

April 6, 2018

Federal Trade Commission
Office of the Secretary
Constitution Center
400 7th Street, SW
Fifth Floor, Suite 5610 (Annex C)
Washington, DC 20580

**Re: Comments of 1-800 CONTACTS, Inc., Contact Lens Rule, 16 CFR Part 315,
Project No. R511995**

1-800 CONTACTS (“1-800” or “the Company”) thanks the Federal Trade Commission (“FTC”) for having included us in its March 7, 2018 Workshop on the Contact Lens Rule and the Evolving Contact Lens Marketplace (“Workshop”) and for the opportunity to provide these comments.¹ 1-800 continues to support the proposed amendment to the Contact Lens Rule (“CLR” or “Rule”), which, if adopted, will (1) require prescribers to ask patients to acknowledge receipt of their contact lens prescription and (2) maintain a record of that acknowledgment for at least three years (“Proposed Amendment”).² As the Company has stated in prior submissions, we believe that the Proposed Amendment is a cost-effective way to increase automatic prescription release and enhance consumer choice and competition in the marketplace. The Proposed Amendment will educate consumers about their rights and, importantly, provide the FTC with the evidentiary basis it needs to adequately enforce the Rule.

1-800 submits these comments to provide the FTC with additional evidence to support the Proposed Amendment and to respond to particular remarks or issues raised at the Workshop.³

¹ Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule, 82 Fed. Reg. 57889 (Dec. 8, 2017), https://www.ftc.gov/system/files/documents/federal_register_notices/2017/12/contact_lens_rule_fm_12-8-2017.pdf.

² Notice of Proposed Rulemaking and Request for Comment, 81 Fed. Reg. 88526–59 (Dec. 7, 2016) at 88534–35, <https://www.ftc.gov/policy/federal-register-notices/16-cfr-part-315-contact-lens-rule-notice-proposed-rulemaking-request> (“NPRM”).

³ 1-800 also directs the FTC to its prior CLR comments in this Rulemaking, public comments on license portability and telehealth associated with the FTC’s Economic Liberty Roundtables, as well as the expert report of Dr. Lawrence Baker on the costs and benefits of the Proposed Amendment, all of which have been posted to the public record.

- Comments of 1-800 CONTACTS, Inc. on the Contact Lens Rule, 16 C.F.R. § 315 (Project No. R511995), filed Oct. 26, 2015 (Comment #568), <https://www.ftc.gov/policy/public-comments/2015/10/26/comment-00568> (“1-800 October 2015 Comments”).
- Comments of 1-800 CONTACTS, Inc. on the Contact Lens Rule, 16 C.F.R. § 315 (Project No. R511995), filed Jan. 30, 2017 (Comment #3898), https://www.ftc.gov/system/files/documents/public_comments/2017/01/03898-138466.pdf (“1-800 January 2017 Comments”).

(Continued...)

A review of the Workshop transcript provides no reason for the FTC to deviate from the positions and proposals advanced in the Notice of Proposed Rulemaking (“NPRM”). 1-800 thus urges the FTC to move forward and finalize the Proposed Amendment and conclude this Rulemaking.

1-800 also recommends that the FTC go beyond steps to fully implement the FCLCA and use its research, policy, and, where appropriate, enforcement tools to open new avenues for competition. Though Workshop panelists made several valuable suggestions, 1-800 recommends that the FTC prioritize steps to enhance consumer choice in brand and modality selection, and to protect emerging ocular telehealth technologies from anticompetitive market behavior and regulation.

I. THE WORKSHOP AND RULEMAKING RECORD SUPPORT THE PROPOSED AMENDMENT

The majority of contact lens wearers are not automatically provided with a copy of their prescription.

Survey evidence from multiple sources conducted over more than a decade supports the FTC’s conclusion that “compliance with the automatic prescription release provision could be substantially improved.”⁴ For example, in the last comment period, Consumer Action submitted consumer survey evidence showing that less than half of all consumers (44%) were automatically provided with a copy of their prescription.⁵ This same survey showed that although some patients will ask for a copy, nearly 60% of consumers do not understand that they have a right to receive their prescription. As a result, approximately 30% of patients never receive a copy of their prescription. The Consumer Action survey is consistent with the results of surveys sponsored by 1-800 and conducted by third-party analytics firm Survey Sampling International (“SSI”) and submitted for the record.⁶

-
- Lawrence C. Baker, Analysis of Costs and Benefits of the FTC Proposed Patient Acknowledgment and Recordkeeping Amendment to the Contact Lens Rule, Sept. 25, 2017, https://www.ftc.gov/system/files/summaries/initiatives/677/10192017_meeting_summary_from_mko_for_the_contact_lens_rule_rulemaking_proceeding.pdf (“Baker Cost/Benefit Analysis”).
 - Comments of 1-800 CONTACTS on License Portability, Sept. 5, 2017, https://www.ftc.gov/system/files/documents/public_comments/2017/09/00031-141382.pdf (“1-800 Ocular Telehealth Comment”).

1-800 incorporates these materials and all attached exhibits by reference into this comment.

⁴ NPRM at 88532.

⁵ Consumer Action (Comment # 3721) (Jan. 30, 2017) at 1–2.

⁶ 1-800 has submitted the results from several consumer surveys on prescription release conducted SSI and sponsored by 1-800. These surveys were fielded in November 2014, May 2015, October 2015 (attached as Exhibits B & C to 1-800 October 2015 Comment), and January 2017 (attached as Exhibit A to 1-800 January 2017 Comment). These surveys show automatic release ranging from 35% to 45% of consumers, with between 25% and 35% of consumers never receiving a prescription at all.

The American Optometric Association (“AOA”) claims that its analysis of consumer complaints filed with the FTC (which it obtained through a Freedom of Information Act request) shows that compliance is adequate.⁷ However, even assuming the AOA correctly reviewed and analyzed these complaints, the number filed with the FTC is not a reliable measure of prescriber compliance. As Dr. Laurence Baker explains in his expert report, there are many reasons why a consumer would not complain to the FTC if their rights were violated. Importantly, survey evidence shows that about 60% of consumers do not understand that they have a right to receive a copy of their prescription, and even fewer are likely to understand that the FTC protects that right, that they can complain to the FTC, or how to do so.⁸

The Proposed Amendment is a cost-effective solution to poor prescriber compliance.

We agree with the FTC that the Proposed Amendment is a cost-effective solution to the problem of poor prescriber compliance, which has not meaningfully changed since the FTC issued the CLR. Despite more than a decade of widespread compliance issues, to date, the FTC has not brought a single enforcement action or sought fines against prescribers for failing to release prescriptions. The FTC acknowledges that more enforcement is warranted, but has stated that “the absence of documentation makes it difficult to determine whether a prescriber did or did not provide a patient with a prescription as required in any particular case.”⁹ Recordkeeping—combined with occasional enforcement sweeps with corresponding penalties—will change prescriber behavior by increasing the expected costs of a violation relative to the benefit, encouraging more prescribers to release.¹⁰

The Proposed Amendment is also likely to encourage release when it matters—when the consumer can use that prescription to comparison shop for lenses. Survey evidence shows that today, about 38% of consumers who receive a copy of their prescription (either automatically or upon request) receive it either at the same time as or after purchasing contact lenses.¹¹ Those consumers, though they receive their prescription, are still not getting the full benefit of prescription release, because they are deprived of the opportunity to comparison shop. The Proposed Amendment will change the dynamic within a prescriber’s office. It will be difficult for a prescriber to ask their patient to acknowledge receipt of their prescription and knowledge of

⁷ Through a Freedom of Information Act request, the AOA claims to have obtained consumer complaints filed with the FTC relating to the CLR for a four-year period covering 2012–2016. Based on its own analysis of these complaints, the AOA claims that 123 consumers submitted a valid complaint to the FTC for a prescriber’s failure to release a prescription over that four-year period (for maximum impact, the AOA describes the number of complaints as .0003% of the 41 million contact lens wearers). American Optometric Association (Comment #3830) (Jan. 30, 2017) at 4.

⁸ Consumer Action (Comment #3721) (Jan. 30, 2017) at 1; 1-800 October 2015 Comment at 13 (Exhibit B, SSI October 2015 Survey at 5). Consumers may also be reluctant to offend their prescriber by filing a complaint. Moreover, “consumers often do not submit complaints when they are dissatisfied with a product or service, particularly if the costs (in time, money, or other things) are larger than the economic benefit of remedying their dissatisfaction. Baker Cost/Benefit Analysis at 11.

