

Approved: May 10, 2002
Date

MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE.

The meeting was called to order by Chairperson Senator Susan Wagle at 1:30 p.m. on March 21, 2002 in Room 231-N of the Capitol.

All members were present except: Senator David Haley
Senator Nick Jordan
Mr. Norm Furse, Revisor of Statutes

Committee staff present: Ms. Lisa Montgomery, Revisor of Statutes
Ms. Emalene Correll, Kansas Legislative Research Department
Ms. Margaret Cianciarulo, Administrative Assistant

Conferees appearing before the committee: Ms. Phyllis Gilmore, Executive Director of the Behavioral Sciences Regulatory Board
Mr. Ron Hein, Legislative Counsel for the Mental Health Credentialing Coalition
Dr. Michael Cooper, Optometrist
Mr. Kevin McCallum, Vice President - Marketing for 1-800 CONTACTS
Mr. Frank Rozak, Legislative Consultant, for Cole Vision Corporation
Ms. Charlotte Norton, District Manager, Wal-Mart

Others attending: See attached guest list.

Hearing on HB2372 - an act concerning the board of behavioral sciences; marriage and family therapists and psychologists

Chairperson Susan Wagle opened the meeting by announcing there would be a hearing on HB2372, as stated above, and asked Ms. Lisa Montgomery, Revisor of Statutes to give a brief explanation of the bill.

Ms. Montgomery stated that the bill has two language changes related to licensure: from "at least equivalent to or exceed: to "substantially the equivalent" in Sec. 1, and from "or" to "in Sec. 2 regarding licensing of psychologists.

As there were no questions for Ms. Montgomery, the Chair then called on the first of the two proponent conferees, Ms. Phyllis Gilmore, Executive Director of the Behavioral Sciences Regulatory Board (BRSB). Ms. Gilmore stated that the bill, at the request of the board:

- 1) amends part of the marriage and family act by changing the standard to be used in determining whether a person who is licensed in another state may be licensed in Kansas; and;
- 2) amends the psychology act by directing the BRSB to issue a license to an applicant on the basis of the applicant's training and experience "and" who passed an examination in psychology.

A copy of her testimony is (Attachment 1) attached hereto and incorporated into the Minutes by reference.

The next proponent to testify was Mr. Ron Hein, legislative counsel for the Mental Health Credentialing Coalition who stated the bill, for professionals who are credentialed through the BSRB, clarifies:

- 1) those comparable standards and makes the MFT statute comparable to and consistent with the other licensed professionals of the BSRB; and,
- 2) the applicant should satisfy the Board in both the applicant's training and experience and pass an examination in psychology. A copy of his testimony is (Attachment 2) attached hereto and incorporated into the Minutes by reference.

As there was no opponent or written testimony presented and no questions for the proponents, Senator Jordan motioned that the bill be passed out favorably as is. Senator Barnett seconded and the motion carried.

Hearing on HB2285 - an act concerning optometry; relating to contact lens

Next on the agenda was the opponent hearing on HB2285 as stated above. The Chair recognized, Dr. Michael Cooper stated he was here to demonstrate that the motivations of many eye care professionals are driven by economics, not necessarily patient health concerns. He stated that once law, the bill will: inhibit competition by establishing a quasi-monopoly, add an estimated \$19 to \$38 M in yearly professional fees, and create greater ocular health risks and incidence of disease to the public. And finally, he provided "Plaintiff's Statement of Facts" in the Contact Lens Antitrust Litigation in the U.S. District Court in Jacksonville, Florida. A copy of his testimony and the litigation is (Attachment 3) attached hereto and incorporated into the Minutes by reference.

The next opponent was Mr. Kevin, McCallum, Vice President - Marketing for 1-800-CONTACTS, who stated that this bill was never publicly heard in the Kansas House and is an attempt by organized optometry in the state of Kansas to regulate competition. He stated four issues which will reward anti-consumer and anti-competitive behavior:

1. Sec. 2 (a) - prescription release "upon request" (ensures all contact lens wearers get the same price and extends the same rights to contact lens wearers that eyeglass wearers enjoy as mandated by a federal statute);
2. Sec. 2 - prescription expiration period of no less than 12 months (intended to minimize the financial conflict of interest that exists);
3. Sec. 3 - registration under the Kansas Board of Optometry (organized optometry asking for legislation for a board of optometrists to regulate their competition and levy \$10,000.00 fines); and
4. Missing language - required response to prescription verification requests (this bill carries no requirement for optometrists to respond to third party prescription requests. His attachments show examples)

Mr. McCallum also presented a short video of people with hidden cameras in the above situations. A copy of his testimony and his attachments are (Attachment 4) attached hereto and incorporated into the Minutes by reference.

The third opponent to be called on was Mr. Frank Rozak, legislative consultant for Cole Vision Corporation which operates nine "Sears Optical" and five "Target Optical" who testified they strongly endorse the proposed amendments offered yesterday by representatives of the Kansas Optometric Association to ensure consumers will continue to possess a maximum of "freedom of choice" in selecting a provider for their replacement contact lenses. A copy of his testimony is (Attachment 5) attached hereto and incorporated into the Minutes by reference.

The last to testify as an opponent was Ms. Charlotte Norton, District Manager of Wal-Mart Optical Centers who stated they oppose this bill for four reasons:

1. Against a certification requirement to sell or dispense contact, which would not improve the quality of eye care in Kansas, may push some optical stores out of business and would limit the choice patients have when filling their eyewear prescription;
2. Opposes giving the Board of Examiners in Optometry the power to supervise and certify eyewear sellers, better suited for a health-related agency such and KDHE;
3. Concerned that the bill's current language could require every store in an optical chain to have a license or be certified, citing the same reasons as in the first reason above; and,
4. Opposes the proposed fine language, believing that the maximum \$10,000 fine is excessive.

Ms. Norton also share Wal-Mart's principals it supports when evaluating optical legislation. A copy of her testimony is (Attachment 6) attached hereto and incorporated into the Minutes by reference.

A question and answer discussion followed between Senators Wagle, Salmans, Barnett, Harrington, Jordan, Brungardt, and Praeger and Mr. McCallum, Ms. Norton, Dr. Cooper, Mr. Rozak, and Mr. Gary Robbins who testified at yesterday's proponent hearing on this bill. Questions ranged from the 2-year prescription versus 1-year, follow-up care, the "Warning" response, the 2-hour release of prescriptions, asking a nurse to check, handling of defective lenses, issue of insurance, fees, standard of care, the Nebraska and pending legislation, to implications of HIPPA.

As there was no further discussion, the Chair closed the hearing.

Adjournment

Adjournment time was at 2:30 p.m.

The next meeting is scheduled for March 25, 2002.

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

35 in att.

GUEST LIST

DATE: Wednesday 3-21-02

NAME	REPRESENTING
RANDY FORBES	OPTOMETRY BOARD
GARY Robbing	KS opt ASSN
Michelle West	1-800-CONTACTS
Matt Bergmann	Pat Hubble Assoc.
Pat Hubble	1-800-CONTACTS
STEVE KEARNEY	1-800-CONTACTS
Gina Postner	Sen Jim Barnett
Mike Malone	KS opt ASSN
Todd Stewart	KS opt ASSN
Ron Hein	Hein Law Firm Child
SCOTT SCHNEIDER	COLE VISION/LENSCRAFTERS
Charlotte Norton	Wal-mart Inc.
Marlee Carpenter	KCOT
Mary A. Kluse	Kids ^{Mental} Physical Health
Mary E. Mayo	Children's Mental Health
Larry Campbell	XSOS

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State of Kansas
Behavioral Sciences Regulatory Board

BILL GRAVES
Governor

PHYLLIS GILMORE
Executive Director



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**SENATE TESTIMONY
PUBLIC HEALTH AND WELFARE
MARCH 21, 2002**

HB2372

Chair Wagle and Committee Members:

Thank you for the opportunity to testify today in support of HB 2372. I am Phyllis Gilmore the Executive Director of the Behavioral Sciences Regulatory Board.

The BSRB is the regulatory board for most of the state's mental health professionals, the doctoral level psychologists, the master level psychologists, the clinical psychotherapists, the bachelor, master and clinical level social workers, the master and clinical level professional counselors, and the master and clinical level marriage and family therapists. Additionally, some of the drug and alcohol counselors are registered with the board, although most of them are registered with SRS at the present time.

This bill amends part of the marriage and family act by changing the standard to be used in determining whether a person who is licensed in another state may be licensed in Kansas. The current standard is that the requirements of the other state are "at least equivalent to or exceed" the requirements of Kansas. The new standard would be that the requirements of the other state are "substantially the equivalent of" Kansas's requirements. This is the standard used by the other BSRB professions. The amendment comes forth as a request by the Marriage and Family Therapy advisory committee and the full board. It is my understanding the Kansas Association of Marriage and Family Therapists has no objection to this amendment.

The bill also amends the psychology act by directing the BSRB to issue a license to an applicant on the basis of the applicant's training and experience "and" who has passed an examination in psychology. Currently, the statute allows a license to be issued if one "or" the other criteria has been met. The current law has been in place for many years, but is not actually the procedure we use for licensure. The board currently requires both elements and this amendment just bring the law and current practice together. It comes forth at the request of the Psychology advisory committee and the full board. It is my understanding the Kansas Psychological Association has no objection to this amendment.

Thank you and I will be happy to stand for questions.

*Senate Public Health & Welfare Committee
Date: March 21, 2002
Attachment #1*

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**Testimony re: HB 2372
Senate Public Health and Welfare Committee
Presented by Ronald R. Hein
on behalf of
Mental Health Credentialing Coalition
March 21, 2002**

Madam Chairman, Members of the Committee:

My name is Ron Hein, and I am legislative counsel for the Mental Health Credentialing Coalition. The Coalition is comprised of the members of the Kansas Association for Marriage and Family Therapy, the Kansas Association of Masters in Psychology, and the Kansas Counseling Association/Kansas Mental Health Counselors Association.

The MHCC supports HB 2372 which clarifies two issues for professionals who are credentialed through the Behavioral Sciences Regulatory Board (BSRB).

The first issue relates to the certification standards for marriage and family therapists. Current law states that the certification standards of a person from another state must be at least equivalent to or in excess of the standards of Kansas. This bill changes that to require the certification standards of another state be "substantially" equivalent to the Kansas standards. This seems to clarify those comparable standards and makes the MFT statute comparable to and consistent with the other licensed professionals of the BSRB.

The second issue relates to doctorate level psychologists. I believe there has been an error in the statute for many years and the BSRB and the doctorate level psychologists have always been in agreement on how this should be handled. The statute requires the BSRB to issue a license to an applicant who has satisfied the Board as to the applicant's training and experience or who has passed an examination in psychology. The doctorate level psychologists and BSRB are in agreement that the applicant should satisfy the Board in both 1) the applicant's training and experience, and 2) pass an examination in psychology.

We urge the committee to support HB 2372.

Thank you very much for permitting me to testify, and I will be happy to yield to questions.

*Senate Public Health & Welfare Committee
Date: March 21, 2002
attachment #2*

Michael A. Cooper, O.D.

- Professional** 2002 – Present Independent OD & Professional Consulting
- 1994 - 2001 KDCPEC (Optio®, Vision by Kahn & Diehl)
Licensed Optometrist (Partner)
- Transitioned from traditional exam duties to full time business executive
- 1984 – 1994 Drs. Kahn & Diehl, O.D.'s, Inc.
- Professional vision care services
 - Initial direct mail experience 1988 (Contact Solution, Inc.)
- 1983 – 1984
- OD Independent contractor. DOC Optical (Toledo, Lima, and Elyria OH)
- Education** 1979 - 1983 The Ohio State University College of Optometry
Optometry / Physiological Optics
- 1975 – 1979 The Ohio State University
Bachelor Science - Zoology
- Accreditation** 1995 – Present OD License Washington State
1992 – Present Ohio Therapeutic Pharmaceutical Certificate
1992 National Board of Optometric Examiners (TMOD)
1992 Post Graduate TPA Course Completion
1989 – Present OD License State of Michigan
1983 – Present OD License States of Ohio & California
- Professional memberships** Beta Sigma Kappa Optometric Honorary Society
Southern College of Optometry – Adjunct Faculty (preceptor program)
- Community** Past President, Greater Toledo Jewish Community Center
Former Executive Committee, Jewish Federation of Greater Toledo
Former Finance Committee, Temple Shomer Emunim
Past Member, U.J.A. National Young Leadership Cabinet
- Honors & Awards** Elected Honorary Life Member, Toledo Jewish Community Center
Ernst & Young 'Entrepreneur of the Year Award' Business Recognition

*Senate Public Health & Welfare Committee
Note: March 21, 2002
Attachment #3*

Intro

Dr. Michael Cooper—Licensed in several states and am an independent practicing optometrist in Ohio.

