

October 26, 2015

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**RE: Contact Lens Rule, 16 CFR part 315, Project No. R511995**

The American Optometric Association (AOA) represents 33,000 doctors of optometry and optometry students. The AOA is the voice of the nation's family eye doctors and a leading authority on eye health, vision care, and patient safety issues. On a daily basis, doctors of optometry prescribe contact lenses to patients. However, improper lens use can lead to injuries and infections. Our members are essential in mitigating this risk and ensuring that the use of contact lenses results in optimal vision. Since the passage of the Fairness to Contact Lens Consumers Act (FCLCA) in December 2003, the AOA has educated our members on the requirements of the law and has also guided our members and the public to report violations of the law. We appreciate this opportunity to offer comment on the Contact Lens Rule review (80 Fed. Reg. 53272 (Sept. 3, 2015)).

**1. Is there a continuing need for the Rule? Why or why not?**

The contact lens rule is required by statute. However, the rule is primarily needed today for patient safety reasons. The original justification to enhance market competition through prescription portability has been solved. That is, the problem of prescription portability that the law and Rule originally sought to address no longer exists. It's our understanding that one theoretical outcome of prescription portability is narrower price differences between sellers, and in fact there's less difference in price between sellers today than there was prior to the FCLCA. Conversely, the rule remains necessary and in need of improvement to address retailers who are acting anti-competitively. During the past ten years, the contact lens marketplace has expanded with the maturation of online channels. To take full advantage of this expanded marketplace, it is imperative common-sense safeguards remain in place to protect the public. The rule remains necessary to ensure that contact lens retailers recognize the risks of contact lens use, treat contact lenses as the regulated medical devices that they are, and not develop business practices that focus on sales and profits while compromising the health of the patients who rely on contact lenses. Such deceptive and unfair practices hurt competition. The rule should be retained to provide the necessary guidance that allows for strong competition in the marketplace including competition for ensuring patient safety. If eye care professionals are the only distribution channel

ethically or legally required to protect patient safety, then other competitors in the market have an unfair advantage that will ultimately lead to patient harm and less competition.

Moving forward, the AOA encourages the Federal Trade Commission (FTC) to update the regulations to account for current issues in the market. When the rule was initially developed, the FTC and the public lacked experience with the requirements of the FCLCA. We can now work to improve the rule for patients using the knowledge we have gained over the past ten years.

## **2. What benefits has the Rule provided to consumers? What evidence supports the asserted benefits?**

The ability to shop around for contact lenses is only a clear benefit to patients if those contact lenses can be used safely and all sellers are operating on a level playing field when it comes to consumer safety. The AOA fully supports a robust contact lens marketplace, and believes the competition for price or convenience must not eliminate innovation or concern for patient safety. While the Rule outlined some basic safeguards to protect patients, the AOA is concerned that lack of enforcement is allowing the Rule to be manipulated by retailers for their own financial benefit. Evidence of anti-competitive and misleading behavior by sellers is detailed later in these comments.

Consumers recognize independent eye care professionals as experts with the highest credentials and the highest quality materials, according to one published study.<sup>1</sup> The authors also found consumers recognize Internet seller 1-800 CONTACTS as having the greatest availability of lenses. Internet sellers and discount brick-and-mortar retailers were viewed by consumers as providing the most convenience. The market for contact lenses allows consumers to make these judgments. However, anti-competitive practices by some sellers are threatening the ability of consumers to make accurate distinctions between sellers, undermining the benefit of the Rule.

These results were confirmed this year in a national consumer survey by See Clearly, America, which found consumers are very satisfied with the care they receive from their family eye doctor, and that they trust their family eye doctor most to protect their health information, far more than other contact lens sellers. Conversely, consumers overwhelmingly said it was riskiest to purchase lenses from sellers other than their family eye doctors. Finally, 93 percent of consumers agreed that their family eye doctor is the best source of information about proper use and care of contact lenses.

## **3. What modifications, if any, should be made to the Rule to increase its benefits to consumers? What evidence supports the proposed modifications? How would these modifications affect the costs the Rule imposes on businesses, including small businesses? How would these modifications affect the benefits to consumers?**

The AOA believes several changes should be made to the Rule to benefit patients. Given the complications that can occur with improper contact lens wear, steps must be taken to ensure contact lens consumers receive necessary eye examinations and instruction on appropriate lens

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<sup>1</sup> Petito, Olivares, Schnider and Alford, "Study of Market Segmentation in Vision Care: How Consumers Make Choices in Vision Care Purchases," *Journal of the American Optometric Association*, Vo. 83, No. 6, June 2012.

use to protect the patient's eye health. At a minimum, the AOA requests greater enforcement of the requirements already outlined in the Contact Lens Rule. Retailers should not be allowed to sell lenses without a prescription, and the FTC must penalize violating retailers to send a message both to the offender and to the larger contact lens retailer community. Large retailers as well as individuals who attempt to sell lenses through websites, such as Facebook, must be penalized in accordance with the FCLCA. It's our understanding the FTC brought ten different enforcement actions against individuals and entities in the first five years of the Contact Lens Rule, but none in the last five years.

Other agencies have also provided some enforcement of contact lens sale laws in recent years. For example, Operation Cat Eyes in 2014 and Operation Fright Night in 2015 by the U.S. Attorney's Office in California charged retailers for illegally selling contact lenses without a prescription. Also in 2015, Operation Pangea by the FDA and Interpol, which usually fights illegal sales of prescription drugs online, cracked down on illegal sales of medical devices online too. In some cases, websites or specific products were taken down; in other cases, websites lost their ability to accept payments through Visa or Mastercard. It's our understanding that 1/3 of the sites found by Interpol to be selling medical devices illegally were selling contact lenses.

To ensure that patients are sold lenses that have been appropriately fitted for their eyes and eye health, the type of lens prescribed to the patient should be the lens type sold to the patient, regardless of where the patient purchases the lenses. Retailers must not be allowed to encourage patients to experiment with new lenses as this poses a potential risk to eye health. Additionally, although the passive verification system was delineated in statute, we believe there are serious flaws with this system. The AOA strongly urges the FTC to take steps to better ensure the regulations related to contact lens sales appropriately consider the status of contact lenses as regulated medical devices that require physician oversight. Going beyond the need for increased enforcement of the basic safeguards of the law and to improve the Rule for consumers, the AOA requests the following:

- 1) FTC should limit the quantity of contact lens boxes that retailers advertise as being able to be purchased at one time.
- 2) FTC should prohibit sellers from marketing contact lenses to patients whose prescription has expired, and to include the issue date or expiration date in the information the seller provides to the prescriber to verify.
- 3) FTC should require contact lens prescriptions to include a maximum quantity of lenses that can be purchased prior to the prescription's expiration.

