Act Number:	09-058	
Bill Number:	781	
Senate Pages:	1222, 1263, 1690-1693, 1819-1821	**9**
House Pages:	3757-3760, 3874-3876	**7**
Committee:	Public Health: 396-401, 479-491, 563-564	**21**
	Page Total:	**37**

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Calendar 159, Senate Bill Number 938, Mr. President, I move to place this item on the foot of the calendar.

THE CHAIR:

Without objection, so ordered.

SENATOR LOONEY:

Thank you, Mr. President. Calendar 163, PR.

Moving to calendar page 6, Calendar 164, passed temporarily.

Calendar 165, Senate Bill Number 781, Mr. President, I move to place this item on the Consent Calendar.

THE CHAIR:

Without objection, so ordered.

SENATOR LOONEY:

Thank you, Mr. President. Calendar 174, PR.

Calendar 175, Senate Bill Number 617, Mr. President, I move to refer this item to Committee on Finance, Revenue, and Bonding.

THE CHAIR:

Without objection, so ordered.

SENATOR LOONEY:

Thank you, Mr. President. Calendar 176, Senate Bill Number 619, I move to refer this item to the

Calendar 470, Senate Bill Number 1126, Mr. President, I move to refer that item to the Education Committee.

THE CHAIR:

Without objection, so ordered.

SENATOR LOONEY:

And Mr. President, removing an item from the Consent Calendar placed there earlier -- on calendar page 6, Calendar 165, Senate Bill 781, would remove that item from the Consent Calendar and mark it PR.

Yes, also, another item to remove --

THE CHAIR:

Without objection, so ordered.

Go ahead, sir.

SENATOR LOONEY:

Thank you, Mr. President. Also calendar page 23, Calendar 420, would remove that item from the Consent Calendar and to mark it, also, PR. SB325

THE CHAIR:

The Senate will stand at ease.

SENATOR LOONEY:

Mr. President, a couple changes in markings. First of all, calendar page 18, Calendar 392 -- page 18, Calendar 392 should be, I think, was marked for

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THE CHAIR:

Without objection, so ordered.

SENATOR LOONEY:

And also on calendar page 25. Mr. President, Calendar 280, Senate Bill 982, marked PR.

THE CHAIR:

Without objection, so ordered.

SENATOR LOONEY:

Thank you, and calendar, final item, Mr. President, calendar page 28, Calendar 367, Senate Bill 785, marked PR.

THE CHAIR:

Without objection, so ordered.

SENATOR LOONEY:

Thank you, Mr. President.

THE CHAIR:

Thank you, sir.

Mr. Clerk, back to the call of the calendar.

THE CLERK: --

Calendar page 3, Calendar 165, File Number 138, substitute for Senate Bill 781, AN ACT CONCERNING THERAPEUTIC CONTACT LENSES, favorable report of the Committee on Public Health. Clerk is in possession of amendments.

THE CHAIR:

Senator Harris.

SENATOR HARRIS:

Thank you, Mr. President. Good morning.

THE CHAIR:

Good morning, sir.

SENATOR HARRIS:

I move --

THE CHAIR:

Good morning in California, sir. Depends where you say that.

SENATOR HARRIS:

I just took the redeye in, Mr. President.

THE CHAIR:

There you go.

SENATOR HARRIS:

I move acceptance of the joint committee's favorable report and passage of the bill. and.

THE CHAIR:

Acting on approval and passage of the bill, will you remark further, sir?

SENATOR HARRIS:

Yes, Mr. President. This bill is fairly simple. It will allow optometrists and physicians

and surgeons trained in specializing in eye disease to prescribe and sell contact lenses that actually have medications on the contact lenses.

Mr. President, the Clerk is in possession of an Amendment, LCO Number 6335. I ask that it be called and I be granted permission to summarize.

THE CHAIR:

Mr. Clerk.

THE CLERK:

LCO 6335, which will be designated Senate Amendment Schedule A. It is offered by Senator Harris of the 5th District, et al.

THE CHAIR:

Senator Harris.

SENATOR HARRIS:

Thank you, Mr. President. I move adoption.

THE CHAIR:

Motion is on adoption. Will you remark further, sir?

SENATOR HARRIS:

Yes, Mr. President. This amendment simply strikes Section 2 of the underlying bill to clarify that ophthalmologists will also be allowed to sell and dispense the type of contact lens I

discussed previously. And also, makes a correction to ensure that optometrists can still do this, and by eliminating another conflicting section of the law. I urge the adoption of the amendment.

THE CHAIR:

Thank you, sir. The motion on adoption of Senate A. Will you remark further on adoption of Senate A? If not, let me try your minds. All those in favor signify by saying aye.

SENATORS:

Aye.

THE CHAIR:

Opposed, nays.

The ayes have it. Senate A is adopted. Senator Harris.

SENATOR HARRIS:

Thank you, Mr. President. If there's no objection, I ask that this be placed on the consent calendar.

THE CHAIR:

Motion on the floor to place the item on consent as amended by Senate A. Seeing no objection, so ordered, sir. Mr. Clerk.

Senator Looney.

SENATOR LOONEY:

Yes. Mr. President, that item might be marked passed, retaining its place on the calendar.

THE CHAIR:

Without objection, so ordered, sir. Senator Looney.

SENATOR LOONEY:

Yes. Mr. President, if the remaining items that we had marked earlier, Calendar page 28, Calendar 367; Calendar page 29, Calendar 415; might also be marked passed, retaining their place on the calendar. And if the Clerk might proceed to vote on the consent calendar.

THE CHAIR:

Mr. Clerk, please call consent calendar.

THE CLERK:

Roll call has been ordered in the Senate on the consent calendar. Will all senators please return to the chamber. Roll call has been ordered in the Senate on the consent calendar. Will all senators please return to the chamber.