Consumer choice and patient advocate since 1988

Well known to the contact lens industry and a consultant to Lens1st

Lens1st is a responsible nationwide D to C contact lens replacement service.

Health Concerns

Yesterday, my professional colleagues correctly stated that contact lens wear poses certain eye health risks. I am here today to demonstrate that the motivations of many eye care professionals are driven by economics, not necessarily patient health concerns. That conflict is not new and elements of it exist in the Kansas Bill as proposed. This Bill, once law will inhibit competition by establishing a quasi-monopoly. It will add an estimated \$19 to \$38 M in yearly professional fees, effectively a contact lens 'tax' to the citizens of Kansas. Most importantly, it creates greater ocular health risks and incidence of disease to the public.

Dr. Feigel stated that eye health problems can originate when mechanical abrasion, dirty lenses, and over-wear lead to corneal disease or infection. He is right. My professional colleagues have historically held contact lens Rx's hostage—effectively forcing patients to overuse lenses and stretch existing supplies. Industry data shows that patient compliance is 54% more likely when consumers have ready access to affordable, factory fresh replacements. This fact is supported by leading lens makers, replacement industry data, and FTC findings. **“Easier access to, and lower prices for, replacement lenses encourage consumers to wear and use lenses properly, thereby increasing patient safety.” [FTC Sept. 1997]**

Yesterday, we heard several references to the FDA. Lens Rx's were then likened to controlled narcotics. FDA approved soft lenses are sterile, safe, and effective. There simply are no reports of adverse medical problems in the FDA's MedWatch system related to lens safety, lens care, or lens related eye health issues.

Yesterday we were told the AOA standard-of-care interval is 6 months to 1 year for contact lens wear. This is contradicted by the AOA's own public web site which states up to 2 years for contact lens wearers. The KOA is an affiliate of the American Optometric Association.

The AOA responded to the following questions in the recently settled 32 State Contact Lens Antitrust Case. Kansas is one of the 32 plaintiff states.

Q. Identify and describe all studies of which you are aware that discuss any effect the dispensing of contacts by alternative channels has on ocular health.

A. The AOA states it is aware of no specific study...

Q. Identify and describe all studies of which you are aware that discuss, or make any conclusions about, whether contact lens prescriptions should be valid for a limited period of time.

A. The AOA states it is aware of no specific study...

In April 2001 the AOA paid \$750,000 *and agrees it will no longer object to the release of contact prescriptions, and agrees to no longer represent that there are health risks associated with purchasing contact lenses from alternate suppliers.*

- During the legal proceedings, there was never a single documented case of any consumer that had been injured or harmed when they purchased their lens from alternative or direct-to-consumer contact lens providers**.

2-Year Prescription Versus 1-Year

I have concerns relating to Kansas (HB 2285) would make contact lens prescriptions effective for a ONLY minimum of 1 year. A 2 year expiration date *is* a medically appropriate period.

Concern

My professional colleagues receive substantial income from professional fees and the retail sale of contact lenses. This is a professional conflict-of-interest. Eye doctors will be economically rewarded by writing 1-year expirations. The AOA states that the appropriate exam interval for age 18-60 at-risk (contact lens) population is up to 2 years or less if physician advised. Consumers will be forced to pay unnecessary additional yearly exam fees.

- Estimate of Kansas contact lens wearers	375,000
- <u>Average cost of contact lens exam approximately</u>	<u>\$100</u>
<i>Estimated annual fees to physicians</i>	<i>Between \$19M & \$38M</i>

- **Many** optical plans do not provide annual coverage. This will create additional financial burden on consumers, businesses, and insurance companies.
- Patients regularly purchase 1-year lens supplies from the doctor at the time of exam. The 1-year minimum effectively hinders consumer choice. 2 years is consistent with good practice standards. It is a medically safe period for lens replacement.

Remedy – A maximum 2-year prescription expiration date for contact lenses, unless medically warranted.

A doctor can still determine that 2 years is too long in medically appropriate cases.

Automatic Contact Lens Prescription Release

Pending legislation (HB 2285) would **require** physicians or optometrists to provide a valid contact lens prescription to a patient **only upon request**. Currently, Kansas has no such requirement.

Issue

- Most Kansas consumers won't know to ask for a prescription. Patients are intimidated to ask for it. There is no ethical or medical reason to force consumers to ask for a valid Rx copy...It is a patient retention tool used by doctors designed to limit consumer choice, and keep lens revenues in the practice. Upon request contact lens release is specifically contrary to the American Medical Association Code of Ethics.

Solution – Automatically release a patient's prescription to them upon payment of services.

- This change is consistent with nationwide physician prescribing standards, the American Academy of Ophthalmology, and the Federal Trade Commission's Ophthalmic Practice Rules Study.
 - Automatic Prescription Release provides the same rights to contact lens wearers that eyeglass wearers have had since 1978.
 - Yesterday my colleagues agreed to automatic release when questioned by Senator Wagle. Automatic release will allow consumers the freedom to choose where they want to buy their contact lenses. It is the only ethical and appropriate choice.
- Plaintiff's Statement of Facts, Contact Lens Antitrust Litigation, U.S. District Court, Jacksonville, Florida

BEFORE THE
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

In the Matter of:

16 CFR Part 456

COMMENTS OF THE ATTORNEYS GENERAL OF
ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, CONNECTICUT,
DELAWARE, FLORIDA, ILLINOIS, IOWA, MARYLAND, MICHIGAN, MINNESOTA
NEW YORK, OHIO, PENNSYLVANIA, WEST VIRGINIA AND WISCONSIN

The Attorneys General of Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Illinois, Iowa, Maryland, Michigan, Minnesota, New York, Ohio, Pennsylvania, West Virginia and Wisconsin submit their Comments in response to the Federal Trade Commission's ("Commission") Request for Comments concerning Ophthalmic Practice Rules, 16 CFR Part 456, issued on April 3, 1997 ("Spectacle Prescription Release Rule". This Rule requires eye-care practitioners to release eyeglass prescriptions to their patients. The Commission is seeking comments on whether to continue or amend that Rule. The Attorneys General are the chief enforcers of (1) state and federal antitrust laws, and (2) state consumer protection laws which sometimes incorporate administrative regulatory rules such as the "Prescription Release Rule." The Attorneys General believe the rule has served consumers well over the past 20 years and should be continued. The Rule should also be expanded to cover contact lens prescriptions. The Attorneys General submit the following comments on behalf of their citizens.

SUMMARY OF THE POSITION OF THE ATTORNEYS GENERAL

The Attorneys General believe that the Spectacle Prescription Release Rule should be retained and expanded to require the release of contact lens prescriptions. The existing rule relating to eyeglass prescriptions has presented consumers with a wide variety of alternatives to obtain their eyeglasses. These alternatives have allowed consumers to choose among suppliers at varying price points and service levels. Consumers can have eyeglasses made in as little as one hour and at a very low cost. The Attorney Generals are aware of no harm that has come to consumers as a result of the existing Spectacle Prescription Release Rule.

The Attorneys General assert that the release of contact lens prescriptions will lower consumer costs for contact lenses and increase the safety of these lenses to consumers. The Attorneys General also urge the Commission to expand the applicability of the Prescription Release Rule to contact lens prescriptions, and contend that eye-care practitioners and their trade associations have participated in a conspiracy to refuse to release contact lenses to consumers. Requiring the release of contact lens prescriptions will mitigate the effect of the conspiracy.

INTEREST OF THE ATTORNEYS GENERAL

The Attorneys General, in enforcing both federal and state antitrust laws, have an interest in maintaining an open and competitive marketplace for eyeglasses and contact lens sales. The Attorneys General represent 110,900,621 consumers, an estimated 40% of whom use eyeglasses or contact lenses. In addition, the Attorneys General of 27 states are involved in litigation against several contact lens manufacturers, eye-care practitioners and eye-care practitioner trade associations alleging two conspiracies: (1) that the manufacturers and the practitioners and their trade associations conspired to eliminate sales of contact lenses by pharmacies, mail order and other alternative sellers; and (2) that the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers. A copy of the complaint is attached as Exhibit A.'

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PRESCRIPTION RELEASE RULE

Twenty years ago, eye-care practitioners attempted to dominate the eyeglass market by withholding prescriptions. This attempt at controlling the eyeglass market prompted the Commission to adopt the Spectacle Prescription Release Rule, which mandates the release of eyeglass prescriptions to patients. This Rule was adopted based on the finding that many consumers were deterred from comparison shopping for eyeglasses because eye-care practitioners refused to release prescriptions. "The rule requires an optometrist or ophthalmologist to provide the patient with a copy of the patient's eyeglass prescription immediately after the eye examination is completed at no extra cost." 16 CFR 456(a) and (c). The rule also has two additional requirements: (1) it prohibits the eye-care practitioner from conditioning the availability of an eye care examination on an agreement to purchase ophthalmic goods; and (2) eye-care practitioner must release copies of eyeglass prescriptions to their customers (patients) regardless of whether they request the prescription. The automatic release rule alerts the consumer to the fact that the purchase of eyeglasses can be separate from obtaining an eye exam. "The Commission also determined not to extend the 'Prescription Release Rule' to contact lens prescriptions. In making its decision, the Commission concluded that there was not sufficient evidence on the record to permit a conclusion that the practice not to release contact lens prescriptions was prevalent." Moreover, the last time the FTC fully considered the rule in 1989, disposable and frequent planned replacement soft contact lenses had only recently come on the market. Prior to that time and at the time of the Eyeglass I and Eyeglass II proceedings, lenses were not manufactured in a way that always accurately reproduced the same prescription.

Twenty years of actual experience and our investigation of the past three years has shown that not only are restrictions on the release of contact lens prescriptions prevalent, but that eye care practitioners regularly shared among themselves and discussed in their trade journals, numerous methods to discourage consumers from requesting their prescriptions, or how to make the prescriptions they were forced by law to release less useful. Eye-care professionals have advised colleagues to outright refuse to give consumers prescriptions or make consumers or other possible dispensers of contact lenses sign a waiver of liability which absolves the eye-care practitioner from liability in connection with the prescription. See e.g. Koetting "I want my Contact Lens RX" *Optometric Economics*, 30-37, (February 1991); Kirkner, 10 Ways to Keep RXs from Walking, *Review of Optometry*, 59-64, (Sept. 15, 1994) (article about a roundtable of optometrists discussing how to keep patients from using competitors); Snyder, *Winning the War Against Mail Order Contact Lenses*, *Optometry Today*, Vol., No. 1, (1993).

Another example of the types of restrictions on eye-care practitioners used can be found in Exhibit B to the Settlement Agreement between certain Attorneys General and the Contact Lens Association of Ophthalmologists, Inc. That exhibit shows a release form distributed by an ophthalmologic trade association for use by eye-care practitioners in response to a request from a consumer for a prescription. The document states that it may not be used as a prescription. Given various eye-care practitioners' organized efforts to resist release of prescriptions, the Attorneys General advocate that the Commission order release of prescriptions. A copy of the Settlement Agreement is attached as Exhibit B.