### **Needed Modification: Addressing Retailer Advertised Quantities**

The FCLCA establishes the default expectation that prescriptions are valid for one year, unless state law provides for a greater time period. However, some online retailers may attempt to circumvent this rule by selling contact lenses in large volumes. For example, 1-800 CONTACTS allows consumers to purchase up to eight boxes of 1-DAY ACUVUE® TruEye® 90-day pack for each eye. An order of eight boxes of 90-day contacts for each eye provides 720 lenses per eye. Similarly, 1-800 CONTACTS allows consumers to purchase up to 24 boxes per eye of the 1-DAY ACUVUE® MOIST® 30 pack. Again, this provides a consumer with 720 lenses per eye.

Lens.com allows patients to order up to 50 boxes of Dailies AquaComfort Plus contact lenses per eye. With 90 lenses per box this results in the patient being able to order 4,500 lenses per eye (See Appendix A). Retailers who are able to sell nearly a two-year supply or more of lenses for a prescription that is likely valid for only one year can put the patient at risk, because many patients may experience a change in eye health and/or vision, develop complications that go untreated, or may have been counseled to stop wearing contact lenses. It's also possible that such large bulk purchases are being used by individuals seeking to illegally re-sell or distribute lenses to others, with no oversight. Imagine if such practices were common among online pharmacies. It's time to halt these practices in the contact lens market.

### **Needed Modification: Respecting and Enforcing Prescription Expirations**

One significant step we urge the FTC to take is to ban sellers from marketing to specific customers to reorder their lenses after the prescription has expired (more than one year after the issue date or when the customer originally ordered lenses from the seller) unless the seller has specific knowledge the customer's prescription is valid for more than one year. Surely the FTC does not intend for sellers to continue supplying contact lenses to consumers long after the prescription has expired. Yet surveys<sup>2</sup> and studies<sup>3</sup> find a large percent of consumers reorder contact lenses with expired prescriptions. The AOA believes an expired prescription is no longer a valid prescription, and that the FTC should take action against sellers who fill such reorders. A flaw to the prescription verification scheme created by the FCLCA is that a retailer can request verification of an otherwise expired prescription and can ship the lenses if the prescriber does not recognize within eight business hours that the expiration date has passed and inform the seller. Many patients have prescription changes from year to year. Allowing repurchases based on long-expired prescriptions may be, at the time, convenient for the patient and profitable for the seller, but increases the risk of patient harm. Patients might not have seen the prescriber in years, depriving them of a professional assessment of their eye health and the opportunity for education to reinforce proper lens wear and care habits, which have been shown to mitigate many potential adverse health effects. An expiration date and issue date are required elements of a prescription. The FTC should require the expiration date or issue date to be provided in prescription verification. This would incentivize sellers to make sure patients know their expirations when placing orders. The AOA believes sellers already know the prescription expiration as they often market to consumers to reorder in the final month or weeks that the prescription is valid. By including the prescription issue and/or expiration date in the verification, sellers would also be aware, nor could they deny, when they are using an invalid prescription. The prescription verification scheme should not be abused by sellers to knowingly push contact lenses to consumers with expired prescriptions, hoping the error is not noticed by whichever prescriber receives the verification request.

### **Needed Modification: Quantity Limits on Prescriptions**

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<sup>2</sup> APCO Insight August 2015 telephone survey among adult contact lens consumers 18 years and older on behalf of Johnson & Johnson Vision Care, Inc.

<sup>3</sup> Fogel J, et al., "Contact lenses purchased over the Internet place individuals potentially at risk for harmful eye care practices," *Journal of the American Optometric Association*, Vo. 79, No. 1, January 2008.

In the development of the Contact Lens Rule, the FTC contemplated whether there should be quantity limits noted on prescriptions. Ultimately, the Commission decided not to require the inclusion of the quantity of lenses or refills allowed on prescriptions. The Commission stated:

It is not necessary to include the quantity of lenses on the prescription to limit patients' ability to circumvent the expiration date. Section 315.5(b) requires verification requests to contain the quantity of lenses ordered, and as discussed below in section 315.5(d), the quantity ordered may be a legitimate basis for a prescriber to treat a request for verification of a prescription as "inaccurate." The verification process itself thus generally allows prescribers to prevent patients from ordering excessive contact lenses.

However, the verification process is not triggered when a patient provides a contact lens retailer with a complete copy of a prescription. More and more frequently retailers are encouraging consumers to use mobile technology to submit copies of prescriptions via email or by text message, bypassing the prescription verification process. The checks and balances the FTC anticipated when the Rule was first written do not function in many instances, to the detriment of consumers. The lack of physician involvement, coupled with retailers' ability to sell large quantities of contact lenses, could easily mislead consumers, giving them a false sense of security with regard to their eye health. Including a quantity limit on the prescription would be beneficial to patients' health and safety. This safeguard would help patients avoid painful eye infections and injuries that could seriously compromise the patient's vision. A quantity limit would also better underscore to consumers that contact lenses are regulated medical devices which can cause harm when misused.

#### **4. What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers?**

The AOA is concerned there is widespread public misunderstanding regarding the basic requirements of the Contact Lens Rule and the need for a prescription when buying and selling contact lenses. Despite the current requirements of the Rule, retailers continue to sell contact lenses without a prescription, which deceptively leads consumers to believe contact lenses are simple over-the-counter products. The AOA has identified 41 online contact lens retailers who we believe may be illegally allowing consumers to purchase contact lenses without a prescription (See Appendix B). Some retailers sell non-corrective, decorative lenses, while others sell corrective lenses. Regardless of the lens type, the FCLCA clearly states that contact lenses require a prescription and those who sell lenses without a prescription will be penalized: "Any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription." The AOA and its members have reported many of these retailers to the FTC in the past year, yet these retailers continue to sell lenses and continue to put the public at risk.

Contact lenses are regulated medical devices that are personally fit to each individual based on the patient's eye health needs. Therefore, it is critical the availability of contact lenses from a

wide range of retailers is not interpreted as an indication that contact lenses are simple products that don't require physician supervision.

While the AOA is not a regulatory enforcement entity, a central mission of the AOA is to serve as a resource to the public for reliable and current information related to eye care and health care policy. As such, AOA investigates our members' reports of retailers who are selling contact lenses without a prescription. The AOA took just this type of action when reports were received that Global Lens<sup>4</sup> was selling contact lenses without a prescription. As of June 30, 2015, Global Lens announced they would begin to require current prescriptions for all orders outside of Canada (See Appendix C). While this policy change is necessary, in the company's announcement of the change, the company also noted to consumers, "Now's your last chance to stock up!" The retailer also indicated "GlobalLens understands the disappointment this will cause many of our customers for which we're truly sorry."<sup>5</sup> This type of deceptive announcement from a retailer misleads and confuses consumers by portraying the eye exam and prescription as an inconvenience, such that consumers are encouraged to inappropriately "stock up" on lenses while they can. This is clearly not how a company should message a policy change which brings it into compliance with US law. This retailer's action is indicative of a larger problem with online retailers mischaracterizing the requirement for a prescription for contact lenses as an unnecessary burden, rather than a requirement to ensure safety.

