



[Filed Electronically]

April 6, 2018

Federal Trade Commission  
Office of the Secretary  
600 Pennsylvania Avenue NW  
Washington, DC 20024

**RE: Contact Lens Rule, 16 CFR Part 315, Comment, Project No. R511995;  
Public Workshop Examining Contact Lens Marketplace and Analyzing  
Proposed Changes to the Contact Lens Rule, 82 Fed. Reg. 57889**

The Contact Lens Institute is pleased to offer these comments regarding the above-referenced March 7, 2018 FTC Workshop.

The Contact Lens Institute (CLI) is a not-for-profit trade association of research-based manufacturers of contact lenses. The members of CLI are: Alcon (a Novartis company), Bausch + Lomb, CooperVision and Johnson & Johnson Vision Care. The members of CLI previously commented on the December 7, 2016 proposed amendments to the Contact Lens Rule (81 Fed. Reg. 88526) through comments submitted on January 30, 2017 by the Coalition for Patient Vision Care Safety (the Coalition).

CLI members have been the primary drivers of the dramatic innovations in the design and manufacture of contact lenses that have enabled contact lenses to be safely and successfully used by millions of patients around the world. As part of this mission, CLI members fully support a regulatory framework that ensures consumer choice and access to the right lenses for their needs. Consistent with this goal, CLI also strongly supports the critical role of eye care professionals in evaluating patients for potential contact lens wear, in contact lens selection and fitting and in supervising the ongoing health, comfort and overall satisfaction of contact lens wearers.

### **In Considering Changes To The Contact Lens Rule, FTC Should Reinforce The Status Of Contact Lenses As Non-Interchangeable Prescription Medical Devices**

Contact lenses are classified under Federal law as high risk (Class III) and moderate risk (Class II) medical devices that may be sold only pursuant to the prescription of an authorized eye care professional (ECP). The design, manufacture, testing, promotion and sale of contact lenses are regulated by the US Food and Drug

Administration (FDA). For over 34 years, CLI has supported 1) the regulatory controls under which manufacturers and distributors of contact lenses are required to demonstrate the safety and efficacy of those devices and 2) the requirements for FDA to review the supporting data (including clinical data) before clearing those devices for sale in the United States. These requirements have been strongly reiterated in Federal law under the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990. The 2004 Fairness to Contact Lens Consumers Act (FCLCA) and the Contact Lens Rule (CLR) were enacted to help advance the opportunities for consumers to freely choose where they purchase the contact lenses while, at the same time, preserving and effectively enforcing their strict prescription-only status. In 2005, Congress further reinforced the medical device status of contact lenses in response to the well-established, significant risks associated with the sale and use of contact lenses outside of the FDA-regulated, medically-supervised prescription-only context. (See Public Law 109-96, approved November 9, 2005, amending Section 520 of the Federal Food, Drug, and Cosmetic Act (FFDCA) to explicitly declare all contact lenses – including non-corrective lenses – to be medical devices.)

The March 7, 2018 Workshop panel that addressed Contact Lens Health and Safety Issues, including representatives of the Centers for Disease Control and Prevention (CDC) and FDA, provided clear and definitive testimony on the technological, public health and patient safety reasons why contact lenses are regulated by law as medical devices and are required under the FFDCA to be dispensed only pursuant to the order of a qualified and authorized prescriber. The members of that panel also explained that no contact lens product can be considered interchangeable or “substitutable” for another.<sup>1</sup> Based on this authoritative testimony from highly qualified representatives of agencies with the medical and scientific expertise and the legal responsibility to make such judgments, CLI believes that FTC should defer to this expert consensus and reject any action that would contradict or undercut it. In this regard, FTC should not entertain suggestions that 1) contact lenses are or should be treated as if they were interchangeable “commodities,” 2) contact lenses do not require initial and ongoing expert professional patient evaluation, fitting and follow-up care, or 3) patients should be able to obtain lenses other than those specifically prescribed for them or to obtain refills of contact lenses beyond those provided for under their prescription.

