Approved: May 10, 2002
Date

MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE.

The meeting was called to order by Chairperson Senator Susan Wagle at 1:30 p.m. on March 20, 2002 in Room 231-N of the Capitol.

All members were present except: Ms. Emalene Correll, Kansas Legislative Research Department

Committee staff present: Mr. Norm Furse, Revisor of Statutes

Ms. Lisa Montgomery, Revisor of Statutes

Ms. Margaret Cianciarulo, Administrative Assistant

Conferees appearing before the committee: Mr. Garry Robbins, Executive Director,

KS Optometric Association Dr. Mike Malone, Optometrist Dr. Chuck Kissling, Optometrist

Dr. Ron Fingel, Optometrist Dr. Mike Feifarek, Optometrist

Ms. Amy Campbell, Executive Director, KS State Ophthalological Society

Others attending: See attached guest list.

Reconsider intentions of bills

Chairperson Wagle opened the meeting by referring to the bills worked yesterday, March 19, 2002. In the matter of **HB2665**, an act concerning emergency medical services; relating to certification, the Committee found a one-word technical problem. In the matter of **HB2718**, an act concerning vital statistics records, including certificates of birth, death, adoption, marriage, and divorce, and the manner in which the Department of Health and Environment makes records it maintains available to eligible applicants, a problem was found with the criminal section. A motion was made by Senator Praeger and seconded by Senator Jordan that the Committee reconsider their intentions to pull back **HB2718** and **HB2665** in Committee. The motion passed.

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

The Chair then announced she would begin the hearing on <u>HB2285</u> by calling on Mr. Norm Furse, Revisor of Statutes, to give an overview of the bill. Highlights of his presentation included:

Sec. 1 states that the act be known as patients contact lens prescription release act;

Sec.2 amendatory section, the subsections addressing unlawful acts;

Sec.3 provides purposes;

Sec.4 deals with meeting criteria and payment of registration fee;

Subsection (h) covers writing warning notification to patients;

Sec.5 covers revoking registrations or licenses

The Chair thanked Mr. Furse and proceeded to call on the first proponent, Mr. Gary Robbins, Executive Director of the Kansas Optometric Association who stated that this legislation makes it clear that patients have a right to their contact lens prescription. He gave a brief history of the bill, introduced in 1999, and proposed a balloon, attached to his testimony, to clarify that "an ophthalmic lens shall include a contact lens with or without power". A copy of his testimony and proposed balloon are (Attached 1) attached hereto and incorporated into the Minutes by reference.

MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE, Room 231-N, Statehouse, on March 20, 2002 Page 2

The second proponent was Dr. Mike Malone, a practicing optometrist in Topeka who shared the American Optometric Association Contact Lens Section recommendations, cited studies, and spoke on the 1-800 fax verification system and the optometry rules, regulations and requirements, and provided letters from optometrists expressing the difficulties they had experienced with 1-800-CONTACTS. A copy of his testimony and the optometrists' letters are (<u>Attachment 2</u>) hereto and incorporated into the Minutes by reference.

The third proponent was Dr. Charles Kissling, practicing optometrist in Wichita, who stated that the FDA requires all contact lenses be sold only pursuant to a prescription from an appropriate licensed professional and requires the manufacturer to label every lens so as to signify that it is a prescription item. Also, present Kansas law states "it is unlawful for any person to dispense an ophthalmic lens without first having obtained a prescription and this bill seeks to place retailers under regulatory authority of the State Board of Examiners in Optometry. He also provided examples of retailers selling lenses without a prescription and a "requests and verification" study. A copy of his testimony and his examples and references are (Attachment 3) attached hereto and incorporated into the Minutes by reference.

The fourth proponent was Dr. Ron Fiegel, practicing optometrist in Wichita, who stated: his three goals for contact lens wearing patients, conditions of a healthy eye becoming stressed; his concerns with the bill; and the universally accepted standard of care. A copy of his testimony is (Attachment 4) attached hereto and incorporated into the Minutes by reference.

The fifth proponent was Dr. Mike Feifarek, practicing optometrist in Topeka, gave a brief description of the cornea and then expressed his concerns regarding: care of the patient, risks of lenses, cost to society when the cornea is infected, the issue of cost, and the policy set must be safe for all. No written testimony was provided.

The last proponent to testify was Ms. Amy Campbell, Executive Director, Kansas State Ophthalmological Society, who stated KSOS supports the release of prescriptions to the patient, however, this responsibility does not automatically transfer to a third party. And also, they request an amendment, specifically referring the regulation of ophthalmologists back to the Board of Healing Arts. A copy of her testimony is (Attachment 5) attached hereto and incorporated into the Minutes by reference.

The two written testimonies were presented, one from the Kansas Medical Society and the other from Kansas State Ophthalmological Society. A copy of these written testimonies is (<u>Attachment 6</u>) attached hereto and incorporated into the Minutes by reference.

The Chair then asked for questions or comments from the Committee. Questions were asked by Senators Haley, Praeger, Wagle, and Barnett ranging from where did this concept come from, is there similar in Missouri, were the conferees aware of the other two statutes Mr. Furse referred to, what if staff division in a small hospital, statute does not permit but does not permit, to what is the law on patients receiving advance notice.

As there was no further discussions, comments, or questions, the Chair adjourned the meeting.

Adjournment

Adjournment time was at 2:35 p.m.

The next meeting is scheduled for March 21, 2002.

SENATE PUBLIC HEALT ND WELFARE COMMITTEE

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GUEST LIST

DATE: Wednesday 3-20-02

NAME	REPRESENTING
Jan (Jaches	Coke Vizam/Cons Cond.
Scott SCHNEIDER	COLE VISKON / LENG CATTE
FRANKLIN D. ROZAK	Cole Vision Corporation
Marlee Carpender	RCCI
Charles W. Kissling	KoA
Michael P. Malone	KOA.
Matt Bergmann	Pet Hobbell Assoc. Inc.
Todd fleisch	FOR
Amy A graphell	KS State Ophthalmological Soie
Df Kenned	am Concir Joint
Sean Kinnedy	am Carrey Society
Judich spor	American Cancer Society
Sames Stepien	American Cancer Societa
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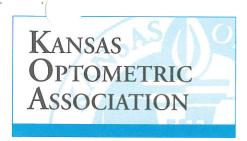
SENATE PUBLIC HEALT AND WELFARE COMMITTEE

GUEST LIST

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DATE: Whatslay 3-20-02

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STEVE KEARNEY	1-800 CONTAIN
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1266 SW Topeka Blvd. • Topeka, KS 66612 (785) 232-0225 • (785) 232-6151(FAX)

koa@cjnetworks.com

TESTIMONY ON SUBSTITUTE FOR H.B. 2285 SENATE PUBLIC HEALTH AND WELFARE COMMITTEE March 20, 2002

I am Gary Robbins, Executive Director of the Kansas Optometric Association. We are appearing in support of Substitute for House Bill 2285. This legislation makes it clear that patients have a right to their contact lens prescription. This legislation is modeled after the Kansas mail order pharmacy law, which requires mail order pharmacies to register under the Kansas Board of Pharmacy.

