



Association of Regulatory Boards of Optometry

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March 26, 2004

National Contact Lens Enforcement Petition
FDA Docket #2003P-0291
Dockets Management Branch
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

In a presentation at the 2002 Association of Regulatory Boards of Optometry (ARBO) Annual Meeting, Mr. John R. Tennis, Assistant Attorney General of Maryland, speaking on behalf of the state attorneys general who were parties to the multi-state antitrust lawsuit, indicated that they were not aware of injuries, complications, or other medical problems associated with the wearing of contact lenses when dispensed without a valid prescription.

One of the stated purposes of ARBO is "improving the standards of the profession, the delivery of health services and the services of the regulatory licensing agencies, all for the welfare and protection of the general public."

To this end, in response to Mr. Tennis' presentation, the Contemporary Issues Committee of ARBO developed a form for use by eye care professionals in reporting complications due to wearing contact lenses dispensed without a valid contact lens prescription. A copy of the form is attached to this report.

In January 2003, this form was placed on the ARBO web site at: <http://www.arbo.org/complications.htm>

In the relatively short time that the form has been available, ARBO has received 116 reports. As promised, ARBO has gathered the data reported by eye care professionals and is making it available to the Food and Drug Administration, the Federal Trade Commission, the state attorneys general, other licensing agencies, state legislatures, and other interested persons in order to fulfill ARBO's mission of protecting the health of the public.

Enclosed are five (5) copies of the summary of the initial reports and the actual data information from the first 116 reports.

I would be pleased to discuss these findings with you in person in order that there can be a better understanding of this important matter. ARBO will continue to compile information in regard to the complications from the improper dispensing of contact lenses. We will periodically update this report as more data is reported to us.

Sincerely,

Russell W. Jones, O.D.
President

Enclosures

2003P-0291

SUP 1



Formerly the International Association of Boards of Examiners in Optometry, Inc.



Association of Regulatory Boards of Optometry, Inc.

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**2003
REPORT ON
COMPLICATION(S)
DUE TO CONTACT LENSES
DISPENSED WITHOUT A
VALID PRESCRIPTION**

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FOR IMMEDIATE RELEASE

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**ARBO RELEASES INITIAL STUDY OF COMPLICATIONS ASSOCIATED WITH INVALID CONTACT LENS PRESCRIPTIONS
Results Indicate The Need For Further Documentation.**

St. Louis, MO (February 20, 2004) – The Association of Regulatory Boards of Optometry (ARBO) has released the initial results of its initiative to document complications caused by contact lenses dispensed without a valid prescription.

ARBO started this program one year ago and is leading the effort to gather and document information in order for the state attorneys general, the Food & Drug Administration (FDA), and the Federal Trade Commission (FTC) to be better able to understand the extent and severity of contact lens complications associated with invalid prescriptions.

“The initial results are demonstrating just the ‘tip of the iceberg’ of a much larger issue. Contact lenses are medical devices that must be properly dispensed to patients to ensure good comfort and visual health. Patients who obtain contact lenses without a valid prescription put themselves at risk for potential loss of vision.” warned ARBO President Russell W. Jones, OD

The following is a brief summary of the 116 reports received in 2003 and is listed by categories. Responses are expressed in percentages of total respondents. A more detailed summary of results is attached to this release.

Signs and Symptoms Experienced By Patients:

The most reported sign or symptom was stinging (42%), followed by neovascularization / pannus (37%), foreign body sensation (36%), burning (35%), and corneal edema (34%). Others were corneal epithelial defect (29%), pain (29%), conjunctivitis (27%), corneal infiltrate (25%), ocular inflammation (24%), corneal distortion (22%), dry eye (22%), keratitis (22%), giant papillary conjunctivitis (GPC) (19%), corneal ulcer (18%), itching (15%), discharge (13%), other (11%), corneal opacity (10%), blurred vision (5%), and iritis (2%).

Treatment Plans Used to Respond to Signs and Symptoms:

The most common treatment plan included the prescription of topical antibacterial/anti-inflammatory medications (46%), followed by lubricants (34%), topical and oral antibacterial medications (22%), other treatment plan (10%), refit contact lenses (7%), and the decrease or discontinuation of contact lens wear (7%).

