



April 6, 2018

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

Dear Secretary Clark,

The American Optometric Association (AOA) appreciates the opportunity to provide comments as the Federal Trade Commission (FTC) continues its ten-year review of the Contact Lens Rule. The AOA represents 33,000 doctors of optometry and optometry students. The AOA is the voice of the nation's family eye doctors and the leading authority on eye health, vision care, and patient safety issues. Doctors of optometry prescribe the majority of contact lenses for patients in the United States. Contact lenses are a popular choice for vision correction and are effective and safe when prescribed and used in accordance with a doctor's instructions. Because improper use can lead to injuries and infections that may cause vision loss or blindness, our member doctors are essential in mitigating this risk and ensuring that the use of contact lenses results in optimal vision and eye health.

The AOA supports the right of patients to purchase contact lenses from the seller of their choice. In accordance with federal law, contact lenses should be sold only based upon a prescriber's prescription. Since the passage of the Fairness to Contact Lens Consumers Act (FCLCA), the AOA has worked to educate our contact lens prescribing members of their responsibilities under the law. The FTC's workshop to explore issues relating to competition in the contact lens marketplace, consumer access to contact lenses, prescription release and portability, provided a useful opportunity to bring together all parties with interest in the contact lens market and we appreciated that opportunity.

### **Proposal for Signed Acknowledgment Form**

While we understand that the Commission may consider accepting recommendations from interested stakeholders regarding how to improve safety and compliance in the contact lens market, we are concerned that the Commission has adopted a recommendation made by 1-800 CONTACTS, a company that has a concerning record of business practices and may be motivated by a desire to discourage in-person eye exams and drive patients to their own products. The FTC is well aware of previous concerning anti-competitive practices conducted by 1-800 CONTACTS as Chief Administrative Law Judge D. Michael Chappell upheld a FTC complaint against 1-800 CONTACTS, and ruled:

[T]he agency has proved that the nation's largest online retailer of contact lenses unlawfully orchestrated a web of anticompetitive agreements with rival online contact lens sellers.... The complaint alleges that these bidding agreements constituted an unfair method of competition in violation of federal law, by unreasonably suppressing price competition in certain online search advertising auctions, and restricting truthful and non-

misleading advertising to consumers. As a result, some consumers paid higher retail prices for contact lenses.<sup>1</sup>

In addition to this significant ruling regarding the anti-competitive business tactics employed by 1-800 CONTACTS, the company also previously used a pre-checked box located at the bottom line of the company's contact lens order form that indicated authorization to act as the patient's agent in obtaining a complete copy of the patient's prescription. The Commission has a history of recommending against this type of default system to obtain consent and ultimately, 1-800 CONTACTS changed their approach to obtaining consent.<sup>2</sup> While this issue was corrected, it may never be fully appreciated how many patients may have unknowingly provided the company with authorization to act as the patient's agent. In addition, in 2016 1-800 CONTACTS received a warning letter indicating that the Commission had received complaints regarding potential company violations of the FCLCA. Taken together, all of these factors raise important red flags regarding the company's concern for patients and their reliability when it comes to appropriate changes needed to improve the contact lens market.

Additionally, 1-800 CONTACTS is now offering the "Express Exam" service which the company indicates is "powered by Opternative." 1-800 CONTACTS encourages patients to use its new online vision testing systems to "Skip the trip to the doctor's office" and to use the company's new app to renew contact lens prescriptions.<sup>3</sup> By working to damage the reputation of doctors of optometry and to support new regulatory red tape requirements that would add additional costs to independent physician offices, the company stands to profit by encouraging the use of their online vision test. We are also concerned that the company may not appropriately respect current regulatory requirements. The "Terms of Use" for the Express Exam service essentially indicates that the company is not beholden to contact lens and eyeglasses regulations.<sup>4</sup> The terms state:

### **Disclaimer of Warranties**

EXCLUDING THE ACCURACY OF THE VISION TEST AND ACCURACY OF OPHTHALMIC GOODS AND SERVICES DISPENSED BY ANOTHER SELLER, COMPANY DOES NOT WARRANT THAT ACCESS TO OR USE OF THE SITE AND/OR THE CONTENT WILL BE UNINTERRUPTED OR ERROR-FREE. EXCLUDING THE ACCURACY OF THE VISION TEST AND ACCURACY OF OPHTHALMIC GOODS AND SERVICES DISPENSED BY ANOTHER SELLER, THIS SITE (INCLUDING (A) ANY SITE-RELATED SERVICE AND (B) ANY CONTENT OR INFORMATION CONTAINED WITHIN, ACCESSED THROUGH, SENT THROUGH OR MADE AVAILABLE FOR USE OR DOWNLOAD THROUGH THE SITE), IS PROVIDED "AS IS," WITH ALL FAULTS, WITH NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, QUALITY OF INFORMATION, QUIET ENJOYMENT, AND TITLE/NON-INFRINGEMENT. EXCLUDING THE ACCURACY OF THE VISION TEST AND ACCURACY OF OPHTHALMIC GOODS AND SERVICES DISPENSED BY ANOTHER SELLER, COMPANY, TO THE FULLEST EXTENT PERMITTED BY LAW, EXPRESSLY DISCLAIM ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE. EXCLUDING THE ACCURACY OF THE VISION TEST AND ACCURACY OF OPHTHALMIC GOODS AND SERVICES DISPENSED BY ANOTHER SELLER, COMPANY DOES NOT WARRANT THE ACCURACY, COMPLETENESS OR TIMELINESS OF THE CONTENT OR INFORMATION OBTAINED THROUGH THE SITE.

Without limiting the foregoing, and excluding the accuracy of the vision test and accuracy of ophthalmic goods and services dispensed by another seller, Company, its licensors, and its suppliers make no representations or warranties about the following:

- A. The accuracy, reliability, completeness, currentness, or timeliness of the Content, software, text, graphics, links, or communications provided on or through the use of the Site or the Company's services.
- B. The satisfaction of any government regulations requiring disclosure of information on prescription eyeglass or contact lens products (or other products) or the approval or compliance of any software tools with regard to the Content contained on the Site.

Essentially, the company is indicating that it will not confirm whether the company satisfies certain government regulations. This type of disregard for the company's own obligations under the law and rule

<sup>1</sup> <https://www.ftc.gov/news-events/press-releases/2017/10/administrative-law-judge-upholds-ftcs-complaint-1-800-contacts>

<sup>2</sup> <https://www.ftc.gov/sites/default/files/documents/reports/negative-options-federal-trade-commission-workshop-analyzing-negative-option-marketing-report-staff/p064202negativeoptionreport.pdf>

<sup>3</sup> <https://www.1800contacts.com/online-contact-lens-prescription>

<sup>4</sup> <https://rx.1800contacts.com/terms>

is troubling. It is also important to note that Opternative, the maker of the online vision test used in 1-800 CONTACTS's Express Exam product, has marketed its app-based vision test without clearance or approval required by the government, in violation of federal law, the U.S. Food and Drug Administration (FDA) warned in an enforcement action.<sup>5</sup>

FTC should also consider that the Coalition for Contact Lens Consumers Choice (the Coalition), of which 1-800 CONTACTS is a member, was recently outed for using "paid-for content that does not disclose its origin" in order to make it appear as though the issue of contact lens regulation and the FTC proposed rule is garnering extensive press coverage.<sup>6</sup> A BuzzFeed News investigation linked "authors of at least some of the wave of contact lens op-eds to a stealth corporate propaganda campaign that saw a Washington, DC, public relations firm place articles for its clients—often without the knowledge of the editors who published advocacy for everything from payday lenders to online gambling." Yet again, this is another incident which calls into serious question the credibility of the company that the FTC is relying on for regulatory recommendations.

Furthermore, we question the legitimacy of the information on alleged non-compliance that 1-800 CONTACTS has provided to the Commission. In 2016, 1-800 Contacts filed 3,200 complaints with the Arizona Board of Optometry. The law firm representing 1-800 CONTACTS noted that these complaints were filed, "in order to compel all eye care professionals to follow the law and give their patients the options they deserve. The filed complaints are against the worst offending optometrists who failed to comply with federal and state law."<sup>7</sup> The Arizona Board of Optometry spent a total of two years to hear all the cases; March 2016 to Feb 2018 and in order to appropriately review all cases, total expenditures from the Board of Optometry increased from \$193,700 in 2015 to an expected \$225,000 in 2018.<sup>8,9</sup> All of the documentation of the investigated complaints is retained by the Arizona Board of Optometry and is worthy of FTC review. We would be happy to assist in ensuring FTC has that information. Based upon the investigation of all reported complaints, many of the cases fell into three categories:

- 1) The named 1-800 customer was not a patient of that doctor or could not be identified as a patient by the information given.
- 2) The fax or call was never received by the doctor's office; wrong fax number used, wrong office faxed, wrong doctor in the group practice named.
- 3) The doctor responded, but 1-800 claimed it had no record of it, but the doctor did.

There were also several doctors that 1-800 CONTACTS reported for non-compliance, however, the doctor disputed the complaint because the doctor does not fit patients for contact lenses in their practice. While doctors in Arizona were accused of being "the worst offending optometrists" the actual documentation presented based on the complaints tells a different story. Many doctors provided the Board with copies of the faxes they sent to 1-800 CONTACTS to disprove the accusation of non-compliance. One doctor employs a specific form to be able to easily respond to verification requests (see Appendix A). A doctor who was looking to disregard the law and ignore the requests of an online contact lens seller would likely not have a specific form developed to address the seller's requests. Another doctor noted in their response to the complaint, "I often recommended 1-800 CONTACTS to my patients for those that wanted to buy online because they are at least a US company that doesn't sell lenses illegally." While 1-800 CONTACTS has attempted to paint these doctors in a very negative light, the documentation revealed in the investigations demonstrates that the levels of non-compliance reported by 1-800 CONTACTS are simply not accurate.

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<sup>5</sup> <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm600029.htm>

<sup>6</sup> [https://www.buzzfeed.com/janelytvynenko/this-public-relations-firm-has-been-secretly-placing?utm\\_term=.cg6kqg5Q5#.eq3nzKQZQ](https://www.buzzfeed.com/janelytvynenko/this-public-relations-firm-has-been-secretly-placing?utm_term=.cg6kqg5Q5#.eq3nzKQZQ)

<sup>7</sup> <https://roselawgroupreporter.com/2016/03/3000-complaints-filed-arizona-optometrists-failing-follow-law/>

<sup>8</sup> <https://azgovernor.gov/sites/default/files/governor/documents/executivebudget-agencydetailbook1-14-2016.pdf>

<sup>9</sup> <https://azgovernor.gov/sites/default/files/governor/documents/executivebudget-stateagencybudgets.pdf>

These concerns regarding the legitimacy of complaints from 1-800 CONTACTS also are consistent with statements made by Thomas L. Steinemann, MD who indicated that in his private practice up to 62% of verifications are incorrect and 50% are for prescriptions that are expired. The incorrect verifications include patients with no patient record and patients who did not complete the contact lens fitting or don't have a contact lens prescription. While 1-800 CONTACTS may attempt to raise concerns with compliance on the prescriber side, we believe that their complaints should be carefully considered for legitimacy. Based upon these patterns of concerning business practices, which we believe may be misleading and some of which have been shown by FTC itself to be anti-competitive in nature, we believe it is inappropriate for the Commission to adopt this recommendation as its own and to propose that all prescribers be required to obtain a signed acknowledgment form from patients following the provision of the contact lens prescription. We believe that 1-800 CONTACTS' recommendation may be anti-competitive, similar to other actions designed to reduce patient choice, raise costs, and mislead the public.

