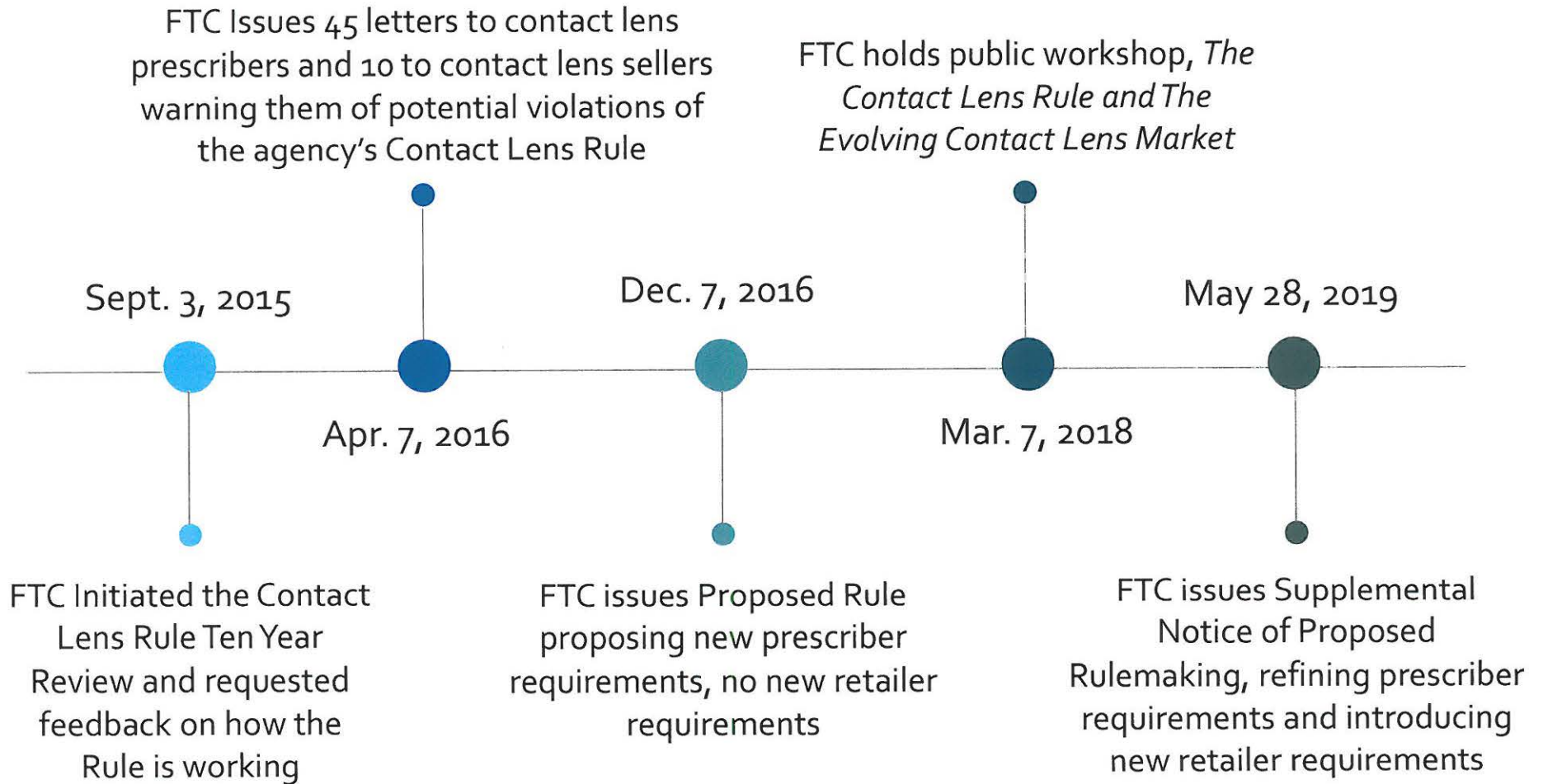


Contact Lens Rule – Proposed Rulemaking

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

September 18, 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 with 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

Reevaluating the basis for this proposed rule: contact lens prices are competitive

- 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

Reevaluating the basis for this proposed rule: the contact lens market is not unique

"Several commenters said the amendment is necessary because the market for contact lenses remains unique in that—unlike most other medical doctors—eye doctors sell the items they prescribe, and thus are rewarded financially for driving patients to their own retail channels." (FTC SPRM 2019)

- Attempts to paint contact lens market and the role of doctors in that market as unique is inaccurate
- FTC lawyers refuted this argument in 2017

"[...] it is common knowledge that healthcare professionals at ambulatory surgery centers, orthopedic centers, dental service providers, and many other 'healthcare providers' may sell the products that they prescribe."