Patient Outcomes:

The most common outcome was short-term vision loss (22%), followed by other outcomes (10%) return to pre-incident status (7%), permanent vision loss (6%), permanent scarring (5%) and penetrating keratoplasty (less than 1%).

Financial Impact of Complications:

- The patient paid an average of \$67.79 out of pocket expense per incident.
- Third party payers paid an average of \$118.24 per incident.
- The patient loss of income averaged \$24.31 per incident.
- The average total cost per incident was \$210.34.

The actual documentation of patient complications is conducted by the eye care professionals completing the Contact Lens Complications Form provided through ARBO. The eye care professional fills out a form for each incident of a patient who obtained contact lenses without a valid prescription and returns the form to ARBO via fax or e-mail. ARBO compiles the information for this ongoing study. ARBO will periodically update its Summary of Results by providing information to eye care professionals, state attorneys general, the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) through the ARBO web site and articles in professional and trade journals.

Dr. Jones urged eye care professionals to use the ARBO forms to report complications from contact lenses with invalid prescriptions. “As professionals concerned about the health of our patients, each of us needs to take the time to document the many problems that we observe in our practices virtually every day,” Dr. Jones stated.

Eye care professionals can download the Contact Lens Complications Form from the ARBO web site at www.arbo.org. The forms can also be requested by contacting ARBO at (314) 785-6000, FAX (314) 785-6002; e-mail at arbo@arbo.org.



February 18, 2004

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Dear Mr. Tennis:

For your information, (and that of the other recipients):

In your presentation at the 2002 Association of Regulatory Boards of Optometry (ARBO) Annual Meeting, speaking on behalf of the state attorneys general who were parties to the multi-state antitrust lawsuit, you indicated that they were not aware of injuries, complications, or other medical problems associated with the wearing of contact lenses when dispensed without a valid prescription.

One of the stated purposes of ARBO is "improving the standards of the profession, the delivery of health services and the services of the regulatory licensing agencies, all for the welfare and protection of the general public."

To this end, in response to your presentation, the Contemporary Issues Committee of ARBO developed a form for use by eye care professionals in reporting complications due to wearing contact lenses dispensed without a valid contact lens prescription. A copy of the form is attached to this report.

In January 2003, this form was placed on the ARBO web site at: <http://www.arbo.org/complications.htm>

In the relatively short time that the form has been available, ARBO has received 116 reports. As promised, ARBO has gathered the data reported by eye care professionals and is making it available to the Food and Drug Administration, the Federal Trade Commission, the state attorneys general, other licensing agencies, state legislatures, and other interested persons in order to fulfill ARBO's mission of protecting the health of the public.

Following, is a summary of the initial reports and the actual data information from the first 116 reports.

I would be pleased to discuss these findings with you (or any recipient) in person in order that there can be a better understanding of this important matter. ARBO will continue to compile information in regard to the complications from the improper dispensing of contact lenses. We will periodically update this report as more data is reported to us.

Sincerely,

Russell W. Jones, O.D.
President

Enclosures

Summary of Results

A total of 116 reports were received in the year 2003. A summary of the signs/symptoms, treatment plans, outcome, and financial impact of the 116 reports is as follows:

Stinging (49 of 116) was the most reported sign/symptom, followed by neovascularization/pannus (43), foreign body sensation (42), burning (41), and corneal edema (39). Others were corneal epithelial defect (34), pain (34), conjunctivitis (31), corneal infiltrate (29), ocular inflammation (28), corneal distortion (26), dry eye (26), keratitis (25), giant papillary conjunctivitis (GPC) (22), corneal ulcer (21), itching (17), discharge (15), other (13), corneal opacity (12), blurred vision (6), and iritis (2).

The most common of the treatment plans was antibacterial/anti-inflammatory topical/oral (53), followed by lubricants (40), antibacterial topical/oral (25), other treatment plan (11), refit into correct contact lenses (8), and decrease/discontinue contact lens wear (8).

Long term but not permanent vision loss (25) was the most common outcome reported, followed by other outcome (12), return to pre-incident status (8), permanent vision loss (7), permanent scarring (6), and penetrating keratoplasty (1).

Financial impact was divided into the categories of: medical costs out of pocket, medical costs by third party payer, loss of income/total or partial disability/etc., and sick days lost. A total of \$7,864.00 was reported to have been spent out of pocket, an average of \$67.79 per report. Third party payers paid a total of \$13,715.29, an average of \$118.24 per report. A total loss of income of \$2,820.00 was reported, an average of \$24.31 per report. A total of 14.5 sick days were reported.