At a minimum, FTC should preserve the requirement for a prescription to include specification of both the contact lens manufacturer and the brand of the prescribed lens so that there is no ambiguity about the specific lenses a patient should be able to purchase under the prescription. Additionally, FTC should revise the Contact Lens Rule to eliminate the loopholes, discussed below, which have allowed contact lenses to be dispensed outside of the scope of valid prescriptions and without the proper professional supervision that the FCLCA was intended to preserve. FTC should also

---

<sup>1</sup> The only exception to this is for “private label” lenses: identical contact lenses made by the same manufacturer and sold under different labels.

reinforce these safeguards by prioritizing investigations and taking enforcement actions against violators of these requirements.

### **FTC Should Not Reduce Safeguards Under US Law Based On Unsubstantiated Assertions by Workshop Participants About How Contact Lenses Are Regulated Or Sold In Other Countries**

Some panelists during the workshop made assertions regarding the different regulatory status of contact lenses outside of the US. While there are different regulatory systems applicable to contact lenses sold in other parts of the world, it is FTC's responsibility to support the health and safety of contact lens consumers in the US in accordance with US law and in deference to the FDA and CDC's public health expertise, mandate and responsibility.

Moreover, some of the statements made at the workshop regarding the experience in other countries were incorrect, misleading, and/or based solely on anecdotal information. For instance, during the Workshop, the FTC heard testimony from Dr. Edward Chaum who asserted that contact lenses are available in vending machines in every country in Europe and that the incidence of microbial keratitis is the same or lower in these countries. Dr. Chaum also asserted that microbial keratitis infections increase following an eye exam. Careful studies of the risks of microbial keratitis and other inflammatory events associated with contact lens wear, however, have identified risk factors such as overnight wear, smoking, reuse of disinfecting solutions (topping off); the age of the wearer; the type of lenses worn; the frequency of lens replacement; exposure of lenses to water; lens case contamination; and source of purchase.<sup>2</sup> These are risk factors that warrant appropriate regulatory controls over the sale of contact lenses and close professional supervision of contact lens prescribing and use. Indeed, there is growing evidence that contact lens markets subject to higher regulatory standards and greater ECP involvement in contact lens prescribing and wear (e.g., the US) have greater levels of patient satisfaction – as measured by the lower rate of permanent drop-out from contact lens wear. (See attached Exhibit 1.)

The medical literature is clear that contact lens-related complications can and do occur, and that signs can occur before symptoms. In addition, the facts are clear that these complications can lead to the loss of vision or, in the worst cases, the loss of an eye. FTC should not take actions that undercut the US regulatory standards or

---

<sup>2</sup> See Sauer A, et al. Risk Factors for Contact Lens-Related Microbial Keratitis: A Case-Control Multicenter Study. *Eye and Contact Lens*. May 2016. Volume 42, Number 3; and Sorbara L, Zimmerman AB, Mitchell GL, Richdale K, Lam DY, Kinoshita BT, Chalmers RL, Wagner H. Multicenter Testing of a Risk Assessment Survey for Soft Contact Lens Wearers With Adverse Events: A Contact Lens Assessment in Youth Study, *Eye and Contact Lens*. 2018 Jan;44(1):21-28.

standards of care that help to control and mitigate these risks based on unsubstantiated assertions about alleged experience in other countries.

## **FTC Should Not Take Action On Medical Matters Related To Prescribing Or Renewing Prescriptions For Contact Lenses, Including The Propriety Of Telemedicine**

CLI believes that only eye care professionals, in the exercise of their professional responsibilities and judgment, are in a position to decide whether and how their patients can safely and effectively wear the contact lenses those professionals prescribe specifically for them. CLI also believes, based on the nature, design, purpose, classification and labeling of contact lenses, that there is no substitute today for a comprehensive eye examination that evaluates the fit of the contact lens and health of the eye as a basis for the initial and ongoing prescription and wear of contact lenses. Because a contact lens is placed directly on the eye, the physiological response of the cornea, as well as the eyes' adnexa, including the conjunctiva and eyelids, must be monitored to ensure safe wear. Serious conditions such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious adverse events such as abrasions, infiltrates, and bacterial conjunctivitis must be diagnosed, managed and treated early in order to avoid more serious complications. As the FTC representatives acknowledged at the Workshop, FTC does not make judgments on medical matters. Therefore, in considering changes to the CLR, or any other possible FTC actions, FTC should not substitute its views for the judgments of the FDA, state professional practice regulators, responsible professional organizations and individual eye care professionals in exercising their expert professional and regulatory responsibilities.

