

2009 SENATE HUMAN SERVICES

SB 2164

2009 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. SB 2164

Senate Human Services Committee

Check here for Conference Committee

Hearing Date: 1-21-09

Recorder Job Number: 7438, 7469

Committee Clerk Signature

Mary K. Monson

Minutes:

Senator J. Lee opened the hearing on SB 2164 relating to optometrists dispensing therapeutic pharmaceutical agents.

Senator Tim Flakoll, Dist. 44, introduced SB 2164 and spoke in favor of it. Attachment #1.

Senator Dever wanted to know if the combination of the contact and medication is done at the factory.

Sen. Flakoll said it would not be done locally and said others would address it.

Rep. Lois Delmore, Dist. 43, stated that medical technology is moving along and as a state we need to make sure we do the same thing. She encouraged support for SB 2164.

Nancy Kopp, ND Optometric Association, testified in favor of SB 2164. Attachment #2.

Sharon D'Agostino, Johnson and Johnson, was present because Vistakon is one of their operating companies and the manufacturer of the first lens coming out in this category. She introduced Damian May from Vistakon to provide the technical background on the product.

Damian M. May, Vistakon, spoke about the product manufactured by their company and how it impacts the practice statute in ND. Attachment #3.

Senator J. Lee asked if this only pertained to soft lenses.

Mr. May said at this time it did.

Senator Dever asked if there was any potential for abuse.

Mr. May said it was highly unlikely for abuse with this category of drug.

Senator J. Lee asked about the allergy issues at night.

Mr. May explained that this type of medication really only works locally. Other allergy symptoms would be treated with something else.

Senator Erbele asked if it is only anti allergy drugs being considered now.

Mr. May said that is the drug that is in late development right now. There are others in early development.

Senator Heckaman asked about the length of time these can be used.

Mr. May said the studies they are pursuing are supporting the fact that the product could be used year round.

Mr. May said they are in the pre-market phase and do not have approval from the FDA to move forward with the marketing so are not able to comment on the specific pricing.

There was discussion that it would have to be priced competitively. The insurance aspect was also discussed. As it comes out of the FDA it will be brought to market as prescription drug product. From an insurer and reimbursement perspective, it causes some interesting gray areas.

Dr. Brian Beattie, an Optometrist, spoke in favor of SB 2164. Attachment #4.

Dr. Amy Fleck, ND State Board of Optometry, testified in favor of SB 2164. The state board feels this bill reflects new technology available to the citizens of ND. They believe that this bill does not represent an expansion of the practice act.

Howard Anderson, Executive Director of the ND State Board of Pharmacy, spoke in favor of SB 2164. Attachment #5.

Bruce Levy, Executive Director of the ND Society of Eye Physicians and Surgeons, testified in support of amendments they are proposing to SB 2164.

Senator Dever asked if ophthalmologists have the same issue with dispensing medication.

Mr. Levy said there is a statute in place that would allow an ophthalmologist to dispense these lenses as well.

There was no opposing testimony.

There was no neutral testimony.

Senator Heckaman asked Ms. Kopp why she was opposing the amendments by Mr. Levy.

Ms. Kopp said they felt section 1 did specifically list the prescriptive authority under diagnostic and therapeutic pharmaceutical agents. They have a scope of practice and the board regulates that.

Senator J. Lee closed the hearing on SB 2164.

Job # 7469

Senator J. Lee opened SB 2164 for committee work.

There was discussion that this was just combining two things they can already do.

Senator J. Lee recognized Ms. Kopp.

Ms. Kopp explained that the purpose of the bill is to (1) allow optometrists to dispense therapeutic pharmaceutical agents. Dispense means that they can continue to sample. (2) to address the new product which is a combination of a contact lens and a therapeutic pharmaceutical agent. It's allowing them to dispense drugs through the contact lens.

Senator Heckaman moved a **Do Pass**.

Seconded by **Senator Erbele**.

