

October 19, 2015

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

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

The Wisconsin Optometric Association (WOA), a professional association representing over 630 licensed doctors of optometry in Wisconsin, would like to submit the following comments regarding the Contact Lens Rule.

The Contact Lens Rule required by the Fairness to Contact Lens Consumers Act (FCLCA) created a federal right of patients to receive their contact lens prescriptions. In Wisconsin, state lawmakers passed a similar prescription release law ten years ago, just prior to enactment of the federal law. Both the state and federal laws recognize that as a regulated medical device, contact lenses require a valid prescription from a licensed optometrist or ophthalmologist. The WOA believes the FTC should continually strive to enhance competition in the fair and appropriate delivery of contact lenses to consumers. Additionally, we believe the FTC should ensure that competitive practices designed for unregulated products do not undermine or elude critical contact lens patient safety protections. We are concerned that over 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. We further believe 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.

Consumers benefit from this 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 understanding that consumers have benefited from a wide selection of innovative products that are prescribed by their eye doctor, allowing more patients the option to use contact lenses for their vision needs. However, patients do not benefit when their eye health is sacrificed by unscrupulous sellers. The WOA 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, any lack of enforcement is more beneficial to sellers than to patients.

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

- 1) The Federal Trade Commission (FTC) should decisively prohibit the sale of contact lenses, if the prescription has expired. This protection has been a requirement under Wisconsin's optometry practice act for the last 25 years and should be a cornerstone to the federal law as well. 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.

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

While contact lenses are generally safe and effective medical devices, the WOA is 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 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.<sup>1</sup> WOA 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.

Each year in Wisconsin, especially during Halloween, the WOA receives reports from our member doctors of patients who they have seen with infections and other eye injuries resulting from the purchase of contact lenses without a prescription. Again, all of these incidents require treatment that leads to increased health care costs and loss of productivity, which are a significant cost for consumers.

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 patients are aware that contact lenses are regulated medical devices, and safe use and optimal performance depends on eye examinations and professional supervision.

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.<sup>2</sup> Therefore, while the FCLCA intended to increase competition, an unintended consequence has been the emergence of one dominating online retailer.

To improve the Rule for small business, including the practices of doctors of optometry, the WOA 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.

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<sup>1</sup> <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a3.htm>

<sup>2</sup> <http://www.judiciary.senate.gov/hearings/watch?hearingid=12e98234-5056-a032-52ea-90f98e940d9b> (minute 111)

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 they often interfere with treating patients and can tie up phone lines that may be needed for urgent patient matters. An inability to reach a human person at a large contact lens retailer is another cost to physician small businesses that may spend significant time on hold or attempting to use various phone numbers or automated prompts 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, there would be no added costs related to robocalls or an inability to appropriately reach contacts at retailers.

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.

Therefore, we believe 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 ten years since the Rule was drafted.

Thank you for the opportunity to comment on this important issue. If you need additional information, please contact Mr. Peter Theo, Executive Vice President of the Wisconsin Optometric Association.

Sincerely,

Peter Theo  
WOA Executive Vice President