AMERICAN OPTOMETRIC ASSOCIATION

July 29, 2019

The Honorable Joseph Simons
Chair
Federal Trade Commission
600 Pennsylvania Avenue NW
Suite CC–5610 (Annex B)
Washington, DC 20580

Dear Chairman Simons,

The American Optometric Association (AOA) appreciates the opportunity to provide these comments in response to the May 28, 2019 Supplemental Notice of Proposed Rulemaking; request for public comment. The AOA represents approximately 33,000 doctors of optometry and optometry students. Doctors of optometry are eye and vision care professionals who, during a comprehensive eye exam, diagnose and treat diseases and conditions of the eye, such as glaucoma, diabetic retinopathy, macular degeneration, cataract, refractive error, oculomotor dysfunction, and strabismus, among others. Additionally, a number of systemic diseases – such as hypertension, cardiovascular disease, neurologic disease, and diabetes – manifest with ocular symptoms and doctors of optometry play a key role in the management of those diseases.

Doctors of optometry deliver up to 80 percent of all primary vision and eye health care provided through Medicaid in the United States. Recognized as Medicare physicians for more than 30 years, doctors of optometry also provide medical eye care to over six million Medicare beneficiaries annually. The AOA serves the needs of the public and health professionals through the provision of evidence-based clinical practice guidelines that promote prevention, identification, treatment, and management strategies for eye and vision conditions/diseases to improve the nation's health. In addition to the range of care our doctors provide, doctors of optometry also evaluate patients for contact lens wear and prescribe these medical devices. The AOA's 2018 American Eye-Q survey found 94 percent of Americans responding to the survey say they trust doctors of optometry for accurate and reliable information about eye health. When asked which information source they trust the most, over half select doctors of optometry-significantly more than other sources.

Compliance with Prescription Provision Requirements

We understand the Commission's explanation of how survey data is viewed and assessed and that the Commission has indicated it is cognizant of the interests of submitting parties. However, we remain concerned that the 1-800-CONTACTS data regarding compliance is misleading. The survey indicated that 28 percent of those surveyed received his/her prescription after asking for it. The Commission considers the response to this question as an indication of non-compliance. However, we know from our doctors' experiences with patient care that it is not unusual for

patients to request their prescription early on in the visit prior to completion of the contact lens fitting. AOA conducted our own survey in June 2019 to assess prescription provision practices. 91.7 percent of doctor of optometry respondents indicated that there are times when a patient will ask for his/her prescription prior to the finalization of the contact lens fitting. Given the high number of doctors reporting that patients will ask for the prescription prior to its availability, we believe that the data from 1-800-CONTACTS regarding patients asking for their prescription cannot be interpreted as indicative of non-compliance with the Rule.

The Commission has also attempted to explain the relatively low number of Contact Lens Rule related complaints received by noting that "even consumers who are aware that they have a right to their prescription are unlikely to file complaints with the Commission if they ultimately receive their prescription after they have asked for them." In this case, the Commission is again directly equating a patient asking for his/her prescription with non-compliance. But from our survey data we know this is an inaccurate assessment. It is very typical for patients to ask for their prescription prior to the contact lens fitting completion. As such, a patient asking for a prescription before a doctor can actually provide it must not be viewed as indicative of non-compliance.

The Commission has repeatedly noted its view that the patient complaints received related to the Contact Lens Rule are not fully indicative of the prevalence of non-compliance. We feel that it is noteworthy to reiterate that in the AOA's 2015 comments on the Rule, our organization recommended that a dedicated complaint system be set up related to contact lens related issues. AOA indicated at that time, "The AOA requests the FTC set up a specific complaint system for FCLCA-related concerns. The online complaint assistant service currently operated by the FTC is not appropriately set up to receive these types of complaints and doctors who take time out of their practices to report issues of concern often feel their reports go unnoticed by the FTC. Setting up a distinct FCLCA complaint system would be a benefit to patients as well, providing them with a simple process to follow in case they have contact lens sale-related concerns." We also include information on how to report contact lens related concerns on the AOA website. By contrast, in the Consumer Action "Know Your Eyecare and Eyewear Rights" video, the organization provides information on patient rights but provides no information directing patients where to go to report a concern.[1] Instead, the organization provides information about online vision testing. Information from 1-800-CONTACTS on prescriber requirements similarly omits FTC complaint reporting information. More time seems to be dedicated to questioning the ethics of doctors of optometry than to ensuring that patients know the appropriate steps to remedy a concern.

Overall, we are very concerned that in the Commission's assessment of prescriber compliance, the Commission may have misinterpreted survey data leading to an inflated view of potential non-compliance. Additionally, we are concerned that the Commission is unwilling to simplify the complaint system for the Contact Lens Rule so that more data can be captured, but at the same time the Commission is willing to take the data it does have as sufficient indication that there are widespread compliance issues. We believe that increased efforts should be undertaken to better understand patient experience.

[1] https://www.youtube.com/watch?v=nqdHxc8i3bs&feature=youtu.be

The High Number of Seller Verifications

The Commission continues to cite the number of contact lens prescription verifications as an indication of patients' not being provided their contact lens prescription, despite the Commission also recognizing that some contact lens retailers have no mechanism by which to accept a copy of a contact lens prescription. We believe that the Commission's perception of the number of verification calls occurring should be given no weight when it comes to attempting to determine compliance with prescription provision requirements. In addition to the reality that some retailers do not have a method for patients to provide a copy of their prescription, there are also new companies who have entered the market over the past few years who are attempting to sell contact lenses by taking advantage of the passive verification system and they rely exclusively on verification calls.

Hubble contacts launched in November 2016. As FTC has acknowledged, over the past few years there has been an "emergence of business models that rely exclusively, or almost exclusively, on passive verification as a means to substitute their own brand of daily contact lenses." We know from our own member surveys that very few doctors have Hubble fitting kits; however, there are hundreds of verification calls conducted to attempt to verify a prescription for Hubble contacts. The AOA continuously receives member reports of contact-lens related sales concerns. Since 2017, the AOA has received 1,028 physician complaints. 176 reports were related to problems with verification calls. Out of the total problematic verification calls, 58 percent were related to Hubble contacts. By comparison, between 2013 and 2015 only 6 percent of physician complaints received related to contact lenses were regarding quality of verification calls. Given recent market changes, we believe that a high volume of verification calls are occurring based on a prescription that was never written. Given that reality, the number of verification calls is simply not an appropriate measure for assessing contact lens prescription provision requirements and again should be afforded no weight in the Commission's continued evaluation of the Contact Lens Rule. Additionally, we encourage the Commission to use what data it appears to have regarding verification calls to further investigate the verification calls initiated by Hubble contacts. We would like to connect the Commission with the doctors who reported verification call concerns from Hubble contacts for further investigation. At no time should a contact lens seller initiate a prescription verification for a prescription it knows does not exist, or for a prescription it knows is expired.

We also believe that in some cases patients may find it easier to rely on verification than to provide a copy of their prescription to the retailer. As an example, Coastal Contacts allows patients to provide a doctor's contact information for prescription verification. Alternatively, Coastal Contacts notes, "Send us a copy of your prescription later. We will let you know how to send in your prescription for verification once your order is complete." (Appendix A) In those cases, the patient provides all of their payment information before providing a copy of their prescription to the retailer. Some patients may find it easier to provide the name of their doctor rather than to wait and provide all of their credit card information before submitting the prescription. Additionally, Lens.com asks patients to provide their doctor's contact information and seems to suggest that sending a copy of the patients' prescription is only necessary if the patient's doctor is outside of the United States. Lens.com has patients check a box that indicates "My doctor is outside of the U.S., Canada, and Caribbean Islands. I will fax/email my

prescription." (Appendix A) Again, due to a multitude of confounding factors, relying on the number of verification calls cannot be a measure of prescription provision requirements.

Posted Sign Alternative Proposal

The AOA has long argued that an alternative approach to increase consumer awareness, while also limiting burden on physicians, would be for the Commission to require physicians to post a sign in their offices notifying patients of their right to their prescription. The Commission has previously raised issues with this approach and most recently noted that the signed acknowledgment form is similar to the current HIPAA Notice of Privacy Practice (NPP) acknowledgment that physicians are already obtaining from each patient. The Commission also indicated that the Department of Health and Human Services (HHS) "rejected the idea of relying on signage or providing the notice only upon request, since it determined that the burden of enforcing an important right afforded to individuals by the rule should not be placed on the individual." However, we believe that the Commission should further consider the fact that HHS is currently revisiting that very issue. In the December 14, 2018 Request for Information, HHS indicated it is considering, "eliminating or modifying the requirement for covered health care providers to make a good faith effort to obtain individuals' written acknowledgment of receipt of providers' Notice of Privacy Practices, to reduce burden and free up resources for covered entities to devote to coordinated care without compromising transparency or an individual's awareness of his or her rights."[2]

The physician community is united in its belief that the requirement to have patients sign the NPP should be eliminated. The American Medical Association has noted, "Removing the written acknowledgement requirement would reduce administrative burden by decreasing the amount of paperwork to print and store; it would also limit unneeded compliance monitoring."[3] The American Osteopathic Association has stated, "Privacy disclosure requirements place a significant administrative burden on physicians while not effectively informing patients in an accessible manner of how their PHI will be used. The American Osteopathic Association would support easing administrative burden by eliminating the requirement that physicians and non-physician clinicians make a good faith effort to obtain written acknowledgement of receipt of the provider's Notice of Privacy Practices (NPP)…written acknowledgements do not necessarily demonstrate patient understanding of their rights and do not affect other provider compliance requirements."[4] The American Hospital Association (AHA) also supported the elimination of the NPP requirement stating, "The AHA supports the elimination of the requirement for covered health care providers to make a good faith effort to obtain individuals' written acknowledgment of receipt of providers' Notice of Privacy Practices. We agree with OCR's assessment that the elimination of the requirement would reduce burden and free up resources for covered entities to devote to coordinated care without compromising transparency or an individual's awareness of his or her rights."[5] Given that the need for the NPP is currently under question in 2019, we believe that the Commission cannot rely on statements from the HHS in August 2002 as a reason to dismiss the AOA's alternative signage proposal.

[2] https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf
[3] https://www.regulations.gov/document?D=HHS-OCR-2018-0028-0657
[4] https://www.regulations.gov/document?D=HHS-OCR-2018-0028-1184
[5] https://www.regulations.gov/document?D=HHS-OCR-2018-0028-1084

Additionally, the Commission has again relied on evidence provided by 1-800-CONTACTS to support the decision not to seriously consider the alternative posted sign proposal as a pathway forward. 1–800 CONTACTS invested time and money to undercut the proposal put forward by our organization and our member doctors. Our alternative proposal to require prescribers to post signs notifying patients of their rights is a proposal that is supported more than 100 Members of Congress, both Democrats and Republicans. Despite having support from the physician community and broad bipartisan support, we are concerned that this alternative was not appropriately considered and instead the Commission has given tremendous weight to the 1-800-CONTACTS sponsored survey.

We understand that the Commission has raised concerns with increasing its ability to enforce the Contact Lens Rule and that the posted sign requirement would be difficult to enforce. In the Supplementary Rulemaking, the Commission noted:

> Under the current Rule, to investigate a complaint and bring an enforcement action, the Commission might be required to issue a Civil Investigative Demand for the names and contact information of a prescriber's recent patients (perhaps within the past two months), and then survey or interview them to ascertain whether they received their prescriptions. The Commission might also have to conduct investigational hearings with prescribers' office staff to determine if there was any proof that prescriptions had been provided. Such an investigation would be resource intensive for the Commission and costly, time-consuming, and disruptive for a prescriber, even if the Commission never ultimately brought an enforcement action.

The Commission has described the potential use of Civil Investigative Demands (CID) related to potential non-compliance as burdensome. However, on March 6, 2019 FTC attorneys published the article, "The FTC takes its subpoenas and CIDs seriously – and you should, too." The article noted, "The FTC's ability to obtain information through subpoenas and civil investigative demands (CIDs) is critical to the task of investigating potential law violations. The FTC uses this authority deliberately and responsibly, avoiding unnecessary burdens on businesses and individuals and consistent with our obligations to enforce the law."[6] Given that the use of CIDs appears to be a fairly typical approach for the Commission to take when investigating possible law violations, we question why the Commission views enforcement and the potential use of CIDs related to the FCLCA and Contact Lens Rule as more burdensome or as a limitation on the Commission's ability to take enforcement action. To date, the Commission has indicated that some additional requirement on prescribers and documentation is necessary for enforcement but based on the historical use of CIDs and the Commission's recent education regarding their use, we believe the current law and the enforcement authority already granted to the Commission would be sufficient for enforcing the law and Rule.

[6] https://www.ftc.gov/news-events/blogs/competition-matters/2019/03/ftc-takes-its-subpoenas-cids-seriously-you-should-too

The Commission also noted, "The argument put forth in some comments that the cost of the Rule's burden falls disproportionately on prescribers, and that this proposal aggravates that imbalance, is not persuasive." However, it would be helpful if the Commission can address why some retailers have been able to continue to operate in complete violation of the law for the past several years when the evidence of the retailer's non-compliance is so clear. The Commission argues that additional documentation is needed for better enforcement on the prescriber side. However, on the retailer side there is already clear documentation demonstrating a total lack of compliance and yet nothing has been done to stop these retailers. Saveonlens.com indicates on its website, "Buying contact lenses online has never been easier with SaveOnLens. No prescription required, no customs delay, no tax." (Appendix B) FTC staff has previously indicated that there are challenges to enforcement because some of these companies operate outside of the United States. Given that this company indicates orders from the United States ship from the United States warehouse, we believe that some action could be feasible on the part of the Commission. This is especially concerning since AOA reported Saveonlens.com back in October 2015 and no action has been taken. The AOA also raised concerns with the online retailer, Wish, and reached out directly to the company to inform them of the legal and regulatory framework that surrounds the sales of contact lenses. That outreach has been ignored and the company has been allowed to operate is disregard of the regulations and the law. Additionally, it is extremely concerning that the company's owner recognizes the potential for patient risk but takes no responsibility. In an article published in Forbes in March 2019, the author noted that the Wish CEO, Peter Szulczewski, was "unfazed by the quality-control challenge, pointing out that sometimes customers themselves are the problem." Szulczewski commented, "We sell 5 million contact lenses a year…someone's going to sleep in them."[7]

FTC has indicated AOA's concerns with a lack of balance in the rulemaking regard to burden is not persuasive, but it is alarming to us that the Commission is considering implementing significant documentation requirements for small business physicians when evidence of online retailers' non-compliance already exists, no enforcement actions are being taken and patients are being harmed. Additional retailers who advertise and thereby document their law and Rule violations are listed in Appendix C.