⁹ NPRM at 88533.

¹⁰ Baker Cost/Benefit Analysis at 5–10.

¹¹ 1-800 October 2015 Comment at 13 (Exhibit B, SSI October 15, 2015 Survey at 10).

their right to shop around only after selling that patient a six-month supply of lenses. Automatic release will also make it difficult for prescribers to price-discriminate, offering lower prices only to consumers who ask for a copy of their prescription.¹² If knowledgeable consumers don't have to ask for their prescription, prescribers will not be able to selectively lower prices to just those consumers who signal that they are likely to comparison shop. As a result, prescribers may be forced to lower prices to all consumers instead.

The patient's signature could be obtained and stored in either hard copy or digital format, and should not interfere with the efforts of prescribers to adopt electronic health records. Though some prescribers complained in written comments that the Proposed Amendment would burden consumers who might otherwise complete their fitting remotely, a survey of prescribers showed fittings are completed by phone or email in just about 8% of cases.¹³ At the Workshop, Dr. Cockrell, Past President of the AOA, largely agreed that it was uncommon for prescribers to complete fittings remotely.¹⁴ Moreover, as 1-800 previously suggested, for those limited cases where a fitting is completed remotely, the prescriber is already required to provide the patient with a copy of their prescription. The Proposed Amendment form could be transmitted at the same time, and a copy of the email, fax, or text could serve as the required record.¹⁵ And although some prescribers complain that this simple form will reflect poorly on a practitioner, creating "patient doubt," 1-800 respectfully suggests that patients are used to forms.¹⁶ There is nothing in the form itself to suggest prior bad behavior. Patients who already receive a copy of their prescriptions are unlikely to be fazed by a form that simply asks them to acknowledge this right. One would not expect this simple form to create "patient doubt" unless a prescriber has failed to routinely release prescriptions in the past. Prescribers fostered the current environment and have benefited far too long at the expense of patients.

As discussed in detail in Dr. Baker's report, the costs of the Proposed Amendment are minimal and likely more than outweighed by its benefits. Increasing the number of prescriptions in the hands of patients will reduce the number of verification requests for both sellers and prescribers. Based on reasonable estimates of relevant parameters drawn from prior FTC regulatory submissions and survey evidence, Dr. Baker concludes that if all consumers received a copy of their prescription and used it when placing an order at the same rate that consumers who receive a prescription do so today, the reduction in verification costs would outweigh any modest additional costs to prescribers associated with implementing the Proposed Amendment.¹⁷ Accounting for the benefits from enhanced consumer choice, Dr. Baker concludes that the total

¹² Today, savvy consumers who are not provided with a copy of their prescription will ask and may pull out their smartphone in their prescriber's office in order to bargain for the best price, or decide to buy elsewhere. With the Proposed Amendment, all consumers will have that same opportunity, and the inability to price discriminate may lead to lower prices for all.

¹³ 1-800 January 2017 Comment at 11 (Exhibit B, M3 Global Research Optometrist Study at 6).

¹⁴ Transcript, Prescription Release and Consumer Choice at 11.

¹⁵ 1-800 January 2017 Comments at 12-14.

¹⁶ Transcript, Prescription Release and Consumer Choice at 6.

¹⁷ Baker Cost/Benefit Analysis at 12-17.

benefits of the Proposed Amendment are likely to outweigh any costs.¹⁸ Dr. Baker also concluded that the AOA-sponsored study by Avalon Health Economics grossly overstates the costs of the Proposed Amendment, due to poor underlying survey methodology, and, importantly, by conflating the additional cost associated with the Proposed Amendment with the “the total cost of compliance with the existing Rule *and* the Proposed Amendment (*and* all other rules, regulations, and policies).”¹⁹

Signs are not a good alternative.

Commenters have raised alternatives to the Proposed Amendment and several proposals were discussed at the Workshop. The AOA has recommended that instead of the Proposed Amendment, the FTC amend the CLR to require that prescribers post a sign in their office to notify consumers of their rights,²⁰ and panelists affiliated with the AOA continued to urge signage at the Workshop. Dr. McCarty, the current President of the Tennessee Association of Optometric Physicians and Chair of the AOA’s Quality Improvement and Registry Committee, argued that since certain regulations relating to nondiscrimination require that businesses post a sign, a sign should certainly be good enough for “*this little piddly thing we’re talking about—contact lens release.*”²¹

FTC had good reasons to reject signage, which is based on a California law that took effect in January 2016. Most importantly, a posted sign would not provide a record showing that the prescriber actually automatically released the prescription, so it would do nothing to aid enforcement.²² Absent a more credible threat of enforcement, prescribers will not change their behavior.

The empirical evidence to date shows that the California law had no effect on automatic release rates in the state.²³ State-level consumer survey data show no meaningful difference in automatic release rates in California between October 2015 (a few months before the law took effect) and January 2017 (one year after the law took effect).²⁴ In October 2015, just 33% of

¹⁸ *Id.* at 3.

¹⁹ *Id.* at 19–26.

²⁰ American Optometric Association (Comment #3830) (Jan. 30, 2017) at 5.

²¹ Transcript, Prescription Release and Consumer Choice at 12.

²² The FTC also noted that a sign may be less effective than an individual notice in educating consumers. NPRM at 88534. SSI consumer survey evidence confirms that intuition, showing that about three-fourths of consumers report that they are more likely to pay attention to a notice of their rights presented to them than to a notice provided on a posted sign. Baker Cost/Benefit Analysis (Exh. B, SSI August 2017 at 9).

²³ As noted during the Workshop, however, both FTC staff and Consumer Action conducted informal investigations of optometric offices to evaluate compliance with just the requirement to post the sign itself. Both found dismal compliance, with the FTC reporting that none of the 15 offices they visited had a sign visibly posted. Transcript, Prescription Release and Consumer Choice at 12–14.

²⁴ See Exhibit A. As discussed in *supra* note 6, 1-800 has sponsored several consumer surveys of prescription release, including surveys in October 2015 and January 2017. Though 1-800 presented national results to the FTC, the survey tracked responses by state. Thus, California results could be pulled from the prior survey results for comparison purposes.

California contact lens consumers were automatically provided with a copy of their prescription; 35% received a copy upon request and about 25% never received a copy. Those figures were nearly identical in January 2017. California automatic release rates were also very close to the national average in both October 2015 and January 2017, showing no improvement relative to the rest of the country. In January 2017, 35% of California consumers were automatically provided with a copy of their prescription compared to a rate of 37% for the national average. As long as prescribers sell what they prescribe, their economic interest will continue to weigh against automatic release unless there is a meaningful risk of enforcement and penalties for violating the Rule.

Some “small a” alternatives that retain the core features of the Proposed Amendment should be considered.

Alternatives that would retain the core features of the Proposed Amendment (acknowledgment of release and recordkeeping to overcome the conflict of interest) were also discussed. 1-800 would support some degree of flexibility for prescribers in implementing a notice and recordkeeping requirement for each prescription, such as giving the prescriber the option to use alternative formats for the signed acknowledgment, *e.g.* including the notice of rights on the patient’s prescription and requesting that the patient countersign the prescription for the prescriber to maintain as the record.²⁵ However, prescribers should be required to provide patients with a notice of rights similar to what is included in the Proposed Amendment (to encourage prescribers to automatically release when it matters, before selling lenses) and some method for patients to acknowledge receipt. Absent adequate proof of notice and receipt, a violation should be presumed. 1-800 also agrees with the National Association of Optometrists and Opticians that any acknowledgment proposal must be accompanied by at least some routine enforcement to encourage prescribers to take the requirement seriously.²⁶

1-800 would also support an exemption for prescribers who certify that their practice does not sell contact lenses (or that they do not otherwise earn revenue from sales from an affiliated retailer or have any other conflict of interest with regard to the sale of lenses). Prescribers who do not have a conflict of interest have every incentive to release prescriptions so that their patients can buy lenses from the retailer of their choice. They have no obvious incentive to withhold the prescription. Though the burden of the Proposed Amendment is minimal, and likely offset entirely by a drop in time spent verifying orders, the FTC could reduce the burden further while preserving the benefits for consumers by exempting prescribers who do not sell and do not have a conflict. Of course, the FTC must write and implement any exemption carefully to prevent prescribers from gaming the system to conceal a financial conflict that affects their incentives with regard to automatic release.