Mr. President, before voting on the consent calendar, those items placed on the consent

calendar began on calendar page 3, Calendar Number 165, substitute for Senate Bill 781; Calendar page 4, Calendar 208, substitute for Senate Bill 881; Calendar 244, House Bill 6263; Calendar page 7, Calendar 394, substitute for House Bill 5834; Calendar page 17, Calendar Number 102, substitute for Senate Bill 710; Calendar page 19, Calendar 145, Senate Bill 974; Calendar page 20, Calendar 155, substitute for Senate Bill 451; Calendar page 22, Calendar 198, Senate Bill 989; Calendar page 23, Calendar 222, substitute for Senate Bill 957; Calendar page 28, Calendar Number 354, substitute for Senate Bill 499. Mr. President, I believe that completes those items previously placed on the consent calendar.

THE CHAIR:

Okay. The Clerk, please call the consent calendar for a roll call. The machine will be open.

THE CLERK:

Immediate roll call has been ordered in the Senate on the consent calendar. Will all senators please return to the chamber. Immediate roll call

has been ordered in the Senate on the consent calendar. Will all senators please return to the chamber.

THE CHAIR:

Have all senators voted? If all senators have voted, please check your vote. The machine will be locked. The Clerk will call the tally.

THE CLERK:

Motion is on adoption of Consent Calendar Number 1.

Total Number Voting	35
Those voting Yea	35
Those voting Nay	0
Those absent and not voting	1

THE CHAIR:

The consent calendar passes.

Senator Looney.

SENATOR LOONEY:

Yes. Thank you, Mr. President. Mr. President, I believe the Clerk is in possession of Senate Agendas 1 and 2.

THE CHAIR:

Mr. Clerk.

THE CLERK:

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Total Number Voting	143
Necessary for Passage	72
Those voting Yea	143
Those voting Nay	0
Those absent and not voting	8

DEPUTY SPEAKER ORANGE:

The Bill passes.

Will the Clerk please call Calendar Number 594.

CLERK:

On Page 25, Calendar Number 594, Substitute for Senate Bill Number 781 AN ACT CONCERNING THERAPEUTIC CONTACT LENSES. Favorable Report of the Committee on Public Health.

DEPUTY SPEAKER ORANGE:

Representative Betsy Ritter, you have the floor, Sir, Ma'am.

REP. RITTER: (38th)

Thank you, Madam Speaker. It's a pleasure to see you up there this evening.

DEPUTY SPEAKER ORANGE:

A pleasure to see you, too, Ma'am.

REP. RITTER: (38th)

Madam Speaker, I move for acceptance of the Joint Committee's Favorable Report and passage of the Bill.

DEPUTY SPEAKER ORANGE:

The question is acceptance of the Joint Committee's Favorable Report and passage of the Bill. Will you remark?

REP. RITTER: (38th)

Thank you, Madam Speaker. Madam Speaker, the Clerk has an Amendment, LCO Number 6335. I request, excuse me, I would ask the Clerk to please call the Amendment and I be granted leave of the Chamber to summarize.

DEPUTY SPEAKER ORANGE:

Will the Clerk please call LCO Number 6335 designated Senate Amendment Schedule "A".

CLERK:

LCO Number 6635, Senate "A", offered by Senator Harris, Representative Ritter, Senator Debicella and Representative Giegler.

DEPUTY SPEAKER ORANGE:

The Representative seeks leave of the Chamber to summarize the Amendment. Is there objection to summarization? Is there objection? Hearing none, please proceed, Ma'am.

REP. RITTER: (38th)

Thank you, Madam Speaker. Madam Speaker, this Amendment clarifies the language in the underlying Bill to reflect the agreement between both the optometrists and the ophthalmologists regarding the sale of therapeutic contact lenses. I urge adoption.

DEPUTY SPEAKER ORANGE:

The question before the Chamber is adoption of Senate Amendment Schedule "A". Will you remark further on Senate "A"?

Then I will try your minds. All those in favor please signify by saying Aye.

REPRESENTATIVES:

Aye.

DEPUTY SPEAKER ORANGE:

All those opposed, Nay. The Ayes have it. The Amendment is adopted.

Will you care to remark further on the Bill as amended?

REP. RITTER: (38th)

Yes, I will. Thank you, Madam Speaker. Madam Speaker, I would move that this Bill as amended be placed on the Consent Calendar.

DEPUTY SPEAKER ORANGE:

Is there objection for this Calendar Number 781 to be placed on the Consent Calendar?

Hearing none, so ordered.

Will the Clerk please call Calendar Number 340.

CLERK:

On Page 40, Calendar Number 340, Substitute for House Bill Number 6426 AN ACT IMPROVING BROADBAND ACCESS. Favorable Report by the Committee on Government Administration and Elections.

DEPUTY SPEAKER ORANGE:

Representative Nardello, you have the floor, Ma'am.

REP. NARDELLO: (89th)

Good evening, Madam Speaker. It's good to see you there in your green.

I move acceptance of the Joint Committee's Favorable Report and passage of the Bill.

DEPUTY SPEAKER ORANGE:

The question is on the Committee's Joint Favorable Joint. Will you remark further on the Bill?

REP. NARDELLO: (89th)

Yes, Madam Speaker. This Bill requires the Department of Public Utility Control to develop a statewide technology initiative system, which includes

I move for the immediate transmittal of Calendar Number 603 to the Governor, please.

SPEAKER DONOVAN:

The motion is for immediate transmittal of Calendar Number 603 to the Governor. Is there any objection? Any objection? Representative Cafero? Hearing no objection, the Bill is immediately transmitted.

Will the Clerk please call Calendar Number 476.

CLERK:

On Page 15, Calendar Number 476, House Bill Number 6493 AN ACT CONCERNING REGIONAL SCHOOL DISTRICTS. Favorable Report of the Committee on Education.