Medical Device Sales by Physicians

In AOA's meetings with the FTC, the FTC has indicated that the contact lens market is unique in that physicians are selling the medical devices they have prescribed to the patient. In the Supplementary Rulemaking, the Commission noted, "Several commenters said the amendment is necessary because the market for contact lenses remains unique in that—unlike most other medical doctors—eye doctors sell the items they prescribe, and thus are rewarded financially for driving patients to their own retail channels." We are concerned that this view point regarding the unique nature of the contact lens market continues to be noted in both the rule and during in-person meetings with FTC when it is both inaccurate and in direct contrast to FTC attorneys' statements regarding the contact lens market.

[7] https://www.forbes.com/sites/parmyolson/2019/03/13/meet-the-billionaire-who-defied-amazon-and-built-wish-the-worlds-most-downloaded-e-commerce-app/#376d9f470f52

In an FTC administrative complaint, which charged that 1-800-CONTACTS unlawfully created anticompetitive agreements with other online contact lens sellers, 1-800-CONTACTS asserted that eye care providers "have a unique position in the healthcare industry in that they are healthcare providers and are permitted to sell the product that they prescribe." In the FTC Complaint Counsel's Post-Trial Reply Findings of Fact, the FTC's own lawyers rejected this assertion. The July 19, 2017 document indicates

> Complaint Counsel objects to this Proposed Finding as it misstates testimony, the evidence cited is unreliable and lacks an adequate foundation, and it is factually inaccurate. CX9029 (Bethers Dep. at 111) is silent as to whether Eye Care Professionals (ECPs) have a unique position "in the healthcare industry," and Mr. Bethers has no foundation to testify regarding whether others in "the healthcare industry" are permitted to sell the product that they prescribe. CX9017 (Blackwood, Dep. at 101) simply says, "unlike other doctors, they [ECP's] sell the product they prescribe." This statement does not support an assertion that ECPs have a unique position in the healthcare industry, as "doctors" are not the only "healthcare providers" who are permitted to write prescriptions and sell products. Moreover, Ms. Blackwood has no foundation to testify about practices in "the PUBLIC 5 healthcare industry," as her only professional responsibilities relate to marketing. (CX9017 (Blackwood, Dep. at 10). Further, it is common knowledge that healthcare professionals at ambulatory surgery centers, orthopedic centers, dental service providers, and many other "healthcare providers" may sell the products that they prescribe. (emphasis added)[8]

In addition to the FTC's own assessment of the contact lens market and sales of medical devices, it is also important to recognize that many physicians (including but not limited to optometrists and ophthalmologists) provide durable medical equipment, prostheses and orthotics, and supplies (DMEPOS) to patients. Thousands of physicians are enrolled by the Centers for Medicare & Medicaid Services (CMS) to furnish DMEPOS to patients. Many physicians (including medical doctors) are reimbursed for providing drugs to patients, including drugs that are injected into the eye and help prevent blindness. Surgeons and facilities charge patients for medical devices implanted in the body during procedures. Finally, nearly all physicians who treat patients provide treatments (which can include procedures and devices) that they recommended to the patients. Helping patients obtain treatment while in their doctor's office builds strong doctor-patient relationships and promotes patient-centered care.[9] These attempts to paint the contact lens market and the role of physicians in that market as unique is inaccurate and unfair. We are also concerned that the Commission also lends additional credibility to the false allegation in citing commenters who asserted, ''Relying on existing market forces and industry professional norms to advance the intent and purposes of the FCLCA and Contact Lens Rule does not work because prescribers have both an incentive and ability to limit consumer choice." We are very concerned that the Commission seems to have used the inaccurate belief that contact lens prescribers' role in the market is entirely unique as a justification for implementing new regulations on physicians. Given that the presumption is false, we believe the entire argument for supporting prescriber rule changes must be reevaluated.

[8] https://www.ftc.gov/system/files/documents/cases/d09372ccfindingsoffact587557.pdf
[9] http://www.aoa.org/hpi

Exclusion for Doctors Without a Financial Interest in Contact Lenses

The Commission has proposed that the latest Confirmation of Prescription Release proposal would not be required of prescribers who do not have a financial interest in the sale of contact lenses. While the Commission may have viewed this exemption as a practical exclusion, it concerns the AOA that the exclusion is actually indicative of the Commission's belief that doctors of optometry put their own financial interests above the interests of their patients. This is a completely inaccurate view of the care our doctors provide in serving their communities. As such, we cannot support the exclusion as we do not condone or agree with the proposal's underlying assessment of doctors of optometry.

It is also important to consider that the Act and the Rule do not distinguish between the doctors who do and do not sell contact lenses with regard to the requirement for providing a copy of the patient's contact lens prescription. If the goal of the acknowledgement is to create a paper trail for investigators of compliance, then the FTC should ensure compliance of all elements of the Act and the Rule.

The AOA would also like FTC to confirm whether the exclusion would apply to the doctors working in concert with companies like ExpressExam and Opternative, or if these doctors would also be required to comply.

Additional Copies of Prescriptions

The Commission proposed to amend the Rule to ensure that patients' agents can obtain additional copies of prescriptions in a timely manner. We do not believe it was the intent of Congress for retailers to be given authorization to serve as a patient's agent. We assume that Congress implemented this provision to account for cases in which a family member or caregiver needed authorization to obtain a patient's prescription. However, in practice it is 1-800-CONTACTS who is most typically seeking this designation from patients. Given that this is the prevailing scenario in which patient agency is triggered, we believe that retailers that have been designated as the patient's agent should maintain records of that outreach, rather than requiring this documentation to be maintained by the physician. We also believe setting a timeframe on the patient agent requests is unnecessary.

The Commission seems to be putting forth these new proposals based on the input of 1-800-CONTACTS, which indicated that in 2016 it requested approximately 558,000 prescriptions from prescribers and received the prescription around 46% of the time. 1-800-CONTACTS indicated that 90 percent of prescribers who responded provided the copy of the prescription within two calendar days. By contrast, a panelist from Walmart indicated their company had been successful in obtaining a copy of the prescription within the same business day after calling the prescriber. Walmart representatives also noted they did not believe that any requirement to respond was necessary. The AOA believes it would be beneficial to further consider the data that 1-800-CONTACTS presented. In 2015, 1-800-CONTACTS implemented a process whereby all patients using its website had a prechecked box included on their order form that gave 1-800-CONTACTS the authority to act as the patient's agent. We believe that the statistics cited by 1-800-CONTACTS in 2016 may include patients who have not truly provided consent to the company to act as the patient's agent and that physician concern regarding this fact may have

impacted responses to the company's requests. Given 1-800-CONTACTS' manipulation of the patient agent provision in previous years, we are concerned that the Commission is moving forward with policy proposals that are being pushed by the very company that sought to take advantage of the system.

Automated Phone Calls

We understand that the Commission believes that the Act expressly permits telephone communication for verification and believes it would be contrary to Congressional intent to prohibit use of automated technology for the purpose of prescription verification. Increasingly we are seeing online contact lens sellers using verification robocalls that are difficult to understand, do not include all of the necessary information to confirm the prescription, and create barriers for doctors to communicate back the necessary prescription corrections—including that the request is being made for the wrong devices or for an individual that is not a patient of that doctor. As FTC acknowledges, some online sellers are knowingly taking advantage of the current "passive verification" system in order to sell medical devices to consumers not prescribed by an eye doctor—needlessly placing patients at risk. While in almost every other sector, robocalls are being eliminated or further regulated, in our survey of over 600 doctors of optometry we found that 85 percent reported that the use of robocalls for prescription verifications has increased in the past five years. Of even greater concern is that 88.2 percent of doctors indicated that the quality of robocalls has decreased in the past five years. Increasingly poor quality robocalls are being employed to manipulate the passive verification. Our doctors' primary concern is the health and safety of patients. It is clear that these robocalls, resulting in patients receiving contact lenses that were not prescribed, jeopardize eye health. Appendix D includes a listing of adverse events related to contact lenses. Nearly half of the adverse events reported are related to Hubble contacts which the Commission has acknowledged is relying fully on automated phone calls to sell its own brand of contact lenses.

While we support the proposals put forward to require verification calls to be delivered in a slow and deliberate manner, at a reasonably understandable volume, and with an option to give the prescriber the ability to repeat this information, we fear these new requirements are coming too late. Many patients have already received contact lenses without a prescription as a result of poor quality robocalls. Many of those patients have been harmed from use of the lenses that were inappropriately obtained. We are also concerned that the Commission has not taken seriously the adverse events our organization has previously provided for the record. The Commission noted, "Although the Commission has anecdotal reports of eye injury to patients from wearing lenses that were not prescribed for them, the Commission does not have definitive evidence of the incidence of such injury." We would like to provide the Commission with whatever additional evidence is necessary to help the Commission better understand the incidence of injury.

Clear and Prominent Method to Present a Prescription

We support the Commission's proposal to require sellers to provide a clear and prominent method for the patient to present the seller with a copy of the patient's prescription.

Seller Requirement to Verify Only the Contact Lens Brand or Manufacturer That Consumers Indicate Is on Their Prescriptions

We understand that the Commission is attempting to address issues with companies that request a patient's "prescription," but only ask for the lens power. We support the proposal to require sellers to ask their customers to provide the manufacturer or brand listed on their prescription. However, we are concerned that the way the provision has been described in the Supplementary Rulemaking is confusing. FTC noted, "If the consumer responds to the seller's inquiry by providing a manufacturer or brand other than that on his or her prescription, whether intentionally or not, the seller would not violate the Rule by indicating that manufacturer on a verification request. Thus, the passive verification framework could allow a consumer to obtain lenses other than those prescribed. Congress, however, was aware of this risk when opting for a passive verification framework for the Act." It should be made clear that if a patient requests a lens that is not on the prescription that this selection does not override the physician's prescription. In these cases, the verification process would continue, and the doctor would be able to correct the prescription to ensure the patient is being provided the lens that was evaluated on the patient's eye and was prescribed by the physician.

Questionable Need for Additional Physician Regulation

Overall, we believe that the Commission should reevaluate the evidence and data that led to the Commission's view that prescriber compliance with the Rule needs to be addressed. The Commission's proposal was based on flawed information, including the inaccurate belief that the contact lens market is somehow unique in that physicians sell what they prescribe. Additionally, the data given significant weight regarding prescriber compliance was also questionable with regard to patient's asking for prescriptions. Finally, while the Commission notes that it attempts to consider potential bias in information submitted by various stakeholders, we believe that due to the recent actions of 1-800-CONTACTS and their blatant encouragement of the public to avoid doctors of optometry, that any information provided by the company must be considered with that reality in mind.

We urge the Commission to commit to a program of basic enforcement focused on outliers shown to be violating the law. To address concerns with lack of public awareness of their rights, the Commission could partner with its sister agencies, the Centers for Disease Control and Prevention and the Food and Drug Administration to initiate a public awareness campaign regarding contact lens health and safety and the regulatory framework that provides the structure for the market. The AOA also remains supportive of the Commission implementing a requirement whereby prescribers post signs notifying patients of their right to their contact lens prescription. We believe that approach reduces physician burden and would be educational for patients.

The Evolving Contact Lens Market

The contact lens market has changed significantly since the Fairness to Contact Lens Consumers Act (FCLCA) was enacted and the Contact Lens Rule went into effect on August 2, 2004. Before any final action is taken by the Commission, we believe that there would be tremendous

benefit in more carefully considering aspects of market change. In the past several years, new technologies have entered the market as well as additional contact lens manufacturers. Despite significant and real changes in the market, there continue to be allegations made that physicians are somehow suppressing innovation and competition in the contact lens market. This assertion is patently false. We are also 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.

During the March 2018 FTC workshop, 1-800-CONTACTS CEO John Graham discussed how his company had attempted to develop their own contact lenses, stating, "Before I joined the company, we actually owned a manufacturing plant and facility and brand… But it was really hard to get that going, because we are just a pharmacy. And if you can't get someone to fit what it is you sell, you don't sell it. And so, we were in a situation where we couldn't get the lens fit, even if we could get it developed. And so we ended up selling that business for a loss." However, that very year, 1-800-CONTACTS again began selling their own brand of "Aquasoft" lenses.[10]

In addition to selling its own brand of contact lenses, in August 2016, 1-800-CONTACTS launched an online vision test.[11] In marketing 1-800-CONTACTS ExpressExam online vision test, there is a blatant effort on the part of 1-800-CONTACTS to direct patients away from comprehensive eye examinations provided by doctors of optometry. 1-800-CONTACTS ads make such statements as, "Skip the trip to the optometrist and use our ExpressExam to renew your contact lens prescription." "Save yourself an unnecessary trip to the optometrist by renewing your prescription online at home!" Advertisements also indicate "Need your #contactlens prescription renewed but don't have time to go to the optometrist? No problem! Our ExpressExam renews your prescription right from home." Other ads note, "Less time at the eye doctor's office = more time in bed." (Appendix E) Additionally, a May 31, 2017 commercial states, "Which is better one or two? One, putting that silly appointment card to use, or two enjoying your morning coffee?" These are all very clear and direct attempts to push patients away from their doctors. We believe that the motivations of this company deserve additional consideration by the Commission.

