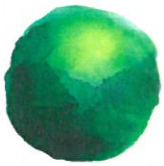


CooperVision™

Clay Arnold, *Senior Counsel*
209 High Point Drive
Victor, New York 14564

T +1 585 756 9571
E: carnold@coopervision.com

By electronic submission

January 30, 2017

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

Re: Proposed Rule Concerning the Contact Lens Rule, 16 CFR Part 315, Project No. R511995 (the "Proposed Rule")

Dear Secretary Clark:

These comments are submitted on behalf of CooperVision, Inc. ("CVI"), a manufacturer of contact lenses with headquarters in Pleasanton, California. CVI manufactures, distributes and sells contact lenses throughout the United States and many other countries. It sells through all channels of distribution, including Eye Care Professionals ("ECPs"), brick and mortar retails stores, and online sellers. CVI previously submitted comments in response to the Commission's initial request for comments[1] and that submission is incorporated by reference.

Introduction

CVI continues to support the Federal Trade Commission's (the "Commission") Contact Lens Rule[2] (the "Rule"), which has promoted competition, increased options for consumers and lowered prices. The contact lens market today in the United States is highly competitive and compares favorably with the contact lens market in any other country in the world. United States consumers have more options for high quality lenses at lower prices compared to many other places in the world. The Rule has made a major contribution to how the market functions.

Despite these successes, there are still some serious flaws in the functioning of the Rule, which the Commission failed to address in its recent proposal. First, the Rule allows sellers to use automated, computer-generated calls ("robocalls") to serve as a "direct communication" to ECP's for a verification request. Second, some sellers, particularly in the online market, sell

[1] 80 Fed. Reg. 53272 et seq. (September 3, 2015) (FTC September 2015 Request for Comments)
[2] 16 CFR part 315; 69 Fed. Reg. 40482 et seq. (July 2, 2004)

very large quantities of lenses in a single order, far in excess of the amount needed to supply consumers during the life of the prescription. This practice discourages consumers from visiting their ECP's on a regular basis and creates risks for patients' eye health and contact lense performance. Unfortunately, the Commission failed to address either of these issues in its recent proposal.

On the other hand, the Commission has proposed that ECPs require patients to sign an acknowledgment when they receive their contact lens prescription. Such a requirement is unnecessary in light of the unreliable evidence the Commission found in support of the proposal. CooperVision believes that significantly less burdensome alternatives exist, such as stronger guidance and better educating consumers and ECPs about the requirement for providing contact lens prescriptions after the final fitting.

Robocalls

The use of robocalls was not mentioned in the statutory language of the Fairness to Contract Lens Consumers Act ("FCLCA") or the legislative history. While the Commission assumed Congress intended to include robocalls in the definition of "direct communication," it indicated it might revisit the issue of robocalls if there is evidence that robocalls are an inadequate means of making verification requests. See 69 FR 40482, 40489 (July 2, 2004). In fact, substantial evidence has been provided to the Commission demonstrating that robocalls are not a reliable and effective method of direct communication. That is particularly troubling since robocalls are much more widely used than when the Rule was adopted. In addition, the Commission has acquired substantial evidence about problems created by robocalls.

A large percentage of robocalls rely on computer-generated voices. There is likely little monitoring by sellers of individual computer-generated calls, thereby making it more likely that defects in the calls are overlooked or ignored. These calls routinely omit certain information or, if the information is contained in the calls, it may be difficult to understand. Often, these calls are truncated and the contact information, which is at the end of the message, is omitted. In all of these cases, it may be impossible for a prescriber to evaluate the accuracy of the request or to respond to the originator of the request. Prescribers also have the frustrating experience of receiving such calls when they should be directed at some other prescriber.

