Comment #: 19

American Academy of Optometry

ORIGINAL

June 23, 2004

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

RE: Fairness to Contact Lens Consumers Act, 15 U.S.C. 7601 – Contact Lens Study, Project V040010

Dear Sirs:

On behalf of the Section on Cornea and Contact Lenses of the American Academy of Optometry I would like to comment and make a recommendation regarding the Act and the Study mentioned above.

The Federal Register/Vol. 69, No 78 of April 24 makes numerous references to the price and the cost of contact lenses to our patients. Certainly we would all agree that our patients have the right to fair trade, competition in the marketplace, and a fair price for their contact lenses. However, our concern transcends this right. Our greatest concern it is the safety and health of our patients. Therefore, we recommend that in all of your deliberations regarding this "the Act", that the welfare of the patient, especially their safety and eye health, be your greatest concern.

The attached reference, Steinemann TL, Pinninti U, Szczotka LB, Eiferman RA, Price FW. Ocular complications associated with the use of cosmetic contact lenses from unlicensed vendors. Eye & Contact Lens 29(4):196-200, 2003, demonstrates how important patient care and education and examination are, as compared to price and cost.

Respectfully,

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Eye & Contact Lens 29(4): 196–200, 2003

Ocular Complications Associated with the Use of Cosmetic Contact Lenses from Unlicensed Vendors

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Purpose: To call attention to the unauthorized sale of cosmetic contact lenses, resulting in ocular complications. **Design:** Observational case report. **Methods:** Retrospective, observational, clinical practice setting. **Results:** Six patients (five female and one male) were seen urgently for acute eye pain and redness after wearing cosmetic plano contact lenses. None of the patients had previously worn a contact lens or spectacle correction. None of the lenses were dispensed by eye care professionals. One patient developed pseudomonal keratitis, ultimately requiring penetrating keratoplasty for visual rehabilitation. **Conclusions:** Colored contact lenses are being dispensed without a prescription or fitting from unlicensed vendors, such as cosmetics, convenience, and accessory stores. Lenses are sold individually and without care instructions. Consequently, uninformed lens wearers are experiencing acute, vision-threatening infections and inflammation.

Key Words: Cosmetic contact lens—Colored contact lens—Decorative contact lens—Soft contact lens complications—Keratitis—Corneal ulcer—Conjunctivitis.

The sale of colored cosmetic contact lenses by vendors other than eye care professionals has recently been reported ("20/20." Colored Contact Lenses, ABC television. September 13, 2002).[1] Targeted consumers include young people with no need for vision correction who are unaware and uninformed of the proper use and care of contact lenses. Noted here are six cases of patients with pseudomonal keratitis, presumed bacterial keratitis, iridocyclitis, giant papillary conjunctivitis, and contact lens overwear syndrome after using cosmetic contact lenses from unlicensed retail vendors. All patients were sold individual contact lenses without a prescription or fitting, without information on proper use, and without ongoing supervision. All patients experienced acute vision-threatening problems.

PATIENT 1

A 14-year-old girl complained of burning, pain, photophobia, and poor vision in her left eye after wearing colored contact lenses for a few hours the previous day. She had purchased the lenses from a video rental store. A checkout clerk sold individual lenses to her from an opened box. The patient was seen by her pediatrician and was treated with ophthalmic bacitracin ointment and urgently referred to MetroHealth Medical Center for further care. Her entering visual acuity was hand motions in the left eye and 20/25 in the right eye. She had no history of vision correction with eyeglasses or contact lenses. Noted on examination were lid edema, copious purulent discharge, a central corneal ulcer with 50% thinning, and hypopyon (Fig. 1). The right eye appeared healthy. Cultures were obtained; the patient was admitted to the hospital, and hourly fortified cefazolin (50 mg/mL) and tobramycin (14 mg/mL) eyedrops were begun. Cultures showed heavy growth of *Pseudomonas aeruginosa*, sensitive to tobramycin and ciprofloxacin and coagulase-negative staphylococci sensitive to cefazolin. The patient was treated in the hospital for 4 days and discharged from the hospital with treatment consisting of topical tobramycin, cefazolin, ciprofloxacin, and diclofenac. Nine months later, she had a visually significant scar in the central cornea with 30% thinning. Her best-corrected visual acuity in that eye had improved from hand motions to 20/80. Penetrating keratoplasty was performed to improve visual acuity, and one year after surgery, her visual acuity had improved to 20/25 with correction.

