



HEALTH CARE ALLIANCE FOR
PATIENT SAFETY

April 6, 2018

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

By electronic submission

Re: March 7 Public Workshop to Examine the Contact Lens Marketplace and Proposed Changes to Federal Trade Commission's ("FTC" or "Commission") Contact Lens Rule.

Dear Secretary Clark:

The Health Care Alliance for Patient Safety ("APS") submits these comments in response to the above-referenced announced workshop and comment period to discuss competition in the contact lens market. With the announcement, the Commission requested comments from the public for purposes of reviewing the Contact Lens Rule as part of its 10-year review process.

APS is comprised of health care providers, medical device manufacturers, vision insurers and other organizations that support the need for heightened awareness regarding pressing threats to a patient's health and safety. We recognize the need to educate consumers about the safety risks involved in wearing contact lenses. Our mission is to build awareness while advocating for enforcement of the law and other public policy solutions designed to safeguard public health. APS understands the need to provide both competition and safety in the sale of contact lenses. However, we are concerned that the FTC has not fully considered the overall safety risks associated with contact lens wear in an evolving marketplace. Our hope is that the March 7, 2018 workshop provided insight and avenues to ensure that the law is enforced without deterring technological advancements or undermining doctor-patient relationships.

When the Fairness to Contact Lens Consumers Act was signed into law in 2004, congressional intent was to promote competition of retail sales of contact lenses while decreasing the overall cost of purchasing contact lenses. At the same time, Congress sought to ensure that new developments in the market upheld a high quality of patient eye care. Unfortunately, APS believes certain aspects of the original congressional intent have not been met. In the FTC's Proposed Rule Concerning the Contact Lens Rule ("Proposed Rule") issued on December 7, 2016, the FTC failed to address several fundamental problems with the current contact lens market.

Specifically, APS is very concerned with several patient-safety issues regarding excessive-quantity sales, contact lens brand substitution and out-of-date communication methods that may undermine patient safety in the prescription passive-verification process. Individually, each of these issues pose significant threats to patient eye health. In addition, we are deeply concerned about the FTC's proposed signed acknowledgment form for every contact lens wearer that will create additional and unnecessary burdens on our nation's eye doctors while ultimately threatening access to care. As a whole, these issues create an environment where eye health problems become more prevalent due to patients' growing disregard for regular eye health exams and the evaluation of contact lens interaction with patients' eyes.¹ In addition, this approach fails to follow congressional intent as well as scientific recommendations from the Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"). This intent and these recommendations were put in place because inappropriate use of contact lenses can lead to serious eye injury, including impaired or full loss of vision. For this reason, the proper "Standard of Care" dictates that contact lens wearers receive periodic comprehensive eye exams to determine the proper ocular response and the continuation of safe contact lens. The push to devalue the doctor-patient relationship for contact lenses will lead to more patients experiencing adverse events based on either poor hygiene practices or changes in eye physiology, ultimately leading to more vision problems for contact lens wearers and possibly more Americans losing their vision.

Excessive Quantity Limits

The Commission has already acknowledged that online consumers receive notices to purchase more contact lenses in excess of the remaining life of their prescription. The Commission acknowledged a Johnson & Johnson Vision Care, Inc., survey showing that "58% of the online consumers that were surveyed indicated that they had received an email or letter from their retailer reminding them that their prescription was expiring soon and that the majority of these consumers had ordered more lenses as a result."²

It is essential for sellers to follow the terms and intent of contact lens prescriptions. If a prescription is written for one year, then the most a seller should be allowed to sell to a consumer during the life of that prescription should be 730 lenses. This underlining premise of quantity sales is based off the original intent of the law and the rules and requirements by the FDA and the FTC related to the integrity of prescriptions. This premise is also clearly implied in the FTC's Rule by requiring sellers only to sell lenses "in accordance with a contact lens prescription."³ APS also understands that emergency situations arise where patients need a limited refill to replace ripped or lost contact lenses. Fortunately, some states have provided precedence for these situations. The Texas Department of Health clarifies that a patient may receive a two-month extension of their current contact lens prescription if their doctor determines that an emergency exists. With this in mind, APS encourages the FTC to follow their own intent, enforce limitations on excessive contact lens quantities and issue a statement indicating the Commission's clear intent regarding this Rule while following precedence. In following precedence, the APS asks

¹ <https://www.cdc.gov/mmwr/volumes/65/wr/mm6532a1.htm>

² Proposed Rule at 88542.