For many years, Kansas law has prohibited any company from selling contact lenses unless it has obtained a valid prescription for these lenses. This requirement is very similar to the requirement that a Kansas pharmacy obtain a prescription before it sells drugs. In 1999, the Kansas State Board of Examiners in Optometry filed a lawsuit against 1-800-CONTACTS to force it to cease violating Kansas law. In the lawsuit, the State Board alleged multiple instances of 1-800 dispensing contacts without a prescription. During the 2000 legislative session, 1-800-CONTACTS introduced House Bill 2285 in response to the lawsuit. The bill dictated expiration dates beyond the standard of care for contact lenses, which infringes upon the professional judgment of doctors. It allowed mail order and Internet companies to sell a contact lens without the specific authorization of an optometrist or a physician, if the seller merely attempted to verify the existence of a prescription. They also sought liability protection for both themselves and the doctors if a prescription was dispensed incorrectly. And finally the bill amended KSA 65-1532 to prevent the State Board of Examiners in Optometry from taking action to prevent mail order companies from openly violating Kansas law. The House Health and Human Services Committee rejected the 1-800-CONTACTS proposal. They substituted our proposal (House Bill 2745) which requires release of the prescription, registration and oversight of the mail order companies by the State Board of Examiners in Optometry. In addition, equal fines and penalties could levied against both doctors and mail order companies. This bill passed the House 121-0.

After the House Health and Human Services Committee hearings on these issues, a Wichita television station aired a consumer report about local beauty salons selling colored contact lenses to teenagers. The lenses, which are referred to as plano lenses, had no power and were used to change the color of the teenagers' eyes for "cosmetic reasons," rather than to correct nearsightedness or farsightedness. Wichita optometrists were treating teenagers with potentially serious eye infections sometimes seen in contact lens wearers. At first doctors were confused because these patients didn't have a refractive error or a prescription — and their parents weren't even aware they were wearing contact lenses. Apparently, the lenses were sold without a prescription, weren't fitted to the eye, and the Food and Drug Administration (FDA) warnings on the lenses requiring a prescription were ignored. The point is that a contact lens rests directly on the eye and restricts the flow of oxygen to the eye regardless if it has any power or refractive prescription.

The House committee solution was to amend this bill to require registration of anyone selling a contact lens. During recent discussions with interested optical companies, we discovered a simple alternative that resolves the problem and clarifies the optometry law. Currently optometrists are authorized to prescribe any lens to correct insufficiencies or abnormalities of the eye. Since this issue doesn't cover any refractive correction, we are proposing in the attached balloon amendment to clarify that: "An ophthalmic lens shall include a contact lens with or without power."

Other changes would remove the requirement that persons directly dispensing a contact lens pursuant to a prescription be registered with the Kansas State Board of Examiners in Optometry.

There are doctors present who need to testify who have graciously re-arranged their schedules to appear, so I will conclude my remarks. I will be available for questions at the end.



Senste fudicilenth Wilfall Committee Dete: March 20.2002 Attachment 1

Substitute for HOUSE BILL No. 2285

By Committee on Health and Human Services

2-25

AN ACT concerning optometry; relating to contact lens; amending K.S.A. 65-1504b and repealing the existing section.

Be it enacted by the Legislature of the State of Kansas:

New Section 1. This act shall be known as the patient's contact lens prescription release act.

Sec. 2. K.S.A. 65-1504b is hereby amended to read as follows: 65-1504b. (a) Each patient shall be entitled to receive upon request a copy of such patient's contact lens prescription once the same prescription has been determined and the adaptation period has been completed. Any prescription for a specific brand of contact lenses available only from the licensee or person licensed to practice medicine and surgery, but which are generally marketed under an alternate brand, must disclose the name of the manufacturer and the trade name of the alternate brand. No contact lens prescription may be limited by an expiration date or otherwise to a period of less than 12 months from either the date the prescription is first determined or the last date of the contact lens evaluation by a licensee or a person licensed to practice medicine and surgery, whichever date is later, unless a health related reason for the limitation is noted in the patient's medical record.

(b) It shall be unlawful for any person to dispense an ophthalmic lens or lenses without first having obtained a prescription valid, unexpired prescription as defined in K.S.A. 65-1501a, and amendments thereto, or order therefor from a duly licensed optometrist or a person licensed to practice medicine and surgery.

(c) It shall be unlawful for any person to dispense contact lenses within 60 days prior to the prescription expiration date for such contact lenses in a greater quantity than necessary to complete the prescription, however, nothing in this act shall be interpreted to prohibit a contact lens prescription from being rewritten by a licensee prior to its expiration. The rewritten prescription shall then become the patient's current contact lens prescription.

New Sec. 3. For purposes of this section and section 4 and amendments thereto a person dispensing contact lenses means a person or entity not licensed under K.S.A. 65-1505, and amendments thereto, or licensed

An ophthalmic lens shall include a contact lens with or without power.

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to practice medicine and surgery in Kansas who mails or dispenses contact lenses to patients in Kansas pursuant to a contact lens prescription which such person or entity did not determine.

New Sec. 4. Persons who fall within the scope of section 3, and amendments thereto, may dispense contact lenses through the mail upon meeting the criteria of this section and payment of a registration fee set by the board of examiners in optometry. Registration fees shall not exceed the annual fee for an initial or renewal permit to practice optometry in this state as provided in K.S.A. 65-1505 and amendments thereto. Approval of the registration for dispensing contact lenses shall be provided by the board upon certification by the person dispensing the contact lenses that such person:

(a) Is licensed or registered to dispense contact lenses in the state where the dispensing facility is located.

(b) provides the location, names and titles of all principal corporate officers and of the person who is responsible for overseeing the dispensing of contact lenses in Kansas;

(c) complies with directions and appropriate requests for information from the regulating agency of each state where such licensee is licensed or registered;

(d) certifies that such licensee will respond directly and within a reasonable period of time, not to exceed 15 days, to all communications from the board concerning the dispensing of contact lenses in Kansas;

(e) maintains records of contact lenses and their corresponding valid, unexpired prescription dispensed in Kansas;

(f) agrees to cooperate with the board in providing information to the regulatory agency of any state where it is licensed or registered concerning matters related to the dispensing of contact lenses in Kansas;

(g) provides a toll-free telephone service for responding to questions and complaints from individuals in Kansas during the licensee's regular hours of operation and agrees to (a) include the toll-free number in literature provided with mailed contact lenses and (b) refer all questions relating to eye care for the lenses prescribed to the licensee licensed to practice medicine and surgery who determined the contact lens prescription;

(h) provides the following, or substantially equivalent, written notification to the patient whenever contact lenses are supplied:

WARNING: IF YOU ARE HAVING ANY OF THE FOLLOWING SYMPTOMS, REMOVE YOUR LENSES IMMEDIATELY AND CONSULT YOUR EYE CARE PRACTITIONER BEFORE WEARING YOUR LENSES AGAIN: UNEXPLAINED EYE DISCOMFORT, WATERING, VISION CHANGE OR REDNESS;

(i) fills contact lens prescriptions according to the strict directions of

if required.