1-800 is skeptical that a one-time “Bill of Rights” and signed acknowledgment only at a patient’s initial visit has sufficient bite to change prescriber incentives and behavior.²⁷ Though

²⁵ This proposal was originally suggested by National Association of Optometrist and Opticians in comments filed in this Rulemaking. NAOO (Comment #03851) (Jan. 30, 2017).

²⁶ Transcript, Prescription Release and Consumer Choice at 14.

²⁷ Transcript, Prescription Release and Consumer Choice at 24–26.

1-800 would support a requirement that prescribers present new patients with a Bill of Rights (which could provide them with a more detailed explanation of their rights under the CLR than the language included in the Proposed Amendment, perhaps combined with healthy wear information), to facilitate enforcement and thus change prescriber incentives, initial patient education materials must be coupled with an acknowledgment of prescription release for each prescription. Even if a Bill of Rights was successful in educating more patients about their rights, education alone puts the burden on patients to ask for their prescription, which some may be reluctant to do, and leads to the kind of price discrimination that may keep prices higher overall. The Fairness to Contact Lens Consumers Act (“FCLCA”) expressly provides for automatic release, not release upon request, and the CLR should effectively implement that mandate. Prescribers should be required to request the patient’s acknowledgment and document compliance each time a prescription is provided, just as sellers are required to document each verification request.

II. THE CURRENT VERIFICATION SYSTEM WORKS WELL AND SERVES CONSUMER INTERESTS

Error rates for verification requests have been vastly overstated.

Prescribers participating in the Workshop continued to urge the FTC to change the verification system in ways that the agency has already considered and rejected. These recommendations continue to be grounded in nothing but anecdote and opinion that is belied by more systematic data.²⁸

Dr. Steinemann, a Professor of Ophthalmology at Case Western University who is also in clinical practice in Cleveland, Ohio, complained that significant numbers of consumers order contact lenses with an expired prescription or provide sellers with inaccurate parameters or prescriber contact information. He stated that for the locations where he practices, an informal audit of verification requests showed that between 25% and 50% of verification requests were either invalid or incorrect, with the majority invalid due to an expired prescription.²⁹ Though Dr. Steinemann claims to respond to every verification request, he asked the FTC to make that easier by requiring that all verification requests be provided in writing, that prescribers be afforded two business days to respond before an order is passively verified, and that sellers provide prescribers with a means for “two-way communication.” Dr. Steinemann also echoed prior requests that the FTC require prescribers to include a quantity limit on a prescription to prevent consumers from stockpiling large quantities of contact lenses to avoid visiting their prescriber.³⁰

Dr. Steinemann’s sample—if accurate—is clearly an outlier. 1-800 has provided the FTC with survey and other evidence to rebut claims that the current verification systems allows a

²⁸ Furthermore, the health risks associated with contact lens wear are well-established and associated with modifiable behaviors, not sales channel. There are no studies reliably demonstrating a link between internet purchase and increased risk of ocular health problems. See Exhibit B, Statement of Dr. Paul Donzis.

²⁹ Transcript, Examining the Verification Process at 8–9.

³⁰ NPRM at 88549.

large number of consumers to buy lenses from online sellers with invalid or expired prescriptions, that inaccurate orders routinely ship, or that consumers are stockpiling lenses to avoid eye exams. That evidence shows that market-wide, only about 11% of contact lens consumers received (as opposed to ordered) contact lenses using expired prescriptions, and importantly, that the number was about the same regardless of whether the consumer purchases from an online retailer, a big box store, or a prescriber's office.³¹

There are other reasons to doubt Dr. Steinemann's data. Survey evidence from multiple sources shows that contact lens wearers have regular eye exams that fall within even the AOA's own guidelines of 1–2 years. Vision Council information presented at the Workshop showed that 82% of contact lens wearers had an eye exam within the last 12 months.³² According to the Vision Council, eye exams for contact lens users were up by 3.1% in 2017, and were “one of the handful of growth segments for the eye exam sector.”³³ These results are consistent with a Johnson & Johnson survey submitted in this Rulemaking, showing 87% of contact lens wearers had an eye exam within the last year, with 11% reporting an exam within the last 1–2 years.³⁴ Other evidence points to the same conclusion.³⁵ The exam frequency data does not support allegations that large numbers of contact lens consumers are even trying to order lenses with long-expired prescriptions. Confronted with that inconsistency at the Workshop, Dr. Steinemann's explanation was merely that “*you know what you know.*”³⁶

Evidence on the average size of contact lens orders is also inconsistent with the “hoarding” hypothesis. Vision Council data presented at the Workshop showed that average consumer out-of-pocket spend on contact lenses is \$51 per transaction, and \$121 per year, which hardly suggests stockpiling.³⁷ Dr. Cockrell responded to that data with his own hyperbole. “I

³¹ 1-800 January 2017 Comment, Exhibit D (SSI August 2016 Survey at 3). This same survey showed that nearly all consumers receive the brand of lenses they ordered with little variation across retail channels. Only 1% of online consumers received a non-approved substitute brand of lenses; 2% for consumers buying from a prescriber; 3% from other retailers such as big-box stores. *Id.* at 5.

³² The Vision Council, U.S. Optical Market Eyewear Overview (March 7, 2018) at 13, https://www.ftc.gov/sites/default/files/filefield_paths/steve_kodey_ppt_presentation.pdf (“Vision Council Presentation”).

³³ *Id.*

³⁴ Johnson & Johnson Comments (Comment #582) (Oct. 26, 2015), (Appendix at 18, APCO Insight U.S. Contact Lens Consumers Telephone Survey, Question 10).

³⁵ SSI survey evidence shows that contact lens consumers have an eye exam every 13 months regardless of where they purchase their contact lenses (online, big box, or prescriber). 1-800 January 2017 Comment at 20; n. 87. An informal survey of 1-800's own customers shows exam frequency of about 16 months, which is consistent with a 2016 report by *Contact Lens Spectrum* showing an exam frequency of 15 months for contact lens wearers. Both the SSI and 1-800 customer surveys show that only about 11% of contact lens wearers have an exam less often than once every two years. *Id.*

³⁶ Transcript, Examining the Verification Process at 12.

³⁷ Vision Council Presentation at 9. 1-800 has also provided data showing that on average consumers purchase about a six-month supply of lenses per order (assuming wear according to manufacturer recommendations). 1-800 January 2017 Comment at 21.

*doubt seriously there's a single doctor in this room that doesn't have that problem I just described. And that's just this room with 70 or 80 doctors in it.”*³⁸

Finally, though 1-800 does not believe that Dr. Steinemann's data is representative, he claims to respond and either cancels or corrects every inaccurate order, showing that the system works as intended and provides prescribers with ample opportunity to block inaccurate orders if they are inclined to do so.³⁹ There is no evidentiary basis to require consumers, who may be down to their last pair of lenses when placing an order, to wait longer for their lenses to ship.

Congress considered the costs and benefits of passive versus active verification when it passed the FCLCA. It determined that given prescribers' inherent conflict of interest and the health and safety profile for contact lens wear, passive verification best served the interests of consumers. That cost-benefit determination holds true today. There is no persuasive evidence that the FCLCA or the advent of a nationwide verification system that allows for passive verification has had any adverse impact on patient health, and all prescribers are free to actively verify every order if they would like, as Dr. Steinemann clearly prefers to do. Although sellers like Walmart may prefer to actively verify orders, that is a choice that suits their business model (where the majority of in-store sales are made to customers with a prescription from a co-located prescriber, and placing a call to a prescriber allows Walmart to complete a customer's order in one trip to the store). It is common practice for independent prescribers and brick and mortar retailers to simply call and get a prescription verified real time, as Jennifer Sommer from Walmart described at the Workshop.⁴⁰ 1-800 has the same experience when it verifies prescriptions for its own brick & mortar business, Lumen Optical. That model will not work for a large internet seller like 1-800, who has faced nothing but obstacles from prescribers since it first opened its phone lines more than 20 years ago.

Compliant automated phone systems are an efficient verification method.

