

MINUTES OF THE HOUSE COMMITTEE ON HEALTH AND HUMAN SERVICES.

The meeting was called to order by Chairperson Garry Boston at 1:30 p.m. on January 29, 2002 in Room 210 Memorial Hall

Committee staff present: Emalene Correll, Kansas Legislative Research Department
Dr. Bill Wolff, Kansas Legislative Research Department
Norman Furse, Revisor of Statute's Office
Renea Jefferies, Revisor of Statute's Office
June Evans, Secretary

Conferees appearing before the committee: Kevin McCallum, 1-800 Contact
Dr. Terry Carney, Kansas Optometric Association
Dr. Ron Fiegel, Wichita
Gary D. White, Jr., Kansas Trial Lawyers Association
Randy Forbes, Attorney, Kansas Board of Examiners in Optometry
Amy Campbell, Kansas State Ophthalmological Society

Others Attending: See Attached Sheet

Representative Morrison moved and Representative Swenson seconded to approve the minutes of January 16, 22, 23, and 24. The motion carried.

The Chairperson opened the hearing on **HB 2285 - Amending and supplementing the optometry law.**

Norman Furse, Revisor of Statutes gave a briefing on the bill with the update and changes needed.

Kevin McCallum on behalf of 1-800 CONTACTS testified in support of **HB 2285** stating optometrists have excessive powers that no family doctor has ever been granted – the right to prescribe prescription remedies AND sell them. This arrangement is an anomaly among all other forms of health care in the United states in that these health care providers are also retailers. Normally, prescription drugs are sold by a pharmacy or drug store. This system separates the delivery of health care from the profits made off the sale of these prescription products to ensure a health care provider's priorities are never compromised. Allowing health care providers to prescribe AND sell prescription products creates a conflict of interest and introduces the specter of patient abuse.

In order to protect the consumers right to choose where they get their prescriptions filled, foster a competitive marketplace where consumers benefit from lower prices, provide better service and create more convenience, ALL of the following elements should be enacted into law: (1) Automatic prescription release upon completion of an eye examination. (2) Minimum 2-year prescription expiration date (unless a shorter date is medically warranted). (3) Immediate response to requests for prescription verifications. (4) Forbidding private label or "doctor exclusive" contact lenses and (5) Equitable and Equal Enforcement (Attachment 1).

Dr. Terry Carney, Kansas Optometric Association, testified in opposition to **HB 2285**, stating he is a practicing optometrist serving as the Legislative Chairman. The Association met with 1-800-CONTACTS in the fall of 2000 until January 2001. We openly discussed their concerns and could agree on some things. Other questions arose which we could not agree upon.

For our patients to receive proper, safe vision care, expiration dates must be honored so we

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can monitor the patient's eye and keep them healthy. Healthy, human cornea was not meant to have a piece of hydrated plastic on it, so routine follow-up care is essential. We want to be sure that patients get accurate, unexpired prescriptions to assure optimal vision, consistent with federal and state laws.

We have encouraged our members to cooperate with voluntary verification from any company and see if fax verification is workable. We have encountered some problems which make verification with 1-800-CONTACTS unworkable. In our negotiations, we tried to get 1-800-CONTACTS to understand that doctors and their staffs are sometimes too busy to check every fax, review a patient's chart, and respond within even 24 hours, especially if the doctor is out or the office is closed.

A couple of specific points in the bill that seem only to help 1-800-CONTACTS do business and are not in the best interest of the patient are: (1) making expiration dates on contact lens prescriptions last two years instead of one is simply a health problem waiting to happen. (2) Lessening second and subsequent offenses of the law from a Class B misdemeanor to a Class C is important to a company that freely breaks state laws anyway. (3) Allowing the optometry board to only take optometrists to court and not unlicensed persons or entities like 1-800 CONTACTS speaks for itself (Attachment 2).

Dr. Charles Kissling, OD, testified as an opponent to **HB 2285**, stating long ago the Food and Drug Administration determined that contact lenses posed sufficient health risk to consumers as to required consumer protection. Thus, the FDA requires that all contact lenses be sold only pursuant to a prescription from an appropriate licensed professional (an optometrist or a physician). In fact, the FDA requires the contact lens manufacturer to label every contact lens with the following statement: "Caution! Federal law prohibits dispensing without prescription".

A patient with an expired prescription could provide the information from their old lenses, and then receive new lenses. Any patient with a box of contact lenses could order lenses of a different brand so that they might get colored lenses. A non-contact lens wearer with a glasses prescription in hand could order contact lenses by specifying the power of lenses from their eyeglass prescription and then guessing as to contact lens brand and fitting parameters (Attachment 3).

Dr. Ronald L. Fiegel, O.D., an opponent to **HB 2285** testified he had always released prescriptions to his patients unless it was medically inappropriate to do so. Dr. Fiegel stated he had also been witness to the numerous problems that can occur when lenses are not properly fit or maintained. Many consumers believe that contact lenses, much like lipstick, are harmless cosmetic devices that enhance their life style. The only purpose this legislation serves is to allow an alternative supplier to immediately sell a contact lens without a valid prescription or before the patient's prescription can be properly verified (Attachment 4).

Gary D. White, Jr., Kansas Trial Lawyers Association, testified in opposition to **HB 2285** because it grants immunity under Section 2(b) to an optometrist or physician who verifies a contact lens prescription to a seller of lenses in interstate commerce. This provision provides immunity to a health care provider even if the verification is performed incorrectly and causes permanent injuries to the patient (Attachment 5).

Randy Forbes, attorney for the Kansas Board of Examiners in Optometry (the "Board"), opposed **HB 2285** as the Board feels these proposed changes to the Kansas Optometry Law are extremely ill advised for many reasons. For many years the Kansas Optometry Law has declared that it shall be unlawful for any person to dispense an ophthalmic lens or lenses without first having obtained a prescription or order therefor from a duly licensed optometrist or a person licensed to practice medicine and surgery.

On April 7, 1999 the Board was forced to file suit against the author of this bill, 1-800-CONTACTS in an attempt to force 1-800 CONTACTS to cease violating K.S.A. 65-1504b. In the lawsuit, the Board alleges multiple instances of 1-800 CONTACTS dispensing contact

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lenses without a prescription. The Board has filed a witness and exhibit list that includes no less than 10 instances involving 1-800 CONTACTS dispensing contact lenses in violation of the Kansas law.

If this bill were to be passed, 1-800 CONTACTS would be able to sell contact lenses without having first obtained a prescription (thereby placing the customer's ocular health at risk) if it "attempted to verify" the prescription.