Roll call vote 6-0-0. Motion passed.

Carrier is **Senator Erbele**.

Date: 1-21-09

Roll Call Vote #: 1

2009 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. SB 2164

Senate Human Services Committee

Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass Do Not Pass Amended Rerefer to Appropriations
 Adopt Amendment Reconsider

Motion Made By Sen. Heckaman Seconded By Sen. Erbele

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee, Chairman	✓		Senator Joan Heckaman	✓	
Senator Robert Erbele, V.Chair	✓		Senator Richard Marcellais	✓	
Senator Dick Dever	✓		Senator Jim Pomeroy	✓	

Total (Yes) 6 No 0

Absent 0

Floor Assignment Sen. Erbele

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

REPORT OF STANDING COMMITTEE

SB 2164: Human Services Committee (Sen. J. Lee, Chairman) recommends DO PASS
(6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2164 was placed on the
Eleventh order on the calendar.

2009 HOUSE HUMAN SERVICES

SB 2164

2009 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. 2164

House Human Services Committee

Check here for Conference Committee

Hearing Date: March 3, 2009

Recorder Job Number: No recording.

Committee Clerk Signature

Vicky Crabtree

Minutes:

Chairman Weisz opened the hearing on SB 2164.

Sen. Tim Flakoll, District 44 Fargo sponsored and introduced the bill: See Testimony #1.

Chairman Weisz: Currently can dispense the drugs?

Sen. Flakoll: Can dispense separately not combined together.

Rep. Delmore, District 43 Grand Forks: Voiced support of bill.

Nancy Kopp, representing the ND Optometric Association: Testified in support. **See**

Testimony #2.

Chairman Weisz: Concerned if language and definition of dispensing

Rep. Porter: Page 2, Subsection 2 any school that is now not doing what is in

Nancy Kopp: Varying scopes of practices.

Rep. Porter: Wonder if language still needs to be in there.

Sharon D'Agostino, Senior Director, State Government Affairs-Johnson & Johnson Inc.:

Testified in support. **See Testimony #3.**

Chairman Weisz: How long are contacts good for?

Sharon D'Agostino: Daily use.

Dr. Amy Fleck, optometrist: Voiced support of bill on behalf of optometrist board.

Dr. Brian Beattie, optometrist: Testified in support. **See Testimony #4.**

Rep. Nathe: Do you see this as a preferred way?

Dr. Beattie: I would.

Howard Anderson, Executive Director ND State board of Pharmacy: Testified in support.

See Testimony #5.

Rep. Hofstad: In Section 2, that seems to be a broad statement and is that a concern for you?

Howard Anderson: I don't think it expands.

Mike Schwab, Ph A: Voiced support of bill.

NO OPPOSITION.

Chairman Weisz closed the hearing.

2009 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. 2164

House Human Services Committee

Check here for Conference Committee

Hearing Date: March 3, 2009

Recorder Job Number: 10109

Committee Clerk Signature

Nicky Crabtree

Minutes:

Chairman Weisz: Let's take up 2164.

Rep. Conrad: Motion Do Pass.

Rep. Porter: Second.

Roll Call Vote: 13 yes, 0 no, 0 absent.

MOTION CARRIED DO PASS.

BILL CARRIER: Rep. Conrad.

Date: 3-3-07

Roll Call Vote #:

2009 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2164

House HUMAN SERVICES Committee

Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass Do Not Pass Amended

Motion Made By Rep. Conrad Seconded By Rep. Porter

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN ROBIN WEISZ	✓		REP. TOM CONKLIN	✓	
VICE-CHAIR VONNIE PIETSCH	✓		REP. KARI L CONRAD	✓	
REP. CHUCK DAMSCHEN	✓		REP. RICHARD HOLMAN	✓	
REP. ROBERT FRANTSVOG	✓		REP. ROBERT KILICHOWSKI	✓	
REP. CURT HOFSTAD	✓		REP. LOUISE POTTER	✓	
REP. MICHAEL R. NATHE	✓				
REP. TODD PORTER	✓				
REP. GERRY UGLEM	✓				

Total (Yes) 13 No 0

Absent 0

Bill Carrier Rep Conrad

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

motion carried DO PASS

REPORT OF STANDING COMMITTEE

SB 2164: Human Services Committee (Rep. Welsz, Chairman) recommends DO PASS
(13 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2164 was placed on the
Fourteenth order on the calendar.