1-800 CONTACTS similarly mischaracterizes the legal requirement for a valid prescription in voicemail messages to consumers when an order cannot be filled based on an expired prescription. The message to consumers indicates

This message is for [patient name]. This is 1-800 CONTACTS calling in regard to the order you recently placed with us. Unfortunately, your eye care provider listed on the account informed us that your contact lens prescription has expired. I am so sorry. We had to hold the order and for your convenience your card won't be charged. You may see a pending charge, but that falls off on its own after 3-10 business days. **We'd like to send your lenses out to you with free overnight delivery once your prescription is up-to-date but your eye doctor won't allow us to do that until you have an exam.** If you have any questions or once you get a new prescription please give us a call at any time.

This type of communication pits consumers against their physicians and does not accurately describe anti-competitive impact when an order is denied based on an expired prescription. A similarly misleading approach is used by Coastal.com which reports to patients the following:

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<sup>4</sup> <http://www.globallens.com>

<sup>5</sup> <http://www.globallens.com/blog/last-chance/>

**Please note:** Under the Fairness to Contact Lens Consumers Act, we are required to let you know that we didn't hear back from your eye care professional when we tried to verify your prescription. This means that, by law, we are allowed to process and ship your order. If we do hear from your eye care professional at a later time and there is an issue, we'll make sure to you let you know. No action is required on your part.

Thanks!

[Coastal.com](http://Coastal.com) Vision Care Team

This message from Coastal.com is inaccurate, as it suggests that the FCLCA requires retailers to communicate to patients when a doctor does not respond to a prescription verification. The way this is communicated to patients suggests some sort of lack of interest or compliance on the part of the physician. This message is also concerning because the form Coastal.com uses for verifying prescriptions does not include an option for physicians to indicate the prescription is accurate (See Appendix D). The AOA believes these types of deceptive messages to patients are purposefully misleading and intended to erode the doctor-patient relationship.

In addition to misleading business practices by large contact lens retailers, the AOA is also very concerned with individuals who hold themselves out as contact lens sellers. Since the FCLCA was passed, social media has evolved to play a huge role in American society. Social media sites allow individuals to become entrepreneurs, selling a variety of services and products. Of significant concern to the AOA is the use of social media to sell contact lenses. The AOA has identified several individuals who attempt to sell contact lenses through Facebook. Many of these individuals have been provided information regarding the legal requirement for a prescription when contact lenses are sold, but this has not impacted individual behavior. The AOA has engaged Facebook on this issue, citing Facebook's own policy of not allowing the sale of regulated goods through its website,<sup>6</sup> but to date we have received no response from the company and individuals appear to continue using Facebook as a safe haven to sell lenses without a prescription. As recently as September 22, 2015, one individual attempted to use Facebook to swap or sell "two unopened boxes (6 pack) acuvue oasis [sic] contact lenses -2.50." The individual wrote she had moved and couldn't return the lenses and wanted to sell them to another individual through Facebook. Other individuals attempt to sell decorative lenses and claim these lenses do not require a prescription (See Appendix E). There are also e-commerce sites, such as Groupon, that allow retailers to promote contact lenses through their sites and offer discounts to purchases. These advertisements will sometimes refer to the availability of "non-prescription" lenses (See Appendix F). Since all lenses require a prescription, this is entirely misleading to consumers. These types of blatant violations of the FCLCA must be stopped, and the AOA calls on the FTC to increase their enforcement of the current Contact Lens Rule.

It is clear there is widespread public misunderstanding regarding the basic requirements of the Contact Lens Rule and the need for a prescription when buying and selling contact lenses. This misunderstanding comes in part from the high prevalence of retailers who violate the requirements of the FCLCA in addition to lack of enforcement from the FTC. Public misunderstanding regarding the Rule exists despite efforts by the Food and Drug Administration

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<sup>6</sup> <https://en-gb.facebook.com/communitystandards#>

(FDA) and the Centers for Disease Control and Prevention (CDC) to notify the public of the need for a prescription when purchasing lenses. The FDA has specific guidance to consumers explaining that selling contact lenses as though they are over-the-counter devices both misbrands the device and is a violation of FTC regulations.<sup>7</sup> Additionally, for the past two years, the CDC has organized Contact Lens Health Week and specifically warned the public about purchasing lenses without a prescription and the need for appropriate contact lens care.<sup>8</sup> The U.S. Immigration and Customs Enforcement (ICE) National Intellectual Property Rights Coordination Center (IPR Center) has also coordinated a cross-agency effort to stop illegal contact lens sales called “Operation Double Vision.”<sup>9</sup> The FDA Office of Criminal Investigations (OCI), ICE Homeland Security Investigations (HSI) and U.S. Customs and Border Protection (CBP) have all partnered to seize counterfeit contact lenses, illegally imported decorative lenses, and lenses unapproved by the FDA. In 2014 alone, this collaboration resulted in more than 20,000 pairs of counterfeit and decorative contact lenses being seized.<sup>10</sup> Additionally, just this month, the U.S. Attorney’s Office carried out Operation ‘Fright Night’ to target retailers of cosmetic contact lenses that were being sold illegally without a prescription thereby putting the public at risk. Ultimately, ten businesses in Southern California had charges brought against them.<sup>11</sup> Others in Southern California were charged in Operation “Cats Eyes” in 2014. Unfortunately, these federal actions and public health information campaigns regarding the need for an appropriate prescription and proper contact lens care is lost on consumers when websites allowing consumers to purchase lenses without a prescription continue to proliferate. A lack of enforcement of the Rule allows deceptive information regarding the legal and regulatory requirements related to the sale of contact lenses to spread unchecked.

It’s also important to recognize that where a patient purchases their lenses may have an impact on the patient’s behavior. In a national online consumer opinion survey which targeted contact lens wearers, 63 percent of those surveyed indicated they would be more likely to follow FDA and doctor-recommended contact lens care recommendations when lenses were purchased from family eye doctors rather than from an online retailers.<sup>12</sup> Additionally, 61 percent of those surveyed indicated they would be more likely to routinely see an eye doctor for check-ups if lenses were purchased from family eye doctors, rather than from online retailers. Previously, studies found that contact lens consumers had less awareness<sup>13</sup> of and compliance<sup>14</sup> with recommended contact lens care. Allowing online retailers to misrepresent the necessary precautions that must be taken when using medical devices may lead to risky patient behavior when wearing and caring for contact lenses. It is also clear certain online retailers are attempting to damage the positive doctor-patient relationships many patients have by misrepresenting the role of the physician in the FCLCA.

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<sup>7</sup><http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm062347.htm>

<sup>8</sup> <http://www.cdc.gov/contactlenses/infographic-underwear.html>

<sup>9</sup> <http://www.ice.gov/news/releases/federal-agencies-warn-against-counterfeit-decorative-contact-lenses-0>

<sup>10</sup> <https://www.ice.gov/news/releases/federal-agencies-warn-against-counterfeit-decorative-contact-lenses-1>

<sup>11</sup> <http://www.justice.gov/usao-cdca/pr/operation-fright-night-targets-cosmetic-contact-lenses-are-illegally-sold-without>

<sup>12</sup> <http://www.americaseyedoctors.com/content.aspx?page=pressreleases>

<sup>13</sup> Wu, Y, et al., “Contact lens user profile, attitudes and level of compliance to lens care,” *Contact Lens & Anterior Eye*, 33 (2010) 183–188.

