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

Re: FTC Workshop & Contact Lens Rule

The American Academy of Ophthalmology is writing to provide our comments on proposed changes to the Contact Lens Rule (CLR) and the recent Federal Trade Commission Workshop on the CLR. The American Academy of Ophthalmology is the largest national member's association of ophthalmologists—medical and osteopathic doctors who provide comprehensive eye care including medical, surgical, and optical care. The Academy seeks to protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public.

Since 2015, the Academy has engaged with the FTC on its review of the CLR, its proposed changes to the CLR, and most recently the Commission's Workshop on the issue. The Academy is a firm believer in the benefits that have been gained by consumers through the issuance of the CLR. We fervently support our patient's right to a copy of their prescription and a robust marketplace for consumers to shop for affordable lenses. The Academy has sought improvements to the Contact Lens Rule that would ensure and protect patient eye health These improvements include strengthening communication between prescribers and sellers and cracking down on those selling contact lenses without a prescription. We believe that these suggestions align with the initial intended purpose of the review of the CLR, specifically to identify ways the Rule could be improved.

Unfortunately, it has become increasingly clear to the Academy that the review of the CLR has diverged into an effort by sellers to de-regulate the contact lens marketplace and hoist undue blame onto those in the prescriber community. As it stands, we do not believe that the Commission has promoted any policy change or considered anything that will strengthen or improve the CLR. Instead, this review has served only to promote tension between the seller and prescriber communities. The following comments outline, re-assert, and clarify our positions on proposed changes to the CLR and ideas discussed at the recent FTC Workshop.

Proposed Patient-Prescription Acknowledgement Form

In previous comments to the FTC, the Academy has stated that it does not support the proposed patient-prescription acknowledgement form. The Commission has informed stakeholder groups, including the Academy, that the proposal is due to extensive failure by prescribers to release prescriptions to their patients. Despite this view by the Commission, we

remain unaware of issues with ophthalmologists failing to release prescriptions to patients, as required under the Fairness to Contact Lens Consumers Act (FCLCA). The Academy hoped that the recent FTC Workshop related to the CLR would include discussion of the existing evidence that underscored the extent of the prescription release problem. Instead, the Academy learned that the FTC did not have extensive evidence of non-compliance by prescribers. Instead, FTC staff told attendees that they had a "feeling" that the small number of complaints received reflected "just the tip of the iceberg."

One of the continual messages coming out of the FTC since 2015 was that changes to the CLR would be evidence-based, not anecdotal or based on the opinions of stakeholders. The Academy is very concerned that proposed changes to the Contact Lens Rule are not supported by evidence but rather the speculative feeling at the Commission. This concern is on top of previously mentioned concerns that FTC's policy proposal is nearly an exact copy of a proposal by contact lens seller organizations during the initial review period in 2015. It is the Academy's viewpoint that the Commission should honor their stated principles that changes to the rule would be evidence-based. It is our opinion that evidence should not include industry-sponsored surveys, seeking a specific result, to propel a specific narrative for their benefit.

To reiterate, the Academy supports the right of each patient to receive a copy of their prescription, ensuring their ability to comparison shop for contact lenses in an open marketplace. Our members have diligently complied with this component of the Rule since 2004 and we remain unaware of compliance issues among the ophthalmic community. If the Commission is unable to provide evidence of non-compliance among ophthalmologists, we see no reason why the policy should be finalized.

Contact Lens Examination Recommendations

The FTC's recent workshop on the "Contact Lens Rule and Contact Lens Marketplace" included discussion about how often patients needed to see their physician or eye-care provider for follow up contact lens examinations. The Academy's recommendation is that contact lens wearers should have a contact lens examination every 1 to 2 years. This recommendation is found in the Academy's Refractive Error & Refractive Surgery Preferred Practice Pattern.