### **Prescriber Compliance**

AOA is fully committed to ensuring compliance with the FCLCA on both the prescriber and seller side. We understand that 1-800 CONTACTS makes a concerning claim that only 35 percent of patients automatically receive a copy of their contact lens prescription following the contact lens fitting.<sup>10</sup> While any non-compliance is unacceptable, it is important to consider that these numbers are based on patient reported data and FTC has acknowledged that there is confusion regarding the requirements under the law. FTC has noted, "because a fitting may not be complete until a follow-up visit, a patient might incorrectly believe that she should have been provided with her prescription at the conclusion of the first visit."<sup>11</sup> We believe it's possible that this confusion may influence the data 1-800 CONTACTS has presented. Because we wanted to better assess whether there are true compliance concerns, the AOA conducted a survey of high volume contact lens practices to seek information directly from contact lens prescribers regarding compliance. Our survey found that 93.22 percent of survey respondents indicated they follow Federal law and provide patients with a copy of their contact lens prescription upon completion of a contact lens fitting. The survey respondents fit an average of 794 contact lens patients annually (Appendix B). The AOA take seriously our role in regulatory education and is committed to assisting in additional educational efforts to ensure compliance.

### **Alternative Approach**

It is unprecedented in the healthcare arena for a patient to be required to sign a form indicating he/she received a prescription from their healthcare provider and we believe this approach would be inappropriate for contact lens prescribers. However, given the Commission's continued concerns with prescriber compliance, we have offered an alternative to the 1-800 CONTACTS proposal regarding a signed acknowledgment form. If the FTC believes some additional requirement must be implemented, we recommend that prescribers be required to post a sign notifying patients of their right to their contact lens prescription. This is an alternative approach that is supported by more than 60 Members of Congress who understand that the FTC's new proposal would negatively impact small businesses and that the goals of the Commission could be achieved without a significant new regulatory burden.

We recognize that during the development of the proposed rule-making, the FTC considered the use of appropriate signage in eye doctors' offices to advise patients of their rights to receive a prescription. In considering this approach, Commission staff stated, "it is unclear how many patients actually read posted notices at doctors' offices, particularly in locations where there are already numerous ads or other

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<sup>10</sup> [https://www.ftc.gov/system/files/documents/public\\_comments/2017/01/03898-138466.pdf](https://www.ftc.gov/system/files/documents/public_comments/2017/01/03898-138466.pdf)

<sup>11</sup> [https://www.ftc.gov/system/files/documents/federal\\_register\\_notices/2016/12/contact\\_lens\\_rule\\_published\\_frn12716.pdf](https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/contact_lens_rule_published_frn12716.pdf)

postings about various rights, requirements, and obligations.”<sup>12</sup> While the FTC has raised concerns with our alternative approach to require a posted sign notifying patients of their rights, this is a fairly common tool that is used to educate patients and consumers in a variety of other settings. It is noteworthy that, with respect to efficacy of signage, when it comes to contact lenses, the Commission appears to be taking a position that is in direct opposition with a position that it has previously taken in a different context. Specifically, in a communication entitled “Facing Facts: Best Practices for Common Uses of Facial Recognition Technologies,”<sup>13</sup> the Commission seemed to indicate that signage could be effective in warning consumers of the threat to personal privacy and individual security posed by facial recognition technology. In that communication, the Commission recommended that signage warning of concerns with such technology must be visible to the public—and that “at a minimum, a notice should clearly state the purpose of the technology and indicate how consumers can find more information about the technology and the practices of the company operating the signs in that venue.”<sup>14</sup> We are certain that the Commission would concede that the impacts of misused facial recognition technology could have a very dangerous impact on the public and it is difficult to understand how posted signs would be appropriate in those scenarios, but would be inappropriate in the medical office of a contact lens prescriber. The FTC has previously raised the concern that a posted sign is not truly indicative of whether a patient has been provided with a copy of their contact lens prescription. While that may be accurate, it is equally accurate to note that under our current system the completion of a robocall to verify a prescription does not ensure that a seller addressed a prescriber’s correction to a verification request, or that the seller has not sold lenses to the patient that should not have been provided. There are weaknesses in our current system with regards to ensuring compliance and we believe that these concerns should not preclude careful consideration of how posted signage may be a useful tool to increase compliance and patient education.

The FTC noted in the Proposed Rule that the Commission did not have good evidence about the effects of California’s requirement for contact lens prescribers to post clear and visible signage informing patients of their right to their prescriptions. To address this data gap, the AOA commissioned a survey of 1,000 18- to 40-year-old contact lens wearers in California to better assess the impact of the California law and to get more information on consumer perspectives of the requirement. The survey found that California contact lens wearers support the law and believe it is the best way to ensure contact lens wearers are well informed of their rights.

- The majority (96 percent) of California contact wearers support the law.
- California contact wearers overwhelmingly (97 percent) think the law makes patients more aware of their rights.
- Patients view the requirement as a positive for competition, as 93 percent think the law helps enable patients to find the best prices for contact lenses.
- Survey respondents were in favor of this type of communication method, as 88 percent believe the law is the best way to make sure contact lens wearers are as informed as possible about their contact lens purchasing options.

The complete survey conducted in California has already been provided to the FTC, but is also included in the Appendix C for review. During the FTC workshop, FTC staff indicated, “When we got the sign as an alternative, we did reach out to the California state board of optometry and there is really nothing there in terms of enforcement of the signs or even them looking for the signs.” Based on recent events, we believe that the FTC should reevaluate this conclusion. In March 2018, the California Board of Optometry was notified by Consumer Action of possible lack of adherence to state requirements related

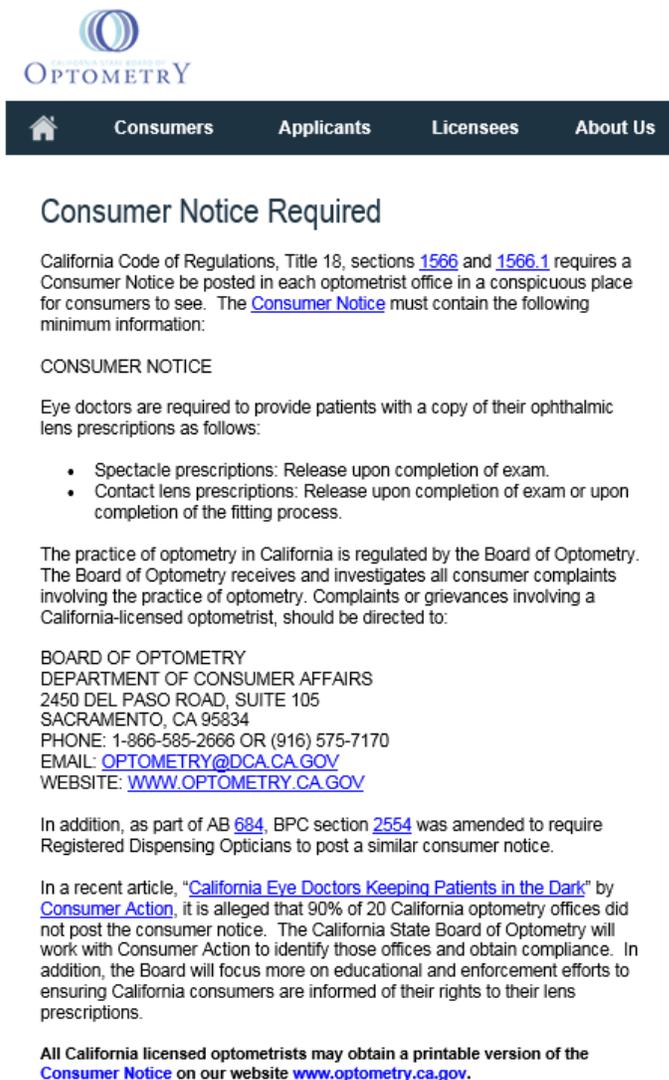
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<sup>12</sup>[https://www.ftc.gov/system/files/documents/federal\\_register\\_notices/2016/12/contact\\_lens\\_rule\\_published\\_frn12716.pdf](https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/contact_lens_rule_published_frn12716.pdf)

<sup>13</sup> <https://www.ftc.gov/sites/default/files/documents/reports/facing-facts-best-practices-common-uses-facial-recognition-technologies/121022facialechrpt.pdf>

<sup>14</sup> <https://www.ftc.gov/sites/default/files/documents/reports/facing-facts-best-practices-common-uses-facial-recognition-technologies/121022facialechrpt.pdf>

to posted signage. In response, the Board immediately released to doctors of optometry a reminder regarding requirements under the law. The Board further committed to compliance by indicating, “The California State Board of Optometry will work with Consumer Action to identify those offices and obtain compliance.” On March 28<sup>th</sup>, the following notice was issued:



The screenshot shows the website for the California State Board of Optometry. At the top is the logo, which consists of a stylized 'O' inside a circle, with the text 'CALIFORNIA STATE BOARD OF OPTOMETRY' below it. Below the logo is a dark blue navigation bar with white text and icons for 'Home', 'Consumers', 'Applicants', 'Licensees', and 'About Us'. The main content area has a heading 'Consumer Notice Required'. Below this heading is a paragraph stating that California Code of Regulations, Title 18, sections 1566 and 1566.1 requires a Consumer Notice be posted in each optometrist office in a conspicuous place for consumers to see. The Consumer Notice must contain the following minimum information:

CONSUMER NOTICE

Eye doctors are required to provide patients with a copy of their ophthalmic lens prescriptions as follows:

- Spectacle prescriptions: Release upon completion of exam.
- Contact lens prescriptions: Release upon completion of exam or upon completion of the fitting process.

The practice of optometry in California is regulated by the Board of Optometry. The Board of Optometry receives and investigates all consumer complaints involving the practice of optometry. Complaints or grievances involving a California-licensed optometrist, should be directed to:

BOARD OF OPTOMETRY  
DEPARTMENT OF CONSUMER AFFAIRS  
2450 DEL PASO ROAD, SUITE 105  
SACRAMENTO, CA 95834  
PHONE: 1-866-585-2666 OR (916) 575-7170  
EMAIL: [OPTOMETRY@DCA.CA.GOV](mailto:OPTOMETRY@DCA.CA.GOV)  
WEBSITE: [WWW.OPTOMETRY.CA.GOV](http://WWW.OPTOMETRY.CA.GOV)

In addition, as part of AB 684, BPC section 2554 was amended to require Registered Dispensing Opticians to post a similar consumer notice.

