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Date 3 / 29 / 07

ATTN: Patrick Eddington, AAO

Fax #: 202 737 7061

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From: R. PANTON, MD

Notes:

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March 28, 2004
 Re: HR 3140
 (Contact Lens Rule, Project #R411002)

Michael D. Maves, MD
 Executive Vice President, CEO
 American Medical Association
 515 N. State Street
 Chicago, IL 60610
 FAX: 312-464-4184

Dear Dr. Maves:

I wish to thank you for your interest in passive (or default) prescription of contact lenses. You were kind enough to respond to my October 26, 2003 letter describing the proposed legislation. By the time I wrote again in December, HR 3140 had been adopted. I also appreciate your attendance at the March 9, 2004 Council Meeting of the Chicago Medical Society, which unanimously passed a resolution calling for positive verification of all prescriptions. At the meeting, we reviewed the inherent difficulties in passive (or default) prescriptions.

1. Default prescriptions promote errors.

At the end of 2002, the largest mail order company, 1-800 CONTACTS, reached an agreement with Vistakon (a division of Johnson and Johnson), the largest producer of disposable contact lenses. 1-800 CONTACTS agreed to verify the physician's prescription prior to dispensing Vistakon lenses. The obvious concern was that 1-800 CONTACTS would make no effort to verify the prescriptions of the other brands.

For the one-year period starting January 29, 2003, our office has received 110 Prescription Verification Requests from 1-800 CONTACTS. We classified the requests:

1) Accurate, and prescription verified	42/110 (38.2%)
2) Inaccurate, revised, then contacts dispensed	7/110 (6.4%)
3) Expired prescriptions	55/110 (50.0%)
4) Not our patients	5/110 (4.5%)
5) Contact lenses contraindicated	1/110 (0.9%)

If 1-800 CONTACTS had filled these 110 prescriptions through passive verification, over 61% of the prescriptions would have been filled inaccurately.

Incredibly during the time that we received 110 Prescription Verification Requests from 1-800 CONTACTS for Vistakon lenses, we received no verification requests for all other lens companies combined. The obvious conclusion is that 1-800 CONTACTS used the controversial practice of passive prescription verification for Vistakon lenses and performed no verification whatsoever for all other lenses.

2. Oral verification systems are inherently flawed. The difficulties with oral verification processes are well documented in a multi-center study (Enclosure A). Our own experience is the same. We have had automated phone calls to "verify" prescriptions for patients who are identified only by their patient number. Attempts to stop the verification process were cut off. Essentially, our office has "verified" a prescription

without knowing either the name of the patient or the prescription to be verified. I even followed up in writing to get the name of a patient, and 1-800 CONTACTS has not responded (Enclosure B).

3. The AMA should recommend continued monitoring of passive prescriptions. The huge risk of passive prescriptions is that incorrect prescriptions are dispensed, and the physician is not even informed. Even as a physician who closely tracks his patients, I know that the 110 Prescription Verification Requests constitute only a small percentage of the contact lenses being dispensed under my name. Specifically, I do not know who many oral prescriptions were supposedly "verified" by our office.

Given that passive prescription is a new phenomenon and there is a very significant health issue involved, the safety of this process should be monitored (HR 3140, Section 10, Study and Report). Specifically, the mail order contact lens company should send to physicians on a monthly (or bimonthly) basis a list of the prescriptions actually filled so the physician can verify the accuracy of these passive prescriptions. Frankly, this process will waken physicians as to how many prescriptions are being filled in their name without their knowledge. Of note, when I requested similar information from 1-800 CONTACTS (Enclosure B), they did not respond.

4. The entire concept of passive (or default) prescription is simply unprecedented in the field of medicine. Prescriptions for pharmaceuticals and all other medical devices need to be positively verified. It is difficult to understand why the entire definition of a "prescription" is being undermined in the field of mail order contact lenses, which may already have the worst track record of compliance to existing laws.

HR 3140 passed the Congress and was signed by the President on December 6, 2003. In a desire to improve access to contact lens prescriptions, a dangerous precedent of default prescription has become law. The Federal Trade Commission (FTC) is required to conduct an expedited public rule making process. Comments to the FTC are due by April 6, 2004 and are addressed to Chairman Muris at:

Federal Trade Commission
Office of the Secretary
Room 159-H (Annex A)
600 Pennsylvania Avenue, NW
Washington, DC 20580

I have communicated extensively with the American Academy of Ophthalmology Vice-President for Governmental Affairs Catherine Cohen and the FTC liaison Patrick Eddington (202-737-6662). Although we cannot immediately overturn passive prescription, we do need the help of the AMA in emphasizing to the FTC that default prescriptions are unprecedented in medicine and need to be monitored for their effects on the nation's health.