<sup>14</sup> Fogel J, et al. “Contact lenses purchased over the Internet place individuals potentially at risk for harmful eye care practices,” *Journal of the American Optometric Association*, Vo. 79, No 1, January 2008.

The AOA is also seriously concerned that over the past ten years 1-800 CONTACTS has been implementing various anti-competitive tactics to deceptively obtain patient consent to act as the patient's agent and obtain his or her contact lens prescription. While 1-800 CONTACTS has apparently ceased its recent practice of using of a pre-checked box on the bottom of the contact lens order form to attempt to obtain patient authorization, the AOA remains concerned additional deceptive practices may be implemented in the future in an effort to eliminate the physician entirely from the contact lens sale process. The AOA believes allowing retailers to unilaterally initiate a request to a physician for a copy of a customer's prescription, when that step is not needed in order to fill an order, is an abuse of the plain language of the FCLCA, not an intended result of its prescription release requirement and verification process. The FCLCA requires prescribers to provide the prescription to the patient and those designated by the patient (for example, a caregiver). If the law intended for sellers to step into the shoes of the patient and grab the prescription at any time, then the entire verification process would have been all but unnecessary. Instead, as we know, proper verification is crucial to protect patient's health and safety.

**5. What significant costs, if any, has the Rule imposed on consumers? What evidence supports the asserted costs?**

In 2014, the CDC reported Americans make an estimated 930,000 visits to outpatient clinics and 58,000 emergency room visits annually due to eye infections, and at least \$175 million in added health care costs were connected to keratitis—a typically preventable eye condition associated with improper contact lens use.<sup>15</sup> The AOA's members frequently care for patients who have experienced contact lens-related infections and complications. The eye care visits and treatments associated with these events is an increased cost to consumers. For example, the following incidents have been reported to the AOA:

- A doctor of optometry reported a patient purchased lenses through GlobalLens.Com, prior to the company's policy change to require a prescription. The patient was not only able to order lenses without a prescription, the patient was also able to purchase lenses that were different from what was originally prescribed. After experiencing discomfort with the lenses, the patient presented to the physician with a conjunctival abrasion.
- A doctor of optometry reported a patient presented with central corneal keratitis as a result of purchasing colored contact lenses at a market in Columbus, Ohio. The patient purchased the lenses without a prescription, received no physician guidance on appropriate wear of the lenses, and slept in the lenses for two months.
- A patient indicated to a doctor of optometry he had purchased contact lenses from 1-800 CONTACTS with a prescription from three years ago. The patient had severe corneal disruption, swelling, infiltrates and haze with reduced best-corrected vision. In addition to being treated with anti-inflammatories and antibiotics, the patient had to miss two days of work due to pain. Loss of work productivity, in addition to medical costs, must be considered when evaluating the overall costs.

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<sup>15</sup> <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a3.htm>

- A doctor of optometry reported two patients had purchased contact lenses from a local dollar store. One patient suffered acute red eye with a small peripheral corneal infiltrate acute and the other experienced keratoconjunctivitis.
- A doctor of optometry reported treating a patient who experienced a corneal ulcer after wearing lenses purchased at a beauty supply store.

All of these incidents threaten patients with permanent vision loss and require treatment that leads to increased health care costs and loss of productivity, which are a significant cost for consumers.

**6. What modifications, if any, should be made to the Rule to reduce any costs imposed on consumers? What evidence supports the proposed modifications? How would these modifications affect the benefits provided by the Rule?**

At a minimum, the basic patient safeguards outlined in the FCLCA must be enforced to protect patients and reduce unnecessary costs. Retailers should be punished for selling contact lenses without a valid prescription. Individuals who attempt to sell products via social media and the companies that host the social media sites must be informed of the legal requirements surrounding the sale of contact lenses and violators must be punished. As was noted above, steps must be taken to ensure retailers do not sell large quantities of contact lenses when that sale could compromise a patient's eye health. Additionally, more needs to be done so patients are aware regular eye examinations are essential to prevent harm and ensure optimal vision.

**7. What benefits, if any, has the Rule provided to businesses, including small businesses? What evidence supports the asserted benefits?**

The Internet facilitates an increasing number of contact lens retailers, which presumably is beneficial for those businesses, both large and small. However, while the Rule was intended to increase competition, the online contact lens market is dominated by one retailer. On July 30, 2014, during a hearing before the Senate Judiciary Committee's antitrust panel, R. Joe Zeidner, General Counsel for 1-800 CONTACTS, indicated his company controlled approximately three quarters of the online contact lens retail market.<sup>16</sup> So, while the FCLCA was intended to increase competition, an unintended anti-competitive consequence has been the emergence of one dominating online retailer.

**8. What modifications, if any, should be made to the Rule to increase its benefits to businesses, including small businesses? What evidence supports the proposed modifications? How would these modifications affect the costs the Rule imposes on businesses, including small businesses? How would these modifications affect the benefits to consumers?**

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<sup>16</sup> <http://www.judiciary.senate.gov/hearings/watch?hearingid=12e98234-5056-a032-52ea-90f98e940d9b> (minute 111)

To improve the Rule for small business, including the practices of doctors of optometry, the AOA requests the following:

- 1) FTC must no longer allow the use of robocalls for verifying patient prescriptions.
- 2) FTC should ban marketing reorders to consumers after prescriptions have expired, unless or until the seller has actual knowledge that the prescription has not expired, or an identical new prescription has been issued.
- 3) FTC should develop a distinct complaint submission process for contact lens-related concerns.
- 4) FTC should require the contact lens seller to respond to prescriber verification questions within eight business hours, or cancel the sale without verification.
- 5) FTC should state a preference for the use of an improved verification process by sellers instead of sellers requesting copies of actual prescriptions from customer's physicians as a way to verify a customer's order.

The FCLCA clearly allows sellers to use telephone, facsimile, or electronic mail for verifying prescriptions. However, in the development of the Contact Lens Rule, it was the FTC who interpreted this language to mean "automated telephone systems" or "robocalls" were acceptable forms of communication. The FTC did note the Commission would "monitor whether full, valid requests for verification of a prescription are being made through the use of automated telephone systems." The FTC went on to say, "If evidence demonstrates that sellers are not making valid verification requests but are providing consumers with contact lenses despite deficient requests, the Commission may revisit this issue." Over the past ten years, AOA has often received complaints from doctors of optometry that robocalls from 1-800 CONTACTS were difficult to understand or did not include all of the necessary information to confirm a prescription.

