed, is there an alternative motion?

Vice Chairman Kasper: Moves a Do Not Pass as Amended.

Representative Amerman: Second.

Chairman Keiser: Further discussion, I do believe we need to address this issue in one of these bills. The one I do like requires a plan to be approved after a certain period of utilization. This is a managed health care system.

Roll Call was taken on HB 1053 for a Do Not Pass as Amended with 9 yea's, 5 nay's, 0 absent and Representative Gruchalla is the carrier.

FISCAL NOTE

Requested by Legislative Council
01/15/2011

Amendment to: HB 1053

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.*

	2009-2011 Biennium		2011-2013 Biennium		2013-2015 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures						
Appropriations						

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

2009-2011 Biennium			2011-2013 Biennium			2013-2015 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts

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 engrossed bill establishes payment criteria for prescribed medications when a generic equivalent exists; provides for a report to legislative management; and includes a sunset.

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.*

WORKFORCE SAFETY & INSURANCE
2011 LEGISLATION
SUMMARY OF ACTUARIAL INFORMATION

BILL NO: Engrossed HB 1053

BILL DESCRIPTION: Dispense as Written Medications

SUMMARY OF ACTUARIAL INFORMATION: Workforce Safety & Insurance, together with its actuarial firm, Bickerstaff, Whatley, Ryan & Burkhalter Consulting Actuaries, has reviewed the legislation proposed in this bill in conformance with Section 54-03-25 of the North Dakota Century Code.

The engrossed bill establishes payment criteria for prescribed medications when a generic equivalent exists; provides for a report to legislative management; and includes a sunset.

Rate Level Impact: Based on historical data it is anticipated that the proposed legislation will serve to reduce medical prescription costs by approximately $250,000 per year. To the extent that prescription costs are reduced, future rate levels will be adjusted accordingly.

Reserve Level Impact: The proposed legislation should not have a material impact on statewide reserve levels.

DATE: January 15, 2011

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.

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.*

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.*

Name:	John Halvorson	**Agency:**	WSI
Phone Number:	328-6016	**Date Prepared:**	01/15/2011

FISCAL NOTE

Requested by Legislative Council
12/15/2010

Bill/Resolution No.: HB 1053

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.*

	2009-2011 Biennium		2011-2013 Biennium		2013-2015 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures						
Appropriations						

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

2009-2011 Biennium			2011-2013 Biennium			2013-2015 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts

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 proposed legislation establishes payment criteria for prescribed medications when a generic equivalent exists.

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.*

WORKFORCE SAFETY & INSURANCE
2011 LEGISLATION
SUMMARY OF ACTUARIAL INFORMATION

BILL NO: HB 1053

BILL DESCRIPTION: Dispense as Written Medications

SUMMARY OF ACTUARIAL INFORMATION: Workforce Safety & Insurance, together with its actuarial firm, Bickerstaff, Whatley, Ryan & Burkhalter Consulting Actuaries, has reviewed the legislation proposed in this bill in conformance with Section 54-03-25 of the North Dakota Century Code.

The proposed legislation establishes payment criteria for prescribed medications when a generic equivalent exists.

Rate Level Impact: Based on historical data it is anticipated that the proposed legislation will serve to reduce medical prescription costs by approximately $350,000 per year or less than 0.5 percent of statewide premium rate levels. To the extent that prescription costs are reduced, future rate levels will be adjusted accordingly.

Reserve Level Impact: The proposed legislation should not have a material impact on statewide reserve levels.

DATE: December 15, 2010

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.*

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.*

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.*

Name:	John Halvorson	**Agency:**	WSI
Phone Number:	328-6016	**Date Prepared:**	12/22/2010

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1053

Page 1, line 7, replace "If a" with "For all controlled substances identified at section 19-03.5-01(3), should a"

Page 1, line 7, replace "is" with "be"

Page 1, line 8, replace "not create a life-threatening side effect" with "not produce a verifiable allergic reaction"

Page 1, line 11, after the underscored period, insert "The director or director's designee shall prepare and present a report regarding dispense as written (DAW) utilization information to the legislative council interim workers' compensation review committee during the 2011-12 interim."

Page 1, after line 13, insert:

SECTION 3. EXPIRATION DATE. This Act is effective through July 31, 2013, and after that date is ineffective.