The Board believes **HB 2285** is extremely bad policy and would foster situations that could be dangerous to the ocular health of Kansas citizens (Attachment 6).

Amy Campbell, Kansas State Ophthalmological Society, testified in opposition to **HB 2285**, stating the members are acutely aware of the complications and potential problems that contact lens wear can create. It is strongly believed that contact lenses are a prescription item as required by the Federal Food and Drug Administration and should be treated with respect. The KSOS supports contact lens prescription release and our members do so on a regular basis (Attachment 7).

The Chairperson closed the hearing at 3:10 p.m. The next meeting will be January 31, 2002.

Testimony on behalf of 1-800 CONTACTS Regarding House Bill 2285
Before the House Health and Human Services Committee
January 29, 2002

Chairman Boston and members of the House Health and Human Services Committee:

My name is Kevin McCallum and I am here on behalf of 1-800 CONTACTS and our 22,000 Kansas customers who purchase their replacement contact lenses from us to testify in support of House Bill 2285 and would offer the following thoughts and comments for the committee.

Optometrists have excessive powers that no family doctor has ever been granted – the right to prescribe prescription remedies AND sell them. This arrangement is an anomaly among all other forms of health care in the United States in that these health care providers are also retailers. Normally, prescription drugs are sold by a pharmacy or drug store. This system separates the delivery of health care from the profits made off the sale of these prescription products to ensure a health care provider's priorities are never compromised. Allowing health care providers to prescribe AND sell prescription products creates a conflict of interest and introduces the specter of patient abuse.

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

The ocular health care system creates non-traditional doctor behavior that is well documented. For example, in response to numerous consumer complaints regarding optometrists withholding eyeglass prescriptions, the Federal Trade Commission issued the Spectacle Prescription Release Rule in 1978 that requires optometrists to automatically release eyeglass prescriptions immediately following an eye examination. The Detroit Free Press and Consumers Union both have conducted surveys that have concluded the practice of optometrists withholding contact lens prescriptions is prevalent, widespread and results in contact lens wearers paying higher prices for their contact lenses.

Many legislators' current perceptions with regard to the delivery of contact lenses via the mail are the product of misinformation. Without any quantitative data or study to support, the American Optometric Association (AOA) began inferring that there were health risks associated with purchasing contact lenses from alternative channels of distribution. These claims became one of the primary focus areas of a federal lawsuit filed by 32 State Attorneys General (including Kansas) in the mid-1990s against the AOA. Specifically, the Attorneys General complained that the AOA falsely represented to the public and to the Food and Drug Administration that a survey supported the conclusion that consumers who obtained contact lenses through alternative channels encountered health care problems as a result. Since then, the suit has been settled. The settlement specifically states 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."

Disturbed by reports of optometrists not releasing prescriptions or creating barriers to releasing prescriptions, 20 State Attorneys General were prompted to conduct their own investigation which resulted in a unified petition to the Federal Trade Commission in 1997. The Attorneys General concluded that the release of contact lens prescriptions will lower consumer costs for contact lenses and increase the safety of these lenses to consumers: "Easier access to, and lower prices for, replacement contact lenses should encourage consumers to wear and use the lenses properly, thereby increasing patient safety." Therefore, they requested that contact lenses be included in the same statute that now covers the automatic release eyeglass prescriptions.

In order to protect the consumers right to choose where they get their prescriptions filled, foster a competitive marketplace where consumers benefit from lower prices, provide better service and create more convenience, ALL of the following elements should be enacted into law:

1. **Automatic prescription release upon completion of an eye examination**

- Consistent with the American Medical Association's Code of Ethics.
- Consistent with the Federal Trade Commission's Ophthalmic Practice Rules.
- Consistent with 20 State Attorneys General Multi-State Investigation findings.
- Note. Optometrists will often be proponents of prescription release "upon request" of the patient. Recognize that this creates perfect price discrimination for the optometrist. Forcing patients to ask for their prescription in order to obtain it, forces those who choose to purchase somewhere else to identify themselves to the optometrist. These patients get offered a better price, those who don't ask do not. Hence, patients who understand their rights

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get subsidized by those who don't. Automatic release ensures all contact lens wearers benefit from the best price, service and convenience.

2. **Minimum 2-year prescription expiration date (unless a shorter date is medically warranted)**

- Maryland, New Jersey, Maine, Ohio, Utah and Florida have 2-year minimums.
- Minnesota and Mississippi have introduced 2-year minimum bills in the past 8 weeks.
- A bill introduced by Congress in July, 2001 calls for 2-year minimums nationally.

3. **Immediate response to requests for prescription verifications**

- Family Doctor's offices respond immediately to Pharmacies' requests for verification.
- Optometrists have a financial incentive not to respond to third party requests.
- Immediate response to prescription requests is in the contact lens wearer's best interest.
- A requirement to respond to requests for prescription verifications balances the requirement to verify a prescription prior to selling contact lenses.

4. **Forbidding Private Label or "doctor exclusive" contact lenses**

- Private label lenses defeat the spirit of this legislation.
- Private label lenses offer no consumer choice.
- Optometrist's quotes in an Optometric Trade Journal ('Contact Lens Spectrum') in January, 2002 make clear the intent of prescribing these lenses:

"I often don't give patients a choice. I don't say it is a private label lens. I say, 'This lens is the best for you. It's the one you should be wearing'" – Charles Hom, OD

"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. One of the strategies was private labeling." -- Charles Hom, OD

5. **Equitable and Equal Enforcement**

- Enforcement needs to be implemented by a neutral body (e.g. the Medical Board). Currently, the Optometric Board is responsible for enforcement. This permits one competitor to regulate the other. This system will not work fairly.
- Penalties need to be the same. Specifically, penalties imposed for selling contact lenses without a verified prescription must be matched with penalties for non-response to requests for prescription verification.

Thank you for the opportunity to present our comments today and I would be happy to respond to any questions.