A range from \$0 spent to \$1,000+ spent was reported for medical costs out of pocket. Medical costs by third party payers ranged from \$0 spent to \$5,000 spent. Loss of income ranged from \$0 lost to \$480 lost, and sick days lost ranged from 0 days to 6 days lost.

Although most reports received were contemporaneous, a few doctors reported incidents occurring in years previous to 2003, going back to 1999. Of the 116 reports received, 15 were from incidents occurring from 1999 - 2002. The number of incidents per month in 2003 is as follows: January-8, February-20, March-19, April-6, May-9, June-1, July-6, August-12, September-6, October-8, November-2, and December-4.

**2003 Report on Complication(s)
Due to Contact Lenses Dispensed Without a Valid Prescription**

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Signs/Symptoms																		
Blurred Vision														X				
Burning	X			X					X	X		X	X					X
Conjunctivitis		X		X	X		X		X	X			X					
Corneal Distortion				X														
Corneal Edema						X				X							X	X
Corneal Epithelial Defect										X					X			X
Corneal Infiltrate					X			X			X		X					
Corneal Opacity												X						
Corneal Ulcer		X										X						
Discharge											X							
Dry Eye						X	X		X							X	X	
Foreign Body Sensation	X	X									X	X						
GPC											X							X
Iritis																		X
Itching						X	X											
Keratitis	X				X					X			X					X
Neovascularization/Pannus			X			X		X								X	X	
Ocular Inflammation					X					X								X
Pain	X	X			X			X		X		X	X		X			X
Stinging		X	X		X		X	X	X	X	X				X	X	X	
Other																		
Treatment Plans																		
Lubricants				X		X	X		X							X	X	X
Antibacterial Topical/Oral	X	X													X			X
Antibacterial/Anti-Inflammatory Topical/Oral					X			X		X	X	X	X					X
Surgical Intervention																		
Refit into correct contact lenses			X															
Decrease/Discontinue CL wear																		
Other																		
Outcome																		
Return to Pre-Incident Status				X														
Long Term but Not Permanent Vision Loss						X												
Permanent Vision Loss																		
Penetrating Keratoplasty																		
Permanent Scarring																		
Other			X															
Financial Impact																		
Medical Costs (Out of Pocket)	\$100	\$150	\$50					\$155			\$80	\$200		\$50	\$40			\$650
Medical Costs (Third Party Payer)				\$60		\$100					\$105	\$200			\$200			
Sick Days Lost															3 Days			
Loss of Income/Total or Partial Disability/etc								\$132										\$150
See footnote on page 11		*	*															*

**2003 Report on Complication(s)
Due to Contact Lenses Dispensed Without a Valid Prescription**

	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
Signs/Symptoms																
Blurred Vision																
Burning						X	X	X			X					X
Conjunctivitis	X		X	X		X	X		X						X	
Corneal Distortion				X		X	X									
Corneal Edema		X		X		X	X	X								X
Corneal Epithelial Defect		X			X	X										
Corneal Infiltrate		X			X											X
Corneal Opacity												X				
Corneal Ulcer		X			X	X				X		X				X
Discharge	X							X								X
Dry Eye									X		X			X	X	
Foreign Body Sensation	X	X	X			X	X							X	X	X
GPC	X			X			X		X						X	
Iritis																X
Itching	X			X					X							
Keratitis	X		X				X	X								X
Neovascularization/Pannus				X			X	X	X				X	X		
Ocular Inflammation	X	X		X	X			X						X		X
Pain	X	X	X		X	X		X			X					X
Stinging	X		X					X			X					
Other													X			
Treatment Plans																
Lubricants				X			X		X		X			X	X	
Antibacterial Topical/Oral						X			X		X					X
Antibacterial/Anti-Inflammatory Topical/Oral	X	X	X		X		X	X	X	X		X				
Surgical Intervention																
Refit into correct contact lenses															X	
Decrease/Discontinue CL wear																
Other	X												X	X		
Outcome																
Return to Pre-Incident Status									X							
Long Term but Not Permanent Vision Loss		X		X			X									X
Permanent Vision Loss						X*						X*				
Penetrating Keratoplasty												X				
Permanent Scarring		X								X						
Other					X			X							X	
Financial Impact																
Medical Costs (Out of Pocket)		\$30	\$50	\$100			\$100	\$50		\$30	\$51			\$76	\$35	
Medical Costs (Third Party Payer)	\$59	\$170			\$65	\$1,500	\$100	\$500		\$165					\$50	\$250
Sick Days Lost																X
Loss of Income/Total or Partial Disability/etc							\$200									
See footnote on page 11	*	*			*	*		*		*		*	*	*	*	