Date: Jan 10, 2011

Roll Call Vote # 1

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 1053

House **House Industry, Business and Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☐ Do Pass ☐ Do Not Pass ☐ Amended ☒ Adopt Amendment

Motion Made By Rep Ruby Seconded By Rep Gruchalla

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser			Representative Amerman		
Vice Chairman Kasper			Representative Boe		
Representative Clark			Representative Gruchalla		
Representative Frantsvog			Representative M Nelson		
Representative N Johnson					
Representative Kreun					
Representative Nathe					
Representative Ruby					
Representative Sukut					
Representative Vigesaa					

Total Yes _____ No _____

Absent _____

Floor Assignment _____

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

Voice vote motion carried

WSI Amendment

Date: Jan 12 - 2011

Roll Call Vote # 1

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 1053

House **House Industry, Business and Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☐ Do Pass ☐ Do Not Pass ☐ Amended ☒ Adopt Amendment

Motion Made By Rep Ruby Seconded By Rep Gruchalla

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	✓		Representative Amerman	✓	
Vice Chairman Kasper	✓		Representative Boe	✓	
Representative Clark		✓	Representative Gruchalla	✓	
Representative Frantsvog	✓		Representative M Nelson	✓	
Representative N Johnson	✓				
Representative Kreun	✓				
Representative Nathe	✓				
Representative Ruby	✓				
Representative Sukut	✓				
Representative Vigesaa	✓				

Total Yes 13 No 1

Absent 0

Floor Assignment _____

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

Adopt.

Date: Jan 12-2011

Roll Call Vote # 2

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 1053

House **House Industry, Business and Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☒ Do Pass ☐ Do Not Pass ☒ Amended ☐ Adopt Amendment

Motion Made By Rep Ruby Seconded By Rep Vigesaa

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser		✓	Representative Amerman		✓
Vice Chairman Kasper		✓	Representative Boe		✓
Representative Clark		✓	Representative Gruchalla	✓	
Representative Frantsvog		✓	Representative M Nelson		✓
Representative N Johnson		✓			
Representative Kreun	✓				
Representative Nathe	✓				
Representative Ruby	✓				
Representative Sukut	✓				
Representative Vigesaa	✓				

Total Yes 6 No 8

Absent 0

Floor Assignment _____

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

Motion failed

VK
1/13/11

11.0239.02001
Title.03000

Adopted by the Industry, Business and Labor Committee

January 12, 2011

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1053

Page 1, line 2, replace "and" with "to provide for a report;"

Page 1, line 2, after "application" insert "; and to provide an expiration date"

Page 1, line 7, replace "If" with "For all controlled substances identified under subsection 3 of section 19-03.5-01, if"

Page 1, line 7, replace "is" with "becomes"

Page 1, line 8, replace "create a life-threatening side effect" with "produce a verifiable allergic reaction"

Page 1, after line 11, insert:

"**SECTION 2. REPORT TO LEGISLATIVE MANAGEMENT.** During the 2011-12 interim, the director of workforce safety and insurance or director's designee shall prepare and present a report regarding dispense as written utilization information to the legislative management."

Page 1, after line 13, insert:

"**SECTION 4. EXPIRATION DATE.** This Act is effective through July 31, 2013, and after that date is ineffective."

Renumber accordingly

Date: Jan 12 - 2011

Roll Call Vote # 3

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 1053

House **House Industry, Business and Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 11.0239.02601 Title #.03000

Action Taken: ☐ Do Pass ☒ Do Not Pass ☒ Amended ☐ Adopt Amendment

Motion Made By Rep Kasper Seconded By Rep. Amerman

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	✓		Representative Amerman	✓	
Vice Chairman Kasper	✓		Representative Boe	✓	
Representative Clark	✓		Representative Gruchalla	✓	
Representative Frantsvog	✓		Representative M Nelson	✓	
Representative N Johnson	✓				
Representative Kreun		✓			
Representative Nathe		✓			
Representative Ruby		✓			
Representative Sukut		✓			
Representative Vigesaa		✓			

Total Yes 9 No 5

Absent 0

Floor Assignment Rep Gruchalla

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

REPORT OF STANDING COMMITTEE

HB 1053: Industry, Business and Labor Committee (Rep. Keiser, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO NOT PASS** (9 YEAS, 5 NAYS, 0 ABSENT AND NOT VOTING). HB 1053 was placed on the Sixth order on the calendar.