SPEAKER DONOVAN:

Representative Olson.

REP. OLSON: (46th)

Thank you, Mr. Speaker. We will now be voting on the Consent Calendar. There are three items that we moved to the Consent Calendar earlier in today's Session, Calendar Number 476, Calendar Number 582 and Calendar Number 614. And in fact, we can't forget Calendar Number 594.

HB 6493
SB 963
SB 1028
SB 781

Thank you, Mr. Speaker.

SPEAKER DONOVAN:

The question before us is on passage of the Bills on today's Consent Calendar. Will you remark?

Representative Cafero.

REP. CAFERO: (142nd)

Thank you, Mr. Speaker. Mr. Speaker, unless, and may be I did not hear, those four Bills that are on the Consent Calendar, I heard Representative Olson say something toward the end there, and I didn't quite catch that.

SPEAKER DONOVAN:

Representative Olson, can you repeat what you said?

REP. OLSON: (46th)

Yes. In fact, those are the four items that we moved to the Consent Calendar during today's Session.

SPEAKER DONOVAN:

Representative Cafero.

REP. CAFERO: (142nd)

Thank you.

SPEAKER DONOVAN:

Thank you. Will you remark on today's Consent Calendar? Will you remark?

If not, staff and guests come to the Well of the House. Members take their seats. The machine will be opened.

CLERK:

The House of Representatives is voting by Roll Call. Members to the Chamber.

The House is voting today's Consent Calendar by Roll Call. Members to the Chamber.

SPEAKER DONOVAN:

Have all the Members voted? Have all the Members voted? Members please check the board to make sure your vote has been properly cast.

If all the Members have voted, the machine will be locked, and the Clerk will please take a tally.

Will the Clerk please announce the tally.

CLERK:

On today's Consent Calendar.

Total Number Voting	144
Necessary for Passage	73
Those voting Yea	144
Those voting Nay	0
Those absent and not voting	7

SPEAKER DONOVAN:

The Consent Calendar passes.

JOINT
STANDING
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hands of unqualified personnel. In very high medical doses, initial radiation effect can be seen in a short-term in the form of skin burns, but the most frightening thing about radiation exposure is the long-term effects that are not seen until many years down the road, in the form of cancers and genetic effect. National Cancer Institute estimates that 3,500 cancer deaths per year, are due to the long-term effects of overexposure to radiation.

The PA's in our state are currently interested in being allowed to perform fluoroscopic procedures. This type of radiologic procedure delivers a much higher dose to the patient than regular x-rays. I don't know if you realize that. With their limited knowledge of radiation, safety and exposure, they should not be allowed to do this. This is an ethical issue. Public safety needs to be our primary and sole concern when it comes to determining who can and cannot administer radiation to human beings.

The RA is qualified to do this, the PA is not.

Thank you.

REP. RITTER: Thank you very much for you testimony.

Are there any questions from the committee?

Hearing none.

We will go to our last bill, An Act Concerning Therapeutic Contact Lenses. And the first speaker I have is Carol Allocco, followed by Bill Ehler. SB781

CAROL ALLOCCO: Good evening, Senator Harris, Representative Ritter, and members of the committee. My name is Carol Allocco. I'm a senior director of government affairs for Johnson & Johnson.

Today, I represent one of our operating companies Vistakon, a division of Johnson & Johnson Vision Care. I'm here today to offer comments in regards to Senate Bill 781.

New technology, in the form of contact lenses that emit therapeutic pharmaceutical agents is emerging to treat eye disorders. Under current U.S., State Optometry, Medical and Pharmacy Practice Acts these combination contact lens/drug products would be available immediately for prescription and dispensing by Vision Care professionals in 34 states -- and we have an attached table that should be there with the testimony for which state those are -- and this represents an increase of 13 states since the issue was heard in Connecticut last year. Connecticut remains a state that requires clarification through the introduction of this bill, the language surrounding the abilities of Version Care professionals to prescribe and dispense this technology to their patients. I would like to make the following points.

This 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 would provide therapeutic pharmaceutical agents 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 the current law.

Optometrists can currently prescribe and dispense contact lenses in their practice. Optometrists, as per statute, are able to prescribe therapeutic pharmaceutical agents to their patients.

Only those lenses with pharmaceutical agents that are within the scope of practice would be available to optometrists. Nothing in legislation alters the scope of practice for any of the professions.

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 Connecticut once FDA approval.

It's important to note that the same bill was raised in last year session as House Bill 5811. House Bill 5811 was raised out of committee, passed the House unanimously. It was not raised by the Senate prior to the expiration of the session.

I would like to conclude by thanking the committee for hearing this issue. Vistakon and I stand ready to work with you on this legislation as the 2008 session proceeds.

I'd be happy to answer any question you may have at this time.

REP. RITTER: Well timed. Thank you very much.

CAROL ALLOCCO: We practiced it.

REP. RITTER: Question from the committee?

Representative Lesser.

REP. LESSER: Yeah, I'm a little bit -- well, thank

you, Madam Chair.

Just a little clarification on this, are you asking -- and then -- well, I guess the question is, if you are allowing any licensed optometrist to prescribe medicine, what qualification do they have to make sure that there no drugs interaction or manage the pharmaceuticals with other pharmaceuticals that the person may be taking --

CAROL ALLOCCO: Well --

REP. LESSER: -- and I'm just trying to see what sort of training they have to be able to do this.

CAROL ALLOCCO: Well, I'm not and expert in your particular state statute, but they're already allow to prescribe pharmaceutical agents.

REP. LESSER: They are. Okay.

CAROL ALLOCCO: What's different with -- with this bill is it's allowing them to use -- to basically dispense a contact that has a drug coating on it, and they currently can dispense the drug, and they can currently can dispense contacts. So what it is, is that why there's clarification, but it's not changing anything else as far as they're -- any kind of training or any kind of scope.