COMPARING FORMS OF HEALTH CARE

	<u>Health Care Provider</u>	<u>Prescription Fulfiller</u>
Family Health Care	Family Doctor	Pharmacy
Ocular Health Care	Optometrist	Optometrist

A history of the struggle between optometrists and consumers

- mid-1970s** Many optometrists withhold eyeglass prescriptions - forcing consumers to buy eyeglasses from the optometrist's office.
- 1978** In response to numerous consumer complaints, the Federal Trade Commission issues the *Spectacle Prescription Release Rule* mandating that optometrists automatically release eyeglass prescriptions immediately after an examination. Retail chains like LensCrafters and Pearle Vision thrive and consumers benefit from lower prices and more convenience.
- mid-1980s** Disposable contact lenses are introduced. These lenses offer consumers a more healthy and convenient way to wear contacts. Disposable contacts come in 6 packs that are small, light, easy to ship, and are purchased frequently. Entrepreneurial companies begin offering replacement lenses by mail order. Consumers benefit from lower prices and more convenience.
- 1989** A group of influential optometrist allegedly respond to this new form of competition by pressuring the contact lens manufacturers to stop selling to mail order companies.
- 1991** American Optometric Association presents to the Food and Drug Administration and claims that consumers who obtain contact lenses through alternative channels encountered health problems as a result.
- 1996** 32 State Attorneys General, including Kansas, file suit against the American Optometric Association and several contact lens manufacturers for illegal and anti-competitive conduct. State Attorneys General also complain that the American Optometric Association misrepresented false health claims to the Food and Drug Administration concerning alternative channels of distribution.
- 1997** 20 State Attorneys General, upon the completion of a multi-state investigation, petition the Federal Trade Commission (FTC) to include contact lenses in the *Spectacle Prescription Release Rule* and require optometrists to release contact lens prescriptions automatically after an eye exam. FTC begins review.
- early-2001** American Optometric Association reaches settlement in Attorneys General lawsuit. Pays \$750,000 fine, 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 alternative suppliers.
- mid-2001** U.S. Representatives co-sponsor a bipartisan bill in Congress that would require optometrists to automatically release contact lens prescriptions, set a minimum 2-year prescription expiration date, and require optometrists to respond promptly to requests for prescription verification.



American Medical Association Code of Ethics

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.

Federal Trade Commission

Part 456—Ophthalmic Practice Rules—

THIS DATA CURRENT AS OF THE FEDERAL REGISTER DATED JANUARY 1, 2002

16 CFR - CHAPTER I - PART 456

§ 456.2 Separation of examination and dispensing.

It is an unfair act or practice for an ophthalmologist or optometrist to:

(a) Fail to provide to the patient one copy of the patient's prescription immediately after the eye examination is completed. Provided: An ophthalmologist or optometrist may refuse to give the patient a copy of the patient's prescription until the patient has paid for the eye examination, but only if that ophthalmologist or optometrist would have required immediate payment from that patient had the examination revealed that no ophthalmic goods were required;

(b) Condition the availability of an eye examination to any person on a requirement that the patient agree to purchase any ophthalmic goods from the ophthalmologist or optometrist;

(c) Charge the patient any fee in addition to the ophthalmologist's or optometrist's examination fee as a condition to releasing the prescription to the patient. Provided: An ophthalmologist or optometrist may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed; or

(d) Place on the prescription, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the ophthalmologist or optometrist for the accuracy of the eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

- can be found at:

http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_16/16cfr456_00.html

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, 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 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 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.

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 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."

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MAR 28 2001

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

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

Unsealed
per order #1139
on 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

- (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

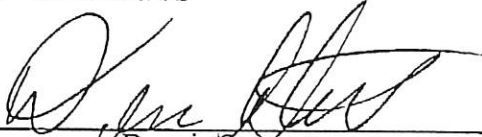
DATED: March 27, 2001

Respectfully submitted,
FLORIDA


BY: 
R. Scott Palmer

Special Assistant Attorney General
Burt & Pucillo

CLASS PLAINTIFFS

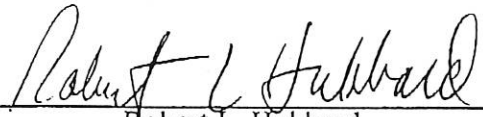
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Douglas D. Chunn, P.A.

STATE PLAINTIFFS

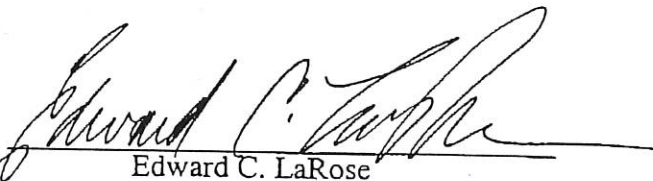
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DATED: March 27, 2001

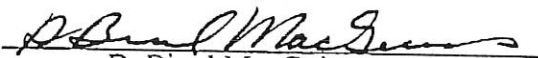
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BEFORE THE
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

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 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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Using Private Label Lenses to Keep Patients in The Practice¹¹

Private label lenses, or a lens not available without a valid prescription, can help keep patients returning to the practice and safely wearing contact lenses.

JOSEPH BARR, OD: If you use private label contact lenses, how do you position those lenses in your practice? Do they help with patient retention? Do they help to keep patients from thinking about alternate sources of contact lens distribution?

BRUCE GADDIE, OD: The closest we come to a private label contact lens is the Ocular Sciences Hydrogenics UV 60. We toyed with using the Biomedics 55 under private label, and we decided that the prestige of using the brand name was better than

our private label. For the most part, using the UV 60 has thwarted 1-800 as they call, grilling our technicians as to who manufactures the Hydrogenics UV



By providing a lens that is not available without a valid prescription, I believe we're providing a safer contact lens to our patients.

-James Maul, OD

60 lens. We did have some irate patients who wanted to be re-fit with lenses they could buy from 1-800. But for the most part, using the UV 60 lens and another brand has been quite successful for us.

JAMES MAUL, OD: We've run into the same problem to a certain extent. We've been using Hydrogenics 60 lenses for a while, and there have been a number of patients calling. We have been telling

They are abusing their eyes and, by providing a lens that is not available without a valid prescription, I believe we're providing a safer contact lens to our patients. If you're putting patients in the safest lens that's out there, and they choose to wear an unsafe lens, at least you are not legally liable for the abuse that can occur when they use that lens.

DR. BARR: Can you explain to our readers, what

you mean by "This contact lens isn't available to them" or "This contact lens is available only to you."

DR. MAUL: I'm referring to the Hydrogenics lens from Ocular Sciences. It is not sold to 1-800 Contacts or on the Internet. It is provided only to doctors who actually see patients and perform examinations in their office. If a patient takes a Hydrogenics 60 prescription and fills it in one of my colleague's offices, I know that she is receiving proper eye care. If she fills out a form at 1-800 Contacts and sends it in five years after I saw her, at least as the lens is currently being marketed, it won't be available. That provides a degree of safety.