2009 TESTIMONY

SB 2164

SB 2164

Madam Chairman

For the record I am Tim Flakoll of District 44 of Fargo.

Technology is a wonderful thing that helps save lives and improves the quality of our lives.

Some bills we get are in response to technology and some are forward thinking and allow us to address emerging technological improvements so that we are ready ~~as a state~~ to use them. *when they hit the market*

SB 2164 opens up the optometrists practice act to allow us to use improved technology and methodology that will improve and simplify people's lives.

Chairman Lee

There is currently a contact lens product that is in the ~~late~~ *final* stages of ~~development and it poised to be released.~~ *pre release* It involves a process whereby they embed contact lenses with allergy medications.

Currently optometrists are permitted to sell and dispense both contact lens and allergy medications. The bill before you asks that they be allowed to sell and dispense them as a combined product.

The product would have a number of advantages.

- 1) Convenience –
- 2) Accuracy – 2 drops 3 times a day or 3 drops 2 times a day.
- 3) No worry about the drops missing your eye, splatter or spillage or contaminated tips of the dropper.
- 4) Don't have to worry about forgetting to bring your meds with you as ^{with this new product} they are in the contact lenses - translation if you can't see you are not getting the prescription.
- 5) More uniform release of product. Not the big spikes that can occur with products that are delivered once, twice or three times a day - - Much like an I.V. infusion that you might get in the hospital these products could provide a more uniform release pattern.

Simple example:

When we were kids there was one general kind of band aid ^{brand} adhesive strip.

So you would apply the antibiotic to the area or band aid and then apply it. Then some clever person combined the antibiotic into the telfa pad of the band aid and ~~V~~olla they was an all-in-one product.

To my way of thinking that is essentially what we have here. To me it is that simple.

Industry and scientific experts here who will testify after me ~~to~~ but I would be happy to stand for any questions.

SB 2164

Good Morning Madam Chair and Members of the Committee,

For the record, my name is Nancy Kopp. I represent the North Dakota Optometric Association.

I appear before you in support of SB 2164 and do understand there may be proposed amendments forthcoming, however after review we would oppose.

The NDOA represents 128 out of approximately 150 practicing optometrists in North Dakota and provides eyecare services in 39 out of 53 counties.

I will be brief in my comments, as those to follow me, are more qualified than I, to fully explain the therapeutic contact lens bill, being introduced and its clinical application.

1. The revisions do not enhance the practice of optometry in North Dakota, rather address the dispensing and sampling of drugs currently within prescriptive authority. The definition of dispensing seemed a little vague and does not include, specifically a sale.

2. The NDOA, prior to the bill's introduction, garnered support of:
 1. ND Pharmacists Association
 2. ND State Board of Pharmacy
 3. ND State Board of Optometry
 4. Communication with the ND Medical Association.

I urge your support of SB 2164 and a do pass recommendation, to allow optometrists to take advantage of the most current technologies available in the delivery of eyecare services to North Dakotans.

Testimony to Support Senate Bill 2164 That Amends Title 43, Chapter 13, Section 13-01 to Exempt Optometrist In-Office Dispensing of Ophthalmic Devices, Including Contact Lenses, That Are Classified by The FDA As Drug

Submitted on behalf of Vistakon by Damian M. May, Pharm.D. MBA – Director of Managed Markets

New technology, in the form of contact lenses that emit therapeutic pharmaceutical agents, is emerging to treat eye disorders. Under current US state optometry and pharmacy statutes, these combination contact lens/drug products would be available immediately for prescription and dispensing by vision care professionals in 34 states. North Dakota is a state that requires modification of existing statutes (43-13-01) to enable optometry professionals to dispense this technology to their patients.

