United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Office of Commissioner
Rohit Chopra

To: April Tabor

From: Samuel Levine

Date: November 20, 2019

Re: Contact Lens SNPRM: Comments to be placed on the public record

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On November 4, 2019, Commissioner Rohit Chopra met with representatives of various organizations, at the request of the American Optometric Association ("AOA").[1] The purpose of the meeting was to discuss their perspective on the Commission's Supplemental Notice of Proposed Rulemaking ("SNPRM") regarding the Contact Lens Rule ("Rule").

During the meeting, the representatives raised concerns about the prescription release non-compliance surveys submitted to the public record, contending that they were unreliable because patients frequently request prescriptions before the completion of their fitting.

Commissioner Chopra asked the representatives about the origin of the non-compliance surveys on record, and whether they were funded directly or indirectly by sellers or other interested parties. The representatives stated that one of the surveys on the public record was funded by 1-800 Contacts. Another survey was conducted by Consumer Action, and the representatives noted that 1-800 Contacts was a donor to that organization. Commissioner Chopra then asked if AOA was aware of other probative data, and AOA stated that they have conducted surveys showing high compliance, but are not aware of any other data.

AOA also expressed concern that the Commission fails to appreciate the burden imposed by the signed acknowledgement requirement. Commissioner Chopra agreed that the Commission at times treats small businesses unfairly, while treating larger enterprises more generously, and sought to better understand the burden the Rule was imposing on AOA members. AOA responded that for smaller practices, the burden is considerable, especially with the advent of electronic medical records. Small optometry practices are also burdened through passive verification exploitation and robocalls, AOA added.

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[1] In attendance from AOA were Kara Webb (Director of Coding and Regulatory Policy), David Cockrell (Advocacy Chair), and Emily Dalgo (Regulatory Specialist). Also in attendance were Jillian Winans (Regulatory Affairs Specialist) from The American Society of Cataract and Refractive Surgery, Scott Haber (Manager, Federal Affairs & Public Health), and Rebecca Hyder (Director of Congressional Affairs) from the American Academy of Ophthalmology. Samuel Levine, Commissioner Chopra's Consumer Protection Counsel, also participated in the meeting, as did Paige Carter, the Commissioner's paralegal.

Commissioner Chopra agreed that it was important for the Commission to carefully consider the burden the Rule imposes on small businesses, but added that it was also important to understand whether firms may be incentivized to flout the Rule and impede consumer choice. Commissioner Chopra asked for information related to a typical office's revenue structure and personnel. AOA shared that for most offices, eyeglasses generate more revenue than contacts, and that a typical office with one optometrist has 3.4 employees and $800,000 in revenue.

AOA further noted that the Commission has not received many consumer complaints related to prescription release issues, which they contended demonstrates compliance. Commissioner Chopra responded that a lack of complaints is not a persuasive argument, and urged AOA instead to submit data demonstrating compliance or burden. Commissioner Chopra also asked the representatives to propose alternative frameworks that the Commission should consider, such as limiting the signed acknowledgement requirements to patients who purchase contacts in the office. He stressed that he was open to modifications if they were supported with rigorous data.

Commissioner Chopra asked AOA to further explain their proposal for a posted sign alternative to the signed acknowledgement requirement. The AOA shared that, notwithstanding skeptics' claim that doctors would not make the signs visible, they believe signs would aid in addressing the Commission's immediate concerns, while reducing the compliance burden for small offices.

Commissioner Chopra also discussed with AOA the contact lens market generally. AOA noted that prices were converging among online and in-office sellers, and that consumers had more choices than ever in purchasing lenses, which, in their view, indicated compliance. The largest area of noncompliance, AOA contended, is among retailers who are exposing patients to harm by selling non-prescribed or counterfeit lenses. This is a growing problem on online platforms, AOA added, including on platforms that purport to prohibit the sale of medical devices.

