

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. Most patients wear contact lenses to correct their vision while others choose them for cosmetic reasons. Younger patients and patients with eye disease might wear contacts for therapeutic reasons. For therapeutic patients, wearing contact lenses is not just the best option to attain functional vision; it is sometimes the only option. 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), 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 the law and Rule originally sought to address no longer exists. On the other hand, 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 that 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 that 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 develop regulations that are responsive to the major competitive issues that currently exist. When the rule was initially developed, the FTC grappled with certain subjects which we can now revisit using the knowledge we have gained over the past 10 years to improve the rule for patients.

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, but 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 with lack of enforcement the Rule is being manipulated by retailers for their own financial benefit as 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 (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). The authors also found that consumers recognize internet seller 1-800 CONTACTS as having the greatest availability. Internet sellers and discount brick-and-mortar retailers provide the most convenience, consumers reported. 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.

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 that 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 that contact lens consumers receive necessary eye examinations and instruction on appropriate lens 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 to the larger contact lens retailer community. Both large retailers and individuals who attempt to sell lenses through websites, such as Facebook, must be penalized in accordance with the FCLCA. 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 that the patient is sold, regardless of where the patient purchases the lenses. Retailers should not be

allowed to encourage patients to experiment with new lenses and potentially compromise their eye health. Additionally, although the passive verification system was delineated in statute, we believe there are serious flaws with this system and the AOA urges FTC to take steps to better ensure that 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 require that contact lens prescriptions include a maximum quantity of lenses that can be purchased prior to the prescription's expiration.
- 2) FTC should limit the number of contact lens boxes that retailers advertise as being able to be purchased at one time.

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 circumvent this rule by selling contact lenses in large volumes. For example, 1-800 CONTACTS allows consumers to purchase up to 8 boxes of 1-DAY ACUVUE® TruEye® 90 pack for each eye. An order of 8 boxes of 90-day contacts for each eye would provide 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 would provide 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 would result in the patient being able to order 4,500 lenses per eye (See Appendix A). Retailers who are able to sell nearly two years supply or more of lenses for a prescription that is likely valid for only one year can put the patient at risk, as many patients may experience a change in eye health, develop complications that go untreated, or 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.

Needed Modification: Respecting and Enforcing Prescription Expirations

In addition, some retailers market lens reordering after the 1-year prescription expiration. One significant step the FTC should take is to ban sellers from marketing to specific customers to reorder their lenses after the prescription has expired, or more than 1 year after the customer originally ordered lenses from the seller, unless the seller has specific knowledge that 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. 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 8 business hours that the expiration date has passed and inform the seller. Most patients have prescription changes from year to year, and allowing repurchases based on long-expired prescriptions increases the risk of patient harm solely for the convenience of the consumer and the profits of

sellers. Patients might not have seen the prescriber in years, allowing eye health risks to manifest and fester. The patient might even be seeing a different doctor, and the previous prescriber is still the only party obligated to stop an improper sale. The 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 based on the marketing 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 that they are not using a valid prescription.

Needed Modification: Quantity Limits on Prescriptions

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 that the FTC anticipated when the Rule was first written do not function in many instances, to the detriment of consumers. That 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 that 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 that contact lenses are simple over the counter products. The AOA has identified 41 online contact lens retailers who illegally allow consumers to purchase contact lenses without a prescription (See Appendix

B). Some retailers sell non-corrective, decorative lenses, while others, such as SaveonLens and Daysoft, 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 that the availability of contact lenses from a wide range of retailers is not misinterpreted 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 Lens¹ 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."² This type of deceptive announcement from a retailer 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 them 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 their voicemail messages to consumers when an order cannot be filled based on an expired prescription. The message to consumers indicates

This message is for X, this is 1-800 CONTACTS calling in regard to the order you recently place 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.

¹ <http://www.globallens.com>

² <http://www.globallens.com/blog/last-chance/>

This type of communication pits consumers against their physicians and does not accurately describe the 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:

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](#) Vision Care Team

This message from Coastal.com is misleading 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 that 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 at contact lens sellers. Since the FCLCA was passed, social media has evolved into a huge role in American society. Social media sites, such as Facebook, allow individuals to become entrepreneurs selling a variety of services and products. Of significant concern to the AOA is the use of Facebook 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 their website,³ but to date we have received no response from the company and individuals continue to attempt use 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 oasys contact lenses -2.50." The individual noted 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 that 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 site 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.

³ <https://en-gb.facebook.com/communitystandards#>

It is clear that 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 (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.⁴ Additionally, for the past two years, the CDC has organized National Contact Lens Health Week and specifically warned the public about purchasing lenses without a prescription and the need for appropriate contact lens care.⁵ However, this information regarding the need for an appropriate prescription and proper contact lens care is lost on consumers when websites which allow 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 Food and Drug Administration and doctor-recommended contact lens care recommendations when lenses were purchased from family eye doctors rather than from an online retailer like 1-800 CONTACTS, Vision Direct, Coastal Contacts, or Lens.com.⁶ 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 the online retailers noted above. The survey also found that there may not only be a connection between where lenses are purchased and patient behavior but those surveyed were also far more satisfied with their health care providers than with online retailers. 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 that certain online retailers are attempting to damage the positive doctor-patient relationships that many patients have by misrepresenting the role of the physician in the FCLCA.

The AOA is also seriously concerned that over the past 10 years 1-800 CONTACTS has been implementing various anti-competitive tactics in an effort to deceptively obtain patient consent to act as the patient's agent to obtain the patient's contact lens prescription. While 1-800 CONTACTS has ceased its most 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 that 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 that allowing retailers to unilaterally initiate a request to a physician for a copy of a customer's

⁴<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm062347.htm>

⁵ <http://www.cdc.gov/contactlenses/infographic-underwear.html>

⁶ <http://www.americaseyedocors.com/content.aspx?page=pressreleases>

prescription when that step is not needed in order to fill an order is an abuse of the plain language of the Fairness to Contact Lens Consumers Act, 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've learned, proper verification is crucial to competition that protects patient's health and safety.