In a recent article, "[California Eye Doctors Keeping Patients in the Dark](#)" by [Consumer Action](#), it is alleged that 90% of 20 California optometry offices did not post the consumer notice. The California State Board of Optometry will work with Consumer Action to identify those offices and obtain compliance. In addition, the Board will focus more on educational and enforcement efforts to ensuring California consumers are informed of their rights to their lens prescriptions.

All California licensed optometrists may obtain a printable version of the [Consumer Notice](#) on our website [www.optometry.ca.gov](http://www.optometry.ca.gov).

When an optometry board is made aware of a compliance concern, immediate action is typically taken. The AOA has also done the same when FTC has issued warning letters to doctors regarding concerns with FCLCA compliance. When warning letters have been issued or compliance concerns have been raised we work to education our members. Additionally, the AOA has shared our educational materials with the FTC for review to ensure that messaging is appropriate and AOA has been responsive to FTC recommendations. We are not aware of any instance where we have not followed FTC recommendations for educational releases and believe we have proven to be a reliable education partner.

However, for AOA and boards of optometry to be the most useful partners in doctor education related to compliance, we need to be aware of violations that may be occurring. While it is clear that the FTC should investigate and act on legitimate violations of the law and the rule, the number of complaints the

FTC has received, which are part of the public record, account for a relatively small percentage of complaints in relation to nearly 40 million contact lens prescriptions each year. The FTC has indicated there is an “ongoing pattern of consumer complaints” regarding prescription release, however, the FTC’s proposal to significantly change the regulatory requirements for contact lens prescribers came after only 45 warning letters were sent to prescribers in 2016<sup>15</sup> and 10 warning letters were sent on September 14, 2007.<sup>16</sup> Additionally, data obtained through a 2017 Freedom of Information Act (FOIA) request showed that the FTC received a total of 309 complaints (of which roughly half were unrelated to any violation of the law) regarding prescription release between 2011 and 2016. At the FTC workshop, an FTC representative asserted that the Commission feels that the complaints it received regarding contact lens prescriptions were “just the tip of the iceberg.”<sup>17</sup> However, no facts were given that would support this conclusion. We would like to know what additional data is influencing the Commission to conclude that the non-compliance problem is bigger than its own figures would suggest, leading it to impose such a significant new requirement for all contact lens prescribers.

For a thorough and accurate review of the rule to occur, we think it’s important to see all the data that FTC is relying on to make significant regulatory changes. The FTC itself has acknowledged that “Many reports of compliance and noncompliance are anecdotal, and robust empirical data are sparse. Although the Commission would prefer better empirical evidence about compliance and noncompliance with the Rule, and about the effects of the Rule, some survey evidence has been submitted by sellers, prescribers, and manufacturers. The Commission considers these submissions to be suggestive and, to an extent, informative, but none can be regarded as definitive.”<sup>18</sup> Overall, we would like better accounting of the data that is being used to determine FTC actions. During the FTC workshop on the contact lens rule, it was noted by FTC, “we did do a little bit of a, you know, let’s send out some investigators in California and no signs were found. They did ask the receptionist about them and no receptionist knew about a sign requirement so I don’t know if that was the luck of the draw but that was kind of a sad result.”<sup>19</sup> On March 9, 2018, AOA requested additional data regarding the FTC investigation that was cited during the workshop, but no additional information has been provided. Instead, on March 27, the FTC shared with AOA a press release from Consumer Action regarding an investigation the company conducted to gather information on compliance with the signage requirement in California.<sup>20</sup> However, we still are not aware of the details of the investigation that was alluded to in the workshop. The AOA believes that the specifics regarding the information obtained by the investigators that the FTC directed in California to gather more information on compliance with California state law should be made part of the public record. Without such information, we are left to question whether there may have been a predetermined position regarding the recommendation to require posted signs as an alternative to the signed acknowledgement form.

During the workshop, Linda Sherry from Consumer Action also stated, “Signs don’t really work. I think they can be hidden. In California there is such a requirement that you post a sign about your rights to get a prescription and having learned of that we took a look around just in San Francisco and San Jose and we did not see a lot of compliance.”<sup>21</sup> The AOA is aware of the findings from Consumer Action based on a spot check investigation that occurred on March 8-15, but the AOA is unaware of the findings that led to Consumer Action’s publicly stated positions against signage that was made during the workshop on March 7. We believe this information should also be part of the public record for this rulemaking. Both the FTC and Consumer Action made very specific statements regarding the effectiveness of California

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<sup>15</sup> <https://www.ftc.gov/news-events/press-releases/2016/04/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule>

<sup>16</sup> <https://www.ftc.gov/news-events/press-releases/2007/09/ftc-warns-ten-contact-lens-prescribers-provide-patients>

<sup>17</sup> [https://www.ftc.gov/system/files/documents/public\\_events/1285493/panel\\_iv\\_examining\\_the\\_verification\\_process.pdf](https://www.ftc.gov/system/files/documents/public_events/1285493/panel_iv_examining_the_verification_process.pdf)

<sup>18</sup> [https://www.ftc.gov/system/files/documents/federal\\_register\\_notices/2016/12/contact\\_lens\\_rule\\_published\\_frn12716.pdf](https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/contact_lens_rule_published_frn12716.pdf)

<sup>19</sup> <https://www.ftc.gov/news-events/audio-video/video/contact-lens-rule-evolving-contact-lens-marketplace-session-3> (1:42:30)

<sup>20</sup> [https://www.consumer-action.org/press/articles/california\\_eye\\_doctors\\_keeping\\_patients\\_in\\_the\\_dark](https://www.consumer-action.org/press/articles/california_eye_doctors_keeping_patients_in_the_dark)

<sup>21</sup> <https://www.ftc.gov/news-events/audio-video/video/contact-lens-rule-evolving-contact-lens-marketplace-session-3> (137:12)

state law which call into question the reputation of contact lens prescribing physicians, but no firm data has been provided thus far to support the March 7 statements.

Furthermore, we are surprised at the very strong position of Consumer Action in opposition to the posted sign recommendation, given that the consumer group has been vocal in the past regarding the need for prominent displays of information to better inform consumers of their rights. In response to the Used Car Rule, Consumer Action noted:

One of our primary concerns is that crucial information about availability of a manufacturer's warranty would be hidden on the back of the Buyer's Guide where consumers are likely to miss it. This is a step backward from the goals of transparency and disclosure. We would like to see a required disclosure about warranties on the front of the form, including this statement: The dealer will pay 100% of the labor and costs for covered systems that fail for a (specified) period of time. Only the systems that are circled on the OTHER SIDE OF THIS FORM are covered systems. Prior to your purchase, the dealer must make available to you a copy of the warranty that explains the warranty coverage, exclusions, and the dealer's repair obligations. Implied warranties under your state's laws may provide you with additional rights.<sup>22</sup>

A posted sign notifying patients of their right to their contact lens prescription could mimic closely the approach taken in other industries with prominent displays of rights under the law. Additionally, it is important to recognize that other consumer groups often support the use of signage to inform patients and consumers of their rights. The National Consumers League (NCL) has a policy on consumer education and specifically notes, "The more consumers know about their rights and responsibilities as well as about the goods and services they buy, the better they are able to protect themselves, make sound purchasing decisions, and contribute to the economy." To achieve this goal, NCL specifically notes, "NCL supports... that all providers of goods and services furnish consumer information at the point of purchase in a form that will be most easily understood by consumers, including alternate languages where appropriate"<sup>23</sup> NCL also recommends that "consumers should be provided with easy access to complain or inquire both at companies offering goods and services for sale and to agencies empowered to enforce consumer protection laws."<sup>24</sup> A posted sign at the front desk of a contact lens prescriber's office with information regarding how and where to report complaints would achieve the NCL recommended approach to ensure that patients are informed of their rights and that they are aware of how to report a concern to state and federal agencies. The NCL also supports the idea of posted signs and indicated,

We understand from the *Federal Register* December 7, 2016 Contact Lens Rule posting that the Commission has considered a number of suggested approaches to improving compliance with the requirement that consumers receive their prescriptions upon completion of the eye exam. We have reviewed those and, in the interest of best informing consumers of their rights, NCL believes it would be a positive and reasonable approach to require all contact lens prescribers to post a sign in their offices, which is clear and conspicuous, noting that patients have a right to a copy of their contact lens prescription at the completion of their contact lens fitting.

In the ongoing deliberations of the Rule, we encourage the FTC to consider the overall support from consumer groups for conspicuous signage as a method for educating patients of their rights. We also believe it's important for the FTC to be fully aware of financial and business connections

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<sup>22</sup> [https://www.ftc.gov/sites/default/files/documents/public\\_comments/16-cfr-part-455-used-motor-vehicle-trade-regulation-rule-project-no.p087604-563688-00123/563688-00123-85709.pdf](https://www.ftc.gov/sites/default/files/documents/public_comments/16-cfr-part-455-used-motor-vehicle-trade-regulation-rule-project-no.p087604-563688-00123/563688-00123-85709.pdf)

<sup>23</sup> [http://www.nclnet.org/policy\\_statements](http://www.nclnet.org/policy_statements)

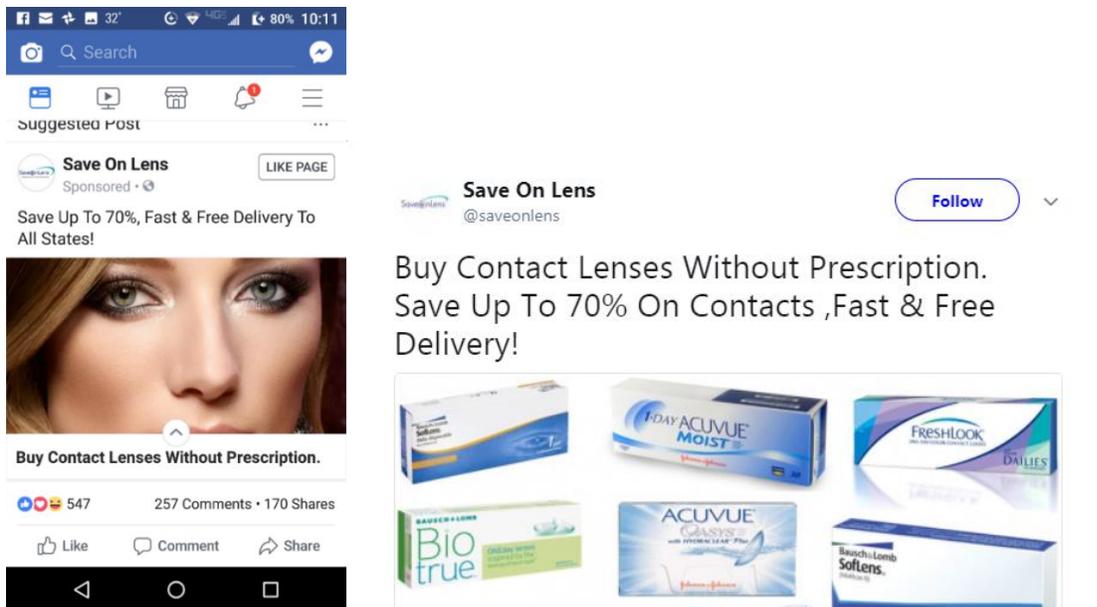
<sup>24</sup> [http://www.nclnet.org/policy\\_statements](http://www.nclnet.org/policy_statements)

among those who are offering their insight and recommendations to the FTC. 1-800 CONTACTS is a corporate sponsor of Consumer Action.<sup>25</sup> While partnerships and arrangements may be fully legitimate we believe it's useful to be fully transparent in the connections that may exist among the voices selected by the FTC to address the contact lens market during the public workshop.