Page 1, line 2, replace "and" with "to provide for a report;"

Page 1, line 2, after "application" insert "; and to provide an expiration date"

Page 1, line 7, replace "If" with "For all controlled substances identified under subsection 3 of section 19-03.5-01, if"

Page 1, line 7, replace "is" with "becomes"

Page 1, line 8, replace "create a life-threatening side effect" with "produce a verifiable allergic reaction"

Page 1, after line 11, insert:

"**SECTION 2. REPORT TO LEGISLATIVE MANAGEMENT.** During the 2011-12 interim, the director of workforce safety and insurance or director's designee shall prepare and present a report regarding dispense as written utilization information to the legislative management."

Page 1, after line 13, insert:

"**SECTION 4. EXPIRATION DATE.** This Act is effective through July 31, 2013, and after that date is ineffective."

Renumber accordingly

2011 TESTIMONY

HB 1053

2011 House Bill No. 1053
Testimony before the House Industry, Business & Labor Committee
Presented by: Tim Wahlin, Chief of Injury Services
Workforce Safety & Insurance
January 10, 2011

Mr. Chairman, Members of the Committee:

My name is Tim Wahlin, Chief of Injury Services at WSI. I am here on behalf of WSI to provide information to the Committee to assist in making its determination.

This bill originated through the WSI Interim Legislative Workers' Compensation Review Committee meetings. WSI staff attended those meetings and provided input on the issues discussed.

For several years, WSI staff has been concerned with two issues which, on the surface, appear to be unrelated, but are ultimately related. The first issue is the high utilization of opioid analgesics in North Dakota. That is the basis for another House Bill, HB 1054. The second issue is the high incidence of requests for a brand name medication in lieu of the bioequivalent generic medication. Following more in depth analysis into the types and dosages of these brand name medication overrides, the link between the two becomes clear.

At the present, approximately two percent of all prescriptions covered by WSI are for brand name medications where there is an equivalent generic product. These overrides of WSI's existing generic requirements are referred to as "Dispense as Written" (here after DAW) prescriptions. In order to be dispensed, the prescribing physician must provide some evidence as to why the generic is not preferred.

When comparing WSI's DAW rates of two to three percent to the 0.2 to 0.3 percent as provided to us by the North Dakota Department of Human Services, it begs the question of; why is there such a large difference between the two? The high utilization of the

DAW override was also highlighted in the latest biennial Performance Evaluation completed by Sedgwick CMS.

WSI's data shows this trend mainly occurs in the opioid analgesics category and the rate dramatically increases with the increased dosages of medication being prescribed.

The types of opioid analgesic, as well as the dosage of the medication, appear to correlate with an increased desire for the branded product. As an example, the percentage of requests for the brand name pain medication patch, Duragesic, significantly increases with each subsequent increase in strength. This is also seen with escalating strengths of Percocet, a product which combines acetaminophen with oxycodone, as well as with the highest strengths of MS Contin.

These medications are subject to abuse and are highly valued on the street. With the rising concern of the diversion and abuse of legitimate medications, we feel there is a correlation between this increase in requests for brand name pain medications and the diversion of these products. Interestingly, anecdotal evidence indicates the branded medications often fetch double the price of the generic medications in these illegal markets.

To illustrate, two medications within this category are Soma and Flexeril. Both are skeletal muscle relaxant medications and both are commonly used to treat muscle spasms after an injury. The major difference between the two is that Soma is a medication that is commonly abused, so much so, that the Drug Enforcement Administration (DEA) is contemplating scheduling the medication as a controlled substance. The DAW override rate for carisoprodol (the generic name of the medication) is 7.7 percent. This is in contrast to a more realistic DAW rate of 0.3% for brand name Flexeril. Again, the major difference, one has abuse potential, the other does not. As a result, patients ask for the drug by name and by brand. Patients appear to insist and the physicians appear to comply.

The arguments have long been proffered that generic medications are inferior to the brand name, innovator products. That is simply not true. The Food and Drug Administration has published a guide we have appended to this testimony regarding the myths surrounding generic medications.

These medications are required to have the same active ingredient, strength, dosage form, and route of administration as the respective brand name product. They are manufactured according to the same rigorous standards as the brand name products and have to pass strict bioequivalence testing before being approved for marketing. The variations from tablet to tablet or from capsule to capsule are no different than those seen with the brand name product.