DR. BARR: So this lens is like a semi-exclusive franchise.

DR. MAUL: Well, in the sense that any independent

private practitioner in the country can sell the lens, it's not very exclusive, but it does provide a lens that is available only with proper care.

RANDY HIEBER, OD: There is one issue I'm confused about. I started to say that the Hydrogenics was the safest lens, but then my associate came to me and said, "How can you say that to a patient when the Dk is lower than the Acuvue lens?" So I'm confused now, and maybe everybody else is in the coun-



The closest we came to a private label lens is the Hydrogenics UV 60. For the most part, it has thwarted 1-800, calling to grill our technicians as to who makes the lens.

-Bruce Gaddie, OD



I often don't give the patients a choice. I don't say it is a private label lens. I say, "This lens is the best lens for you. It's the one you should be wearing."

-Charles Hom, OD

our patients that this is the newest, most advanced technology. They can buy older technology, but this new lens is not currently available via other distributors. I tell my patients that it's the safest lens on the market. With the prescription expiration, and the inability to get this lens without a valid prescription, it ends up being a safer lens. I see patients who have not had their eyes examined in a number of years getting their contact lenses without a prescription.

1-25

try, on Dk/L, Dk/T. It would be nice to get some standardization in our industry. Since I've been using the Hydrogenics lens, I like it better, but then I look at the numbers and I see we've got a Dk of 24.3 vs. 28 for an Acuvue. Can we make that statement that it is a safer lens? I'd like to ask Dr. Barr about that.

DR. BARR: Vistakon lists the 58 percent water content Acuvue 2 at Dk 28 and center thickness 0.84mm at -3.00D. OSI lists Hydrogenics 60 at 60 percent water and Dk of 24.3 and center thickness 0.07mm at -3.00D. That makes the Dk/T about equal, but remember that these measurements provide only a general idea of the actual oxygen transmissibility. There are a lot of things that go into making a safe lens. Oxygen transmissibility would be one. The quality of the lens, the reproducibility of the lens and the wettability of the lens would be others. Does anyone else want to talk about their experience with using private label lenses?

CHARLES HOM, OD: [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. One of the strategies was private labeling.] I didn't know of any company other than Ocular Sciences that was doing it, or is doing that now effectively. Now when patients want to order a lens, they like the particular lens that we provide. [It's a private label, so they can't get it anywhere else. It makes it a lot easier for them to come back to us.] If they go down to Wal-Mart or Costco or someplace like that and ask, "Do you have this lens?" Costco or Wal-Mart or 1-800 would say, "Yes, we do, but it's a different name on the box." That creates the problem within the patient's mind about whether or not it's the same lens.

DR. BARR: Tell us how it works. What is the lens? Tell us the process that you use in the practice to talk to patients about it, positioning and so forth.



Dr. Hom uses private label contact lenses as a strategy to prevent patients from filling their possibly expired contact lens prescriptions at alternate distributors.



Dr. Gaddie finds that choosing the Hydrogenics 60 lens has been a right choice for his practice.

DR. HOM: I often don't give the patients a choice. I don't say this is a private label lens. I just say, "This is the best lens for you. It's the one you should be wearing." It's easy because I think the Hydrogenics 60 is better than the Acuvue or the Acuvue 2. It has better handling, vision and comfort. The other lens that's really top-notch is the new toric lens from Ocular Science, the Biomedics Toric. They are comfortable, stable and have excellent vision. I don't think there's a disposable toric lens out there that can really compete with that lens, and Ocular Sciences does have that in private labeling. That makes it easy for the practitioner to prescribe the lens. **CLS**

Contact Lens Prescription Release Act of 2001 (Introduced in the House)

HR 2663 IH

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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TESTIMONY FOR THE HOUSE HEALTH AND HUMAN AND SERVICES COMMITTEE ON H.B. 2285 JANUARY 29, 2002

Good afternoon. I'm Dr. Terry Carney and a practicing optometrist in Topeka, Kansas. Currently, I am serving as the Legislative Chairman for the Kansas Optometric Association. Beginning in the fall of 2000, we began a series of meetings with 1-800-CONTACTS that lasted until January 2001. We openly discussed their concerns and ours, and the meetings were cordial and frank. Some questions arose that we could agree upon. Should every successfully fit contact lens patient have the right to their contact lens prescription? Absolutely. Should that patient have the right to fill that prescription anywhere that they can legally do so? Absolutely. Some other questions arose which we could not agree. Should any company have the right to fill expired, incomplete, or non-existent contact lens prescriptions? Absolutely not. Should an out-of-state company selling contact lenses in Kansas be registered to do so? Yes. These questions are why the Kansas Optometric Association has asked your committee to introduce legislation that supports mandatory contact lens release, and would also require contact lens retail companies to register as would an out-of-state pharmacy.

For our patients to receive proper, safe vision care, expiration dates must be honored so we can monitor the patient's eye and keep it healthy. Healthy, human cornea was not meant to have a piece of hydrated plastic on it, so routine follow-up care is essential. We want to be sure that patients get accurate, unexpired prescriptions to assure optimal vision, consistent with federal and state laws. Unfortunately, our patients are receiving expired, sometimes inaccurate, prescriptions. 1-800-CONTACTS freely admits to not having honored expiration dates. In fact, credit card expiration dates were the only expiration dates being put on their main computer screens. We offered to support and work with them on developing a voluntary verification system for contact lens prescriptions using fax numbers.

We have encouraged our members to cooperate with voluntary verification from any company and see if fax verification is workable. We have encountered some problems which make verification with 1-800-CONTACTS unworkable. H.B. 2285 states that an optometrist or physician respond within an undefined, medically reasonable period of time that 1-800-CONTACTS has deemed to be 1 hour. In our negotiations, we tried to get 1-800-CONTACTS to understand that doctors and their staffs are sometimes too busy to check every fax, review a patient's chart, and respond within even 24 hours, especially if the doctor is out or the office is closed. Their response was that it is impossible for



Affiliated with
American Optometric Association

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them to do business if lenses cannot be ready to ship within 2 hours. Attempted verification can also have a wide definition. In my office alone, we receive faxes from 1-800-CONTACTS about people listing me as their doctor who have never set foot in my office. We have 1-800-CONTACTS faxes being sent on weekends, holidays and in the middle of the night. I might point out that not one other company has ever sent one such untimely verification fax. Some of the faxes are for expired prescriptions and some are legitimate prescriptions. 1-800-CONTACTS has made it impossible for a doctor to call them to talk about an individual patient. How many legislators could respond within 2 hours to all of your e-mails, faxes, and telephone messages?