REP. LESSER: Okay. Thank you.

REP. RITTER: Representative Giegler.

REP. GIEGLER: Thank you very much. Just a question.

As you made reference to last year, we had this bill and we did pass it out of committee,

with the idea that the lens was going to be FDA approved. Now it's a year later, and we're looking at passing it out of the committee again, do you have any idea when or you anticipate FDA approval?

CAROL ALLOCCO: We -- we were told that, perhaps, it might be towards the end this year, most likely beginning of next year, and so that's why our -- our recommendation is to pass it this year just because of the way your processes here with laws being effective in October of that year.

REP. GIEGLER: So that would mean that right now it's on its last trials?

CAROL ALLOCCO: I'm wouldn't -- I'm not sure as far as exact trial, but it's in the last phase of review of for FDA approval.

REP. GIEGLER: Okay. Thank you very much.

REP. RITTER: Are there any other further questions from the committee?

Thank you very much.

CAROL ALLOCCO: Thank you.

REP. RITTER: Have a safe trip home.

Bill Ehler followed by Brian Lynch.

WILLIAM EHLERS: Good evening. I've invited Dr. Lynch to join me up here if that is acceptable to the committee. I'm Dr. Bill Ehlers, and we have submitted testimony on this matter. I want the Chairs of the committee and the members of the committee who stayed here late, and you're going be rewarded by witnessing an historic event, and Dr. Lynch

and I have been able to come to an agreement on language that we feel can be substituted for the current bill that we find acceptable to both groups, and so this is, hopefully, a good end to your evening.

REP. RITTER: Thank you.

WILLIAM EHLERS: I also would like to thank you for your patience and I commend you stamina. We have submitted substitute language to the committee administrator for your review on Monday, unless you all want to stick around later on tonight, which I don't think. And you should have this on Monday for your review and, hopefully, a favorable consideration.

I thank you again for your help.

BRIAN LYNCH: The only additional comment that I would like to make is that it is not part of the language that was submitted, but that ophthalmology will seek to have appropriate language inserted into the medical statutes that allow ophthalmologists to dispense and charge for these lenses as well.

REP. RITTER: Thank you.

I would like to suggest that, perhaps, futures strategies for us is to just lock the participants into a small room until they either get tired or fall asleep or reach agreement. Fourteen-hours later we can produce an agreement.

Thank you very much.

Are there any questions from the committee?

A VOICE: Thank you. Do you hear the sound of the glass breaking. Mazeltov, or something like

VISTAKON
Division of
Johnson & Johnson Vision Care, Inc.

Statement of Carol Allocco before the Public Health Committee
in support of Senate Bill 781 – February 6, 2009

Sen. Harris, Rep Ritter and members of the committee·

My name is Carol Allocco. I am the Senior Director of Government Affairs for Johnson & Johnson Today, I represent one of our Operating Companies - VISTAKON, a division of Johnson& Johnson Vision Care, Inc. I am here today to offer comments in regard to Senate Bill 781, **An Act Concerning Therapeutic Contact Lenses**

New technology, in the form of contact lenses that emit therapeutic pharmaceutical agents, is emerging to treat eye disorders Under current US state optometry, medical and pharmacy practice act statutes, these combination contact lens/drug products would be available immediately for prescription and dispensing by vision care professionals in 34 states (see attached table), which represents an increase of 13 states since this issue was heard in Connecticut last year. Connecticut remains a state that requires clarification, through the introduction of this bill, of the language surrounding the abilities of vision care professionals to prescribe and dispense this technology to their patients I would like to make the following points

- This 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 (Chapter 380, Sect 20-127(5)), are able to prescribe therapeutic pharmaceutical agents to their patients
- Pharmacies in the State of Connecticut are prohibited from dispensing contact lenses. The definition of "device" (which pharmacies are legally allowed to dispense) in the pharmacy statute specifically excludes "contact lenses" from the definition.
- Only those lenses with pharmaceutical agents that are within scope of practice would be available to the optometrists. **Nothing in this legislation alters the scope of practice of the profession.**
- If no change is enacted, patients will either have to seek to have their prescriptions filled at an ophthalmologist's office or through a licensed provider on the Internet.
- Most consumers in Connecticut have their vision tested and contact lenses prescribed by an Optometrist If this bill is not passed, we fear the marketplace as it now exists in Connecticut will dramatically change and confuse consumers.
- 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 Connecticut once FDA approved
- The first of the products combines a vision correction device (Acuvue Contact Lens) with an over-the-counter anti-allergy product (ketotifen) When combined together, there is a restricted ability for patients to access this technology.
- It is important to note that this same bill was raised in last year's Session as HB 5811. HB 5811 was raised out of committee, passed the House unanimously and was not raised by the Senate prior to the expiration of the Session

I would like to conclude by thanking the Committee for hearing this issue. VISTAKON and I stand ready to work with you on this legislation as the 2008 session proceeds I would be happy to answer any questions you may have.

VISTAKON Division of Johnson & Johnson Vision Care, Inc
7500 Centurion Parkway
Jacksonville, FL 32256

VISTAKON
Division of
Johnson & Johnson Vision Care, Inc.