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

While contact lenses are generally safe and effective medical devices, there is a widespread public misunderstanding regarding the need for appropriate care of lenses and physician oversight when using contact lenses. The AOA has received many reports from doctors of optometry related to patient complications due to contact lens wear. Often these cases occur when the patient has purchased lenses from an online retailer or from a retailer who does not require a prescription.

In 2014, the CDC reported that annually Americans make an estimated 930,000 visits to doctor's offices and outpatient clinics, 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 infection associated with improper contact lens use.⁷ 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 that 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 that 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, had received no physician guidance on appropriate wear of the lenses, and had been sleeping in the lenses for two months.
- A doctor of optometry reported that a patient indicated 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.

⁷ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a3.htm>

- A doctor of optometry reported that 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.
- A doctor of optometry reported treating a patient who had not had an eye exam in 4 years and had been wearing contact lenses during that time period. The patient presented with vision pinholes, diffuse superficial punctate corneal staining bilaterally, diffuse corneal infiltrates, and corneal neovascularization.

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 that a 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 that patients are aware that regular eye examinations are not an unnecessary inconvenience, but 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 has facilitated an increased the 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 that his company controlled approximately three quarters of the online contact lens retail market.⁸ So, while the FCLCA was intended to increase competition, an unintended consequence has been the emergence of one dominating online retailer.

⁸ <http://www.judiciary.senate.gov/hearings/watch?hearingid=12e98234-5056-a032-52ea-90f98e940d9b> (minute 111)

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?

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

- 1) FTC should 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 that the prescription has been renewed.
- 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 8 business hours, or cancel the sale without verification.
- 5) FTC should state a preference for the use of an improved verification process by sellers vs. sellers requesting copies of actual prescriptions from customer's physicians as a way to verify a customer's order.

The FCLCA clearly indicates that for verifying prescriptions, telephone, facsimile, or electronic mail are all allowable. However, in the development of the Contact Lens Rule, it was the FTC that interpreted this language to mean that "automated telephone systems" or "robocalls" were acceptable forms of communication. The FTC did note that 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 10 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 10 years to better regulate robocalls. Ideally, the AOA would like to see all prescription requests from retailers come in writing, either via fax or email. However, as 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 that physicians who are confirming the accuracy of prescriptions for regulated medical devices are able to speak with a live person. This would clearly benefit consumers as there would be a greater likelihood that prescription information was properly communicated. While 1-800 CONTACTS claims that 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,”⁹ we understand from doctors of optometry that, in practice, this is simply not true.

The FCLCA allows telephone calls for prescription verification, but the law does not specify that 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 commonly understood that automated telephone systems are an abuse of telephone communication. The FTC indicated it would be against congressional intent to disallow robocalls. However, as technology has evolved over the past 10 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 1 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.¹⁰ 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 could impede the contact lens prescription verification process. It's time to specifically end the use of robocalls for verifying contact lens prescriptions.

The Rule indicates that 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 that have difficulty reaching an individual at 1-800 CONTACTS to discuss prescription concerns. While, the Rule notes that the person whose name is provided on the verification form need not personally handle the verification, it is clear that a contact person must be reasonably available for physicians. The company has trademarked their tagline boasting the company is "The World's Largest Contact Lens Store," with hundreds of customer service representatives, but they seem unable to provide one reliable contact who physicians can reasonably access. 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 that 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 8 business hour expectation for prescribers to verify prescriptions. That is, when a seller contacts a prescriber to verify a prescription and the prescriber has a legitimate concern to discuss with the seller to enable verification, then the seller may not assume the prescription is verified but instead must personally contact the prescriber within 8 business hours, or cancel the sale.

Given the widespread non-compliance of the FCLCA noted throughout these comments, the AOA requests that the FTC set up a specific complaint system for FCLCA related concerns. The

⁹ <http://www.1800contacts.com/connect/articles/rx-verification-info>

¹⁰ http://www.consumer.ftc.gov/articles/0259-robocalls#Prerecorded_Calls

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 that their reports go unnoticed by the FTC. Setting up a distinct FCLCA complaint system would be a benefit to patients as well because they would have a simple process to follow if they had contact lens sale related concerns.

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 its customer's actual prescription, the seller could also use the 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 that may be 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 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 there would be no added costs 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? a. What evidence supports the proposed modifications? b. 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 8 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 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 that there is wide spread non-compliance with several components of the Rule.

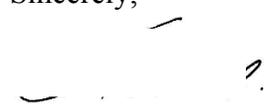
1. **Selling Lenses Without A Prescription:** There are many retailers that sell contact lenses without a prescription when despite the Act and Rule “would prohibit any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses from representing, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.” A listing of websites potentially violating this aspect 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. **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 violates the pro-competitive benefits of the Rule (See Appendix A) by restricting a patient to a single seller for potentially many years.
3. **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 that the information received via phone was not complete and did not provide sufficient information to verify a prescription.
4. **Lack of Retailer Contact Person:** While the Rule specifies that retailers must have a contact person that 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. Therefore the AOA strongly urges the FTC to require sellers to respond to prescriber requests within 8 business hours.
5. **Brand Switching:** While the Rule indicates that 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 change would account for changes in technology and an overall attitude shift regarding the use of automated phone calls that has occurred in the 10 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

Sincerely,


Steven A. Loomis, O.D.
AOA President

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