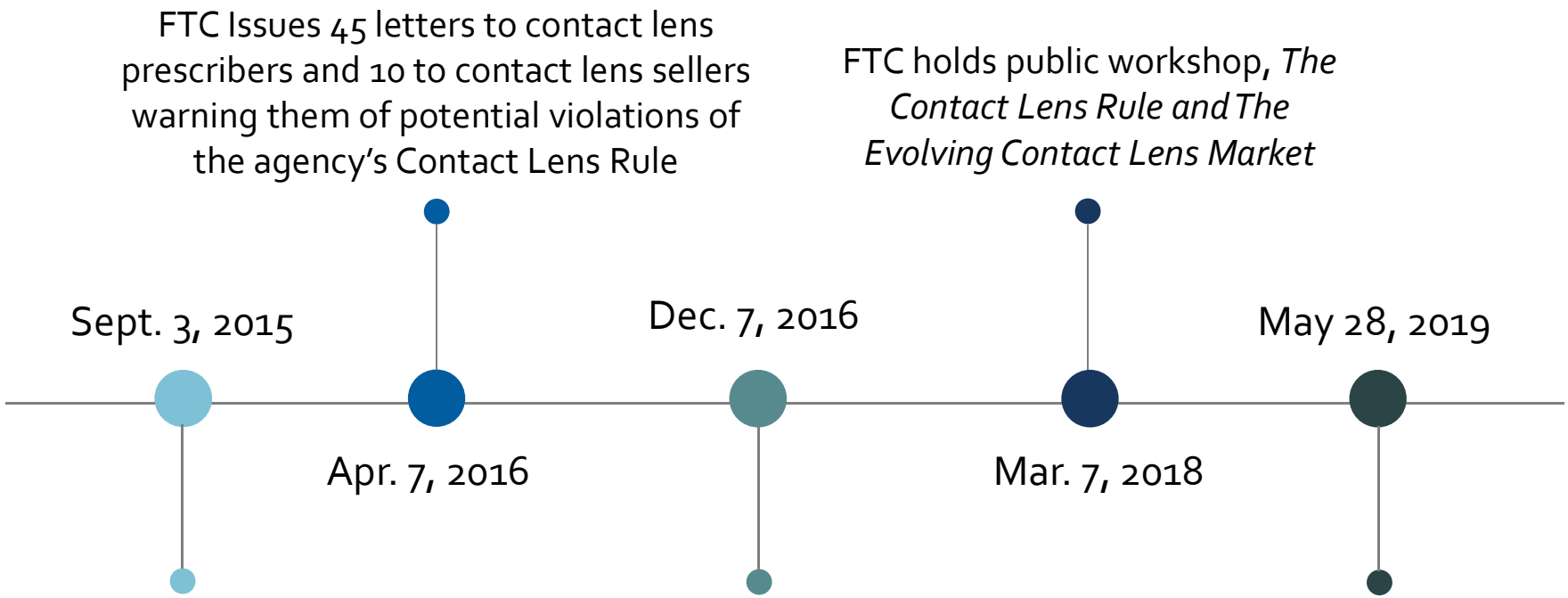
Commissioner Chopra expressed his appreciation to the representatives for their input and noted that he would be monitoring the proceeding carefully.

Contact Lens Rule – Proposed Rulemaking

Comments from the American Optometric Association Prepared for the Federal Trade Commission

