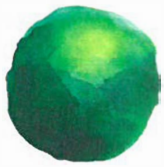

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By electronic submission

July 29, 2019

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW
Suite CC-5610 (Annex B)
Washington, DC 20580

Re: Supplemental Notice of Proposed Rulemaking Concerning the Contact Lens Rule, 16 CFR Part 315, Project No. R511995 (the "Proposed Rule")[1]

Dear Acting Secretary Tabor:

These comments are submitted on behalf of CooperVision, Inc. ("CooperVision"), which manufactures, distributes and sells contact lenses throughout the United States and many other countries. CooperVision has previously submitted comments in response to the Federal Trade Commission's (the "Commission" or the "FTC") initial request for comments[2], as well as comments to the Notice of Proposed Rulemaking[3]. In addition, CooperVision participated in the Commission's public workshop on the Contact Lens Rule and the Evolving Contact Lens Marketplace on March 7, 2018[4] (and, on April 6, 2018, provided supplemental comments in connection with the workshop[5]). This letter supplements our previous comments, which are incorporated herein.

Introduction

The Contact Lens Rule[6] (the "Rule") has helped to promote competition, increase options for consumers and lower prices, leading to a more competitive contact lens market in the United

[1] 84 Fed. Reg. 24664 et seq. (May 28, 2019).
[2] 80 Fed. Reg. 53272 et seq. (September 3, 2015) (FTC September 2015 Request for Comments); https://www.ftc.gov/system/files/documents/public_comments/2015/10/00591-99422.pdf.
[3] Notice of Proposed Rulemaking, 81 FR 88526 (Dec. 7, 2016); https://www.ftc.gov/system/files/documents/public_comments/2017/01/03841-138572.pdf.
[4] Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule, 82 FR 57889 (Dec. 8, 2017).
[5] https://www.ftc.gov/system/files/documents/public_comments/2018/04/03077-146878.pdf.
[6] 16 CFR part 315; 69 Fed. Reg. 40482 et seq. (July 2, 2004).

States. Consumers in the U.S. have more options for high quality lenses compared to many other places in the world, and they can purchase contact lenses competitively through numerous sellers.

Although the increased number of options is good for competition, patient safety remains CooperVision's highest priority. A contact lens is properly classified as a regulated medical device that requires a prescription for dispensing. As the Commission considers changes to the Rule, we strongly encourage it to keep patient health and safety at the forefront of its concerns. CooperVision believes in a competitive marketplace with good choices for consumers. But as access to contact lenses has improved, lenses are being sold through new market entrants and new selling models fueled primarily by the internet. Fostering competition should not come at the expense of patient safety and excellent lens wearing experiences. From that perspective, CooperVision continues to be concerned that there are flaws in the functioning of the Rule and in some of the proposals made by the Commission in the Supplemental Notice of Proposed Rulemaking concerning the Contact Lens Rule (the "SNPRM").

Alteration of Prescriptions

The Commission has acknowledged there have been changes in the selling of contact lenses that have led some sellers to switch prescriptions by manipulating and abusing the verification process.[7] As a contact lens manufacturer, CooperVision appreciates the Commission's view that "[a]ny attempt to substitute another lens, including a seller's own brand, for the prescribed lens thwarts the purpose of the Act, which is to allow sellers to sell contact lenses *as prescribed* by the consumer's eye-care provider" (emphasis added).[8] This statement confirms the important role eye care professionals play to ensure that patients have safe and successful wearing experiences. Accordingly, CooperVision welcomes the proposed modifications concerning alteration of prescriptions and improper lens substitution.

FTC's proposal depends, in part, on requiring sellers to provide a clear and prominent method for patients to present a copy of their written (or electronic) prescription. CooperVision agrees that there is less chance a seller with an actual copy of the prescription will engage in illegal lens substitution. But, as addressed in the "Signed Acknowledgment" section below, it is equally important for the Commission to modify and enforce the Rule to ensure that sellers do not sell lenses based on an expired or otherwise incorrect prescription. Accordingly, the proposed Rule requires improvements to adequately address that concern (as described later in this letter).