It is important to note that our recommendation on contact lens examinations differs from our recommendation reflected in our Comprehensive Adult Medical Eye Evaluation Preferred Practice Pattern. That recommendation is specific to adult, asymptomatic patients, who do not have risk factors for eye disease. Contact lens wear is a risk factor for blinding corneal infections. We were disappointed to hear our recommendation for contact lens examinations be misrepresented at the FTC Workshop not only by a panelist but also by FTC staff.

Contact lens wearers should have a contact lens examination every 1 to 2 years for many reasons including to check for adverse effects of contact lens wear, to review fit and to discuss proper contact lens wear and care practices.

Position on Proposals to Lengthen or Eliminate the Expiration of CL Prescriptions

The Academy was dismayed to hear viewpoints shared at the FTC workshop that promoted the idea of contact lenses being sold out of vending machines and disputing the need for prescriptions or definitive guidelines around contact lens use. While we understand that entities that sell contact lenses, and consumer groups that align with those entities, may want

to see broader consumption or purchase of contact lenses, the Academy opposes these efforts due to significant patient safety concerns.

The Academy would also not be supportive of efforts to extend or eliminate the expiration of contact lens prescriptions. We would not be supportive of any broader effort to de-regulate the contact lens market. Contact lenses are medical devices and their misuse can compromise eye health and vision of consumers. Corneal infections are associated with contact lens use and can lead to vision loss. Contact lens wear can have adverse effect on the ocular surface, which underscores the need for examination at an interval of one to two years.

The Academy stands firmly behind our mission to protect the sight of our patients. We believe efforts to promote policy that could be detrimental to patient safety does not reflect the public interest and therefore shouldn't be considered by the Federal Trade Commission. The Academy encourages the FTC to reflect on whether such policies under consideration are in the best interest of consumers or the best interest of retail organizations looking to sell contact lenses. The Commission should not prioritize the sale of contact lenses over safe and effective use of contact lenses.

Sharing Copies of Prescription's with Third Parties

At the FTC Workshop, discussion included whether the sharing of copies of the prescriptions by prescribers to third parties would be beneficial to patients and improve the Rule. Policy changes to this extent would not be opposed by the Academy, if it allowed enough time as to not be a burden on ophthalmology practices.

If the FTC considers such a proposal, the Academy would recommend a time window of 5 business days. Further, patients would need to understand and seller adhere to the fact that the date on the prescription needs to be the date of the exam and cannot be extended for a year from obtaining the copy.

Additional Comments on the FTC Workshop

In previous comments, the Academy has urged consideration of proposals that would seek to mitigate the number of prescriptions being passively verified. Our support of such proposals, including those to improve communication between prescribers and sellers of contact lenses, was rooted in the idea that lower passive-verification rates would result in fewer incorrect prescriptions being filled.

At the workshop, the panel on "Examining the Verification Process" included panelists from two contact lens retailers that outlined vastly different statistical rates of passive verification. One retailer panelist told workshop attendees that roughly 40% of their prescriptions were being passively verified, while another reported a much lower rate of 10%. This lower rate was due to practices by opticians at the retailer that more actively engaged with prescribers to confirm prescriptions. The retailer outlining evidence of higher rates of passive verification outlined their use of a live-caller but ultimately automated system.

The Academy believes that the FTC should consider reviewing the practices of the retailer who outlined a lower rate of passive verification. This would be done to determine whether implementation of more "active" verification measures across retailers would lead to lower rates of passive verification. With specific statistics and data showing low rates of passive verification, this would seem to us to be an evidence-based action that could provide tangible benefits for patients, prescribers, and retailers.

Conclusion

We call on the Commission to rethink proposed changes to the Rule and reaffirm their commitment to protecting consumers by prioritizing contact lens safety over contact lens sales. Should you have questions about any of our comments or seek additional input, please feel free to contact myself or Scott Haber, Government Affairs Representative, at shaber@aaodc.org or via phone at 202-737-6662.
Sincerely,

Michael X. Repka, MD, MBA
Medical Director for Governmental Affairs
American Academy of Ophthalmology