All medications, whether brand name or generic must be manufactured according to the latest Good Manufacturing Practices established by the FDA. And, most importantly, there are no credible reports of any differences in allergic reactions between the brand name product and the generic product.

It is true that generic equivalent medications cost less than the brand. The average branded cost is $257.76 per prescription as compared to the average generic cost of $26.10. This represents a ten fold difference for the same medication. However, the real basis behind this bill is to attempt to minimize the illegal diversion of these dangerous medications to the general North Dakota population.

This is an attempt, which we submit is reasonable, to minimize the diversion of medications that, while necessary and worthwhile, also have the potential to cause extreme harm when diverted and abused.

Also, please note the proposed amendment, attached to this testimony, whereby the terms "create a life-threatening side effect" are being replaced by "produce a verifiable allergic reaction." The reason for this proposed amendment is to allow for a less stringent standard in order to qualify for brand name medications. This proposed

amendment was recommended by the Legislative Workers' Compensation Review Committee.

This concludes my testimony. I would be happy to answer any questions at this time.

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1053

Page 1, line 8, replace "create a life-threatening side effect" with "produce a verifiable allergic reaction"

Renumber accordingly.

From the FDA: Myths and Facts About Generic Drugs

MYTH: Generics take longer to act in the body.

FACT: The firm seeking to sell a generic drug must show that its drug delivers the same amount of active ingredient in the same timeframe as the original product.

MYTH: Generics are not as potent as brand-name drugs.

FACT: FDA requires generics to have the same quality, strength, purity, and stability as brand-name drugs.

MYTH: Generics are not as safe as brand-name drugs.

FACT: FDA requires that all drugs be safe and effective and that their benefits outweigh their risks. Since generics use the same active ingredients and are shown to work the same way in the body, they have the same risk-benefit profile as their brand-name counterparts.

MYTH: Brand-name drugs are made in modern manufacturing facilities, and generics are often made in substandard facilities.

FACT: FDA won't permit drugs to be made in substandard facilities. FDA conducts about 3,500 inspections a year in all firms to ensure standards are met. Generic firms have facilities comparable to those of brand-name firms. In fact, brand-name firms account for an estimated 50 percent of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name.

MYTH: Generic drugs are likely to cause more side effects.

FACT: There is no evidence of this. FDA monitors reports of adverse drug reactions and has found no difference in the rates between generic and brand-name drugs.

Developed by the U.S. Food and Drug Administration

U.S. Food and Drug Administration

Drugs

Facts and Myths about Generic Drugs

Today, 7 in 10 prescriptions filled in the United States are for generic drugs. This fact sheet explains how generic drugs are made and approved and debunks some common myths about these products.

FACT: FDA requires generic drugs to have the same quality and performance as the brand name drugs

- When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency. Some variability can and does occur during manufacturing, for both brand name and generic drugs. When a drug, generic or brand name, is mass produced, very small variations in purity, size, strength and other parameters are permitted. FDA puts limits on how much variability in composition or performance of a drug is acceptable.
- Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name (or reference) product. Generic drugs do not need to contain the same inactive ingredients as the brand product.
- Through review of bioequivalence data, FDA assures that the generic product will perform the same as its respective brand name (or reference) product. This standard applies to all generic drugs, whether immediate or controlled release.
- A generic drug must be shown to be bioequivalent to the reference drug; that is, it must be shown to give blood levels that are very similar to those of the reference product. If blood levels are the same, the therapeutic effect will be the same. In that case, there is no need to carry out a clinical effectiveness study and they are not required.
- All generic manufacturing, packaging and testing sites must pass the same quality standards as those of brand name drugs and the generic products must meet the same exacting specifications as any innovator brand name product. In fact, many generic drugs are made in the same plants as innovator brand name drug products.
- If an innovator of a brand name drug switches drug production to an alternative manufacturing site, or they change formulation of their brand name drug, these companies are held to the same rigorous manufacturing requirements as those that apply to generic drug companies.

FACT: Research shows that generics work just as well as brand name drugs.

- A recent study evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand-name counterparts. There was no evidence that brand-name heart drugs worked any better than generic heart drugs. [Kesselheim et al. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21)2514-2526].

