California Optometric Association

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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

Dear Mr. Clark,

The California Optometric Association (COA) represents doctors of optometry across the Golden State. The mission of COA is to support and advance the profession of optometry to assure quality health care for all Californians. COA appreciates this opportunity to offer comment on the Contact Lens Rule (the Rule).

The Rule and the Fairness to Contact Lens Consumers Act (FCLCA) were intended to enhance competition in the market for contact lenses by creating a federal right of patients to receive a copy of 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. Too often in the last decade, the FTC has silently allowed some sellers to game the system through the use of the passive verification system - in some instances putting the patients' sight in jeopardy.

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. Contact lenses are regulated medical devices that require professional supervision and care to mitigate the risks of misuse and its affiliated health care costs.

Consumers' eye health is put at risk by unscrupulous companies seeking to maximize sales. The distribution of contact lenses without the supervision of an eye care professional results in patient harm. Individuals can suffer from vision and other health complications stemming from the improper use of optical prescriptions. All of these incidents require treatment that leads to increased health care costs and loss of productivity, which are a significant cost for consumers.

While contact lenses are generally safe and effective medical devices, COA is concerned that there is widespread public misunderstanding regarding the need for appropriate care of lenses and doctor 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.[1] COA's members frequently care for patients who purchased lenses from contact lens sellers that subsequently resulted in contact lens-related infections and complications. The preventable eye care visits and treatments associated with these events are an increased cost to consumers.

[1] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a3.htm

In order to protect the public's eye health, COA urges the FTC to strengthen the Rule in the following ways:

1. **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. Require that contact lens **prescriptions include a maximum quantity of lenses** that can be purchased prior to the prescription's expiration.
3. **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. **Prohibit sellers from sending prescription verifications after business hours and on weekends**. Sellers frequently fill unverified prescriptions because the prescriber has not had eight business hours to respond due to his or her practice being closed at these times.
5. **Prohibit the use of robocalls** for verifying patient prescriptions. The calls are often too long and confusing. Robocalls, which automatically redial until a message is fully communicated to someone at a health care provider's practice, provide no opportunity for seller-doctor dialogue and can tie up phone lines that may be needed for urgent patient matters.
6. 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 optometrist questions and concerns.
7. **Develop a distinct complaint submission process** for contact lens-related concerns.
8. **Replace the passive verification system with an <u>active verification</u> model**. In the U.S., we utilize an active verification system for prescription drugs for the safety of patients. Contact lenses are medical devices. Therefore, it is reasonable to replace passive verification with active verification for contact lenses.

Consumers' eye health is put at risk by unscrupulous companies seeking to maximize sales. Therefore, COA strongly urges the FTC to bolster the Rule to protect the public. Thank you for the opportunity to comment on this important issue.

Sincerely,

David Redman, OD
Chair, Legislation and Regulation Committee
California Optometric Association