Large internet sellers use robocalls because they are inexpensive and facilitate large-scale verification requests. There is no doubt that robocalls save money for sellers compared to other communication methods. Therefore, the Commission's recent statement claims that it is in the consumer's interest to allow these calls because they promote efficiency. The flaw in the Commission's reasoning is that it takes into account only sellers' efficiencies, not the overall impact on the efficiency of the verification request process. Additionally, correcting information or obtaining details about a prescription lost in an incomplete or unintelligible robocall can cause

unnecessary delays in providing patients with their contact lenses. It is not in the interest of consumers if these automated calls do not enable a provider to respond in the event that a proposed sale is based on inaccurate information or an invalid prescription. In those cases, the check on invalid prescriptions is absent. As a result, there is a risk that consumers will receive lenses with the wrong specifications or that invalid prescriptions will be filled, threatening the consumer's eye health. Similarly, it is not in the interest of consumers if robocalls promote sales of excessive quantities of lenses, which have the effect of discouraging regular visits to ECP's, thereby risking consumers' eye health.

If robocalls were prohibited, sellers would have a variety of other means to submit a verification request, including faxes, live calls and e-mail. While all three methods would continue to be used, it is likely that e-mails would be the preferred method for many sellers, particularly those who sell high volumes of lenses. E-mails are an extremely efficient way of communicating a verification request and they have substantial advantages over robocalls. They automatically create a written record; they are clearly legible; and they provide an easy, efficient way for ECP's to respond if there is a problem. They provide a record for monitoring seller compliance with the Rule.

In contrast, robocalls are often incomplete or inaudible and the only way the ECP can respond is to call a telephone number which is often omitted from the robocalls recording. Even if there is a telephone number that is audible, there is typically no live person who answers the call for the seller. It may be that some sellers deliberately use robocalls to make it difficult for providers to block sales on the grounds that they are inaccurate or invalid. However, whether or not sellers intend to make it difficult for ECP's to respond, that is the practical effect of many of these calls. In short, robocalls offer substantial disadvantages compared to e-mails and no advantages.

Quantity Limits

The Commission fails to appreciate the dangers to patients' eye health that arise when sellers provide lenses in quantities far in excess of those required to supply patients for the remaining life of their prescription. The danger is not simply that consumers will continue to use lenses that have the wrong refraction and, therefore, experience poorer vision than they should. The greater danger is that infections, glaucoma or other dangers to long-term eye health will go undetected. Eyes are complex organs, and the ability to correct vision through placing lenses next to the cornea is generally safe. However, the interaction between the lens and the cornea is one that must be monitored regularly by the patient and by the ECP. In addition, regular visits to ECP's can help detect other eye conditions that are not directly related to the use of contact lenses, such as glaucoma. That is why all the medical societies, Centers for Disease Control and the Food and Drug Administration recommend annual visits to an ECP.

The Commission recognized the problem of excessive quantities of lenses supplied by sellers in its 2004 statement regarding the Rule. *Id.* at 40487. The Commission assumed that the problem would be avoided because ECP's have the ability to block the sale by communicating with the seller that the prescription is invalid or inaccurate. That theoretical remedy works in some cases but it has failed in many others for two principal reasons. First, if the verification request is incomplete or inaudible, the prescriber does not have a method of responding to the seller. Robocalls are the primary cause of this problem. That is why it is particularly important to ban these calls as discussed above. Second, if the seller has a written copy of the prescription, there is no need for a verification request at all. There is evidence that sellers that have the prescription contact consumers when it is about to expire to encourage them to refill in large quantities. In these cases, there is no ECP involvement in the transaction. In these cases, the sellers are well aware that they are supplying quantities of lenses well beyond the prescription expiration date. In connection with the Commission's 10-year review of the Rule, the Commission received evidence of websites offering a two or even three year supply of lenses at discount prices when the prescription was about to expire.[3] Evidence was also submitted to the Commission showing that over 60% of consumers reported being contacted by sellers encouraging them to refill when their prescription was close to expiration.[4]

The Coalition for Patient Vision Care Safety ("Coalition"), of which CVI is a member, recommended that the Commission incorporate into the Rule a reasonable limit on the quantities of lenses that can be provided in response to a verification request or a request from patients directly. Alternatively, the Commission could publish guidance which sets out an enforcement policy of bringing an action if sellers knowingly provided lenses far in excess of the number needed for the remaining life of the prescription. However, the Commission rejected these alternatives because: 1) the Coalition did not provide sufficient empirical data to show that there is a problem; and 2) it would be difficult to administer a limitation on quantities. With all due respect, the Commission is wrong on both counts. The evidence of the high number of patients being contacted during the last days of their prescription provides a powerful inference that sales in many situations are excessive. Second, the Coalition has submitted a practical and easily enforceable method for enforcing quantity lenses in a reasonable way that allows consumers to have extra lenses for emergencies and for delays in seeing their ECP.