³ See Section 315.5(a) of the Rule.

the FTC, when acting on quantity limits, to defer to the patient-doctor relationship, which should hold the final decision for any patient health care decision.

Contact Lens Brand Substitution

As with Quantity Limits, the Commission has already acknowledged the serious consequences that come from freely substituting contact lenses. Contact lenses are not commodities, but rather Class II and Class III medical devices regulated by the FDA. Manufacturers and prescribers both agree that freely substituting contact lenses could result in significant injury including corneal ulcers and impaired or full loss of vision, but also undermine consumers' confidence in the assurance that they are always receiving the exact lenses prescribed to them by their doctor.

The Commission has already decided that “unauthorized alterations violate the Rule as currently written, and thus there is no need to amend the Rule to address this issue.”⁴ Yet, given that the FTC has stated, “it is unclear how frequently illegal substitutions are occurring, or how many sellers are engaged in this activity,” the FTC has declined to take any further action to gather evidence of illegal substitutions.⁵

APS recommends that the FTC seek further evidence of the illegal substitution of contact lenses, and increase enforcement efforts to correct any illegal action.

Out-of-Date Methods for Passive-Verification

In the proposed rule in December 2016, the FTC took the position that updates to the methods used in the verification process were not needed “because the current regulatory framework sufficiently prohibits the use of expired prescriptions.” APS believes the current advancements in technology allow for the FTC to issue guidance on new acceptable forms of verification, (e.g. emails) and disallow outdated forms of verification, like robocalls. Many of the outdated methods currently used do not constitute “direct communication” as intended by Congress.

APS supports the passive-verification process. However, advancements in technology now allow both sellers and prescribers to keep electronic health records. FTC action to modernize its guidance around passive-verification communication while excluding antiquated technology (e.g. robocalls) would provide greater documentation and the possibility of greater oversight in the verification process. Greater oversight, understanding and documentation will ultimately create a safer and more efficient environment for contact lens wearers and the verification of their prescriptions through clearer, concise and accurate communication between the prescriber and the seller.

Signed Acknowledgment

In the FTC's proposed rule, the Commission proposed to require a signed acknowledgment form of prescription release that would allow the patient to acknowledge receipt of their contact lens

⁴ Proposed Rule at 88552.

⁵ Proposed Rule at 88551.

prescription. In addition, the prescriber would be required to maintain this acknowledgement form for not less than three (3) years so they may be available for inspection by the FTC.

APS understands that the proposed requirement was in response to a small number of claims that suggest that prescribers were not freely giving patients their contact lens prescription as required under the law. In fact, the FTC itself conceded that “many reports of compliance and noncompliance are anecdotal and robust empirical data is sparse.”⁶ It is our belief that the Commission’s purpose for the signed acknowledgment form was to educate consumers of their rights while also subjecting doctors to spot investigations regarding the adherence to the law. APS believes that less intrusive means can be used to educate consumers of their rights to freely receive their prescriptions while also ensuring doctors follow the law.

Signage can inform patients of their rights under the law while at the same time providing a form of communication (e.g. phone number) to report any bad actors. This form of education is less intrusive and less burdensome while arguable more informative than a signed paper acknowledgment. APS urges the Commission to consider signage or other forms of educating consumers of their rights that are less intrusive and less burdensome than a signed acknowledgment form.

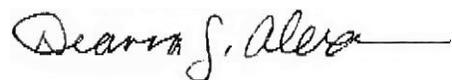
Conclusion

APS is encouraged by the FTC’s interest in gathering input from doctors, contact lens manufacturers, retailers, patients and health agencies like FDA and CDC, and we look forward to furthering discussions on how to better the contact lens market. The work that has been done over the last year is extremely important to ensure updates to the Contact Lens Rule prioritizes patient health and education.

APS asks the FTC to consider carefully the patient health risks that come with excessive quantity limits and free substitution. APS also asks that the FTC consider updates to methods used in the passive-verification system to ensure direct communication is accomplished and patients receive the correct contact lens prescription. Finally, APS would ask the FTC to consider other forms of educating patients of their rights under the law rather than a signed acknowledgment form. A signed acknowledgment form is intrusive to the doctor-patient relationship and is less effective to other forms that can achieve the same objective.

APS commends the FTC for their thoughtful review of these comments on the Proposed Rule and thanks the FTC for their time and consideration.

Sincerely,



Deanna Alexander, O.D.
Chair, Health Care Alliance for Patient Safety

⁶ Proposed Rule at 88531.