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36 37 a licensee or person licensed to practice medicine and surgery in Kansas, without any deviation or substitution of lenses; and

(j) consents in writing to the personal and subject matter jurisdiction of the district courts and board of examiners in optometry for actions arising out of this act.

New Sec. 5. (a) The board of examiners in optometry may revoke the registration or license of any person dispensing contact lenses in Kansas under this act for failure to comply with the requirements set forth in sections 1 through section 4, and amendments thereto, and the Kansas optometry law pursuant to K.S.A. 65-1501 et seq., and amendments thereto.

- (b) Upon a finding of any violation of this act or any optometry law in Kansas, in lieu of or in addition to any other action, the board may assess a civil fine not in excess of \$10,000 against such person dispensing contact lenses under this act. The board shall remit all moneys received by it under this section to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of such remittance the state treasurer shall deposit the entire amount in the state treasury. The state treasurer shall then deposit into the optometry fee fund an amount from such deposits equal to the board's actual costs, including attorney fees, related to fine assessment and enforcement as certified by the president of the board. All expenditures from such funds shall be made in accordance with appropriation acts upon warrants of the director of accounts and reports issued pursuant to vouchers approved by the president of the board or by a person designated by the president.
- (c) If a person dispensing contact lenses is operating in violation of the patient's contact lens prescription release act or the Kansas optometry law or both, the board of examiners in optometry or the attorney general may commence an action to enjoin such person from further violations of the act or from mailing, shipping or otherwise dispensing contact lenses in Kansas.

New Sec. 6. The board of examiners in optometry shall administer and enforce the provisions of this act, and the board is hereby granted such specific powers as are necessary for the purpose of administering and enforcing such law, including adopting rules and regulations, which rules and regulations shall not be inconsistent with the provisions of this act.

Sec. 7. K.S.A. 65-1504b is hereby repealed.

Sec. 8. This act shall take effect and be in force from and after its publication in the statute book.

delivering



Michael P. Malone, O.D.

I am Dr. Mike Malone, a practicing optometrist in Topeka. Beginning the fall of 2000, the Kansas Optometric Association began a series of meetings with 1-800-CONTACTS that lasted until January 2001. We openly discussed their concerns and ours. The meetings were cordial and frank. Some issues we could agree upon and some we could not. We agreed that every successfully fit contact lens patient should have the right to his or her contact lens prescription. We agreed that patients should have the right to fill that prescription anywhere they can legally do so. We disagreed on whether contact lens mail order companies should be regulated and required to follow federal and state regulations. We also disagreed on whether a valid, complete, unexpired contact lens prescription should be required before a contact lens is sold. 1-800 indicated that waiting for a prescription before selling a contact lens hurt their business model and bottom line. Selling contact lenses without a prescription can endanger the ocular health of the contact lens wearing citizens of Kansas. These issues are why the Kansas Optometric Association asked the House Health and Human Services committee to introduce legislation requiring mandatory contact lens release and regulation of mail order contact lens companies as a solution to both issues.

For our patients to receive proper, safe vision care, contact lens prescription expiration dates must be honored so that the patient's eye health can be monitored and kept healthy. Contact lenses are not like spectacles. Contact lenses rest directly on the eye and have the potential to cause serious eye problems. The American Optometric Association Contact Lens Section recommends that "evaluation should occur during the initial weeks and months of CL wear to allow any necessary mechanical or optical refinements in lens prescription(s), to monitor adaptation and minimize ocular complications, and to reinforce appropriate CL care." "Established contact lens wearing patients should be seen on a six to twelve month basis to allow early detection of changes in the eye, which can lead to more serious problems." All of the Colleges and Schools of Optometry in the United States teach that annual examination of contact lens wearers is the standard of care.

Studies have shown that each year approximately 6% of contact lens wearers will develop complications, some of which are sight threatening. It should be noted that many of these problems could be avoided if the doctor is able to discern the early stages of these conditions and modify the patient's contact lens regimen. I quote from the package insert for a contact lens: "Serious eye injury, scarring of the cornea and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regimen including hand washing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules and follow-up visit schedules."

A clinical study on one of the more recent contact lenses to come on the market shows 9.4% of the eyes in the study had at least one adverse effect. This is a study with the patients being seen much more frequently than annually and probably much more likely to be following wearing and lens care instructions. With proper care and follow up contact lenses can be worn safely. The notion that contact lenses don't have the potential for harm is just not correct. Patients must get accurate, unexpired prescriptions to assure optimal vision, consistent with federal and state laws. Unfortunately, our patients are receiving contact lenses using expired, sometimes inaccurate prescriptions. 1-800 freely admits to selling contact lenses without a prescription and not honoring expiration dates. In fact, during our initial meetings, the only expiration date found on the contact lens data screens of their computers was for the consumer's credit card.

2144 S.W. 36TH ST. (36TH AND BURLINGAME RD.) TOPEKA, KANSAS 66611 TELEPHONE (785) 266-1010

Senate Public Hatth & Welfre Committel Notle: Murch 20, 2002 auachment 2 The KOA offered to support and work with 1-800 on developing a voluntary verification system for contact lens prescriptions using fax numbers. The telephone verification system 1-800 has in place is not acceptable. An automated system asks you to press "1" if you agree to release information or "2" if you do not agree to release information. I have letters from doctors complaining that when you press 1, the system does not recognize the tone and a recorded message says they are recording your response as not agreeing to release information.

The 1-800 fax verification system gives a printed copy of the request, patient information and doctor's response. Unfortunately, what we have found is that doctors are receiving faxes after hours, at night, and on weekends. When 1-800 doesn't receive a reply immediately they ship the contact lenses to the patient. We have examples of contact lenses being shipped to the patient before the fax for verification has been sent to the doctor. We have examples of contact lenses being shipped after the doctor responded in a timely manner that the prescription was incorrect or expired. 1-800's idea of a timely response is two hours. Would any member of the legislature feel it reasonable if they were required to respond to constituent's telephone calls, letters, and faxes in two hours? Would you find it reasonable if constituents could assume your answer was what they wanted it to be because you hadn't responded in two hours? Contact lens prescriptions are not emergency items. Patient's can order contact lenses at their leisure before they run out of lenses. No one is going to lose vision if they go a day without their contact lenses, but they might if they are given the incorrect lenses.

Optometry rules and regulations require Kansas doctors to release current contact lens prescriptions to patients on their request. Failure to do so is a violation of the optometry law and subjects the doctor to disciplinary action, including fines up to \$10,000. If your doctor is not releasing prescriptions report him or her to the State Board of Optometry. The State Board's job is to protect the public and enforce the Optometry Law. Almost every mailing 1-800 makes to consumers reminds them that the law requires doctors to release contact lens prescriptions. Their website even has a page where consumers can report doctors who don't release contact lens prescriptions. The State Board has received only one complaint of a doctor not releasing a prescription. The doctor's fax machine was only on during business hours. When the doctor became aware of the request the prescription was released. The lack of complaints evidences that the current regulation regarding releasing prescriptions to the patient on request works.