Since the Commission promulgated the original rule in 1978, the contact lens industry has changed radically in other ways. Twenty years ago, the soft contact lens industry relied on lenses that were designed to be replaced annually, coinciding with the period typically recommended for reexamination by eye-care practitioners. Beginning in the late 1980's, lens manufacturers began to market and sell what are now known commonly as "disposable" lens or "frequent replacement" lenses, which are designed to be replaced daily, weekly or monthly. Manufacturers have developed manufacturing methods that eliminated the reproducibility problems of 20 years ago. Consumers have increasingly chosen these lenses over "conventional" soft contact lenses, and a market has developed for their resupply. Today, more than 26 million consumers wear contact lenses. This increase in contact lens wear and sales volume led to the development of alternative suppliers, like pharmacies, buying clubs, department stores, mass merchandisers, and mail order houses. Despite some restrictions on their supply of lenses, these alternative suppliers gave consumers a convenient and cost-effective method of purchasing contact lenses. The alternative suppliers typically apply a smaller markup on the price of the lens relative to that of most eye-

care practitioners. These savings were passed on to the eye care consumer in the form of lower costs. Obtaining contact lenses from alternative suppliers may also spare consumers the cost of an extra office visit to an eye-care practitioner.

IMPORTANCE OF PRESCRIPTION RELEASE

The existing prescription release rule has already saved consumers money on eyeglasses. Expanding the rule to cover contact lenses will likewise allow consumers to save money on contact lenses and increase the safety of using lenses for most consumers. Requiring the ready release of a prescription would have almost no cost impact on eye-care practitioners.

Allowing consumers to shop for lenses at multiple possible dispensing locations rather than only from their eye-care practitioners will increase their options. Generally, when consumers have more choices, they pay lower prices. In this instance, this is particularly true because the expanded distribution of contact lenses through traditionally lower cost suppliers, like pharmacies, buying clubs, mail order and mass merchandisers, results in distribution cost savings which normally will be passed on to consumers

As costs of lenses come down, the eye health of consumers using soft lenses, particularly disposable or frequent replacement lenses, will benefit. At present, consumers may exceed the recommended wearing schedule for a lens or engage in other possibly injurious conduct in an attempt to save money by extending the life of their disposable lenses. Such conduct could harm consumers should their lenses become dirty or carry bacteria or viruses which would not have a chance to develop if they were worn and disposed of properly. **Easier access to, and lower prices for, replacement lenses should encourage consumers to wear and use the lenses properly, thereby increasing patient safety.**

Not only would costs to consumers go down and safety increase as the result of an expanded prescription release rule, but the costs to eye-care practitioners of releasing prescriptions is nominal. Eye-care practitioners must simply provide the consumer with a copy of a prescription he or she is recording anyway. The slight cost of providing a written copy of a prescription does not justify a failure to mandate the release of prescriptions.

Eye-care practitioners may complain that a prescription release rule may "cost" them lost profits or the sale of contact lenses to their patients. This is not a "cost." Eye-care practitioners are free to compete for sales to their own patients and those of other practitioners.

ARGUMENTS AGAINST RELEASE

Eye-care practitioners cite two main reasons in defense of their practice of withholding prescriptions: (1) liability and (2) consumer eye health. The argument involving liability is simply that, if alternative suppliers incorrectly provide the wrong contact lenses, the eye-care practitioner can be held liable. While the ability of plaintiffs' lawyers to create liability theories is endless, physicians are not normally held liable when a pharmacist provides the wrong drug in response to a prescription. It is unclear how misfilling a contact lens prescription by a pharmacist, for example, would create grounds for liability for the eye-care practitioner.

The second argument against releasing prescriptions involves consumer eye health. By withholding prescriptions, eye-care practitioners argue they are ensuring the patient comes back for eye care. If a consumer wants a new batch of lenses, the eye-care practitioner theoretically uses the trip to the office to check the general eye health by a range of activities, from having a receptionist or nurse interrogate the consumer or by having the eye-care practitioner actually perform an examination. This "consumer health" argument is based on a contention that a contact lens, a "medical device," somehow requires an eye care professionals' care and attention at every possible wearing of both the original and replacement lenses. **In**

fact, as a Class II medical device, a disposable contact lens is subject to the same standards of FDA review as a toothbrush.

As such, it is clear that to claim that contact lenses should be marketed only by eye-care professionals, is to claim they are only safe to use after the inspection of each and every lens by an eye-care practitioner. In fact, almost all manufacturers now provide direct shipment of replacement contact lenses to consumers as a means of general commercial practice. Our investigation has revealed that many eye-care practitioners mail replacement contact lenses to their patients without an office visit during the life of the prescription.

Purchasers from alternative channels have had no greater ocular health problems than purchasers from eye-care practitioners. Our multistate investigation has failed to reveal any study showing any correlation between compromised ocular health and receipt of lenses through alternative channels. Many other medical products, such as pharmaceutical drugs, have been and are regularly dispensed safely via these same alternative channels of distribution. Clearly, if these methods of distribution are acceptable for prescription drugs, which can cause far more potential harm if the prescription is filled improperly than an improperly filled contact lens prescription, then using the alternative channels of distribution for contact lenses should be acceptable as well. Prescription drugs are widely available through grocery stores, mass merchandisers, pharmacies and through mail order and require only that the consumer have a prescription readily available. The more than 26 million consumers who use soft contact lenses should have the same financial and convenience benefits available to them as those consumers who purchase prescription drugs or eyeglasses.

CONCLUSION

The foregoing comments are submitted to demonstrate the need for continuing the Prescription Release Rule. Moreover, the Attorneys General believe the interests of consumers will be best served by expanding coverage of the rule to contact lenses. Dated: September 2, 1997

Respectfully submitted,

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Lens users pay high prices

Buying contact lenses from someone other than your doctor can save you big bucks. But it's not easy in Michigan, where many offices won't simply hand over the prescription.

December 4, 1998

BY ALISON YOUNG

Free Press Consumer Affairs Writer

Contact lens wearers can cut their costs in half by shopping around or ordering from discount outlets or mail-order companies. But good luck getting an optometrist to hand over a copy of the prescription.

Because Michigan has no state law requiring eye doctors to release contact prescriptions to their patients, consumers are forced to purchase lenses from their doctors -- often at much-inflated prices -- according to a Free Press survey of metro Detroit optometrists' policies and prices.

Of 50 optometry offices surveyed in Wayne, Oakland and Macomb counties, only one would release a contact-lens prescription to patients after an exam. Nearly all the rest require patients to purchase lenses from them -- for an average price that was almost triple the best price available elsewhere.

Among the findings:

- Prices ranged from \$48 to \$185 for one pair of the same brand and type of soft daily wear lenses. The average price was \$85. The same pair costs \$30 at Costco wholesale club. The best mail-order price was around \$47,

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including shipping.

- Prices for an eye exam ranged from \$30 to \$105. The average was \$76.
- 54 percent of optometry offices said they never release contact prescriptions to patients.
- 40 percent of optometry offices were willing to give patients a copy of their contact prescriptions -- but only after they purchased a pair of contacts from their office. It made no difference that the consumer was a longtime wearer of the same type and brand of contacts and did not need a first-time fitting.

The Free Press survey, patterned after one done last year in Texas by the nonprofit product-testing group Consumers Union, was designed to re-create the experience of a consumer shopping by phone for the best buy in daily wear soft contact lenses and exams. It included calls last month to major chains and independent doctors offices.

Twenty-four states have passed laws requiring the release of contact-lens prescriptions as a way to encourage price competition and prevent gouging. Michigan is not one of them. Nationwide, 30 million Americans wear contact lenses and spend \$2.5 billion on them annually.

Michigan regulators -- as well as many optometrists -- say they don't believe that requiring the release of lens prescriptions is in patients' best interest.

To protect eye health, contacts must be properly fitted to the curve of each individual's eyes and wear must be supervised by doctors, according to optometrists, the eye-care professionals who issue most contact-lens prescriptions.

Many consumers don't properly care for lenses, they say. And if consumers are given their prescriptions and allowed to purchase lenses at will, they will be more likely to ignore check-up schedules, wear worn-out or ill-fitting

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lenses and suffer serious eye damage and infections.

"Contact lenses are a medical device that can affect your general health as well as your eye health.... It's not a commodity like shopping for shoes," said Tom Lindsay, whose office regulates optometrists for the Michigan Department of Consumer and Industry Services.

That's the reason the Michigan Board of Optometry doesn't think optometrists should be required to release prescriptions to patients. "We know that's controversial," Lindsay said.

But Lisa McGiffert, a senior policy analyst who has studied the issue for Consumers Union's southwest regional office in Austin, Texas, said, "People should have the right to go out and get their prescription filled."

Consumers Union publishes Consumer Reports magazine.

Consumers Union contends that being fitted for contact lenses is comparable to getting a prescription for pharmaceutical drugs from a medical doctor. Consumers are accustomed to getting a prescription from a doctor, having it filled elsewhere and returning to their doctor if a problem arises.

Though optometrists argue a special need for patient supervision, "We feel that holding them hostage to buy contact lenses from them is not the way to do it," McGiffert said.

Dr. Harvey Hanlen, president-elect of the American Optometric Association, said he agrees, adding that he thinks withholding prescriptions from patients may be detrimental to good doctor-patient relationships.

"I just don't think it's good practice management," said Hanlen, whose practice is in State College, Pa.

In Hanlen's opinion, doctors should be focusing on health-care services -- not product sales. "A

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lot of doctors don't necessarily agree with my philosophy," he said.

Since the 1970s, eye doctors have been required by the Federal Trade Commission to provide patients with a copy of their eyeglass prescription after each exam -- even if a patient doesn't ask for it.

The federal rule does not require the release of contact-lens prescriptions. But the FTC is reviewing the rule. A decision is expected next year, FTC staff attorney Renee Kinscheck said.

Even though a 1995 FTC survey concluded that nearly 92 percent of patients nationwide are able to obtain copies of their contact-lens prescriptions, the commission continues to hear from consumers who can't get them. A 1997 survey by Consumers Union found that 65 percent of Texas optometrists were unwilling to release such prescriptions to patients. Texas has since passed a prescription-release law.

The commission is trying to determine whether the financial harm to consumers nationwide outweighs the health risks claimed by eye doctors. "This has been more of a controversial and difficult issue than many of our others," Kinscheck said.

Among those opposed to a federal rule requiring the release of contact prescriptions to patients are the American Optometric Association, individual optometrists and some state optometry boards.

Among those who want such a rule are the National Association of Optometrists and Opticians, whose members are large retail optical chains; opticians; the attorneys general of 18 states, including Michigan and mail-order contact lens companies.

In the meantime -- without a state or federal law requiring the release of contact prescriptions -- Michigan consumers can save by shopping around and comparing the lens prices and release policies of local optometrists.

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Though the Free Press survey found that Michigan optometrists tend to charge inflated prices for contact lenses, the optometrists contend their patients get better service for that extra cost, such as being allowed to try out different types or brands of lenses before buying.

Many optometrists say they will price-match if a patient asks, as a way to keep supervising a patient's care.

By purchasing from a mail-order house "a patient may save, but in the long run are they really saving by taking risks?" asked Dr. Susan Mithoff, a Trenton optometrist, who is among the many who won't give contact prescriptions to patients.

Village Optician in Birmingham was the only office surveyed where an optometrist will give patients their contact-lens prescriptions without requiring that at least one pair of lenses be purchased on site.

"If they request it, we release it. It's as simple as that," said Bill Martin, who owns the business. While the office recommends that clients purchase their first pair of lenses through the office, it's not required, Martin said.

Heavy marketing by mail-order companies has prompted an increasing number of patients to ask for their prescriptions, said Dr. Fred Lichota, an optometrist who has offices in Troy, Romeo and New Baltimore.

Lichota is among those doctors who will give patients their prescriptions after they purchase a pair of lenses from him, and his follow-up exams show no problems.

But not all patients want to purchase lenses elsewhere. "There are some people who know they should not go someplace else," Lichota said, because they are difficult to fit or have other unusual eye conditions. "There are others who are very typical patients who understand they can go anywhere and purchase the same

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lenses," he said.