As Dr. Carol Lakkis, Dr. Steinemann and Dr. Cockrell testified at the Workshop, only professional evaluation through regular follow-up visits and comprehensive eye examinations can identify asymptomatic conditions that contact lens wearers can experience which, left unrecognized or untreated, can lead to more serious problems that can interfere with the safe and successful wear of contact lenses and compromise the continued health of a patient's eyes. Current Standard of Care recommendations<sup>3</sup> and guidelines in many contact lens package inserts state that contact lens patients should see their ECP once each year, or more often, as recommended by their ECP.

---

<sup>3</sup> See the recommendations of CDC at <https://www.cdc.gov/contactlenses/protect-your-eyes.html> (Visit your eye doctor yearly or as often as he or she recommends); AAO at <https://www.aao.org/eye-health/glasses-contacts/contact-lens-care> (Get regular eye exams. If you wear contact lenses, you should be examined by an eye care provider annually, and more often as needed); and AOA at [https://www.aoa.org/documents/EBO/Comprehensive Adult Eye and Vision%20QRG.pdf](https://www.aoa.org/documents/EBO/Comprehensive%20Adult%20Eye%20and%20Vision%20QRG.pdf) (at least annually).

As it is admittedly not within the FTC's jurisdiction or expertise to determine the adequacy of remote medical diagnostics, or of any other means for either prescribing contact lenses, renewing contact lens prescriptions, or determining the appropriate frequency of eye exams, we recommend the FTC not engage on these issues and defer to other state and federal agencies who have responsibility to do so.

### **FTC Should Eliminate The Current Loopholes In The Enforcement Of Contact Lens Prescription Requirements**

CLI respects the intent of Congress and the FTC to establish a system that ensures patients' timely and efficient access to purchase their prescribed contact lenses from the seller of their choice. As manufacturers, it is important to us that our products are used safely, appropriately, and as prescribed by responsible ECPs. CLI therefore supports effective enforcement by FTC against sellers who suggest that consumers can obtain lenses from them without a valid, current (or any) prescription, or that they can obtain lenses other than those that have been specifically prescribed for them. We believe these actions, and related modifications or clarifications of the CLR will help to ensure that patients always receive the exact lenses prescribed by their ECP.

The FCLCA and the CLR set up a system that relies in part on "passive" verification of contact lens prescriptions. Under that system, a prescription is deemed to be valid when a request for verification is transmitted to a contact lens prescriber who does not respond to the request within eight business hours. While permitting requests for lenses to be filled quickly, the reliability of this system depends entirely on the accuracy and completeness of the transmission of the verification request and the ready availability to the prescriber of effective means for responding to the request if the request is either incomplete or the purported prescription is invalid. When transmitted accurately and in a verifiable manner, using written or electronic documentation such as email or fax that also allow for timely and documented responses, errors in verification can be prevented and valid prescriptions timely verified.

As FTC is well aware, and as many Workshop participants described, many online sellers of contact lenses use automated or semi-automated telephone calls ("robocalls") to transmit requests for prescribers to "verify" prescriptions for contact lenses. As testimony at the Workshop indicated, robocalls are often not intelligible, and opportunities for prescribers to seek clarification and/or to respond on a timely basis are often lacking or inadequate. Importantly, the robocall procedure entails no written record of the content of the information supplied or even of the transmission and receipt of the request. To reduce verification of invalid, erroneous or nonexistent prescriptions that can lead to compromise of consumer health and safety, CLI requests

the FTC modernize the passive verification process, restrict error-prone robocalls and require more reliable methods of communication for verification (e.g., email and fax).

Finally, as reflected in the January 30, 2017 Coalition comments, CLI recommends that the FTC 1) preserve the current one-year minimum validity period for contact lens prescriptions where the ECP has not specified a shorter period based on medical judgment or the health of the patient; 2) clarify that contact lenses should not be dispensed in quantities beyond those reasonably needed for patient use during the term of a prescription; and 3) clarify and enforce the requirement that patients be dispensed only the specific contact lenses they have been prescribed.