Optometrists are required to meet all federal and state regulations before they dispense contact lenses. Failure to do so can result in fines, loss of license, censure and loss of patients. Mail order contact lens companies should be required to meet federal and state regulations and face similar penalties for not complying. This bill uses the same approach the Legislature used with mail-order pharmacies that requires them to be registered under the Board of Pharmacy. The State Board of Optometry is the appropriate agency to do this. They are familiar with the issue. Their function is the same as all the health care boards, to protect the public's health and welfare. 1-800 and other mail order companies have demonstrated a disregard for state and federal law. The need for registration and oversight is apparent.

Thank you for supporting Substitute for House Bill 2285.

643 Nieman Road Shawnee, Kansas 66203 913-631-6959

Dr. Clifford L. Holt

Optometrist

FAMILY VISION CARE
CONTACT LENS

January 28, 2002

Dear 1-800-Contacts:

We just received a request for verification of a contact lens prescription. Your automated system asks us to hit "1" if we agree to release information or "2" if we do not release information. We repeatedly hit "1" but your automated phone system would not recognize it. Finally a message came on stating that you are putting us down as not agreeing to verify information which we would have, had your phone system given us the opportunity to do so.

For a company that purports to be "cutting edge" it seems odd that you employ a telephone verification system that does not work. I have had office staff call your company three times over three incidents in the last two weeks.

I believe it would be best for your company to verify all prescriptions with our office by fax. Our fax number is 913-631-5930.

Please call our office at 913-631-6959 to ensure that this received. The most appropriate people to talk to would be Mark, Julie, Stacy, or Dr. Holt. I look forward to hearing from you.

Sincerely,

Clifford I. Nolt, O.D.



James A. Whiitaker, O.D. P.O. Box 228 • 1000 Main Sabetha, Kansas 66534

Telephone: (785) 284-2139

August 23, 2001

Gary Robbins, Executive Director Kansas Optometric Office 1266 SW Topeka Blvd. Topeka, Kansas 66612

Dear Mr. Robbins,

This office was contacted by telephone on Wednesday, August 22 by the 1-800 Contact lens company. The call was a recorded message and ask specifically if this office released contact lens prescriptions. To respond yes, they asked that you push the number one button on your touch tone phone, to respond no, do nothing. The question was asked twice, and both times this office responded by pressing the 1 which was to confirm that we did release prescriptions, but the recording indicated we did not respond to the question and recorded this office as an office that does not release contact information.

Diana Bauman, our optometric assistant, called back on the 800 number and talked to a Lisa and explained what had happened. Lisa was not very interested in the situation, indicating it seemed to happen with regularity, but would try to set the record straight.

Sincerely,

James A. Whittaker, O.D.

WENTZ EYECARE



MONTE S. WENTZ, O.D. 117 E. 6th St. Concordía, KS 66901

(785) 243-3937 (EYES)

Attention Gary

Re: Contact Lens phone calls

Dear Gary,

I wanted to let you know about some phone calls I received regarding contact lens prescriptions. On Sunday Aug 19th I received three computer-generated messages on my answering machine that stated the following; "Not have a policy of releasing prescriptions if you do not press 1 now."

1207	ADE
121	100

"We have noted that your office does not release prescriptions, Thank you"

This message was repeated on my answering machine at 11:37 am, 1:38 pm, and 4:18 pm Sunday Aug 19th.

Since my phone from Salina Forwards to the Concordia office when it is closed, I do not know which number they called.

Let me know if you have any questions.

Sincerely,

F= M. William + Grand

Monte S Wentz O.D.

OPTOMETRIST

9390 E. Central, #101 Wichita, KS 67206-2555 (316) 636-2080 Fax (316) 636-2965

January 4, 2002

Gary Robbins, CAE Kansas Optometric Association 1266 SW Topeka Blvd Topeka, KS 66612

RE: 1-800-Contacts, Inc.

Dear Gary:

Please find enclosed a request for Rx verification, which my office received last summer. Unfortunately I cannot document the date, as 1-800-Contacts correspondence is not dated. In this case we responded, as you will see, unable to identify the patient by the name given. As it turns out, Michelle has been my patient but my records did not reflect her relatively new married name. Michelle returned to my office today to purchase replacement contacts. On questioning by my staff, she reports that in spite of my inability to verify the Rx the contacts were mailed to her by 1-800-Contacts upon request. She is very dissatisfied with the service and feels like the lenses have not demonstrated normal durability. I cannot, of course, explain the lack of durability because I have not inspected the lenses she was provided by 1-800-Contacts. My primary concern in this case is the fact that the Rx was filled without verification by the doctor.

I hope this helps you in resolving the ongoing difficulty with the tactics of this company.

Sincerely,

David L. Waldie, O.D.

DLW:Ic

Enclosure

37 2007 2001 11:33 3107230032 MARKY MODINE 35

MARK D. MOORE, O.D.

FAMILY VISION CARE

42'S E. 61st NORTH 1A WICHITA, KS 67219 Telephone (316) 744-2422

FAX 316-729-0052

2020 N. TYLER RD. WICHITA KS. 67212 Telephone (316) 729-0083

Jerry Conder, J.D.
Office of the General Cousel
1-800 Contacts

fx 12

1-800665-1088

RE Dispensing of Contact Lenses Prior to Validation/Verification of Current Prescription

Mr. Conder,

I am formally requesting a re-call of contact lenses which were sold, shipped and/or received by patients without validation of unexpired prescription for such contact lenses. Both of the following patients had either received their contact lenses or the lenses had already been shipped by your company PRIOR to my office receiveing any request for verification of prescription and expiration dates of any previous contact lens prescriptions.

Patient #1

Cary

Contact Lens Prescription Expired 12-23-2000
Attempted Verification by 1-800Contacts 8-28-2001

I contacted patient 8-28-2001 to let her know that her prescription was expired, and she needed new examination prior to release of current contact prescription to 1-800Contacts. Patient informed me that she had received her contact lenses "at least one week ago"

Patient #2

Jeanna.

Contact Lens Prescription Expired 10-1-1999
Attempted Verification by 1-800Contacts 09-04-2001

I contacted 1-800Contacts 09-04-2001 and was informed by your customer service department representative (Tamara) that the contact lenses were shipped 08-27-2001. This prescription has been expired for 23 months.

I also request fax verification of receipt of this letter and proof of recall of these contact lens orders.

Should you have any questions please contact my office.

Sincerely,

Mark Moore, O.D.