While 1-800-CONTACTS in its public comments accuses contact lens manufacturers of aligning with prescribers in ways that may not be beneficial to patients, the company is not forthright about its own contact lens manufacturing, its support of an online vision test platform, or its efforts to devalue the need for comprehensive eye care. It is clear that the company is working to create a business model based on encouraging patients to "skip the trip to the optometrist" and instead use the company's online vision exam and then to purchase the 1-800-CONTACTS brand of contact lenses.

When patients use 1-800-CONTACTS ExpressExam service, at the conclusion of the vision test, two prescriptions are provided. One is for the requested contact lens, which we would assume is the lens type that has been evaluated and fit on the patient's eye. The other is a prescription for 1-

[10] https://www.1800contacts.com/lens/aquasoft-15

[11] https://www.mobihealthnews.com/content/opternative-partners-1-800-contacts-launch-online-eye-exam

800-CONTACTS own brand of AquaSoft contact lenses. In the AOA's evaluation of the service, the power listed on each prescription was the same, but the base curve varied. (Appendix F) As the FTC has clarified,

> The Contact Lens Institute, an association of contact lens manufacturers, explained that a contact lens fitting must be the basis for the initial and ongoing prescription and wear of contact lenses and ''because a contact lens is placed directly on the eye, the physiological response [] must be monitored to ensure safe wear.'' Dr. Malvina Eydelman of the FDA explained that different brands of lenses, even those with the same technical measurements, such as base curve and diameter, do not fit the same and therefore need to be evaluated on the patient's eyes to determine whether they are appropriate for that patient. Dr. Eydelman's statement that ''the current clinical care paradigm does not support substitution of contact lens brands without a clinical evaluation'' bolsters the Commission's continued adherence to the Rule's prohibition on illegal alteration.

1-800-CONTACTS' latest business model recommends the avoidance of comprehensive care by doctors of optometry and instead directs patients to a cursory online vision test that results in a prescription that may not have even been requested for 1-800-CONTACTS' own brand of lenses, regardless of whether or not that was preferred by or appropriate for the patient. This is the type of business model with which our organization would assume that the FTC would have concerns. We urge the FTC to further investigate this issue.

We are also concerned that real data regarding pricing changes in the market have not been adequately considered. While the FTC commented in its Supplementary Rulemaking that pricing in the contact lens market is not competitive and/or should be made more competitive, the AOA is concerned that the FTC is relying on outdated data to support this claim and resultant stance. The FTC stated in the Supplementary Rulemaking that "when consumers' ability to comparison shop is diminished, the normal competitive pressures on the eye-care industry to offer competitive prices—or the combination of prices, features, and services most in demand—are themselves diminished." However, there has been no comprehensive analysis to determine the impact of the increased ability of consumers to comparison shop on the pricing of contact lenses since the FTC's 2006 study,[12] the results of which do not reflect the market's current state.

To determine the current state of the post-FCLCA contact lens market, the AOA conducted a price comparison analysis in which we compared online retailer cost vs the average in-office cost to determine the dollar price difference and percent change in price for 81 different contact lenses. Our study included lenses across brands, materials, and designs.

Of the 81 lenses studied, 28 were more expensive online, while 53 were more expensive in the doctor's office. Lenses that were more expensive online were, on average, $3.56 more expensive (or 4.42% higher) than in the office, while the lenses that were costlier in-office were just $2.37 higher (4.13%) than they are online. Across all lenses included in the AOA's price comparison analysis, there was an average price difference of just $0.32. The price differences are minimal,

[12] https://www.ftc.gov/sites/default/files/documents/reports/prices-and-price-dispersion-online-and-offline-markets-contact-lenses/wp283revised_0.pdf

even without taking into consideration the impact of various patient rebates or the reality that large online retailers are able to make purchases in higher quantities and at more reduced rates than the small business physician practices considered in these comparisons.

In the 2006 study, the FTC noted that we should expect to see online and in-office contact lens prices converge "as more consumers become informed about their marketplace options." We believe the findings from our price comparison analysis can serve as evidence that the FCLCA is working, and that the competitive pressures on the eye-care industry that the FTC anticipated were triggered.

Since the implementation of the Contact Lens Rule, patients also have increased options for purchasing their contact lenses. During the March 2018 FTC workshop, the Vision Council noted, "The fastest growing distribution channel for CL sales in the USA was the online / Internet channel. In 2017, online retailers generated $786 million in sales—growing by 4.9% during the 12 month ending period Dec'17 and growing by 11.1% over the 24 month-ending period Dec'17. Even though only one-fifth of CL lens consumers are buying their lenses online, another one-fifth of all CL buyers are using the Internet to research and conduct 'window shopping functions' before eventually making a purchase in-person at a physical brick and mortar location." This data on cost and distribution channels is incredibly important for assessing how FCLCA and the Contact Lens Rule is working, and we are concerned that these factors have not been carefully weighed in the Commission's analysis.

With the data showing how the market changed, with regard to pricing, new technologies, and new entrants to the market, we believe that the accusations that physicians are restricting competition are clearly false. This misperception cannot be used to justify additional regulatory burdens for physicians. The focus on creating a paper trail to increase investigations into health care practices is especially confusing when one considers that the Contact Lens Rule has been deemed a success. 1-800-CONTACTS itself indicated:

> The FCLCA and CLR have succeeded in encouraging greater competition and choice in the contact lens marketplace. Consumers today have more choice and more convenience. The competitive benefits have gone beyond price. According to 1-800's CEO John Graham, consumers today "can also find just better service models . . . more convenient service models." That choice has led to additional innovation and more options for consumers—"that's why you see every player of consequence at this point has a ship-to-home program, has a website . . . . [It has] spawned competition in those areas as well. . . . And I think that spreads out to other areas . . . . [M]ore people buying glasses online. . . . And this proliferation at this point of different business models and different ways to service the customer and the patient is just accelerating. So I think that the FTC can consider this a successful rule."[13]

On the 1-800-CONTACTS website, the company continues its efforts to create a divide between patients and their doctors, but also acknowledges that the Rule is working stating, "Eye care

[13] https://www.ftc.gov/system/files/documents/public_events/1285493/panel_iii_competition_in_the_contact_lens_marketplace.pdf

providers are required by law to give contact lens prescriptions to patients when the fitting process is complete. This requirement is generally understood but recognize there can be bad actors in any industry."[14] Data on consumer choice, pricing and the significant changes to the contact lens market must be more carefully considered as the Commission determines how best to move forward.

In addition, we would also like to provide feedback to the specific questions asked by the Commission.

General Questions on Proposed Amendments

What benefits would a proposed change confer and on whom? The Commission in particular seeks information on any benefits a change would confer on consumers of contact lenses.

We believe that the proposed amendments do not offer significant benefit. The FTC currently has the authority it needs to enforce the FCLCA and the Rule. We believe the evidence used to determine levels of prescriber non-compliance is unreliable to support the prescriber related proposals. With regard to the new proposals recommended for retailers, while these are a positive step we believe there would be greater impact in FTC taking immediate and direct steps to address the blatant publicly documented violations that are occurring and to further investigate the concerns that have been reported regarding retailers.

What costs or burdens would a proposed change impose and on whom? The Commission in particular seeks information on any burdens a change would impose on small businesses.

The proposed amendments for prescribers would impose additional reporting and recordkeeping requirements counter to the goals of the Paperwork Reduction Act of 1995, which aims to minimize the paperwork burden for small businesses and other persons resulting from the collection of information by or for the federal government. Considering that most doctors of optometry are small business owners and the majority are Medicare and Medicaid providers, these additional recordkeeping requirements would pose a substantial burden on their practices.[15]

As the Commission knows, a small business is defined as one with less than $7.5 million in average annual receipts.[16] According to the AOA's most recent data available, the average gross receipts collected among owner optometrists was $845,541. We are concerned that the Commission has concluded that the "Commission certifies that amending the Rule as proposed will not have a significant economic impact on a substantial number of small businesses." Given the vast majority of doctor of optometry practices would fall under the small business definition, it is clear that the proposed amendments to the Rule, if implemented, would directly and significantly impact small businesses.

[14] https://www.1800contacts.com/connect/articles/doctor/when-doc-says-no

[15] https://www.govinfo.gov/content/pkg/USCODE-2017-title44/html/USCODE-2017-title44-chap35-subchapI-sec3501.htm

[16] https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf

FTC's new burden estimate with the revised options for compliance is higher than the initial burden estimate. The 2016 burden estimate was $10,475,495,71. The 2019 burden estimate is $13,244,727. With the high number of small businesses that will be impacted, we are concerned with these latest numbers. Additionally, we believe the Commission has not fully considered the regulatory burden under which physicians are already operating. The Office of Advocacy of the U.S. Small Business Administration in their FY 2018 Report on the Regulatory Flexibility Act indicated, "Small businesses have told Advocacy stories that exemplify how federal regulations drain small businesses' resources, energy, and in some cases even their desire to stay in business." Sadly, the AOA has heard the same concerns voiced by doctors of optometry who after years of service in patient care find that the regulatory framework is so intrusive to the doctor patient relationship, that some consider leaving the profession.

What regulatory alternatives to the proposed changes are available that would reduce the burdens of the proposed changes while providing the same benefits?

There are many alternatives to the proposed changes. Given how much the contact lens market has changed since the passage of the FCLCA, the Commission could determine that the current law should be revisited to better account for changes in the market. The Commission could also consider implementing the proposed additional prescribers' requirements subsequent to FTC's receipt of a patient complaint about a specific provider, rather than imposing regulatory changes across the profession. The Commission could more fully consider the AOA's recommendation to require physicians to post signs in their practices notifying patients of their rights. The Commission could implement this requirement while also streamlining the online contact lens related patient complaint system so that the Commission best assess problems in the marketplace.

The Commission could partner with interested stakeholders to engage in a public awareness campaign regarding contact lens safety and the legal and regulatory requirements that are a key component of the market. The Commission could consider a patient bill of rights for contact lens wearers be provided to patients that includes the FDA information on considerations for buying contact lenses.[17]

What additional information, tools, or guidance might the Commission provide to assist industry in meeting extant or proposed requirements efficiently?

Joint messaging from the Centers for Disease Control and Prevention, Food and Drug Administration, and Federal Trade Commission regarding contact lens health and safety and the regulatory framework that provides the structure for the market could be useful.

[17] https://www.fda.gov/medical-devices/contact-lenses/buying-contact-lenses

Electronic Delivery of Prescriptions

Would prescribers choose to satisfy the automatic prescription-release requirement through electronic delivery if permitted by the Rule?

Our survey of over 600 practicing doctors of optometry shows that 50.6 percent of doctors email patient contact lens prescriptions and 47.5 percent have an electronic health record with a patient portal, though few doctors supply contact lens prescriptions through the portal. Doctors noted the limitations of patient portals including the inability to indicate that the prescription is expired or that the appropriate supply of lenses has been sold. Respondents noted that in some states, supplying a contact lens prescription through the online portal would not be compliant with state regulations. In New Jersey, for example, contact lens prescriptions must be written on state-approved paper forms, leaving the portal copy invalid. Many doctors stated that their current electronic health records systems do not have the option to allow doctors to upload prescriptions. Others stated that their patient portals are "cumbersome" or "not user friendly" and many respondents noted the limited patient use of the portal. Regarding the emailing of prescriptions, doctors also noted potential HIPAA violation and security concerns due to the lack of encryption abilities and potential for data insecurity. Given these concerns, we are concerned that the least burdensome proposal outlined by the Commission would not be accessible for the majority of contact lens prescribers.

Would a patient portal, email, or text message be feasible methods for prescribers to provide digital copies of prescriptions to patients? Are prescribers using any other electronic methods to provide patients with prescriptions?

According to the AOA survey of over 600 practicing doctors of optometry, 50.6 percent respondents email copies of patient contact lens prescriptions to patients, while 46.6 percent stated that they do not email prescriptions, primarily citing concerns over data security. Less than half (47.5%) of surveyed doctors report using a patient portal, and even fewer provide contact lens prescriptions via the portal due to state regulations, concerns over prescription expiration, and cumbersome electronic health record software, among other reasons.

Should prescribers be required to keep any records documenting a patient's verifiable affirmative consent to receive the prescription electronically? If yes, what records should be kept and for how long? Should the documentation specify the electronic method(s) by which the patient has agreed to receive the prescription?

The AOA would not be supportive of a requirement for prescribers to keep records to document patients' consent to receive contact lens prescriptions electronically. This practice is burdensome on the patient and on the doctor and, even more importantly, provides no obvious benefit to the patient. Patients do not have to consent to the electronic delivery of other prescriptions, and a prescription for contact lenses should not be an exception. Furthermore, the likelihood of harm from a patient receiving a contact lens prescription electronically is low to nonexistent. Our doctors work to serve their patients' best interests, and the documentation of consent to receive an electronic contact lens prescription is unnecessary in serving that goal.

In practice, the AOA can envision many scenarios in which the requirement to document a patient's consent to receive a contact lens prescription electronically would be burdensome to patients. Many patients elect to receive electronic prescriptions due to concerns over wasteful printing practices; requiring a patient to sign a form consenting to receive an electronic prescription would thus be counterintuitive. Some patients opt to receive an email with their prescription to improve the efficiency of the prescribing process if they are in a hurry to leave the doctor's office; having to read and sign additional paperwork consenting to receive an e-prescription would thus decrease patient satisfaction.