### FTC Contact Lens Seller Warning Letters

In 2016, the FTC wrote warning letters to 10 sellers for whom the Commission had received complaints that the seller was possibly in violation of the FCLCA. We are aware of at least two of these sellers who continue to allow the purchase of contact lenses without a prescription. In March 2018, the AOA was able to purchase contact lenses from *ClearViewContacts.com* without providing a prescription. The company at no point in the order process makes any mention of the need for a prescription from an eye doctor.

In 2016, FTC also sent a warning letter to *SaveOnLens.com*. That company continues to blatantly advertise the availability of contact lenses without a prescription as illustrated in the following:



In March 2018, the AOA was also able to purchase contact lenses from Save On Lens without a prescription. At no point in the order process does the company make mention of the need for a prescription from an eye doctor. With only 10 sellers warned in 2016, we would like to know more about the FTC process that is followed to determine whether companies who have been warned for non-compliance have corrected their business practices. With these two sellers in particular, the ability to confirm compliance took only minutes. In addition to concerns with these two sellers, in Appendix D we have included a listing of other sellers who have been reported to AOA for possible violations of the FCLCA. Given the ongoing issues with sellers already identified as potentially problematic by the Commission and our additional reports of potentially problematic sellers, we believe the public would be best served by additional FTC action towards sellers to ensure the current regulations in place are being appropriately followed.

<sup>25</sup> [http://ww.money-wise.org/articles/consumer\\_action\\_insider\\_december\\_2017](http://ww.money-wise.org/articles/consumer_action_insider_december_2017)

## **Economic Burden of the Signed Acknowledgment Form**

As previously reported, Avalon Health Economics conducted an online survey of doctors of optometry to assess the total cost per optometric practice in the United States related to the introduction of new processes in doctors' offices and the potential impact of the FTC's signed acknowledgment proposal. Based on this analysis, Avalon found that in the initial year of implementation, the economic burden of complying with this new FTC proposal could be as high as \$49,913 for optometric practices with three doctors of optometry. The cost burden for a practice with one doctor of optometry could be as high as \$18,795. For practices that have a higher than average volume of contact lens patients and have more than one doctor of optometry, the total cost could be as high as \$74,667.<sup>26</sup> Thousands of doctors of optometry are small business owners who run their practices on tight margins. A regulatory burden of this weight could lead these doctors to eliminate staff positions, or to defer new equipment purchases and health information technology advancements. This proposal is an urgent and immediate threat to independent optometric practices in all fifty states.

We are aware that 1-800 CONTACTS has sought outside guidance regarding the Avalon estimates and has criticized the report for asking prescribers for their insight on possible changes to contact lens regulations, rather than consumers. The purpose of the survey was to gather additional data on the time and resources necessary for physicians to implement new regulatory requirements. Asking physicians about these processes is the only way to gather this information. 1-800 CONTACTS criticized a number of facets regarding the survey, all of which are lacking in merit. 1-800 CONTACTS criticized the survey for being posed with binary yes/no choices. This is simply false. All questions included options that provided time ranges, numerical ranges or yes/no/uncertain. 1-800 CONTACTS also raised concerns that "some closed-ended questions had answer options that may have suggested particular intervals of time, all of which were too high." For questions involving issues related to time spent, the answer options provided were "less than 5 minutes," "0-5 minutes," or "Less than 1 minute." The complete survey is included in the following materials and the veracity of the criticisms regarding the survey can be verified. These accusations which are intended to discredit the survey data are simply unfounded. The AOA takes seriously the data submitted for the public record for consideration of this rulemaking. As such, Avalon Health Economics has also provided a supplementary report to address the concerns raised. That report is included in the Appendix E.

## **Protecting Patients from Harm**

The Commission initiated the ten-year review of the Contact Lens Rule to assess the economic impact, and the continuing need for the Rule; its benefits; impact on consumers; the degree of industry compliance; and the need for any modifications to increase its benefits. Thus far in the review process, we have not seen the Commission consider additional ways to ensure seller compliance with the rule, rather the focus has been on prescribers. We believe this is a serious and significant oversight and urge the Commission to do more to ensure seller compliance with the Rule. This is an area where we believe violations are occurring daily. The AOA often hears from doctors regarding the impacts of seller non-compliance and the damaging impact that has on the public. In Appendix F we have included 78 reports of non-compliance which, in many cases, caused patient harm. These accounts illustrate how lack of compliance impacts public health. We would be happy to connect the FTC with the doctors who have reported these incidents.

While much attention is often paid to the cost of the contact lenses themselves, we believe that the Commission needs to better assess the added costs to the health care system and impacts on quality of life that occur due to contact lens misuse. As the Centers for Disease Control and Prevention (CDC) has

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<sup>26</sup> Avalon Health Economics "Economic Evaluation of FTC Ruling on Contact Lens Prescriptions."

previously reported, “Keratitis—a painful eye infection often linked to improper contact lens use—leads to 1 million doctor and hospital visits annually, at a cost of \$175 million to the US healthcare system.”<sup>27</sup> These are not insignificant costs and the FTC can play an important role in reducing these unnecessary costs by ensuring that the authority granted to the FTC by Congress is fully utilized.

Patients would also benefit from greater consistency between federal agencies regarding contact lens use. The Food and Drug Administration (FDA) offers patients recommendations for contact lens use and notes, “Best strategies for reducing your risk of infection involve proper hygiene; following recommended wearing schedules; using proper lens care practices for cleaning, disinfecting and storing your lenses (which includes reading and following all product labeling instructions); and having routine eye exams.”<sup>28</sup> The CDC also recommends that patients, “visit your eye doctor yearly or as often as he or she recommends.”<sup>29</sup> However, during the FTC workshop it was suggested by FTC that eye exams are not “the end all be all.” This attitude which questions the value of the eye examination for contact lens wearing patients is in direct opposition to care recommendations of both the American Academy of Ophthalmology (AAO) and the American Optometric Association. The AAO indicates, “Get regular eye exams. If you wear contact lenses, you should be examined by an eye care provider annually, and more often as needed.”<sup>30</sup> The AOA recommends, “Contact lens wearers should see their optometrist at least once per year. More frequent visits may be recommended for those patients who have experienced complications from contact lens wear, who require specialty lens designs or who have other eye disease.”<sup>31</sup> We urge the commission to do more to ensure patient safety in the contact lens market.

More could be done to protect contact lens wearing patients from harm and to stop sellers who blatantly violate the law. The AOA would welcome the opportunity to work with the FTC to ensure compliance with all aspects of the FCLCA and the Rule. Based on the evidence available, we believe that the signed acknowledgement proposal is unnecessary and burdensome. The AOA’s alternate recommendation to require doctors to post a sign notifying patients of their rights would be less burdensome, help to better educate patients, is in line with other public warnings FTC has supported, and is fully endorsed by the only national organization representing doctors of optometry who is committed to assisting FTC with compliance. If you have any questions regarding the information included in these comments, please contact Kara Webb, Director of Coding and Regulatory Policy at: [kcwebb@aoa.org](mailto:kcwebb@aoa.org) or 703-837-1018.

Sincerely,



Christopher J. Quinn, O.D.  
President  
American Optometric Association

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<sup>27</sup> Collier SA, Gronostaj MP, MacGurn AK, Cope JR, Awsumb KL, Yoder JS, Beach MJ. [Estimated burden of keratitis — United States, 2010](#). MMWR Morb Mortal Wkly Rep. 2014;63(45):1027-30.

<sup>28</sup> <https://www.fda.gov/forconsumers/consumerupdates/ucm048893.htm>

<sup>29</sup> <https://www.cdc.gov/contactlenses/protect-your-eyes.html>

<sup>30</sup> <https://www.aoa.org/eye-health/glasses-contacts/contact-lens-care>

<sup>31</sup> <http://www.contactlenssafety.org/lenstypes.html>

Appendix A

2/9/16

Fixed 2/9/16  
\$37 JOB

1-800-CONTACTS RX CONFIRMATION FORM

Time of Call 8:29

Fax # 1-

OKAY  
TO  
ORDER

Contact RX

	Brand	Power	BC	Dia	Cyc	Axis	# of boxes
OD	DVOASS	+0.75	8.60	14.5	-2.25	90	1
OS	Ashg Lept	+0.75	8.60	14.5	-2.25	90	1

Pts Address \_\_\_\_\_

Zip \_\_\_\_\_

Pts Name \_\_\_\_\_

Record # \_\_\_\_\_

**Appendix B**  
**AOA Survey of Contact Lens Prescribers**

<b>How many patients do you typically fit for contact lenses in a year?</b>	<b>Do you follow Federal law and provide patients with a copy of their contact lens prescription upon completion of a contact lens fitting?</b>	<b>How many of your patients do you believe are obtaining lenses from internet retailers after the prescription has expired or are obtaining lenses that are different from what has been prescribed</b>	<b>Have you been subject to any enforcement actions related to the Fairness to Contact Lens Consumers Act and the requirement to provide patients with a copy of their contact lens prescription?</b>
1,000	Yes	31+	No
2,000	Yes	31+	No
250	Yes	1-10	No
1,500	Yes	0	No
600	Yes	31+	No
650	Yes	31+	No
265	Yes	1-10	No
400	Yes	11-20	No
300	Yes	21-30	No
250	Yes	31+	No
1,000	Yes	1-10	No
1,200	Yes	31+	No
520	Yes	1-10	No
45	Yes	1-10	No
500	Yes	11-20	No
700	Yes	1-10	No
400	Yes	31+	No
500	Yes	1-10	No
100	Yes	11-20	No
1,000	Yes	31+	No
75	Yes	11-20	No
2,600	Yes	31+	No
25	Yes	11-20	No
50	Yes	1-10	No
500	Yes	11-20	No
1,000	Yes	31+	No
750	Yes	31+	No
800	Yes	1-10	No
250	No		No
1,200	Yes	1-10	No
800	Yes	31+	No
2,500	Yes	31+	No
1,000	Yes	31+	No
1,000	Yes	21-30	No
250	Yes	31+	No
750	Yes	31+	No
300	Yes	1-10	No
300	Yes	11-20	No
1,200	Yes	11-20	No
1,800	Yes	31+	No
800	Yes	31+	No
520	Yes	1-10	No
250	Yes	1-10	No
500	No		No
240	Yes	31+	No
4,000	Yes	11-20	No
400	Yes	31+	No
500	Yes	31+	No
175	Yes	21-30	No
1,100	Yes	31+	No
500	No		No
3,500	Yes	31+	No
700	Yes	11-20	No
1,000	Yes	31+	No
400	No		No
500	Yes	1-10	No
200	Yes	11-20	No
40	Yes	1-10	No
1,200	Yes	11-20	No