I appreciate your continued interest in this matter and apologize for the short notice.

Respectfully,

Robert W. Pantan
Robert W. Pantan, M.D.

Enclosures: A-B

Cc: Patrick Eddington
American Academy of Ophthalmology
1101 Vermont Ave NW, Suite 700
Washington, DC 20005
FAX:202-737-7061

A

MAIL ORDER

Finding the Right Prescription for Mail-order Sales

How easy is it to obtain contact lenses without a valid prescription from leading mail-order and Internet companies?

Dr. Teague has a private practice in Little Rock, AR, that focuses on contact lenses.

Dr. Arima is in private practice in Mill Creek, WA.

Dr. Briggs has a private practice in Dunwoody, GA, that focuses on hard-to-fit contact lens cases.

Dr. Cloninger has a private practice in Cary, NC, that specializes in contact lenses.

Dr. Mint practices in Jacksonville, FL where she specializes in contact lenses and eye disease.

Dr. Morgan practices general optometry in a Chicago suburb.

Dr. Pearson practices with emphasis on contact lenses and children's vision in Tempe, AZ.

Dr. Rouse practices in Sunrise, FL, where he specializes in contact lens fitting and emergency eye care.

Dr. Kurfirst has a single-doctor practice in New York, New York.

By Randall Teague, OD, Fred M. Arima, OD, FAAO, Judson Briggs, OD, Don R. Cloninger, OD, Janet M. Mint, OD, FAAO, Gary J. Morgan, OD, John D. Pearson, OD, David W. Rouse, OD, and Alan Kurfirst, OD

Many vision-corrected consumers now purchase their eyewear, specifically contact lenses, without leaving home by shopping online and over the telephone. Although this shopping method may save patients time, money and hassle, it may present some potential risks.

The main issue is that many mail-order and Internet contact lens sales go through without proper prescription verification. It also appears that many mail-order and Internet companies use different criteria and methods for verifying prescriptions based on lens manufacturer requirements.

We tested the Bausch & Lomb, CIBA Vision, CooperVision, Ocular Sciences (OSI) and Vistakon lens prescription verification processes by ordering their lenses through top mail-order and Internet companies.

The objectives of our study were:

- To better understand how mail-

order and Internet companies verify prescriptions for different manufacturers' products

- To determine the availability of contact lens brands through mail-order and Internet companies

- To determine the availability and possible substitution rates of private-label contact lenses by mail-order and Internet companies

Study Methods

This study focused on the attempted purchase of five top-selling contact lens brands: Vistakon's Acuvue 2, CIBA Vision's Focus 1-2 week, Bausch & Lomb's Soflens 66, CooperVision's Frequency 55 and OSI's Biomedics 55.

We also tested the availability of Medflex, Perspecta, Polysoft, Softuned, Ultraflex and Versaflex (six popular private-label brands from OSI available through national optical retailers and their affiliated practitioners). We made purchases through the

MAIL ORDER

top five U.S.-based mail-order and Internet companies, which collectively represent approximately 90 percent of the contact lens mail-order and Internet industry.

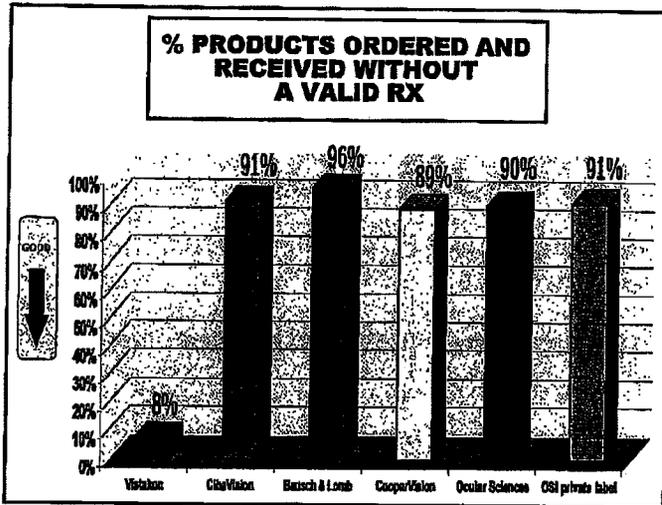


Figure 1. Mail-order and Internet companies filled orders for most manufacturers' lens products without verifying prescriptions.