(FTC Complaint Counsel Finding of Fact In the Matter of 1-800 CONTACTS, INC., a corporation, Docket No. 9372)

Reevaluating the basis for this proposed rule: 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

The reality of the Contact Lens Rule: online retailer practices and growth

The image contains three screenshots of online retailer websites:

- Coastal:** Shows a 'Prescription Verification' section with a progress bar (My Cart, 1. Shipping, 2. Doctor Info, 3. Payment) and a promotional banner for 10% off. It offers two options: 'Have us contact your doctor' and 'Send us a copy of your prescription later', each with a 'Select' button.
- 1800contacts:** Features a 'How would you like to provide your prescription?' screen with two main options: 'Upload a photo' and 'Enter manually'. A 'Ships Fastest' badge is present on the left.
- lens.com:** Displays a 'Doctor Information' form for '1-Day Acuvue' lenses. It includes fields for Patient Name, Date of Birth, Doctor/Store Name, and Phone. A 'Need Help?' section offers a 'Search For My Doctor' feature with fields for Dr. Last Name, State/Province, and City.

- Online retailers encourage the use of passive verification
- The FTC’s 2005 report included data indicating independent doctors represented 68.6 % of the contact lens market share
- Vision Council 2017 data shows that independent physician share was 39%
- The fastest-growing distribution channel for CL sales in the US was the online/Internet channel

Reevaluating the basis for this proposed rule: 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

1-800-CONTACTS advertisements direct patients away from comprehensive eye examinations

The company is creating a business model built on pushing people away from their doctors and instead use 1-800-CONTACTS' online vision exam and purchase its own brand of contact lenses

1-800 CONTACTS ✓
July 11, 2018

Skip the trip to the optometrist and use our Express Exam to renew your contact lens prescription. <https://www.1800contacts.com/online-contact-lens-prescription>



12 9 Comments

Share

1800 Like Share Suggest Edits ...

1-800 CONTACTS ✓
May 10

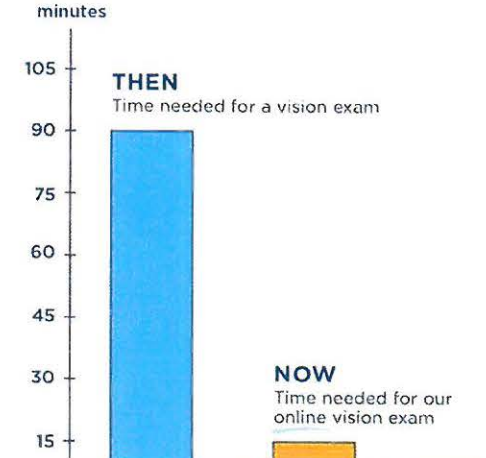
Then vs Now. Less time at the eye doctor's office=more time in bed 😊
Winning! What will you do with your extra time? Follow the link to our online vision exam <http://bit.ly/2vSEgMM>

1-800 CONTACTS ✓
1800Contacts

- Home
- About
- Posts
- Photos
- Videos
- Job Openings
- Events
- Notes
- Community

Create a Page

minutes



Time Period	Time needed for a vision exam (minutes)
THEN	90
NOW	15

Time needed for a vision exam

Time needed for our online vision exam

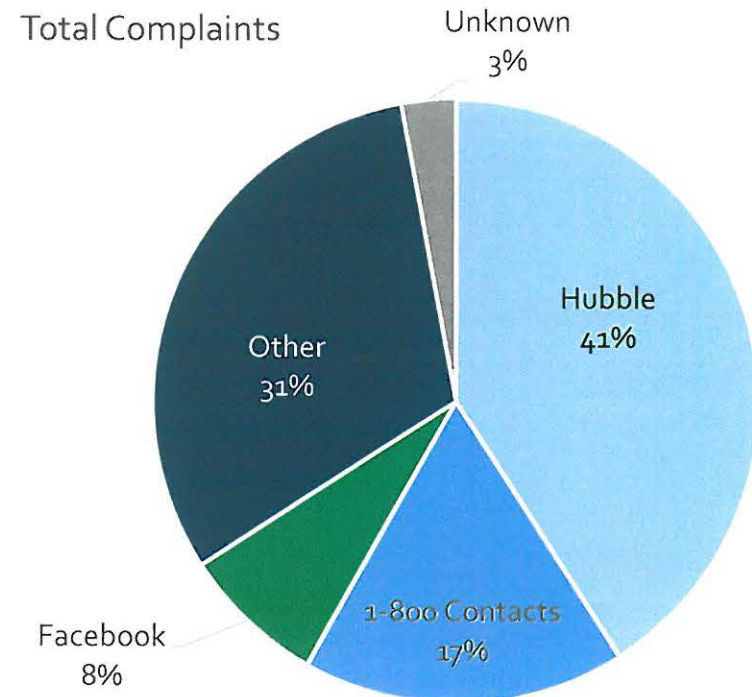
1-800-CONTACTS advertisements direct patients away from comprehensive eye examinations