Kansas State Board of Examiners in Optometry

(Aret Blood

Mark Moore, O.D. Family Vision Care Kansas License # 1367

425 East 61st North 1A Wichita, Ks 67219 316-744-2422 ph 316-744-2455 fx

2020 North Tyler Rd #124 Wichita, Ks 67212 316-729-0083 ph 316-729-0052 fx

Date: 09/04/2001			T :	•
To: 1-800 CONTACTS Ph: 1-800-266-8228 Fx: 1-888-426-2584 1-801-924-9900	RE QUITO	Jeanna		
Having been authorized by 7/4/6 Avrour office releases to	maked phone call	patient (parerthe follow	n/guardian), by written release ing information:	•33
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Mark Moore, O.D. Family Vision Care Kansas License # 1367

425 East 61st North 1A Wichita, Ks 67219 316-744-2422 ph 316-744-2455 fx

2020 North Tyler Rd #124 Wichita, Ks 67212 316-729-0083 ph 316-729-0052 fx

Date: 8/28/2001	
To: 1800 CONTACTS Ph: 1-800 26 6 8278	RE: CAMY
Ph: 1-800 26 6 8228 Fx: 1-800 -645 - 1088 1-801 - 924 - 9900	
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BCDiam	Dlam Dlam
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# Re-fills authorized	
Instructions	
Expires 12/23/2000 authorized.	and may <u>not</u> be filled (or re-filled) after this date &/or beyond the #lenses/boxes
Mark Moore, O.D.	
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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.

PAT	IENT: Kristina			-	
	Item Frequency 55-6pk Frequency 55-6pk	Power -2.00	8.70 14.20	Cyl 0.00 0.00	Ax15 0.00 0.00
	May not substitute 2/25/03		Dr. P. V. YOU License 93/- Phone: 620.66	N9 2 3.54	- 78-
	•		Signature HOL	eg Oi	Q.
	Prescription information is correct. New prescription attached hereto by fax. Prescription has expired. Date of last exam	n was	0		
	Other (specify)	I Was	*	·	

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.

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.

BX0010242288N04537341Y1906120EX

2-10

ARRIVER BETWEEN 9:00 APR 10:00 A.M. SUNDAY 2/24/02 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:	John			· · · · · · · · · · · · · · · · · · ·		
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Our agents are not equipped to handle your inquiries. We will only respond to

BX0010080902Nd4597702Y1757727EX

written requests faxed to 1-888-476-2584.

HERNDON & BETTIS, P.A.

1202 WEST MAPLE WICHITA, KANSAS 67213 PHONE 262-3716 FAX 262-0784



711 NORTH MAIN GODDARD, KANSAS 67052 PHONE 794-2228

Senate Public Health and Welfare Committee Testimony Sub. HB2285 Charles W. Kissling, O.D.

Thank you for this opportunity to speak to you today. I am Chuck Kissling, I have practiced Optometry in Wichita for 17 years. I rise to speak in favor of Sub. HB2285.

The Food and Drug Administration has determined that contact lenses pose a sufficient eye health risk to the consumer 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. In fact, the FDA requires the contact lens manufacturer to label every contact lens so as to signify that it is a prescription item. A Typically, this is a statement such as "Caution! Federal law prohibits dispensing without prescription". The Federal Government leaves enforcement of the prescription requirement to the States. Present Kansas law (KSA 65-1504b) states "it is unlawful for any person to dispense an ophthalmic lens or lenses without first having obtained a prescription".

The S.E.C. filing from 1-800-Contacts, dated November 13. 2001, reveals that they have been taken to court by the states of Kansas and Texas.^B Both times for selling contact lenses without a prescription. Both cases are nearly three years old and still in court and unresolved. The same S.E.C. filing tells us that it is their general practice to ship contact lenses even when a prescription has not been received or verified.^{B1} The Company also freely admits that a significant portion of its' sales may not comply with State Laws.^{B2}

This Bill seeks to place contact lens retailers under regulatory authority of the State Board of Examiners in Optometry. While 1-800-Contacts may claim that they should not be regulated, their S.E.C. filing admits they are regulated in some states. They also observe that "As a result of state regulatory requirements, the Company's liquidity ... may be negatively impacted in the future if the Company ... is prohibited from selling its products in a particular state(s)... due to the enforcement of requirements by state regulatory agencies." B3 They are telling investors that if states enforce the laws, their income will suffer. I suggest that if they simply obeyed the laws, their income would be fine.

Let me provide examples of a retailer selling contact lenses without a prescription. New York Times columnist Gretchen Morgenson, writing in a January 6, 2002 column related her experience, successfully purchasing contact lenses from 1-800 Contacts without a prescription.^C

Another example, this time a personal example. Last Fall, I ordered contact lenses for myself, from 1-800-Contacts. I provided the name of one of my partners as the doctor, and his phone number as requested. Two days later I received the lenses in the mail. My partner was never contacted to verify the existence of a contact lens prescription for me. About six weeks later, I received an e-mail from the retailer offering

Senate Public Hulth + Welfare Connittee March 20, 2002 Attachment 3

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to sell me more contact lenses if I needed them. Last month, on February 5 at 3:13PM, I ordered more contact lenses. My doctor received a fax five minutes later which requested verification of my prescription. The fax was returned at 5:07PM, less than two hours later, stating that no contact lens prescription existed for me. P At 7:05PM, my e-mail server received e-mail confirmation that my contact lenses had been shipped. I received them two days later. To summarize, two hours after receiving a prescription denial from my doctor, 1-800-Contacts sent confirmation that my contact lenses had been shipped.

You will likely hear that doctors are uncooperative and fail to respond, or do not respond in a timely fashion, to prescription verification requests. I was able to review 43 Requests for Prescription Verification which have been received in my office in the past few months, all from 1-800-Contacts. We responded to all of the 43 requests. In 34 of those requests, I was able to determine both the time we received the request, and the time we responded . 44% of these requests were received after hours (evenings, nights, or weekends). When the request was received during office hours, we had a median response time of 32 minutes. When looking at our responses, 42% were affirmative responses of valid and current prescriptions, 42% were negative responses due to expired prescriptions, and 16% were corrective responses due to inaccurate prescription information supplied by 1-800-Contacts. If the corrective responses were ignored in the same manner as my doctor's prescription denial, then 16% of my patients receiving their contact lenses from 1-800-Contacts are wearing the wrong contact lenses. I ask you, how will any amendment, addressing doctor's response to verification attempts, help the patients of Kansas when those responses are ignored even when prompt?

Current Rules and Regulations established by the Kansas State Board of Examiners in Optometry require doctors to provide a contact lens prescription upon request when such prescription exists and is current. The same Rule prevents the prescription from expiring in less than one year without medical reason. The proposed legislation before you brings this existing Rules and Regulations language into Optometry Law and provides appropriate enforcement provisions for violations.

The opponents of this Bill have publicly charged that doctors lower their contact lens price when a patient asks for the prescription. We can all agree, I'm sure, that to do so is clearly unethical. I can promise you that I have never done that, nor do I have need to. My price for the most popular contact lens in the USA (Acuvue) is \$22.50 per box, while 1-800-Contacts price as confirmed yesterday is \$22.95. My price is already lower than theirs.

The one year expiration period is a minimum. It is not a mandated one year expiration period. Nothing in the Rule prevents the expiration period from being longer when appropriate. The Standard of Care is generally one year exams for contact lens wearers, and in fact the American Optometric Association Practice Guidelines for contact lens wearers state that follow-up visits should be every six to twelve months. If you legislate a mandated contact lens prescription expiration of two years, you will remove professional judgment from the process. Are you then prepared to tell me what the minimum expiration period should be for the glaucoma medicine I prescribe? After

all, the contact lens wearer and the glaucoma patient both have the same thing at risk......Their eyesight.