Table 1 – Status of US States on Vision Care Professionals Ability to In-Office Dispense Therapeutic Contact Lenses

STATUS	States
States That Required No Changes (20)	Pennsylvania, Indiana, Alabama, Oklahoma, South Dakota, Wyoming, Montana, Idaho, Utah, New Mexico, North Carolina, Missouri, Florida, Michigan, New Mexico, Arizona, Washington, Hawaii, Delaware, District of Columbia
States That Still Require Legislative Changes to Be Made (17)	Connecticut, Maine, New Hampshire, Massachusetts, New York, New Jersey, West Virginia, Maryland, Arkansas, Wisconsin, Iowa, Kansas, Nebraska, Texas, Colorado, Mississippi, North Dakota
States That Required Clarification Through Enacted Legislation, Board Rules or Interpretation of Existing Language (14)	Ohio, Kentucky, Minnesota, Louisiana, California, Oregon, South Carolina, Nevada, Virginia, Illinois, Vermont, Rhode Island, Tennessee, Georgia

Testimony of the Connecticut Society of Eye Physicians

On SB 781; AAC Therapeutic Contact Lenses

Before the Public Health Committee

February 6, 2009

Good afternoon, Senator Harris, Representative Ritter, and members of the Public Health Committee. I am Dr. William Ehlers, a corneal specialist and Past President of the Contact Lens Association of Ophthalmologists. I am here today representing the Connecticut Society of Eye Physicians to speak in opposition to HB 781, AAC therapeutic Contact Lenses as it is written.

I want to make it clear that we are here today to oppose HB 781 as written, but not the principle of optometrists being allowed to sell and dispense contact lenses that contain antihistamines or specific other drugs, once the safety of such lenses has been proven. We feel, as we did last year, that in the absence of any publicly reviewable data on the safety and efficacy of these lenses, and with FDA approval at least a year off, it is premature to be considering statutory changes to allow their distribution. More importantly, though, we feel the language of the amendment as proposed is vague, and improperly placed. We would recommend that the term "therapeutic drug" be defined as those agents allowed for topical administration in Section 20-127 (5) and designated as "ocular agent T" drugs, which have already been agreed to by both optometrists and ophthalmologists in a compromise in 2007, as the scope of advanced optometric prescribing. Our specific suggestions regarding language changes can be found appended to our written testimony.

This legislation is similar to legislation introduced last year because a completely new type of contact lens may become available next year. The K lens – under development by Vistakon incorporates an anti-allergy medicine, ketotifen, into the matrix of the lens. It is intended to provide contact lens wearers who suffer from seasonal allergies with relief of symptoms. According to information received from Vistakon and available on the website clinicaltrials.gov, these lenses are in Phase III testing. Phase III testing involves healthy volunteers who wear the lenses to determine their safety. The information that I have received is a description of the study design only. To date, I have seen no data regarding either the efficacy or the safety profile of these lenses.

The issue of contact lens safety is one that is near and dear to my heart. I have lectured and published peer-reviewed articles on this subject, and personally conducted comparative studies on contact lens safety. Although contact lenses are an exceptionally safe means of vision correction, several news

stories in recent years have underscored the fact that contact lens wearers can experience serious complications and loss of vision. Despite the efforts of the best minds in Ophthalmology, Optometry, and the contact lens industry, a small number of wearers experience sight threatening complications each year, and the percentage of people experiencing the most feared contact lens related complication – microbial keratitis, a bacterial infection of the cornea – hasn't changed in 20 years.

The causes of contact lens related complications are complex. Contact lenses are a foreign body that has to interact with the ocular surface and the tear film. Although ketotifen has an excellent safety profile and is available as an over-the-counter allergy drop, it is certainly possible that incorporating this drug into a contact lens that will be held right against the eye for hours - or even days - may alter the safety profile. It must also be remembered that patients don't always follow directions exactly, and that places them at risk for complications. Adding a chemical, such as a medication, to that equation increases that risk.

A valid concern has been raised about the limited distribution infrastructure for a lens of this type, and I thank Linda Kowalski, Vistakon, and Connecticut Optometrists for bringing this matter to public attention. Although the need for a distribution system for these lenses is an important consideration, it is not a critical need. It is, in fact, a business consideration – not a public welfare concern. If this matter is considered and approved in the next legislative session, when we will presumably have more information regarding the safety of these lenses, any new legislation would go into effect on October 1, 2010. The earliest anticipated time frame from Vistakon for FDA approval would be late spring or early summer of 2010. Perhaps they will be approved in that time frame – and perhaps not. Perhaps they will be the best treatment for contact lens wearers with allergies, and perhaps they will be a disappointment. We will have more of these answers in one year. In the interim, it must be remembered that there are treatment options in place to meet the needs of contact lens wearers with allergies.

It will be said today that as long as FDA approval is stipulated in the language of this legislation, we need not concern ourselves with whether this combination of a drug and a medical device is safe – that is the job of the FDA. Although the FDA certainly bears the major responsibility for determining the safety and efficacy of drugs and devices, everyone in this room can think of instances where the FDA got it wrong. In addition, I will argue that the overall safety of this new and exciting modality should be the concern of everyone in this room. You became legislators because of your concern for public welfare. Physicians

have a long history of public service and concern over public welfare. I am here today – as are others to express that concern. I believe in the area of contact lenses, safety is the shared responsibility of the FDA, the contact lens industry, eye care professionals, legislators, and even patients.

This lens is apparently the first in a series of lenses under development by the contact lens industry for drug delivery. We have attempted to satisfy our concerns regarding the safety and efficacy of these lenses in several conference calls with Vistakon, but they have chosen not to share data with us, despite our offer to sign any confidentiality agreement they might require. We also believe this legislation is premature as the earliest anticipated date for approval is early 2010.

Although the concerns we expressed on this matter both last year and this year are valid, we are not opposed to the concept of Optometrists dispensing this lens - or any other lens - that contains a therapeutic agent within the scope of their practice. For this reason, we will not oppose this legislation if the minor changes suggested are made in the language. In addition, optometrists who dispense such lenses will be required to meet the same record keeping requirements and requirements of notification to the Commissioner of Consumer Protection regarding their intent to dispense drugs other than professional samples. We also feel Ophthalmologists should have language added to Connecticut Statutes on Medicine and Surgery that specify the same rights to dispense contact lenses that contain medications but such medications will be consistent with the prescriptive limits of medical practice, and ophthalmologists will have the same record keeping and reporting responsibilities.