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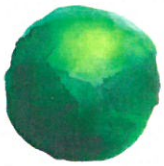
[7] 84 Fed. Reg. at 24688.
[8] *Id.*



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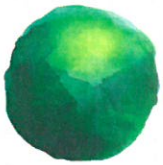
As for protecting against improper substitutions during the verification process, the Commission proposes to define "alteration" of a prescription to include sellers giving the prescriber the name of a product (manufacturer or brand) different from what is stated on the prescription. Although that requirement is implied in the existing Rule, the proposal would create an exception from liability if the patient provides the incorrect manufacturer or product to the seller. In order to take advantage of this exception, the seller must affirmatively ask the patient for this information. Nevertheless, there are still elements of this exception that need to be strengthened or clarified, to prevent it from being abused:

- Sellers should ensure that patients understand that they need to request the lens that is specified on their prescription. Additionally, sellers should be required to state prominently and conspicuously that if patients want a different lens, they must discuss the request with, and make the change through, their prescribers. Without these elements, the exception proposal runs the risk of suggesting that sellers are not responsible if the consumer requests a lens that is different from the prescription (regardless of intent), which in turn may encourage more sellers to exploit this exception.

- The Rule and/or FTC guidance should also make it clear that sellers cannot induce, suggest, advertise or otherwise cause patients to provide the wrong name (so that the seller can take advantage of the exception). For example, an online seller of its brand of contact lenses should not be able to advertise a message that causes the patient to provide the wrong name of the prescribed lens or ask for a lens different than what was prescribed (saying something like, "just tell us that you want our lenses…"). These and similar examples should be explained in a guidance document.

- CooperVision strongly recommends that the Commission reconsider not requiring sellers to keep records related to the "patient mistake" exception.[9] Other parts of the Proposed Rule rely heavily on requiring written evidence; so it is unclear why the Commission's proposal lacks a record-keeping obligation. Not only does the proposal create a gap that could be exploited, but it also fails to require important record-keeping that would be helpful for FTC enforcement activity – something that the FTC recognizes as being needed in other parts of the Proposed Rule.[10]

[9] 84 Fed. Reg. at 24689.
[10] See, e.g., 84 Fed. Reg. at 24681.



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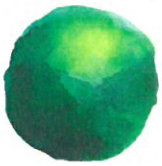
Signed Acknowledgment

As previously commented, CooperVision supports the current requirement to provide a prescription to patients. The vast majority of ECPs regularly provide a copy of the prescription to patients, and the best way to address the small number of cases where prescriptions are not furnished is through education and enforcement, rather than imposing additional administrative burdens on ECPs. In particular, the FTC and sellers should continue to communicate to patients through social media, websites, advertising and other channels so that patients become even more aware that they can leave their final fitting with a copy of their right prescription.

As CooperVision has previously observed, the FTC's proposal of a signed acknowledgement form is a burden for eye care professionals. The Commission's proposal might be something that larger retailers would be able to cope with (though at a cost). However, a good deal of eye care professionals operate as individuals or in small offices where the cost of the collecting and maintaining acknowledgements would add unnecessary expense with little gain. As well-intentioned as the proposal may be, other approaches (as described above) would be far better suited for all parties involved in the contact lens marketplace.

That being said, CooperVision supports one of the concepts outlined in the "signed acknowledgment" section of the SNPRM -- namely, that electronic platforms should play a larger role in communication exchanges between consumers, seller and prescribers. Electronically available prescriptions, upon the affirmative consent of the patient (or by paper if the patient declines electronic delivery), is a common-sense, low burden method for giving patients better access to their prescriptions. Combined with better education, making prescriptions available through doctor-patient portals, over email and through other electronic means certainly help to modernize the Rule. CooperVision also believes the increased use of electronic means to deliver written communications should be used for the verification process rather than antiquated robocalls. A move toward electronic written communications would strengthen the Rule overall.