Lichota said he is realistic and knows that his practice must be able to compete with low-cost mail-order houses. "We've had to bring our prices down to that level to keep patients in the fold," he said. "We have to be competitive to keep them coming back."

Alison Young can be reached at 1-248-586-2603 or by E-mail at young@freepress.com

SHOPPING TIPS

Call optometrists and ask what they charge for exams, contacts and any related fees.

One office surveyed by the Free Press said it charged \$50 for a contact lens exam; when pressed, it was revealed that the office also charged a fitting fee of up to \$50. Ask whether the price being quoted for contacts is for one lens or for a pair.

The Free Press found that some optometry offices were unable to quote an exact price for certain brands of lenses. Others would quote only prices for package deals that included such items as exams, lenses (not necessarily the brand the shopper had been wearing), solutions and other items.

- If you want a copy of your contact lens prescription, ask when shopping by phone what the doctor's policy is. Then ask the doctor on the day of your appointment.

During the Free Press survey, people answering the phones at two optometry offices, both part of a large chain, insisted that contact prescriptions would be released without any conditions. But store managers later said the prescriptions wouldn't be released until after a pair of lenses had been purchased.

- Pick an office you like and stick with it.

Consumers can improve their care this way -- and often save money. Many offices may charge as much as \$100 for a first exam, but subsequent annual exams at the same location can be about half that price.

- Look for package deals that include an exam and lenses for a price significantly less than purchasing them separately.

These may be the best deals for first-time lens wearers. Established wearers need to check whether their usual brand and type of lens is available at the package price; often it's not.

- If you are already wearing contacts and have had success with a particular brand and type of lens, do a price check with some of the large mail-order companies or discounters.

Be aware that the shipping charges and membership fees some of these firms charge can significantly drive up the quoted price. Ask about specials: Some mail-order houses will waive shipping or other fees if you order by mail or through the Internet, rather than by phone.

Two companies to try: 1-800-CONTACTS and Lens Express, 1-800-666-5367. When ordering by mail, ask what the company's policy is for replacing damaged or defective lenses. Look for companies that will send replacements at no charge.

Discounters, such as Costco and Wal-Mart, may also be able to offer significant savings. Keep in mind that Costco costs \$40 a year to belong.

- Ask your optometrist whether he or she will price match.

What the rules are

The Federal Trade Commission requires eye doctors to release prescriptions for eyeglasses, but not for contact lenses.

Michigan has no state law or rule requiring the release of contact prescriptions, but 24 other states do: Alabama, Arizona, Colorado, Delaware, Florida, Georgia, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, South Dakota, Texas, Vermont, Virginia, Washington and Wyoming.

To be heard

- To comment on whether the FTC should require eye doctors nationwide to release contact-lens prescriptions to patients, write to: FTC, Room 200, 600 Pennsylvania Ave. NW, Washington, D.C. 20580

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- To comment on whether Michigan should have a law requiring release of contact-lens prescriptions, write to: Tom Lindsay, Office of Health Services, Michigan Department of Consumer and Industry Services, Ottawa Tower Building, First Floor, Lansing 48909

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American College of Clinical Pharmacy

American Medical Association

Association of American Medical Colleges

BlueCross BlueShield Association

Consumer Healthcare Products Association

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Standards of Care

The following represents the published Standards of Care for the leading optometric and ophthalmology organizations

I. Optometric - Founded in 1898, The American Optometric Association (AOA) is the premiere authority in the optometric industry with more than 32,000 members in 6,660 U.S. and foreign communities. The AOA public recommendations for regular optometric care:

Public At Large:

<u>Optometric Care</u>	<u>Risk Free</u>	<u>At Risk</u>
Age 6-18 (starting in 1 st grade)	Every 2 Years	Annually or as Recommended
Age 18-40	Every 2-3 Years	Every 1-2 Years or as Recommended
Age 41-60	Every 2-3 Years	Every 1-2 Years or as Recommended
61 +	Annually	Annually

Adult & Pediatric Patients:

<u>Exam Frequency</u>	<u>Risk Free</u>	<u>At Risk</u>
Age 6-18 (starting in 1 st grade)	Every 2 Years	Annually or as Recommended
Age 18-40	Every 2-3 Years	Every 1-2 Years or as Recommended
Age 41-60	Every 2-3 Years	Every 1-2 Years or as Recommended
61 +	Annually	Annually

For more information, please see their website at www.aoanet.org.

II. Ophthalmic - The American Academy of Ophthalmology is the largest national membership association of ophthalmologists. More than ninety-four percent of practicing U.S. ophthalmologists are Academy members. The Academy was founded in 1896.

The American Academy of Ophthalmology's mission is to advance the lifelong learning and professional interests of ophthalmologists to ensure that the public can obtain the best possible eye care. It is the vision of the Board of Trustees that the Academy be the most valuable and credible professional eye organization in the world.

Ophthalmic (MD) Examination

Age	Frequency
6-19	every 2 years
20-39	periodically 2-5 years, then age 40
40-64	2-4 years
65 +	1-2 years

For more information, please see their website at www.aao.org



American Optometric Association

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Recommended Examination Frequency for Pediatric Patients and Adults

Recommended Examination Frequency For the Pediatric Patient

< [Primary Care Committee](#)

Patient Age	Examination Interval	
	Asymptomatic/Risk Free	At Risk
Birth to 24 Months	By 6 months of age	By 6 months of age or as recommended
2 to 5 years	At 3 years of age	At 3 years of age or as recommended
6 to 18 years	Before first grade and every two years thereafter	Annually or as recommended

Children considered to be at risk for the development of eye and vision problems may need additional testing or more frequent re-evaluation. Factors placing an infant, toddler, or child at significant risk for visual impairment include

- Prematurity, low birth weight, oxygen at birth, grade III or IV intraventricular hemorrhage
- Family history of retinoblastoma, congenital cataracts, or metabolic or genetic disease
- Infection of mother during pregnancy (e.g., rubella, toxoplasmosis, venereal disease, herpes, cytomegalovirus, or AIDS)
- Difficult or assisted labor, which may be associated with fetal distress or low Apgar scores
- High refractive error
- Strabismus
- Anisometropia
- Known or suspected central nervous system dysfunction evidenced by developmental delay, cerebral palsy, dysmorphic features, seizures, or hydrocephalus

Recommended Examination Frequency For the Adult Patient

Patient Age	Examination Interval	
	Asymptomatic/Risk Free	At Risk
18 to 40years	Every two to three years	Every one to two years or as recommended
41 to 60years	Every two years	Every one to two years or as recommended
61 and older	Annually	Annually or as recommended

Patients at risk include those with diabetes, hypertension, or a family history of ocular

disease (e.g., glaucoma, macular degeneration); those working in occupations that are highly demanding visually or eye hazardous; those taking prescription or nonprescription drugs with ocular side effects; those wearing contact lenses; and those with other health concerns or conditions.



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Health Tips on How Often to Have an Eye Exam

Many people want to know how often they should have their eyes examined. The answer depends on your age, medical background and risk factors for disease.

In general, Eye M.D.s recommend the following exam schedules:

Children

(Screening for eye disease by trained personnel: Eye M.D., pediatrician or trained screener.)

- Newborn to 3 months
- 6 months to 1 year
- 3 years (approximately)
- 5 years (approximately)

Adults

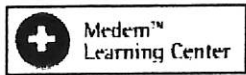
(Comprehensive medical eye exam by an Eye M.D.)

- Once between age 20 and 39
- Age 40-64, every two to four years
- Age 65 and older, every one to two years.

Some factors may put you at increased risk for eye disease. **If any of these factors applies to you, check with your Eye M.D. to see how often you should have a medical eye exam:**

- Developmental delay
- Premature birth
- Personal or family history of eye disease
- African-American heritage (African-Americans are at increased risk for glaucoma)
- Previous serious eye injury
- Use of certain medications (check with your Eye M.D.)

Addressing the issues and concerns associated with online physician-patient interaction and communication. [\[Read more\]](#)



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Health Spotlight

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- Some diseases that affect the whole body (such as diabetes or HIV infection)

Take good care of your eyes-because there's so much more in life to see!



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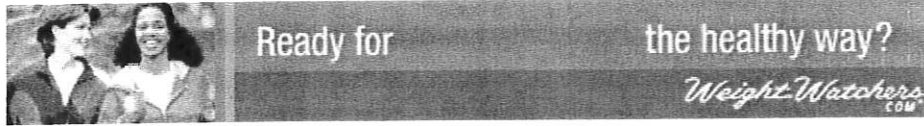


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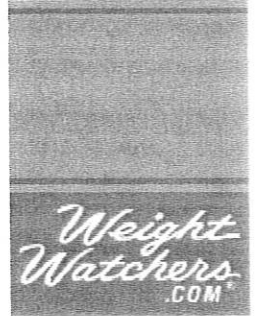
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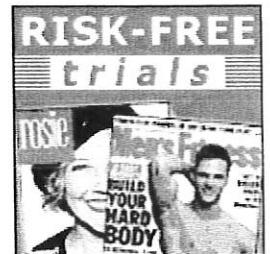
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Checking Up on Your Eyes

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How often should you have your eyes examined? Different professional organizations, such as the American Academy of Ophthalmology (AAO) and the American Optometric Association (AOA), have somewhat different recommendations. But they are close enough in principle to give you some ballpark guidelines.

Infants and Children

Babies should be screened for eye disease soon after birth, or no later than 6 months of age. Children should have their eyes checked at about age 3, and again around age 5 or 6.

Infants and young children may need to be followed more closely if they were premature, the mother had certain diseases during pregnancy, or if eye disease or severe vision problems run in the family. After age 6, barring special circumstances, kids should have eye exams every two years until they are in their teens.

Recommendations for Adults

For adults age 18 to 60, the AOA advises exams every two or three years, followed by annual exams after 60. However, the AAO recommends "occasional" exams between the ages of 18 and 40. Around age 40, the AAO urges a comprehensive eye exam, followed by a check-up every two to five years.

The AAO used to recommend more regular exams, but now the group thinks the schedule should be determined by existing vision problems and



eye disease, and whether an individual is at risk for such problems.

Special Considerations

These recommendations are for people in good health. If you have diabetes, hypertension, AIDS, or a family history of glaucoma, cataracts or other eye disease, ask your eye doctor how often you should have your eyes checked. You may also need more frequent checkups if you are taking medication with side effects that can affect vision.

African-Americans have a much higher risk of glaucoma and tend to get it at a much earlier age. Glaucoma is the leading cause of blindness among African-Americans, but as with Caucasians, blindness is preventable if the disease is detected early enough.

Since glaucoma rarely shows symptoms until some damage is done, African-Americans are advised to have a glaucoma exam by age 35 or 40 at the latest. Those who have a family history of glaucoma may want to begin their exams even earlier.

After age 40, most people will start to have some deterioration in their vision. If you are having trouble seeing, or have any other symptoms involving your eyes, possibly including headaches, do not wait until you are "due" to have an exam. Call your eye doctor right away for an appointment.

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

IN RE: DISPOSABLE CONTACT LENS
ANTITRUST LITIGATION

MDL Docket No. 1030

This document relates to:

- Civil Action Nos. 97-698-Civ-J-21C
- 97-861-Civ-J-20A
- 97-928-Civ-J-20A
- 98-93-Civ-J-21A
- 98-511-Civ-J-21B
- 98-515-Civ-J-21C
- 98-536-Civ-J-20A
- 98-638-Civ-J-21A

**THE AMERICAN OPTOMETRIC ASSOCIATION'S RESPONSE TO
"STATES' THIRD DISCOVERY REQUESTS TO THE AOA"**

Defendant, the American Optometric Association ("AOA"), by and through its undersigned counsel and pursuant to Fed. R. Civ. P. 33, 34, hereby responds to the "States' Third Discovery Requests to the AOA," served December 24, 1998 ("the Third Request").¹

GENERAL OBJECTIONS

The AOA incorporates the following General Objections into its response to each interrogatory:

¹ Plaintiff States agreed that the AOA could serve responses to the Third Request on or before February 8, 1999.