An independent company that specializes in product investigations was contracted to employ "buyers" who made 422 purchases of the target products. We assigned each buyer to purchase a selection of the five brand name and private label products from selected mail-order and Internet companies between May 14 and June 30, 2003. The buyers resided in 10 states across the country. These buyers did not have valid contact lens prescriptions to place their orders. Buyers tracked their own orders while we tracked any attempts by the mail-order and Internet companies to verify the prescriptions.

When placing orders, each buyer named one of us as the prescribing doctor. Each of the 11 practices used a formal tracking system to ensure accuracy. Aware of the day, the product and the mail-order or Internet company through which the attempted purchase would be made, we tracked any attempt by the mail-order and Internet companies to contact our offices either through a faxed verification inquiry form, a personal phone call or an automated phone call. If the companies contacted us, then the respective office denied the prescription by saying it was

invalid. We also tracked when we did not receive any communication from the mail-order or Internet company involved.

The study took place over the course of seven weeks and used normal purchasing patterns and quantities. Therefore, these results represent what patients, customers and practitioners experience on a daily basis. Additionally, because these companies represent approximately 90 percent of the mail-order and Internet industry, these results should accurately reflect the marketplace.

Results

Purchases Received Results show that of the 422 attempted contact lens purchases made without a valid prescription, companies routinely verified only those for Vistakon products with the doctor. Between 89 percent and 96 percent of all orders for CIBA Vision, Bausch & Lomb, CooperVision and OSI products were ordered, shipped and received without a valid prescription. Companies dispensed only eight percent of Vistakon products ordered using

invalid prescriptions (Figure 1).

Verification of Prescriptions Prescription verification methods used by the mail-order and Internet companies varied among manufacturers (Figure 2). Companies verified 64 percent of orders for Vistakon products using faxed forms. They dispensed between 68 percent and 78 percent of prescriptions for CIBA Vision, Bausch & Lomb, CooperVision and OSI products with no attempted verification.

	Vistakon	CibaVision	Bausch & Lomb	CooperVision	Ocular Sciences
FAX	64%	0%	0%	1%	0%
PHONE	34%	32%	22%	31%	31%
- Automated	3%	46%	69%	58%	87%
- Personal	97%	54%	31%	42%	13%
NO PROCESS	2%	68%	78%	68%	69%

NOTE: Only invalid RX's used

Figure 2. Mail-order and Internet companies used different methods to verify prescriptions for different manufacturers.

MAIL ORDER

Mail-order and Internet companies attempted to verify orders for CIBA Vision, Bausch & Lomb, CooperVision and OSI products through phone calls 22 percent to 32 percent of the time. Of those phone calls, 46 percent, 69 percent, 58 percent and 87 percent (respectively by manufacturer) were automated. Ninety-seven percent of the prescription verification phone calls we received for Vistakon products were personal calls rather than automated, which allowed us to respond to the verification request.

When mail-order and Internet companies attempted to verify prescriptions for CIBA Vision, Bausch & Lomb, CooperVision and OSI products, we responded that the buyers' prescriptions were invalid. Even so, the mail-order and Internet companies dispensed these lenses approximately nine out of 10 times (Figure 1).

Product Availability Of the five manufacturer brands purchased for the study (not including private label brands), 100 percent were available through mail-order and Internet companies.

Private Label Brands OSI is a leading manufacturer of private-label contact lenses, which are "exclusive" products designed to indirectly help eyecare practitioners and retailers retain patients. Buyers attempted to purchase Medflex, Perspecta, Polysoft, Softmed, Ultraflex and Versaflex, which are all equivalents of OSI Biomedics 55 brand. Seventy-eight percent of the time, mail-order and Internet companies indicated that they could substitute Biomedics 55 for the requested private-label brands (Figure 3). The companies advised patients that Biomedics 55 lenses are equivalent to the six private label brands.