Holding online retailers accountable: documented violations resulting in patient harm (1/2)

While new proposals recommended for retailers are a positive step, we believe FTC should take immediate and direct steps to investigate and address the blatant FCLCA violations of online sellers

- 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



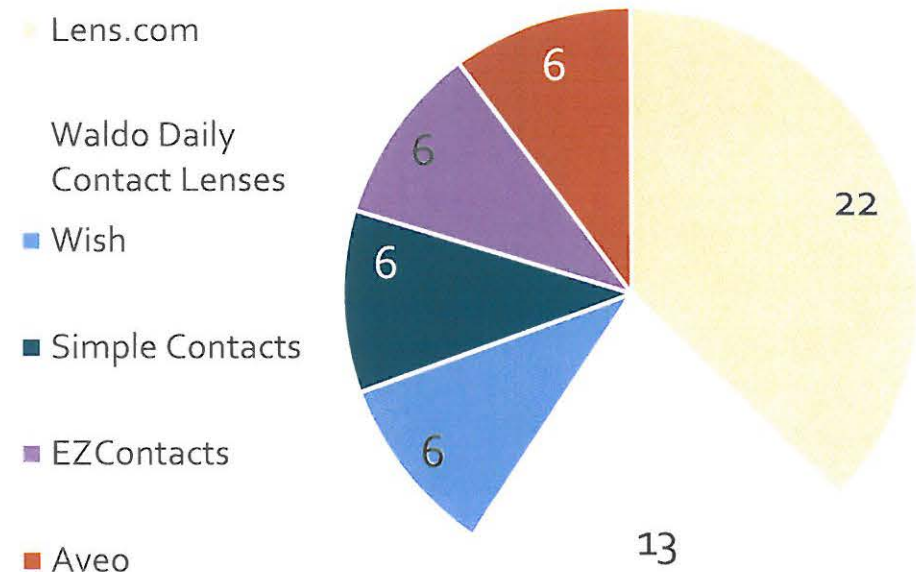
Holding online retailers accountable: documented violations resulting in patient harm (2/2)

While new proposals recommended for retailers are a positive step, we believe FTC should take immediate and direct steps to investigate and address the blatant FCLCA violations of online sellers

AOA has received complaints from doctors of optometry who have seen patients with illegally obtained contact lenses that 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

"Other" Retailers: Number of Complaints

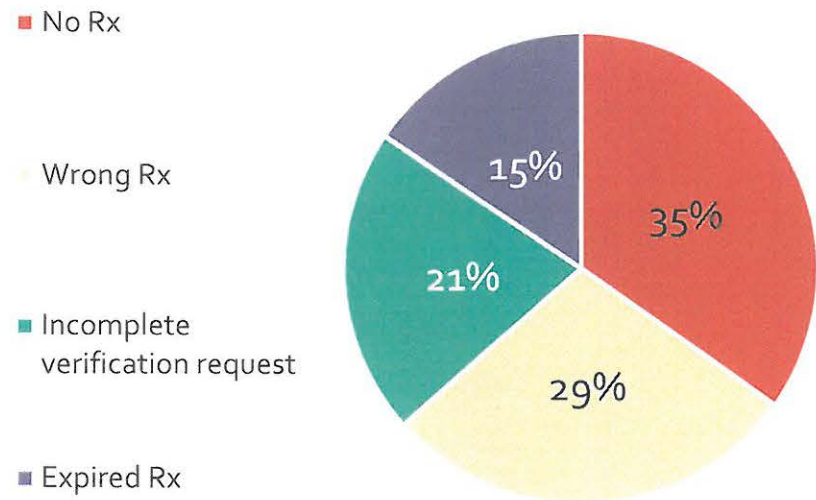


Holding online retailers accountable: passive verification exploitation and robocalls

While new proposals recommended for retailers are a positive step, we believe FTC should take immediate and direct steps to investigate and address the blatant FCLCA violations of online sellers

- 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

Reason for Complaint



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

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