



CooperVision™

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April 6, 2018

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

Re: Contact Lens Rule, 16 CFR Part 315
Additional Comments, Project No. R511995

Dear Secretary Clark:

CooperVision, Inc. (CVI) submits these comments in response to the discussions at the March 7, 2018, *Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule*. A CVI representative, Shaun Schooley, participated in the panel discussion regarding verification.

The Verification Process

The verification process in the FTC Contact Lens Rule is an essential element of the changes Congress made to the contact lens marketplace in the Fairness to Contact Lens Consumers Act (FCLCA) in 2003. The Contact Lens Rule was issued by the FTC in the following year. The FTC began its review of the Contact Lens Rule, which became effective in 2004, based on its regular ten-year review. Because of the importance of the verification process to the effectiveness of the Rule and the significant impact of the process on sellers, Eye Care Professionals (ECPs) and patients, the verification process has been the subject of considerable comment during the review process. When done correctly, the verification process can ensure patients have the proper lenses and can purchase additional lenses conveniently. On the other hand, when the process is not effective or inefficient, it can result in incorrect prescriptions and impose a significant burden on ECPs.

CVI, like other manufacturers, is not a party to the verification process. However, CVI does have a strong interest in making sure the verification process is reliable and efficient and that patients who use our lenses have the best wearing experience, health and vision possible. The accuracy of the prescription and the eye health of patients at the time of the initial examination is an important starting point. The patient's long-term eye health and wearing experience depend upon revising the patient's prescription when necessary and regular monitoring by qualified Eye Care Professionals (ECPs) for risk factors and other conditions that could undermine the patient's long-term eye health.



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The Role of ECPs

ECPs play a critical role in the ensuring that patients have success – and good health outcomes – when wearing our products. They are responsible for evaluating patient’s ability to successfully wear contact lenses, selecting and fitting contact lenses that are appropriate, training and monitoring the patient in beginning to wear lenses, and reinforcing proper wear and care practices. The importance of the role of ECPs in enabling patients to have a good wearing experience is shown in the attached chart. The “dropout rate,” that is the rate at which patients give up on wearing lenses, is dramatically lower in the United States and Canada where ECPs play a more significant role in the selection, fitting and management of the patient’s contact lens wearing experience.

Prescribers are responsible for choosing the right lenses, retaining information about their patients, and responding to seller verification requests in a short period of time. In addition, they are the primary contact point between the health care system and the patient and they may be legally responsible in the event of a negative wearing experience. Therefore, their views about how the verifications process works deserve considerable weight.

Improving the Verification Process

We have some suggestions about the how the verification process can be improved. First, as recognized by the FTC in its proposal, electronic “written” systems are more reliable than live or recorded telephone communications between sellers and ECPs. Consequently, we were disappointed that the FTC chose not to address the frequent use of robocalls, which create a number of problems that can undermine the accuracy and timeliness of verifying and renewing prescriptions. We have frequently heard from ECPs that robocalls are often incomplete or difficult to understand. Thus, the information about the proposed sale is difficult to confirm.

Emails, on the other hand, are equally – if not more - efficient in accomplishing ECP-seller communications and have the benefit of creating a written record. We feel that they would be a better method for sellers and prescribers to use in engaging in the direct communications contemplated by the Rule. Congress expressly included e-mails and telephone communications in the definition of “direct communications” in the FCLCA but did not expressly include robocalls. 15 U.S.C. § 7603(g). Thus, the FTC has the discretion to narrow the definition of telephone communications to exclude robocalls. We understand that there are some challenges in using e-mails such as ensuring that HIPPA standards are met, e-mails are not relegated to junk mail, and so on. However, any method of communication has certain disadvantages, and we believe that with proper patient authorization and monitoring, e-mails can be more reliable and likely less costly than any other means of communication.