**CHI\_2292 AOA CA Contact Wearers**

**QVersion: Programmer Note: For every live change received, please increase the version here by 1.**

**What is your gender?**

<b>Total</b>	N=1000
Male	39%
Female	61%

**Please indicate your current age:**

<b>Total</b>	100%
<i>Mean</i>	29.89
<i>Median</i>	30.00
<i>Standard Deviation</i>	5.85
Prefer not to answer	0%

**AGE\_RECODE**

<b>Total</b>	N=1000
Under 18	0%
18-29	46%
30-40	54%
Over 40	0%
Prefer not to answer	0%
None of These Classifications Apply	0%

**Do you or does anyone in your household work in the following fields?**

<b>Total</b>	N=1000
Advertising, Marketing, or Market Research	0%
Journalism or Public Relations	0%
Medical or Pharmaceutical	0%
For a company that provides eyewear or vision correction	0%
IT/Computers	8%
Education	10%
None of the above	83%

**In which state do you live?**

<b>Total</b>	N=1000
Alabama	0%
Alaska	0%
Arizona	0%
Arkansas	0%
California	100%
Colorado	0%
Connecticut	0%
Delaware	0%
District of Columbia	0%
Florida	0%
Georgia	0%
Hawaii	0%
Idaho	0%
Illinois	0%

## Appendix D

### Sellers Reported to AOA for Possible FCLCA Violation

- <https://vampfangs.com/>
- <http://www.prettyfabulouz.com>
- [Daysoft.com](http://Daysoft.com)
- [Nextdoor.com](http://Nextdoor.com)
- [spookyeyes.com](http://spookyeyes.com)
- [coloureyoueyes.com](http://coloureyoueyes.com)
- [colouredcontacts.com](http://colouredcontacts.com)
- [extremesfx.com](http://extremesfx.com)
- [halloweenbase.com](http://halloweenbase.com)
- [Postmark.com](http://Postmark.com)
- [www.aclens.com](http://www.aclens.com)
- <https://ohmykitty4u.com/>
- <https://www.pinkyparadise.com/>
- <http://www.guiltyinnocencebtq.com/>
- [turtlecontacts.com](http://turtlecontacts.com)
- [http://www.saveonlens.com/how\\_us.htm](http://www.saveonlens.com/how_us.htm)
- [lensdiscounters.com](http://lensdiscounters.com)
- [www.ttdeye.com](http://www.ttdeye.com)
- <https://www.uniqso2u.com>
- [desiolens.com/](http://desiolens.com/)
- [www.insighteyecareknoxville.com/](http://www.insighteyecareknoxville.com/)
- [turtlecontacts.com](http://turtlecontacts.com)
- [ohmykitty.com](http://ohmykitty.com)
- <http://www.prettyfabulouz.com>
- [turtlecontacts.com](http://turtlecontacts.com)
- <https://www.lenstore.co.uk/contact-lenses-without-prescription>
- <https://www.nextdaylenses.com/buy-contact-lenses-online-without-a-prescription>
- <https://www.feelgoodcontacts.com/information/noprescription.aspx>
- [http://www.saveonlens.com/contact\\_lenses\\_no\\_prescription.html](http://www.saveonlens.com/contact_lenses_no_prescription.html)
- <http://faqeo.com/BestCompaniesForOrderingContactLensesWithoutA/>
- <https://www.pinkyparadise.com/>
- <https://www.alensa.co.uk/information/lenses-without-prescription.html>
- <https://contactsadvice.com/order-contact-lenses-without-a-prescription>
- <https://velmer.co.uk/content/order-lenses-without-prescription/>
- <http://www.contacts-4us.com/info/contacts-without-prescription.html>
- <http://buying-beauty.com>

Appendix E



AVALON HEALTH ECONOMICS

**Economic Evaluation of FTC Ruling on Contact Lens Prescriptions**

**Response to 1-800-Contacts Comments**

March 6, 2018

Submitted by:

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## 1. INTRODUCTION & BACKGROUND

The American Optometric Association (“AOA”) engaged Avalon Health Economics to conduct a study examining the burden of implementing the Federal Trade Commission proposal to require contact lens prescribers to obtain a signed patient acknowledgment after providing a contact lens wearing patient a copy of their prescription (see Contact Lens Rule, 16 CFR part 315 Federal Register / Vol. 81, No. 235 / Wednesday, December 7, 2016 / Proposed Rules<sup>1</sup>); hereafter referred to as “Rule”. This FTC proposal was the result of the Commission’s standard 10-year regulatory review process.

In December of 2003, the FTC promulgated a rule pursuant to the Fairness to Contact Lens Consumers Act (FCLCA), which enabled consumers to purchase contact lenses from any seller of their choice.<sup>2</sup> The rule requires that doctors verify and release contact lens prescriptions to patients, and contains a series of recordkeeping requirements that apply not only to physicians, but to contact lens sellers as well. Moreover, the law currently mandates that sellers may only sell lenses if the seller has either received the prescription from the patient or prescriber or has verified the prescription through direct communication with the prescriber

During the FTC scheduled 10-year review of the Contact Lens Rule, the Commission put forth a new proposal that would require prescribers to obtain a signed acknowledgement receipt from patients after they receive their contact lens fitting. If the proposal is finalized, the “Patient Receipt of Contact Lens Prescription” would have to be kept on file for a minimum of three years either in electronic or paper form. The form generally would be required to state: “My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice,” followed by a signature line. The FTC claims that this mandate will assist with educating patients about their purchasing rights, and will assure that more patients receive their prescriptions. In addition, the FTC claims that this modification will reduce the need for doctors to verify the prescription later.

## 2. ADMINISTRATIVE BURDEN

Misguided regulations can impede productivity and force the reallocation of staffed resources, deterring employees from performing core business activities. The combined cost of regulatory changes can have a significant cost impact on businesses in the long run.<sup>3</sup> The new FTC regulation would change the current prescription contact lens administrative guidelines and would prove to be burdensome on the optometry industry as a whole. There is a relatively large body of literature describing the operating and administrative costs that certain types of regulations impose on industries, and how many regulations can be a drag on industry productivity.<sup>4</sup> The U.S. healthcare industry is no exception. In their article on cost control strategies in U.S. healthcare, Berwick and Hackbarth (2012) argue that the reduction of waste—

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<sup>1</sup>[https://www.ftc.gov/system/files/documents/federal\\_register\\_notices/2016/12/contact\\_lens\\_rule\\_published\\_frn12716.pdf](https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/contact_lens_rule_published_frn12716.pdf)

<sup>2</sup> Vietti-Cook. A, "Contact Lens Rule Vol 81 No 175," ed. Federal Trade Commission (2016).

<sup>3</sup> PricewaterhouseCoopers, "Patients or Paperwork? The Regulatory Burden Facing America's Hospitals," (American Hospital Association, 2010).

<sup>4</sup> See generally G. Stigler, ed. *Chicago Studies in Political Economy* (Chicago: The University of Chicago Press, 1988).

including high administrative costs—can save the U.S. healthcare system a substantial amount of resources.<sup>5</sup> The authors state that “overtreatment, failures of care coordination, failures in execution of care processes, administrative complexity, pricing failures, and fraud and abuse—the sum of the lowest available estimates exceeds 20% of total health care expenditures.” Similarly, others have argued that administrative costs in the U.S. are unreasonably high and unsustainable.<sup>6</sup>

### 3. SUMMARY OF AVALON ANALYSIS

In January 2017 Avalon Health Economics undertook an analysis of the effect of the FTC rules on U.S. optometry practices. One part of the analysis was to conduct a survey of optometry practices nationwide. The base for the survey was the membership of the American Optometric Association (AOA). Data collection took place in December of 2016. A total of 130 responses were recorded during the survey period. Practices responding to the survey have an average of 12.68 staff members, with the average practice composition consisting of 9.05 administrators and 3.63 optometrists. According to survey results, an average optometric practice sees 9,415 patients annually, however recent AOA data depicts that a practice may see as many as 11,739 patients a year. The total average number of contact lens patients per year at an optometric practice as reported by AOA is 2,246 per practice.

The main findings of the survey were that, on average, a practice spends about 13 minutes per staff member to introduce a new patient engagement process into the office workflow. In addition, 108 respondents stated that they spend an average of about 11 minutes per staff member to conduct periodic assessments of new policies and protocols when a new engagement process is introduced into their office. Specifically, regarding the FTC requirement, practices believed that it may take an average of just over 3 minutes to explain the purpose of the acknowledgement to a patient, and most respondents (84%) believed that an additional 3.4 minutes per patient would be required to explain the acknowledgement.

Using the survey data and salary statistics from the United States Bureau of Labor Statistics (“BLS”), Avalon Health Economics was able to conduct an economic analysis on the financial impact of the new FTC regulations on optometric practices across the United States. Using data reported in hours or minutes by survey respondents, we were able to calculate the total number of annual hours contributed to specific tasks as estimated by respondent averages. Using this information, we were then able to calculate the total annual cost for each presumed event that will occur if the new mandate is passed. These total calculations were computed by optometrist, staff member, optometric practice, and all optometric practices in the US.

Based on this methodology, the total cost per optometric practice in the United States for staff engagement training, periodic assessments of new policies, explanation of new FTC rules, answering questions concerning new FTC rules, and administrative time associated with adhering to rules could be as high as \$68,367 for optometrists (\$49,913 for staff members) per practice per year. While the practices surveyed had an average of 3.63 optometrists and 9.05 staff members, there are many smaller practices

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<sup>5</sup> D. M. Berwick and A. D. Hackbarth, "Eliminating Waste in Us Health Care," *Jama* 307, no. 14 (2012).