- This issue is about an emerging technology, not a single product. The technology is described as using a contact lens as a drug delivery device. This device will provide therapeutic pharmaceutical agent directly into the eye.
- Optometrists, where the majority of patients seek vision care, would not be able to dispense these products to their patients under current law.
- Optometrists can currently prescribe and dispense contact lenses in their practice.
- Optometrists, as per statute, are able to prescribe therapeutic pharmaceutical agents for their patients.
- Pharmacies in the State of North Dakota are not explicitly prohibited from dispensing contact lenses, however most pharmacies elect not to for various reasons. Nothing in this language would prohibit pharmacy from dispensing this type of product if they chose to do so.
- It is important to note that this language change affects only those ophthalmic devices with pharmaceutical agents that are within existing scope of practice. Nothing in this legislation alters the scope of practice of the profession.
- If no language change is enacted in the statute, patients will have greatly limited options to have these contact lenses dispensed. This will create a great barrier to patients seeking eye care.
- Nothing in this law circumvents the authority of the FDA and its approval of drug products. This law is intended to ensure that these products are available to the people of North Dakota once approved by the FDA.
- The first of these products combines a vision correction device (Acuvue Contact Lens) with an over-the-counter anti-allergy pharmaceutical agent (ketotifen). When combined together, there is a restricted ability for patients to access this technology through their eye doctor.
- Proposed language would craft an exemption for therapeutic contact lenses (contact lenses with a therapeutic pharmaceutical agent incorporated) to the existing prohibition for dispensing of pharmaceutical agents. The exemption would explicitly address "ophthalmic devices, including contact lenses, that are classified by the FDA as a drug" (43-13-01). With no change to the statute, optometrists would still be able to prescribe (while not dispense) this technology.
- This language change strictly addresses the issue of dispensing (and sale) of these products. The issues of prescriptive authority and in-office administration are addressed elsewhere in the statute.
- Many states have already passed similar bills to enable this practice (California, Minnesota, Ohio, etc.). Similar bills will be introduced early in the '09 legislative session in another 6-8 states. A bill is currently circulating in the State of New York.
- The surrounding states (Minnesota, South Dakota and Montana) all currently have statutes that allow in-office dispensing of this type of product for the optometric and medical professions.

SB 2164

Good Morning Madam Chair and Members of the Committee:

My name is Dr. Brian Beattie and I am an optometrist. I have been practicing in Bismarck for the last 28 years.

I support SB 2164 without amendments.

As a practicing optometrist, I am licensed to prescribe certain medications in the form of pills or eye drops. The medications I can prescribe are spelled out in our practice act. We are asking for no change in this list of drugs, that we as optometrists are allowed, by state law, to prescribe.

The new technology that bill SB 2164 references, is a new way of delivering a medication to the eye. The vehicle being used is a contact lens. North Dakota optometrists are experts in the application and fitting of contact lenses. Optometrists currently prescribe the vast majority of contact lenses worn in the state.

The combination of a contact lens with a drug, both items that North Dakota optometrists handle daily with great effectiveness, is a logical modification to our practice act. I do not think this can be seen as an expansion of our allowed treatments, but rather a change to keep up with the changes technology brings.

This new technology needs to be available to your constituents, the citizens of North Dakota, to allow them the very best medical care. A drug administered by way of a contact lens is like putting eye drops in continuously around the clock. It will greatly enhance treatment of certain infections and inflammations, that require aggressive drug therapy. The effectiveness of a treatment depends on how well a patient complies with that treatment. Putting drops in every 2 hours or twice in the middle of the night, is not the easiest thing for any of us to accomplish. Having your doctor put in a contact lens that you have to do nothing with, is a much better treatment for the patient compliance.