A couple of specific points in the bill that seem only to help 1-800-CONTACTS do business and are not in the best interest of the patient are: 1) Making expiration dates on contact lens prescriptions last two years instead of one is simply a health problem waiting to happen. 2) Lessening second and subsequent offenses of the law from a Class B misdemeanor to a Class C is important to a company that freely breaks state laws anyway. 3) Allowing the optometry board to only take optometrists to court and not unlicensed persons or entities like 1-800-CONTACTS speaks for itself. No law can release a prescribing doctor from liability and damage even if verification is accurate as 1-800-CONTACTS would have you believe.

When disposable contact lenses were only a future idea, I was being taught in optometry school that if you are going to fit contact lenses, then you had better learn how to properly care for them. This includes seeing all contact lens patients at least on a yearly basis. Corneal and conjunctival infections, ulcers, and other eye problems directly related to contact lens wear can often be prevented, and definitely more easily treated, if patients eye health is followed properly. 1-800-CONTACTS would have you believe that seeing patients yearly is merely a marketing ploy to get more patients in the door more frequently in order to sell more contact lenses. This comment is insulting. More importantly, this proposed legislation is a dangerous risk to our patient's vision. For your constituents visual well being, please vote down H.B. 2285.

REQUEST FOR VERIFICATION OF CONTACT LENS PRESCRIPTION

The customer listed below has placed an order for replacement contact lenses with us, and has expressly authorized 1-800 CONTACTS, Inc. to verify his/her prescription information. Please verify, sign and return this fax to us at our toll free fax number, 1-888-476-2584 as soon as possible, so that your patient's access to replacement lenses is not delayed. Kansas law governing the practice of optometry now requires that in absence of a valid health reason, Kansas residents are entitled to receive their prescription in order to purchase replacement contact lenses from their provider of choice. KADC 65-8-5. If for any reason you cannot comply with this request, please state the specific reason(s) for your refusal to release your patient's contact lens prescription. This information will be copied and delivered to your patient for prompt follow-up.

PATIENT: Lopez, Thalia *Not a pt.*

Item	Power	B.C.	Dia.	Cyl	Axis
O.D.: SeeQuence 2 (Optima FW) 6pk	-4.25	8.70	14.00	0.00	0.00
O.S.: SeeQuence 2 (Optima FW) 6pk	-4.25	8.70	14.00	0.00	0.00

May not substitute _____
 Refillable through _____

Dr. _____
 License _____
 Phone: _____

Signature

Prescription information is correct.
 New prescription attached hereto by fax.
 Prescription has expired. Date of last exam was _____.
 Other (specify) patient is not, or ever has been, a patient here.

We will notify your patient of your prompt response. If there is no reason provided for refusing to fill this order, replacement contact lenses conforming to the specifications provided will be shipped to the patient. Thank you in advance for your assistance.

*Farped back
12-23-01*

1-800-CONTACTS, Inc.
P.O. Box 1800
Sandy, Utah 84091
Fax: (888) 476-2584

Please do not attempt to contact us regarding this fax through our call center. Our agents are not equipped to handle your inquiries. We will only respond to written requests faxed to 1-888-476-2584.

BX0009662291N00454440Y1376941EX
Terry Pohlenz Fax 17852662441

*→ for Terry Carney CO
or
Randy Pohlenz CO*

January 29, 2002

TO: HOUSE HEALTH AND HUMAN SERVICES COMMITTEE
FROM: CHARLES KISSLING, OD
RE: TESTIMONY ON H.B. 2285, TUESDAY, JANUARY 29, 2002

What the law is now

Long ago the Food and Drug Administration determined that contact lenses posed sufficient health risk to consumers so as to require consumer protection. Thus, the FDA requires that all contact lenses be sold only pursuant to a prescription from an appropriate licensed professional (an optometrist or a physician). In fact, the FDA requires the contact lens manufacturer to label every contact lens with the following statement: "Caution! Federal law prohibits dispensing without prescription."

What this proposed law changes

H.B. 2285 would create a State law which, contrary to Federal law, would allow the selling of contact lenses without a prescription. H.B. 2285 modifies existing KSA 65-1504b (pg. 3, lines 34-39) which currently states that "it is unlawful for any person to dispense an ophthalmic lens or lenses without first having obtained a prescription." This Bill adds the wording "or verified, or attempted to verify" after the word obtained. Thus, H.B. 2285 would allow the sale of an ophthalmic lens if the seller had merely made an attempt to verify the prescription. They would not actually have to obtain a prescription. A phone call with no answer would be an attempt to verify. A phone call with a busy signal would be an attempt to verify. A midnight fax with no response by morning might be an attempt to verify. Lest you think this a bit far fetched, the current verification attempts by 1-800-CONTACTS include late night and weekend faxes, as well as automated phone calls requesting verification. Automated messages have been left on after hours answering machines. When the answering machine did not respond, the prescription was considered verified.

A patient with an expired prescription could provide the information from their old lenses, and then receive new lenses. Any patient with a box of contact lenses could order lenses of a different brand so that they might get colored lenses. A non-contact lens wearer with a glasses prescription in hand could order contact lenses by specifying the

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power of lenses from their eyeglass prescription and then guessing as to contact lens brand and fitting parameters. These patients' eyes will be at greater risk for harm, but the only thing that the seller would be required to do is attempt to verify that the person placing the order has truly been prescribed the lenses.

I personally ordered contact lenses for myself. I do not wear contact lenses. I provided the name of one of my partners as the doctor. I provided the phone number as requested. Two days later I received the lenses in the mail. My partner is still waiting for 1-800-CONTACTS to call him to verify the prescription. Since then, I received an e-mail from 1-800-CONTACTS offering to send more contacts if I needed them. Under current law, this is illegal.

I believe that my personal experience was not an isolated event. In fact, in the January 6 *New York Times*, columnist Gretchen Morgenson told of a similar personal experience. Referring to 1-800-CONTACTS, she wrote "Last month, I ordered lenses from the company's web site. Since I do not have a prescription, I supplied a fictitious doctor's name and telephone number. My lenses arrived in the mail without a hitch a few days later." These actions demonstrate complete disregard for existing Federal and State laws.

The FDA website (www.fda.gov/cdrh/consumer/buycontactqa.html) makes it clear that the purchaser in such scenarios is not breaking any laws, "but the company is selling you a prescription device as if it were an over-the-counter device. This is a violation of the Federal prescription device regulation." (emphasis by FDA) H.B. 2285 would legalize these actions if the seller merely attempts to verify the prescription as provided to them by the buyer.