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The Use of Internet and E-Tools

The Internet and E-tools can be useful to both ECPs and sellers in the verification process. For example, E-tools can be used to transmit written records between the parties involved in the verification process and to keep track of those communications. They can be used to store the prescription and call it up when necessary. Thus, they can help lessen the burden on prescribers, which can be substantial in the frequent case when a single ECP receives a large number of verification requests every day. They can also be used to remind ECPs and patients when a prescription is expiring. Finally, they can be designed to enable patients to easily purchase additional lenses and to provide information to the patient, including access to a prescription through patient portals. In sum, such tools can help the patient be even more actively involved with their selection and purchase of contact lenses. We encourage the FTC to continue to evaluate the use of the Internet and E-tools in connection with the verification process and to make sure that the Rule is applied to enable ECPs, sellers and patients to use these tools most effectively.

LensFerry

One of CVI's subsidiaries has developed a web-based program for prescribers called LensFerry, which allows prescribers and their patients to easily refill the patient's requests for lenses based on the original prescription. LensFerry can be used by ECPs to provide additional lenses from any manufacturer, not just CVI. Patients who enroll in LensFerry can do so when they first receive their prescription from an ECP or later, after they have explored other options for purchasing their lenses. Because LensFerry is linked to the electronic health records within the practice, the opportunity for prescription error is greatly reduced and ECPs can quickly and easily confirm valid prescriptions. In addition, patients have the option to purchase lens quantities of their choice through LensFerry, and they can easily cancel their enrollment in LensFerry if they decide to change their source of lenses. LensFerry is designed to make it easy for patients to purchase additional lenses, but it is not designed as a patient portal to allow access to patient records. However, there are several Internet-based programs available in the market that provide that functionality.

Quantities of Lens Purchases

The verification process addresses not just the type of lenses purchased but the quantity as well. In seeking verification, sellers provide ECPs with the quantity of lenses ordered. There is substantial evidence that many sellers promote purchases of lenses by consumers in the last weeks of the life of their prescription. Moreover, some sellers promote sales of one, two or even three years of lenses when the prescription is about to expire. This conduct by sellers may constitute a violation of the Rule under some circumstances if the seller knows that the sales of such a large quantity of lenses would be invalid based on the consumer's prescription.



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This conduct also risks patient's eye health by encouraging patients to continue to purchase lenses without visiting their ECP for appropriate eye health evaluation and education. Patients can obtain substantial quantities of lenses that are no longer appropriate for their vision needs and dangerous eye conditions such as infections, can go undetected, and clinical and behavioral risk factors can go unaddressed. Thus, we were disappointed that the FTC chose not to address this problem in its proposed revisions to the Rule, for example, by setting some guidelines as to the quantity of lenses that can be sold at any time based on the remaining life of a prescription. We encourage the Commission to revisit this issue in its Final Rule.

The Proposal to Require Patient Acknowledgment

Although it is not part of the verification process, we would like to address the proposal of the FTC to require ECPs to obtain a written acknowledgment by the patient of receipt of the prescription. We understand the importance of ECPs providing the prescription to patients. This requirement is central to the purpose and effectiveness of the Rule. However, the proposed patient acknowledgment adds an additional administrative burden on ECPs who must also deal with substantial numbers of verification requests and the associated record-keeping, often with small staffs. Moreover, the evidence of non-compliance with the prescription release requirement is not particularly strong. As the FTC noted in its proposed rule statement, "many reports of compliance and noncompliance are anecdotal and robust empirical data is sparse."¹ We encourage the Commission to consider alternative ways to accomplish the objective of this proposal in a less burdensome way, for example, by requiring ECPs to post signs prominently in their waiting room to remind both patients and staff that the patients should receive a copy of their prescription.

¹ Proposed Rule at 88531

We appreciate your consideration of these views. Please contact us if you have any questions.