Prescribers at the Workshop continued to complain about automated phone systems used to verify orders, but again provided no evidence that should lead the FTC to revisit its prior positions. As 1-800 has previously explained, its Human Initiated Voice Response (HUVR) system is the gold standard for CLR compliance. It conveys verification information clearly and accurately with minimal burden to prescribers, while allowing 1-800 to efficiently process a large volume of orders and document compliance with the CLR. Every call is initiated by a live agent who confirms that the call is received by the right person or office.⁴¹ 1-800 immediately identifies itself and states that it is calling “with a prescription verification request.” Prescribers

³⁸ Transcript, Examining the Verification Process at 20.

³⁹ Two business days is clearly too long for consumers to wait for lenses to ship. Many consumers order when they are down to their last pair of lenses. Only 23% of consumers report that they always have extra lenses on hand and 65% report that they will engage in the unhealthy practice of overwearing their last pair of lenses. 1-800 January 2017 Comment, Exhibit A, SSI Consumer Survey at 4–5.

⁴⁰ Transcript, Examining the Verification Process at 4.

⁴¹ 1-800 October 2015 Comment at 20; 1-800 October 2017 Comment at 23.

and their staff should all be very familiar with the CLR and recognize the 1-800 brand. No reasonable office would mistake a 1-800 verification call for a marketing call.

As the FTC has previously stated, the FCLCA authorizes sellers to use telephone for verification, which “is commonly understood to include automated telephone systems. . . . [I]t would thus seem to be contrary to Congressional intent to prohibit use of this technology.”⁴² 1-800 agrees with the FTC, however, that such systems must convey complete information and be delivered “in a volume and cadence that a reasonable person can understand.”⁴³ 1-800 is confident its HUVR system meets this standard and would encourage the FTC to use enforcement to remedy a problem with sellers who do not meet the same high standards. Requiring live agents to read the entire verification request would only increase costs and lower compliance without any offsetting benefits to consumers.

Additional issues related to verification.

Time-frame for prescribers to respond to seller request for copy of customer prescription. Even with better compliance, verification will still be required. Some consumers may not have their prescription handy at the time they place an order. In passing the FCLCA, Congress determined that consumers should be automatically provided with a copy of their prescription, but should have the option to buy lenses from alternative channels by either using their prescription or having that prescription verified by a direct communication. However, when consumers do not submit a copy of their prescription, sellers can eliminate verification for future orders by obtaining a copy directly from their prescriber. As previously discussed, however, today only about 50% of prescribers respond to 1-800’s authorized requests for a copy of a customer’s prescriptions.⁴⁴ While the FTC has determined that the FCLCA and CLR require prescribers to respond to such requests, they do not have the corresponding ability to enforce this requirement.⁴⁵ 1-800 has previously recommended that prescribers be required to respond within five business days.⁴⁶ 1-800’s internal records show that for those prescribers that do respond, 90% do so within two calendar days.⁴⁷ Thus, five business days should be more than sufficient to accommodate even small offices that may close for vacations or family emergencies, and the FTC can use its prosecutorial discretion to excuse delay for good cause.

Two-way communication. Prescribers on the panel complained that they are unable to reach sellers to cancel or correct verification requests, asking that the FTC require that sellers provide for “two-way communication.” However, sellers that place verification requests are already required to provide prescribers with contact information.⁴⁸ As part of every verification

⁴² NPRM at 88540.

⁴³ *Id.*

⁴⁴ 1-800 January 2017 Comment at 14–16.

⁴⁵ NPRM at 88537.

⁴⁶ 1-800 January 2017 Comment at 14.

⁴⁷ *Id.* at 15.

⁴⁸ 16 CFR § 315.5.

call, 1-800 provides prescribers with a contact name, fax number, and phone number. Calls from prescribers are routed to 1-800's doctor service line ("DSL") and faxes are reviewed by compliance agents. Calls are answered live Monday through Friday 7 a.m. to 7 p.m. If lines are busy, the prescriber can leave a message on voicemail. 1-800's internal data show that most prescribers who call the DSL do so within two business hours of receiving a verification request. During business hours, if a response is required, a 1-800 agent will typically respond within one hour. If a message is left outside of normal business hours, an agent will respond shortly after operations resume the next business day, giving the prescriber plenty of time to correct, cancel, or actively verify an order during the 8 business-hour verification window. This same process and timing applies when prescribers contact 1-800 by fax.

Of course, prescribers have always had the ability to reach 1-800 by just calling its toll-free number. That number should be easy for them to remember as it is the name of the Company. Prescribers who simply call the 1-800 toll-free number can be transferred to the DSL; it's very easy.

Date-of-birth as identifier. 1-800 strongly recommends against requiring that sellers provide a patient's date of birth to verify a prescription. Requiring consumers to provide online sellers with their date of birth would raise unnecessary privacy and data security risks and would likely discourage some consumers from shopping online.⁴⁹ The CLR already requires sellers to provide prescribers with the patient's full name and address, as well as the prescription parameters.⁵⁰ That should be more than sufficient for prescribers to easily identify the correct patient for the vast majority of orders.

Best practices. Finally, FTC staff raised the issue of potentially issuing "best practices" for seller verifications. Though difficult to evaluate in the abstract, 1-800 does not support best practices for seller verifications beyond what is required by the CLR. Best practices can often become *de facto* regulations. Absent evidence of a significant problem that requires additional intervention, which the FTC did not find, each seller should be allowed the flexibility to determine for itself the best way to comply with the requirements of the CLR. Best practices may stifle creativity and efforts to find better ways to serve customers and reduce the costs of regulatory compliance. 1-800 takes its compliance obligations seriously, but needs the flexibility to determine the most efficient way to both comply and provide great service to its customers. We recommend instead that absent evidence of a market wide problem, the FTC ensure compliance through individual enforcement actions against sellers who violate the CLR.

⁴⁹ Birthdate requires a far more complex environment to maintain with encryption and access control. It is a key attribute that is used as PIN, passwords, and authorization to prove identity. Birthdate is a key attribute used for credit verification and approval for credit used by all credit bureaus. Not requiring and storing protects customer data better than any form of encryption currently available.

⁵⁰ 16 CFR § 315.5.

III. BEYOND THE CONTACT LENS RULE

Promote consumer brand choice.

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."⁵¹

Improving prescription release by adopting the Proposed Amendment and pursuing appropriate enforcement against prescribers who do not automatically release prescriptions will build on these gains and help consumers realize the full benefits the FCLCA was designed to achieve. 1-800 encourages the FTC to take this step.

But there is more that the FTC can do to unleash competition and innovation in the contact lens and ocular healthcare markets beyond full implementation of the FCLCA. As discussed during the Workshop, while the FCLCA and CLR have enhanced price and non-price competition in the contact lens market, competition at the retail level is limited to the specific brand (or private label equivalent) that was prescribed.⁵² Greater brand choice will allow consumers to switch to more convenient or affordable lenses, introducing additional competitive pressure throughout the supply chain, including among manufacturers. Allowing greater brand substitution will also reduce entry barriers for new manufacturers, who may find it difficult to gain traction with prescribers.⁵³

Four contact lens manufacturers dominate the supply of soft disposable contact lenses worn by U.S. consumers.⁵⁴ Because prescribers are gatekeepers to the market, manufacturers tend to align themselves with prescribers in ways that do not necessarily benefit consumers. Those incentives led manufacturers to join a group boycott against third-party sellers in the 1990s, and more recently (in near industry-wide unison) to adopt resale price maintenance policies (known as UPP) for popular lenses. Johnson & Johnson described UPP as an effort to make sure that

⁵¹ Transcript, Competition in the Contact Lens Marketplace at 19.

⁵² Private label brands are not generic equivalents. They are merely the manufacturer's lens sold under a limited distribution label and are not generally less expensive.

⁵³ At the Workshop, 1-800 CEO John Graham described 1-800's past effort to manufacture and sell its own FDA-approved, high-quality daily disposable lens. Ultimately, 1-800 was forced to abandon that business because of the challenge it faced getting the lens prescribed. Transcript, Competition in the Contact Lens Marketplace at 17-18.

⁵⁴ The major manufacturers are Johnson & Johnson, the Cooper Company, Novartis (Alcon), and Valeant Pharmaceuticals (Bausch & Lomb).