The use of robocalls to confirm the accuracy of a prescription, which includes specific numbers for strength, base curve and quantity, is far too complicated for an automated phone system. The FTC must revisit this issue and consider the Congressional and federal agency action that has been taken in the past ten years to better limit robocalls. Ideally, the AOA would like to see all prescription requests from retailers come in writing, either via fax or email. However, because the use of phone calls is allowable under the FCLCA, the AOA urges the FTC to, at a minimum, prohibit the use of robocalls and to ensure physicians who are confirming the accuracy of prescriptions for regulated medical devices are able to speak with a live person working for the seller. This would clearly benefit consumers because there would be a greater likelihood that prescription information was properly communicated. While 1-800 CONTACTS claims the phone verification provides "an absolutely consistent approach that conveys all of the required information, we use a system that works exactly the same—every time,"<sup>17</sup> we understand from doctors of optometry that, in practice, this is simply not true. Verification by robocall does not work.

The FCLCA allows telephone calls for prescription verification, but the law does not specify telephone communication must include automatic dialers. The AOA takes exception with the FTC's interpretation that telephone communication, "is commonly understood to include automated telephone systems." It's also more commonly understood automated telephone

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<sup>17</sup> <http://www.1800contacts.com/connect/articles/rx-verification-info>

systems are an abuse of telephone communication. The FTC previously indicated that disallowing robocalls would be against Congressional intent. However, as technology has evolved over the past ten years, so has the view of automated phone systems. The FTC has reported receiving as many as 200,000 complaints about robocalls every month, and as recently as August confirmed that it's the number one consumer complaint received by the FTC. Companies have been fined millions of dollars for inappropriate robocalls. In June, the Federal Communications Commission (FCC) cracked down on the use of robocalls and the FTC has specifically noted that robocalls are only acceptable in limited circumstances, such as for informational purposes.<sup>18</sup> The FCC had held contests and workshops to come up with ways to block robocalls. Why would the FTC want to allow them under the Contact Lens Rule? In testimony to Congress in June, Lois Greisman, FTC associate director of the Division of Marketing Practices, described robocalls as an epidemic, and acknowledged that telephone companies could legally use call-blocking technology to provide relief from such calls. Widespread use of such technology impedes the contact lens prescription verification process. It's time to specifically end the use of robocalls for verifying contact lens prescriptions.

The Rule indicates it is a requirement for the prescription verification request to include the name of a contact person at the seller's company. The AOA often hears from doctors of optometry who have difficulty reaching an individual at 1-800 CONTACTS to discuss prescription concerns. While the Rule notes the person whose name is provided on the verification form need not personally handle the verification, it is clear a contact person must be reasonably available for physicians. The company has trademarked its tagline boasting the company is "The World's Largest Contact Lens Store," with 350 customer service representatives, but they seem unable to provide one reliable contact who physicians can reasonably access.<sup>19</sup> This unfair practice places a burden on eye care professionals who seek crucial clarification or other information to facilitate the sale of contact lenses by a competitor. Ensuring that physicians have an individual to discuss concerns with would ultimately benefit patients and ensure the patient received the appropriate lenses. The AOA recommends the FTC require sellers to respond to prescriber concerns in the verification process within the same eight business hour expectation for prescribers to verify prescriptions. That is, when a seller contacts a prescriber to verify a prescription and the prescriber responds on a timely basis with a legitimate concern to discuss with the seller to enable verification, the seller may not assume the prescription is verified but instead must personally contact the prescriber and discuss the concerns within eight business hours, or cancel the sale.

Given the widespread non-compliance with the FCLCA noted throughout these comments, the AOA requests the FTC set up a specific complaint system for FCLCA-related concerns. The online complaint assistant service currently operated by the FTC is not appropriately set up to receive these types of complaints and doctors who take time out of their practices to report issues of concern often feel their reports go unnoticed by the FTC. Setting up a distinct FCLCA complaint system would be a benefit to patients as well, providing them with a simple process to follow in case they have contact lens sale-related concerns.

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<sup>18</sup> [http://www.consumer.ftc.gov/articles/0259-robocalls#Prerecorded\\_Calls](http://www.consumer.ftc.gov/articles/0259-robocalls#Prerecorded_Calls)

<sup>19</sup> <http://www.1800contacts.com/the-company.html>

Requests by sellers directly to physicians for copies of patient prescriptions should be disfavored. In virtually all instances in which a seller might request a copy of a customer's actual prescription, the seller could also use the established verification process. Verifications, while in need of improvement as described elsewhere in these comments, consume less physician and staff time than retrieving, copying, and transmitting a copy of the patient's actual prescription to sellers. The verification process also contains safeguards that requests for copies of prescriptions do not. Sellers would only need to request a copy of a prescription directly from the customer's physician when (i) the patient does not submit the prescription; and (ii) the patient is unable to provide any information about the prescription to the seller (e.g. from a copy of the prescription, personal notes, documentation from previous purchases, or a box of lenses currently being used) in order to permit use of the verification process. This combination of circumstances would reasonably be expected to be uncommon, and likely only occur at the time of the first purchase of contact lenses after a recent visit to the doctor when the prescription has been lost and the information on the prescription forgotten.

**9. What significant costs, if any, including costs of compliance, has the Rule imposed on businesses, including small businesses? What evidence supports the asserted costs?**

Physician small-business owners spend significant time responding to prescription verifications that are inaccurate or incomplete. Robocalls, which automatically redial until a message is broadcast to someone at a physician's practice, are a cost to businesses as this outreach often interferes with treating patients and can tie up phone lines needed for urgent patient matters. An inability to reach a contact person at a retailer is another cost to physician small businesses who may spend significant time on hold or attempting to use various phone numbers to reach a live person. The costs that physician small business owners expend related to the Rule are actually most often related to non-compliance on the part of retailers. If physician small business owners only received accurate prescription verification requests for lenses that were appropriately prescribed then there would be much fewer added costs such as those related to robocalls or an inability to appropriately reach contacts at retailers.

**10. What modifications, if any, should be made to the Rule to reduce the costs imposed on businesses, including small businesses? What evidence supports the proposed modifications? How would these modifications affect the benefits provided by the Rule?**

As noted in questions 8 and 9, eliminating robocalls, providing verifications in writing, prohibiting reorders of expired prescriptions, and requiring the prescription verification contact person at a retailer to discuss prescription concerns within eight hours would reduce the burden on the small business doctors of optometry.

As stated in response to Question 8, requests from sellers to physicians for copies of actual prescriptions consume more physician and staff time than responding to verifications, thereby adding to the cost of compliance with the Rule. Modifying the Rule to favor use of an improved verification process, whenever feasible, would save optometrist and staff time and not undermine any of the stated purposes and benefits of the Rule – in fact, it would enhance the patient safety purposes of the Rule by encouraging appropriate use of the verification process, which includes safeguards that enhance patient safety.

## 11. What evidence is available concerning the degree of industry compliance with the Rule?

It is clear there is wide spread non-compliance with several components of the Rule.