What evidence supports your responses?

The AOA conducted a survey of practicing doctors of optometry in May 2019. The 629 responses from this survey serve as the basis for this feedback.

Confirmation of Prescription Release

Would the proposed Confirmation of Prescription Release provision increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

We believe there are better options available. Primarily, the Commission could commit to a program of basic enforcement focused on outliers shown to be violating the law. Enforcing the current Rule would likely be most effective at increasing compliance.

Compared to the Commission's prior proposal for a signed acknowledgment, would the proposed Confirmation of Prescription Release provision have more, less, or about the same effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

We don't agree with the premise that the signed acknowledgement or confirmation of prescription release would actually increase compliance. There may be instances in which a patient receives their prescription, but did not have the signed acknowledgment form executed due to extenuating circumstance.

Would the proposed requirement that prescribers would have to maintain evidence of the Confirmation of Prescription Release for at least three years increase, decrease, or have no effect on the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? Why?

Under the current Rule, we believe the Commission has the tools necessary to enforce the law. We do not believe that additional documentation requirements are necessary to ensure that the Commission can enforce the Rule.

Compared to the Commission's prior proposal for a signed acknowledgment, would the proposed Confirmation of Prescription Release provision have more, less, or about the

same effect on the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? Why?

Again, under the current Rule, we believe the Commission has the tools necessary to enforce the law. We do not believe that additional documentation requirements are necessary to ensure that the Commission can enforce the Rule.

Would the proposed Confirmation of Prescription Release requirement increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

In addition to being burdensome to physicians, we believe the proposal would not impact patient understanding of their rights. Posted signage would be a better mode through which to educate patients.

Does the new proposal to allow prescribers to choose from different delivery methods for the Confirmation of Prescription Release increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

We are concerned that the less burdensome tracking options will not be able to be used by the majority of doctors given patient portal limitations. As such, many doctors will be forced to maintain paper records of prescription acknowledgement.

Does the new proposal to allow prescribers to devise their own language for the Confirmation of Prescription Release increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

While language flexibility is an improvement over the initial proposal, we don't believe this feature specifically impacts compliance or that it would reduce the overall burden, administratively or financially.

Are there alternate ways that the Commission has not yet considered in this Rule review to increase compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? What are they and how do they compare to the current proposal?

The Commission could commit to a program of basic enforcement focused on outliers shown to be violating the law.

Are there alternate ways that the Commission has not yet considered in its Rule review to increase the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? What are they and how do they compare to the current proposal?

The Commission could monitor and enforce the law in many ways. If a question is raised regarding prescriber non-compliance, the Commission could ask the prescriber what their process is for providing prescriptions. The Commission could also investigate complaints received regarding compliance. We believe starting with that simple process is preferable to instituting wide-reaching new regulations.

Are there alternate ways that the Commission has not yet considered in its Rule review to increase the extent to which patients understand their rights under the Rule? What are they and how do they compare to the current proposal?

Joint messaging from the Centers for Disease Control and Prevention, Food and Drug Administration, and Federal Trade Commission regarding contact lens health and safety and the regulatory framework that provides the structure for the market could be useful.

Under the Commission's proposal, the confirmation of prescription release and the accompanying recordkeeping provision shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of contact lenses, including, but not limited to, through an association, affiliation, or co- location with a contact lens seller. Aside from associations, affiliations, and co- locations with contact lens sellers, what other indirect financial interests exist in the sale of contact lenses that should disqualify a prescriber from the proposed exemption?

It concerns the AOA that the exclusion for prescribers who don't sell lenses is indicative of the Commission's belief that doctors of optometry put their own financial interests above the interests of their patients. This is a completely inaccurate view of the care our doctors provide in serving their communities. As such, we cannot support the exclusion as we do not condone or agree with the proposal's underlying assessment of doctors of optometry.

Prescriber Responses to Requests for an Additional Copy of a Prescription

The Commission believes that the Act requires that prescribers provide additional copies of contact lens prescriptions to authorized agents of patients. Should the Commission require that prescribers respond to such requests within a certain period of time?

We believe it is unnecessary to set such a timeframe. Doctors have a responsibility to their patients and take that responsibility seriously.

Would forty business hours, which the Commission proposes, be an appropriate amount of time to respond to a request for an additional copy of a prescription?

If the Commission must set a timeframe, 40 business hours is reasonable.

Should a prescriber be required to keep any records to document the request and response? If yes, what records should be kept and for how long?

As noted above, we believe that retailers should be required to retain documentation of the request and response, given that it is retailers who are leveraging the patient agent provision to obtain patient prescriptions.

What evidence supports your responses?

Our understanding of who is utilizing the patient agent provision is based on physician reports to AOA and the data provided by 1-800-CONTACTS to the FTC.

Automated Telephone Verification Messages

The Commission believes that allowing calls that use automated messages for verification requests is consistent with the Act. To address concerns with incomplete and incomprehensible automated messages, the Commission proposes additional requirements for sellers. What benefits or burdens would each proposal involving automated telephone verification messages confer?

We believe that requiring robocalls to be comprehensible is completely reasonable given the risk to patient eye health when contact lenses that were not prescribed are utilized.

Would each of the proposed modifications address the concerns raised by prescribers about incomprehensible or incomplete automated messages? If so, how?

While the proposed modifications may be useful, we strongly believe that action needs to be taken now to address Hubble contacts use of robocalls.

When using an automated message for a verification request, what are the costs and burdens to sellers of meeting each of the proposed requirements, especially recording the entire call and making the message repeatable at the prescriber's option?

The AOA believes any costs of making these adjustments would be justified given the widespread issues with robocalls that currently exist.

Illegal Prescription Alteration

What percent of contact lens sales consist of illegal alterations?

The AOA conducted an extensive survey and created an email account where doctors of optometry, patients, and paraoptometric staff could voluntarily submit information on their instances of illegal contact lens sales. While we do not have an exact percentage to represent the entire market of illegal contact lens sales, we did collect 1,028 complaints of contact lens sale violations. The four most common complaints related to:

1.) The sale of contact lenses without a prescription (35%)
2.) The sale of contact lenses that were not prescribed to the patient/wrong prescription (29%)

3.) Incomplete verification requests, such as a robocall that was incomprehensible (21%)
4.) The sale of contact lenses with an expired prescription (15%)

Of the 1,028 complaints, 421 (41 percent) were related to Hubble Contacts (aka Vision Path Inc.). There were 177 complaints of violations (17 percent) by 1-800-CONTACTS, and 79 violations (8 percent) by various individuals and groups on Facebook. Another 30 complaints (3 percent) were related to an unknown seller, primarily because the sellers did not identify themselves or were incomprehensible when conducting prescription verification requests. There were 321 complaints (31 percent) related to 132 various other sellers, with the two most-reported being Lens.com (2.14 percent) and Waldo Daily Contact Lenses (1.26 percent)

Has the introduction of sellers who sell their own brand of contact lenses directly to consumers affected the incidence of illegal alteration? If so, how?

As previously mentioned, the highest volume of complaints reported to the AOA were related to Hubble contacts, which sells its own brand of contact lenses. Of the 421 complaints related to Hubble, the most common violation, with 139 incidences, was the sale of contact lenses that were not prescribed to the patient. This commonly came in the form of Hubble selling the wrong brand, fit, or material of lenses to a patient, e.g., selling spherical lenses to a patient who was prescribed toric lenses; selling lenses without the prescribed oxygen transmissibility. One doctor in California reported in 2018:

> *My patient seen in 2016 informed me that she used hubblecontacts.com last year to buy new lenses. I prescribed Alcon Total1 dailies and [Hubble] sent her lenses not based on my prescription. Their lenses are the wrong [material]. She had a prior history of a corneal ulcer and I switched her to dailies with high oxygen transmissibility.*

The FTC has previously stated that "any attempt to substitute another lens, including a seller's own brand, for the prescribed lens thwarts the purpose of the Act, which is to allow sellers to sell contact lenses as prescribed by the consumer's eye-care provider." Hubble's sale of its own lens in place of the prescribed brand is a clear violation of the Act.

The sale of contact lenses without a prescription was the second most common complaint regarding Hubble, with 116 incidences. This violation is extremely dangerous and has the potential to cause permanent vision impairment, since individuals have reportedly been able to enter false prescription information online and receive contact lenses with no medical supervision, fitting, or instruction on proper eye health safety or care. Most reports related to Hubble concerning this violation were of particular concern to our doctors, primarily because it most frequently resulted in patient harm. A doctor from California reported in 2019:

> *A patient received contact lenses from Hubble that I did not prescribe for him. He wore those Hubble contacts and developed an infiltrative keratitis as a result of wearing those contacts.*

A doctor from Virginia reported in 2019:

Patient ordered contact lenses without a prescription from Hubble. There was no verification sent to our office. Upon examination, she had diffuse superficial punctate keratitis with injection from wearing her Hubble contact lenses.

There were also 102 incidences of incomplete verification requests from Hubble. Doctors and their staff have reported that Hubble's methods for verifying prescriptions are unscrupulous, including using robocalls that are incomprehensible, failing to state the patient's name or other identifying information in the call, and having no viable contact number or email address to deny the verification request when it is inaccurate. One doctor in Colorado reported in 2019:

Received an incomprehensible message from Vision Path with a request for verification on a contact lens prescription that I attempted to deny but the line was disconnected. I tried faxing and calling back to retrieve more information to no avail. The line is connected through Google Voice, if and when the line does connect to a person, but those people have not been able to help in finding that particular patient, even with the address.

Another 32 instances were reported wherein Hubble sold contact lenses to patients based on expired prescription.

Hubble's sale of its own brand of contact lenses has resulted in patient harm and has placed an unjustifiable burden on doctors of optometry to act as watchdogs over this company's violations.

As noted previously, we believe that FTC should investigate the use of ExpressExam by 1-800-CONTACTS and how that platform is being use to direct patients to the company's own brand of lenses. When patients use 1-800-CONTACTS ExpressExam service, at the conclusion of the vision test when the patient prescription is provided to them, two prescriptions are provided. One is for the requested contact lens that the patient requested, which we would assume is the lens type that has been evaluated and fit on the patient's eye and a prescription for 1-800-CONTACTS own brand of AquaSoft contact lenses. In the AOA's evaluation of the service, the power for each lens was the same, but the base curve varied. We believe this attempt to substitute the company's own brand of lenses would be considered an alteration of the prescription. The FTC should further investigate this issue.

What percent of the overall contact lens market consists of sellers who sell their own brand of contact lenses directly to consumers and is that percentage increasing, decreasing, or staying the same? What percentage of eye-care prescribers prescribe these lenses, and what portion of the prescriptions written are for these lenses?

The number of direct-to-consumer brands is increasing. Based on the data we have collected, Hubble, Waldo Daily Contact Lenses, and Aveo are all new entrants to the market that sell their own brand of lenses and have been reported for replacing a prescribed brand with their own brand. The following are just a few examples of the many that AOA has received of Hubble replacing a patient's prescription with their own brand:

In 2018, a doctor from Iowa reported:

> *This past couple of weeks we have gotten multiple calls for contact lens verification for patients from Hubble. Many of these patients have never worn contact lenses, have an active prescription for a different brand or are not even patients at our office. We have tried to call the company back multiple times, but we cannot get in contact with them other than an answering machine.*

A doctor from California reported in 2018:

> *I don't prescribe Hubble contact lenses, but I keep getting calls, either after hours or on the weekends from Hubble. It is so hard to understand the patient's information. I tried calling the person [whose name is on the voicemail], but that person never answers. I left a voicemail, but he never returned my call.*

A doctor from Virginia reported in 2018:

> *Received robocall from Paul Rogers […] about a patient ordering 375 lenses per eye. The patient information was not included on the call. I do not prescribe Hubble lenses in my practice, so I left a message stating that any prescriptions for Hubble contact lenses are not valid. Have not received a return call to date.*

Would the proposed amendment requiring sellers to accept prescription presentation increase, decrease, or have no effect on the incidence of illegal alterations? Why?

This may assist in compliance, but it is long overdue.

Would the proposed amendment requiring sellers to accept prescription presentation increase, decrease, or have no effect on the number of verification requests that prescribers must respond to?

We do not view the number of prescription verification calls as pertinent to this discussion. The real issue is that thousands of individuals are able to purchase lenses that have not been fitted on their eye, which they have not been prescribed at all, or that are based on prescriptions that have been expired for years. This has caused widespread harm to the vision and ocular health of countless people.

Under the proposed amendment, a verification request that includes a manufacturer or brand provided by, or identical to that provided by, the consumer would not be deemed an alteration of a prescription. Would this provision increase, decrease, or have no effect on the incidence of alterations of prescriptions? Why? What risks to patients, if any, would result?

We are concerned that this provision could cause confusion and gives the impression that a patient could request to have a lens that is different from the prescription, and that this request would supersede what is on the prescription. Risks to the patient primarily stem from a

misinterpretation of or disregard for the rationale for the prescribed lens brand/manufacturer (e.g., a need for a material with increased oxygen transmissibility, need for daily contacts rather than monthly contacts, need for toric lens rather than spherical lens). Wearing contact lenses that do not fit properly can result in a wide range of visual or ocular harm, including eye pain, blurred vision, corneal neovascularization, keratitis, and corneal ulcers. If a doctor prescribes a particular contact lens manufacturer or brand, it is because the doctor has determined that the particular lens is the safest medical device to correct the patient's vision.

What risks, if any, are associated with the substitution of contact lenses different and not identical to the manufacturer or brand of lenses fitted and prescribed by the prescriber? Would the proposed amendment increase, decrease, or have no effect on these risks?