<sup>6</sup> See generally A. Jiwani et al., "Billing and Insurance-Related Administrative Costs in United States' Health Care: Synthesis of Micro-Costing Evidence," *BMC Health Serv Res* 14 (2014); I. Mathauer and E. Nicolle, "A Global Overview of Health Insurance Administrative Costs: What Are the Reasons for Variations Found?," *Health Policy* 102, no. 2-3 (2011); R. SoRelle, "Inspector General Wants to Curb Administrative Costs for Managed Care Organizations," *Circulation* 101, no. 7 (2000).

across the country. The cost burden for a practice with one optometrist and one staff member could be as high as \$24,310.

Thus, according to survey data, a support staff member or optometrist would spend an average of 38.27 hours annually explaining the new FTC rule at every visit, and an average of 41.74 hours annually answering patient questions that may arise as a result of the implementation of the new rule. Presupposing that a practice treats 2,246 contact lens patients annually, the estimated annual cost per administrative staff member is \$382, and \$1,301 per optometrist to explain the new Rule; and an additional \$416 per administrative staff member, and \$1,419 per optometrist for answering questions about the Rule.

1-800-CONTACTS estimates that the annual industry cost burden for the new Rule will be approximately \$73,082,912. However, our economic analysis conducted with data from practitioners and staff members estimates that the annual cost associated with various aspects of the implementation of the new Rule will total to at least \$743,905,990 if we assume that only optometrists are providing an explanation of the rule, and \$543,106,326 if we assume only staff members are providing an explanation of the rule, per year across all U.S. optometric practices.

#### **4. COMMENT ON 1800-CONTACTS REBUTTAL**

Recently the 1-800-CONTACTS provided some feedback on the Avalon analysis. In the comments below we provide some responses to the main criticisms put forward by 1-800-CONTACTS.

- 1) *Overall Survey Methodology.* There are several comments by the 1-800-CONTACTS on the Avalon survey methodology. First, 1-800-CONTACTS argues that the sampling is flawed. Avalon relied on a sample of optometry practices supplied by the AOA. The AOA membership includes the majority of optometry practices in the U.S., and the AOA believes that their membership is representative of the vast majority of practices in the U.S. In the absence of data on the universe of optometry practices, Avalon assumed that the AOA contention of representativeness was generally accurate. Second, 1-800-CONTACTS argues that the Avalon survey results could suffer from response bias. Again, Avalon and AOA expended considerable effort to increase response rates. While the resulting response rate and sample were not large, the response rate was consistent with other surveys of trade association membership. Note that, to our knowledge, the survey was disseminated to approximately 1,000 members. Therefore, the response rate is estimated to be 13%, not the 0.5% assumed in the 1-800-CONTACTS remarks. Moreover, we believe that the majority of optometry practices have similar standard operating procedures and organizational structure. Thus, there would be a point of diminishing returns to surveying a substantially larger number of practices. Also, while it is true that optimal survey design implies taking steps to minimize bias, it is very rare for any survey to be completely free of biases.
- 2) *Role of AOA Communications.* In an ideal survey, respondents would have only a broad understanding of the research goals of the survey. The rebuttal states “best practices for survey design dictate that respondents should be blind to the purpose of sponsorship of a survey to minimize the bias that results from respondents giving the answers that they *think* the surveyor wants to find”<sup>7</sup> However, the Avalon survey responses were completely voluntary and respondents did not receive compensation for their time or efforts. The AOA is responsible for

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<sup>7</sup> See Summary of Communications

keeping their members up to date on rules and regulations that may impact the overall operation of their member's practices. The correspondence sent out on November 2016, and the Avalon Survey was disseminated a full month after this correspondence. There is no indication that the delivery of the correspondence coincided with the dissemination of the survey and the time-frame of the survey.

- 3) *Accuracy of Survey Data*. In order to verify the accuracy of the data collected, Avalon conducted informal interviews with optometrists to advise on survey design, interpretation of survey data, and plausibility of responses. In addition, all labor estimates were acquired from the Bureau of Labor Statistics and outside sources that spoke to the overall cost burden of regulations on the U.S. healthcare system. In regards to the claim that cost assumptions were made using outside sources, and not collected during the surveying process, it is common practice in economic evaluation to use cost data from outside sources to augment survey data in final calculations. The 1-800-CONTACTS contention that the results are "misleading" due to biases and flawed study design is unsubstantiated. The survey results are plausible at face value, and consistent with informal communications with optometry practices, published data, and BLS data.

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- Vietti-Cook. A. "Contact Lens Rule Vol 81 No 175." edited by Federal Trade Commission, 2016.

## Contact Lens Prescription Requirements Survey

1) Zip code of practice:

\_\_\_\_\_

2) How many full time equivalent staff members do you have in your office?

Administrative staff: \_\_\_\_\_

Licensed Optometrists: \_\_\_\_\_

3) At this practice, what is the total number of *patients* that are treated per year, by all doctors at the location?

\_\_\_\_\_

4) What is the total number of *patient visits* per year, at the location?

\_\_\_\_\_

5) When you introduce a new patient engagement process into your office workflow (eg. the requirement for patients to sign additional paperwork) how much staff training does this require?

Less than 5 minutes per staff member

5-10 minutes per staff member

10-15 minutes per staff member

15-20 minutes per staff member

20 or more minutes per staff member

6) When a new patient engagement process is introduced into your office, do you conduct periodic assessments to determine if protocols are being appropriately followed?

Yes

No

7) How much time do periodic assessments of new policies and protocols generally take?

0-5 minutes

5-10 minutes

10-15 minutes

15 or more minutes

Other: \_\_\_\_\_\*

8) The Federal Trade Commission has proposed to require that patients sign an acknowledgement after receiving a copy of their contact lens prescription. How much time do you anticipate it would take to explain to a patient the purpose of an acknowledgement that reads, "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice".

Less than 1 minute

2 minutes

3 minutes

4 minutes

More than 5 minutes Avalon Health Economics, Morristown, NJ | [www.avalonecon.com](http://www.avalonecon.com) | Page 7 of 9

- 9) Do you anticipate that patients would have questions before signing this type of acknowledgement?  
 Yes  
 No  
 Uncertain
- 10) If patients have questions regarding this acknowledgement, how much time do you anticipate would be necessary to answer these questions?  
 Less than 1 minute  
 2 minutes  
 3 minutes  
 4 minutes  
 More than 5 minutes
- 11) If the requirement to use this type of acknowledgement is finalized, do you anticipate that your staff members would be trained to answer all possible questions from patients regarding this acknowledgment?  
 Yes  
 No  
 Uncertain
- 12) When you implement new policies that lead to increased patient questions, how much time do you spend in additional staff training to address patient concerns?  
 0-5 minutes  
 5-10 minutes  
 10-15 minutes  
 15 or more minutes  
 Other: \_\_\_\_\_\*
- 13) How many contact lens prescription verifications do you receive per week?  
 1-5  
 6-10  
 11-15  
 16-20  
 20 or more
- 14) Of the contact lens prescription verifications you receive per week, on average, how many are difficult to confirm?  
 0  
 1-5  
 6-10  
 11-15  
 16-20  
 20 or more
- 15) Of the contact lens prescription verifications you receive per week, on average, how many require you to correct the information sent in the verifications? (Reasons for correction may include: the patient is not your patient, the prescription is expired, the prescription is incorrect, etc

## **Appendix F**

### **Reports of Patient harm**

- A doctor from Texas reported an experience with a patient who damaged their eye because they purchased contact lenses illegally online. The doctor had an office visit with a college educated man in his late 20's who had been buying contact lenses online without a prescription for well over four years. As a result he had developed a large corneal ulcer and resultant 4 mm round opaque central corneal scar which caused a permanent loss of vision in one eye. Because of his using the illegal contact lenses he had induced a common bacteria (*pseudomonas aeruginosa*) in his eye which has been known to cause complete loss of vision in an eye within days. Fortunately he received aggressive and expensive treatment which required daily monitoring. While his eye was saved he nonetheless suffered permanent loss in one eye. His best corrected vision is now only 20/50+ with glasses - not good enough to pass a driver's test. He will now require an expensive specialty contact lens, for the rest of his life, in order to have usable vision in his eye. He came to the doctor, as he said, " looking for a doctor who could perform a miracle" and give him his sight back.
- A doctor from Washington, DC reported that a patient ordered contacts several times from an online contact lens supplier without verification from the doctor and only disposed of his lenses away when the they became uncomfortable. After ordering these lenses online, she wore her 2-week approved daily wear soft contact lens for 3 months or more. She was able to order lenses online after her prescription was expired. At the visit, the patient complained of very red, irritated and sensitive to light left eye. She was found to have a large inferior temporal corneal ulcer. After treatment and resolving the medical emergency, she showed a corneal scar in the area of the previous ulcer.
- A doctor from Washington, DC reported that a patient ordered lenses online well past the 1-year expiration date and wore a pair of lenses for over 2 months continuously. The doctor had not seen the patient in about 2 ¼ years. Upon examination, the patient complained of burning, red eyes with light sensitivity for the previous 2 days. A slit lamp examination showed bacterial corneal ulcer of the right eye. After treatment and a comprehensive presentation on the proper wearing and caring for lenses, the patient is now left with a corneal scar when the ulcer presented itself and is no longer capable of wearing extended wear lenses.
- A doctor from the Washington, D.C. reported examining a new patient wearing Hubble lenses for several days at time. The patient had a corneal neovascularization and 20/25 BVA. The patient's last exam was 3 years ago. After a follow-up visit, the patient had a re-refraction (now 20/20+ BVA) and commented how much whiter her eyes had become.
- A doctor from the Washington, D.C. reported receiving a "second request" prescription verification from Lens.com via fax. The request stated that Lens.com would notify the attorney general and my patient if the doctor did not respond. The doctor already responded to the original request that the prescription was expired 2 weeks prior to the receiving the "second request.
- Last year, a doctor reported a patient who obtained her contact lenses online. The patient had not received an eye exam for 5 or 6 years. The patient was suffering from superior neovascularization of about 3.5 mm into the cornea.
- A doctor from Wisconsin reported that a patient obtained contact lenses from an online retailer who disregarded a significant part of the prescription. The patient complained of blurring vision to a point that it would have been difficult to successfully pass a driver's license exam.
- A doctor from Wisconsin reported that a patient wearing decorative non-prescription contact lenses which were purchased at a convenience store and never been properly evaluated or fit by an eye doctor. The patient complained of a red, painful eye and blurry vision and was found to have a corneal ulcer caused by the improper fit and care of these lenses.

