

Testimony of the Connecticut Society of Eye Physicians

On SB 781; AAC Therapeutic Contact Lenses

Before the Public Health Committee

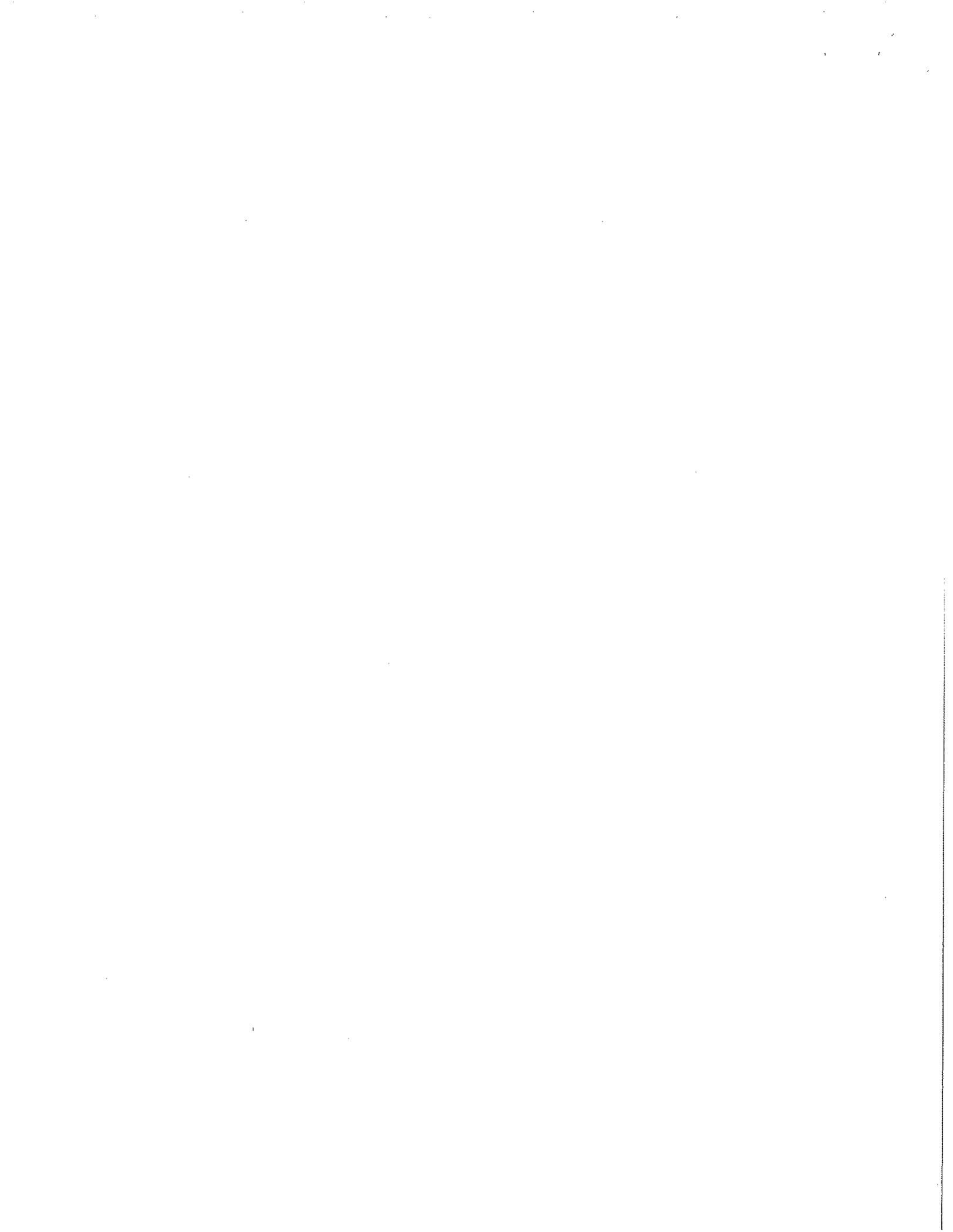
February 6, 2009

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

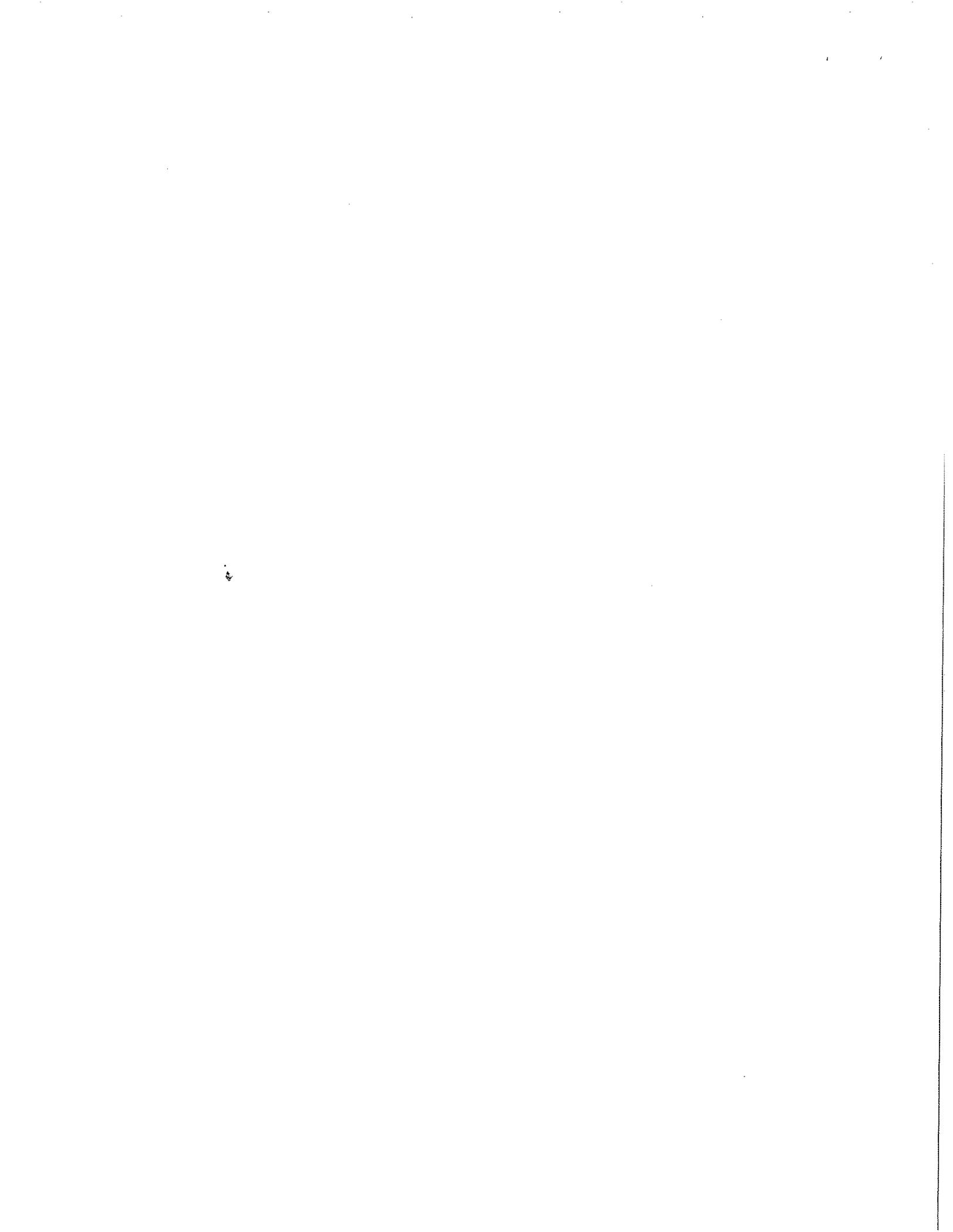


stories in recent years have underscored the fact that contact lens wearers can experience serious complications and loss of vision. Despite the efforts of the best minds in Ophthalmology, Optometry, and the contact lens industry, a small number of wearers experience sight threatening complications each 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