“the patient has no incentive to shop around.”⁵⁵ Though manufacturers have abandoned UPP, they have put in place consumer rebate programs that apply only if the consumer buys their lenses from their prescriber.⁵⁶

Manufacturers at the Workshop describe their alignment with prescribers as flowing from a shared interest in putting each patient into the lens that provides the optimal fit, claiming that lenses are simply not interchangeable. Peter Menziuso, North American President for Johnson & Johnson Vision Care, said the choice is made based on “physiology, anatomy, the lifestyle of a patient [B]rand choice is much more than material . . . like is there wetting agents involved . . . what are the optical zones . . . what’s [the] edge design?”⁵⁷ According to Mr. Menziuso (who represents a company that safely sells its lenses over-the-counter and in vending machines to consumers in many countries outside the United States), when it comes to U.S. consumers, there is one optimal lens for each patient and a consumer must visit a prescriber for a comprehensive eye examination to identify that lens or suffer adverse consequences.⁵⁸ (“So when someone considers this point of interchangeability, it’s not something that is easily able to be accomplished and can’t be.”)⁵⁹

The evidence shows otherwise. The behavior of both manufacturers and prescribers suggests that brand selection is more about economics than physiology and that consumers would benefit from greater brand choice. One retail industry expert explained that “One of the things that we’re starting to see sort of change is the—I call them sales reps . . . it’s more of a business consultant relationship. So you have what would have traditionally been someone who is going in and competing with the other manufacturers around features and benefits of their lenses, you have manufacturers who are trying to build a deeper relationship with that practitioner by helping them with non-product related services. So different business consulting services. How can I help you set up onto a ship-to-home model?”⁶⁰ Manufacturers also have prescriber loyalty programs, offering rebates and other financial incentives for hitting certain sales or growth targets for their products.⁶¹

⁵⁵ 1-800 October 2015 Comment at 4, 8–12, n.30 (discussing *In re Disposable Contact Lens Antitrust Litig.* MDL 1030 (M.D. Fla.) and the history of the more recent unilateral pricing policy and citing Laura Angelini, then President of Johnson & Johnson Vision Care).

⁵⁶ *Johnson & Johnson Vision Care, Inc. Focuses Advocacy Efforts to Defend Regulation of the Contact Lens Industry*, Press Release, Apr. 13, 2016, <https://www.jnjvisionpro.com/contact-lens-update-jjvci>; Cooper Vision Rebate Instructions, 2018 Rebate Offers, <https://coopervision.com/coopervision-rebate>. Although a policy that reduces prices for at least some consumers is an improvement over one that raises prices for everyone, the form of this rebate policy continues to favor the interests of prescribers over those of consumers, who must shop in a particular channel to take advantage of the rebate, perhaps sacrificing service and convenience in the process.

⁵⁷ Transcript, Looking Ahead at 5.

⁵⁸ See Exhibit C (contact lens sales in Japan).

⁵⁹ *Id.*

⁶⁰ Transcript, Competition in the Contact Lens Marketplace at 10.

⁶¹ For example, Cooper Vision currently has a “1-day escalator program” that offers prescribers rebates for meeting certain sales and growth targets for Cooper Vision 1-day lenses. Association of Leaseholding Lenscrafters Doctors (Continued...)

1-800's experience suggests that most practices lean heavily towards prescribing one manufacturer's lenses over others ("Johnson & Johnson practices" or "Alcon practices"). Based on a small sample of 1-800 orders, 1-800 identified 73 prescribers who, based on orders placed with 1-800, wrote on average about 80% of their prescriptions for Johnson & Johnson lenses. For each of these 73 Johnson & Johnson prescribers, 1-800 was able to identify a prescriber in close geographic proximity (between .2 and 10 miles away) who, on average, wrote more than 70% of their prescriptions for Alcon lenses.⁶² This informal sample shows that prescribers who are likely serving similar patient populations lean heavily towards prescribing one manufacturer. These prescribing patterns seem more consistent with prescriber loyalty programs and other incentives than objective criteria related to optimal fit.⁶³ We would not see these patterns if physiology drove brand selection; we would not see loyalty programs and near exclusive relationships if manufacturers and prescribers did not themselves understand that brands are often interchangeable.

Reacting to Johnson & Johnson claims that point-of-sale brand substitution is entirely untenable, New York Assistant Attorney General, Bob Hubbard, who has a long history of policing anticompetitive behavior in the contact lens sector, stated that "it was striking to me how these themes about the eye health problems have recurred whenever competition activities arise."⁶⁴ 1-800 agrees with AAG Hubbard's suggestion that the FTC partner with the FDA to evaluate whether the restrictions on competition associated with a brand-specific prescription are justified by legitimate health and safety concerns,⁶⁵ and to use its research and competition policy tools more broadly to change the status quo on brand choice to introduce more competition into the market. Government regulation should not foreclose brand-level competition absent evidence that the restriction is justified to protect patient health and safety. The evidence here tends to suggest far more consumer choice than exists today is warranted under any reasonable cost-benefit analysis. The FTC may also want to consider whether certain products are designed specifically to avoid the substitution between identical lenses that is permitted under the CLR. At the Workshop, 1-800 CEO John Graham explained that in the contact lens industry, private label rarely means less expensive and can be used merely to restrict competition. Mr. Graham gave the example of a national brand lens (which 1-800 sells) as well as a private label lens (which 1-800 cannot sell) made by the same manufacturer that are identical in nearly all respects: "same material, same base curve, and 1 [pauses to self-correct] .1

(March 30, 2018),

<https://www.facebook.com/alldocsLC/photos/pcb.900232936805469/900232796805483/?type=3&theater>.

⁶² See Exhibit D.

⁶³ This small sample is used for illustration. 1-800 believes a larger analysis of its order records would show this pattern is widespread.

⁶⁴ Transcript, Looking Ahead at 11.

⁶⁵ "And I think that there's a big regulatory issue that ought to be understood fully. . . . I think that it gets distorted by those within the industry. And I think that probing that kind of stuff, the competition advocacy with the FDA, where they understand that a brand specific prescription has adverse competitive consequences. I think is all very useful things." Transcript, Looking Ahead at 19.

millimeter difference in diameter. So we can't sell it. Probably not a clinical reason for that, but there may be.”⁶⁶

Protect consumer access to ocular telehealth technologies and business models.

1-800 also encourages the FTC to continue to use both its antitrust enforcement and competition policy tools to protect consumer access to ocular telehealth technologies and business models.⁶⁷ A growing number of providers now offer consumers the convenience of testing their vision and renewing either an eyeglass or contact lens prescription online. These services not only expand access and choice; telemedicine may advance patient health by providing contact lens wearers with targeted behavioral advice on healthy wear habits. Telemedicine can also provide consumers with a convenient and affordable way to change brands under the existing regulatory framework.⁶⁸

Although ophthalmologists have largely embraced online vision tests as a way to safely expand access and choice for patients, the AOA is working to prevent their more innovative rivals from providing this service by pushing rigid anticompetitive rules and regulations at the state level. 1-800 agrees with the FTC that consumers are best served if qualified vision care professionals are allowed to determine for themselves whether ocular telehealth services, including an online vision test, provide the appropriate level of care. 1-800 appreciates the FTC staff's thoughtful letter to Representative Paul Graves, State of Washington, House of Representatives,⁶⁹ and encourages staff to continue to monitor regulation and the potentially anticompetitive activity of state boards to block ocular telehealth, and to take appropriate action to allow innovation and consumer access to these services.

⁶⁶ Transcript, Competition in the Contact Lens Marketplace at 6–7.

⁶⁷ See 1-800 Ocular Telehealth Comment for a more detailed discussion of these issues.

⁶⁸ Alex Bargar, Director of Clinical Services at Simple Contacts stated, “And one of the things that we’ve heard is a recurring theme in this panel is that one of the largest, or the largest, risk factor associated with the usage of contact lenses is the behavior around how patients choose to use those lenses. Our platform allows us to provide targeted education and advice to those patients on a much more frequent basis than a patient could ever receive from just an annual in-person exam. We’re able to calibrate that and adjust it on the fly for what the patient needs down to the level of specificity of how frequently that patient wears their lenses. So yes, there are some things that they’re not getting with the online assessment. But there are some things that they’re getting that technology enables that they would never be able to get anywhere else, just from a practical standpoint. And I think that’s a really incredible development.” Transcript, Looking Ahead at 13.

⁶⁹ Letter from FTC Staff to the Hon. Paul Graves, State of Washington, House of Representatives (Feb, 9, 2017), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-washington-state-rep-paul-graves-regarding-ssb-5411/hb-1473/proposed_advocacy_comment_-_wa_eye_care_final_2-9-18.pdf.