1. **Selling Lenses Without a Prescription:** There are many retailers selling contact lenses without a prescription when the Act and Rule “prohibit any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses from representing, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.” A listing of websites potentially violating this requirement is included below in Appendix B. These larger retailers violate the Rule along with individuals who attempt to sell contact lenses through websites such as Facebook, eBay, and Amazon.com.
2. **Selling Lenses With an Expired Prescription:** Consumers have acknowledged in several surveys or studies they often buy contact lenses after their prescription has expired. Some sellers ask customers to reorder lenses after the prescription has expired. An expired prescription is an invalid prescription, and sellers should not knowingly seek to verify an invalid prescription.
3. **Quantities of Lenses:** Retailers who allow patients to purchase large amounts of contact lenses beyond what is reasonably necessary for the duration of a prescription also violate the pro-competitive benefits of the Rule (See Appendix A) by restricting a patient to a single seller for potentially many years.
4. **Incomplete Robocalls:** While the AOA believes the Rule should no longer allow robocalls to be used to verify prescriptions, the Rule is clear in that “calls from automated telephone systems must fully comply with all applicable Rule requirements” just like calls that are not robocalls. The AOA often hears from doctors of optometry who indicate the information received via phone was not complete and did not provide sufficient information to verify a prescription.
5. **Lack of Retailer Contact Person:** While the Rule specifies retailers must have a contact person who is “reasonably accessible to the prescriber,” the AOA has received many reports from doctors of optometry that it is extremely difficult to get in contact with anyone at 1-800 CONTACTS to discuss problems with a patient’s order. Therefore the AOA strongly urges the FTC to require sellers to respond to prescriber verification questions within eight business hours and prior to any sale.
6. **Brand Switching:** While the Rule indicates a “seller may not alter a contact lens prescription,” the AOA has received reports from members that patients have been able to select lenses from online retailers other than those prescribed by their doctor.

## 12. What modifications, if any, should be made to the Rule to account for changes in relevant technology or economic conditions? What evidence supports the proposed modifications?

As is detailed above in questions 8-12, allowing the use of robocalls must be eliminated. This revision would account for changes in technology and an overall attitude shift regarding the use of automated phone calls that has occurred in the ten years since the Rule was drafted.

The AOA stands ready to assist the FTC in working towards the best and safest contact lens market for patients. We appreciate the opportunity to comment on this Rule. If you have questions or need additional information, please contact Rodney Peele, Associate General Counsel for Public Policy, at [rpeele@aoa.org](mailto:rpeele@aoa.org)

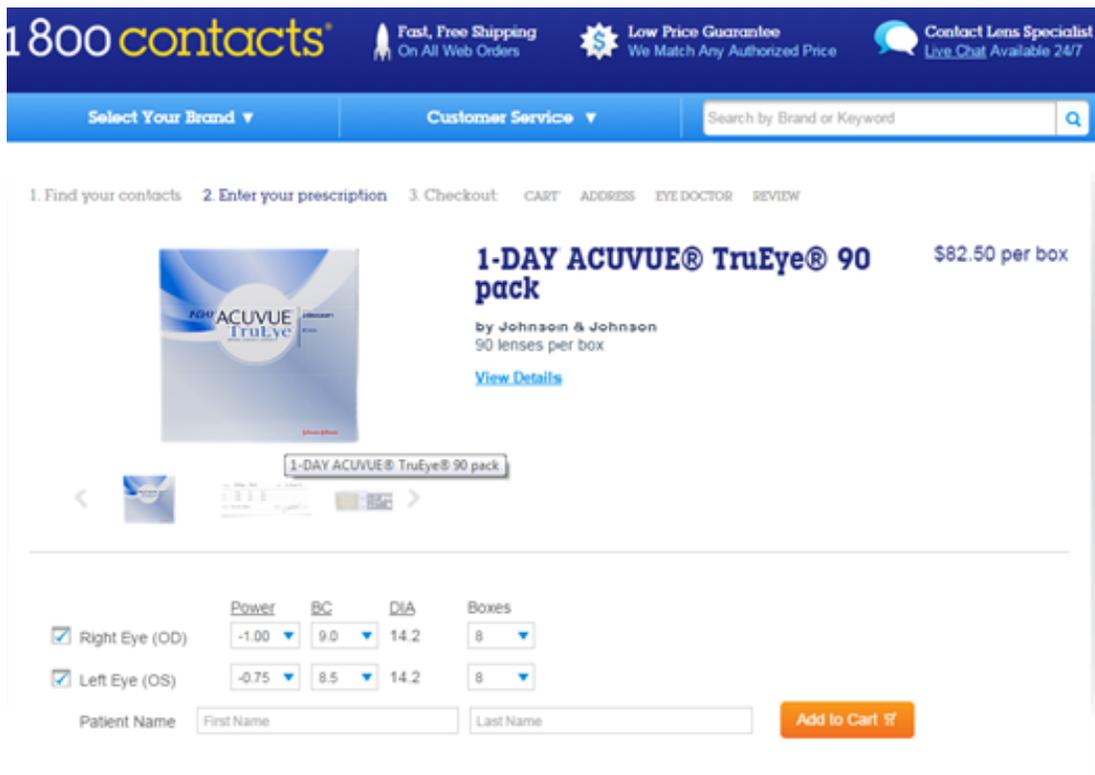
Sincerely,



Steven A. Loomis, O.D.  
AOA President

## APPENDIX A

### Retailer Quantities Available



The screenshot shows the product page for 1-DAY ACUVUE® TruEye® 90 pack on the 1800contacts.com website. The page includes a navigation bar with the company logo, shipping and price guarantees, and a search bar. Below the navigation bar, there are steps for finding contacts, entering prescriptions, and checkout. The main product area displays the product image, name, price (\$82.50 per box), and manufacturer (Johnson & Johnson). A 'View Details' link is provided. Below the product information, there is a form to select the number of boxes for the Right Eye (OD) and Left Eye (OS), with dropdown menus for Power, BC, and DIA. The form also includes fields for Patient Name (First Name and Last Name) and an 'Add to Cart' button.

	Power	BC	DIA	Boxes
<input checked="" type="checkbox"/> Right Eye (OD)	-1.00	9.0	14.2	8
<input checked="" type="checkbox"/> Left Eye (OS)	-0.75	8.5	14.2	8

Patient Name:  First Name  Last Name

1. Find your contacts 2. Enter your prescription 3. Checkout CART ADDRESS EYE DOCTOR REVIEW



**1-DAY ACUVUE® MOIST® 30 pack**

\$33.00 per box

by Johnson & Johnson  
30 lenses per box

[View Details](#)



<input checked="" type="checkbox"/> Right Eye (OD)	Power	BC	DIA	Boxes
<input checked="" type="checkbox"/> Left Eye (OS)	<input type="text"/>	<input type="text"/>	14.2	24
	<input type="text"/>	<input type="text"/>	14.2	24

Patient Name  First Name  Last Name

Add to Cart

Home > Contact Lenses > CIBA Vision > Daily Disposable > Dailies AquaComfort Plus Contact Lenses

**Dailies AquaComfort Plus Contact Lenses**

As Low As: **\$39.99 per box**  
 Manufacturer: [CIBA Vision](#)  
 Type: Daily Disposable  
 Contains: 90 Lenses per Box  
[Email to a Friend](#) [FSA Eligible](#)