I encourage a do pass recommendation from this committee. This will insure that the best eye care continues to be available to the residents of North Dakota. The good news is that this involves treatment modalities that are currently approved for, and widely used by North Dakota optometrists. This is not an expansion of our practice act, but merely a step to keep up with changes in technology.

Respectfully;

Brian C. Beattie, O.D.



BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

OFFICE OF THE EXECUTIVE DIRECTOR

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William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

**SENATE BILL #2164 - SENATE HUMAN SERVICES COMMITTEE
9:00 AM - WEDNESDAY - JANUARY 21, 2009
RED RIVER ROOM**

Chairperson Lee, members of the Senate 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 to you today.

The Optometrists contacted me sometime ago indicating that they were planning on introducing a Bill that would allow them to dispense and sell contact lenses which contained drugs for therapeutic purposes. I discussed this with the Board of Pharmacy and they felt that since Optometrists now sell most of the contact lenses in the state, that this was perhaps a logical addition to their practice.

Obviously, there are some additional risks whenever a drug is introduced, as the drug delivered through the eye may affect the patient systemically, may interact with other drugs that the patient is also taking and may affect other conditions the patient has as well. We all remember when the drug Timolol was first introduced as an eye drop and began being prescribed and used by practitioners without considering the cardiac condition of the patient and there were some negative consequences in the early days of that release. Optometrists are aware through their prescribing of topical steroids in the eye that these drugs affect many body functions, even though they may be delivered through the eye. With proper training and consideration of the whole patient, these products should be safe for the Optometrists to use.

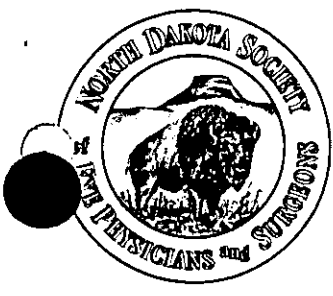
I believe there are going to be some suggested amendments to make it clear that the dispensing of free samples by an Optometrist is limited to the drugs that they would otherwise use in their practice and does not extend to samples beyond their usual scope of practice and prescription drug use. This was their intent anyway, I am sure.

The Board of Pharmacy is generally in support of the concept of the Optometrists being able to dispense and sell the drug eluting contact lenses.

#6

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**Testimony for Amendments on Senate Bill No. 2164
Senate Human Services Committee
January 21, 2009**

Madam Chair Lee and members of the Committee. I'm Bruce Levi and I serve as the Executive Director of the North Dakota Society of Eye Physicians and Surgeons, as well as the North Dakota Medical Association. The North Dakota Society of Eye Physicians and Surgeons is the state professional membership for our state's Eye MDs or ophthalmologists, affiliated with the American Academy of Ophthalmology. The North Dakota Medical Association is the professional membership organization for all North Dakota physicians, residents, and medical students.

While the NDSEPS does not oppose optometrists dispensing therapeutic contact lenses or drug samples, both NDSEPS and NDMA believe the proposed language is inappropriately broad, that could be construed in the future, depending on the development of future ophthalmic devices, to exceed the current scope of practice of optometrists. The contact lenses and other ophthalmic devices referred to in this bill are not yet on the market and it would seem, in our view, to be premature to enact broad language. We propose an amendment to SB No. 2164 that would more appropriately describe the preference of optometrists to sell therapeutic contact lenses and provide samples, without raising the specter of a future disagreement.

Currently, the Optometry Practice Act does not allow an optometrist to dispense "therapeutic pharmaceutical agents" as defined in section 43-13-01. SB 2164 would continue to prohibit such dispensing, but would provide exceptions using the following language:

3. An optometrist may not dispense therapeutic pharmaceutical agents, except an optometrist may:
 - a. Provide a patient a drug sample at no cost to the patient; or
 - b. Sell contact lenses or ophthalmic devices that are classified by the federal food and drug administration as a drug.