IV. CONCLUSION

1-800 appreciates the opportunity to have participated in the Workshop and to submit these comments. 1-800 urges the FTC to complete its review of the CLR and finalize the Proposed Amendment. 1-800 also recommends that the FTC look beyond the CLR and use its full range of policy and enforcement tools to promote greater brand choice for contact lens consumers, and to protect ocular telehealth technologies and business models from protectionist legislation and anticompetitive market activity.

Respectfully submitted,

/s/ John Graham

John Graham
Chief Executive Officer
1-800 CONTACTS

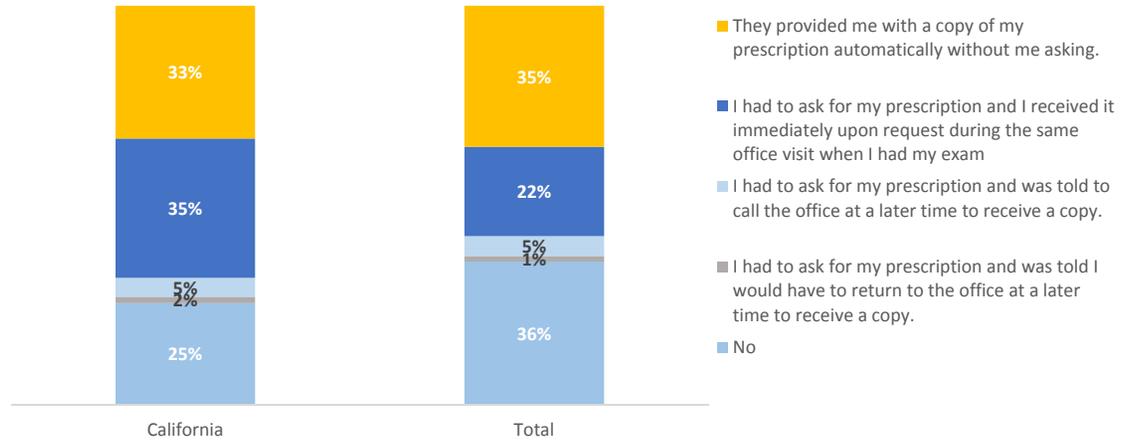
EXHIBIT A

CLR October 2015 Survey

Only 33% of California consumers were provided a copy of their prescription automatically (2% less than nationwide)

- 25% of California respondents did not receive a copy at all (11% better than nationwide)

Provided a Paper Copy of Your Prescription
(% of total respondents)



	Q13	Q14
California	63	47
Total	500	321

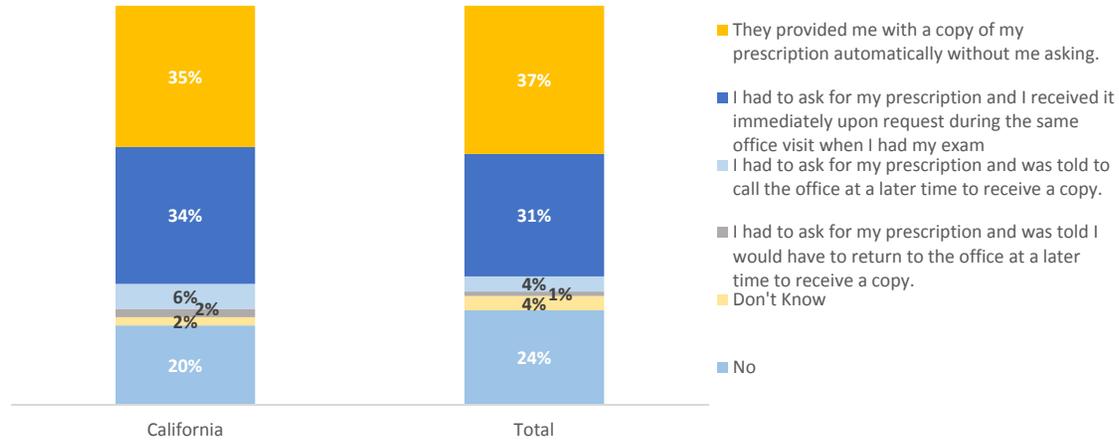
Q13. At your last exam, did the doctor provide you with a paper copy of your prescription? (All respondents n=500)

Q14. Which of the following best describes how you received an actual paper copy of your prescription? (All answering, n=321)

CLR January 2017 Survey

- Only 35% of California consumers were provided a copy of their prescription automatically (2% less than nationwide)
- 20% of California respondents did not receive a copy at all (4% better than nationwide)

Provided a Paper Copy of Your Prescription
(% of total respondents)



Q3. At your last exam, did the doctor provide you with a paper copy of your prescription? (All respondents n=1000)

Q4. Which of the following best describes how you received an actual paper copy of your prescription? (All answering, n=728)

CLR January 2017 Survey

	Q3	Q4
California	96	75
Total	1000	728

EXHIBIT B



Paul B. Donzis, M.D.

Cataract and Refractive Surgery
Diplomate, American Board of Ophthalmology

2222 Santa Monica Blvd., Suite 107
Santa Monica, CA 90403
Tel: 310-822-0022 Fax: 310-822-9636

April 6, 2018

To Whom It May Concern:

I have been asked to follow up on my prior comments regarding the health issues that are associated with contact lens wear in light of the discussion at the Federal Trade Commission's ("FTC's") March 7, 2018 Workshop on The Contact Lens Rule and the Evolving Contact Lens Marketplace. The discussion at the Workshop reinforced my prior comments to the FTC that the primary visual threatening complication of contact lens wear is microbial keratitis, and the primary risk factors for microbial keratitis are extended wear and poor hygiene. There are no studies reliably demonstrating that source of supply is a risk factor for microbial keratitis, and none of the studies discussed at the Workshop change my conclusion on this topic.

I would like to focus in this comment on two specific studies that were referenced in the "Contact Lens Health and Safety" panel discussion at the Workshop. First, I will address the impact, if any, of online sales of contact lenses on the incidence of serious ocular complications that was a subject of the recent article by Sorbara, et al.¹ Second, I will address the French Study that was referenced by Dr. Tarver.²

With regards to online sales, I agree with the comments of Dr. Chaum, who stated in his presentation that the "data clearly shows that open access through channels of large retailers, or online [purchase] really has no impact on the incidence of keratitis and complications."² Rather, the incidence of keratitis is closely tied to patient behavior. In fact Dr. Cope, in her initial presentation, noted that the risky contact lens behaviors such as sleeping in the lenses, napping in lenses, and topping off solutions occurred regardless of the point of purchase. The majority of patients in the 2014 and 2016 studies she referenced purchased their lenses from Eye Care Providers ("ECP").^{3,4} These studies

¹ Sorbara L., et al., Multicenter Testing of a Risk Assessment Survey for Soft Contact Lens Wearers With Adverse Events: A Contact Lens Assessment in Youth Study: *Eye & Contact Lens* 2018;44: 21–28.

² Sauer A., et al., Risk Factors for Contact Lens–Related Microbial Keratitis: A Case–Control Multicenter Study: *Eye & Contact Lens* 2016;42: 158–162.

² Transcript, Panel II, at 12, *available at* https://www.ftc.gov/system/files/documents/public_events/1285493/panel_ii_contact_lens_health_and_safety_issues.pdf

³ Cope J.R., et al., Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections —United States, 2014: *Morbidity and Mortality Weekly Report Weekly / Vol. 64 / No. 32* August 21, 2015.

⁴ Cope J.R., et al., Risk Behaviors for Contact Lens–Related Eye Infections Among Adults and Adolescents — United States, 2016: *August 18, 2017 / 66(32);841–845.*

show that only about 20% of these patients purchased their lenses online. Thus, purchasing lenses from the ECP clearly does not prevent risky behavior. Again, this is all consistent with the 2012 Stapleton study, which noted that the location of purchase had no significant correlation with the incidence of moderate and severe keratitis.⁵

It is with this background in mind that I turn to the comments of Dr. Lakkis, who brought up the point that online sales have been shown to be a risk factor in some studies. As I have previously noted, the earlier 2008 Stapleton study did identify online purchases as a potential risk factor but speculated that this may be due to “care attitudes and behavior.”⁶ Later Stapleton studies – namely the 2012 study referenced above – do not show any significant correlation.