Why are we here?

The S.E.C. filings from 1-800-CONTACTS admit that they may not comply with applicable state laws and regulations regarding the sale of contact lenses. They are asking you to pass legislation so that they can legally continue their current business practice.

Last year, the Kansas State Board of Examiners in Optometry passed a regulation which requires doctors to provide the patient with a contact lens prescription upon request, when such prescription actually exists and is current. The regulation, in keeping with standard of care, also specifies an expiration period no less than one year, unless a health-related reason for a shorter period is recorded in the patient's record.

The KOA expects doctors to follow the law regarding both the prescribing and the dispensing of contact lenses. All we ask of retailers is that they also follow the law. Specifically, we ask that they actually obtain or verify a contact lens prescription before shipping or dispensing contact lenses. We also ask that they honor the expiration date of the prescription, and not sell lenses after the prescription has expired. Neither of these things is too much to ask. In fact, they are currently the law. Let's keep it that way.

Money & Business

Cloudy Outlook For a Seller Of Contacts

MARKET WATCH
GRETCHEN MORGENSON

TO many investors, 1-800 Contacts Inc. looks like a cheap stock. The company is a top direct marketer of contact lenses that has shown 60 percent earnings growth since 1999. Sales for the first three quarters of 2001 came in at \$131 million, up 21 percent from the period last year. Yet shares of 1-800 Contacts, which traded as high as \$62.50 in September 2000, closed on Friday at \$11.95, only 13 times earnings.

Looks can be deceiving, however, even in shares of a company that sells vision correction.

Based in Draper, Utah, 1-800 Contacts is the entrepreneurial triumph of Jonathan Coon, the company's president, and his co-founder, John F. Nichols, vice president for sales. The company, born in 1995, came public in 1998 and turned a profit a year later.

On its Web site, 1-800 Contacts says it is the world's largest contact lens store, delivering more than 150,000 contact lenses to customers each day. "Our goal is to make it as easy and convenient as possible to purchase your contact lenses," the Web site states.

Therein lies a problem. Because contact lenses are a medical device, they can be dispensed only by an eye-care professional. Customers who buy lenses on the Internet supply that provider's name and phone number so the company selling the lenses can verify the prescription's validity. Ill-fitting lenses, while not a major health hazard, can cause corneal abrasions, infections and, at worst, vision loss.

The company, however, appears to be so eager to sell lenses that it does not al-

ways verify with the eye-care professional that a prescription exists.

Last month, I ordered lenses from the company's Web site. Since I do not have a prescription, I supplied a fictitious doctor's name and telephone number. My lenses arrived in the mail without a hitch a few days later.

Kevin McCallum, a spokesman for 1-800 Contacts, said the company had had difficulty in the past getting prescription information from doctors, and suggested that doctors had a competitive interest in not helping his company.

The company's most recent quarterly filing allowed that a significant portion of its sales might not comply with applicable state laws and regulations on the delivery and sale of contact lenses.

The company has had its share of run-ins with states. In 1999, the Texas Optometry Board sued 1-800 Contacts, accusing it of among other things, dispensing lenses without a prescription; the company is vigorously defending the suit. In 2000, it settled with the Texas Department of Health over similar issues, but last year the department said the company had failed to comply with the settlement. The company says it is in discussions with the department.

Even more worrisome is the company's nonrelationship with Vistakon, the eye-care division of Johnson & Johnson and a giant player in contact lenses. Vistakon has refused to open an account with 1-800 Contacts, so the company has sued to require Vistakon to supply products like its Acuvue lenses. Vistakon has not budged, so its lenses, which have accounted for more than 40 percent of 1-800 Contacts' sales, have become difficult to obtain. The company conceded that this would reduce sales and profits.

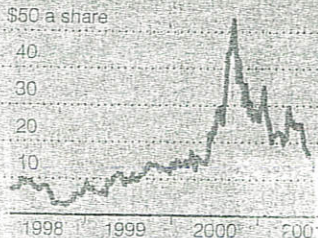
Peter A. Ferguson, in the New York State board office for optometry, said his office had complained to Utah regulators about 1-800 Contacts' sales practices in the past but had received no reply. Officials in Utah said a new licensing law essentially prevented them from cracking down on the company.

Protection for New York consumers may lie in a law passed last year that will require out-of-state pharmacies to register with New York state before they can sell drugs to residents. But whether it applies to companies selling medical devices remains unclear.

Selling lenses without prescriptions is a violation of federal law. But Sharon Snider, spokeswoman for the Food and Drug Administration, said it leaves contact-lens enforcement to states. Buyer — and investor — beware.

Watch Out

Investors in 1-800 Contacts are betting on questionable future sales.



Source: Bloomberg Financial Markets

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DR. RONALD L. FIEGEL, O.D.
DR. MELISSA RAMOS KEUSLER, O.D.
DR. STEVE R. SHOOK, O.D.

Family eyewear ♦ Vision Health care ♦ Guaranteed service

TESTIMONY – HB 2285

Mr. Chairman, members of the committee, thank you for allowing me to be here today to discuss my concerns with House Bill 2285. I am Dr. Ron Fiegel; I have been licensed to practice optometry in Kansas since 1976. During that time I have fit almost every type of contact lens available. I have always released prescriptions to my patients unless it was medically inappropriate to do so. I have also been witness to the numerous problems that can occur when those lenses are not properly fit or maintained.

As a doctor, I have three goals for my contact lens wearing patients. In order of importance, they are that your eyes must remain healthy, you must see well and they must feel good. My patient's goals are a little different. They want to look good, then feel good and then see good. They rarely ask about keeping their eyes healthy. This is not because they don't care about their health. It's because they trust me to think about it for them.

In recent years, there has been another reason they don't think about it. Many consumers now believe that contact lenses, much like lipstick, are harmless cosmetic devices that enhance your life style. Contact lenses make you look good, they don't fog up in the cold, and you can compete better in sports. Those are legitimate benefits. However, those benefits are achieved with a device that when not properly fit or cared for has medical consequences

The cornea of your eye is clear because it has no blood vessels. It gets all of the oxygen it requires to stay healthy from the air around it and from the tear film that covers it. Anything that interferes with that transmission, such as a contact lens, causes lack of oxygen, and that affects the health of your eye. When your cornea becomes stressed enough, it begins to fight back. That fight can take the form of mild redness and irritation, to corneal distortion, to more severe ulceration and corneal scarring, resulting in loss of vision.