Mail-order and Internet companies did not have the OSI brand in stock 16 percent of the time and therefore did not complete the transaction. They referred orders for those lenses to other mail-order and Internet companies for fulfillment six percent of the time. We instructed "buyers" to not purchase lenses from referred sites.

Discussion

This study indicates that inadequate verification systems for four of the five contact lens manufacturers regularly allows most of their lenses to be dispensed without valid prescriptions. Mail-order and Internet companies, as a general rule, consistently verify prescriptions for only Vistakon products.

As practitioners know, prescription expiration dates notify patients that it is time to

have their eyes re-examined and their vision-correction devices monitored. We feel that patients who wear Vistakon lenses are more likely to return for an eye health examination because of the prescription verification process in place for Vistakon products.

Before this study, we did not anticipate any significant difference in the way mail-order and Internet companies dispensed brand-name contact lenses. But our findings suggest that CIBA Vision, Bausch & Lomb, CooperVision and OSI do not have an effective system in place to ensure that their products are dispensed with a valid prescription.

Based on our data, Vistakon is the only manufacturer that has effectively implemented a prescription verification process that mail-order and Internet companies follow.

Study results also indicate that automated phone calls, which represent the primary mode of contact that mail-order and Internet companies use to verify Bausch & Lomb, CooperVision and OSI products, are an ineffective way to verify prescriptions. Each of us who participated in this study found that automated calls were typically inaudible, did not clearly state the patient's name and failed to make clear our next course of action.

We preferred to communicate with mail-order and Internet companies by fax. We felt that this gave us more flexibility to respond, ensured more accurate communication about the patient's data and provided a copy of communication for the patient's chart. We believe that it was essential to respond to help ensure the patient's eye health.

We were all surprised at the availability of OSI



Figure 3.

MAIL ORDER

products at mail-order and Internet companies. Moreover, contrary to popular belief, OSI private-label brands are also available through mail-order and Internet companies because they are substituted at the point of sale for the parent brand, Biomedics 55. This contrasts what many practitioners believe about private-label contact lenses — that they retain patients and increase contact lens businesses through “exclusive” lens sales.

Conclusions

The results of this study indicate that:

- Only one of five manufacturers appears to control how its products are sold and distributed through mail-order and Internet companies. This difference results from the contact lens prescription verification requirements the manufacturer has in place for its products

- All manufacturer brands included in this study were widely and readily available through mail-order and Internet companies

- Mail-order and Internet companies substitute private label lenses with the manufacturer’s branded equivalent

- Mail-order and Internet companies appeared to honor our prescription verification responses for only one of the manufacturers’ products

We encourage all manufacturers to take responsibility for how their products are distributed and dispensed. A required prescription verification process should encourage patients to return to their eyecare practitioner for regular eye examinations. **CLS**

This study was sponsored by Vistakon, a Division of Johnson & Johnson Vision Care, Inc.

(B)

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ELIZABETH PANTON KARKAZIS, O.D.

September 14, 2003

1-800 CONTACTS

Attn: Jeff

FAX: 1-866-512-3978

Dear Sir:

On Friday, September 5, 2003, at 6:48 pm, Jeff from 1-800 CONTACTS contacted our office through an emergency-only phone line for a contact lens verification on patient #5155220. Our office called back to request a written Prescription Verification Request by FAX, but your phone lines would not accept our area code of "708." We also could not access an individual to discuss the matter for the same reason.

On Monday, September 8, 2003 at 8:02 am, our office received a recorded voice to our emergency-only line, "We have noted you will not reply to our request to verify the prescription your patient has provided us."

Again, our office tried to clarify this prescription request through your automated phone system. Our area code was not accepted, and we could not access a human being.

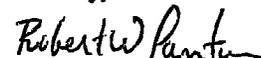
Essentially, 1-800 CONTACTS claims to have "verified" a prescription by processes which do not provide the physician with the name of the patient or the prescription to be verified.

We demand the following from 1-800 CONTACTS:

1. 1-800 CONTACTS must provide the name of patient #5155220 and the contact lenses prescribed so we may verify the accuracy.
2. 1-800 CONTACTS is not to use this phone verification system for our office. We expect all Prescription Verification Requests in writing to the FAX number above.

We expect written confirmation of the above within 5 days. We reserve the right to share this case with the Illinois Department of Professional Regulation.

Sincerely,


Robert W. Pantan, M.D.