November 4, 2019

Rulemaking History

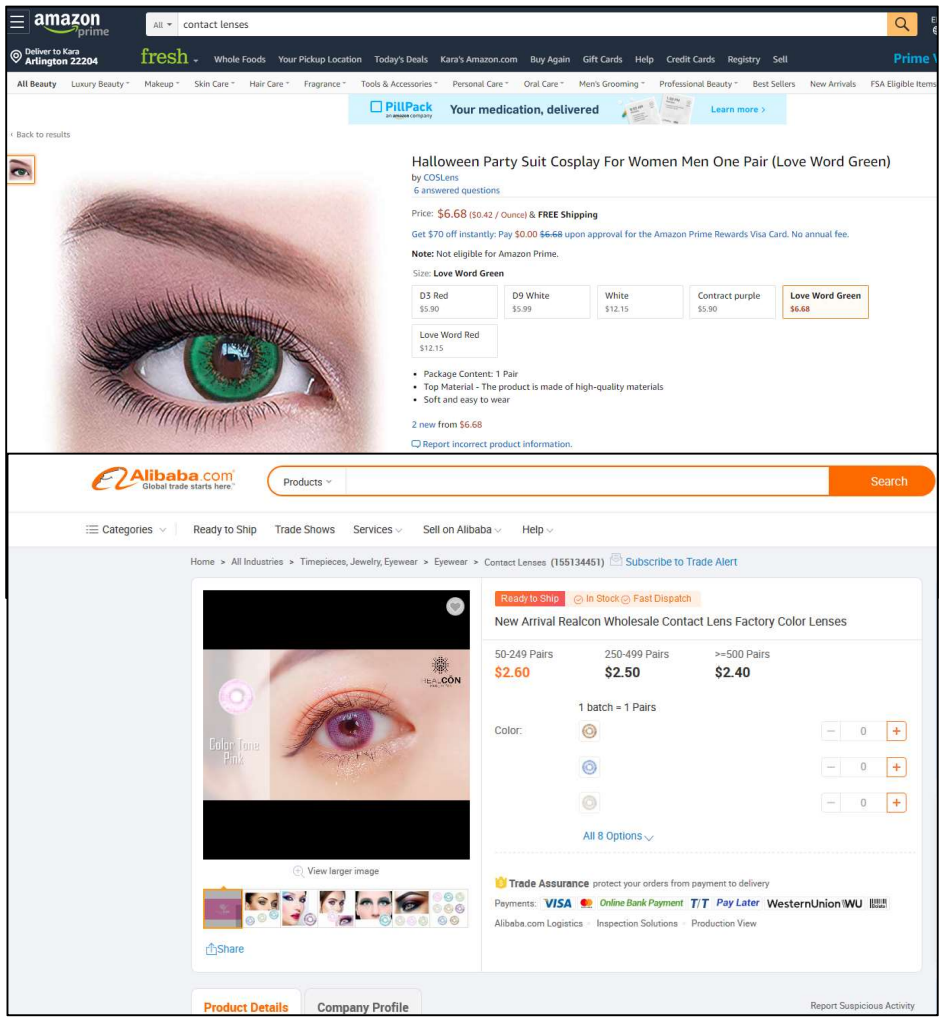


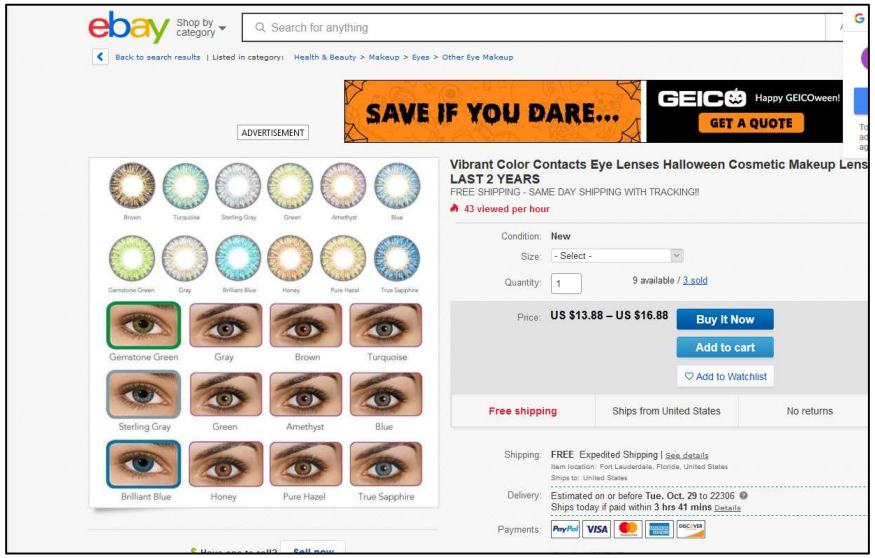
Contact Lens Market Evolution

Much has changed in the contact lens market since 2015, when the 10-year review on the CLR was initiated:

- Opternative/Visibly entered the market in 2015 providing an online vision test
- Simple Contacts entered the market in 2015 providing an online vision test for contact lens renewal
- Opternative/Visibly partnered with 1-800-CONTACTS to offer an online vision test in 2016
- Hubble Contacts entered the market their own brand of daily contact lenses in 2016
- Waldo Contacts entered the market with their own brand of daily contact lenses in 2017
- Aveo Contacts entered the market with their own brand of daily contact lenses in 2018
- 1-800-CONTACTS disengaged with Opternative/Visibly in 2017/18 and ExpressExam (the company's own online vision test) was launched
- 1-800-CONTACTS launched its own brand of daily contact lenses (AquaSoft) in 2018
- In 2019, Opternative/Visibly recalled their online vision test after FDA engagement. The reason for the recall was prompted because the company "has not received authorization from FDA to market the product."
- Simple Contacts, ExpressExam, Hubble Contacts, AquaSoft, Waldo, Aveo are all currently on the market

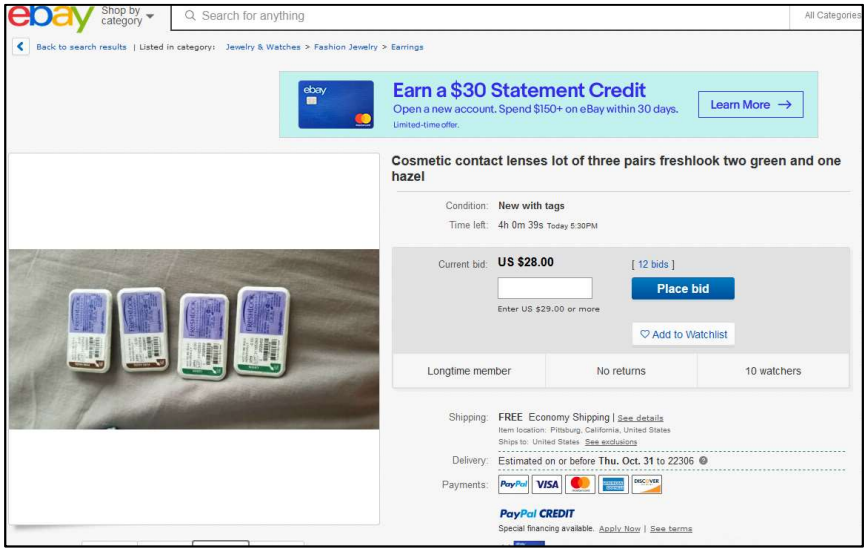
Market Changes Since FCLCA: Sellers use leading online platforms to sell contact lenses with a prescription