As you can tell, I believe very strongly in what I speak of. I believe that the FDA had just cause to regard contact lenses as a potential threat to ocular health. I believe that a contact lens prescription should be treated just as importantly as a prescription for glaucoma medicine or a prescription for narcotic pain killers. I believe that the doctor should ultimately decide the appropriate expiration period, using his or her professional judgment and intimate knowledge of the ocular status of the individual patient. I believe that those people who fill contact lens prescriptions should be regulated in the same manner as those who fill medicine prescriptions. That is what Sub. HB 2285 does. It was modeled after existing pharmacy law designed to deal with mail order and internet pharmacies. It simply helps to enforce current law by establishing regulatory authority in Kansas.

Please, as you consider this Bill, do so with the ocular health of your fellow Kansas citizens in mind. Thank you.

Examples of Contact Lens Packaging





VISTAKON, a division of Johnson & Johnson Vision Products, inc. P.O. Box 10157, Jacksonville, FL 32247-0157.
Contents: Six sterile lenses immersad in buffered staffine softwickod, 42% polymer (etaflicon A), 58% water.
Caution: Federal law prohibits dispensing without prescription.

Pleasa recycle.

Made in USA

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Reference

FORM 10-Q

(Mark one)
[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 29, 2001

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to ____

Commission file number: 0-23633

1-800 CONTACTS, INC. (Exact name of registrant as specified in its charter)

Delaware 87-0571643

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

66 E. Wadsworth Park Drive, 3/rd/ Floor

Draper, UT

84020

(Address of principal executive offices)

(Zip Code)

(801) 924-9800

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

[X] Yes No [_]

As of November 6, 2001, the Registrant had 11,574,269 shares of Common Stock, par value \$0.01 per share outstanding.

1-800 CONTACTS, INC.

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intan assets beginning in the first quarter of fit 002. Also during fiscal 2, the Company will perform the first of the red impairment tests of goodwill and indefinite lived intangible assets, to the extent applicable. The Company has not yet determined what the effect of these Statements will be on the Company's results of operations and financial position.

NOTE 8. SOURCES OF SUPPLY

On May 22, 2001, the Middle District Court in Jacksonville, Florida announced a preliminary settlement with Johnson & Johnson with respect to the multi-district litigation brought by the attorneys general of 32 states on behalf of a nationwide class of consumers. The court finalized the settlement agreement on November 1, 2001. The agreement will be effective on December 1, 2001 provided there are no appeals to the settlement agreement. Johnson & Johnson's current interpretation of the settlement agreement, and its subsequent actions, have made products produced by its eye care division, Vistakon, more difficult for the Company to obtain. This restricted supply and the resulting wholesale price increases have reduced the Company's expectations for its short-term net sales and gross profit. During the third quarter of fiscal 2001, gross profit was impacted by the increase in wholesale prices paid for Vistakon products. At the beginning of the third quarter of fiscal 2001, the Company had approximately a three to four month supply of Vistakon lenses; therefore, the impact of the increase in wholesale prices was less significant in the third quarter. Gross profit in the fourth quarter of fiscal 2001 will be more significantly impacted by this increase in wholesale prices. The Company's wholesale prices on Vistakon products have continued to increase substantially and Vistakon products account for more than 40% of the Company's net sales. If supply of Vistakon products remains limited and wholesale prices remain higher than expected, gross profit will continue to be impacted significantly in future quarters.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

The Company is a leading direct marketer of replacement contact lenses. The Company was formed in February 1995 and is the successor to the mail order business founded by the Company's Vice President of Sales in March 1991. Since its formation, the Company's net sales have grown rapidly, from \$3.6 million in fiscal 1996 to \$145.0 million in fiscal 2000 and from \$107.9 million in the first three quarters of fiscal 2000 to \$131.4 million in the first three quarters of fiscal 2001. Internet sales have grown from an insignificant amount in fiscal 1996 to approximately \$53.8 million in fiscal 2000 and from \$38.1 million in the first three quarters of fiscal 2001.

The Company's fiscal year consists of a 52/53 week period ending on the Saturday nearest to December 31.

The Company expenses all advertising costs when the advertising first takes place. As a result, quarter-to-quarter comparisons are impacted within and between quarters by the timing of television, radio and Internet advertisements and by the mailing of the Company's printed advertisements. The volume of mailings and other advertising may vary in different quarters and from year to year depending on the Company's assessment of prevailing market opportunities.

The sale and delivery of contact lenses are governed by both federal and state laws and regulations. The Company sells to customers in all 50 states, and each sale is likely to be subject to the laws of the state where the customer is located. In some states, the Company operates according to agreements it has entered into with local regulatory authorities or medical boards or agencies. The Company's general operating practice is to attempt to obtain a valid prescription from each of its customers or his/her eye care practitioner. If the customer does not have a copy of his/her prescription but does have the prescription information obtained directly from the customer's eye care practitioner, the Company attempts to contact the customer's eye care practitioner to obtain a copy of or verify the customer's prescription. If 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 based on the prescription information provided by the customer. The Company retains copies of the written prescriptions that it receives and maintains records of its communications with the customer's prescriber.

On May 22, 2001, the Middle District Court in Jacksonville, Florida announced a preliminary settlement with Johnson & Johnson with respect to the

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Finan (counting Standards No. 141, "Business Combons," and No. 142, "Good and Other Intangible Assets," effective for interpretable assets deemed to have indefinite lives will no longer be amortized but will be subject to annual impairment tests in accordance with the Statements. Other intangible assets will continue to be amortized over their useful lives.

The Company will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of fiscal 2002. Also during fiscal 2002, the Company will perform the first of the required impairment tests of goodwill and indefinite lived intangible assets, to the extent applicable. The Company has not yet determined what the effect of these Statements will be on the Company's results of operations and financial position.

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Forward-Looking Statements

Except for the historical information contained herein, the matters discussed in this Form 10-Q are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements involve risks and uncertainties and often depend on assumptions, data or methods that may be incorrect or imprecise. The Company's future operating results may differ materially from the results discussed in, or implied by, forward-looking statements made by the Company. Factors that may cause such differences include, but are not limited to, those discussed below and the other risks detailed in the Company's other reports filed with the Securities and Exchange Commission. The words such as "believes," "anticipates," "expects," "future," "intends," "would," "may" and similar expressions are intended to identify forward-looking statements. The Company undertakes no obligation to revise any of these forward-looking statements to reflect events or circumstances after the date hereof.