- A doctor from Nebraska reported a patient who obtained their contact lenses from online retailers, but had not undergone an eye exam in over 5 years. The doctor was never contacted by any of the online retailers to verify the patient's prescription. The patient complained of redness and irritation in both eyes and was not wearing the contact lenses that the doctor had prescribed. The lenses were fitting tight and the patient had neovascularization on his corneas with multiple areas of keratitis and decreased vision. The patient now suffers from permanent scarring on his corneas.
- A doctor from New Mexico reported that online retailers would routinely send his patients new contacts without verifying the prescription for 5 years. The patient received the wrong prescription and the wrong brand from the retailers. The patient visited the doctor after being treated by two local emergency rooms for a painful red eye. He was found a 4mm central corneal ulcer caused by over wear of contact lenses. He was left with a corneal scar and ultimately had to be referred to a corneal specialist where he received a twenty -thousand-dollar corneal transplant. He has regained most of his vision after the surgery but will suffer some permanent vision loss.
- A doctor from Indiana reported a patient wearing Hubble contact lenses. The patient ordered the contact lenses online without a prescription. Even though the patient complained that the lenses were "really uncomfortable for the first two weeks," she continued to wear the contacts because they were inexpensive. Her prescription was never verified by the doctor. At her annual exam, the patient had neovascularization of her corneas, a hallmark of tight, poorly fit and low oxygen-permeable contacts.
- A doctor from Kentucky reported a patient who purchased contacts from a "flea-market." After wearing the contacts for just one day, the patient developed excruciating pain and was found to have epithelium from both corneas completely gone. The ill-fitting contacts were too tight and caused the corneas to swell, forming a tight seal with the contact lenses. When she removed the contacts, she peeled off the damaged corneal epithelium. It took three days for her corneas to completely heal.
- A doctor from Georgia reported a patient was able to purchase generic contact lenses from Hubble without verification and were auto shipped to the patient each month. The patient was able to purchase an indefinite supply of contact lenses of his choice without any verification of a valid prescription.
- Several doctors from Georgia have reported that their patients ordered trial lenses from Hubble without the doctor ever receiving a verification request.
- A doctor from New York reported that a patient received the wrong prescription from Hubble, which resulted in headaches.
- A doctor from New York reported that a patient received lenses from Hubble that did not fit properly and resulted in a limbal SPK.
- A doctor from New York reported that multiple patients received contact lenses from online retailers that were different brands and materials than prescribed.
- A doctor from Florida reported that a contact lens patient who suffered from multiple areas of inflammatory infiltrates piercing through the epithelium (skin) and a wide spread area of cloudy corneal tissue due to edema.
- A doctor from Florida reported that a patient who wore very old and contact lenses that were probably not cleaned as well as they should be. The patient had signs of corneal hypoxia with 1-2 millimeters of neovascularization circumlimbally.
- A doctor from Arkansas reported that a patient was able to order contact lens through an online contact lens retailer without notification or approval from the doctor's office. The lenses he received were not what was prescribed. While traveling to Connecticut the patient called to report the lens was stuck in his eye. He experienced redness and discomfort with the immobile lens.
- A doctor from Arkansas reported examining a contact lens patient with peripheral retinal hemorrhages in one eye and carotid bruits.

- A doctor from New Hampshire reported that a patient ordered a “free supply” of 15 pairs of contact lenses from Hubble without a prescription or verification. The patient had never received a fitting for his contact lenses, nor any instructions on how to use them. He patient complained that he could not successfully insert or remove his contact lenses and that his contact lenses were blurry and very uncomfortable. The patient was not able to wear the contacts without pain, discomfort, or quickly developing red eyes.
- A doctor from New Hampshire reported that their patients were wearing Hubble contacts without any verification from their office. One patient in particular complained of the fit and presented with keratitis at her exam. When the doctor’s office receives a message from Hubble to verify a contact lens prescription, Hubble never states where they are calling from or provide a contact name and phone number. The doctor attempted to contact Hubble but never received a return call.
- A contact lens patient from Florida reported that that she received contact lenses from Hubble that was not the prescription that she entered. She reported the she could not see clearly and that the lenses felt uncomfortable. The company sent three boxes even though she contacted them by email to discontinue mailing contacts.
- A doctor from Ohio reported that an online retailer has been refilling a patient prescription since 2012 without any notification or authorization from the doctor. The patient developed vision problems and it took several visits to get him seeing well again.
- A doctor from Ohio reported that a patient obtained contact lenses from an online retailer with a prescription from 2015 and no verification from the doctor.
- A doctor from Ohio reported that a patient ordered another year of contacts from an online retailer without verification.
- A doctor from Ohio reported that an online retailer filled a contact lens order for her patient after the doctor responded to two separate verification requests, informing the online retailer that the prescription was expired.
- A doctor from South Carolina reported that a patient received unfitted lenses from a retailer after the doctor responded to the seller’s verification. The doctor instructed the seller not to fill the prescription with the unfitted substitute.
- A doctor from South Carolina reported that a patient obtained a Halloween contact from a online retailer without a current prescription. The patient had a raging infection the next day from wearing an unprescribed lens.
- A doctor from South Carolina reported that an online seller had been renewing his patient’s expired prescription. The patient had not had an eye examination in more than 5 years.
- A doctor from South Carolina reported that a patient was shipped lenses from an online retailer with the wrong prescription. The doctor attempted to respond to the retailer’s verifications before the prescription was filled, but never received a response from the seller.
- A doctor from Missouri reported that several of his patients purchased contact lenses from online retailers for years without an eye examination. The doctor never received a verification request for these patients.
- A doctor from Missouri reported that a patient had purchased contact lenses from online retailers for 8 years without an eye examination.
- A doctor from Missouri reported that a patient had purchased contact lenses from online retailers that were not the correct prescription or lens material. As a result, the patient suffered a corneal ulcer that resulted in scarring.
- A doctor from Montana reported that several patients were able to obtain contact lenses from online retailers without obtaining following up care and subsequent eye exams. These patients wore their lenses not as directed, did not change the lenses as directed, and were sleeping in them. The patient’s developed blood vessels growth into the cornea (neovascularization) and damage to the corneal endothelium. Two of these patients will no longer be able to wear contacts and both will need to be closely watched for potential continued consequences. No direction, ocular health

exams, or correction of improper use was given to prevent these negative consequences and outcomes.

- A doctor from Montana reported that a patient was able to purchase contact lenses online without seeing an eye doctor for several years. The doctor found two large corneal ulcers on one of her eyes due to continued use of a contact lens that was too tight and abusive. Because she had no eyeglasses at the time, she was unable to drive until the corneal ulcers were under control. In addition to poor vision, she was severely light sensitive and had to use dark glasses just to function inside. Daylight caused too much pain and discomfort to venture outside. She had to miss over a week of work. Her condition resulted in a permanent vision deficit (20/40+ best corrected) and she continues to have problems with night glare
- A doctor from Connecticut reported that an online retailer “refit” their patient into a different contact lens, without contacting the doctor to verify the old prescription or requesting permission to trial the new contact lens. The patient was wearing the unfitted 2-week replacement contact lens for up to a month. As a result, he suffered from corneal and conjunctival inflammation. After not seeing the doctor for two years, the patient made an emergency appointment due to red and irritated eyes and blurred vision.
- A doctor from Colorado reported that a patient obtained cosmetic contact lenses without an eye doctor. Because the patient had not been properly trained in cleaning and care and wore unfitted contact lenses, he suffered from an infectious ulcer and underwent a corneal transplant.
- A doctor from Colorado reported that a patient purchased daily use contact lenses through Hubble without a proper prescription. Her contact lens prescription was for an Acuvue lens and was not for daily use. She reported that they were the most uncomfortable lenses she had ever worn.
- A doctor from Vermont reported that a younger patient purchased lenses from a website called pinkyparadise.com in an attempt to make her eyes look bigger without a prescription. The patient suffered from cut on the front of the eye, and the doctor had to remove what seemed to be part of the contact lens from her eye. To address the injuries, the doctor prescribed another contact lens to protect the wound, painkillers, artificial tears for lubrication, and appropriate follow-up.
- A doctor from South Carolina reported that patient was using contact lenses for three years without an eye exam. The patient stated that he had been wearing the same pair of contact lenses for about 5 months and never took them out before going to bed. As a result, he was suffering from a central corneal ulcer, reduced vision, redness in the left eye, severe pain, and sensitivity to light.
- A doctor in Florida reported that his office has confirmed two patients who were able to purchase contact lenses without a prescription from Hubble. This doctor also reported a patient who purchased his contact lenses online legally, with a valid 2 year prescription, but who was experiencing very high intraocular pressure and had already sustained significant optic nerve damage.
- A doctor in Florida reported at a patient was able to obtain contact lenses from Hubble without supplying a prescription or a brand name. The doctor never received a request for prescription release from the company and the lenses were received by the patient.
- A doctor in Florida reported that a patient was able to obtain contact lenses from Hubble without prescription verification of any kind.
- A doctor in Florida reported that a patient presented in the office with chronic pain and discomfort in both eyes. He had very high intraocular pressure and moderate glaucomatous damage. It is difficult to say how long the pressure was that high, but it had been three year since that patient’s last eye exam and contact lens check – the patient reported ordering contact lenses online with an expired prescription in the interim years.
- A doctor in Florida reported a patient came to the office after ordering contact lenses through an online retailer utilizing an “online vision test”. The patient reported difficulty seeing through the contacts that he recently ordered. It was determined that the online vision test over-minused the

patient by -2.00 D. This patient demonstrated common accommodative issues within his age group that would have been detected with a comprehensive eye exam. This error disrupted the patient's vision to the point that he would not have passed a driving test in the state of Florida.

- A doctor in Ohio reported a patient presented to her office for a comprehensive ocular examination and wanted to update her contact lens prescription and complained of blurred vision with her current contact lenses. The patient had not been seen in over three years and stated that she had given Hubble her old contact lens prescription and they sent her a two year supply, substituting Hubble lenses in the same power. During the examination it was noted that her corneal health was compromised showing signs of oxygen deprivation which led to blood vessels growing into the cornea and causing hazing of the cornea and therefore reducing her vision.
- A doctor of optometry in Ohio reported treating a patient for giant papillary conjunctivitis and infiltrative keratitis secondary to the use of contact lenses purchased from: <http://www.pinkyparadise.com/Geo-Medical-s/1853.htm>
- A doctor of optometry in Ohio reported treating a patient who had corneal eye infection in both eyes. The patient admitted to buying a pair of colored contact lenses from a convenience store in a neighboring town. This patient had never worn contacts in the past and was unaware of proper contact lens care and hygiene. He washed the lenses in tap water prior to inserting them in his eyes, leading to the infection.
- A doctor in Ohio reported a patient in her office was able to renew his prescription for contact lenses on-line with an expired prescription (and he was switched to another brand without a valid prescription from our office). After several months of red and irritated eyes he presented to the doctor with a request to go back to his old type of contact lenses. It turned out the lenses were not the only problem, but he had a very severe case of Demodex Blepharitis (inflammation of the lids secondary to dust-mite infestation). The condition could have been headed off if he had had a comprehensive ocular examination. As an additional note, the doctor switched him back into his old type of lenses which were a healthier choice for his eye condition.
- A doctor in Arkansas reported seeing a new patient for his comprehensive exam. He reported that he has been filling his contact lens prescription for about the last ten years without having an eye exam, but had recently noticed he was not seeing as sharply as he used to. Upon examination, the doctor noted he had mild neovascularization from contact lens induced hypoxia. The doctor educated the patient on this condition and proper contact lens hygiene and replacement, and, changed his contact lens prescription to lenses that allow for more oxygen transmission.
- A doctor in Arkansas reported a patient in the office complaining of contact lens discomfort. Upon further inquiry, the patient stated that she had submitted her last contact lens prescription, which had been issued by the doctor office, to Hubble Contacts. Hubble filled her contact lens prescription with an unknown brand of daily contact lenses. The contacts she had been issued were not the same parameters as the ones originally prescribed, but they were the same power prescribed. Her complaints of discomfort were related to the way the Hubble contacts were fitting her, as they did not fit as well as the initial brand prescribed.
- A doctor in Louisiana reported a case of a patient with a central corneal ulcer caused by sleeping in contact lenses. While the doctor had initially prescribed lenses approved to sleep in over three years earlier, an online seller had allowed the patient to order a different lens, not approved for overnight use, in addition to providing contact lenses without a valid prescription or an attempt at prescription verification. The doctor treated the ulcer, but the patient's vision was permanently worsened by the incident.
- A doctor in Delaware reported a patient presenting wearing cosmetic/colored contact lenses that she purchased online without a contact lens fitting or Rx. She was complaining of redness and irritation of both eyes after she started wearing these lenses. The doctor had the patient dispose of the contact lenses and started her on topical eyedrops to treat the inflammation.