2003 Report on Complication(s) Due to Contact Lenses Dispensed Without a Valid Prescription

	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50
Signs/Symptoms																
Blurred Vision																
Burning					X			X	X			X				
Conjunctivitis								X			X					
Corneal Distortion									X				X			
Corneal Edema	X					X		X	X			X			X	
Corneal Epithelial Defect								X			X			X	X	
Corneal Infiltrate	X							X	X		X		X			X
Corneal Opacity									X							
Corneal Ulcer				X		X	X	X								
Discharge	X								X	X						
Dry Eye					X			X								
Foreign Body Sensation	X							X	X			X		X		
GPC					X				X			X				
Itis																
Itching								X	X	X						
Keratitis								X				X				
Neovascularization/Pannus	X		X		X	X		X				X				
Ocular Inflammation								X		X				X		X
Pain	X					X		X						X	X	
Reddening	X			X	X	X		X		X	X				X	
Other	X	X														
Treatment Plans																
Lubricants					X			X								
Antibacterial Topical/Oral						X		X		X			X		X	
Antibacterial/Anti-Inflammatory Topical/Oral	X			X			X		X		X	X		X		X
Surgical Intervention																
Switch into correct contact lenses			X													
Increase/Discontinue CL wear						X										
Other		X								X			X			
Outcome																
Return to Pre-Incident Status								X								
Long Term but Not Permanent Vision Loss			X													
Permanent Vision Loss							X*		X*							
Penetrating Keratoplasty																
Permanent Scarring																
Other		X				X				X						
Financial Impact																
Medical Costs (Out of Pocket)	\$35	\$90	\$85				\$200	\$60			\$93	\$75	\$75	\$75	\$46	\$65
Medical Costs (Third Party Payer)				\$120		\$200		\$160	\$900	ER cost	\$29	\$55	\$98			
Sick Days Lost							2 days		6 days							
Loss of Income/Total or Partial Disability/etc					\$75						\$50	\$123	\$54			\$78
See footnote on page 11	*	*	*			*	*		*	*			*			

**2003 Report on Complication(s)
Due to Contact Lenses Dispensed Without a Valid Prescription**

	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65
Signs/Symptoms															
Blurred Vision												X			
Burning				X	X						X				X
Conjunctivitis				X	X										X
Corneal Distortion					X										X
Corneal Edema				X	X	X		X					X		X
Corneal Epithelial Defect		X			X	X		X	X						X
Corneal Infiltrate	X	X	X		X			X	X	X	X				
Corneal Opacity					X			X					X		X
Corneal Ulcer			X		X					X			X	X	
Discharge													X		
Dry Eye				X	X										
Foreign Body Sensation				X	X										X
GPC			X			X									
Iritis															
Itching				X	X										
Keratitis					X					X					
Neovascularization/Pannus			X					X	X						
Ocular Inflammation	X	X											X		X
Pain					X								X		
Stinging			X	X							X	X	X		X
Other												X			
Treatment Plans															
Lubricants				X	X										X
Antibacterial Topical/Oral				X	X								X	X	X
Antibacterial/Anti-Inflammatory Topical/Oral	X	X	X		X	X		X	X	X	X				X
Surgical Intervention															
Refit into correct contact lenses												X			
Decrease/Discontinue CL wear													X		
Other															
Outcome															
Return to Pre-Incident Status															
Long Term but Not Permanent Vision Loss		X						X		X			X		
Permanent Vision Loss					X				X						
Penetrating Keratoplasty															
Permanent Scarring														X	
Other															
Financial Impact															
Medical Costs (Out of Pocket)	\$100	\$75	\$98			\$100		\$35	\$76	\$125			\$160	\$135	\$350
Medical Costs (Third Party Payer)				\$100	X			\$125			\$100			\$130	
Sick Days Lost					school										school
Loss of Income/Total or Partial Disability/etc	\$87	\$123	\$97						\$210	\$132					
See footnote on page 11					*		*					*	*	*	