Regular eye examinations are important to the safe and effective use of contact lenses, and they help to ensure a patient has a successful wearing experience. In its previous comments, CooperVision has expressed concern about changes to the Rule that would unwittingly cause patients to see their eye care professionals less frequently. For example, we have expressed concerns about how the practice of selling excessive quantities of lenses near the end of a contact lens prescription will lead to contact lens wearers going for long stretches without visiting their



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eye care professionals.[11] Similarly, without enhancements, the Commission's acknowledgment form proposal will create the potential for patients to miss out on regular eye examinations.

Once a seller receives a prescription from the patient, it is critically important that it sells lenses only from a valid and unexpired prescription, as is required by the Rule. Although the FTC's acknowledgment form proposal may help to increase patient access to their prescription, it also creates a potential path for lenses to be sold with expired prescriptions, unless sellers carefully check to ensure they have valid and current prescriptions on-file. It is a violation for sellers to sell contact lenses on expired prescriptions. But if violations go unchecked, patients will not be visiting their eye care professionals regularly enough to confirm that their contact lenses are the correct size, power and material to meet their ocular needs. To address that issue, CooperVision believes that a revised Rule should include the following elements:

- Sellers should routinely ask patients to confirm that the prescription has not expired before the sale (unless the order is being placed with a copy of an unexpired prescription). The seller should be required to retain records demonstrating such confirmations and, upon request, make them available to the FTC; something that would help the Commission enforce against violations by sellers that sell with expired prescriptions. This would encourage the patient and seller to ensure that the prescription is valid and still in effect.

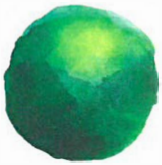
- FTC should increase it efforts for inspecting seller records to ensure that lenses are not being sold on expired prescriptions. These include both cases where the seller has a written prescription and cases where the order is based on information furnished by the patient.

The additional requirements described above are important to help achieve a balance of health and safety issues with the consumer rights concerns that the Rule is designed to address.

Robocalls

As we have previously commented, the use of robocalls was not mentioned in the statutory language of the Fairness to Contract Lens Consumers Act ("FCLCA") or the legislative history.[12] CooperVision continues to believe that there are more reliable ways for verifying prescriptions – such as email and electronic portals through which written communications can take place. Although the Commission should consider eliminating robocalls, the clarifications it has made

[11] *See, e.g.,* https://www.ftc.gov/system/files/documents/public_comments/2015/10/00591-99422.pdf.
[12] See, e.g., https://www.ftc.gov/system/files/documents/public_comments/2017/01/03841-138572.pdf.



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concerning use of that technology - along with the Commission's proposals regarding lens substitution - certainly helps address some of the more troubling issues.

With respect to the proposed "option to repeat", it remains unclear whether the requirement is intended merely to create a mechanism to repeat the message or to provide an opportunity for the eye care professional to respond, especially when the call has incorrect information. Having an option to repeat without some ability for the eye care professional to respond limits the ability to correct information that is important for the patient's eye health or that could present improper substitution of lenses. As such, FTC should not only require an option to repeat the message, but also require sellers to provide the means for the prescriber to immediately disrupt an automatic call in order to connect with a live person and provide correct information (for example, "press '1' to speak with a representative").

Additionally, CooperVision urges the Commission to publish guidance regarding how it intends to interpret and enforce these provisions.

Conclusion

We appreciate the Commission's diligent efforts in reviewing the Rule and considering improvements to help modernize how contact lenses are prescribed and sold. CooperVision stresses the need to adopt an approach that protects competition while protecting patients' safe use of contact lenses and ensures that they have good wearing experiences. Ultimately, giving the interests of patients – their wearing experiences and eye health – the highest priority represents the best way for addressing the competing interests the Rule must address.