As noted in the FTC's Supplementary Rulemaking in May 2019, Dr. Malvina Eydelman of the Food and Drug Administration has explained that different brands of lenses do not fit the same and, therefore, need to be evaluated on the patient's eyes to determine whether they are appropriate for that patient.[18] Dr. Eydelman has stated that even those with the same technical measurements, such as base curve and diameter, can fit differently based on the brand of the lens. Dr. Eydelman stated that "the current clinical care paradigm does not support substitution of contact lens brands without a clinical evaluation." As previously noted, wearing lenses that are not prescribed can result in a wide range of visual or ocular harm, including eye pain, blurred vision, corneal neovascularization, keratitis, and corneal ulcers. The AOA received reports from dozens of doctors whose patients were harmed as a result of brand substitution by Hubble:

- In 2018, a doctor in Texas reported that he saw a patient who was given two months of Hubble contact lenses even though he had faxed her correct contact lens prescription, which was written for 1 Day Acuvue Oasys for Astigmatism. He diagnosed her with moderate infiltrative keratitis and attributed it to the incorrect contact lenses being distributed to her.

- In 2019, a patient was prescribed Biofinity monthly contact lenses and presented to her optometrist wearing Hubble daily disposable contacts with an inaccurate prescription. On exam, she had mild superficial punctate staining on both corneas.

- A doctor in Utah in 2017 reported that a patient was able to order Hubble contact lenses, even though the doctor's office never received any prescription verification. The patient wears toric lenses and returned to the doctor's office complaining that she could not see with her Hubble lenses. The patient was not aware that Hubble does not make toric lenses and reportedly was very upset that Hubble would send her lenses that were not her full contact lens prescription.

- A doctor in Florida in 2018 reported that she prescribed Clariti and Clariti Toric, yet his patient received Hubble spherical lenses for both eyes. In addition, the prescribing doctor received a verification fax which she promptly responded to stating the prescription was expired and it was for a different material. She additionally called the line for customer service and verbally stated the prescription was incorrect and asked for a call back.

[18] https://www.federalregister.gov/documents/2019/05/28/2019-09627/contact-lens-rule

Although the voicemail machine said they would get back to her within 48 hours, they never did. Despite all that effort, the patient received the Hubble contacts and later presented with corneal neovascularization, which was never previously documented.

- In 2017, a doctor from Wisconsin reported that a myopic patient with significant astigmatism was fit in her office with contact lenses for astigmatism and myopia. The patient ordered contact lenses from Hubble. The patient later presented to the doctor's office after wearing the contact lenses with significant blurred vision (20/40 in each eye), due to Hubble sending her the wrong contact lenses by altering her prescription.

In addition to these incidents reported above, the FDA has received dozens of adverse events related to Hubble contacts (Appendix G). We believe these adverse events are extremely concerning and are indicative of a serious problem that warrants FTC attention.

In what circumstances does a contact lens prescription indicate a particular material, brand, or manufacturer because of the prescriber's medical judgment about the ocular health of the patient (for example, because the patient's astigmatism requires toric lenses)? Are these circumstances common?

All lens fittings consider ocular health to determine the best material, brand, manufacturer, and fit.

When a prescription indicates a material, brand, or manufacturer for reasons other than medical judgment about ocular health, what reasons inform the selection? Is it common for a patient to test the fit of more than one material, brand, or manufacturer before receiving a prescription? When more than one material, brand, or manufacturer can achieve a successful fit, is the consumer able to make an informed choice among competing products?

Outside of ocular health, doctors consider the patient's needs; the ability of the patient to be compliant with care of the lenses; the environment in which the lenses will be worn – dusty work environment, dry office spaces, near vision work (at a desk), far vision work (a driver); whether they will be worn with or without spectacle lenses over the contact lenses.[19] A determination is made regarding the most compatible lenses and lens types for the patient with the following considerations:

1. Oxygen transmission
2. Water content
3. Lens thickness
4. Corneal curvature
5. Corneal diameter
6. Prescription needs available (Myopia, Hyperopia)
7. Toric fitting needs (astigmatic/astigmatism parameters of the lens to meet visual specific prescription needs)

[19] https://www.judiciary.senate.gov/imo/media/doc/07-30-14CockrellTestimony.pdf

8. Specialty fit lens needs – might include but are not limited to, specialty gas permeable lenses for the treatment of corneal thinning problems (Keratoconus) and temporary post-surgical or pharmaceutical delivery lenses and amblyopic needs.
9. Extended wear versus daily wear is determined based on the patient's needs and ability of the patient to be compliant with care of the lenses.
10. Determination of the lens use and environment in which the lenses will be worn – dusty work environment, dry office spaces, near vision work (at a desk), far vision work (a driver), and whether they will be worn with or without spectacle lenses over the contact lenses.

As Dr. David A. Cockrell, Past President of the AOA, stated in 2014 to the Senate Subcommittee on Antitrust, Competition Policy and Antitrust, "lens choice is based on the parameters that best meet the individual patient's needs, including heath and eye safety, visual acuity with the lens, and compliance capabilities."[20] Doctors evaluate patients across several criteria to be sure they are safe and effective for long term vision and health. They first complete a comprehensive eye exam, and then complete a contact lens fitting wherein a full evaluation of the tear film and corneal surface are completed to determine dry eye, tear osmolarity and tear evaporation rates as a first indication of the lens material that may be most suitable for the patient. They also measure the corneal surface to determine curvature and minimum patient diameter requirement for the lens.

A trial fit is then performed. Doctors may choose several lens types by various lens manufacturers to try on the patient's cornea for best fit and comfort. Once the lens is on the cornea, doctors examine the fit using a biomicroscope and look for the following:[21]

1. Lens movement on the eye (not too tight on the cornea, as lens movement is needed to pump an adequate amount of tear liquid under the lens with each blink. The lens can't be too loose, or too flat on the eye, or the lens will move too far out of place with each blink, causing poor vision and discomfort)
2. Astigmatic power (if the patient has astigmatism) must be located in the proper axis and return to that location after each blink
3. Tear absorption (the lens must not absorb all the tears to remain comfortable for longer wear)
4. Protein deposits (the lens surface is examined to determine whether there are excess protein deposits on the lens from the tears, which can eventually cause problems to the inside lids. If deposits are seen early, then a lens with a different coating may be considered)
5. Visual acuity (to determine if slightly more or less power is needed for the "best controlled visual acuity")

At this point, the best "first" lens for the patient is determined and doctors are ready to dispense the lenses. Dr. Cockrell also outlined the steps that follow: doctors then review several related, supplementary topics such as tear types and use (when to use, how to use, what types are

[20] https://www.judiciary.senate.gov/imo/media/doc/Cockrell%20QFRs%207-30-14.pdf
[21] https://www.judiciary.senate.gov/imo/media/doc/07-30-14CockrellTestimony.pdf

compatible with the lens, i.e., preserved, non-preserved tears); smoking status of the patient, including exposure to second-hand smoke, to provide information on the correlation between smoke exposure and increased prevalence of adverse contact lens events to the patient. A follow up visit with the patient is scheduled to check for longer wear fit and eye health. This is a fast but very important doctor visit to determine whether the lenses are compatible with the patient's cornea, again utilizing the 15 considerations listed above and to ensure that the patient is not showing any signs of inflammation or infection. Doctors then determine the final lens prescription, which is sometimes the first lens they have fit onto the patient, and other times will be another lens type or lens size/material. Doctors write the final lens prescription and present it to the patient, which includes the manufacturer's name, the base curvature numbers, the diameter and the prescription/power of the lenses and an expiration date of the prescription.

For an initial or subsequent contact lens fitting to be "complete," the doctor must determine that a chosen lens and its complete parameters is compatible with the patient's general health, eye health, physical and environmental conditions in which the patient has been or will be wearing the lens, to produce no substantial compromise to the general or ocular health of the individual.

What are the drawbacks, if any, of each proposal regarding illegal alteration of contact lenses?

One drawback is that the FTC has not taken action against retailers in blatant violation of the law and we are concerned that retailers will be able to continue to operate with impunity. We are also concerned that some of these companies who are manipulating the passive verification system and selling their own brand of lenses are misleading the public and using deceptive and unfair business tactics. When companies dispense lenses that are not prescribed by the physician for which the patient has paid money and which the seller warrants are as good or a better lens (irrespective of being in violation of the Act and the Law), that perform poorly in comfort and acuity and harm a patient, it is a deceptive and unfair trade practice to which FTC should be more vigilant.

What are the benefits, if any, of each proposal regarding illegal alteration of contact lenses?

If enforced, these proposals could help improve the safety of the contact lens market, but we believe if the FTC acted on existing authority the same goal could be achieved.

What is the administrative burden, if any, to sellers, including small sellers, from each of the proposals?

Retailers can address this more directly.

Are these proposals necessary to address illegal alteration of contact lenses?

The AOA believes something must be done to stop the illegal sale of contact lenses, which are medical devices, and should be treated as such. We believe acting on existing authority could suffice.

Are there alternative proposals that the Commission should consider?

The Commission could use its existing authority to take action against retailers who are leveraging loopholes in the verification process and launch an investigation into Hubble contacts. As mentioned previously, between 2017-19 the AOA received over 1,000 individual complaints of illegal contact lens sale practices by a number of retailers which are selling contact lenses without a prescription, based on an expired prescription, with incomplete verification, and/or that were not prescribed to the patient. This has resulted in harm to patient's eye health and wellbeing.

What evidence supports your answers?

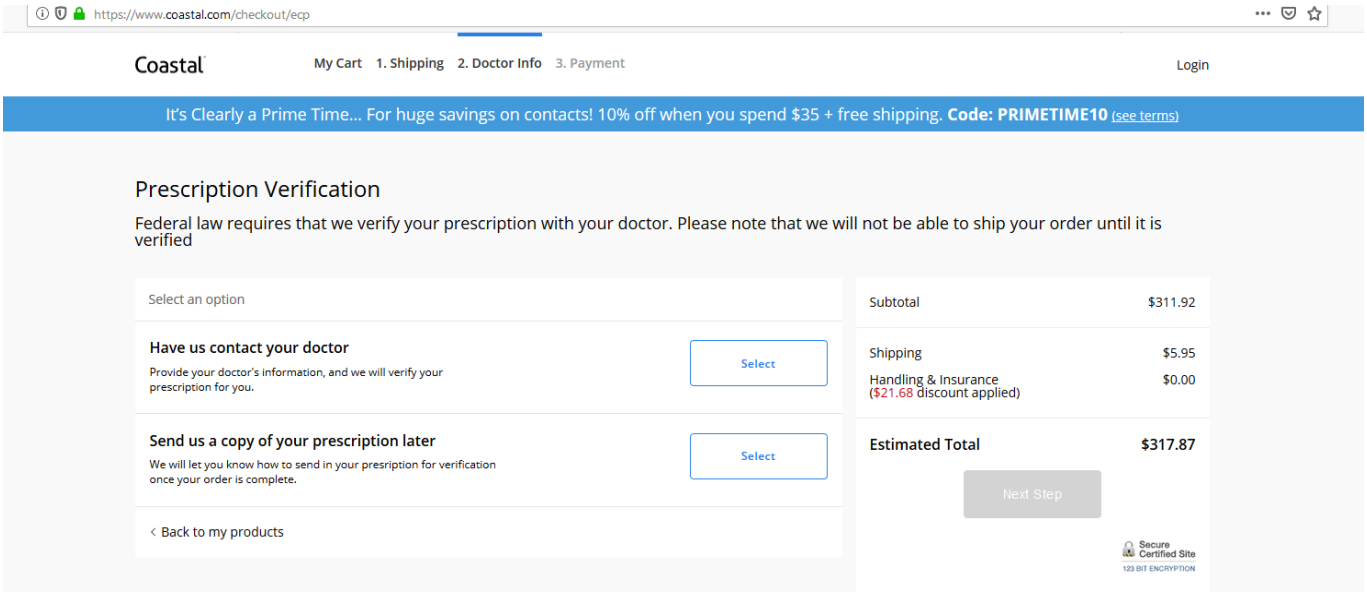
The AOA conducted surveys of practicing doctors of optometry and frequently receives information from our member doctors regarding issues occurring in the field. We received 1,028 unique complaints from 2017-2019.

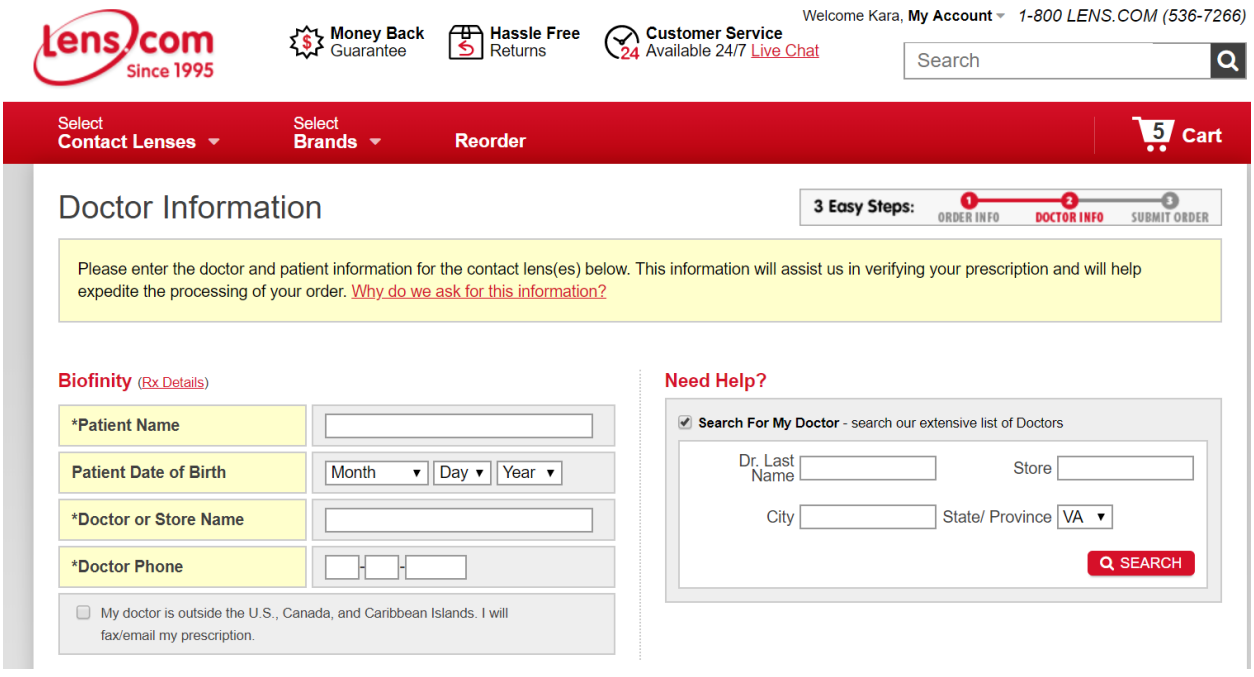
Thank you for the opportunity to provide this feedback. Please contact Kara Webb, Director of Coding and Regulatory Policy, at 703.837.1018 or kcwebb@aoa.org if you need additional information.