**2003 Report on Complication(s),
Due to Contact Lenses Dispensed Without a Valid Prescription**

	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
Signs/Symptoms																
Blurred Vision								X								
Burning	X			X	X	X		X						X		
Conjunctivitis	X				X		X									
Corneal Distortion					X	X					X		X	X		
Corneal Edema					X	X				X						
Corneal Epithelial Defect					X	X				X			X	X	X	
Corneal Infiltrate																
Corneal Opacity										X						
Corneal Ulcer			X													
Discharge	X						X									
Dry Eye							X				X	X				
Foreign Body Sensation	X			X		X	X	X			X	X	X	X		
GPC							X				X					
Iritis																
Itching						X	X	X			X					
Keratitis					X					X			X	X	X	
Neovascularization/Pannus						X			X	X						
Ocular Inflammation	X		X													
Pain	X													X		X
Stinging	X				X		X	X			X	X		X	X	X
Other				X			X						X		X	X
Treatment Plans																
Lubricants						X	X	X			X					
Antibacterial Topical/Oral					X					X			X			
Antibacterial/Anti-Inflammatory Topical/Oral	X	X	X			X	X							X	X	X
Surgical Intervention																
Refit into correct contact lenses				X								X				
Decrease/Discontinue CL wear									X		X					
Other	X						X									X
Outcome																
Return to Pre-Incident Status	X													X		
Long Term but Not Permanent Vision Loss						X			X	X	X					
Permanent Vision Loss																
Penetrating Keratoplasty																
Permanent Scarring			X													
Other																
Financial Impact																
Medical Costs (Out of Pocket)		\$20		\$64	\$180	\$45	\$52	\$100		\$100	\$30		\$155		\$110	
Medical Costs (Third Party Payer)	\$37	\$40	\$600			\$40	\$38				\$66			\$120		
Sick Days Lost		2 days														
Loss of Income/Total or Partial Disability/etc			\$480													
See footnote on page 11	*		*	*					*		*	*	*		*	*

**2003 Report on Complication(s)
Due to Contact Lenses Dispensed Without a Valid Prescription**

	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	
Signs/Symptoms																			
Blurred Vision			X		X														
Burning						X		X		X			X		X				
Conjunctivitis		X				X			X	X									
Corneal Distortion	X	X							X			X	X				X		
Corneal Edema	X		X					X	X	X		X	X						
Corneal Epithelial Defect		X				X					X	X	X			X			
Corneal Infiltrate		X				X		X								X			
Corneal Opacity	X				X														
Corneal Ulcer															X				
Discharge		X														X			
Dry Eye									X	X			X						
Foreign Body Sensation		X	X						X	X	X	X	X						
GPC	X							X		X		X							
Iritis																			
Itching										X									
Keratitis		X							X										X
Neovascularization/Pannus	X	X				X	X	X	X	X		X	X				X		X
Ocular Inflammation		X				X			X							X			X
Pain		X				X					X								
Stinging		X													X				
Other							X												
Treatment Plans																			
Lubricants			X					X	X	X	X	X	X		X				
Antibacterial Topical/Oral															X				
Antibacterial/Anti-Inflammatory Topical/Oral	X	X				X								X		X			X
Surgical Intervention																			
Refit into correct contact lenses					X												X		
Decrease/Discontinue CL wear							X				X								
Other				X															
Outcome																			
Return to Pre-Incident Status			X		X						X								
Long Term but Not Permanent Vision Loss						X		X	X	X		X	X	X					
Permanent Vision Loss	X																		
Penetrating Keratoplasty																			
Permanent Scarring				X															
Other	X						X										X		X
Financial Impact																			
Medical Costs (Out of Pocket)	\$1000+		\$30			\$211		\$30	\$30	\$30		\$40	\$40	\$95	\$20	\$125	\$133	\$30	
Medical Costs (Third Party Payer)	\$5000+	\$50									\$90				\$90				\$120
Sick Days Lost	5-6 days													2 days					1/4 day
Loss of Income/Total or Partial Disability/etc	X	\$100	\$34			\$50										\$45			
See footnote on page 11	*		*	*	*		*				*						*	*	*