**BUY MORE SAVE MORE!**  
**Buy 3+ @ \$39.99 per eye @ \$39.99 per box**  
**LOWEST PRICE GUARANTEE!**



Roll Over Image to Magnify | Click for Larger Image

Like 0 Tweet 0 +1 1

**Enter Prescription** [Can't find your prescription? It's on the side of the box!](#)

	Quantity	Base Curve	Diameter	Power	Price per Box (as low as)
Right Eye (OD)	50 Boxes ▾	8.7	14.0	Select ▾	\$39.99
Left Eye (OS)	50 Boxes ▾	8.7	14.0	Select ▾	\$39.99
Lens Solutions	Add biofresh Multi-Purpose Solution Bottles: Select ▾				\$0.00



Add to Cart

## Appendix B

### Retailers Selling Lenses without Prescriptions

[www.9mmsfx.com](http://www.9mmsfx.com)  
<http://www.aalens.com/>  
<http://www.angelcontacts.com/collections/circle-lenses>  
<http://www.boulonguise.com>  
<http://www.brilliantcontacts.com/>  
<https://www.buyingforbeauty.com>  
<http://candylens.com/>  
<http://circlelens2u.com/>  
<http://colorcontacts.silkfair.com/>  
<http://www.colorlens4less.com>  
<http://www.contactlenshouse.com/index.asp>  
<http://www.cosplayeyez.com/>  
<https://www.daysoftcontactlenses.com/US/Default.aspx>  
<http://e-circlelens.com/shop/main/index.php>  
[www.eyecandys.com](http://www.eyecandys.com)  
<http://www.geocolouredlenses.com/>  
<http://www.hollywoodcolorcontacts.com/index.php>  
<http://honeycolor.com>  
<http://www.iszocirclelens.com/>  
<http://klenspop.com/en/>  
<http://www.kawaiilovebeauty.com>  
<http://www.lensvillage.com/>  
<http://loveshoppingholics.com/>  
<http://magicangeleyes.com/>  
<http://maplelens.com/>  
<http://myeyecolors.com/>  
<http://ohmykitty.com/>  
<http://www.thedollyeye.com/store/circle-lenses/>  
[www.pinkyparadise.com](http://www.pinkyparadise.com)  
<http://www.pricessmartcontacts.com/>  
<http://rainbowcomplete.com/>  
<http://sandysaccessories.com/>  
<http://www.shellysdanceandcostume.com/accessory-products/color-contacts/>  
<http://shopcoloredcontacts.com/>  
[http://shop.playthingsmiami.com/CONTACT-LENSES\\_c6.htm](http://shop.playthingsmiami.com/CONTACT-LENSES_c6.htm)  
<http://www.shop.9mmsfx.net/main.sc>  
<http://thedollyeye.com/>  
<http://uniqso.com/>  
<http://www.whatlenses.com/>  
[http://www.yesstyle.com/en/beauty-circle-contact-lenses/list.html/bcc.11966\\_bpt.46](http://www.yesstyle.com/en/beauty-circle-contact-lenses/list.html/bcc.11966_bpt.46)  
[Saveonlens.com](http://Saveonlens.com)

# APPENDIX C

## GlobalLens Policy Change Announcement

[Home](#) > [Blog](#) > [Last Chance](#)

### LAST CHANCE

Posted on June 17, 2015

[G+](#) [Tweet](#) [Share](#) 5

**Effective June 30th, GlobalLens will require current prescriptions for all orders outside of Canada.**

In March of 2010, the Ministry of Health in the Province of British Columbia made sweeping changes to regulations regarding the sale of eyewear.

"With advances in technology and more consumers turning to the internet, it makes sense to modernize a decades-old system to give British Columbians more choice while maintaining public safety," Health Minister Kevin Falcon said in a new release.

The most significant changes to the regulations are:

- Allowing people to order glasses or contacts online without having to give the seller a copy of their prescription, sight-test assessment or contact-lens specifications.
- Allowing prescriptions issued by medical doctors and optometrists outside of the province to be filled within B.C.

The BC government says "There is no medical evidence to suggest the changes could impact people's health and says the new regulations will modernize eyewear sales."

Although our government believes it's an adult's right to decide what's best for their vision health, and allows us to fill prescriptions without the need to verify, it seems some countries including the US disagree, and have put lobbying pressure on us to conform by the end of June 2015.

#### Now's your last chance to stock up!

GlobalLens understands the disappointment this will cause many of our customers for which we're truly sorry. We also want to thank our customers for their continued patronage in the past, and we're looking forward to serving you for the years to come.

#### RECENT POSTS

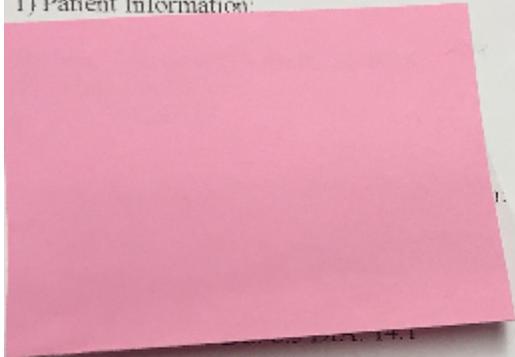
- » [Last Chance](#)
- » [GlobalLens Reviews](#)
- » [Alcon & Ciba Vision - Together as One](#)
- » [GlobalLens - Now Serving 60,000 Customers and Growing](#)
- » [GlobalLens Review](#)

**APPENDIX D**

**Fax Verification from Coastal Contacts**

The individual identified below has authorized Coastal to request that you verify his/her contact lens prescription pursuant to the Federal Trade Commission's Contact Lens Rule and the Fairness to Contact Lens Consumers Act. Please complete and return this form within 8 business hours if this prescription is expired, incorrect, or otherwise invalid. In absence of notification from you, or if you provide corrected prescription information, we will process the order. Completed forms can be returned to us by using our toll free fax number: 1-866-333-6810. You can also e-mail the completed form to [ccverification@coastal.com](mailto:ccverification@coastal.com) or call us at 1-866-333-6888, and our Vision Care team will be happy to assist you. If you return this form within 8 business hours to inform us that the prescription is expired, incorrect, or otherwise invalid, the patient will receive notification and the order will be held. It is Coastal's goal to dispense contact lenses based solely on valid prescriptions. Thank you in advance for your cooperation.

1) Patient Information:



3) If the prescription has expired, you may still approve a ONE-TIME ORDER (up to a maximum of a 3 month supply) by selecting the option below. If you elect to do so, Coastal will process a minimum supply of the order and notify the patient to contact you to schedule a new eye exam.

The patient's prescription has EXPIRED; please process a ONE-TIME ORDER and e-mail the patient to schedule a new eye exam.

4) Please select one of the following. No action is required if the prescription is currently valid.