The panelists also referenced a more recent study from Sorbara et al., referenced above. I agree with Dr. Chaum’s comment at the Workshop that this is a “weak” study, and I further agree with his comment that one must look at the body of evidence and not just a single study.⁶

I have several criticisms regarding the Sorbara study, which, in my opinion, is a flawed and biased study with regards to the issue of online sales. First, although the authors state specifically that “internet sales” are a risk factor, Table 2 has three categories for the point of purchase: (1) All other sources, (2) internet/phone sales, and (3) don’t know. Internet and phone are lumped together without any specific explanation as to the actual source of sale. For example, many ECP offices take telephone orders, and some have an online portal to order lenses. “All other sources” could apparently include purchase at a discount retailer such as Costco to purchase lenses without any interaction with an ECP. So it is unclear what specifically is the relevant “point of purchase” and if there is any educational communication with regards to contact lens care practices. To add further confusion, Table 4 in the article only has two categories for the point of purchase: “internet” and “all other sources.”

Second, even with the confusion as to the actual point of purchase, the Sorbara study makes no attempt to analyze the impact of the point of purchase on the behavioral elements of contact lens care that are *the actual risk factors* for complications. The authors only speculate and reach conclusory opinions. They state, “Perhaps, the lack of opportunity for repeated patient education contributes to internet purchase being a risk factor....”

Third, the authors misrepresent at least one important citation implying that they reach conclusions that they do not. For example, the authors state on the bottom of page 23

⁵ Stapleton F., et al., Risk Factors for Moderate and Severe Microbial Keratitis in Daily Wear Contact Lens Users: *Ophthalmology* 2012;119:1516–1521.

⁶ Stapleton F., et al., The Incidence of Contact Lens–Related Microbial Keratitis in Australia: *Ophthalmology* 2008;115:1655–1662.

⁶ Transcript, Panel II, at 18, *available at* https://www.ftc.gov/system/files/documents/public_events/1285493/panel_ii_contact_lens_health_and_safety_issues.pdf.

that “Young, et al.⁷ found that unregulated and internet purchase was linked to cases of MK [microbial keratitis].” The way this is written by Sorbara, et al. implies that both unregulated *as well as* internet purchase is a risk factor for MK. But the Young study – of which Dr. Lakkis was an author – was an analysis of cases where there was no prescription for the lenses. These were mainly plano cosmetic lenses obtained over the counter, or, in one case, in a “trash bin.” Young noted that “The main risk factors that were noted in most case reports were absence of lens fitting and absence of education regarding usage.” Young went on to state that “Had these patients received fitting and education from an eye care practitioner, it seems less likely that the complications would have occurred.” Importantly, this article involved lenses that were neither fitted nor prescribed. Sorbara attempts to imply that the online purchase of lenses that have been fitted and prescribed by an Eye Care Provider (“ECP”) is the same thing. This misrepresentation shows clear bias by the authors against the regulated online purchase of contact lenses.

Fourth, the authors noted in their very last sentence that internet purchase was a factor that was “confounded with EW [extended wear]”. Not unexpectedly, the authors noted that their study “also agrees with the ophthalmic literature in finding that EW increased the risk of S&S [serious and significant] events by approximately four times.” If internet sales are confounded with this major risk factor, it is difficult, if not impossible, to actually determine the true effect, if any, of internet purchase on complications related to contact lens wear separate and apart from the risk of extended wear. It would be useful to note the actual type of lens (extended v. daily) that was purchased by “internet/phone” compared to “All other sources” for a proper analysis. Again, this relates to behavior patterns that are known risks.

Fifth, as noted by Dr. Chaum, there were other inexplicable factors such as lens purchase by a parent or not sharing a bedroom that were associated with an increased risk of complications, further calling into question the associations made in the study.

Lastly, with regards to the speculation by Sorbara that online purchasers have a “lack of opportunity” for repeated education, I have two criticisms. First, patients who purchase replacement lenses online still have the “opportunity” to interact with a provider if they so choose. Second, studies have shown that the most important education actually occurs during the fitting process. In prior communications with the FTC I have referenced the 2016 study by Chalmers, et al.⁷ That study noted that “SCL [soft contact lens] wearers who purchased lenses on the internet or telephone were no more likely than wearers who purchased in person at an ECP or at a retail store to report known risk behaviors with their SCLs.” That study also concluded that “...training from the ECP on best practices for SCL use occurs primarily when the patient first begins to use lenses....” In other words, it is the initial education and fitting process that is the most important factor in reducing risky contact lens behaviors. As a point of interest, Dr. Chalmers is listed as

⁷ Young G., et al., Review of Complications Associated With Contact Lenses From Unregulated Sources of Supply: Eye & Contact Lens 2014;40: 58–64.

⁷ Chalmers, RL., et al., Is purchasing lenses from the prescriber associated with better habits among soft contact lens wearers?: Cont. Lens Anterior Eye. 2016 Dec; 39(6):435-441.

one of the co-authors of the Sorbara study.

In summary, the Sorbara study, while containing useful information that validates extended wear as a risk factor, is a weak study with regards to determining any differences in risk or behavior in contact lens patients who purchase their contact lenses from a reputable online source after having been fitted and given a prescription for those lenses from their ECP.

In conclusion with regards to this issue, I once more would like to reiterate that the risk of microbial keratitis remains the primary serious health risk associated with contact lens wear. Overall the risk of microbial keratitis remains small and has not changed significantly over time despite the advent of online sales. As noted by the panel, the risk factors for microbial keratitis are well-established and well-documented over decades of research and relate to extended wear of lenses and behavioral factors such as poor hygiene, topping off solutions and not replacing cases or lenses on a timely basis.

Another study I would like to discuss was referenced by panelist Dr. Tarver. This study, by Sauer, et al. and the French Study Group for Contact Lens-Related Microbial Keratitis, was a large multicenter case control study. Over 1000 patients were enrolled and the study sought to determine risk factors for CL related microbial keratitis. Patients were given a detailed questionnaire with over 52 items, and Table 2 in the study categorizes CL-related MK risk factors related to the patients (including factors such as yearly follow up and handling education), factors related to hygiene (such as hand washing, renewal of case and disinfecting solution every 3 months) and factors related to the CL itself (such as the type of lens material, recommended wearing schedule, or overnight wear). They even included a category called “screen workers” that evaluated factors such as smoking, recent plane trip, and working in an air-conditioned environment. The study does not look at sales channel as a variable.

A simple univariate analysis did find significance for ophthalmologist versus optician initial fitting as well as education and annual follow-up. The authors made the recommendation that ECPs should be vigilant in reinforcing hygiene messages to all wearers throughout their follow-up. But the most important time for education is during the initial fitting period. This study confirmed this finding when a multivariate analysis was performed (which better determines cause and effect). The authors found that the significant protective factor was the initial CL adaptation (fitting) by an ophthalmologist (there are no optometrists in France) compared to an optician. The initial medical supervision “decreased the risk of CL-related MK (fitting by an ophthalmologist, OR=0.73)” (see Table 3 of the study).

This data is consistent with the 2016 Chalmers’ study that found an association between an initial fitting by an ECP and proper CL behavior by patients, and the Young article that noted risk of contact lens wear wholly outside the purview of an ECP. However, it should be noted that the Sauer, et al. study does not speak to sales channels or the online purchase of lenses. Therefore, it should not be construed to comment in any way the effect of internet purchase for properly fitted and prescribed lenses.