Sincerely,

Barbara L. Horn, O.D.
President, American Optometric Association

Appendix A
Documentation of Coastal Contacts and Lens.com Process for Obtaining Contact Lens Prescriptions

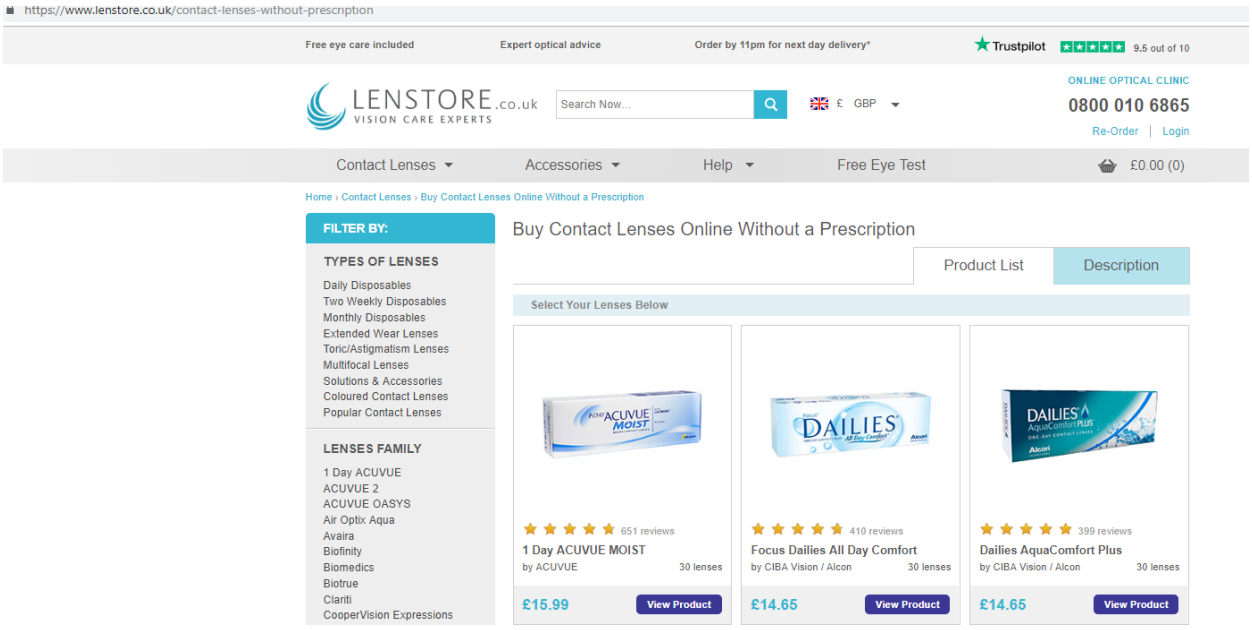




Appendix B
Documentation of Save on Lens Non Compliance

www.saveonlens.com/contact_lenses_no_prescription.html

Appendix C
Additional Retailer Non-Compliance



Appendix D
Contact Lens Adverse Events

6/7/2019
A doctor reported that a 35-year-old patient received Hubble contacts with an outdated prescription for a daily toric contact lens. Using the outdated toric prescription, Hubble sent the patient spherical lenses instead. The patient was reportedly unmonitored before she presented with keratitis and scarring, and a mild decrease in the best corrected vision.

5/9/2019
A doctor in Oklahoma reported that a 25-year-old patient has been getting colored contact lenses without a prescription for 5-7 years from Discount Beauty Supply. The patient presented with a central corneal ulcer that the doctor believes will cause permanent damage from poorly fitting contact lenses and failure to appropriately wear them.

5/8/2019
A patient presented to a doctor for an eye infection. He reported that he has been purchasing contacts from 1-800 CONTACTS since 2013, yet he has not had an eye exam since 2013.

4/19/2019
A doctor reported that he saw a patient who had not had an eye exam in 7 years. The patient has been ordering contact lenses from 1-800 CONTACTS and presented to the doctor with corneal neovascularization, cataracts, and a significantly inaccurate prescription.

4/17/2019
A patient who received contacts from Hubble without a prescription presented to a doctor for red, irritated eyes after wearing Hubble dailies for the past 2-3 weeks.

4/13/2019
A doctor reported treating a patient with an infectious bacterial ulcer and severe corneal neovascularization from wearing non-prescribed colored contact lenses bought at the Citadel Mall in Colorado Springs, CO.

3/12/2019
A patient bought contact lenses from 1-800 CONTACTS without a prescription and presented with a corneal ulcer.

2/20/2019
A doctor reported seeing a patient who was able to order a full year supply of contact lenses multiple times in the course of one year. He was last examined in 2016. He presented with corneal neovascularization and stated that he did not return for his annual eye exam on time because he “had plenty of contacts.”

1/14/2019
A doctor reported receiving a call from Hubble on a Sunday to confirm a patient’s contact lens prescription. The doctor immediately replied once in the office on Monday morning via fax

stating that the contact lens had not been prescribed and to decline to fill the prescription. Hubble filled the prescription anyway, and the patient later presented with eye fatigue and blurred vision.

1/10/2019
A patient was prescribed monthly contact lenses and presented wearing Hubble daily disposable contacts with an inaccurate prescription. On exam, she had mild superficial punctate staining on both corneas.

12/17/2018
A patient ordered contacts from Hubble, which sent her daily disposable contact lenses. The doctor said there is no record of Hubble reaching out to his clinic to approve the Hubble lens prescription. The patient reported that she did not realize she had improperly been sent daily wear lenses and had been wearing them like a full time reusable lens. She was treated at the hospital for a corneal abrasion and continues to show signs of inflammation and neovascularization from the use of the Hubble lenses.

12/12/2018
A doctor reported that a patient has suffered permanent corneal scarring, moderate to severe corneal neovascularization, and pannus after repeatedly ordering lenses without prescription or without being fit properly from daysoft.com.

9/20/2018
A doctor reported seeing a patient who presented with a contact lens related keratitis as a result of wearing a pair of contact lenses purchased without a prescription through Amazon.

9/13/2018
A doctor reported having a patient who may lose vision due to wearing a contact lens that he was not prescribed, which he received from an unnamed contact lens distributor.

9/12/2018
A doctor saw a patient who last had her contact lens prescription updated with an online vision test by 1-800 CONTACTS. He reported that her right eye was overminused by a diopter, and her left eye was underminused by a quarter of a diopter. She reported having vision problems with her contacts from 1-800 CONTACTS.

9/1/2018
A patient reported using Hubble contact lenses without providing a prescription. He reported having foggy vision and concern over the material used in Hubble lenses, which he called “dated technology.”

8/30/2019
A patient presented to a doctor with red eyes. The patient had not had an eye exam for over a year, but had been ordering contacts from Contacts Direct. The doctor was never sent any sort of validation request from the company. Sever months later, the same patient presented with contact lens related keratitis after continuing to use the contact lenses from Contacts Direct without the correct prescription.

8/21/2018
A doctor reported seeing a patient that was given two months of Hubble contact lenses with an inaccurate prescription. She was diagnosed with moderate infiltrative keratitis due to the incorrect fitting of the lenses distributed to her.

8/21/2018
A doctor reported seeing a patient who had been wearing Hubble daily contact lenses, despite being prescribed Acuvue Oasys at her last exam. She presented with corneal complications due to the inaccurate fit of the lenses. The doctor reported that no phone call or inquiry was sent to the doctor's office to verify the prescription.

8/8/2019
A patient who had been ordering contact lenses from 1-800 CONTACTS for 6 years without a valid prescription presented to his doctor with papillary conjunctivitis due to the contact lenses.

7/12/2019
A doctor reported the following to the AOA and FTC:

Below are 6 names of people that Hubble called me at my prior place of employment to "verify" their contact lens prescription for Hubble contacts. Notice all of the dates and times are close to the end of the day or on a Saturday or Sunday. Notice the addresses are from all over the State of Georgia. 1. I have never met any of these people. There can not be a valid prescription without a Dr-pt relationship. 2. I have never fit nor prescribed a Hubble contact lens. There can not be a valid prescription without my having evaluated the exact lens on the exact patient's eyes 3. There was no direct communication to me, because they sent the requests to a phone number that I have not been at for over 18 months. According to the FCLCA, they are responsible for verifying a practice's business hours and keeping records of those including Saturday hours. Had they actually done this, they would have found out that I was not at that place of employment for over 18 months, and that the location was a research location and did not write prescriptions nor sell contact lenses to patients. 3. The law does not permit them to create prescriptions, only to verify valid existing prescriptions. There is no valid prescription for their product for these people written by me, therefore, there can not be passive verification, because there is no valid prescription. 4. The FCLCA imposes penalties of up to $11k for each occurrence of a violation of the law. This text is from a guide that the American Optometric Association put out: Can a contact lens seller sell a contact lens without having any prescription? NO! There are serious penalties of up to $11,000 per violation for a contact lens seller violating any provisions of the FCLCA. The contact lens seller must either have the contact lens prescription delivered to them directly by the patient or prescriber, transmitted to them by facsimile transmission by the patient or prescriber, or transmitted to them by a digitally imaged e-mail from the patient or prescriber - or the contact lens seller must verify the prescription by direct communication to the prescriber. The question is, did they ship the lenses to these people? You should also ask to see when these orders were shipped out. You should ask to see how they attached my name to these requests. Did the people choose my name randomly off of some list or did Hubble decide to just attach my name to the order? Where is the required verification log of "my" business hours at the location that they sent these requests to? I have called and emailed Hubble demanding that they remove

my name from whatever lists that they maintain as I do not and will not prescribe their product.

7/24/2018
A doctor reported seeing a patient who suffered a potentially vision threatening corneal ulcer due to 1-800 CONTACTS selling him over three years' worth of contact lens supply without a valid prescription.

Appendix E
Advertisements from 1-800-CONTACTS

https://www.facebook.com/1800Contacts/?hc_ref=ARRHSX9brKozFW0b8DGusWu4yrhcMSXkjkbfPenKnrdOCxbtrZSeXSP2v1MnL40V-