Factors That May Affect Future Results

- The Company's sales growth will not continue at historical rates and it may encounter unforeseen difficulties in managing its future growth;
- 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;
- Because the Company doesn't manufacture contact lenses, it cannot ensure that the contact lenses it sells meet all federal regulatory requirements;
- . It is possible that the FDA will consider certain of the contact lenses the Company sells to be misbranded;
- The Company currently purchases a substantial portion of its products from unauthorized distributors and is not an authorized distributor for some of the products that it sells;
- The Company obtains a large percentage of its inventory from a limited number of suppliers, with a single distributor accounting for 47%, 38% and 35% of the Company's inventory purchases in fiscal 1998, 1999 and 2000, respectively;
- The Company's quarterly results are likely to vary based upon the level of sales and marketing activity in any particular quarter;
- The Company is dependent on its telephone, Internet and management information systems for the sale and distribution of contact lenses;
- The Company has limited operating history and, as a result, there is only limited financial information and operating information available for a potential investor to evaluate the Company;
- The retail sale of contact lenses is highly competitive; certain of the Company's competitors are large, national optical chains that have greater resources than the Company has;
- The demand for contact lenses could be substantially reduced if alternative technologies to permanently correct vision gain in popularity;

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intar assets for approximately \$0.7 million durin fiscal 2001 period. Durin ch 2000, the Company made a \$220,000 investme in the stock of an entity in which a member of the Company's Board of Directors holds a significant ownership interest and serves as an officer and director. The Company anticipates additional capital expenditures for infrastructure as it continues to expand and improve operating facilities, telecommunications systems and management information systems in order to handle current and future growth. The Company presently anticipates that capital expenditures in fiscal 2001 will be approximately \$1.6 million.

As of September 29, 2001, the Company had certain noncancelable commitments to purchase approximately \$1.3 million of broadcast advertising through December 2001. In addition, the Company has entered into certain noncancelable commitments with various advertising companies that will require the Company to pay approximately \$5.8 million from January 1, 2001 through December 31, 2001.

During the three quarters ended September 29, 2001 and September 30, 2000, the Company used approximately \$3.6 million and \$14.3 million for financing activities, respectively. During the fiscal 2001 period, the Company had net repayments on its credit facility of approximately \$3.3 million and repurchased 22,500 shares

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of its common stock for a total cost of approximately \$438,000. During the fiscal 2000 period, the Company had net borrowings on its credit facility of approximately \$2.5 million and repurchased a total of 1,084,000 shares of its common stock for a total cost of approximately \$16.8 million. In both the fiscal 2001 and 2000 periods, these amounts were offset slightly by proceeds from the exercise of common stock options. In the fiscal 2000 period, the Company also made its final payment of \$300,000 relating to the 1999 purchase of the assets of Contact Lenses Online, Inc.

On April 20, 2001, the Company's Board of Directors authorized an additional repurchase of up to 1,000,000 shares of its common stock, bringing the total authorization to 3,000,000 shares. A purchase of the full 3,000,000 shares would equal approximately 23.3 percent of the total shares issued. The repurchase of common stock is subject to market conditions and is accomplished through periodic purchases at prevailing prices on the open market, by block purchases or in privately negotiated transactions. The repurchased shares will be retained as treasury stock to be used for corporate purposes. Through September 29, 2001, the Company had repurchased 1,506,500 shares for a total cost of approximately \$19.9 million.

The Company has a revolving credit facility to provide for working capital requirements and other corporate purposes. The credit facility provides for borrowings equal to the lesser of \$20.0 million or 50 percent of eligible inventory and bears interest at a floating rate equal to the lender's prime interest rate minus 0.25 percent (5.75 percent as of September 29, 2001). As of September 29, 2001, the Company had no outstanding borrowings on the credit facility. The credit facility is secured by substantially all of the Company's assets and contains financial covenants customary for this type of financing. The credit facility expires April 30, 2003.

The Company believes that its cash on hand, together with cash generated from operations and the cash available through the credit facility, will be sufficient to support current operations and future growth through the next year. The Company may be required to seek additional sources of funds for accelerated growth or continued growth after that point, and there can be no assurance that such funds will be available on satisfactory terms. Failure to obtain such financing could delay or prevent the Company's planned growth, which could adversely affect the Company's business, financial condition and results of operations.

See "Overview" for a discussion regarding the multi-district litigation's potential impact on the Company's results of operations.

As a result of state regulatory requirements, the Company's liquidity, capital resources and results of operations may be negatively impacted in the future if the Company incurs increased costs or fines, is prohibited from selling its products in a particular state(s) or experiences losses of a portion of the Company's customers for whom the Company is unable to obtain or verify a prescription due to the enforcement of requirements by state regulatory agencies,

Recently Issued Accounting Standards

In June 2001, the Financial Accounting Standards Board issued Statement of

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Money&Business

Section 🚭

Cloudy Outlook For a Seller Of Contacts

O 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.

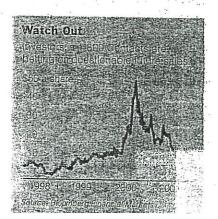
Looks can be deceiving, however, even in shares of a company that sells vision correction.

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-



MARKET WATCH
GRETCHEN MORGENSON

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 runins 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 Ienses, 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.

Reference

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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 Reference 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.

	PATI	IENT: Kissling, Chuck				
	0.D.: 0.S.:	Item Acuvue 2 6pk	Power -2.00 0.00	B.C. Dia. 8.70 14.00 0.00 0.00	Cyl 0.00 0.00	Ax1s 0.00 0.00
	* *	May not substitute Refillable through		Dr. 19 License Phone:		
				Signature		
		Prescription information is correct.		× 10		
		New prescription attached hereto by fax.	-			
		Prescription has expired. Date of last exam	was	Majorest N. ◆		
Į	A	Other (specify) No prescription for con-	acts	exists		

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.

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

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Reference E

65-8-5 Contact lens prescriptions and their release.

(a) A licensee shall provide the contact lens prescription to the patient upon the patient's request if the contact lens adaptation period has been completed, a contact lens prescription has been determined, all associated fees have been paid and if at the time of the request, the determined prescription is still valid and unexpired.

(b) A licensee shall not limit, by expiration date or otherwise, a contact lens prescription to a period of less than twelve months from the date the prescription is first determined or the last date of contact lens evaluation by the licensee unless the licensee records a health related reason therefore in the patient's records.

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TESTIMONY - SUBSTITUTE FOR H.B. 2285

Madam Chair, members of the committee, thank you for allowing me to be here today to testify in support of Substitute for 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 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. Most needed medications; some needed a complete refit or to give up their lenses. Two of these patients ultimately required referral to a corneal specialists for extended care.

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American Optometric Association

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nute Public Health Welfore Committee 8900 Dide March 20,2002 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, allowing the irresponsible filling of contact lens prescriptions to continue will only help to drive up the cost of health care.

Of equal concern when patients get complacent about proper care is how well they see. 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.

In the original HB 2285, there was a requirement for a minimum two-year expiration date on all contact lens prescriptions. The expiration date should not be an arbitrary number. It should instead be based on the clinical interpretation of the patient's current ocular health. It is during periodic eye health evaluations that the doctor looks for the early signs of hypoxia or corneal insult that we know will lead to more severe problems if left unattended. This is the proper time to make adjustments in the fit of the lens that will allow the patient to avoid potential injury as well as more costly corrective measures later on.