7. Identify and describe all studies of which you are aware that discuss any effect the dispensing of contact lenses by alternative channels has on ocular health.

OBJECTION

The AOA objects to the term "studies" as vague and undefined. The AOA will assume that Plaintiff States intend "studies" to mean formal efforts to examine an issue (e.g., clinical research), and not instances in which a person or groups of persons discussed or considered an issue, and not the clinical and other experiences of individuals. Moreover, the AOA objects to conducting a library search for Plaintiff States of publicly available documents.

RESPONSE

The AOA states it is aware of no specific study as defined above.

8. Identify and describe all studies of which you are aware that discuss, or make any conclusions about, whether contact lens prescriptions should be valid for a limited period of time.

OBJECTION

The AOA objects to the term "studies" as vague and undefined. The AOA will assume that Plaintiff States intend "studies" to mean formal efforts to examine an issue (e.g., clinical research), and not instances in which a person or groups of persons discussed or considered an issue, the clinical and other experiences of individuals, articles or textbooks. Moreover, this interrogatory only asks for "studies" discussing or drawing conclusions about how long a prescription should be valid; the AOA is thus not required to identify the numerous texts and articles concerning eye changes over time, concerning eye injury or disease that is caused or aggravated by contact lens wear, and concerning how eye health problems can be reduced or avoided with regular examinations. The AOA objects to conducting a library search for Plaintiff States of publicly available documents.

RESPONSE

The AOA states it is aware of no specific study as defined above.

9. Identify and describe all studies of which you are aware that discuss, or make any conclusions about, whether there is a medical risk from not providing an expiration date for contact lens prescriptions.

SEE OBJECTION AND RESPONSE TO INTERROGATORY 8.

10. Identify and describe all studies of which you are aware that discuss, or make any conclusions about, whether there is any risk from phone or mail order contact lenses sellers selling replacement lens [sic] to consumers who have expired prescriptions.

SEE OBJECTION AND RESPONSE TO INTERROGATORY 8.

11. Identify and describe all studies of which you are aware that discuss, or make any conclusions about, whether any contact lens users have suffered medical problems after purchasing lens [sic] from mail or phone order companies.

SEE OBJECTION AND RESPONSE TO INTERROGATORY 7.

12. Identify and describe all studies of which you are aware that discuss, or make any conclusions about, whether any contact lens users have suffered medical problems after purchasing contact lens [sic] from Os.

OBJECTION

The AOA assumes that Plaintiff States intend to ask for identification of studies that discuss or draw conclusions about contact lens users suffering (or not suffering) medical problems *because* of purchasing contact lenses from Os (instead of some other source), and not studies where the lens wearers involved only happened to have obtained contact lenses from Os. If the AOA's assumption is incorrect, the AOA objects to this interrogatory as overly broad and as seeking information which is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Such an interrogatory would require identification of almost every contact lens study ever conducted.

The AOA objects to the term "studies" as vague and undefined. The AOA will assume that Plaintiff States intend "studies" to mean formal efforts to examine an issue (e.g., clinical research), and not instances in which a person or groups of persons discussed or considered an issue, the clinical and other experiences of individuals, articles or textbooks. Moreover, and assuming the AOA's interpretation in the preceding paragraph is correct, this interrogatory only asks for "studies" discussing or drawing conclusions about whether contact lens users have suffered (or not suffered) medical problems because they purchased their lenses from Os. Accordingly, the AOA is thus not required to identify the numerous texts and articles

American Medical Association Code of Ethics

On the Subject of Doctor's releasing prescriptions:

E-8.06 Drugs and Devices: Prescribing:

"Patients have an ethically and legally recognized right to *prompt* access to the information contained in their individual medical records. The prescription is an essential part of the patient's medical record."

"Patients are entitled to the same freedom of choice in selecting who will fill their prescription needs as they are in the choice of a physician. The prescription is a written direction for a therapeutic or corrective agent. A patient is entitled to a copy of the physician's prescription for drugs, eyeglasses, contact lenses, or other devices as required by the Principles of Medical Ethics and as required by law. The patient has the right to have the prescription filled wherever the patient wishes."

Can be found under "Code of Medical Ethics" at:

<http://www.ama-assn.org/ama/pub/category/2503.html>

Click on the "major sections" link in the second paragraph and find your way to section E-8.06.

Madam Chairman and committee members,

Thank you for the opportunity to testify before you today. My name is Kevin McCallum and I represent 1-800 CONTACTS and our more than 16,000 Kansas customers.

I am especially appreciative for the opportunity to testify on the specific language contained in the Substitute for House Bill 2285 because it was never publicly heard in the Kansas House.

Substitute for House Bill 2285 is an attempt by organized optometry in the state of Kansas to regulate competition. Its intent is not in consumer protection, but rather in self-protection. If passed, it would: 1) foster continued resistance to consumer access to contact lens prescriptions; 2) place a additional financial burden on contact lens wearers that optometrists directly benefit; 3) allow optometrists to hold consumers hostage if they chose to purchase their contact lenses elsewhere; and 4) create a regulatory process that would allow optometrists to regulate their competition.

It is important to understand one underlying issue: Optometrists sell what they prescribe. While the medical profession long ago abandoned selling the products it prescribes because of the conflict of interest, this profession has clung to that practice. Optometrists make more money off the sale of products than off the services they render.

	<u>Health Care Provider</u>	<u>Prescription Retailer</u>
Family Health Care	Family Doctor	Pharmacy/Drug Store
Eye Health Care	Optometrist	Optometrist

Today there is wonderful cooperation between Family doctors' offices and pharmacies, this same relationship does not exist in the contact lens industry because the primary eye care provider and the contact lens retailer remain direct competitors. Consumers will not benefit from the bill as proposed because it will establish a near monopoly for lens fitters.

This conflict of interest has also been the catalyst for non-traditional doctor behavior that is well documented. For example: Eyeglasses. In 1978, the Federal Trade Commission issued a Federal Statute called the Spectacle Prescription Release Rule which mandated the AUTOMATIC release of eyeglass prescriptions to patients. This statute was the result of well-documented cases of optometrists withholding eyeglass prescriptions from patients to limit competition. With this ruling, consumer rights triumphed giving eyeglass wearers the right to buy eyeglasses more conveniently and at lower costs spawning a myriad of thriving national & local retailers such as LensCrafters and Pearle Vision.

This behavior is prevalent in the contact lens industry and is being exposed through the investigative efforts of numerous local journalists, state Attorneys General and consumer advocates. They have uncovered numerous examples of optometrists withholding contact lens prescriptions so that patients would be forced to buy from them, including states where release is mandated. Without exception, these reports also disclosed that consumers paid higher prices – as much as three times more.

Undercover video.

*Senate Public Health & Welfare Committee
Date: March 21, 2002
Attachments # 4*

Probably the best example to demonstrate the self-protection behavior created by a system which allows health care providers to sell what they prescribe is the course of events which led to a lawsuit in which 32 state Attorneys General, including Kansas, sued the American Optometric Association (AOA).

Without any quantitative data or study to support, the AOA, of which the KOA is an affiliate, represented to the public and to the Food & Drug Administration that there were health risks associated with one purchasing contact lenses from alternative channels of distribution. These claims became one of the primary focus areas of the federal lawsuit. Specifically, the Attorneys General complained the:

“AOA falsely represented to the Food & Drug Administration that a survey supported the conclusion that consumers who obtained contact lenses through alternative channels encountered health problems as a result.”

- In re Disposable Contact Lens Anti-Trust Litigation, MDL no 1030 Amended Complaint ¶ 55 (E.D.N.Y. 1997)

This lawsuit was settled during trial last April. Through seven years of discovery, no survey was ever produced by the AOA and now the record is clear. The AOA paid a \$750,000 settlement and the settlement agreement specifically states that the:

“AOA shall not represent directly or indirectly that the incidence or likelihood of eye health problems arising from the use of replacement disposable contact lenses is affected by or casually related to the channel of trade from which the buyer obtains such lenses.”

- In re Disposable Contact Lens Anti-Trust Litigation, MDL no 1030 Preliminary Settlement Agreement ¶ 2h (M.D.F.L. filed April 22, 2001)

To summarize the background up to the introduction of this legislation, the Federal Trade Commission had to issue a federal statute to require optometrists to release eyeglass prescriptions to patients. A plethora of consumer protection groups and media such as Consumers Union and the Detroit Free Press have conducted surveys which have documented the unwillingness of optometrists to release prescriptions which directly resulted in consumers paying higher prices. And, a federal lawsuit against the AOA was settled in which they were accused of making false health claims in order to better protect their financial interests.

Now before you is legislation which will reward anti-consumer and anti-competitive behavior. Specifically there are four issues:

1. Sec. 2 (a) – Prescription release “upon request”.

This language creates perfect price discrimination for the optometrist. Those patients who don't ask for their prescription pay a higher price than those who ask for their prescription (thus notifying the optometrists that they are shopping around). Automatic release ensures all contact lens wearers get the same price and extends the same rights to contact lens wearers that eyeglass wearers enjoy as mandated by a federal statute.

2. Sec. 2 – Prescription expiration period of no less than 12 months

A codified minimum expiration date would not be necessary if optometrists did not sell the products they prescribe. The reason it needs to be codified is because of the financial conflict of interests. Interestingly, all the testimony you heard yesterday pointed to a standard of care, not determined by medical research, not determined by clinical studies, and not supported by one shred of quantitative medical data. The standard of care came from the same organization currently under a federal settlement agreement with the Attorneys General of this state and 31 others for making false health claims to the public and the FDA.

There is not one piece of medical research or clinical study to suggest that a contact lens wearer receives any incremental health benefit for getting their eyes examined every year, every two years or every three years. In those states that have legislation requiring two-year expiration dates there are no reported health epidemics.

It is also undeniable that optometrists benefit financially from shorter expiration dates. Not only does it increase traffic in their stores, but it guarantees them revenue in exam fees on whatever periodicity the law would dictate. In this case it would guarantee Kansas optometrists up to \$37.5 million in annual exam revenue. Contact lens wearers would be required to directly carry that burden and without any proven health benefit.

A two-year expiration date does not take away the clinical judgment of the doctor nor is it intended to. Language already exists in the bill that the prescription can be for shorter periods of length if there is a health reason. What it is intended to do is minimize the financial conflict of interest that exists.

3. Sec. 3 – Registration under the Kansas Board of Optometry

1-800 CONTACTS is not registered in any state under the regulation of a state optometric board. Where we are registered, it is always with an impartial body like the state Medical Board, the Department of Health or some form of business or consumer protection department. What organized optometry in Kansas is asking you to legislate is for a board of optometrists, on which we have no representation, to be able to regulate their competition and levy \$10,000 fines. This would be as unprecedented as it would be outrageously unfair.

4. Missing language – Required response to prescription verification requests.

Not surprisingly, this bill carries no requirement for optometrists to respond to third party prescription requests. Typically when we call an optometrist's office we are hung up on or we are placed on indefinite hold. Not only is this practice the accepted norm, it is actually promoted in optometric trade journals. In your attachments I have noted several examples, here is one:

“When you receive a telephone inquiry for a patient's contact lens prescription, recognize it as an opportunity for a sale. Your contact lens patient is in need of replacement lens.

Any third-part requesting prescription information should be told that you follow the prescription release guidelines of your state law; but that it is your policy not to release information except to the patient or a practitioner who is willing to accept the responsibility for eye care.

When this conversation is finished, your staff can call the patient and explain your prescription policy. At the same time, they can reiterate that your fees are competitive with mail order.”

- Ronald P. Snyder, OD, “Winning the War Against Mail Order Contact Lenses”, Optometry Today

The testimony that you heard yesterday had several optometrists indicating that they respond every time. If this is true, then why does organized optometry resist putting this language in the bill? If they are doing it already, it shouldn't be an issue to codify it.

We would request you add specific language which requires prompt response.