1-800 CONTACTS

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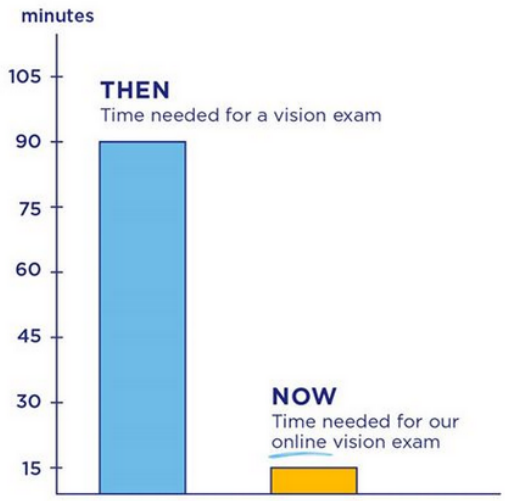
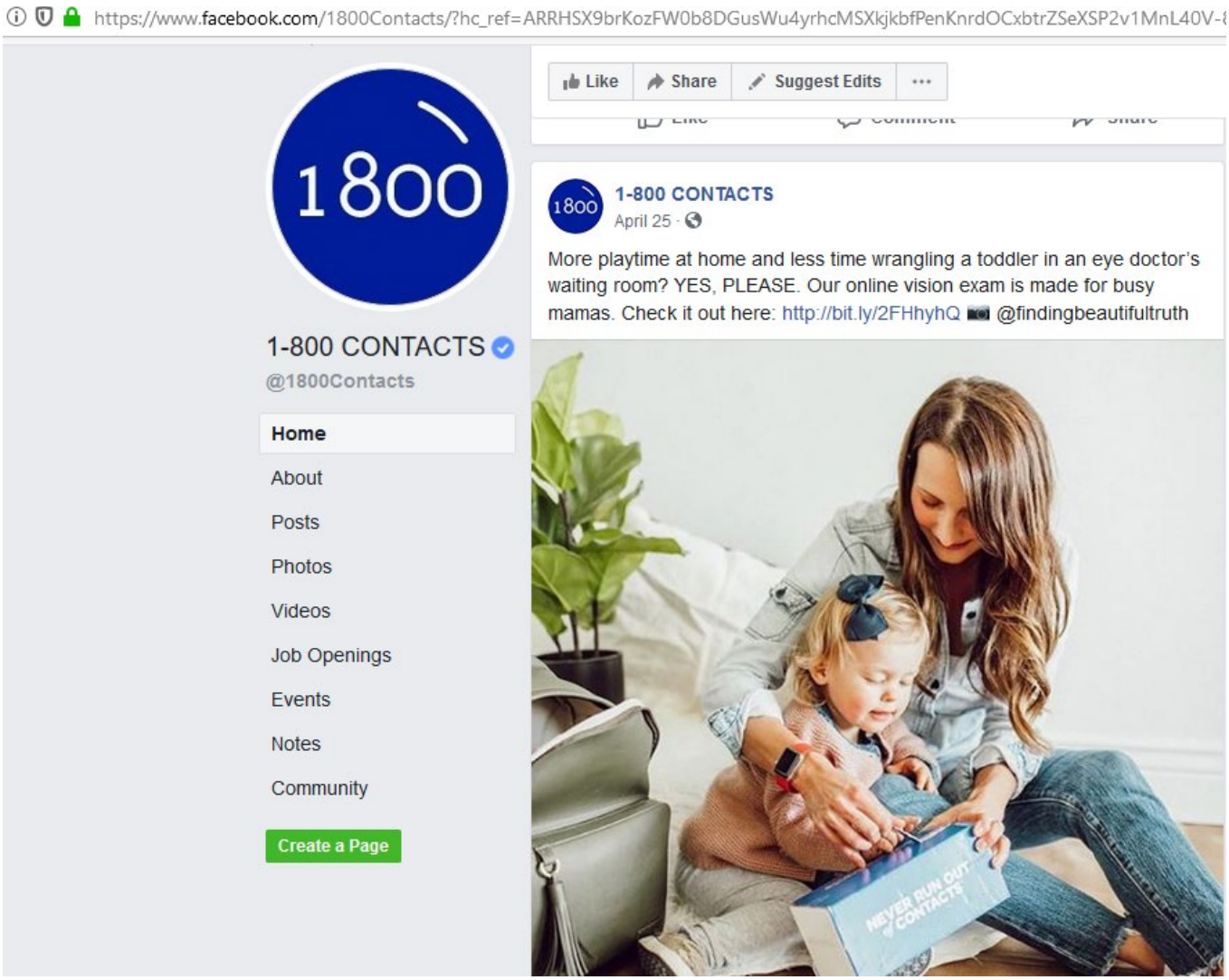
1-800 CONTACTS
May 10 ·

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




https://www.facebook.com/1800Contacts/?hc_ref=ARRHSX9brKozFW0b8DGusWu4yrhcMSXkjkbfPenKnrdOCxbtrZSeXSP2v1MnL40V-
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April 25 ·
More playtime at home and less time wrangling a toddler in an eye doctor's waiting room? YES, PLEASE. Our online vision exam is made for busy mamas. Check it out here: http://bit.ly/2FHhyhQ @findingbeautifultruth
NEVER RUN OUT OF CONTACTS

https://www.facebook.com/1800Contacts/?hc_ref=ARRHSX9brKozFW0b8DGusWu4yrhcMSXkjkbfPenKnrdOCxbtrZSeXSP2v1MnL40V-8

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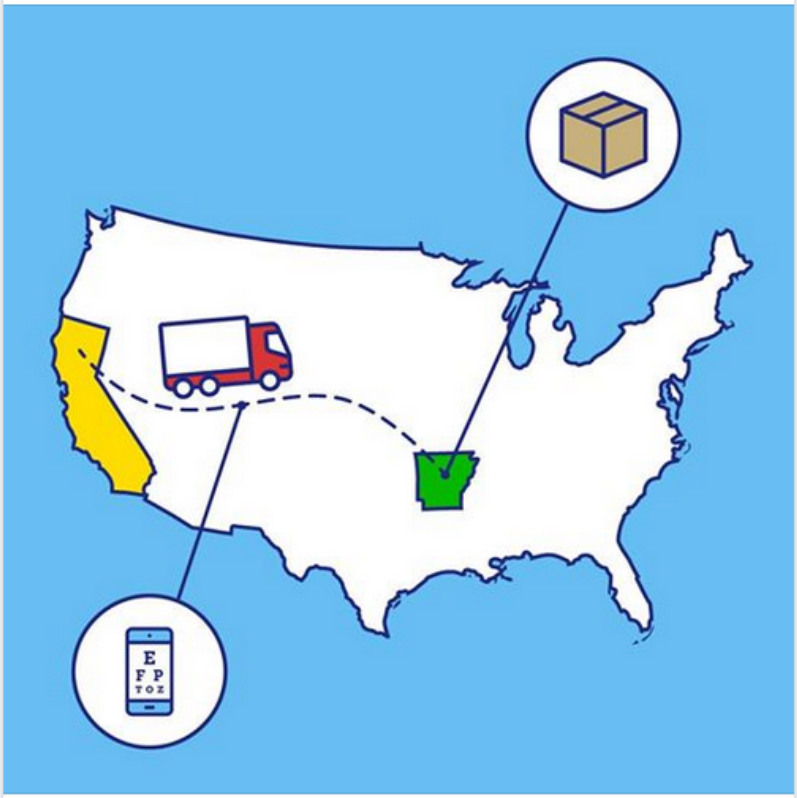
1-800 CONTACTS

March 29 ·

Fitting an eye exam into an already packed schedule is tough, particularly when you just need to order more contacts. Our online vision test came in clutch for long haul truck driver Jonathan as he trekked from California to Arkansas and realized he was out of contacts. He took the test in his truck's cab and we shipped his contacts to his final destination in Arkansas.



Verizon 10:40 AM 57%

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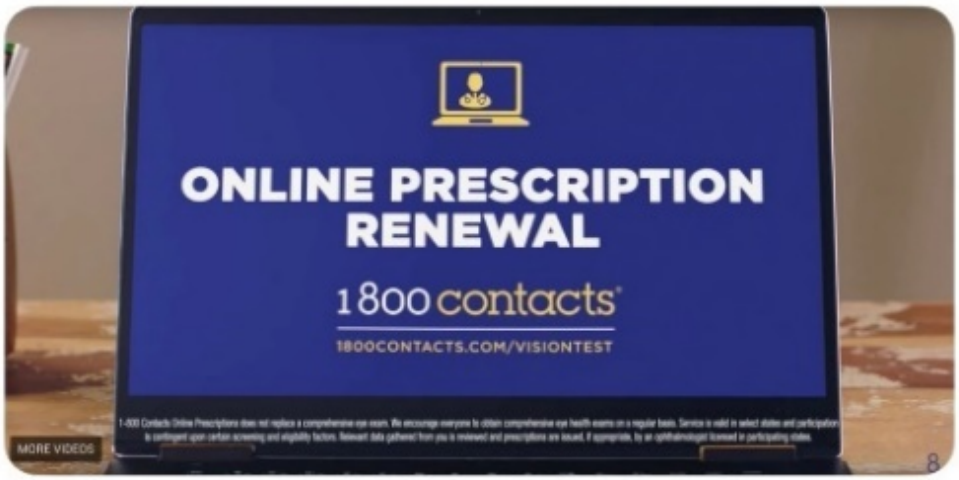
1-800 Contacts
@1800CONTACTS

Save yourself an unnecessary trip to the optometrist by renewing your prescription online at home! Check out our Express Exam: 1800contacts.com/online-contact...



8/14/18, 1:30 PM

1 Retweet

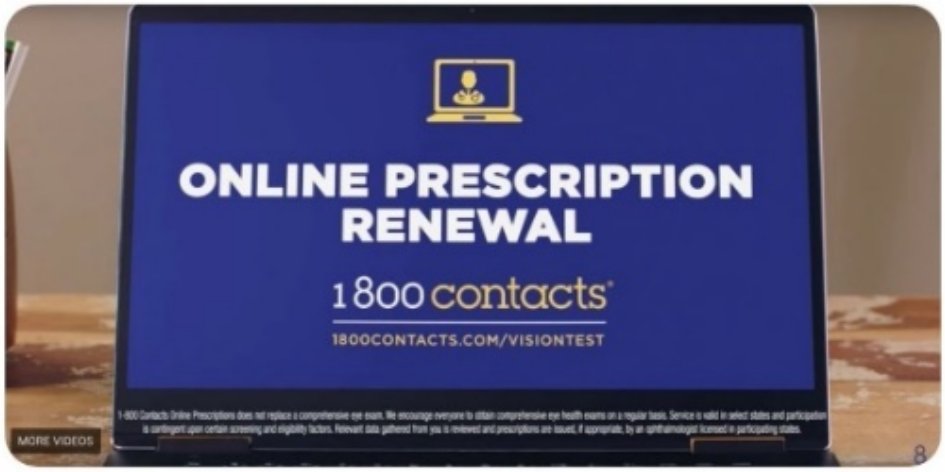
Tweet your reply

Verizon 10:44 AM 55%

Tweet

1-800 Contacts
@1800CONTACTS

Have you tried renewing your #contactlens prescription online with our renewal test? It's easy, quick and saves you the hassle of traveling to your eye doctor. bit.ly/2fZG2aF



4/26/18, 2:53 PM

2 Retweets **2** Likes

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Tweet

1-800 Contacts
@1800CONTACTS

Time to renew your #contactlens prescription? Want to save time and skip the trip to the optometrist? Try renewing your contact lens prescription by taking our Express Exam: bit.ly/2fZG2aF

5/12/18, 12:49 PM

3 Likes

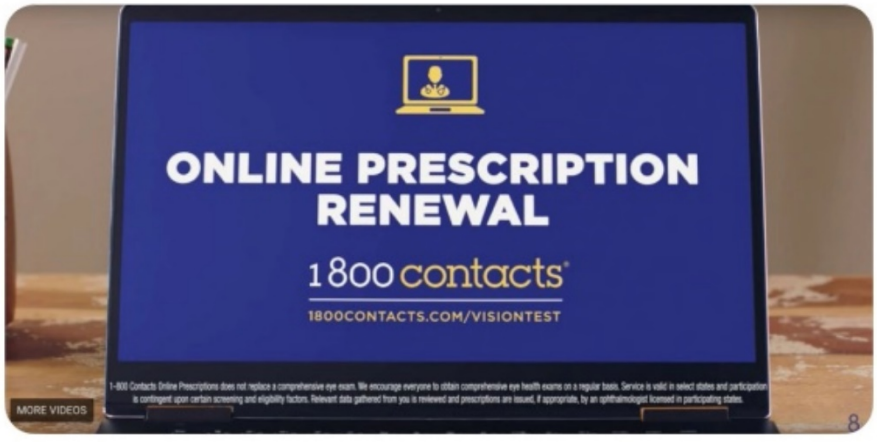
Tweet your reply

Verizon 10:41 AM 57%

Tweet

1-800 Contacts
@1800CONTACTS

Need your #contactlens prescription renewed but don't have time to go to the optometrist? No problem! Our Express Exam renews your prescription right from home: 1800contacts.com/online- contact-lens-prescription



7/23/18 1:30 PM

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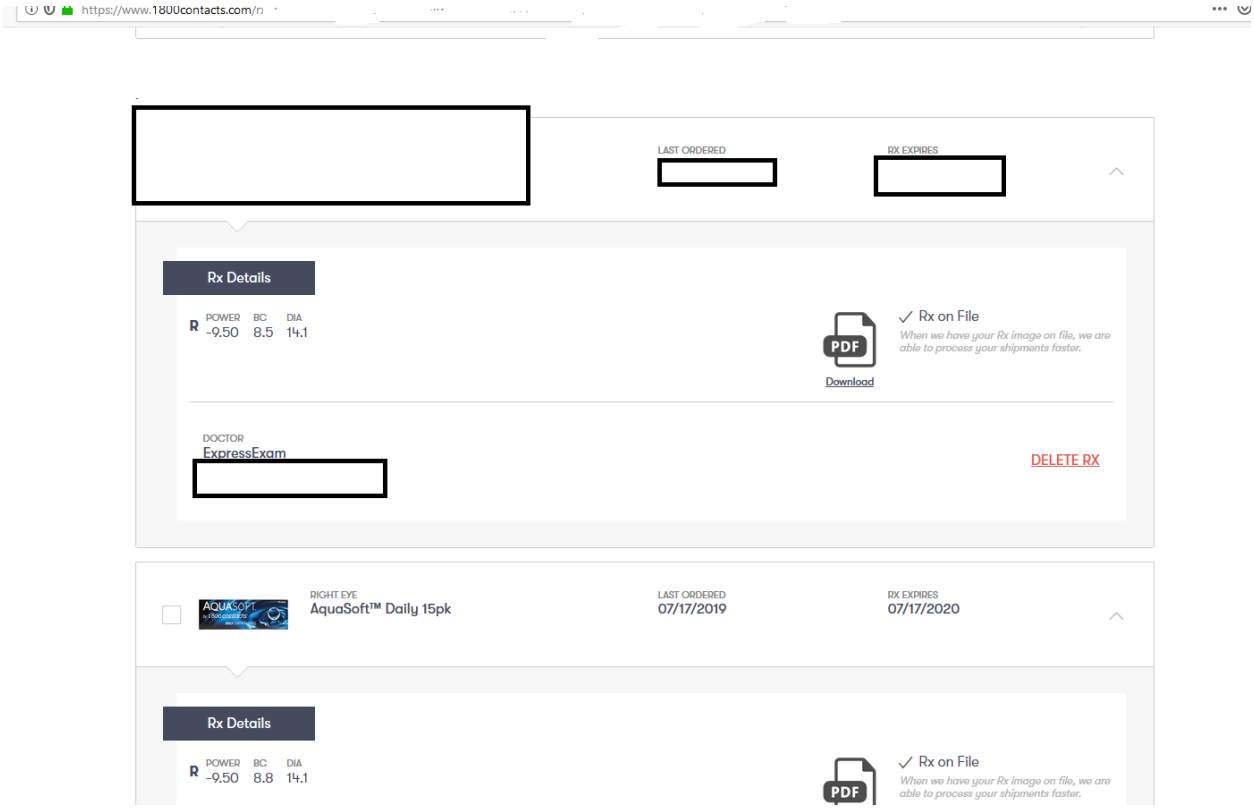
Appendix F

1-800-CONTACTS Prescriptions with Varying Base Curves



Appendix G

Hubble Adverse events reported to FDA

If a report contains trade secret or confidential business information, that text is replaced by "(b)(4)". If a report contains personnel or medical files information, that text is replaced by "(b)(6)". The designations "(b)(4)" and "(b)(6)" refer to the exemptions in the FOIA. For example, "(b)(4)" may be found in place of the product's composition and "(b)(6)" may be found in place of a patient's age. MAUDE is updated monthly and the search page reflects the date of the most recent update. The FDA seeks to include all reports received prior to the update but the inclusion of some reports may be delayed.