## **Conclusion**

CLI supports the intent and purposes of the FCLCA and the CLR and supports appropriate changes to update and better tailor the CLR to those purposes. It is our belief that by making minor modifications to the existing Contact Lens Rule, patient health and safety can be improved, while preserving consumer choice and competition in the evolving U.S. contact lens marketplace.

As leaders in contact lens research, patient education and manufacturing, we look forward to working with and serving as a resource for the FTC and other agencies in the future.

Respectfully submitted,



Stanley J. Rogaski  
Executive Director

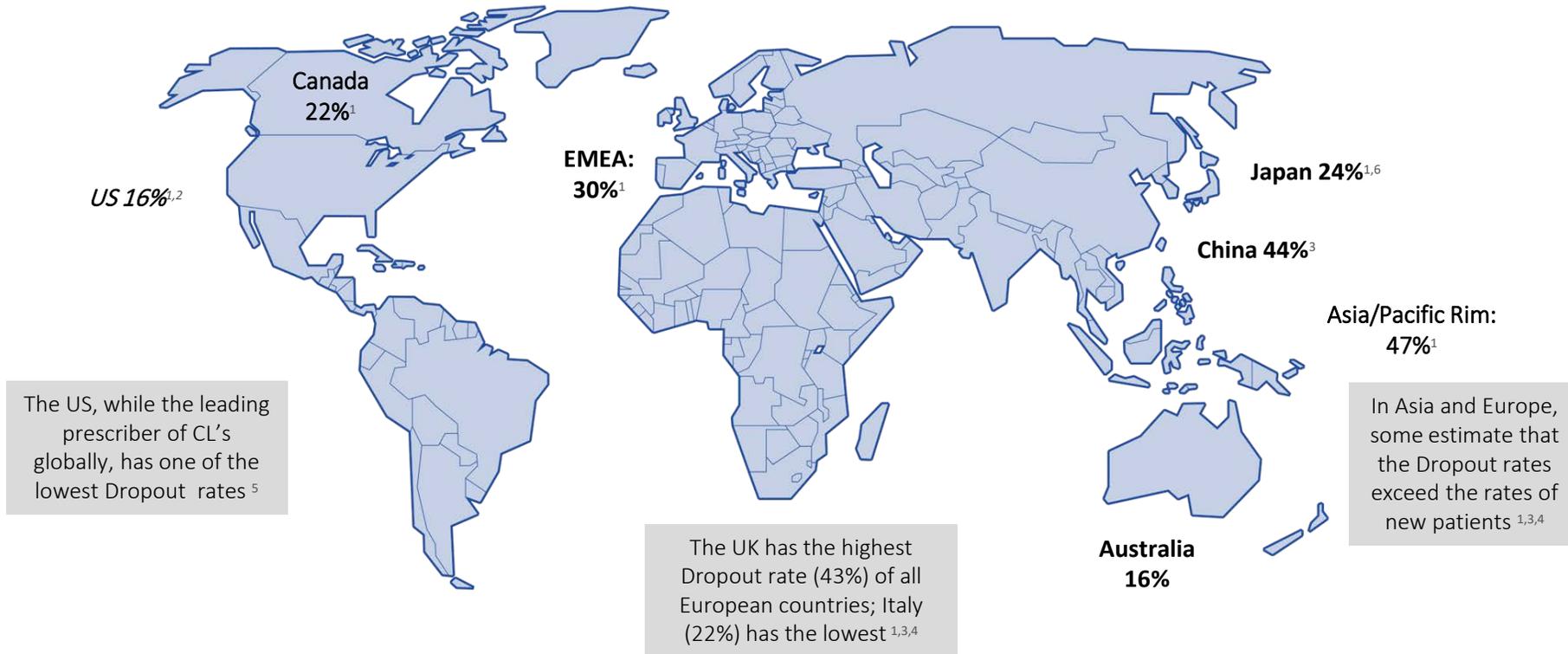
Contact Lens Institute  
1850 M Street NW, Suite 800  
Washington, DC 20036

## Exhibit 1

# 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: 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.