We hope to continue the good faith efforts we have made over the last year to work with optometry to resolve this matter and craft language acceptable to everyone. Thank you for your time and attention.

Raised Bill No. 781

January Session, 2009 LCO No. **2671**

*02671_____PH_*

Referred to Committee on Public Health

Introduced by:

(PH)

AN ACT CONCERNING THERAPEUTIC CONTACT LENSES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (f) of section 20-127 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2009*):

(f) [No] Except as otherwise provided in this subsection, no licensed optometrist authorized pursuant to this section to practice advanced optometric care shall dispense controlled substances under schedules II, III, IV and V or under section 21a-252, to any person unless no charge is imposed for such substances and the quantity dispensed does not exceed a seventy-two-hour supply, except if the minimum available quantity for [said agent] such substances is greater than a seventy-two-hour supply, the optometrist may dispense the minimum available quantity. A licensed optometrist authorized pursuant to this section to practice advanced optometric care may acquire, prescribe, dispense and charge for contact lenses that provide vision correction and contain a therapeutic agent as defined in Section 20-127 a 5 A "Ocular Agents T" for topical administration, and are ~~"a therapeutic drug agent~~ approved by the federal Food and Drug Administration.

This act shall take effect as follows and shall amend the following sections:

Section 1 *October 1, 2009* 20-127(f)

Statement of Purpose:

To allow a licensed optometrist to acquire, prescribe, dispense and charge for contact lenses that provide vision correction and contain a therapeutic drug agent approved by the federal Food and Drug Administration.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it

Raised Bill No. 781

January Session, 2009 LCO No. 2671

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Referred to Committee on Public Health

Introduced by:

(PH)

AN ACT CONCERNING THERAPEUTIC CONTACT LENSES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (a 1 ~~f~~) of section 20-127 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2009*):

~~(f) [No] Except as otherwise provided in this subsection, no licensed optometrist authorized pursuant to this section to practice advanced optometric care shall dispense controlled substances under schedules II, III, IV and V or under section 21a-252, to any person unless no charge is imposed for such substances and the quantity dispensed does not exceed a seventy-two-hour supply, except if the minimum available quantity for [said agent] such substances is greater than a seventy-two-hour supply, the optometrist may dispense the minimum available quantity. A licensed optometrist authorized pursuant to this section to practice advanced optometric care may acquire, prescribe, dispense and charge for contact lenses that provide vision correction and contain "Ocular agents-D~~ a therapeutic drug agent approved by the federal Food and Drug Administration.~~"~~ (1) The "practice of advanced optometric care" means any one or more of the following practices and procedures: (A) Measuring, examining, diagnosing, preventing, enhancing, managing or treating visual functions, defects of vision, muscular functions or anomalies, or other conditions or diseases of the visual system, the eye and ocular adnexae; (B) the prescribing, supplying, adjusting, fitting or adapting of ophthalmic devices and lenses, spectacles, prisms, orthoptic therapy, visual therapy, visual rehabilitation, oculomotor therapy, tinted lenses, filters, contact lenses, diagnosing, preventing, enhancing, managing, treating or relieving visual functions, defects of vision, muscular functions or anomalies, or diseases of the visual system, the eye and ocular adnexae; (C) the administration or prescription of any pharmaceutical agents related to the diagnosis and treatment of conditions and diseases of the eye and ocular adnexae, excluding nonemergency oral glaucoma agents but

including controlled substances under schedules II, III, IV and V in accordance with section 21a-252, subject to the limitations of subsection (f) of this section relating to quantities dispensed, performance or ordering of procedures or laboratory tests related to the diagnosis and treatment of conditions and diseases of the eye and ocular adnexae; these procedures include, but are not limited to, removal of superficial foreign bodies of the cornea, ultrasound and topical, oral or injectable medication to counteract anaphylaxis or anaphylactic reaction; (D) the prescribing, supplying, adjusting, fitting or adapting of contact lenses containing therapeutic agents as defined for ocular agents - T for topical use per subsection (a) 5 A of this section, (E) [(D)] the nonsurgical treatment of glaucoma consistent with subsection (k) of this section; or [(E)] (F) the use of punctal plugs. The "practice of advanced optometric care" does not include surgical treatment of glaucoma, treatment of ocular cancer, treatment of infectious diseases of the retina, diagnosis and treatment of systemic diseases, use of therapeutic lasers, use of injectable medications other than to counteract anaphylaxis or anaphylactic reaction, surgical procedures other than noninvasive procedures, use of general anesthesia, use of intravenous injections, procedures that require the cutting or opening of the globe, enucleation of the eye, extraocular muscle surgery or any invasive procedure performed on the human body other than noninvasive procedures performed on the eye or ocular adnexae.

And

Section 1 Subsection (e) of section 20-127 of of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2009*):

(e) No licensed optometrist authorized pursuant to this section to acquire, administer, dispense and prescribe an ocular agent-T shall dispense such agent to any person unless no charge is imposed for such agent and the quantity dispensed does not exceed a seventy-two-hour supply, except if the minimum available quantity for said agent is greater than a seventy-two-hour supply, the optometrist may dispense the minimum available quantity, or except if the

agent is a contact lens that provides vision correction and contains a therapeutic drug agent consistent with sec 20-127 a 5.

Raised Bill No. 781
LCO No. 2671 {D:\Conversion\Tob\s\2009SB-00781-R00-SB.doc } *2 of 2*
This act shall take effect as follows and shall amend the following sections:
Section 1 *October 1, 2009* 20-127(f)
Statement of Purpose:
To allow a licensed optometrist to acquire, prescribe, dispense and charge for contact lenses that provide vision correction and contain a therapeutic drug agent approved by the federal Food and Drug Administration.
[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it

Statement of Brian T. Lynch, OD
Before the Public Health Committee
In Support of #SB781
Sen. Harris, Rep. Ritter and Members of the Committee:

My name is Dr. Brian T. Lynch. I am an optometrist who has practiced in Branford for 27 years. Currently I serve as legislative chair for the Connecticut Association of Optometrists. I appear before you today to urge your support of SB781, An Act Concerning Therapeutic Contact Lenses.