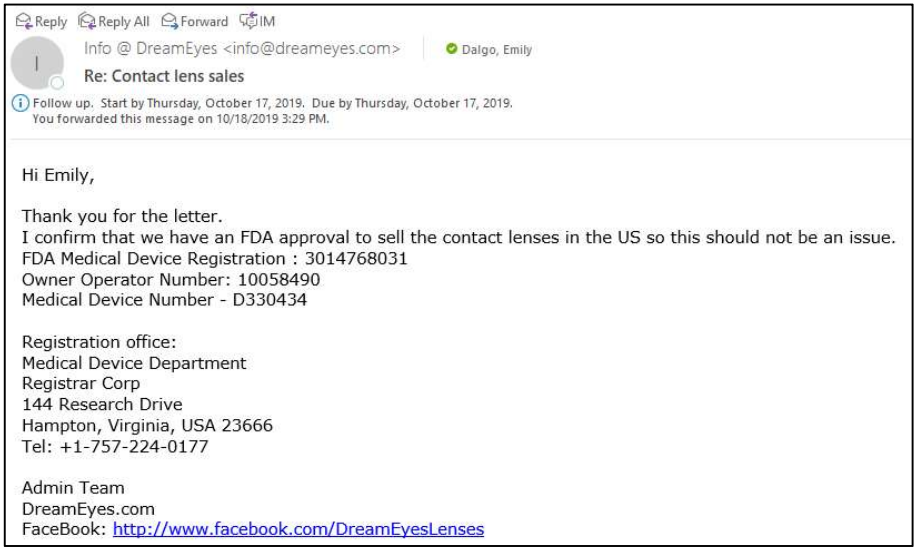


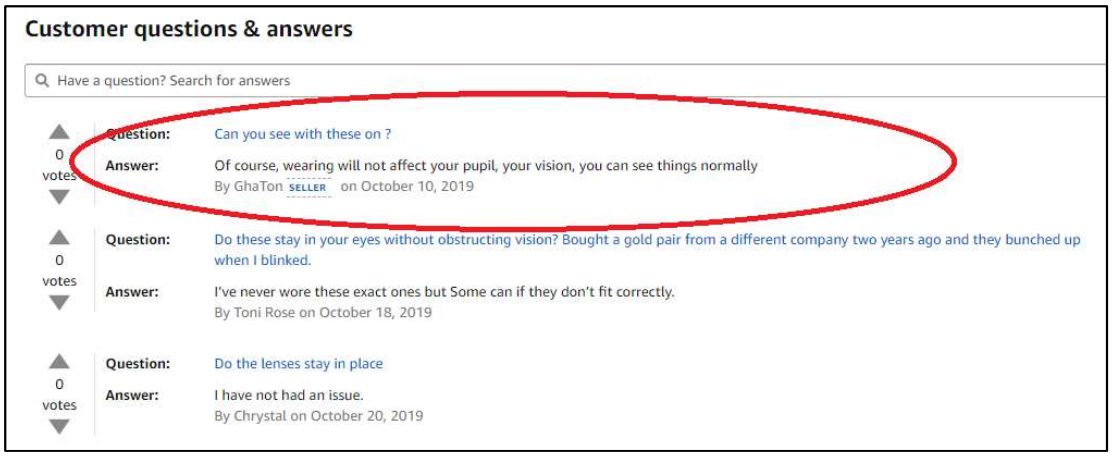


Despite AOA outreach to notify online platforms of problematic retailers, these leading online platforms continue to allow contact lens sales without requiring a prescription.

Market Changes Since FCLCA: Contact lens regulatory requirements and health risks are misstated