The prescription information is INACCURATE. The correct prescription is:

OD: \_\_\_\_\_  
OS: \_\_\_\_\_  
Brand: \_\_\_\_\_

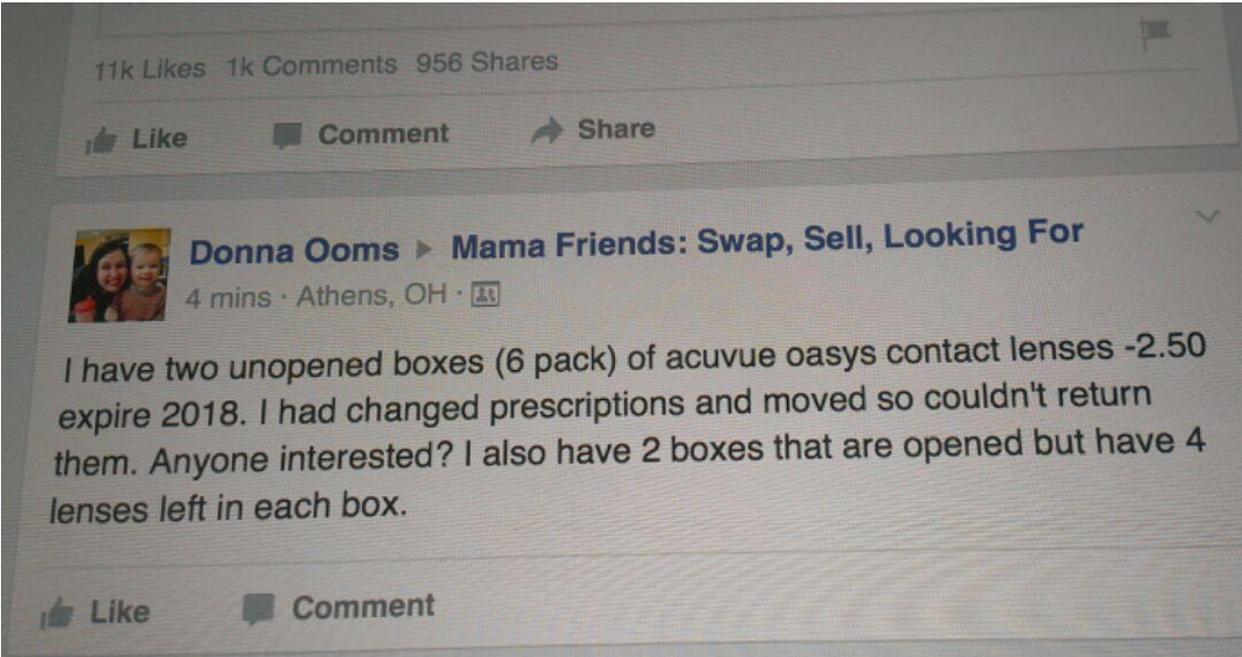
The person listed above is not a patient at this office.

The patient's prescription has expired.

Rx Issue Date: \_\_\_\_\_  
Rx Expiration Date: \_\_\_\_\_

APPENDIX E

FACEBOOK ADVERTISEMENT FOR CONTACT LENSES



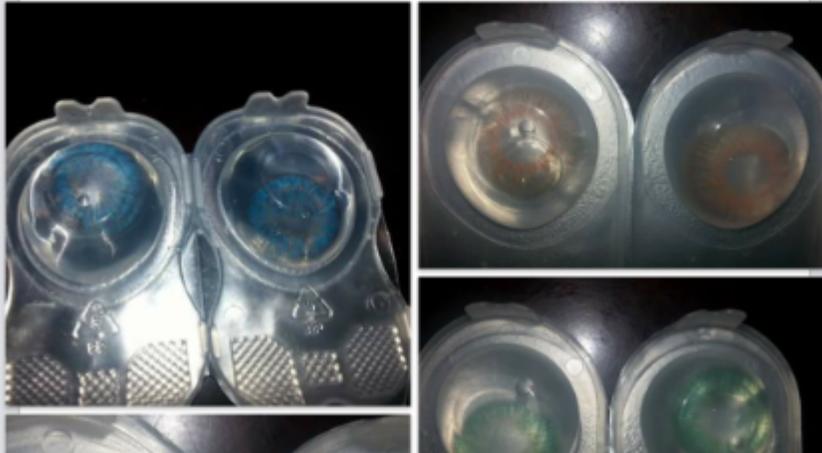
← Posts 🔍



**Crystal Ramos** ▶ **Stuff for sale in Albert Lea MN**

9 hrs Edited 📷

Summer is right around the corner now is the time to get your Non Prescribed Color Contacts Most of the colors I have are supper Bright Please dont comment unless your truly interested please Message me for more info Thank you Colors I have are True Sapphire Blue , Aqua , Violet, True Royal Blue ,Sun Brust Orange , Honey hazel, Gemstone Green , Eclipse Green , Gray im located in Austin but I sometimes go to Albert lea , Rochester ;)





Lee Anne ▶ Las Vegas Craigslist

2 hrs · 🌐

**Colors of the wind**

\$15 — 📍 Spring valley

No hate please keep your negativity to yourself. These are non prescription and for cosmetic fashion only

Annual usage so you can wear these for an entire year with proper care before you need to throw them out.

I have

Moonlight

Silver

Snow man

Sky

Milk violet

Pink mocha

Forest Green

Ice flower



## APPENDIX F

### GROUPON “Non-Prescription Contact Lenses”

The screenshot shows the Groupon website interface. At the top, there is a search bar and navigation links for 'St Louis', 'SEARCH', 'CART', 'HELP', 'SIGN IN', and 'SIGN UP'. Below the navigation, there are categories: 'Home', 'Local', 'Goods', 'Getaways', 'Clearance', 'Coupons', and 'Taste of Groupon'. The main section is titled 'Other Deals That Might Interest You' and features three deal cards:

- Deal 1:** 'Up to 76% Off Prescription Eyewear at SVS Vision Center'. It features an image of three pairs of glasses. Text: 'Over 5,000 bought', 'SVS Vision Center', 'Multiple Locations', '\$260 From \$69'.
- Deal 2:** '48% Off Fashion Accessories at Kings & Queens'. It features an image of jewelry. Text: 'Over 10 bought', 'Kings & Queens', 'Westland', '\$20 From \$11'.
- Deal 3:** '50% Off E-Cigarettes and E-Liquid at Ace of Vapes'. It features an image of e-cigarette bottles and a pen. Text: 'Over 10 bought', 'Ace of Vapes', 'Westland', '\$30 \$15'.

### One Pair of Non-Prescription Contacts in Halloween or Natural Colors at Rude Trendz (50% Off)

Westland



FROM  
**\$30**

NOT YET AVAILABLE

VALUE	DISCOUNT	YOU SAVE
\$60	50%	\$30

GIVE AS A GIFT

LIMITED QUANTITY AVAILABLE  
 Over 10 bought

SHARE THIS DEAL  
 Like

#### Choose Between Two Options

- \$30 for one pair of natural-colored non-prescription contact lenses (\$60 value)
- \$50 for one pair of Halloween non-prescription contact lenses (\$100 value)

#### In a Nutshell

Nonprescription contact lenses come in natural hues and in designs such as flowers and flames