These conditions, from the mild to the severe occur in patients who abuse their lenses, their wearing schedules, their disinfecting regimens or whose lenses do not fit correctly. These problems occur because of two reasons, hypoxia (lack of oxygen) and the mechanical effects of the lens on the eye and eyelid. Because soft lenses are 1/3 to 2/3 water, they shrink as you wear them. This results in tighter lenses that abrade more easily and get dirtier quicker. Dirty lenses no longer transmit oxygen correctly and significantly increase the risk of injury to the eye.

When I first began prescribing disposable contact lenses for my patients, I saw a definite drop in medically related contact lens problems. As this type of lens has become

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and disease

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for dry eye

Prosthetic
contacts to hide
damaged eyes

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of contact lenses

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and children

**Your satisfaction
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Accurate
prescriptions

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on eyewear

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and convenience:**

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Medicare welcome

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and Discover

Handicap access

Morning and
evening hours

DR. RONALD L. FIEGEL, O.D.
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increasingly thought of as a cosmetic device, the incidence of these problems is again on the rise.

In the last few months I have treated several patients for moderate to severe contact lens complications. They ranged from lid conditions to more severe corneal ulcers. Two of these patients ultimately required referral to a corneal specialists for extended care.

Some of these patients purchased their lenses from me, most had had a complete eye exam within 1 – 8 months prior to presenting with a contact lens problem. Some had seen other doctors or purchased their lenses from alternative suppliers. Some had not seen a doctor in over two years or had voluntarily extended the life of their lenses beyond what was prescribed for them. Some needed time out of their lenses, most needed medications, some required a complete lens refit.

The patients treated spent between \$100.00 to \$500.00 dollars in professional fees to resolve their problem. That does not include the costs of medications (\$35.00 - \$80.00 each), replacement contact lenses, contact lens refitting fees, and lost time from work. Since these problems were medical in nature, the patient's health insurance or Medicaid paid the majority of these costs. As these types of problems are increasing, changing the existing law to allow for the irresponsible filling of contact lens prescriptions will only help to drive up the costs of health care.

Of equal concern when we get lax about proper care is how well the patient sees. Not a day goes by that I don't see at least one patient who tells me they are having no problems. But when they read the eye chart, one eye sees fine and the other is blurry. Often the difference between the eyes is more than two to three lines of vision. A difference of that much can effect your depth perception and ability to judge distance while driving. In today's driving environment, the inability to properly judge distance at higher speeds puts not only the patient who thinks they see well at risk, but also their passengers and those in vehicles around them.

The only purpose this legislation serves is to allow an alternative supplier to immediately sell a contact lens without a valid prescription or before the patient's prescription can be properly verified. Given the potential for harm to the patient, how can it be inappropriate to allow sufficient time to properly verify the prescription for a medical device and require that that device only be sold on a valid prescription?

I would strongly encourage you to oppose HB 2285.

Thank you.

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and Discover

Handicap access

Morning and
evening hours



KANSAS TRIAL LAWYERS ASSOCIATION

Lawyers Representing Consumers

To: Members of the House Committee on Health and Human Services

From: Gary D. White, Jr
Kansas Trial Lawyers Association

Re: 2001 HB 2285

Date: January 29, 2002

Chairman Boston and Members of the House Committee on Health and Human Services: thank you for the opportunity to submit comments on HB 2285. I am Gary White, a Topeka attorney and a member of the KTLA Executive Committee.

KTLA opposes this bill because it grants immunity to health care providers and lens dispensers who incorrectly perform contact lens verifications and potentially cause permanent injuries to Kansas consumers.

First, the bill grants immunity under Section 2(b) to an optometrist or physician who verifies a contact lens prescription to a seller of lenses in interstate commerce. This provision provides immunity to a health care provider even if the verification is performed incorrectly and causes permanent injuries to the patient.

Second, the bill grants immunity under Section 2(e) to a lens dispenser who attempted but did not obtain verification of a lens prescription before dispensing the lens or lenses. Section 2(e) provides that such attempted verification is "a complete defense" to a prosecution under the other provisions of Section 2. Section 2(e) provides no protection to Kansas consumers who may unknowingly be given an unverified lens prescription that causes them permanent injuries.

By granting such immunity to optometrists, physicians and lens dispensers, the State excuses careless behavior and sacrifices the safety of all Kansans while leaving injured people who are innocent of fault to deal with their injuries and the resulting financial burdens on their own or, potentially, at the expense of Kansas taxpayers. If such immunity is granted, the State puts all Kansans at risk and excuses those who profit at the expense of safety.

The immunity provision creates other problems as well. For instance, the term "verifies" as used in Section 2(b) is not defined in the bill. Section 2(d), however, provides that "verification of a lens provision shall be presumed following a request for verification if the optometrist or physician fails or refuses to respond..." Accordingly, a health care provider may arguably have immunity under Section 2(b) even where they failed or

Terry Humphrey, Executive Director

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refused to respond to the requested verification. The bill therefore potentially provides immunity to a health care provider who has failed to take timely and appropriate action to protect his or her patient.

The presumption of verification under Section 2(d) also fails to protect Kansas consumers who may be given incorrect lens prescriptions while the lens dispenser is immune under Section 2(e) because he attempted to verify the prescription. Further, the bill does not define what constitutes an attempt to verify. For instance, a voicemail message or message left with a receptionist while the health care provider is with patients may be a sufficient attempt to verify under the bill. Certainly, Kansas consumers are entitled to more from a lens dispenser.

Section 2(c) provides that verification may be established or initiated by telephone or other electronic means of communication. This provision provides no protection to Kansas consumers to ensure that a prescription is properly verified and could result in immunity under Section 2(b) or (e) even where a dispute exists between the health care provider and lens dispenser concerning whether a prescription was verified and dispensed correctly.

The term “seller of lenses in interstate commerce” as used in Section 2(b) is likewise undefined in the bill. Nearly all contact lenses are sold in “interstate commerce” and the bill would potentially grant immunity to every lens prescription made by an optometrist or physician—not just those purchased through companies such as the proponents of this bill.

With regard to the requirement that a verification or attempted verification be maintained for two (2) years, we would respectfully submit that this time period is too short. Kansas law provides that a minor child has eight (8) years within which to file a claim for injuries or damages sustained due to another’s negligence. This should be the minimum period that a lens dispenser be required to maintain the records. Kansas Administrative Regulations currently require health care providers to maintain such records for longer than eight (8) years.

