IOWA OPTOMETRIC ASSOCIATION

October 22, 2015

Donald S. Clark
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW.
Suite CC–5610 (Annex C)
Washington, DC 20580

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

The Iowa Optometric Association (IOA) represents 460 doctors of optometry in the state of Iowa. The IOA represents its members in the areas of professional development, continuing education, third party and government affairs. We appreciate this opportunity to offer comment on the Contact Lens Rule.

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

The Contact Lens Rule (the Rule) is required by statue, the Fairness to Contact Lens Consumers Act (FCLCA). Congress intended the law to enhance competition in the market for contact lenses by creating a federal right of patients to receive their contact lens prescriptions from their eye doctors, and establishing a process for contact lens sellers to verify the prescriptions of lenses ordered by consumers. However, as regulated medical devices that require a prescription from an optometrist or ophthalmologist, contact lenses have always been subject to government oversight. In its role, the Federal Trade Commission should seek to enhance competition in the fair and appropriate delivery of contact lenses to consumers. While most of the provisions of the Rule are required by the text of the FCLCA, the FTC should ensure that competitive practices designed for unregulated products do not undermine or elude critical contact lens patient safety protections. In other words, since the Rule must be maintained and many of its terms are proscribed by statute, moving forward the FTC should focus its efforts to enhance competition that best serves the interests of patients. Too often in the last decade, the FTC has silently allowed some sellers to gamble with patient health at the expense of innovation, improved safety, and other desirable results of competition. The FTC should not allow sellers to deceive patients in the single-minded pursuit of sales. The FCLCA provides rights to patients, so, ultimately, the Rule should protect patients with common sense safeguards.

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

Consumers benefit from the Rule by receiving their contact lens prescriptions from their eye doctors, and by having their prescriptions verified when they order contact lenses. It is our

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understanding that consumers have benefited from a wide selection of innovative products that are prescribed by their eye doctor, allowing more of our patients the option to use contact lenses for their vision needs. However, patients don't benefit when their eye health is sacrificed by unscrupulous sellers. The IOA fully supports the existence of a robust contact lens marketplace, but believes competition is most beneficial when consumer safety is one of the market features. Until all sellers compete on patient safety, the FTC's lack of enforcement is more beneficial to sellers than to patients.

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?

To improve the Rule for consumers, the IOA requests the following:

1) The Federal Trade Commission (FTC) should prohibit the sale of contact lenses with an expired prescription. An expired prescription should be seen as an inherently invalid prescription. The FCLCA established that a prescription is required, and that eye doctors should verify those prescriptions.
2) The FTC should require that contact lens prescriptions include a maximum quantity of lenses that can be purchased prior to the prescription's expiration.
3) The FTC should limit the number of contact lens boxes that can be purchased from a retailer at one time. The amount should not exceed the maximum quantity noted on the patient's prescription.

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

Despite the Rule's requirements, retailers continue to sell contact lenses without proper prescriptions or prescription verification, which deceives consumers into believing that contact lenses are simple over–the-counter products. The proliferation of contact lens retailers over the past ten years has unfortunately resulted in the emergence of certain sellers who attempt to circumvent the FCLCA patient protections and are focused on profits and the number of contact lenses they can sell. Contact lenses are regulated medical devices that require professional supervision and care to mitigate the risks of misuse. One of the main complaints we receive from members is an automated robocall which leaves a message after business hours attempting to verify an often invalid prescription. If the optometrist doesn't return the call within eight hours it's deemed a valid prescription by the retailer and dispensed. Our understanding is the doctors have eight business hours and this appears to be in violation of the law.

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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, we are concerned that there is a widespread public misunderstanding regarding the need for appropriate care of lenses and physician oversight when using contact lenses. In 2014, the Centers for Disease Control and Prevention (CDC) reported that annually Americans make an estimated 930,000 visits to doctors' offices and outpatient clinics and 58,000 emergency room visits annually due to eye infections, adding $175 million in health care costs connected to keratitis—a typically preventable eye infection associated with improper contact lens use.[1] Our 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.

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, which increases risks for the patient and ultimately leads to higher health expenses. 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. The FTC should prevent the sale of large quantities of contact lenses when that sale could compromise a patient's eye health. Additionally, more needs to be done to ensure that patients are aware that contact lenses are regulated medical devices, whose safe use and optimal performance depends on eye examinations and professional supervision.

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

Although the Rule was intended to increase competition, the online contact lens market is dominated by one large business. 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.[2] So, while the FCLCA was intended to increase competition, an unintended 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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[1] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a3.htm

[2] 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 IOA requests the following:

1) FTC should no longer allow the use of robocalls for verifying patient prescriptions. This would protect thousands of small businesses from these disruptive calls which, too often, communicate incomplete information or are difficult to understand.
2) FTC should require that for larger contact lens retailers, the retailer must make available more than one individual at a company to act as the contact person for physician questions and concerns.
3) FTC should develop a distinct complaint submission process for contact lens related concerns.

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 fully communicated to someone at a physician's practice, are a cost to businesses as it often interferes with treating patients and can tie up phone lines that may be needed for urgent patient matters. An inability to reach a human at a large contact lens retailer is another cost to physician small businesses who may spend significant time on hold or attempting to use various phone numbers or automated prompts 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, 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?

Eliminating robocalls, providing verifications in writing, and requiring more than one contact person at a retailer to be available to discuss prescription concerns would reduce the burden on the small businesses of doctors of optometry.

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

1. **Selling Lenses Without A Prescription**: Retailers deem a prescription valid if the prescribing doctor hasn't responded within eight hours, not eight business hours. Robocalls are often placed at night or on weekends when the doctor has no chance of a timely response.
2. **Quantities of Lenses**: We've seen several cases where multiple boxes of contact lenses have been sold to the consumer just prior to their prescription expiring.

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3. **Incomplete Robocalls**: It often takes multiple robocalls to complete the request which requires additional doctor or staff time to retrieve.
4. **Lack of Retailer Contact Person**: Members have expressed frustration about not being able to speak to a retailer contact person directly.
5. **Brand Switching**: No specific examples

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?

The use of robocalls must be banned. This change would account for changes in technology and an overall shift in public opinion regarding the use of automated phone calls that has occurred in the 10 years since the Rule was drafted.

13. Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how? What evidence supports the asserted conflicts? With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not?

We do not anticipate the Rule conflicting with current Iowa statute.

Thank you for the opportunity to comment on this important issue. If you need additional information, please contact me at our state association office.

Sincerely,

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