



AMERICAN ACADEMY
of OPTOMETRY

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October 26, 2015

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

RE: Public Comment on the Contact Lens Rule, 16 CFR part 315, Project No. R511995

Dear Secretary Clark:

The American Academy of Optometry (AAO) welcomes the opportunity to make public comment on the rule contained in the Federal Register, Volume 80, Number 171, referencing 16 CFR Part 315, the rule that relates to the Fairness to Contact Lens Consumers Act contained in 15 USC §7601–7610, as enacted (Hereinafter referred to as “the Contact Lens Rule”).

Founded in 1922, the AAO represents Doctors of Optometry and other vision scientists from the US and roughly 40 other countries. Obtaining the distinction of “Fellow of the AAO” is an earned distinction through a peer-reviewed examination process, and there are currently 4,744 US Fellows and more than 500 international Fellows.

Doctors of Optometry, including those who are AAO Fellows, serve patients in 6,500 communities across the country, and in 3,500 of those communities are the only eye doctors. Doctors of Optometry provide more than two-thirds of all primary vision and eye health care in the United States.

The AAO is aware that the Federal Trade Commission (FTC) is undertaking a prescribed review of the Contact Lens Rule, and wishes to make the following comments.

First, the AAO concurs with the public comments provided to the FTC by the American Optometric Association (AOA). In addition, the AAO wishes to emphasize the following points.

It is the position of the AAO that the protection of consumer rights in the purchasing of prescribed contact lenses is unquestioned; rules that govern those transactions must properly balance patient safety concerns.

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The first ten years of experience with the Contact Lens Rule have exposed significant weaknesses in balancing consumer protection and patient safety. Most of those weaknesses are addressed by the AOA comments. In addition, what has been learned through careful peer reviewed research over the past ten years, performed mostly by AAO Fellows, is that the development of alternative supply chains for the sale of contact lenses—and the use of those alternative supply chains by contact lens patients—has itself become an identifiable risk factor for ocular morbidity in contact lens patients.

In 2008, a large prospective population-based surveillance study was published by Dr. Fiona Stapleton and colleagues in a peer-reviewed journal.¹ They specifically evaluated potential risks of developing microbial keratitis (MK), a serious and painful infection of the cornea that can lead to permanent vision loss. They reported that the odds of developing MK among those who purchased their lenses through the internet or mail order was almost 5 times higher than those who purchased them through a provider's office. The reason for this finding may lie in the following.

In 2010, Wu, Carnt, and Stapleton published data that show a significant difference in the aftercare awareness in those who purchased their lenses from alternative channels of distribution.² They published rates of overall non-compliance as high as 60% and quoted others who have published non-compliance rates as high as 91%. These data were confirmed by the CDC in their MMWR report on August 21, 2015 (August 21, 2015 / 64(32); 865-870). In 2008, Fogel and Zidile found that internet purchasers were more likely to engage in harmful eye care practices and to trust non-evidence based information found on the internet rather than seeking out proper care and best practices as recommended by their prescriber. Overall, about one-in-four contact lens wearing college students do not check to ensure that their prescription is valid and order lenses even though they know their prescription has expired. Only two-thirds of the sellers asked the patients for their prescriber's contact information. About two-in-ten purchased lenses without a prescription. Fewer internet purchasers have their eye care specialist check to make sure their contact lenses fit properly after purchase compared to those patients that do not purchase from the internet. All of these metrics of improper contact lens purchases are in conflict with accepted FDA best practices and those recommended by the contact lens prescribers.³

¹ Stapleton F, Keay L, Edwards K, Naduvilath T, Dart JK, Brian G, et al. The incidence of contact lens-related microbial keratitis in Australia. *Ophthalmology* 2008;115:1655-62.

² Wu, Y, et al. Contact lens user profile, attitudes and level of compliance to lens care. *Contact Lens & Anterior Eye* 33 (2010) 183-188

³ Fogel J, et al. Contact lenses purchased over the Internet place individuals potentially at risk for harmful eye care practices. *Optometry*, Vol 79, No 1, January 2008

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With this information in mind, legislators and regulators should carefully consider the potential risks to patients when trying to assess the manner and level of consumer protections when balanced against patient protections.

The leadership of the American Academy of Optometry hopes that these comments, in addition to those provided by the American Optometric Association, will help guide the FTC in making the proper adjustments to the Contact Lens Rule and its accountable enforcement in the future.

Sincerely,

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President

Loretta Szczotka-Flynn, OD, PhD, FAAO
Chair, Section on Cornea, Contact Lens
and Refractive Technologies

Attachment