Respectfully submitted,

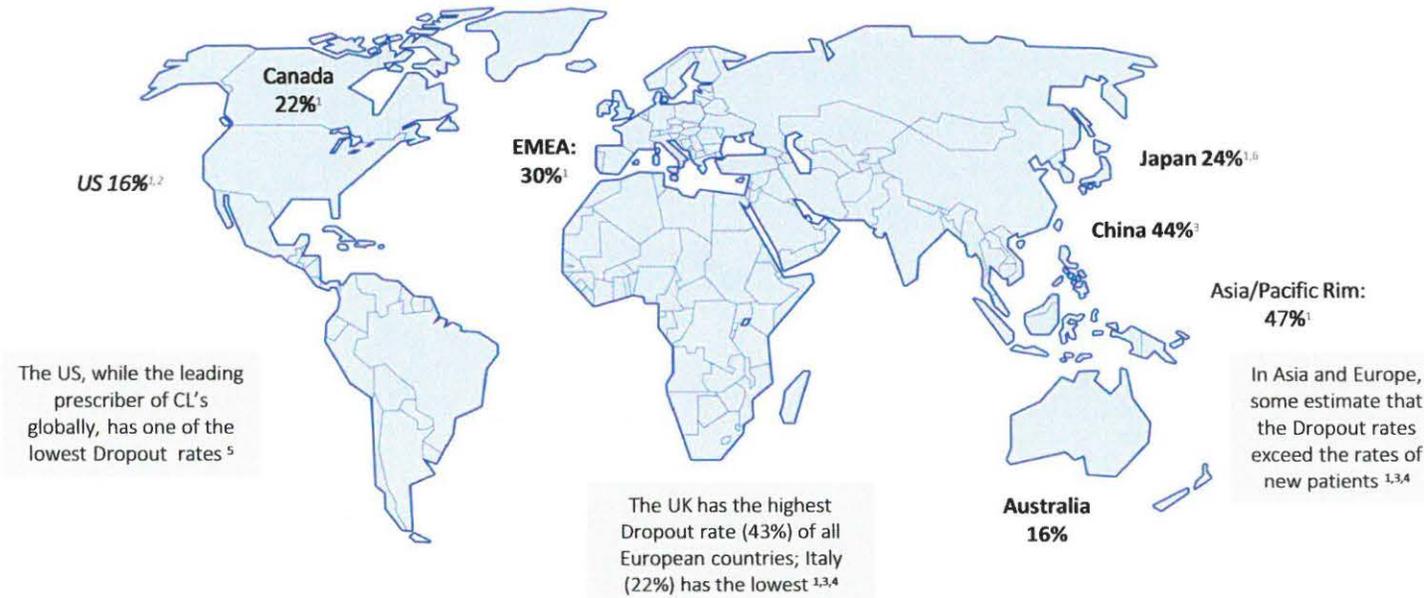
Jerry Warner
President, Americas

Permanent Dropout Rate by Country/Region



Permanent Dropout rates among CL wearers within each market

ECP engagement is a critical factor in stemming dropout. Markets that systematically utilize ECPs in the selection, fitting and management of contact lenses, experience significantly fewer dropouts than those which do not. E.g. US in comparison to China.



1 Rumpakis, J. (2010). New data on contact lens Dropout s: An international perspective. *Review of Optometry*, 147(1), 37.
 2 Rumpakis, J. & Brujic, M. (2014). Preventing Dropout : What contact lens Dropout costs and how to prevent it. *Contact Lens Spectrum*, 29, 18-25
 3 Young. (2004). Why one million contact lens wearers dropped out. *Contact Lens and Anterior Eye*, 27, 83-85.
 4 Optician. (2014). Conversations in practice: Managing the long-term wearer.
 5 Efron, N., Nichols, J., Woods, C., & Morgan, P. (2015). Trends in US contact lens prescribing 2002-2014. *Optometry & Vision Science*, (92)7, 758-767
 6 Japan's higher Dropout rate is closely linked to the use of circle lenses.