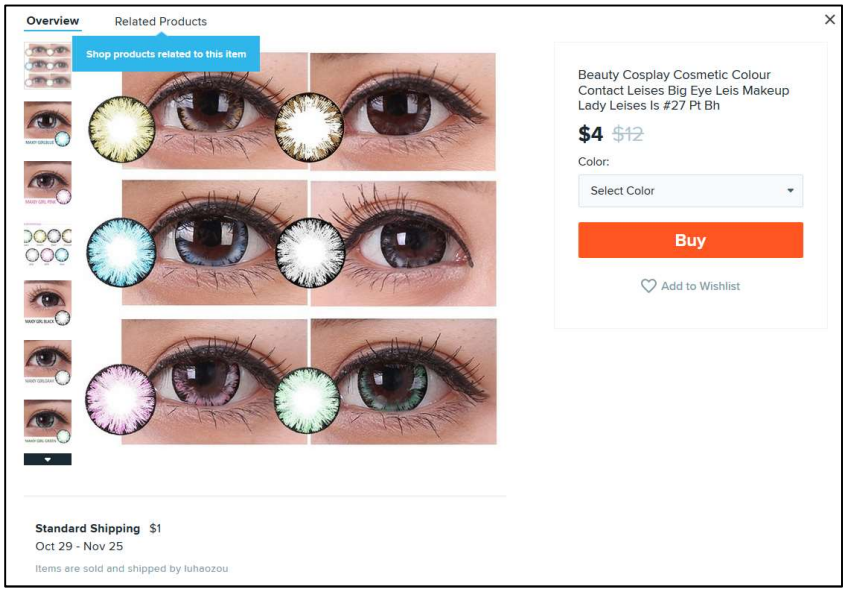


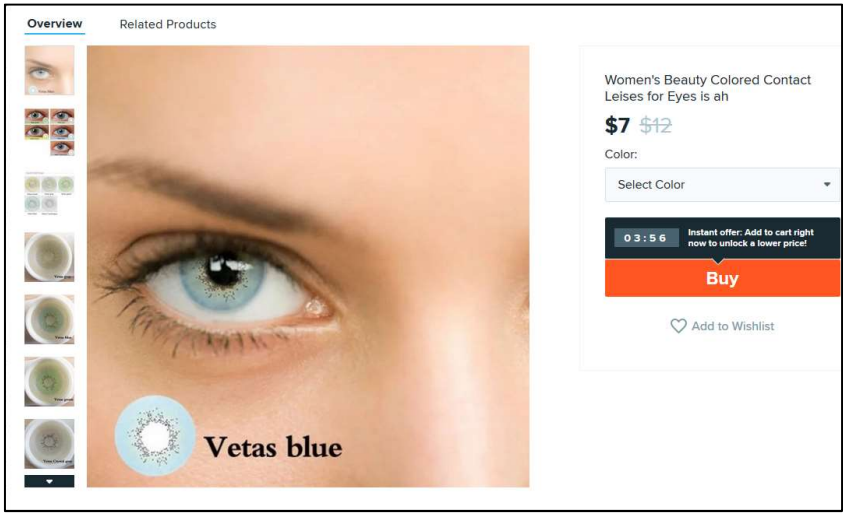




The public is receiving inaccurate and misleading information from sellers using these online platforms and other websites.

Market Changes Since FCLCA: leading online platforms lack accountability





Wish CEO Peter Szulczewski was "unfazed by the quality-control challenge, pointing out that sometimes customers themselves are the problem." He commented, "We sell 5 million contact lenses a year…someone's going to sleep in them."

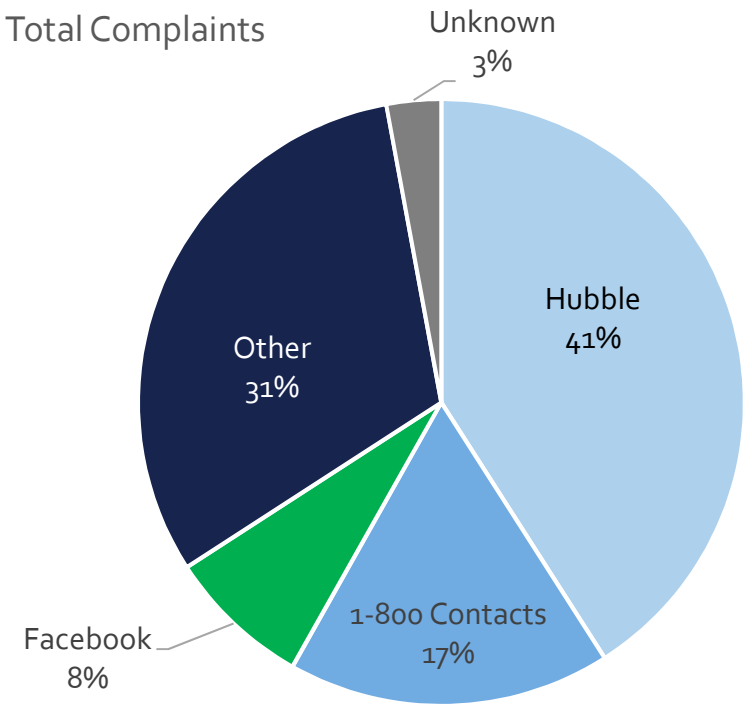
Market Changes Since FCLCA: Contact lens prices converge

- To follow up the FTC's 2005 study of contact lens pricing, AOA conducted a price comparison analysis that shows the FCLCA is working and competitive pressures on eye-care industry have been triggered
- AOA study compared online and in-office costs of 81 contact lenses and found an average price difference of $0.32 across all lenses
- 28 lenses were more expensive online, while 53 were more expensive in the doctor's office.
- FTC's 2005 study had found: "Not accounting for intrachannel differences, contact lenses sold online are on average $15 less expensive than those sold offline"

The FTC should consider the current contact lens market and updated pricing data when making decisions about consumer choice and the competitiveness of the contact lens market