We want to publicly commend Dr. Kissling on his efforts to respond and his timeliness. He should be commended because that is the type of working relationship that is in the patient's best interest. Dr. Kissling indicated that his median time to respond is 32 minutes. We suggested to the KOA a long time ago a mandatory wait time of 2 hours for a response.

We would also request that you add language to require responses within two hours. If a patient walked in to a doctor's office and asked for their prescription I doubt they would be told to wait in the lobby for over two hours.

Finally, the federal lawsuit was settled in April, 2001 and the record became clear with respect to the behavior that occurs from the conflict of interests that exists when health care providers sell what they prescribe. Since that time, A bill (HR 2663) has been introduced in U.S. Congress that would federally mandate automatic prescription release, a 2-year expiration date on contact lens prescriptions, and required prompt response to third-party prescription verification requests. Also, three states have introduced legislation with the same requirements: Minnesota, Georgia and Mississippi. Minnesota's was just passed by the House and Senate on Tuesday. Many other states are following the federal lead in developing legislation that promotes competition. This legislation is one step backward.

Thank you.

4-4

COMPARING FORMS OF HEALTH CARE

54

Health Care Provider

Prescription Fulfiller

Family Health Care

Family Doctor

Pharmacy

Ocular Health Care

Optometrist

Optometrist

American Medical Association Code of Ethics

On the Subject of Doctor's releasing prescriptions:

E-8.06 Drugs and Devices: Prescribing:

“Patients have an ethically and legally recognized right to *prompt* access to the information contained in their individual medical records. The prescription is an essential part of the patient's medical record.”

“Patients are entitled to the same freedom of choice in selecting who will fill their prescription needs as they are in the choice of a physician. The prescription is a written direction for a therapeutic or corrective agent. A patient is entitled to a copy of the physician's prescription for drugs, eyeglasses, contact lenses, or other devices as required by the Principles of Medical Ethics and as required by law. The patient has the right to have the prescription filled wherever the patient wishes.”

Can be found under “Code of Medical Ethics” at:

<http://www.ama-assn.org/ama/pub/category/2503.html>

Click on the “major sections” link in the second paragraph and find your way to section E-8.06.

“When you receive a telephone inquiry for a patient’s contact lens prescription, recognize it as an opportunity for a sale. Your contact lens patient is in need of a replacement lens. Any third-party requesting prescription information should be told that you follow the prescription release guidelines of your state law, but that it is your policy not to release information except to the patient or a practitioner who is willing to accept the responsibility for eye care.

When this conversation is finished, your staff can call the patient and explain your prescription policy. At the same time, they can reiterate that your fees are competitive with mail order.”

- Ronald P. Snyder, OD, Guest Editorial, “Winning the War Against Mail-Order Contact Lenses”, *Optometry Today*, Jan./Feb. 1993

“A “red flag” goes up in Dr. Cole’s practice whenever a patient either calls and asks for a prescription or has an alternative supplier contact the practice. “We take a proactive approach,” Dr. Cole says. “We’ll call the patient and tell him we’re not going to release this information without his permission. Then we say, “Actually, we’re a little surprised because we can get you contact lenses more competitively than you can get them there. And, if the patient’s powers should change, we can exchange any unopened boxes you have at no cost”.”

- Rich Kirkner, Editor-in-Chief, “Can You Survive the Ultimate Challenge?”, *Review of Optometry*, April, 2001

“We use private labeling a lot, and I think that originally we were fitting lenses like those from CIBA and Bausch & Lomb, and we would get calls from patients and 1-800 Contacts asking us for their contact lens prescriptions. I wanted to use another strategy to prevent that from happening.”

- Charles Hom, “Using Private Label Lenses to Keep Patients in The Practice”, *Contact Lens Spectrum*, Supplement, January, 2002

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X
STATE OF CALIFORNIA, by Attorney General Daniel E. Lungren;
STATE OF ILLINOIS, by Attorney General Jim Ryan;
STATE OF MARYLAND, by Attorney General J. Joseph Curran, Jr.;
COMMONWEALTH OF MASSACHUSETTS, by Attorney General Scott Harshbarger;
STATE OF MINNESOTA, by Attorney General Hubert H. Humphrey III;
STATE OF MISSOURI, by Attorney General Jeremiah W. (Jay) Nixon;
STATE OF NEW JERSEY, by Attorney General Peter Verniero;
STATE OF NEW YORK, by Attorney General Dennis C. Vacco;
STATE OF OHIO, by Attorney General Betty D. Montgomery;
STATE OF OREGON, by Attorney General Hardy Myers;
COMMONWEALTH OF PENNSYLVANIA, by Attorney General Thomas W. Corbett, Jr.
STATE OF WEST VIRGINIA, by Attorney General Darrell V. McGraw, Jr.;
STATE OF WISCONSIN, by Attorney General James E. Doyle;
STATE OF ARIZONA, by Attorney General Grant Woods;
STATE OF ARKANSAS, by Attorney General Winston Bryant;
STATE OF CONNECTICUT, by Attorney General Richard Blumenthal;
STATE OF DELAWARE, by Attorney General M. Jane Brady;
STATE OF IDAHO, by Attorney General Alan G. Lance;
STATE OF LOUISIANA, by Attorney General Richard P. Ieyoub;
STATE OF MICHIGAN, by Attorney General Frank J. Kelley;
STATE OF NORTH DAKOTA, by Attorney General Heidi Heitkamp;
COMMONWEALTH OF VIRGINIA, by Attorney General James S. Gilmore, III;
STATE OF IOWA, by Attorney General Thomas J. Miller;
STATE OF NEVADA, by Attorney General Frankie Sue Del Papa,

Plaintiffs,

AMENDED COMPLAINT

-against-

96 Civ. 6200 (ERK)

The American Optometric Association,
Johnson & Johnson Vision Products, Inc.
d/b/a Vistakon, Bausch & Lomb, Inc., CIBA
Vision Corp., Contact Lens and Anterior
Segment Society, Inc., American Society of
Contact Lens Specialists, Society of Eye Care
Specialists, Eye Care Management Group, Vision
Enhancement Council International, Society of
Contact Lens Specialists, National Association
of Contact Lens Specialists, L. Edward Elliott,
John A. Gazaway, Richard Hopping, Paul Klein,
James C. Leadingham, Melvin Remba, Lee Rigel,
Ronald Snyder, Jack Solomon, William David
Sullins, Jr., and Stanley Yamane

JURY DEMAND

Defendants.

Channels gave rise to patient ocular health care problems. Because support for this claim was at best anecdotal, in 1987 and again in 1988, AOA considered either sponsoring or conducting a scientific study to test this claim. On both occasions, AOA rejected undertaking such an effort because AOA concluded it would have to publish any such study and that the purchase of Contact Lenses by consumers from Alternative Channels probably did not give rise to ocular health care problems.

54. AOA continued to represent to the public that the purchase of Contact Lenses by consumers from Alternative Channels did give rise to ocular health problems.

55. In January 1990, AOA falsely represented to the Food and Drug Administration that a survey supported the conclusion that consumers who obtained Contact Lenses through Alternative Channels encountered ocular health problems as a direct result.

56. Defendant O's and Defendant O's Trade Associations sought to restrain or foreclose competition by making representations to mislead the public to believe that Contact Lenses must be purchased from an O (both as a legal matter and as a way to avoid ocular health problems), that federal law required a license to sell or a prescription to buy Contact Lenses, and/or that state laws imposed restrictions on the purchase or sale of Contact Lenses that state law did not in fact impose.

57. Defendant O's Trade Associations sought to limit or foreclose competition by misleading the public to believe that Contact Lenses for both health and legal reasons could lawfully be

CAMERA
FILED IN OPEN COURT

MAR 28 2001

CLERK, U. S. DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE, FLORIDA

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

Unseated #1139
per order 4/23/01

In re DISPOSABLE CONTACT LENS
ANTITRUST LITIGATION

MDL Docket No. 1030

This Document Relates To:

ALL ACTIONS.

FILED

APR 23 2001

CLERK, U. S. DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE, FLORIDA

PRELIMINARY SETTLEMENT AGREEMENT

Defendant, The American Optometric Association ("AOA") and the Class Plaintiffs, State of Florida and State Plaintiffs ("Plaintiffs") collectively, in consideration of the mutual promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, agree as follows:

1. The AOA shall pay into an escrow account in the same manner as provided in the Bausch & Lomb settlement to plaintiffs the total sum of \$750,000, inclusive of all costs and attorneys' fees no later than 21 days from the date of this Agreement;

2. The AOA hereby agrees to the following injunctive terms:

(a) Consistent with state law, the AOA will not object to the release of contact lens prescriptions, except in the affirmative exercise of an optometrist's own medical judgment related to the specific, identified and documented health needs of a particular patient. The AOA will not develop, disseminate, or urge the use of forms designed to limit either the availability or utility of prescriptions. A form may contain reasonable expiration dates, limitations on refills and other provisions which are consistent with state law and good optometric practice;

SCANNED

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(b) The AOA will not ask or encourage any contact lens manufacturer to refuse to sell contact lenses to any channel of trade;

(c) The AOA will not encourage nor support a refusal by optometrists (i) to do business with any contact lens manufacturer; or (ii) to write prescriptions for a particular contact lens manufacturer's contact lenses, based upon the manufacturer's contact lenses being sold by or to non-ECP retail outlets;

(d) The AOA will make no agreement with any manufacturer to restrict the supply of contact lenses to any channels of trade;

(e) The AOA will resist any invitation by any contact lens manufacturer to enlist the AOA's aid in enforcing any manufacturer's distribution policy refusing to sell contact lenses to any channel of trade;

(f) The AOA will not endorse or pass on to others complaints about the sale of replacement disposable lenses to non-ECP retail outlets by any entity or about the sale of such lenses by a non-ECP retail outlet to any person or entity, other than about violations of federal or state laws;

(g) The AOA, for a period of four years, shall continue to maintain and adhere to its written Antitrust Compliance Program;

(h) AOA shall not represent directly or indirectly that the incidence or likelihood of eye health problems arising from the use of replacement disposable contact lenses is affected by or causally related to the channel of trade from which the buyer obtains such lenses. Specifically, AOA shall not represent directly or indirectly that increased eye health risk is inherent in the distribution of replacement disposable contact lenses by mail order or pharmacy or drug stores. This paragraph shall not prohibit the AOA from making such representations where such representations are supported by valid, clinical or scientific data;

(i) Notwithstanding the foregoing, the AOA shall be permitted to

- (i) engage in collective actions protected under the *Noerr-Pennington* doctrine;
- (ii) presenting news, information or the views of its members to the public, manufacturers and others, and conducting surveys, collecting data and disseminating such information, provided that such activities do not violate the proposed limitations on AOA conduct discussed above;
- and (iii) disseminate information about, or encourage compliance with, any federal or state laws and government regulations, including dispensing, antitrust, FTC and FDA laws; and

(j) The AOA shall publish a letter from the president of the AOA setting forth the injunctive terms of this Settlement Agreement or any subsequent Consent Decree in the *AOA News* for four consecutive months, alternating between the "A" and "B" issues of the *AOA News*.

3. The terms of this Settlement Agreement do not constitute and shall not be construed as an admission of liability or guilt by the AOA.

4. The injunctive relief provisions of this Preliminary Settlement Agreement shall last for the period of four years.

5. The parties to this Preliminary Settlement Agreement agree to execute and deliver a Consent Decree containing all the terms set forth above together with such other provisions substantially similar to those set forth in the Bausch & Lomb Settlement

Agreement and Consent Decree and so long as such terms are consistent with the terms of this Agreement.

Agreed to this 27th of March, 2001

DATED: March 27, 2001

Respectfully submitted,

FLORIDA

BY: 

R. Scott Palmer

Special Assistant Attorney General
Burt & Pucillo

CLASS PLAINTIFFS

BY: 

Dennis Stewart

Milberg Weiss Bershad Hynes & Lerach LLP

BY: 

Douglas D. Chunn

Douglas D. Chunn, P.A.