FACT: When it comes to price, there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 80 to 85% lower than the brand name product.

- An IMS National Prescription Audit shows that a typical formulary now charges $6 for generic medications, $29 for preferred branded drugs, and $40 or more for non-preferred branded drugs. [Aitken et al. Prescription drug spending trends in the United States: looking beyond the turning point. Health Aff (Millwood). 2009;28(1):w151-60].
- Independent research has shown that total prescription drug expenditures in the United States only increasec by 4.0% from 2006 to 2007, with total spending rising from $276 billion to $287 billion. This is a sharp decrease from the 8.9% growth rate observed in prescription drug expenditures in 2006. One factor cited as reason for the slowdown is an increase in availability and use of generic drugs [Hoffman et al. Projecting future drug expenditures--2009. Am J Health Syst Pharm. 2009;66(3):237-57].

Recently, some misinformation has raised concerns over generic drugs. Below are some common myths in circulation.

MYTH: FDA lets generic drugs differ from the brand name counterpart by up to 45 percent.

FACT: This claim is false. Anyone who repeats this myth does not understand how FDA reviews and approves generic drugs.

- FDA recently evaluated 2,070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs into a person's body. These studies were submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name was **only 3.5 percent** [Davit et al. Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43(10):1583-97]. Some generics were absorbed slightly more, some slightly less. This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name. In fact, there have been studies in which branded drugs were compared with themselves as well as with a generic. As a rule, the difference for the generic-to-brand comparison was about the same as the brand-to-brand comparison.
- Any generic drug modeled after a single, brand name drug (the reference) must perform approximately the same in the body as the brand name drug. There will always be a slight, but not medically important, level o natural variability – just as there is for one batch of brand name drug to the next.

MYTH: People who are switched to a generic drug are risking treatment failure.

FACT: There is no evidence for this claim. Treatment failures can and do occur when taking generic or brand name drugs. If someone is switched to a generic drug around the time they are relapsing, they may attribute the problem to the switch.

- Many people who have recovered from major depression have a relapse despite continued treatment. These relapses have been shown in trials of long-term therapy. [Byrne and Rothschild. Loss of antidepressant efficacy during maintenance therapy: possible mechanisms and treatments. J Clin Psychiatry. 1998;59(6):279-88].
- Many people who are on a seizure medications will re-experience a seizure despite continued treatment. [Randomised study of antiepileptic drug withdrawal in patients in remission. Medical Research Council Antiepileptic Drug Withdrawal Study Group. Lancet. 1991;337(8751):1175-80].
- A percentage of people will re-experience gastric ulcers, despite an initial, positive response to and continued treatment with prescription strength antacids (cimetidine tablets; http://dailymed.nlm.nih.gov/dailymed /drugInfo.cfm?id=8131#nlm34067-[1]9).

MYTH: Generic drugs cost less because they are inferior to brand name drugs.

FACT: Generic manufacturers are able to sell their products for lower prices, not because the products are of lesser quality, but because generic manufacturers generally do not engage in costly advertising marketing and promotion, or significant research and development.

- When a brand name drug comes off patent and generic drugs are permitted to compete with the brand name drug, the generic products compete by offering lower prices. Unlike the manufacturers of brand name drugs, generic drug companies do not have significant expenses to recoup for advertising, marketing and promotion or research and development activities.

MYTH: There are quality problems with generic drug manufacturing. A recent recall of generic digoxi (called Digitek) shows that generic drugs put patients at risk.

FACT: FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs – generic and brand name – are held.

- In March 2008, FDA performed a scheduled inspection of the Actavis production facility and identified product that were not manufactured to required specifications over a period of time extending back to the year 2006. Included in this list of products was one particular lot of Digitek.
- Actavis detected a very small number of oversized tablets in this lot (specifically, 20 double-sized tablets in a sample of approximately 4.8 million tablets).
- Although Actavis attempted to remove the affected Digitek tablets through visual inspection, FDA determined that this method of removal was inadequate to assure the product's quality and consistency in accordance with the current Good Manufacturing Practice (cGMP) regulations.
- Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that **ALL** potentially affected lots of Digitek tablets have been recalled. In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.
- FDA takes action whenever we find that a drug manufacturer is not following cGMPs. Over the last ten years, FDA has taken enforcement action against many brand name and generic firms for failing to meet FDA manufacturing quality standards.