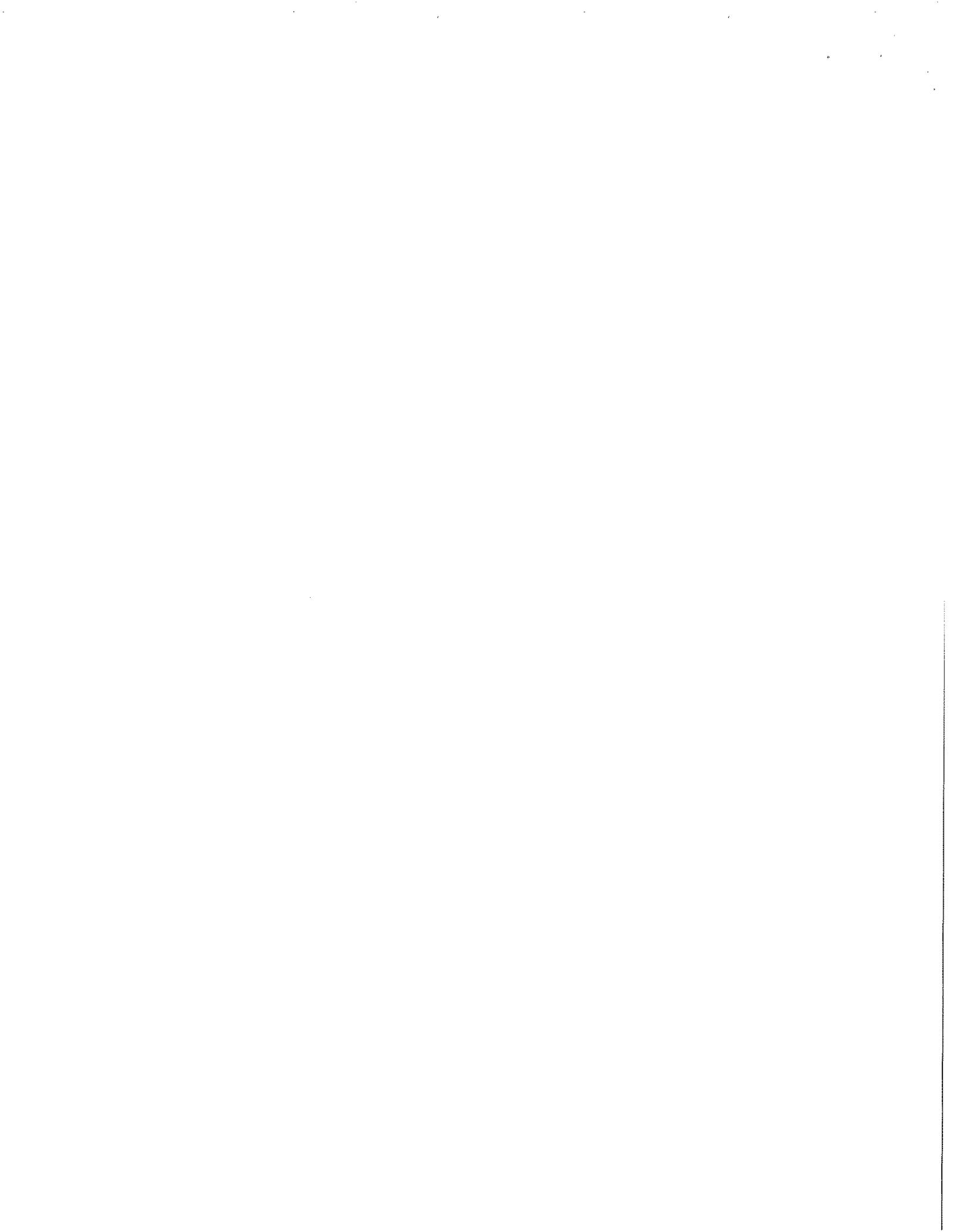


have a long history of public service and concern over public welfare. I am here today – as are others to express that concern. I believe in the area of contact lenses, safety is the shared responsibility of the FDA, the contact lens industry, eye care professionals, legislators, and even patients.

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:

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2 repealed and the following is substituted in lieu thereof (*Effective*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

4 (f) [No] Except as otherwise provided in this subsection, no licensed
5 optometrist authorized pursuant to this section to practice advanced
6 optometric care shall dispense controlled substances under schedules
7 II, III, IV and V or under section 21a-252, to any person unless no
8 charge is imposed for such substances and the quantity dispensed does
9 not exceed a seventy-two-hour supply, except if the minimum

10 available quantity for {said agent}-such substances is greater than a
11 seventy-two-hour supply, the optometrist may dispense the minimum
12 available quantity. A licensed optometrist authorized pursuant to this
13 section to practice advanced optometric care may acquire, prescribe,
14 dispense and charge for contact lenses that provide vision correction

15 and contain a therapeutic agent as defined in Section 20-127 a 5 A "Ocular Agents T" for
16 topical administration, and are ~~---a therapeutic drug agent~~ approved by the federal Food
16 and Drug Administration.