All healthcare providers practice legislated professions. Simply put, how we practice and care for our patients is defined by statutes. In 1996, this committee defined the practice of "advance optometric care" as what it is today. The statutes adopted by the general assembly were based on public safety and need, provider training, and available technologies at that time. As these factors change, we periodically find ourselves needing to "tweak" our statutes to address advances in healthcare and patients' requirements.

In 1996 the concept of a contact lens impregnated with a pharmaceutical to treat a patient's allergy symptoms wasn't on the horizon. Thanks to Johnson and Johnson it will soon be available. However, patients in Connecticut will have very limited access to it.

Currently, optometrists who are the primary suppliers of contact lenses are prohibited from supplying any more than a 72-hour supply of a pharmaceutical to their patients. Pharmacies in Connecticut do not sell contact lenses. Opticians can't supply any pharmaceuticals to their customers, leaving only one supplier: ophthalmologists, whose statutes don't prohibit them from dispensing.

Contrary to what you may have been told, this is not a "scope of practice" issue. Once the FDA approves this product, Connecticut optometrists will be able to sample patients and prescribe for them without any statute change. It is, however, an "access issue." Limiting a patient's access to this revolutionary product and restricting a patient's freedom to choose where they want to purchase this product is not sound policy.

Please support SB781 and empower patients to choose.

Testimony of the Connecticut Society of Eye Physicians

On SB 781; AAC Therapeutic Contact Lenses

Before the Public Health Committee

February 6, 2009

Given by Jamie Weisz

Good afternoon, Senator Harris, Representative Ritter, and members of the Public Health Committee. I am Jamie Weisz,M.D. a retina specialist and Secretary of the Connecticut Society of Eye Physicians. I am here today representing the Connecticut Society of Eye Physicians to speak in opposition to HB 781, AAC therapeutic Contact Lenses as it is written.

I want to make it clear that we are here today to oppose HB 781 as written, but not the principle of optometrists being allowed to sell and dispense contact lenses that contain antihistamines or specific other drugs, once the safety of such lenses has been proven. We feel, as we did last year, that in the absence of any publicly reviewable data on the safety and efficacy of these lenses, and with FDA approval at least a year off, it is premature to be considering statutory changes to allow their distribution. More importantly, though, we feel the language of the amendment as proposed is vague, and improperly placed. We would recommend that the term "therapeutic drug" be defined as those agents allowed for topical administration in Section 20-127 (5) and designated as "ocular agent T" drugs, which have already been agreed to by both optometrists and ophthalmologists in a compromise in 2007, as the scope of advanced optometric prescribing. Our specific suggestions regarding language changes can be found appended to our written testimony.

This legislation is similar to legislation introduced last year because a completely new type of contact lens may become available next year. The K lens – under development by Vistakon incorporates an anti-allergy medicine, ketotifen, into the matrix of the lens. It is intended to provide contact lens wearers who suffer from seasonal allergies with relief of symptoms. According to information received from Vistakon and available on the website clinicaltrials.gov, these lenses are in Phase III testing. Phase III testing involves healthy volunteers who wear the lenses to determine their safety. The information that we have received is a description of the study design only. To date, we have seen no data regarding either the efficacy or the safety profile of these lenses.

Although contact lenses are an exceptionally safe means of vision correction, several news stories in recent years have underscored the fact that contact lens wearers can experience serious complications and loss of vision. Despite the efforts of the best minds in Ophthalmology, Optometry, and the contact lens industry, a small number of wearers experience sight threatening complications each year, and the percentage of people experiencing the most feared contact lens related complication – microbial keratitis, a bacterial infection of the cornea – hasn't changed in 20 years.

The causes of contact lens related complications are complex. Contact lenses are a foreign body that has to interact with the ocular surface and the tear film. Although ketotifen has an excellent safety profile and is available as an over-the-counter allergy drop, it is certainly possible that incorporating this drug into a contact lens that will be held right against the eye for hours - or even days - may alter the safety profile. It must also be remembered that patients don't always follow directions exactly, and that places them at risk for complications. Adding a chemical, such as a medication, to that equation increases that risk.

A valid concern has been raised about the limited distribution infrastructure for a lens of this type, and CSEP thanks Linda Kowalski, Vistakon, and Connecticut Optometrists for bringing this matter to public attention. Although the need for a distribution system for these lenses is an important consideration, it is not a critical need. It is, in fact, a business consideration – not a public welfare concern. If this matter is considered and approved in the next legislative session, when we will presumably have more information regarding the safety of these lenses, any new legislation would go into effect on October 1, 2010. The earliest anticipated time frame from Vistakon for FDA approval would be late spring or early summer of 2010. Perhaps they will be approved in that time frame – and perhaps not. Perhaps they will be the best treatment for contact lens wearers with allergies, and perhaps they will be a disappointment. We will have more of these answers in one year. In the interim, it must be remembered that there are treatment options in place to meet the needs of contact lens wearers with allergies.

It will be said today that as long as FDA approval is stipulated in the language of this legislation, we need not concern ourselves with whether this combination of a drug and a medical device is safe – that is the job of the FDA. Although the FDA certainly bears the major responsibility for determining the safety and efficacy of drugs and devices, everyone in this room can think of instances where the FDA got it wrong. In addition, I will argue that the overall safety of this new and exciting modality should be the concern of

everyone in this room. You became legislators because of your concern for public welfare. Physicians have a long history of public service and concern over public welfare. I am here today – as are others to express that concern. I believe in the area of contact lenses, safety is the shared responsibility of the FDA, the contact lens industry, eye care professionals, legislators, and even patients.