The universally accepted standard of care to which I must adhere in clinical practice is the same for optometry and ophthalmology, one year. These norms of clinical practice are reflected in the professional literature, in current teaching programs, textbooks and in the literature of the contact lens manufacturers. They indicate, as referenced in *Malpractice for Contact Lenses* by H.M. Rosenwasser, that the appropriate time span for this is generally six months to one year for healthy patients. For those with compromised general or ocular health it can be shorter. For patients who have a demonstrated history of healthy lens wear or who wear lenses part time, it may be longer. Rather than request release of liability as was included in the original bill, the more responsible approach is to allow the doctor to make the decision based on the current standard of care and the type of lens being fit.

Given the potential for harm to the patient, how can it be inappropriate to require the seller of any prescription medical device to possess a valid prescription as determined by a doctor prior to the sale.

I would strongly encourage you to support Substitute for House Bill 2285.

Thank you.



Kansas State Ophthalmological Society

700 SW Jackson, Suite 208

Topeka, KS 66603-3757

Mailing Address: P.O. Box 4103 Topeka, KS 66604-8103

Bill Clifford, MD

President

Michael Reynolds, MD Vice President

Dasa Gangadhar, MD Secretary

Gary Weiner, MD Treasurer

Jemshed A. Khan, MD AAO Councillor and Imm. Past President Testimony to Senate Public Heath and Welfare Committee

Public Heath and Welfare Committee
PH: (785) 234-9719
FX: (785) 234-9718
KSOS@amycampbell.com

by Amy Campbell Executive Director Kansas State Ophthalmological Society

Thank you for permitting me to speak today on behalf of the Kansas State Ophthalmological Society. Our president, William Clifford, MD, of Garden City, was not able to be here today, but has respectfully submitted a letter addressing Substitute for HB 2285.

KSOS supports Substitute for HB 2285 as a method to clearly require release of contact lens prescriptions, while also regulating the proper sale of contacts in Kansas.

Ophthalmologists are licensed to practice medicine and surgery by the Kansas Board of Healing Arts. Some prescribe and dispense contact lens, but the primary responsibility of the physician is to the patient's eye care and health. Our members take this responsibility very seriously.

Although there is no law currently in place to require ophthalmologists to release prescriptions for contact lenses, it has long been the recommended practice of the Kansas State Ophthalmological Society and the American Academy of Ophthalmology. That is why our members did not hesitate to accept the requirements of this legislation.

We would respectfully request an amendment to the bill, specifically referring the regulation of ophthalmologists back to the Board of Healing Arts. It is not the intention of this legislation to put regulatory authority over physicians licensed to practice medicine and surgery in the hands of the State Board of Examiners in Optometry.

In regard to the registration of mail order contact lens providers, it did not seem a necessary measure until it became apparent that specific companies are establishing commercial practices which blatantly and intentionally disregard the laws of the State pertaining to dispensing.

We support the release of prescriptions to the patient. However, it is important to recognize that this responsibility does not automatically transfer to a third party. Physicians have been clearly warned by the federal government, through the establishment of HIPPA, that patient information is not to be released without the patient's written authorization. As the requirements of HIPPA become more clear, prescription release to third parties may become more restricted than we have formerly practiced. This is particularly true when the third party dispenser has set up a commercial plan which places an emphasis on avoiding written documentation and puts a burden on the health care provider to have someone available at all times to answer telephone prescription confirmations.

I and the members of the 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. Thank you.

Servite Public Health & Welfare Committee Wale Murch 20, 2002 Ottachment 5



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kmsonline.org

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TO:

Senate Public Health & Welfare Committee

FROM:

Chris Collins ////

Director of Government Affairs

DATE:

March 20, 2002

RE:

Substitute for HB 2285: Amending and Supplementing the Optometry Law

Ladies and Gentlemen of the Committee:

Thank you for the opportunity to present written testimony to you today in support of Substitute for HB 2285.

It is important to note from the outset that the members of the Kansas Medical Society have no economic interest in the issue before you today for consideration. Our ophthalmologist members do not sell contact lenses. However, HB 2285 addresses some very important health issues.

You have doubtless heard testimony today from health care professionals regarding the fragile nature of the human eye and the ease with which it can be damaged by ill-fitting contact lenses. The bill before you today for consideration would allow the Board of Examiners in Optometry some measure of oversight and control of out of state contact lens sellers. This is an important bill because it allows the Board to protect Kansas patients from otherwise inadequately regulated companies that could be free to disregard the obligation to honor the specifications of a prescription. Anecdotal evidence is emerging within the optometric and ophthalmological communities of patient harm caused by mail-order or internet lenses sold in disregard for the brand and fitting specifications or in disregard for the expiration date of a contact lens prescription. This bill represents a logical extension of the same philosophy that requires registration of out of state pharmacies with the Kansas Board of Pharmacy. Both companies sell products requiring a prescription and which carry a great potential for harm if dispensed improperly. For these reasons, the Kansas Medical Society respectfully urges the passage of this bill, which would allow the Kansas Board of Examiners in Optometry to protect the ocular health of Kansans.

Thank you for the opportunity to submit written testimony in support of HB 2285.

Sonite Rublic Hutth & Wolfer Committee Note: March 20, 2002 Attachment 6



Kansas State Ophthalmological Society

Mailing Address: P.O. Box 4103 Topeka, KS 66604-8103

March 18, 2002

700 SW Jackson, Suite 208 Topeka, KS 66603-3757 PH: (785) 234-9719 FX: (785) 234-9718 KSOS@amycampbell.com

Bill Clifford, MD President

Michael Reynolds, MD Vice President

Dasa Gangadhar, MD Secretary

Gary Weiner, MD Treasurer

Jemshed A. Khan, MD AAO Councillor and Imm. Past President The Honorable Susan Wagle Senate Public Health and Welfare Committee State Capitol, Room 128-S Topeka, KS 66612

Re: Substitute for House Bill 2285

Dear Senator Wagle:

I am writing in my capacity as the President of the Kansas State Ophthalmological Society to express our support for the Substitute for HB 2285. As Kansas physicians concerned with eye care, we take great interest in legislation which may impact our patients' vision and health.

As you know, ophthalmologists prescribe contact lenses and treat the serious complications which these medical devices can create. In our practices, we encounter eye damage from contact over wear and sight threatening bacterial corneal ulcers. We know that safe use of contacts requires a close doctor-patient relationship to insure the quality of our patients' eye care. We feel that the legislation's requirement for release of contact lens prescriptions with twelve month expiration periods is safe and in the best interest of our patients. We would discourage amending the bill with a longer period of time. Although a physician can easily waive an exam for a patient who is doing well, there is no way to go back in time to correct degeneration which may have occurred due to misuse or faulty lenses.

We are particularly concerned with formerly suggested language which would interrupt the doctor-patient relationship and discourage periodic interaction between physicians and contact lens users. Complications may go undetected by contact lens wearers for surprising lengths of time.

I appreciate your interest and would be happy to answer any questions you or other members of your committee might have on this issue.

Sincerely,

William S. Clifford, MD President