Raised Bill No. 781

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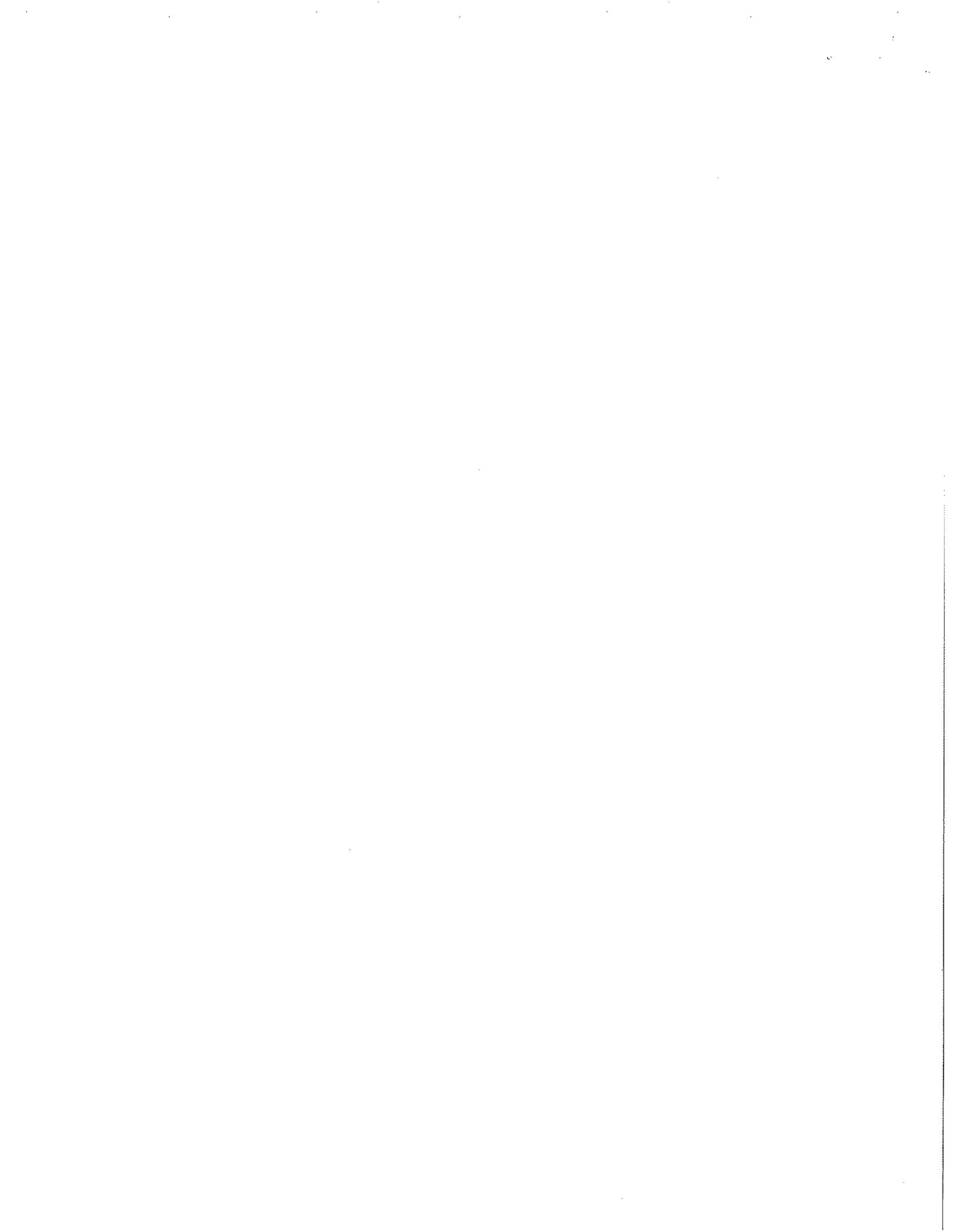
This act shall take effect as follows and shall amend the following sections:

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



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14 ~~dispense and charge for contact lenses that provide vision correction~~
15 ~~and contain "Ocular agents- Da therapeutic drug agent approved by the federal Food~~
16 ~~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 the general statutes is 2 repealed and the following is substituted in lieu thereof (Effective 3 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.

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