PATIENT 2

A 19-year-old woman who had purchased cosmetic contact lenses from a corner store visited the MetroHealth Medical Center Eye Clinic after awakening with burning and light sensitivity in both eyes. She had fallen asleep in the contact lenses. She had purchased colored plano lenses for the past 5 years. Individual cosmetic lenses were sold to her without a prescription from opened box sets. She often wore disposable lenses for months at a time, with the longest continuous wear being 5 months.

Visual acuity was 20/25 in each eye. Examination showed diffuse injection and ciliary flush in the left eye. The anterior chamber showed moderate cells and flare. She was diagnosed with acute iridocyclitis and was advised to discontinue contact lens wear and use artificial tears every 1 or 2 hours. The patient did not report for follow-up examination.

PATIENT 3

A 19-year-old woman complained of 2 days of tearing, redness, light sensitivity, and burning in her right eye. She reported slee-

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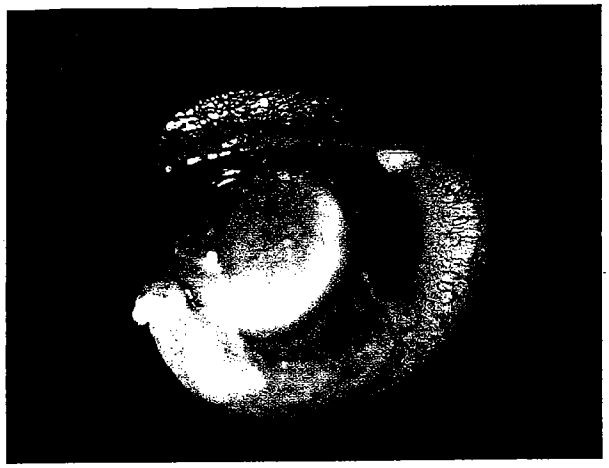

FIG. 1. View of pseudomonal keratitis showing diffuse infiltrate, ulceration, and hypopyon.

ing in her cosmetic contact lenses 2 nights earlier. She had purchased these contact lenses from gas stations, hair salons, and corner stores for the past 6 years. Several of her friends, three teenage sisters, and her mother had also been using such lenses, but she did not report sharing the contact lenses with anyone.

Visual acuity was 20/30 in each eye. Examination of the right eye showed conjunctival injection, limbal flush, and micropapillae of the upper tarsal conjunctiva. She also had microcystic edema of the cornea, superior to the visual axis, and moderate cells in the anterior chamber. It was determined that she had contact lens overwear, iritis, and corneal hypoxia from a tightly fitting contact lens. The left eye also showed early giant papillary conjunctivitis. The patient was taught appropriate contact lens use. She was instructed to discontinue lens use for at least 2 weeks and to use artificial tears. The patient did not keep her follow-up appointment.

PATIENT 4

A 30-year-old woman visited the University Hospitals of Cleveland with right eye pain, tearing, and photophobia accompanied by redness, all of which had worsened during the previous 2 weeks. She had purchased plano cosmetic lenses from a convenience store 1 month earlier without a prescription. No fitting, examination, or instructions on care and handling were given. She had selected an over-the-counter redness reliever to store and lubricate the lenses. She continued to wear the lenses at least 8 hours a day although her symptoms were worsening for several days before her original examination.