This lens is apparently the first in a series of lenses under development by the contact lens industry for drug delivery. We have attempted to satisfy our concerns regarding the safety and efficacy of these lenses in several conference calls with Vistakon, but they have chosen not to share data with us, despite our offer to sign any confidentiality agreement they might require. We also believe this legislation is premature as the earliest anticipated date for approval is early 2010.

Although the concerns we expressed on this matter both last year and this year are valid, we are not opposed to the concept of Optometrists dispensing this lens - or any other lens - that contains a therapeutic agent within the scope of their practice. For this reason, we will not oppose this legislation if the minor changes suggested are made in the language. In addition, optometrists who dispense such lenses will be required to meet the same record keeping requirements and requirements of notification to the Commissioner of Consumer Protection regarding their intent to dispense drugs other than professional samples. We also feel Ophthalmologists should have language added to Connecticut Statutes on Medicine and Surgery that specify the same rights to dispense contact lenses that contain medications but such medications will be consistent with the prescriptive limits of medical practice, and ophthalmologists will have the same record keeping and reporting responsibilities.

We hope to continue the good faith efforts we have made over the last year to work with optometry to resolve this matter and craft language acceptable to everyone. Thank you for your time and attention.

Connecticut State Medical Society
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Connecticut State Medical Society Testimony
Presented to the Public Health Committee on
House Bill 6310 An Act Concerning Direct Access to Laboratory Results
House Bill 6200 An Act Concerning the Use of Long-term Antibiotics for the Treatment of Lyme Disease
Senate Bill 6265 An Act Concerning Speech and Language Pathology
Senate Bill 406 An Act Concerning Licensure of Assistant Radiologists
SB 781 An Act Concerning Therapeutic Contact Lenses
February 6, 2009

Senator Harris, Representative Ritter and members of the Public Health Committee, my name is Dr. William Handelman and I am currently the President of the Connecticut State Medical Society (CSMS). On behalf of our more than 7,000 members thank you for the opportunity to submit this testimony to you today on various pieces of proposed legislation that would in some way impact the healthcare system in Connecticut and the health of our patients.

House Bill 6310 **An Act Concerning Direct Access to Laboratory Results** would require physicians ordering certain medical tests to authorize the entity conducting the test to communicate the results to the patient unless the physician reasonably determines that the communication may be detrimental to the physical or mental health of the patient, or may result in the patient hurting himself, herself or another.

CSMS believes that every patient not only has a right to access his or her medical record, but along with the treating physician owns it. However, the complexity of many medical services and testing require communication and explanation from the treating physician in order to convey a true understanding of the results. Furthermore, the results of testing for many conditions are difficult to interpret and can lead to unnecessary concern and anxiety for a patient prior to a discussion with the treating physician. While it may not elevate to the level of a patient being harmed mentally or physically, such premature access to records may have an unneeded negative impact on the patient.

While we welcome the opportunity to work with members of the committee to ensure that patients have appropriate access to medical test results at the appropriate time, we are obligated to raise the concern about mandating physicians to require access to test results prior to interpretation of such results by the ordering physician. Despite advances in internet, web based information, the best information on medical treatment and care, as well as evaluation and interpretation of test results rests with the treating physician.

House Bill 6200 **An Act Concerning the Use of Long Term Antibiotics for the Treatment of Lyme Disease** (1) allows physicians to prescribe administer or dispense

antibiotic therapy for therapeutic purposes to a person diagnosed with and having symptoms of Lyme disease and (2) protects against disciplinary action when doing so.

CSMS supports this legislation to protect physician treating Lyme disease with long term antibiotics provided that the diagnosis and treatment fall within acceptable medical guidelines. Antibiotic therapy is a proven treatment for Lyme disease. A physician utilizing such therapy should in no way be disciplined or persecuted when reasonably determining that such a treatment is medically necessary for the benefit of the patient.

CSMS joins the Connecticut ENT Society in support of **House Bill 6265 An Act Concerning Speech and Language Pathology.** There is a distinct difference in medicine between the terms "diagnose" and "evaluate." Diagnose is medical in nature and requires the training and education of a physician. We do not believe that it was the intent of the legislature or the sponsoring organization to permit non physicians to medically diagnose.

CSMS supports the concerns raised by the Connecticut Radiological Society (CRS) on **Senate Bill 406 An Act Concerning Licensure of Assistant Radiologists** and does not support the bill at this time with no specific drafted language. CRS has raised serious questions in its testimony regarding credentialing and patient safety. We agree that these questions and the lack of answers to them in the legislation go to the heart of what qualifies someone to be a radiologist's assistant.

Also, any legislation impacting healthcare professionals who assist radiologists should clarify the ability of physician assistants to engage in the use of Fluoroscopy for diagnostic professionals exempt from requirements of the Radiological Technician Statutes. This will ensure that fluoroscopy procedures can be performed in appropriate settings without any confusion or controversy as to who is entitled to assist the radiologist.

Finally, CSMS respectfully asks the committee to oppose **Senate Bill 781 An Act Concerning Therapeutic Contact Lenses.** Currently no publicly reviewable data on the safety and efficacy of these lenses currently exists. Furthermore, these contact lenses have not been approved by the Food and Drug Administration (FDA) at this time. The legislation before you stipulates FDA approval prior to granting optometrists the ability to dispense such contact lenses. We disagree with this approach. Legislating prescriptive authority pending the potential approval of the lenses is premature and not in the best interest of the health and safety of Connecticut citizens. Not only is it the responsibility of this committee to ensure FDA approval, but it also must review data on safety and efficacy to determine whether certain classes of health care providers have the level of training and skill necessary to safety prescribe and dispense.

Thank you for the opportunity to submit this testimony to you today. We look forward to working with committee members on this and other significant legislation that will impact the health and well being of our patients.