Our proposed amendment would clarify that optometrists could dispense a drug sample of any pharmaceutical agent the optometrist is certified to prescribe or administer. Our proposed amendment would also clarify that optometrists could sell therapeutic contact lenses, as they are proposing under this bill, without the broad language authorizing the sale of “ophthalmic devices that are classified by the FDA as a drug.” We are not aware of what other ophthalmic devices might in the future meet this description and believe a specific authorization for therapeutic contact lenses as defined in our proposed amendment is a reasonable approach that clarifies the language and meets the intent of the bill sponsors in authorizing optometrists to provide drug samples and sell therapeutic contact lenses.

We offered our amendment in a mutual exchange of views regarding the bill, and the response was that our amendment is “redundant.” From a basis of statutory construction and my experience, in my view the proposed amendment is not legally redundant. The disagreement we have over the legal language is something I believe we could work out, or if the clarification we receive is that our amendment truly is redundant, then that could be reflected in the record.

On behalf of the North Dakota Eye Physicians and Surgeons and the North Dakota Medical Association, we urge the Committee to adopt our proposed amendments to SB No. 2164.

PROPOSED AMENDMENT TO SENATE BILL NO. 2164

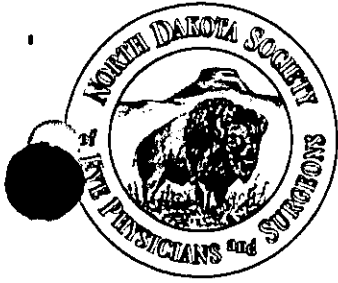
(Page 1, line 19, overstrike "~~locally~~" and insert immediately thereafter "topical".)

Page 2, line 22, after "sample" insert "of any pharmaceutical agent the optometrist is authorized to prescribe or administer under subsection 2"

Page 2, line 23, replace "contact lenses or ophthalmic devices" with "a therapeutic contact lens" and replace "are" with "is"

Page 2, line 24, after the underscored period insert "For purposes of the section, "therapeutic contact lens" means a vision correction device that contains a topical therapeutic pharmaceutical agent listed in section 43-13-01 or contains a nonprescription drug that is commercially available."

Renumber accordingly



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What is an Eye MD?

An Eye MD is an ophthalmologist — a medical doctor who specializes in eye and vision care. Eye MDs are specially trained to provide the full spectrum of eye care, from prescribing glasses and contact lenses to complex and delicate eye surgery. Many Eye MDs are also involved in scientific research into the causes and cures for eye diseases and vision problems. As medical doctors, Eye MDs are available 24 hours a day for the emergency care of the people of North Dakota.

Eye MD Training

In addition to four years of college, four years of medical school and one year of internship, every Eye MD spends a minimum of three years of residency (hospital-based training) in ophthalmology. During residency, Eye MDs receive special training in all aspects of eye care, including prevention, diagnosis, and medical and surgical treatment of eye conditions and diseases.

Often, an Eye MD spends an additional one or two years training in a subspecialty e.g. retina, glaucoma, or pediatric ophthalmology.

Eye MDs and Optometry

The distinction between an Eye MD and optometrist is a frequent source of confusion.

An optometrist receives a Doctor of Optometry (OD) degree and is licensed to practice optometry, not medicine. Optometric training consists of 3 to 4 years of college and 4 years of an optometric college. Their training is significantly shorter and of less intensity than an Eye MD

Eye MD Mission Statement

"We dedicate ourselves to enhancing the quality of life for every individual we treat by helping each to see his or her best and by preserving and protecting our patients' vision and eye health throughout life. We are committed to responding compassionately to our patients' individual needs and to advancing the highest standards of comprehensive eye care."— American Academy of Ophthalmology

SB 2164

House Human Services Committee –
Tuesday, March 3, 2009 - 10:00 a.m. Fort Union Room

Robin Weisz – Chairman, Vonnie Pietsch – Vice chair, Tom Conklin, Kari Conrad, Chuck Damschen,, Robert Frantsvog, Curt Hofstad, Richard Holman, Robert Kilichowski, Mike Nathe, Todd Porter, Louise Potter, and Gerry Uglem.