MYTH: FDA's enforcement action against the generic drug company Ranbaxy demonstrates quality problems with imported generic drugs.

FACT: FDA's action demonstrates FDA's commitment to safe generic drugs.

- FDA has taken several regulatory actions against the generic drug manufacturer Ranbaxy, on the basis of problems at two of Ranbaxy's manufacturing facilities. Ranbaxy is one of many non-U.S. based generic and brand drug manufacturers.
- On Sept. 2008, the FDA issued two warning letters and instituted an Import Alert barring the entry of all finished drug products and active pharmaceutical ingredients from Ranbaxy's Dewas, Paonta Sahib and Batamandi Unit facilities due to violations of U.S. cGMP requirements. That action barred the commercial importation of 30 different generic drugs into the United States and remains in effect today (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149532.htm[2]).
- Subsequent FDA investigations also revealed a pattern of questionable data raising significant questions regarding the reliability of certain generic drug applications from Ranbaxy.
- To address the allegedly falsified data, the FDA has invoked its Application Integrity Policy (AIP) against the Paonta Sahib facility. When the AIP is implemented, the FDA stops all substantive scientific review of any nev or pending drug approval applications that contain data generated by the Paonta Sahib facility. This AIP covers applications that rely on data generated by the Paonta Sahib facility only.
- In the fiscal year 2008, FDA performed 2,221 drug-related inspections. FDA takes many different enforcemer actions, not just against generic drug manufacturers. For a list of enforcement actions in the fiscal year 2008, see http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129812.pdf[3]. It is FDA's responsibility to ensure that the drugs people use, generic or brand name, are safe and effective.

MYTH: Brand name drugs are safer than generic drugs.

FACT: FDA receives very few reports of adverse events about specific generic drugs. Most reports of adverse events are related to side effects of the drug ingredient itself.

- The monitoring of postmarket adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. In most cases, reports of adverse events generally describe a **known reaction** to the active drug ingredient.

MYTH: FDA does not care about concerns over generic drugs.

FACT: FDA is actively engaged in making all regulated products – including generic drugs – safer.

- We are aware that there are reports noting that some people may experience an undesired effect when switching from brand name drug to a generic formulation or from one generic drug to another generic drug. Evidence indicates that if problems with interchangeability of drug formulations occur, they occur only for a very small subset of people.
- FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. The Agency does not have the resources to perform independent clinical studies, and lacks the regulatory authority to require industry to conduct such studies. FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises.

Links on this page:

1. http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=8131#nlm34067-
2. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149532.htm
3. http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129812.pdf

Selected Dispense as Written Rates
Fiscal Year 2010

Category	Medication	DAW1 Rate
Anti-Anxiety Agents	Xanax 0.25mg	14.5%
	Tranxene-T 7.5mg	96.0%
Antidepressants	Prozac 20mg	4.9%
	Prozac 40mg	71.1%
	Zoloft 100mg	5.4%
Hypnotics	Ambien 10mg	6.8%
Opioid Analgesics	Duragesic 25mcg	2.7%
	Duragesic 50mcg	6.1%
	Duragesic 75mcg	8.6%
	Duragesic 100mcg	20.5%
	Dilaudid 2mg	4.7%
	Dilaudid 4mg	4.2%
	MS Contin 15mg	1.4%
	MS Contin 30mg	13.9%
	MS Contin 60mg	9.3%
	Ultram 50mg	2.1%
	Percocet 5-325mg	1.2%
	Percocet 10-325mg	3.6%
	Percocet 10-650mg	7.3%
	Tylox 5-500mg	21.0%
	Tylenol #3	1.9%
	Fioricet with Codeine	52.5%
	Lorcet 10/650mg	12.7%
	Vicodin 5/500mg	0.2%
	Darvocet N-100	7.0%
	Vicoprofen	4.3%
	Ultracet	11.3%

Anticonvulsants	Klonopin 0.5mg	2.4%
	Klonopin 1mg	8.8%
	Klonopin 2mg	5.5%
	Neurontin 100mg	4.2%
	Neurontin 300mg	2.0%
	Neurontin 400mg	4.6%
	Neurontin 600mg	1.5%
	Neurontin 800mg	6.6%
Muscle Relaxants	Soma 350mg	7.7%
	Flexeril 10mg	0.3%