Current state of the contact lens market: retailer violations

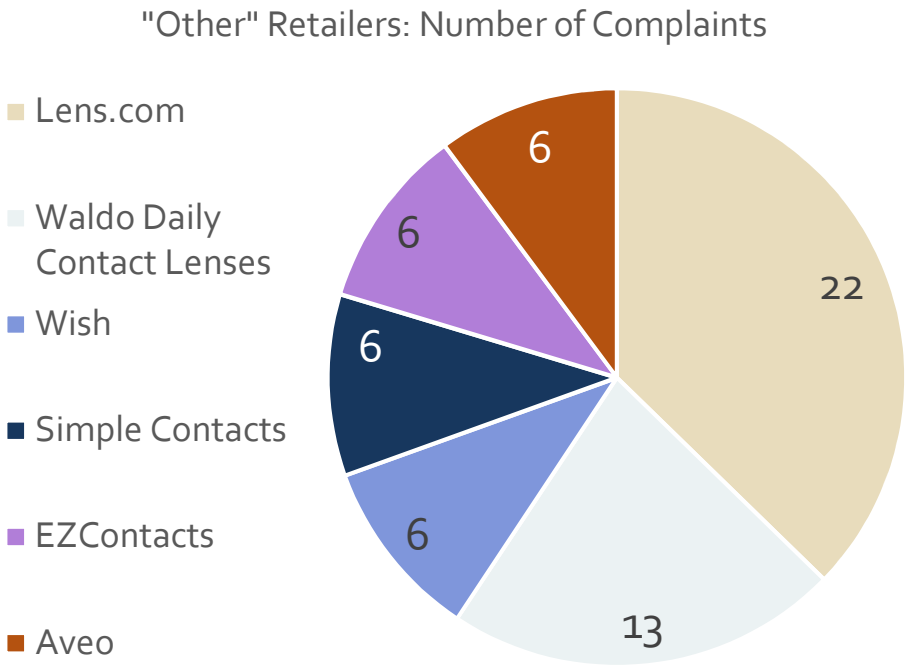
- AOA received 1,028 unique complaints of contact lens sale violations from doctors of optometry and their staff from 2017-July 2019
- 41% of total complaints related to Hubble
- Chief complaints were the sale of contact lenses without a prescription; that were not prescribed to the patient/wrong prescription; incomplete verification requests; an expired prescription
- FTC could use existing authority to take action against retailers leveraging loopholes in the verification process and launch an investigation into Hubble contacts



Current state of the contact lens market: contact lens adverse events resulting in patient harm

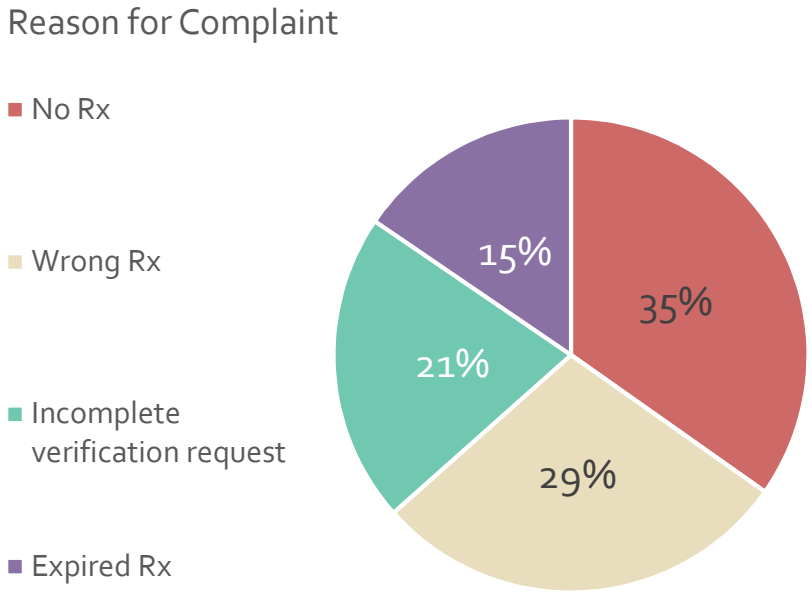
Doctors who have seen patients with illegally obtained contact lenses resulted in the following adverse health outcomes:

- Keratitis
- Scarring
- Decrease in best corrected vision
- Corneal ulcer
- Infection
- Corneal neovascularization
- Redness and irritation
- Infectious bacterial ulcer
- Corneal abrasion
- Inflammation



Current state of the contact lens market: passive verification exploitation and robocalls

- Issues with verification requests, such as an incomprehensible robocall, accounted for 21% of the 1,028 violation complaints sent to AOA
- 85% of doctors report that the use of robocalls for prescription verifications has increased over the past 5 years, according to AOA survey of over 600 doctors of optometry
- 88.2% of doctors indicated that the quality of robocalls has decreased in the past 5 years
- Hubble relies fully on automated phone calls to sell its own brand of contact lenses



Robocalls that are relied on to exploit passive verification result in patients receiving contact lenses that were not prescribed, jeopardizing eye health

Proposed Changes: Burden and Impact on Small Businesses

- AOA annual survey of doctors of optometry found respondents reported collecting $829,106, on average, in gross receipts in 2016.
- The Small Business Administration receipts based size standard for doctors of optometry offices is $8 million.
- FTC estimated that, combining the aggregate labor costs for both prescribers and office staff to obtain patient signed acknowledgments and preserve the associated records, the Commission estimates the total labor burden of the confirmation of prescription release proposal to be $13,244,727.
- For the March 2016 FTC proposal to required the signed acknowledgment form , the estimated total additional labor cost attributable to the proposed modifications to the Rule were estimated at approximately $10,475,495. Despite increased "flexibility" in supplemental rulemaking, the burden estimate increased.
- Current regulatory burden for retailers who currently disregard the rule and law is $0.

Reevaluating the need for prescriber regulatory changes: FTC's data shows low rate of prescription release noncompliance

- 2017 Freedom of Information Act request showed that over the 2011–2016 period, the FTC received complaints from a total of 309 consumers out of roughly 200 million contact lens prescriptions issued
- During the March 2018 workshop, FTC staff noted "from the FTC's perspective, we feel that the complaints we do get are a tip of the iceberg. And if you don't know that you have a right to your prescription, you certainly don't know that you're supposed to complain to the FTC."

The complaints of prescription release noncompliance represent approximately 0.00015% of the contact lens prescriptions issued between 2011-16

Solution: to address the Commission's immediate concern regarding consumers' awareness of their rights, require doctors to post a sign in their offices notifying patients of their right to their prescription

Reevaluating the need for prescriber regulatory changes: data used regarding prescription release compliance is questionable

- FTC relies heavily on misleading data provided by 1-800-CONTACTS regarding prescriber compliance with the release of contact lens prescriptions
- In their July 2019 survey, 1-800-CONTACTS again asked patients if they had to ask for their contact lens prescription
- 1-800 CONTACTS reports 56.9% of patients who were not "automatically provided Rx" had to ask for it
- The data from these past two surveys equate a patient asking for their prescription with non-compliance
- Patient requests for prescription before a fitting is complete are common: 91.7% of ODs say patients ask for prescription prior to finalization of contact lens fitting according to June 2019 AOA study

Solution: better data is needed to fully assess compliance

Solution: create a dedicated complaint system for FCLCA-related concerns

Considerations

Regulatory Timing

- Congress is currently considering legislation related to the contact lens market (The Contact Lens Prescription Verification Modernization Act)
- The FDA is following new market entrants related to contact lenses and online applications and evaluating them for effectiveness and safety
- Given the various changes in the contact lens market with new market entrants, new technologies, is now the appropriate time for the FTC to implement regulatory changes?

Use Existing Authority

- Investigate patient complaints received
- Address non-compliance with retailers

Consider a Less Burdensome Alternative

- If FTC is concerned about public awareness of rights, the AOA supports a new requirement to have prescribers post signs notifying patients of their right to their contact lens prescription. This alternative is supported by more than 100 U.S. Senators and House members who are on record supporting the posted sign alternative to the FTC's proposal.