Chairman Weisz and members of the House Human Services committee.

For the record I am Senator Tim Flakoll of District 44 of Fargo.

Technology is a wonderful thing that helps save lives and improves the quality of our lives.

Some bills we get are in response to technology and some are forward thinking and allow us to address emerging technological improvements so that we are ready as a state to use them.

SB 2164 opens up the optometrists practice act to allow us to use improved technology and methodology that will improve and simplify people's lives.

There is currently a contact lens product that is in the late stages of development and it poised to be released. It involves a process whereby they embed contact lenses with allergy medications.

Currently optometrists are permitted to sell and dispense both contact lens and allergy medications. The bill before you asks that they be allowed to sell and dispense them as a combined product.

The product would have a number of advantages.

- 1) Convenience –
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Simple example:

When I was a kid there was one general kind of band aid adhesive strip.

So you would apply the antibiotic to the area or band aid and then apply it. Then some clever person combined the antibiotic into the telfa pad of the band aid and viola (wa-la) they had an all-in-one product.

To my way of thinking that is essentially what we have here. To me it is that simple.

Industry and scientific experts here who will testify after me by I would be happy to stand for any questions.

#2

SB 2164

Good Morning Mr. Chairman and Members of the Committee.

For the record, my name is Nancy Kopp. I represent the North Dakota Optometric Association.

I appear before you in support of SB 2164.

The NDOA represents 128 out of approximately 150 practicing optometrists in North Dakota and provides eyecare services in 39 out of 53 counties.

The revisions do not enhance the practice of optometry in North Dakota, rather address the dispensing and sampling of drugs currently within prescriptive authority. The definition of dispensing seemed a little vague and does not include, specifically a sale.

Optometrists in North Dakota were granted prescriptive authority of diagnostic pharmaceutical agents in 1979 by the Legislature and of therapeutic pharmaceutical agents in 1987. Please refer to current statute cited on lines 12-23 of the bill.

I would like to bring your attention to the fact that prior to granting the prescriptive authority, optometrists were required to obtain an additional 100 hours of instruction and clinical application. See lines 12-15, Page 2 of SB 2164.

I will be brief in my comments, as those to follow me, are more qualified than I, to fully explain the therapeutic contact lens bill, being introduced and its clinical application.

The NDOA, prior to the bill's introduction, garnered support of:

1. ND Pharmacists Association
2. ND State Board of Pharmacy
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I urge your support of SB 2164 and a do pass recommendation, to allow optometrists to take advantage of the most current technologies available in the delivery of eyecare services to North Dakotans.



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Submitted on behalf of Vistakon by Sharon D'Agostino – Senior Director, State Government Affairs – Johnson & Johnson, Inc.

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- This issue is about an emerging technology, not a single product. The technology is described as using a contact lens as a drug delivery device. This device will provide therapeutic pharmaceutical agent directly into the eye.
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- It is important to note that this language change affects only those ophthalmic devices with pharmaceutical agents that are within existing scope of practice. Nothing in this legislation alters the scope of practice of the profession.
- If no language change is enacted in the statute, patients will have greatly limited options to have these contact lenses dispensed. This will create a great barrier to patients seeking eye care.
- Nothing in this law circumvents the authority of the FDA and its approval of drug products. This law is intended to ensure that these products are available to the people of North Dakota once approved by the FDA.
- The first of these products combines a vision correction device (Acuvue Contact Lens) with an over-the-counter anti-allergy pharmaceutical agent (ketotifen). When combined together, there is a restricted ability for patients to access this technology through their eye doctor.
- Proposed language would craft an exemption for therapeutic contact lenses (contact lenses with a therapeutic pharmaceutical agent incorporated) to the existing prohibition for dispensing of pharmaceutical agents. The exemption would explicitly address "ophthalmic devices, including contact lenses, that are classified by the FDA as a drug" (43-13-01). With no change to the statute, optometrists would still be able to prescribe (while not dispense) this technology.
- This language change strictly addresses the issue of dispensing (and sale) of these products. The issues of prescriptive authority and in-office administration are addressed elsewhere in the statute.
- Many states have already passed similar bills to enable this practice (California, Minnesota, Ohio, etc.). Similar bills will be introduced early in the '09 legislative session in another 6-8 states. A bill is currently circulating in the State of New York.
- The surrounding states (Minnesota, South Dakota and Montana) all currently have statutes that allow in-office dispensing of this type of product for the optometric and medical professions.