Proposal to Require a Signed Acknowledgment

As stated above, CVI is strongly supportive of the current requirement to provide a prescription to patients. While there may be cases when ECPs do not provide a copy of the

[3] Comments of the Coalition for Patient Vision Safety at p. 7 (submitted October 26, 2015) (https://www.ftc.gov/system/files/documents/public_comments/2015/10/00621-99429.pdf).
[4] Comments of Johnson & Johnson Vision Care, Inc. at 13 (submitted October 26, 2015) (https://www.ftc.gov/system/files/documents/public_comments/2015/10/00582-99421.pdf)

prescription to patients, in our view, the estimates of the number of times this occurs is overstated. This overestimation results from the fact that – as the Commission identified[5] – the claims of not receiving a prescription do not distinguish between visits to ECPs that are preliminary to a final prescription and the final visit when the prescription should be submitted, as well as other methodological flaws with the surveys in question. Nevertheless, all members of the industry recognize the importance of this requirement and support efforts to increase compliance.

The evidence does not justify a burdensome requirement to obtain a signed acknowledgment and maintain records. Adding additional paperwork requirements to health care providers – not to mention consumers – can seem insignificant to government regulators who only are required to monitor compliance periodically and at their discretion. To the small businesses that have to comply with these requirements, the cumulative burden is much more significant. It drives up costs and distracts providers and their staffs from actually doing what they do best – treat patients

Additionally, the Commission cites that the high number of verifications performed suggests that patients are not receiving their prescriptions and that there is a need for signed acknowledgment form.[6] This evidence is circumstantial at best and certainly inadequate to support a proposal that, on balance, places an onerous burden on prescribers. Moreover, the Commission's argument takes the very system that was adopted to cure irregularities in providing prescriptions and uses it against prescribers to put in place yet another step prescribers need to go through to provide healthcare to their patients.

CVI urges the Commission to use alternative means to increase compliance, such as increased enforcement in egregious cases and cooperative efforts with the industry to provide more educational efforts. CVI notes that the American Optometric Association itself has initiated an education campaign to increase compliance and has worked with Commission staff to develop accurate informational materials for ECP's. CVI – and no doubt the Coalition – would be pleased to work with the Commission on other educational efforts.

Conclusion

As noted above, CVI supports the goals of the Rule but seeks common sense enhancements to the Rule that protect patients' safe use of contact lenses and ensures that they have good wearing experiences. One of the best ways of ensuring that is by patients visiting their ECPs on a regular basis – as recommended by the CDC and the FDA – in order to manage receive examinations that help manage eye health and contact lens fit. Without changes to the

[5] 81 Fed. Reg. 88526, 88531.
[6] Id. at 88532.

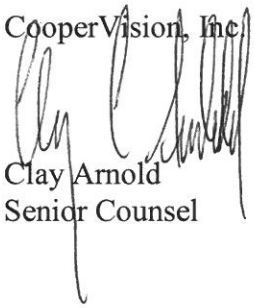
direct communications options (i.e., prohibiting robocalls) or without reasonable quantity limitations to prevent ordering of excess lenses, the impact ECPs can make is significantly reduced – this places patients' ocular health in jeopardy.

On the other hand, imposing the requirement of an acknowledgment form is unnecessary in light of other options available to the Commission to address any perceived issues with the requirement to provide prescriptions at the final fitting. The proposal is a heavy-handed and burdensome response to an issue that would be easily resolved with additional guidance and increased education.

CVI appreciates the opportunity to provide the Commission with comments about the Proposed Rule.

Sincerely,

CooperVision, Inc.



Clay Arnold
Senior Counsel