Finally, the immunity provided by Sections 2(b) and (e) is unnecessary if the optometrist, physician or lens dispenser correctly verifies the prescription because they would not be legally responsible for the injury or damages sustained by the lens wearer under such circumstances. As a result, the bill provides immunity to health care providers and lens dispensers who incorrectly verify a prescription thereby insulating such persons from accountability for their own actions that cause harm to Kansas consumers.

Thank you for the opportunity to express our serious concerns about this bill. We encourage you to oppose this bill.

**TESTIMONY OF
THE KANSAS BOARD OF EXAMINERS IN OPTOMETRY
IN OPPOSITION TO H.B. 2285**

TO: Members of the House Health and Human Services Committee

DATE: January 29, 2002

My name is Randy Forbes. I am the attorney for the Kansas Board of Examiners In Optometry (the "Board"). I have been directed by the Board to present this testimony in opposition to H.B. 2285. The Board feels these proposed changes to the Kansas Optometry Law are extremely ill advised for many reasons. In this testimony we will attempt to highlight a few.

For many years the Kansas Optometry Law has declared that "[i]t shall be unlawful for any person to dispense an ophthalmic lens or lenses without first having obtained a prescription or order therefor from a duly licensed optometrist or a person licensed to practice medicine and surgery." K.S.A. 65-1504b. This statutory prohibition recognizes that wearing contact lenses, other than as prescribed by a healthcare professional, poses significant risks to the wearer's eyes. In most cases, these risks are unknown to the wearer.

On April 7, 1999 the Board was forced to file suit against the author of this bill, 1-800 Contacts ("1-800") in an attempt to force 1-800 to cease violating K.S.A. 65-1504b. In the lawsuit, the Board alleges multiple instances of 1-800 dispensing contact lenses without a prescription. The Board has filed a witness and exhibit list that includes no less than 10 instances involving 1-800 dispensing contact lenses in violation

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of Kansas law. A similar lawsuit is now pending in the state of Texas, where 1-800 is also accused of having dispensed contact lenses without a prescription. 1-800's own Form 10-Q, filed November 13, 2001 with the Securities and Exchange Commission admits that, "[a] significant portion of the Company's sales may not comply with applicable state laws and regulations governing the delivery and sale of contact lenses", and "[i]f the Company is unable to obtain a copy of or verify the customer's prescription, it is the Company's general practice to complete the sale and ship the lenses to the customer" The litigation has been hard fought, but is now coming to an end. This bill is an obvious attempt to avoid that litigation and avoid having to comply with Kansas law.

The 1-800 strategy through this proposed legislation seems really quite simple. If this bill were to be passed, 1-800 would be able to sell contact lenses without having first obtained a prescription (thereby placing the customer's ocular health at risk) if it "attempted to verify" the prescription. The key to this scheme is in the provision that states "[v]erification of a lens prescription shall be presumed following a request for verification if the optometrist or physician fails or refuses to respond within a "medically reasonable period of time." In other words, 1-800, not the patient's healthcare provider, will decide whether the healthcare provider had responded in a "medically reasonable period of time". One might ask how would 1-800 do that without any of the patient's medical records. One might also ask whether the 1-800 personnel involved are capable of making such a decision. 1-800 is primarily a mail order company. It uses sales clerks to process orders. This proposed legislation would permit 1-800's sales clerks, without the benefit of the patient's records and with no relevant training or experience in ocular healthcare, to determine if the patient's optometrist or physician has responded

to a telephone call or facsimile within a "medically reasonable period of time." This legislation would allow 1-800 to sell and ship to Kansans potentially harmful contact lenses based upon a decision by a 1-800's sales clerks that the Kansan's healthcare provider did not respond quickly enough to a telephone call or a facsimile. The Board feels this would create a potentially dangerous situation.

It should also be noted that 1-800 has built into this bill "a complete defense" if it attempted to verify the prescription prior to selling the lenses. In other words, however short a period of time it waits for confirmation (the Board understands 1-800 has previously proposed it wait no longer than 2 hours), it will have a complete defense. 1-800 may respond that it must establish the "medically reasonable period of time" in "good faith" to obtain the complete defense. Notwithstanding the good faith language, since 1-800 will not have any medical records or history to guide it, "good faith" will never cause it to wait more than a period it chooses to pick.

It is also important to understand that this bill would apply not only to 1-800, but to all companies that would sell contact lenses to Kansans in violation of Kansas law. If this legislation is passed, it will serve as a vehicle to permit Kansans to receive incorrect contact lenses, contact lenses other than what their healthcare provider prescribed for them or contact lenses based upon expired prescriptions so as to create ocular health risks.

This bill also amends K.S.A. 65-1523 in a way that would effectively prevent the Board from suing 1-800 or any other nonprofessional individual or corporation selling contact lenses (because they are not "a licensee") to prevent them from violating Kansas law. The Board has stepped up to challenge 1-800's open violation of Kansas

law in the courts and 1-800 is now asking the legislature to prevent such suits to enforce our state's laws.

The Board believes H.B. 2285 is extremely bad policy and would foster situations that could be dangerous to the ocular health of Kansas citizens.

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AAO Councillor
and Imm. Past President

House Health and Human Services Committee

January 29, 2002

Thank you for permitting me to speak to you today on behalf of the Kansas State Ophthalmological Society. Our President, William Clifford, MD, of Garden City, had hoped to be here today, but was unable to rearrange his patient schedule.

On behalf of Dr. Clifford and the KSOS Board of Directors, I am appearing today to oppose House Bill 2285.

Our members are acutely aware of the complications and potential problems that contact lens wear can create. We have members who are corneal specialists who routinely treat the most severe cases involving contact lens complications. In the most extreme cases, this may involve a corneal transplant, which is costly for the health care delivery system and insurance rates.

We strongly believe that contact lenses are a prescription item as required by the Federal Food and Drug Administration and should be treated with respect. The KSOS supports contact lens prescription release and our members do so on a regular basis.

Our priority is to protect the doctor-patient relationship and provide quality medical service to our patients. It does not appear to us that House Bill 2285 is written to protect the safety and health of our patients' vision. Allowing attempted verification over the telephone to expedite sales creates a risk to the visual health of Kansas. There are also implications for the sale of Internet prescription drugs and other medical devices.

Contact lens are not the same as eyeglasses.

I and the members of KSOS would be happy to answer any questions you may have regarding eye care in general and this issue in particular. Please do not hesitate to use us as a resource.

We would ask the committee to defeat House Bill 2285. Thank you.

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