**2003 Report on Complication(s)
Due to Contact Lenses Dispensed Without a Valid Prescription**

	100	101	102	103	104	105	106	107	108	109	110	111	112	113	114	115	116
Signs/Symptoms																	
Blurred Vision																	X
Burning		X	X	X	X	X	X		X	X							X
Conjunctivitis		X				X			X			X				X	
Corneal Distortion	X	X			X	X				X			X			X	
Corneal Edema		X	X		X	X	X	X		X							
Corneal Epithelial Defect						X		X		X	X			X		X	
Corneal Infiltrate			X			X			X							X	
Corneal Opacity	X																
Corneal Ulcer			X				X	X									
Discharge					X	X					X						
Dry Eye		X		X	X		X			X				X		X	
Foreign Body Sensation		X		X		X				X	X					X	X
GPC		X								X		X	X				
Iritis																	
Itching		X										X					
Keratitis		X	X								X						
Neovascularization/Pannus	X	X		X	X	X			X			X	X		X		
Ocular Inflammation	X	X								X							
Pain			X			X	X				X						
Stinging				X	X	X	X	X		X	X	X					X
Other			X		X		X										
Treatment Plans																	
Lubricants		X		X	X	X			X	X		X	X		X	X	X
Antibacterial Topical/Oral		X						X			X						
Antibacterial/Anti-Inflammatory Topical/Oral	X	X	X			X	X										
Surgical Intervention																	
Refit into correct contact lenses																	
Decrease/Discontinue CL wear									X				X				
Other							X										
Outcome																	
Return to Pre-Incident Status																	
Long Term but Not Permanent Vision Loss		X							X					X		X	
Permanent Vision Loss																	
Penetrating Keratoplasty																	
Permanent Scarring	X																
Other			X												X		
Financial Impact																	
Medical Costs (Out of Pocket)	\$200	\$50		\$45	\$75	\$100	\$169	\$75	\$75	\$40	\$60	\$45		\$35		\$75	
Medical Costs (Third Party Payer)	\$400-600	\$89	\$1000+	\$60		\$109		\$120		\$60	\$45						
Sick Days Lost			school					1/2 day									
Loss of Income/Total or Partial Disability/etc						\$400		\$200									
See footnote on page 11	*		*		*		*		*				*		*		