Uncorrected visual acuity was 20/40. Examination showed severe confluent punctate keratitis and moderate microcystic and stromal edema (Fig. 2). No infiltrates or anterior chamber reaction was seen. There were zone 3 upper tarsal conjunctival changes consistent with giant papillary conjunctivitis. The lenses were discarded, and the patient was instructed not to wear them. She continued with hourly nonpreserved artificial tears, ciprofloxacin drops four times a day, and nedocromil sodium drops twice a day. Four days later, her irritative symptoms had resolved. Best-corrected visual acuity was 20/50. Stromal edema and confluent keratopathy were improved, but not resolved. The ciprofloxacin was discontinued; artifical tears were continued every four hours,

FIG. 2. View of injection and diffuse microcystic and stromal edema after contact lens overwear.

and nedocromil sodium was continued twice a day. Two weeks later, she was free of symptoms. The keratitis resolved, but mild giant papillary conjunctivitis remained. The uncorrected visual acuity was 20/20.

PATIENT 5

A 32-year-old man developed severe right eye pain after wearing a novelty contact lens 1 week earlier. He had purchased a contact lens for Halloween at a flea market without a prescription, examination, or care instructions. After insertion and wear for several hours, he had difficulty removing the contact lens and scratched his right eye. He visited a local emergency department, where a corneal abrasion was diagnosed. He was treated with bacitracin ophthalmic ointment. Two days later, he was seen by an ophthalmologist for severe right eye pain. The patient was started on tobramycin eyedrops and referred to a corneal specialist (R.A.E.). Visual acuity was 20/200. Slitlamp examination showed a 5 × 5 mm epithelial defect, stromal edema, and a subconjunctival hemorrhage (Fig. 3). Tight lens syndrome was diagnosed, and the patient began taking topical corticosteroids. Four days later, visual acuity was 20/200, and the abrasion was healing slowly

FIG. 3. View of subconjunctival hemorrhage and injection after patient removal of a tightly fitting contact lens.

Three days later, the patient reported improved comfort, but cloudy vision (20/50). The abrasion had healed, and the antibiotics were discontinued. Six days later, the right eye was comfortable, and the visual acuity was 20/60 and improved to 20/40 with pinhole. Confluent keratopathy and stromal edema were seen, but the anterior chamber was quiet. Topical steroids were tapered, and the patient was lost to follow-up.

PATIENT 6

A 24-year-old woman had purchased and worn a pair of colored soft disposable contact lenses from a grocery store. She had no history of contact lens wear for vision correction, and she received no wear or care instructions at the time of purchase. She wore the colored lenses for approximately 6 months, often sleeping in the lenses. She occasionally cleaned the lenses with over-the-counter contact lens solution and soaked the lenses for approximately 1 hour. She had an assortment of colored lenses, but did not discard any of them after several weeks of wear. One month before referral, she developed "pink eye" in the left eye. She was seen by her local eye doctor, diagnosed with herpes simplex keratitis, and prescribed trifluridine and ofloxacin drops. Despite treatment, the left eye worsened, and significant pain developed. Ofloxacin drops were increased to every hour, and she was referred to a corneal specialist (F.W. P.).

Visual acuity in the left eye was hand motions. A severe tarsal papillary reaction was seen in the left eye, and the bulbar conjunctiva was moderately injected. The cornea had a 4 × 5 mm central ulcer and infiltrate. A small hypopyon and fibrinous anterior chamber reaction were present. The remainder of the examination was unremarkable.

The ulcer was cultured, and the patient was admitted to the hospital for hourly fortified vancomycin (30 mg/mL) and tobramycin (14 mg/mL) drops around the clock. The trifluridine and ofloxacin drops were discontinued, and oral ciprofloxacin (500 mg) was started twice daily. Corneal viral and bacterial cultures remained negative.

After 5 days of intensive topical therapy, the ulcer had nearly epithelialized, and the patient was discharged from the hospital with a prescription for vancomycin and tobramycin drops four times a day. Seven months later, the best-corrected visual acuity in the left eye was 20/200 (legal blindness), and central corneal scarring was present.