4

Re: SB 2164

Dear Sirs and Madams;

My name is Dr. Brian Beattie and I am an optometrist. I have been practicing in Bismarck for the last 28 years.

I support SB 2164 without amendments.

As an optometrist I am licensed to prescribe certain medications in the form of pills or eye drops. The medications I can prescribe are spelled out in our practice act. We are asking for no change in this list of drugs that we, as optometrists, are allowed to prescribe.

The new technology that bill SB 2164 references is a new way of delivering a medication to the eye. The vehicle being used is a contact lens. North Dakota optometrists are expert in the prescribing of contact lenses. Optometry currently prescribes the vast majority of contact lenses worn in the state.

The combination of a contact lens with a drug, both items that North Dakota optometrists handle daily with great effectiveness, is a logical modification to our practice act. I do not think this can be seen as an expansion of our allowed treatments but rather a change to keep up with the changes brought by new technology. We would still be bound by the list of drugs that are approved for our use.

SB 2164 clarifies our ability to prescribe and dispense the combination of contacts and drugs. We currently dispense, or sell contacts, and optometrists are the logical retail outlet for this new technology.

This new technology needs to be available to your constituents, the citizens of North Dakota, to allow them the very best medical care. A drug administered by way of a contact lens is like continuously putting in eye drops. This results in more convenient and effective therapy. The present lens seeking FDA approval will treat allergies and will be a great benefit to North Dakotans. The technology is new and I am sure we will see different drugs delivered in this way. Approval of SB2164 will enable optometrists to continue to deliver the very best care as new therapies are approved by the FDA. Again our practice act will continue to regulate if optometrists may prescribe any new contact lens/drug products.

I encourage a do pass recommendation from this committee. This will insure that the best eye care continues to be available to the residents of North Dakota. The good news is that this involves treatment modalities that are currently approved for, and widely used by North Dakota optometrists. This is not an expansion of our practice act but merely a step to keep up with changes in technology.

Respectfully;
Brian C. Beattie, O.D.



BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

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**SENATE BILL #2164 - HOUSE HUMAN SERVICES COMMITTEE
10:00 AM - TUESDAY - March 3, 2009
FORT UNION ROOM**

Chairperson Weisz, 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 to you today.

The Optometrists contacted me sometime ago indicating that they were planning on introducing a Bill that would allow them to dispense and sell contact lenses which contained drugs for therapeutic purposes. I discussed this with the Board of Pharmacy and they felt that since Optometrists now sell most of the contact lenses in the state, that this was perhaps a logical addition to their practice.

Obviously, there are some additional risks whenever a drug is introduced, as the drug delivered through the eye may affect the patient systemically, may interact with other drugs that the patient is also taking and may affect other conditions the patient has as well. Optometrists are aware through their prescribing of topical steroids in the eye that these drugs affect many body functions, even though they may be delivered through the eye. With proper training and consideration of the whole patient, these products should be safe for the Optometrists to use.

I believe that this bill does not expand the list of drugs an Optometrist would otherwise use in their practice and does not extend to drugs beyond their usual scope of practice and prescription drug authority.

The Board of Pharmacy is generally in support of the concept of the Optometrists being able to dispense and sell the drug eluting contact lenses.