FOOTNOTES

2. Additional information: Expired CL Rx was filled by mail order company on 3/11/02, even after sending a fax stating the Rx was invalid as of 7/15/98.
3. Other Treatment Plan: Refit CLRx.
18. Medical Costs: \$500 of \$650 out of pocket was for ER visit. \$150 for loss of income is estimate by O.D.
19. Other Treatment Plan: Conjunctival Foreign Body Removal.
20. Other Outcome: Corneal Scar.
23. Other Outcome: Patient lost to follow up.
24. Other Outcome: Permanent vision loss was probable/pending – still in follow up.
26. Other Outcome: Significant pannus remains.
28. Other Outcome: Peripheral scarring.
30. *Patient bought CLs from flea market and did not take out lenses as instructed by O.D. Patient was put in hospital. 60% of cornea is scarred. O.D. and M.D. both think scarring was from acanthamoeba infection.
31. Other Symptoms: Patient changed to extended wear via self and mail order company. Other Treatment Plan: D/c CLs from mail order company, educated patient about FDA approved daily wear only.
32. Other Treatment Plan: Not specified,
33. Other Treatment Plan: CL cleaning, replacement. Other Outcome: No progression.
35. Other Symptom: Tearing.
36. Other Symptoms: Mail order company filled incorrect base curve. Rx stated 8.2 base curve, not 8.6. Other Treatment Plan: Copy of fax to mail order company indicating incorrect base curve supplied. Other Outcome: Waiting.
37. Other Treatment Plan: Refit into higher oxygen permeable CLs.
40. Other Treatment Plan: Discontinued CL wear. Other Outcome: Glasses provided.
41. *This patient ordered CLs from a mail order company from 1997 – 2000. BVA was 20/30 at resolution.
43. *This patient purchased non-Rx CL from beauty parlor. BVA was 20/40 at resolution.
44. Other Treatment Plan: Patient was treated at emergency room. Other Outcome: CL wear was discontinued.
47. Other Treatment Plan: Steroid.
55. Medical Costs: Medicaid covered.
57. Patient was wearing daily CLs for 3-5 weeks each lens. Patient was getting CLs without valid Rx from 1990 – 2003, without an exam.
62. Other Symptoms: Redness and discomfort. Other Treatment Plan: Refit with correct CLs.
63. Other Treatment Plan: Discontinue CL wear.
64. Other Outcome: Corneal Scar.
66. Other Treatment Plan: Hot compress.
68. Other Outcome: Mild scarring of central cornea with no loss in VA.
69. Other Sign/Symptom: Patient was switched to cheaper brand of CL by optician. Other Treatment Plan: Switched back to original brand of lenses. Other Symptom: Increased light sensitivity. Other Treatment Plan: Antihistamine/Mast Cell Stabilizer.
74. Other Treatment Plan: Decrease in CL wear.
76. Other Treatment Plan: Discontinue CL wear.
77. Other Treatment Plan: Return to correct CL brand.
78. Other Symptom: Photophobia.
80. Other Symptom: Difficulty with lens sticking to eye.
81. Other Symptom: Corneal abrasion. Other Treatment Plan: Contact lens bandage.
82. Other Outcome: Neovascularization has compromised outcome of future PK or Lasik.
84. Other: CLs were substituted without authorization. The lenses did not fit. Patient presented within 3 days of receiving lenses.
85. Other Treatment Plan: Explained hazards of improper contact lens use. Other Outcome: Permanent corneal scars.
86. Other Treatment Plan: Re-do Rx.
88. Other Symptom: Palpebral Conjunctival Scar. Other Treatment Plan: Patient already discontinued CL wear. Other Outcome: Monitor patient while wearing glasses.
92. Other Treatment Plan: Discontinue CL wear.
98. Other Treatment Plan: Refit CLs and reduce wear time. Other Outcome: Corneal disruption.
99. Other Outcome: Contact lens intolerance.
100. Other Outcome: Permanent scarring, no loss of vision.
102. Other Symptoms: Photophobia. Other Outcome: Currently Under Care. Sick Days Lost: 1 day of school. Other: Patient continued to obtain contact lenses from mail order company after the contact lens prescription expired 07/01, without verification (written or oral) from O.D. The patient had not been followed since 07/00 because he was able to obtain a continual supply of contact lenses from the mail order company.
104. Other Symptoms: Given wrong lenses.
106. Other Symptoms: Photophobia. Other Treatment Plan: Cycloplege.
108. Other Treatment Plan: Discontinue CL use for 6 months.
112. Other Treatment Plan: Discontinue CL wear.
114. Other: Mail order company dispensed expired contact lenses in 11/02. Mail order company sent out an order form in 2002 and 2003 even though contact lens Rx had expired.



Association of Regulatory Boards of Optometry, Inc.

COMPLICATION(S) DUE TO CONTACT LENSES
DISPENSED WITHOUT A VALID PRESCRIPTION
REPORTING FORM

Tel: (314) 785-6000 • Fax: (866) 886-6164 • E-mail: arbo@arbo.org

Reference Letters and/or Numbers for Your Personal Use Only:

[Empty box for reference letters/numbers]

(which does not identify the individual patient)

- Checkboxes for symptoms: Burning, Conjunctivitis, Corneal Distortion, Corneal Edema, Corneal Epithelial Defect, Corneal Infiltrate, Corneal Opacity, Corneal Ulcer, Discharge, Dry Eye, Foreign Body Sensation, GPC, Itching, Keratitis, Neovascularization/Pannus, Ocular Inflammation, Pain, Stinging, and Other.

Treatment Plan:

- Checkboxes for treatment: Lubricants, Antibacterial Topical/Oral, Antibacterial/Anti-Inflammatory Topical/Oral, Surgical Intervention, and Other.

Outcome:

- Checkboxes for outcome: Return to Pre-Incident Status, Long Term but Not Permanent Vision Loss, Permanent Vision Loss, Penetrating Keratoplasty, and Other.

Financial Impact to Patient/Health Care Resources Utilized

- Checkboxes for financial impact: Medical Costs (Out of Pocket) \$, Medical Costs (Third Party Payer) \$, Sick Days Lost \$, Loss of Income Due to Office Visit \$, and Total or Partial Disability, etc.

Please Print: Date: _____ Doctor: _____
Phone: _____ Email: _____

Send or fax this form to:

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