DISCUSSION

The current study illustrates a dangerous trend occurring in the United States: the unlicensed sale of plano colored hydrogel contact lenses by vendors other than eye care professionals. The lenses are designed solely to change the appearance of the eye. Cosmetic lenses enhance or alter natural eye color, and novelty or theatrical lenses display designs or even sports logos and are often used to accessorize costumes. The six patients described were seen urgently for eye pain and complications primarily related to the misuse of lenses between 2001 and 2002. Four of the six patients reside and were seen in the greater Cleveland area. Three of the five female patients were teenagers (all seen at MetroHealth Medical Center). None of the patients had previously worn contact lenses to correct vision. All patients had purchased contact lenses without a prescription from a variety of vendors: gas stations, mini marts, video stores, grocery stores, hair salons, and flea markets. All lenses were purchased without an eye examination, proper fitting, wear and care instructions, or follow-up. One patient, a minor, was sold cosmetic colored lenses without her mother's knowledge or consent. The other teenage patients, both 19 years old, stated that they had been sold lenses in a similar fashion for several years. Three of the six patients admitted to sleeping in the lenses. Two patients required admission to the hospital for blinding bacterial keratitis; despite successful antibiotic treatment, both patients were left with visually significant corneal scarring. No patients reported sharing the contact lenses with family, friends, or colleagues, but at least one patient knew of friends who shared their lenses.

A similar outbreak of colored plano contact lens complications as a result of the unlicensed sale and misuse was reported to the American Academy of Ophthalmology in June 2002 (Gail Royal, M.D., personal communication). Twelve teenagers with severe eye pain were seen by an ophthalmologist in Myrtle Beach, South Carolina in a 1-week span, through the emergency department. All patients had worn plano decorative lenses purchased from beach side kiosks and T-shirt shops. None of these patients had worn contact lenses previously. At least one patient had shared the lenses with a friend. Patients were treated for corneal abrasions, corneal edema, keratitis, and iritis.

Similar activity has been investigated and reported in 2002 by the Food and Drug Administration (FDA), which found "widespread illegal sale of decorative lenses along the east coast."[2] The FDA cited "dozens of reports" of corneal ulcers and "abrasions that can lead to vision-threatening infections." Professional and advocacy groups (e.g., the American Academy of Ophthalmology, the American Optometric Association, the Contact Lens Association of Ophthalmologists, the Contact Lens Institute, and Prevent Blindness of America) presented cases and met with representatives of the FDA. In October 2002, the FDA issued a warning against the use of noncorrective, decorative lenses without a prescription or professional fitting. The FDA announced that it would aggressively move to prevent the distribution of decorative contact lenses directly to consumers. The organization further emphasized that it would seize products that are being marketed and distributed without a prescription and without proper fitting by an eye care professional. Many non–eye care retailers contacted by the FDA voluntarily withdrew these products. The FDA also issued an import alert instructing FDA and customs officials to detain all decorative lenses presented at U.S. ports of entry and emphasizing that these lenses must not be dispensed without a prescription.[3–5]

Efforts led by the contact lens industry were also underway. CIBA Vision sent cease-and-desist letters to 53 vendors illegally distributing plano cosmetic lenses and, in September 2002, filed a lawsuit in U.S. District Court (Northern District, Atlanta, GA) against two companies for widespread illegal distribution and sale of colored contact lenses.[6]

Where are unauthorized distributing vendors obtaining black market lenses? The answer is not clear, but may include theft from manufacturers' or practitioners' stock and samples, overseas imports, or domestic knockoffs of commercially available colored lenses (Rick Weisbarth, O.D., personal communication, May 2002). Internet distribution is also a possibility; an Internet search for "tinted contact lenses" included more than 6,000 Web sites willing to sell and distribute these lenses, in some cases, perhaps, without patient or prescription verification. Moreover, the mail

order and Internet sale of all domestic U.S. contact lenses more than doubled from 1998 to 2000.[7]