NORTH DAKOTA
CHAMBER of COMMERCE

Testimony of Bill Shalhoob
North Dakota Chamber of Commerce
HB 1053
January 10, 2011

Mr. Chairman and members of the committee, My name is Bill Shalhoob and I am here today representing the North Dakota Chamber of Commerce, the principal business advocacy group in North Dakota. Our organization is an economic and geographical cross section of North Dakota's private sector and also includes state associations, local chambers of commerce, development organizations, convention and visitors bureaus and public sector organizations. For purposes of this and all Workforce Safety hearings we are also representing five local chambers with over 5,000 members and seven employer associations. I have attached a list of those parties to my testimony for this hearing only. As a group we stand in support of HB 1053 and urge a do pass from the committee on this bill

Generic alternatives to name brand drugs have been proven to be acceptable alternatives and as long as they will not create a life threatening situation the savings from the lower cost should be realized.

Thank you for the opportunity to appear before you today in support of HB 1053. I would be happy to answer any questions.

PO Box 2639 Bismarck, ND 58502 Toll-free: 800-382-1405 Local: 701-222-0929 Fax: 701-222-1611
www.ndchamber.com ndchamber@ndchamber.com

NDPhA
NORTH DAKOTA PHARMACISTS ASSOCIATION

House Industry, Business and Labor Committee
Hearing – HB 1053
January 10, 2011
Rep. Keiser – Chairman

Good Morning Chairman Keiser and members of the committee. For the record, my name is Mike Schwab, the Executive Vice President of the ND Pharmacists Association. I am here today to offer comments and support for HB 1053.

Policies such as the ones noted in this bill are becoming standard in general insurance plans and Medicare Part D plans. The market place is also seeing more "Generic First Programs" being developed and marketed.

From a pharmacist's perspective, it is less expense to stock generic medications compared to the overhead costs associated with having a large stock of brand name medications.

I felt is was noteworthy and wanted to point out, starting this year and going through 2014, we are going to see an unprecedented number of brand name drugs going off patient. There will be a great number of generics entering the market place over the next few years.

Thank you for your time and attention. I would be more than happy to try and answer any questions you might have.

Respectfully,

Mike

Mike Schwab
EVP - NDPhA

ND AFL- CIO David Kemnitz; President

House IBL January 10, 2011

HB 1053

The ND AFL-CIO is opposed to the idea that something is better than proven pharmaceutical treatment if it "would not create a life-threatening side effect".

The treating physician's decision(s) should not be over-ruled by an insurance company looking to save money.

The dispute resolution process indicated on Page 1 lines 10 &11 should be cause for alarm in that having to resort to a process that could take days and months to resolve a pharmaceutical decision could be "life threatening" in itself. A copy of NDCC 65-02-20 is included with this testimony.

HB 1053 lines 10 & 11 1-10-11

65-02-20. Organization to establish managed care program. The organization shall establish a managed care program, including utilization review and bill review, to effect the best medical solution for an injured employee in a cost-effective manner upon a finding by the organization that the employee suffered a compensable injury. The program shall operate according to guidelines adopted by the organization and shall provide for medical management of claims within the bounds of workforce safety and insurance law. Information compiled and analysis performed pursuant to a managed care program which relate to patterns of treatment, cost, or outcomes by health care providers are confidential and are not open to public inspection to the extent the information and analysis identify a specific health care provider, except to the specific health care provider, organization employees, or persons rendering assistance to the organization in the administration of this title. If an employee, employer, or medical provider disputes a managed care decision, the employee, employer, or medical provider shall request binding dispute resolution on the decision. The organization shall make rules providing for the procedures for dispute resolution. Dispute resolution under this section is not subject to chapter 28-32 or section 65-01-16. A dispute resolution decision under this section requested by a medical provider concerning payment for medical treatment already provided or a request for diagnostic tests or treatment is not reviewable by any court. A dispute resolution decision under this section requested by an employee is reviewable by a court only if medical treatment has been denied to the employee. A dispute resolution decision under this section requested by an employer is reviewable by a court only if medical treatment is awarded to the employee. The dispute resolution decision may be reversed only if the court finds that there has been an abuse of discretion in the dispute resolution process. Any person providing binding dispute resolution services under this section is exempt from civil liability relating to the binding dispute resolution process and decision.