STATE PLAINTIFFS

BY: 

Robert L. Hubbard

N.Y. Assistant Attorney General,
Director of Litigation
Chair of Plaintiff States' Steering Committee

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DATED: March 27, 2001

BY:


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Attorneys for The AOA

Consumer Eye Health:

"This "consumer hearth" argument is based on a contention that a contact lens, a "medical device," somehow requires an eye care professionals' care and attention at every possible wearing of both the original and replacement lenses. **In fact, as a Class II medical device, a disposable contact lens is subject to the same standards of FDA review as a toothbrush.**"

"Our investigation has revealed that many eye-care practitioners mail replacement contact lenses to their patients without an office visit during the life of the prescription."

"Purchasers from alternative channels have had no greater ocular health problems than purchasers from eye-care practitioners. Our multistate investigation has failed to reveal any study showing any correlation between compromised ocular health and receipt of lenses through alternative channels."

- BEFORE THE FEDERAL TRADE COMMISSION, Washington, D.C. 20580, 16 CFR Part 456, September 2nd, 1997, Comments of the Attorneys General of: ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, CONNECTICUT, DELAWARE, FLORIDA, ILLINOIS, IOWA, MARYLAND, MICHIGAN, MINNESOTA, NEW YORK, OHIO, PENNSYLVANIA, WEST VIRGINIA AND WISCONSIN

BEFORE THE
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

In the Matter of:

16 CFR Part 456

COMMENTS OF THE ATTORNEYS GENERAL OF
ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, CONNECTICUT,
DELAWARE, FLORIDA, ILLINOIS, IOWA, MARYLAND, MICHIGAN, MINNESOTA
NEW YORK, OHIO, PENNSYLVANIA, WEST VIRGINIA AND WISCONSIN

The Attorneys General of Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Illinois, Iowa, Maryland, Michigan, Minnesota, New York, Ohio, Pennsylvania, West Virginia and Wisconsin submit their Comments in response to the Federal Trade Commission's ("Commission") Request for Comments concerning Ophthalmic Practice Rules, 16 CFR Part 456, issued on April 3, 1997 ("Spectacle Prescription Release Rule". This Rule requires eye-care practitioners to release eyeglass prescriptions to their patients. The Commission is seeking comments on whether to continue or amend that Rule. The Attorneys General are the chief enforcers of (1) state and federal antitrust laws, and (2) state consumer protection laws which sometimes incorporate administrative regulatory rules such as the "Prescription Release Rule." The Attorneys General believe the rule has served consumers well over the past 20 years and should be continued. The Rule should also be expanded to cover contact lens prescriptions. The Attorneys General submit the following comments on behalf of their citizens.

SUMMARY OF THE POSITION OF THE ATTORNEYS GENERAL

The Attorneys General believe that the Spectacle Prescription Release Rule should be retained and expanded to require the release of contact lens prescriptions. The existing rule relating to eyeglass prescriptions has presented consumers with a wide variety of alternatives to obtain their eyeglasses. These alternatives have allowed consumers to choose among suppliers at varying price points and service levels. Consumers can have eyeglasses made in as little as one hour and at a very low cost. The Attorney Generals are aware of no harm that has come to consumers as a result of the existing Spectacle Prescription Release Rule.

The Attorneys General assert that the release of contact lens prescriptions will lower consumer costs for contact lenses and increase the safety of these lenses to consumers. The Attorneys General also urge the Commission to expand the applicability of the Prescription Release Rule to contact lens prescriptions, and contend that eye-care practitioners and their trade associations have participated in a conspiracy to refuse to release contact lenses to consumers. Requiring the release of contact lens prescriptions will mitigate the effect of the conspiracy.

INTEREST OF THE ATTORNEYS GENERAL

The Attorneys General, in enforcing both federal and state antitrust laws, have an interest in maintaining an open and competitive marketplace for eyeglasses and contact lens sales. The Attorneys General represent 110,900,621 consumers, an estimated 40% of whom use eyeglasses or contact lenses. In addition, the Attorneys General of 27 states are involved in litigation against several contact lens manufacturers, eye-care practitioners and eye-care practitioner trade associations alleging two conspiracies: (1) that the manufacturers and the practitioners and their trade associations conspired to eliminate sales of contact lenses by pharmacies, mail order and other alternative sellers; and (2) that the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers. A copy of the complaint is attached as Exhibit A.'

PRESCRIPTION RELEASE RULE

Twenty years ago, eye-care practitioners attempted to dominate the eyeglass market by withholding prescriptions. This attempt at controlling the eyeglass market prompted the Commission to adopt the Spectacle Prescription Release Rule, which mandates the release of eyeglass prescriptions to patients. This Rule was adopted based on the finding that many consumers were deterred from comparison shopping for eyeglasses because eye-care practitioners refused to release prescriptions. "The rule requires an optometrist or ophthalmologist to provide the patient with a copy of the patient's eyeglass prescription immediately after the eye examination is completed at no extra cost." 16 CFR 456(a) and (c). The rule also has two additional requirements: (1) it prohibits the eye-care practitioner from conditioning the availability of an eye care examination on an agreement to purchase ophthalmic goods; and (2) eye-care practitioner must release copies of eyeglass prescriptions to their customers (patients) regardless of whether they request the prescription. The automatic release rule alerts the consumer to the fact that the purchase of eyeglasses can be separate from obtaining an eye exam. "The Commission also determined not to extend the 'Prescription Release Rule' to contact lens prescriptions. In making its decision, the Commission concluded that there was not sufficient evidence on the record to permit a conclusion that the practice not to release contact lens prescriptions was prevalent." Moreover, the last time the FTC fully considered the rule in 1989, disposable and frequent planned replacement soft contact lenses had only recently come on the market. Prior to that time and at the time of the Eyeglass I and Eyeglass II proceedings, lenses were not manufactured in a way that always accurately reproduced the same prescription.

Twenty years of actual experience and our investigation of the past three years has shown that not only are restrictions on the release of contact lens prescriptions prevalent, but that eye care practitioners regularly shared among themselves and discussed in their trade journals, numerous methods to discourage consumers from requesting their prescriptions, or how to make the prescriptions they were forced by law to release less useful. Eye-care professionals have advised colleagues to outright refuse to give consumers prescriptions or make consumers or other possible dispensers of contact lenses sign a waiver of liability which absolves the eye-care practitioner from liability in connection with the prescription. See e.g. Koetting "I want my Contact Lens RX" *Optometric Economics*, 30-37, (February 1991); Kirkner, 10 Ways to Keep RXs from Walking, *Review of Optometry*, 59-64, (Sept. 15, 1994) (article about a roundtable of optometrists discussing how to keep patients from using competitors); Snyder, *Winning the War Against Mail Order Contact Lenses*, *Optometry Today*, Vol., No. 1, (1993).

Another example of the types of restrictions on eye-care practitioners used can be found in Exhibit B to the Settlement Agreement between certain Attorneys General and the Contact Lens Association of Ophthalmologists, Inc. That exhibit shows a release form distributed by an ophthalmologic trade association for use by eye-care practitioners in response to a request from a consumer for a prescription. The document states that it may not be used as a prescription. Given various eye-care practitioners' organized efforts to resist release of prescriptions, the Attorneys General advocate that the Commission order release of prescriptions. A copy of the Settlement Agreement is attached as Exhibit B.

Since the Commission promulgated the original rule in 1978, the contact lens industry has changed radically in other ways. Twenty years ago, the soft contact lens industry relied on lenses that were designed to be replaced annually, coinciding with the period typically recommended for reexamination by eye-care practitioners. Beginning in the late 1980's, lens manufacturers began to market and sell what are now known commonly as "disposable" lens or "frequent replacement" lenses, which are designed to be replaced daily, weekly or monthly. Manufacturers have developed manufacturing methods that eliminated the reproducibility problems of 20 years ago. Consumers have increasingly chosen these lenses over "conventional" soft contact lenses, and a market has developed for their resupply. Today, more than 26 million consumers wear contact lenses. This increase in contact lens wear and sales volume led to the development of alternative suppliers, like pharmacies, buying clubs, department stores, mass merchandisers, and mail order houses. Despite some restrictions on their supply of lenses, these alternative suppliers gave consumers a convenient and cost-effective method of purchasing contact lenses. The alternative suppliers typically apply a smaller markup on the price of the lens relative to that of most eye-

care practitioners. These savings were passed on to the eye care consumer in the form of lower costs. Obtaining contact lenses from alternative suppliers may also spare consumers the cost of an extra office visit to an eye-care practitioner.

IMPORTANCE OF PRESCRIPTION RELEASE

The existing prescription release rule has already saved consumers money on eyeglasses. Expanding the rule to cover contact lenses will likewise allow consumers to save money on contact lenses and increase the safety of using lenses for most consumers. Requiring the ready release of a prescription would have almost no cost impact on eye-care practitioners.

Allowing consumers to shop for lenses at multiple possible dispensing locations rather than only from their eye-care practitioners will increase their options. Generally, when consumers have more choices, they pay lower prices. In this instance, this is particularly true because the expanded distribution of contact lenses through traditionally lower cost suppliers, like pharmacies, buying clubs, mail order and mass merchandisers, results in distribution cost savings which normally will be passed on to consumers

As costs of lenses come down, the eye health of consumers using soft lenses, particularly disposable or frequent replacement lenses, will benefit. At present, consumers may exceed the recommended wearing schedule for a lens or engage in other possibly injurious conduct in an attempt to save money by extending the life of their disposable lenses. Such conduct could harm consumers should their lenses become dirty or carry bacteria or viruses which would not have a chance to develop if they were worn and disposed of properly. **Easier access to, and lower prices for, replacement lenses should encourage consumers to wear and use the lenses properly, thereby increasing patient safety.**

Not only would costs to consumers go down and safety increase as the result of an expanded prescription release rule, but the costs to eye-care practitioners of releasing prescriptions is nominal. Eye-care practitioners must simply provide the consumer with a copy of a prescription he or she is recording anyway. The slight cost of providing a written copy of a prescription does not justify a failure to mandate the release of prescriptions.

Eye-care practitioners may complain that a prescription release rule may "cost" them lost profits or the sale of contact lenses to their patients. This is not a "cost." Eye-care practitioners are free to compete for sales to their own patients and those of other practitioners.

ARGUMENTS AGAINST RELEASE

Eye-care practitioners cite two reasons in defense of their practice of withholding prescriptions: (1) liability and (2) consumer eye health. The argument involving liability is simply that, if alternative suppliers incorrectly provide the wrong contact lenses, the eye-care practitioner can be held liable. While the ability of plaintiffs' lawyers to create liability theories is endless, physicians are not normally held liable when a pharmacist provides the wrong drug in response to a prescription. It is unclear how misfilling a contact lens prescription by a pharmacist, for example, would create grounds for liability for the eye-care practitioner.

The second argument against releasing prescriptions involves consumer eye health. By withholding prescriptions, eye-care practitioners argue they are ensuring the patient comes back for eye care. If a consumer wants a new batch of lenses, the eye-care practitioner theoretically uses the trip to the office to check the general eye health by a range of activities, from having a receptionist or nurse interrogate the consumer or by having the eye-care practitioner actually perform an examination. This "consumer health" argument is based on a contention that a contact lens, a "medical device," somehow requires an eye care professional's care and attention at every possible wearing of both the original and replacement lenses. In

fact, as a Class II medical device, a disposable contact lens is subject to the same standards of FDA review as a toothbrush.

As such, it is clear that to claim that contact lenses should be marketed only by eye-care professionals, is to claim they are only safe to use after the inspection of each and every lens by an eye-care practitioner. In fact, almost all manufacturers now provide direct shipment of replacement contact lenses to consumers as a matter of general commercial practice. Our investigation has revealed that many eye-care practitioners mail replacement contact lenses to their patients without an office visit during the life of the prescription.