Decorative contact lenses are no different from vision-correcting soft (hydrogel) contact lenses in that they both alter the physiology of the ocular surface. Whether colored or not, contact lenses reduce the amount of oxygen available to the cornea by separating the ocular surface from atmospheric oxygen. Oxygen transmission through the contact lens itself regulates damage to the corneal surface.[8] Short-term daily and extended (overnight) wear can compromise epithelial integrity, which is critical in protecting the ocular surface against infection. Prolonged wearing of contact lenses suppresses normal corneal epithelial proliferation, differentiation, movement, and turnover, leading to a stagnation of corneal epithelium beneath the lens.[9] This potentially leads to abrasions, epithelial keratitis, or even infectious ulcers. Furthermore, soft contact lenses that are dispensed without a fitting or follow-up may fit too tightly, become immobile, or trap debris beneath the lens. Tight lens syndrome is well described, particularly in extended contact lens wear.[10] Another potentially blinding pathogen, *Acanthamoeba*, has been linked with soft contact lens wear. The organisms (trophozoites and cysts) have the ability to quickly adhere to the surface of a contact lens.[11] Thus, the hypoxic corneal state and sharing of contact lenses in naive wearers could put the wearer at risk for abrasions, edema, keratitis, iridocyclitis, and blinding infection. The risk is further increased in patients who sleep in their contact lenses.[12] HIV remains a potential pathogen because the virus has been isolated from contact lenses, corneal tissue, and tears of patients with AIDS.[13,14]

Even when lenses are dispensed by eye care professionals, as many as half of all patients are noncompliant with wear time, replacement schedules, and care instructions.[15,16] Contact lens–related hypoxia and tear film stagnation with reduced epithelial cell turnover and epithelial bacterial debris compartmentalization are exacerbated when patients sleep in contact lenses.[17] Hypoxic states in contact lens wear can lead to bacterial adhesion to damaged corneal epithelium, through increased molecular binding sites to organisms such as *Pseudomonas*.[18] Bacterial binding decreases significantly with higher oxygen transmission through the contact lens.[8]

Snyder et al.[19] reported five cases of severe microbial keratitis associated with the use of plano tinted lenses dispensed by eye care professionals in 1991. Three cases of pseudomonal keratitis and two cases of acanthamebic keratitis were documented in patients between the ages of 19 and 55 years. Four of the five patients were women. All patients wore plano lenses solely to change the color of their eyes. Three of the five patients were noncompliant with lens cleaning and disinfection. In one patient, the lenses were shared, and the lenses were worn without proper instruction on care. Overnight wear was documented in two patients. The authors emphasized that the lack of proper education and perhaps a casual attitude toward contact lenses in these naive patients may have led to poor lens hygiene and perhaps delays in seeking care from an eye care professional. Likewise, wearers of contact lenses that do not correct their vision may erroneously assume that because a decorative lens is not used to correct a refractive error, they do not need a proper lens fit, evaluation, or follow-up by a licensed eye care professional.

The demand for decorative contact lenses continues to increase, particularly among teenage girls and young women. Colored contact lenses are one of the fastest growing segments (6% annual increase) of the U.S. contact lens industry. Approximately 25 million vision-corrected patients and 13 million noncorrected people are interested in colored lenses (Mitch Cassel, O.D., oral communication, January 2003). Industry surveys indicate that 30% to 60% of women between the ages of 16 and 35 years express an interest in changing their eye color with cosmetic contact lenses.[20] There are now approximately 3 million people in the United States wearing cosmetic contact lenses, at least 30% without vision correction. Fifty percent of all decorative lens wearers are first-time contact lens wearers. To date, American consumers have spent approximately $180 million on decorative contact lenses. Marketing research estimates a 15% to 20% growth in the near future (Mitch Cassel, O.D., oral communication, January 2003). Worldwide cosmetic colored lens sales are expected to increase by 14% this year to $400 million.[21]

American young people remain at risk as a major target of the unauthorized sale of decorative contact lenses. Fashion-conscious teenagers are interested in colored contact lenses to change or enhance their eye color as demonstrated by models, movie stars, and music video entertainers. With a proper fit and appropriate instruction and follow-up by an eye care professional, the risks of decorative cosmetic contact lenses can be minimized, and lenses can be worn safely. The sale of decorative lenses by vendors other than eye care professionals, however, represents a clear danger to all buyers, particularly naive minors. The past year has witnessed numerous examples of costly outcomes: emergency department visits, prescription medications, admissions to the hospital, and a corneal transplant to restore vision in one teenager. Federal and state authorities, professional and advocacy groups, the eye care industry, and all eye care professionals must remain vigilant in their efforts to protect the eye health of all Americans, particularly children.

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