Brand Name	Event text
Hubble	Pt ordered contact lenses from (b)(6) without a doctor's prescription. He received the lenses and started to wear them without proper training or professional fitting. The lenses were stuck in the pt's eyes for one week because of the poor fit. Date of use: (b)(6) 2017. Diagnosis or reason for use: myopia.
Hubble	I prescribed the pt contact lenses of the material etafilcon a. shape parameters were base curve 8.5 with a diameter of 14.2mm. Prescription was fraudulently filled by (b)(4), (also known as (b)(4) contacts). (b)(4)., Did not receive or verify the prescription(b)(4) sent the pt contact lenses made from the incorrect material methafilcon a. the shape parameter was also incorrect with a base curve of 8.6, although the diameter of the lens was the same at 14.2. Contact lenses are medical devices regulated by the FDA. It is illegal to distribute contact lenses without a valid prescription. (b)(4) has put my pt at serious risk of infection and hypoxic corneal complications such as neovascularization and infiltrative keratitis.
Hubble	pt presented today with complaints of redness, ocular irritation, and blurred vision in his right eye. examination confirmed an acute conjunctivitis in both eyes, which was worse in the right eye. pt had been prescribed biotrue daily disposable contact lenses in (b)(6) 2017. however, 3 months ago, he successfully filled and was dispensed Hubble contact lenses online, without any verification with our office (in spite of pt's report that he entered Dr. and office info). pt's ocular condition is a direct result of the Hubble contact lenses which he was not prescribed. the material, base curve, diameter, and other parameters all differ significantly from his prescribed contact lenses.
Hubble	marginal corneal ulcer due to contact lens abuse of a lens she purchased on-line without a prescription.
Hubble	patient was dispensed a non prescribed, not approved contact lens by Hubble contact lenses. the lens was not appropriate to the patient. the patient developed bilateral eye inflammation after just 1 week of wear. she also developed an infection. this was treated with antibiotics and steroids. without interventions she could have developed corneal scarring and vision loss. patient has been a long time successful contact lenses wearer and was caring for lenses properly.
Hubble	I've been using Hubble contacts for a while now. I've always had some issues with them staying in, but used lubricant drops to help. after long term use of your contacts, I developed a devastating major eye problem. I wasn't able to see or live my regular daily life because of the state that my eyes were in. I went to 4 different drs in a week's time, including the er at one point because of the severe pain and severe condition that my eyes were in. I lost full vision in both eyes. it was cloudy and blurry, my eyes were fire engine red for an entire week. they slung, they burned, they hurt. the light sensitivity my eyes felt was nothing like I had ever felt before. luckily, I saw a Dr. that was able to get me on a very aggressive treatment once I saw her, because if it had been much longer, I don't know that I would have fully regained my vision. what bothers me the most is that you portray your company and products as FDA approved and good safe products for your eyes. "do you know how important your eyes are. do you realize that I could have permanently lost my vision."I have always kept great care of my eyes, and am a very responsible contact wearer, have been for 15+ yrs. I have never had any of the issues I have encountered within the past two weeks after using Hubble contacts. "what plan or procedure do you have in place for a situation such as this." I don't want anyone else to ever have to deal with what I've had to deal with. it's excruciating and scary. below are photos of my eyes, on different days over a weeks' time, and each is as painful as it looks. (b)(6).
Hubble	Hubble sold me the wrong contact lenses and did not verify my contact lens prescription. the contact lenses hurt when I wore them and I could not see well out of them. I could have gotten in a car accident.
Hubble	patient was switched from her prescribed contact lenses to Hubble contact lenses without a prescription or verification. patient presented and stated that contact lenses were uncomfortable and she stopped wearing them. exam with biomicroscope had a finding of 360 degrees of corneal neovascularization in both eyes. she was instructed to leave all contacts out for 2 weeks and was eventually refit to a FDA approved lens with higher oxygen transmission.
Hubble	The following information was obtained through MedWatch report. report number: mw5076089. the event description was: "pt states she "ordered Hubble lenses, and they are 'horrible'". corneal edema from illegally filled rx (our office was never contacted by Hubble contacts nor gave consent for Hubble contact lenses). pt educated on the condition. rx'ed steroid with taper. pt educated no cls x 7 days and only to re-start cls in 8 days if feels resolved in the first 2-3 days of takin g the meds. pt educated that "this is a make you feel better only drop", if for any reason not feeling better or feeling worse, rtc or call asap. patient educated on the risks of long term use of steroidal eye drops including cataracts and glaucoma, and to not use them other than how they are rx'ed." manufacturer narrative: the lot number is unknown and the products are not made available for evaluation at this time. the information about patient and initial reporter as well as the other informati will be submitted within 30 days of the receipt. subsequent actions regarding the follow-up report will be taken and submitted in accordance with 21 CFR 803.10 and 803.56.
Hubble	pt reported with significant discomfort, previously had used Hubble contacts, diagnosis was a dellen.
Hubble	corneal ulcer from Hubble contact lenses that were purchased without prescription.
Hubble	the patient is a long-time contact lens wearer. she started wearing a Hubble contact lenses a few months ago and her vision gradually became blurrier and blurrier, and her eyes have been very irritated. refraction revealed a -1.75 diopter shift in her vision in each eye. slit lamp examination revealed a corneal ulcer of the right eye and significant punctate keratopathy in the left eye. this is my fifth patient who has presented for an exam with Hubble contact lenses, and she is the fourth who has had a corneal ulcer or significant contact-lens-related corneal problem. I have heard similar reports from other eye care practitioners. I am concerned that this brand of contact lenses is contributing to these potentially sight-threatening corneal issues. I am also concerned that the Hubble contact lens company does

	not properly verify patient contact lens prescriptions.
Hubble	patient ordered contact lenses from online source (Hubblecontacts.com). incorrect prescription was sold despite prescribing doctor notifying them of it prior to sale. patient has high astigmatism and spherical contacts were sold. patient was not legal to drive with diminished acuity and had an adverse reaction to the contact lens material. dates of use: (b)(6) 2018 - (b)(6) 2018. diagnosis or reason for use: myopia and astigmatism.
Hubble	The following information was obtained through MedWatch report. report number: mw5076777. the event description was: "a patient was prescribed alcon dailies comfort plus for astigmatism and the prescription was filled from Hubble without a verification request to our office with their generic spherical daily lens. therefore, due to no astigmatism correction (which the patient did not know she was not given), the patient's visual acuity was decreased to 20/60 in each eye with Hubble's lenses. the patient also experienced extreme dryness and had to use artificial tears several times throughout the day. the patient was unhappy with her vision and dryness but did not know what she was "re-prescribed" by Hubble was drastically different from what she was prescribed by the doctor of optometry. the patient is now being treated for dry eye to prevent long-term damage. the patient is not made away of the decreased oxygen permeability of the generic Hubble lens. the patient experienced severe decrease in vision with non-astigmatism Hubble lenses - vision below (b)(6) driving law." manufacturer narrative: the lot number is unknown and the products are not made available for evaluation at this time. the information about patient and initial reporter as well as the other information required to submit was not provided. if the additional information is received, the follow-up report will be submitted within 30 days of the receipt. subsequent actions regarding the follow-up report will be taken and submitted in accordance with 21 CFR 803.10 and 803.56.
Hubble	Hubble contacts sold contact lenses to a pt without a valid contact lens rx. pt wore contacts resulting in damage to his eye.
Hubble	Hubble contact lenses do not provide an exact prescription. I had been using Hubble daily contact lenses for several months and noticed my vision becoming blurry. I thought perhaps my prescription had changed but decided to put in a pair of my Acuvue brand and all of the sudden I could see again. I tried another pair of the Hubble and the same thing happened - blurry vision. since it's a monthly subscription they had just sent another months worth. I contacted Hubble to cancel my subscription and to inform them of the issues. I also wanted a refund on the latest shipment that was unopened and unused. they would not allow a return and also ignored my concerns with the quality of their product. I went to see my ophthalmologist and he told me that Hubble never contacted them to verify my prescription. they have no way of measuring my eye for fitting the lenses, etc. had I kept using these contacts I could have damaged my eyesight due to constantly straining to see clearly. strength: -3.25% percent. frequency: daily; how was it taken or used: ophthalmic; date the person first started taking or using the product: (b)(6) 2017. date the person stopped taking or using the product: (b)(6) 2018.
Hubble	a pt of mine ordered Hubble contact lenses without an rx for Hubble contact lenses. I was not contacted by Hubble to verify an rx. my pt did not suffer an adverse affect, but these contact lenses are made with outdated material and are not fit correctly. they have the potential to cause long term visual effects including loss of vision. infection and potential blindness. on (b)(6) 2018 I saw the pt for an eye exam and performed a slit lamp examination on her corneas. I also performed a contact lens fitting and evaluation.
Hubble	I switched to Hubble contacts approx a year and a half ago. I never wore the contacts to bed, and always used them as indicated. I went to my regular every two year eye exam and was told my eyes look like they belong to someone who sleeps in ther contacts. my vision worsened, which at my age of (b)(6), is unusual and neovascularization occurred. my optometrist recommended a year without contacts, as well as seeing an ophthalmologist to assess for the possibility of lasik surgery because he was unsure if my topography of my eyes had changed so much that I would not be a candidate for that. the ophthalmologist told me Hubble has a very low oxygen permeability, and agreed that my eyes were not the best candidate for lasik. he stated I could try wearing a high quality contact less frequently.
Hubble	patient was sold Hubble contact lenses without a prescription. her prescription was for a daily disposable lens with a higher dk/t value because of corneal neovascularization. there was no attempt to verify a prescription and since wearing Hubble contact lenses, her neovascularization has worsened.
Hubble	have been using Hubble contacts since (b)(6) 2018. went to my eye Dr. today because I felt my vision wasn't as good as it has been. the eye Dr. said my eyes have dramatically changed, I think he said over a quarter of a difference than last time. he also said he hadn't seen someone my age, (b)(6), who he couldn't get to see 2015 in his eye exam, with the corrective lenses. I told him how I was using daily contacts and I thought they would be doing better and he asked where from and I told him Hubble, an online monthly subscription, and I told him how they weren't the bausch and lomb, and he said how they shouldn't have changed the type of lenses he prescribed me.
Hubble	clarity and clarity toric contact lenses were prescribed and the patient received Hubble spherical in both eyes. in addition, the prescribing doctor received a verification fax which she promptly responded to stating the prescription was expired and it was for different material. she additionally called the line for customer service and verbally stated the prescription was incorrect and asked for a call back. although the voicemail machine said they would get back to her within 48 hours, they never did. despite all that effort, the patient received the Hubble contacts and now has corneal neovascularization (a corneal condition which develops when there is a lack of oxygen), which was never previous documented.
Hubble	I am an optometrist. a patient of mine received contact lenses from Hubble contacts that I did not prescribe for him. he wore those Hubble contacts and developed an infiltrative keratitis (an inflammatory reaction on his cornea) as a result of wearing those contacts.
Hubble	patient has been using Hubble daily contact lenses for the past several months. he came in today to my office complaining of irritation with and without the contact lenses being on. even if he has given his eyes a "break" by wearing glasses. his eyes have giant papillary conjunctivitis from these contact lenses and now required treatment. therapy duration: 7 months. diagnosis or reason for use: contact lenses, used to see.
Hubble	patient ordered Hubble daily use contact lenses online and without a prescription (which is illegal, the company is in violation providing her a supply). she presented for examination yesterday with clinically significant neovascularization on the cornea 360 degrees in both eyes. in order to prevent further damage, the patient had to be fitted in special contact lenses with significantly improved oxygen permeability. these complications could have led to permanent damage of vision if the patient had not presented to the clinic today. patient had previously worn prescribed daily-use contact lenses which were evaluated and determined to be safe to wear by a licensed optometrist, with no difficulties or adverse effects.
Hubble	pt ordered Hubble contact lenses from (b)(6). Hubble never sent any communication to my office (this is one of several occurrences which is prompting me to write to the FDA) for verification. the pt suffered corneal damage and vision changes due to poorly fitting contact lenses. this company is subverting the law, putting pts at risk, and blatantly doing so. the avarice and arrogance exhibited by this company is unprecedented in the contact lens industry. I only hope enough complaints are recorded so the government can put a stop to this. FDA safety report id# (b)(4).
Hubble	pt purchased illegal contact lenses online and caused severe damage to her corneas because of the misuse of this medical device. Hubble sold contact lenses in the wrong, material, size and prescription to my pt who did not have a valid contact lens prescription. they did not even try to verify any rx which would keep them in compliance with the fairness to contact lens consumers act. start: (b)(6) 2017; stop: (b)(6) 2019. is therapy still ongoing? no. event abated after use stopped: no. FDA safety report id# (b)(4).