Purchasers from alternative channels have had no greater ocular health problems than purchasers from eye-care practitioners. Our multistate investigation has failed to reveal any study showing any correlation between compromised ocular health and receipt of lenses through alternative channels. Many other medical products, such as pharmaceutical drugs, have been and are regularly dispensed safely via these same alternative channels of distribution. Clearly, if these methods of distribution are acceptable for prescription drugs, which can cause far more potential harm if the prescription is filled improperly than an improperly filled contact lens prescription, then using the alternative channels of distribution for contact lenses should be acceptable as well. Prescription drugs are widely available through grocery stores, mass merchandisers, pharmacies and through mail order and require only that the consumer have a prescription readily available. The more than 26 million consumers who use soft contact lenses should have the same financial and convenience benefits available to them as those consumers who purchase prescription drugs or eyeglasses.

CONCLUSION

The foregoing comments are submitted to demonstrate the need for continuing the Prescription Release Rule. Moreover, the Attorneys General believe the interests of consumers will be best served by expanding coverage of the rule to contact lenses. Dated: September 2, 1997

Respectfully submitted,

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Lens users pay high prices

Buying contact lenses from someone other than your doctor can save you big bucks. But it's not easy in Michigan, where many offices won't simply hand over the prescription.

December 4, 1998

BY ALISON YOUNG

Free Press Consumer Affairs Writer

Contact lens wearers can cut their costs in half by shopping around or ordering from discount outlets or mail-order companies. But good luck getting an optometrist to hand over a copy of the prescription.

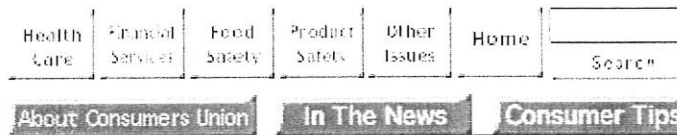
Because Michigan has no state law requiring eye doctors to release contact prescriptions to their patients, consumers are forced to purchase lenses from their doctors -- often at much-inflated prices -- according to a Free Press survey of metro Detroit optometrists' policies and prices.

Of 50 optometry offices surveyed in Wayne, Oakland and Macomb counties, only one would release a contact-lens prescription to patients after an exam. Nearly all the rest require patients to purchase lenses from them -- for an average price that was almost triple the best price available elsewhere.

Among the findings:



Honoring the Publisher of Consumer Reports



March 1997

Out of Focus: Contact Lens Policy in Texas

This article was written by the Consumers Union Southwest Regional Office.
This report is also available in [PDF Format](#)

Executive Summary

The Southwest Regional Office of Consumers Union originally conducted a survey of optometrists and ophthalmologists ("eye doctors") in 1995 to determine whether consumers could get their prescription from their eye doctor and use it to purchase lenses from the dispenser of their choice. At that time, CU found that most eye doctors would not release the prescription to the patient, forcing consumers to purchase their lenses from the eye doctor who provided the exam. Consumers Union also determined that the price of such lenses varied considerably, and the practice of withholding the prescription limited the consumer's ability to shop for the best price.

Consumers Union supports HB 196, which increases competition by giving consumers the right to get their contact lens prescription from the eye doctor and use it to purchase replacement lenses from the lowest cost outlet.

In light of legislation introduced this session to improve competition in the contact lens market by giving consumers access to their prescriptions, Consumers Union again surveyed optometrists in the same nine Texas cities: Austin, Corpus Christi, Dallas, El Paso, Houston, Laredo, Midland/Odessa, San Antonio, and Tyler.

Our March 1997 survey, designed to recreate the actual experience of a consumer shopping for the best buy in contact lens care, confirmed that many Texas optometrists still withhold prescriptions for contact lenses from their patients--forcing the consumer to purchase replacement lenses from their eye doctor, usually at much higher prices than other outlets offer.

- **Sixty-five percent of optometrists surveyed were unwilling to release a contact lens prescription directly to patients.**
- **Prices for replacement contact lenses ranged from \$40 up to \$140 for the same brand and type.**
- **The cost of an eye exam ranged from \$30 to \$160.**

4-24

107th CONGRESS
1st Session
H. R. 2663

To require the Federal Trade Commission to amend the trade regulation rule on ophthalmic practice to require the release of prescriptions for contact lenses, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

July 26, 2001

Mr. STARK (for himself, Mr. SENSENBRENNER, Mr. WAXMAN, Ms. ROYBAL-ALLARD, Mr. SERRANO, and Ms. RIVERS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require the Federal Trade Commission to amend the trade regulation rule on ophthalmic practice to require the release of prescriptions for contact lenses, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Contact Lens Prescription Release Act of 2001'.

SEC. 2. PRESCRIPTIONS FOR CONTACT LENSES.

(a) AVAILABILITY OF CONTACT LENS PRESCRIPTION INFORMATION--
No later than 6 months after the date of enactment of this Act, the Federal Trade Commission shall promulgate a rule on ophthalmic practice under section 553 of title 5, United States Code, to require that a prescriber shall, upon completion of the contact lens fitting process for a patient--

- (1) provide to the patient a copy of the prescriber's prescription for contact lenses, regardless of whether or not the patient requests such a copy; and
- (2) upon request of the patient--

(A) provide a copy of such a prescription to the patient or an agent of the patient; or

(B) promptly verify to an agent of the patient, including by electronic means, the information contained in such a prescription.

(b) EXPIRATION OF PRESCRIPTION- The amendment under subsection (a) shall also provide that any contact lens prescription shall expire 2 years after the date it is issued, unless the prescriber specifies in the prescription for a patient a different expiration date based on the medical judgment of the prescriber with respect to the patient's ocular health.

(c) VIOLATIONS- Any violation of a rule prescribed under subsection (a) shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) regarding unfair or deceptive acts or practices.

SEC. 3. ADVERTISING AND SALES PRESENTATIONS REGARDING CONTACT LENSES.

(a) CONTENT OF ADVERTISEMENTS AND SALES PRESENTATIONS- No later than 6 months after the date of enactment of this Act, the Federal Trade Commission shall promulgate a rule on ophthalmic practices under section 553 of title 5, United States Code, to make it an unfair trade practice for any industry member to publish, or cause to be published, any advertisement or sales presentation relating to contact lenses that represents, directly or by implication, that contact lenses may be obtained without a valid prescription.

(b) VIOLATIONS- Any violation of a rule prescribed under this section shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) regarding unfair or deceptive acts or practices.

SEC. 4. EFFECT ON STATE LAW.

This Act and the regulations issued under this Act shall not affect any State law that--

- (1) authorizes the release of prescriptions for contact lenses only under terms that are not more restrictive than this section;
- (2) regulates who is authorized to fit contact lenses; or
- (3) regulates advertisements or sales presentations regarding contact lenses.

SEC. 5. DEFINITIONS.

For purposes of this Act:

(1) COMPLETION OF THE CONTACT LENS FITTING PROCESS- The term 'completion of the contact lens fitting process' means completion of the process that--

- (A) begins after the initial eye examination;

(B) includes--

- (i) an examination to determine what the lens specifications should be;
- (ii) except in the case of a renewal of a prescription, an initial evaluation of the fit of the lens on the patient's eye; and
- (iii) followup examinations that are medically necessary; and

(C) ends when--

- (i) except in the case of a renewal of a prescription, the prescriber is satisfied that a successful fit has been achieved; or
- (ii) in the case of a renewal of a prescription, the prescriber determines that there is no change in the prescription.

(2) INDUSTRY MEMBER- The term 'industry member' means a person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses.

(3) PRESCRIBER- The term 'prescriber' means an ophthalmologist or optometrist who performs eye examinations under a license issued by a State.

(4) PRESCRIPTION- The term 'prescription' means the specifications necessary for a patient to obtain contact lenses, that include--

- (A) data on the refractive status of patient's eyes; and
- (B) a clear notation that the patient is suitable for contact lenses.

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COMMENTS ON SUBSTITUTE FOR HOUSE BILL 2285

BEFORE THE

SENATE PUBLIC HEALTH COMMITTEE

Thursday, March 21, 2002

My name is Franklin D. Rozak, Legislative Consultant for Cole Vision Corporation which operates nine (9) "Sears Optical" and five (5) "Target Optical" locations in these host store environments. We extend our appreciation to the Chair and the members of this Committee for the opportunity to present our views on this legislative proposal.

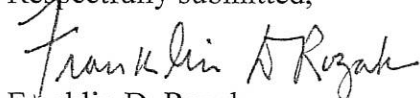
In addition to testifying on behalf of Cole Vision Corporation, these comments reflect support from certain of our competitors namely, Costco Optical, EyeMasters, U.S. Vision, Inc. d/b/a "J. C. Penney Optical" and National Vision which operates several optical departments as a concession of the Wal*Mart Corporation.

We were very concerned about certain of the provisions as approved by the House of Representatives however, our issues have been largely resolved by the amendments offered yesterday by representatives of the Kansas Optometric Association. We strongly endorse those proposed amendments to ensure consumers will continue to possess a maximum of "freedom of choice" in selecting a provider for their replacement contact lenses.

Based on our national experience and consistent with yesterday's testimony, we believe that **any** contact lens whether or not it possesses any corrective power should be prescribed by a licensed Doctor of Optometry or a physician and surgeon. Accordingly, we support the amendment which adds "An ophthalmic lens shall include a contact lens with or without power" to the optometry law. We concur there are numerous clinical issues which could adversely impact consumers who purchase cosmetic contact lenses without the benefits of a comprehensive eye health examination.

Thank you for the opportunity to comment and if there are any questions, I will try to answer them.

Respectfully submitted,


Franklin D. Rozak

Senate Public Health & Welfare Committee
Date: March 21, 2002
Attachment #5



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CHARLOTTE NORTON
DISTRICT MANAGER

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**Comments on Substitute for House Bill 2285
Before the Senate Public Health Committee**

Thursday, March 21, 2002

Good afternoon. My name is Charlotte Norton and I am here on behalf of Wal-Mart Stores, Inc., to speak against Substitute House Bill 2285. On behalf of the thousands of Kansas customers who purchase their eyewear from Wal-Mart, I want to thank you for the opportunity to comment on this legislation.

By way of brief background, I am a District Manager for the Wal-Mart Optical Centers and have managed a district of several Wal-Mart optical centers in Kansas. Wal-Mart values its ability to provide our customers with quality eyecare and feels that the current version of this legislation will unnecessarily interfere with our goal to provide quality eyecare.

Wal-Mart opposes Substitute House Bill 2285 for four reasons. First, Wal-Mart is against a certification requirement to sell or dispense contact lenses. Adding a certification requirement would not improve the quality of eyecare in Kansas. In addition, a certification requirement may push some optical stores out of the eyewear business, which would limit the choice patients have when filling their eyewear prescription.

Second, Wal-Mart opposes giving the Board of Examiners in Optometry the power to supervise and certify eyewear sellers. The responsibility to certify an optical store is better suited for a health-related agency such as the Health and Environment Department.

Third, Wal-Mart is concerned that the bill's current language could require every store in an optical chain to have a license or be certified. This requirement would not improve the quality of eyecare and the additional licensing duties would place an added strain on scarce state resources.

Senate Public Health & Welfare Committee
Date: March 21, 2002
Attachment #6

Page Two

Charlotte Norton/Wal-Mart Stores, Inc. Testimony

March 21, 2002

Finally, Wal-Mart opposes the proposed fine language. Specifically, Wal-Mart believes that the maximum \$10,000 fine is an excessive amount.

Rather than discuss specific alternatives to this bill, Wal-Mart would like to share the principals it supports when evaluating optical legislation:

First, Wal-Mart supports laws that allow customers to fill their optical prescription at the store of their choice. Just as a medical patient has the right to fill a drug prescription at any pharmacy, Wal-Mart believes that an optical customer should have the right to fill a contact lens or glasses prescription at any optical store.

Second, Wal-Mart supports legislation that requires a prescription for the purchase of ANY contact lens. The potential health and infection risks are the same for a cosmetic lens or a lens with optical power so the prescription requirement should be the same for ALL contact lenses.

Finally, Wal-Mart supports laws that require a state-licensed optometrist to write optical prescriptions.

Thank you for your time this afternoon. I am ready to answer your questions.

Respectfully submitted,

Charlotte Norton