- A doctor in Delaware reported a patient complaining of irritation of the eyes from her new contact lenses, ordered online. She was given an Rx for Brand A contact lenses from the doctor. The patient received Brand B contact lenses from the online vendor. The online vendor suggested “Brand B was equivalent to Brand A” and less expensive, and proposed the substitution. The doctor educated the patient about the differences between the different brands of contact lenses available on the market and that trial fittings are important to make sure the fit, comfort, and vision is right for the patient.
- A doctor in North Carolina reported the case of a patient who purchased contact lenses from an online retailer, who did not verify the prescription. The patient ordered 583 lenses (equivalent to 4 years of contacts) and they were shipped to him by a third party site. The patient confirmed that he was reselling the lenses online.
- A doctor in North Carolina reported a college aged patient presenting for a comprehensive eye exam with a central corneal ulcer, which is a high risk for permanent vision loss. She reported that her last exam was over four years prior, but that her preferred online retailer sent her contact lenses without asking to verify the prescription.
- A doctor from North Carolina cared for a patient who ordered contact lenses from an online retailer who did not attempt to verify the prescription. The patient returned to the doctor after several weeks of wearing the lenses with severe headaches, nausea, and difficulty with school. The doctor immediately recognized that the retailer had provided the wrong lenses – the prescription was supposed to be for myopic correction (- prescription) but the retailer sent the opposite power (+ prescription). The doctor worked with the online retailer to get the patient the correct pair of lenses.
- A doctor from North Carolina reported a young male who suffered significant corneal distress due to contact lens over-wear and lack of oxygen to the tissue. He had purchased contact lenses from an online retailer for 3 years with an expired prescription.
- A doctor from Ohio reported the case of a 21 year old college student who was examined in March of 2016. A contact lens Rx was released for the brand that displayed proper fitting alignment, centration, and tear exchange on her eyes. On October 9, 2017 she returned with an extremely painful, red left eye. A central corneal ulcer infection had developed from overwear of an unknown brand of contact lens she obtained elsewhere. The lens fit too tight on the eye, trapping tears and bacteria enough to create an ulcer. After intense antibiotic therapy, she healed with a scar that reduced her best visual acuity.
- A doctor from Kansas cared for a patient diagnosed with a herpetic ulcer in the eye. The patient had an expired prescription and the doctor had declined verification of multiple contact lens orders. Eventually, the patient received contact lenses without a valid prescription from an unidentified source. This allowed her to continue to delay a needed eye exam and to allow the ulcer to develop.
- A doctor from Oregon shared the case of a 19 year old female patient who was able to access and purchase theatrical (colored) contact lenses online. She had never worn contact lenses nor had ever been interested when in the office. She presented to the clinic with the lenses to be evaluated after many unsuccessful attempts to insert them. The doctor placed them on her eyes for her and then proceeded to evaluate them. The fit was dangerous and uncomfortable and her vision was not acceptable. Fortunately, her trip to the office prevented possible complications.
- A doctor in Washington, D.C., saw a new patient complaining of pain, tearing, and light sensitivity. The patient had not had an eye exam in 5 years, but had successfully purchased contact lenses with an expired prescription from an online retailer. The exam revealed contact lens-related keratitis due to inappropriate wear and care of the contact lenses. After appropriate treatment lasting several days, and a refitting of new contact lenses and education about their use, the patient has successfully returned to contact lens wear.

- A doctor from Alabama reported the case of a patient that finished college and moved a city in northern Alabama and continued ordering contact lenses over the internet for 2 ½ years after her contact lens prescription had expired. Not only did her prescription change during that time, but the online supplier also changed her to a different brand of contact lenses that “were less expensive.” The brand she was wearing---but never prescribed--- caused significant corneal edema/swelling which contributed to the central corneal ulcer she developed which resulted in the permanent loss of one line of visual acuity on the eye chart. This was revealed during an emergency visit at the doctor’s office. She happened to be home for a visit and her parents insisted she come in for an evaluation of her red and angry eye.
- A doctor from California cared for a 34 year-old woman complaining of severe eye pain, redness and light sensitivity in both eyes. In her exam, the doctor determined she had not had an eye exam in over 4 years and had been filling her contact lens prescription online. Additionally, she reported episodes of eye problems but “just stopped wearing contacts for the day, or threw them out.” Her exam revealed numerous scars on her cornea from infections due to improper contact lens wear and abuse. More seriously, she had caused permanent damage to the surface of her eye and required corneal surgery. She missed 2 months of work as we treated her eyes, and received part-time disability benefits.
- A doctor in Maine responded in a timely manner to a verification fax from Hubble Contacts rejecting the request as the patient involved had not been properly fit to the lenses to determine if they meet the necessary health and vision requirements of any contact lens fit. Hubble delivered the contact lenses despite the rejection, disregarding state and federal contact lens law.
- A doctor in Texas reported the case of a patient who had five corneal ulcers, resulting in permanent corneal scarring and best corrected vision in that eye below driver’s license vision standards. The ulcers were caused by a contact lens that fit too tightly. Upon further investigation, the doctor found that the patient was wearing a contact lens substituted by an online retailer, without notification, and not the lens prescribed by the doctor.
- A doctor in Wyoming reported multiple interactions with Hubble Contacts, in which the company substituted their own lenses for the prescribed brand, despite different fit parameters, delivered the lenses to the wrong patient, filled an expired prescription despite the doctor’s negative response to the verification attempt, and replaced toric lenses to correct astigmatism with a daily contact lens with only sphere correction. In all cases, the doctor attempted to correct the prescription based on the verification attempt, but the lenses were delivered anyway.
- A doctor in Iowa reported the case of a 35 year-old female truck driver who presented wearing contact lenses she had purchased online three months earlier. Her last visit to an eye doctor had been approximately four years before that. Her left eye was red, painful, and “blurry.” The doctor diagnosed her with a corneal ulcer due to contact lens overwear. This patient was successfully treated, but the ulcer left a scar in the central cornea and she now permanently has 20/70 vision in that eye. As a result, she is no longer able to obtain a commercial driver’s license and has had to find a new career.
- A doctor in Illinois reported the case of a high school-aged patient who had slightly irritated his eye while removing his contact lens and continued wearing it for the 3 days. He presented himself in the office on a Monday morning complaining that his vision became blurred and his eye began to hurt over the last 48 hours. Upon examination, the inside of his eye was filled with pus, caused from a pseudomonas corneal ulcer. He needed to be immediately hospitalized with 24 hour antibiotic administration in order to save the eye. The end result was a residual corneal scar that had caused some permanent reduction of vision. If the ulcer had been 1-2 mm closer to the center, his vision loss would have been much greater.
- A doctor in North Carolina reported receiving numerous verification attempts for individuals who had never been patients in his office.

- A doctor in North Carolina reported the case of a patient who had been purchasing contact lenses from an online retailer for 5 years. The patient's vision had declined, even while wearing contact lenses, to 20/60, making him a danger behind the wheel of a car. However, the patient did not realize how poorly he was seeing because the change was so gradual.
- A doctor in Idaho reported the case of a patient with a red, sore eye, resulting from poorly-fitting contact lenses purchased from Hubble Contacts. It had been years since she had had a contact lens related assessment to determine health status, current prescription and most importantly determine if she was still approved to wear contacts based on eye health. She was given a prescription for unauthorized contact lenses without a current prescription, and no rationale for why she was given the lenses she was given. The patient was treated and fitted with appropriate lenses.
- Multiple doctors reported receiving calls from a "Paul Rogers" requesting a contact lens prescription verification for a patient for whom the doctor has no record. The prescription information is typically incomplete and often for large numbers of lenses. Upon calling the return phone number given, the doctors reach a voicemail for "contact lens verification," leave a message, and never receive a return call. These doctors are concerned that their license numbers are being misused for illegal contact lens activities.
- A doctor in Alabama cared for a new patient who had moved to the area five years prior and who had not had an eye exam since moving. An online supplier continued to furnish this patient contact lenses each year, even after moving across the state and having established no provider in her new city. Not only were her contact lenses continually renewed without a valid prescription, she was able to order a different type of lens without a new prescription from a doctor. The patient no longer wears contact lenses due to contact lens intolerance she developed from years of abuse—abuse promoted and enabled by an online vendor who failed to follow the legal requirements for contact lens sale.
- A doctor from Michigan cared for a new patient who had not had an eye exam or evaluation for over 4 years. She had purchased contact lenses online without a valid prescription. The contact lenses that had been used are a reputable brand. However, they had been seriously over-worn and the cornea was now badly distorted with a damaged surface. The doctor had a difficult time trying to improve the corrected vision. Corneal topography that maps the front surface shows a corrugated/rippled surface. The patient has been prescribed a steroid eye drop, and will be using glasses only for 1 month. The doctor is hopeful that the corneal surface will start to heal, but if the surface does not respond the vision will not recover to 20/20, and the future calculations for cataract surgery are likely to be inaccurate.
- A doctor in Mississippi reported the case of a patient who was also a local family physician suffered from an infiltrative keratitis with early corneal ulcer formation because of contact lens misuse and a lack of regular eye care since purchasing contact lenses online without a valid prescription. The patient had initiated his own treatment, which the doctor replaced with the proper medications. Unfortunately, even highly health literate patients sometimes fail to appreciate the delicate balance in the human eye.