Respectfully Submitted,



Paul B. Donzis, M.D., M.B.A., Esq.
Associate Clinical Professor of Ophthalmology
Stein Eye Institute, UCLA School of Medicine

EXHIBIT C

ゴルフ用品 自転車 フィットネス器具
コンタクトレンズ

Bicycle Fitness Equipment Glasses / Hearing Aid Contact Lenses







ボヤけた視界に乱
毎日が新品レンズだ

クリアな
いつもの

Medalist® Medalist®
ボシュロム メダリスト ワンデープラス

Prism Ballast Design Prism Ballast Design

1-DAY ACUVUE MOIST
FOR ASTIGMATISM
LACREON™
30 Lenses

見本
1日1枚
1週間30枚

① 初めての買、おめでとう!
1Day ACUVUE Moist TC
6ヶ月分と送料等 36,960円
送料1200円
1ヶ月分と送料等 11,520円
送料480円

BAUSCH + LOMB
Medalist
ボシュロム メダリスト ワンデープラス
TORIC (乱視用)
30 LENSES

BAUSCH + LOMB
Medalist
ボシュロム メダリスト ワンデープラス
TORIC (乱視用)
30 LENSES

BAUSCH + LOMB
Medalist
ボシュロム メダリスト ワンデープラス
TORIC (乱視用)
30 LENSES

① 初めての買、おめでとう!
Medalist 1day TC
6ヶ月分と送料等 36,960円
送料1200円
1ヶ月分と送料等 11,520円
送料480円

1Day
超特価
3,180円
2,980円

ご購入カード

1Day
BAUSCH + LOMB
超特価
3,180円
2,980円

ご購入カード

1Day
Alcon
2,980円
2,780円



Fine
見本
ACUVUE
QASYS
HYDRACLEAR PLUS
見本
ACUVUE
紫外線対策
見本
CooperVision
AIR OPTIX
13,990円





EXHIBIT D

Prescribing Patterns

Miles Apart	Pract #1	City	State	Zip	Total Order Count	Vistakon %	Alcon %	Cooper %	BL %	Pract #2	City	State	Zip	Total Order Count	Vistakon %	Alcon %	Cooper %	BL %
0.129	XXX	Lawrence Township	NJ	08648	191	83	7	3	5	XXX	Lawrence	NJ	08648	68	14	70	5	8
0.192	XXX	Butler	PA	16001	120	67	9	15	8	XXX	Butler	PA	16001	143	6	88	4	0
0.213	XXX	Clinton Township	MI	48038	103	90	4	2	1	XXX	Clinton Township	MI	48038	66	15	75	9	0
0.223	XXX	E. Amhersts	NY	14051	50	78	6	12	4	XXX	Williamsville	NY	14221	64	15	81	1	1
0.354	XXX	Toccoa	GA	30577	52	75	15	0	9	XXX	Toccoa	GA	30577	275	17	77	2	2
0.808	XXX	Manchester	NH	03103	132	76	14	4	4	XXX	Manchester	NH	03103	81	22	76	1	0
1.267	XXX	Oxnard	CA	93030	61	78	16	4	0	XXX	Oxnard	CA	93033	121	27	66	3	3
1.513	XXX	Seattle	WA	98115	115	77	9	9	3	XXX	Seattle	WA	98115	234	13	77	5	2
1.575	XXX	Placerville	CA	95667	60	75	6	6	11	XXX	Placerville	CA	95667	78	10	66	10	12
1.663	XXX	Townside	HI	96813	57	87	5	1	5	XXX	Honolulu	HI	96814	105	17	76	0	5
1.959	XXX	Saint Louis	MO	63117	272	86	6	4	1	XXX	Saint Louis	MO	63141	144	14	66	16	2
2.132	XXX	Reading	PA	19606	100	76	9	15	0	XXX	Reading	PA	19602	175	18	73	7	0
2.167	XXX	York	PA	17403	134	75	8	8	7	XXX	York	PA	17402	96	12	75	0	8
2.402	XXX	Midvale	UT	84047	137	82	10	5	1	XXX	Sandy	UT	84093	83	18	71	4	3
2.500	XXX	Yukon	OK	73099	84	69	22	1	7	XXX	Yukon	OK	73099	68	5	77	1	14
2.577	XXX	TAMPA	FL	33603	89	77	17	4	0	XXX	Tampa	FL	33614	59	23	67	6	1
2.657	XXX	Andover	MA	01810	91	74	16	7	1	XXX	Lawrence	MA	01840	183	12	66	3	2
2.685	XXX	Wallingford	CT	06492	50	78	18	2	2	XXX	Meriden	CT	06450	76	18	69	10	1
2.737	XXX	Arlington	TX	76010	94	80	12	2	4	XXX	Arlington	TX	76018	123	9	88	1	0
3.224	XXX	Greenville	SC	29615	122	71	22	5	0	XXX	Greer	SC	29650	144	6	66	1	25
3.444	XXX	Houston	TX	77008	83	85	9	3	1	XXX	Houston	TX	77076	78	8	83	0	7
3.471	XXX	Fairfield	OH	45011	78	75	11	10	2	XXX	Fairfield	OH	45014	57	1	73	10	14
3.560	XXX	West Covina	CA	91790	86	86	11	2	0	XXX	Covina	CA	91723	108	18	74	0	7
3.624	XXX	Los Angeles	CA	90006	143	88	2	1	6	XXX	Los Angeles	CA	90008	85	20	77	2	0
3.647	XXX	Dallas	TX	75231	423	88	6	2	1	XXX	Dallas	TX	75232	55	27	67	3	1
3.677	XXX	Cupertino	CA	95014	89	91	7	1	0	XXX	Sunnyvale	CA	94087	55	25	74	0	0
4.302	XXX	Naugatuck	CT	06770	237	75	12	5	5	XXX	Waterbury	CT	06708	89	11	66	15	6
4.315	XXX	Bloomfield	NJ	07003	229	89	6	3	0	XXX	Orange	NJ	07050	61	9	75	4	9
4.475	XXX	Lake Worth	FL	33461	74	74	20	1	4	XXX	West Palm Beach	FL	33405	158	18	75	3	1

Prescribing Patterns

Miles Apart	Pract #1	City	State	Zip	Total Order Count	Vistakon %	Alcon %	Cooper %	BL %	Pract #2	City	State	Zip	Total Order Count	Vistakon %	Alcon %	Cooper %	BL %
4.719	XXX	Ann Arbor	MI	48103	180	78	9	8	3	XXX	Ann Arbor	MI	48105	255	15	69	11	4
4.773	XXX	Anniston	AL	36201	134	85	9	0	1	XXX	Oxford	AL	36203	104	22	67	4	5
4.889	XXX	Sacramento	CA	95819	67	71	19	1	7	XXX	Sacramento	CA	95823	201	21	74	2	0
4.896	XXX	Encino	CA	91316	135	85	4	9	0	XXX	Panorama City	CA	91402	108	6	73	20	0
5.028	XXX	Anaheim	CA	92807	63	92	4	0	3	XXX	Orange	CA	92867	51	1	86	5	5
5.077	XXX	Decatur	GA	30030	174	77	5	15	1	XXX	Atlanta	GA	30308	607	24	67	4	3
5.163	XXX	Bourne	MA	02532	66	78	6	15	0	XXX	Cohasset	MA	02025	52	23	69	3	3
5.877	XXX	Syosset	NY	11791	176	75	17	5	1	XXX	Huntington	NY	11743	54	24	70	3	1
6.030	XXX	Willingboro	NJ	08046	87	90	8	0	1	XXX	Lumberton	NJ	08048	130	15	72	7	4
6.088	XXX	Washington	DC	20500	366	93	0	4	0	XXX	Falls Church	VA	22042	74	13	71	4	10
6.127	XXX	Saint Augustine	FL	32086	291	74	19	2	3	XXX	Saint Augustine	FL	32084	105	22	67	6	1
6.159	XXX	Indianapolis	IN	46254	62	82	9	1	6	XXX	Indianapolis	IN	46208	88	29	70	0	0
6.264	XXX	Buffalo Grove	IL	60089	89	70	25	1	2	XXX	Long Grove	IL	60047	117	20	73	5	0
6.491	XXX	Pittsburgh	PA	15224	53	81	3	11	3	XXX	Pittsburgh	PA	15235	187	21	70	6	1
6.513	XXX	Potomac	MD	20854	52	92	3	3	0	XXX	Gaithersburg	MD	20877	86	2	97	0	0
6.535	XXX	Ridgewood	NJ	07450	98	93	4	2	0	XXX	Cresskill	NJ	07626	50	10	78	12	0
6.537	XXX	Orlando	FL	32803	132	74	12	12	0	XXX	Orlando	FL	32835	97	20	67	10	1
6.551	XXX	Scituate	MA	02066	150	83	12	4	0	XXX	Norwell	MA	02061	110	24	67	4	3
6.598	XXX	West Hills	CA	91307	182	76	18	3	1	XXX	Westlake Village	CA	91361	123	19	74	5	0
6.723	XXX	Norcross	GA	30092	219	70	15	10	4	XXX	Alpharetta	GA	30005	284	25	66	6	1
6.733	XXX	Waipahu	HI	96797	64	68	25	6	0	XXX	Kapolei	HI	96707	92	20	66	3	9
6.748	XXX	Fishkill	NY	12524	1338	67	16	9	5	XXX	Marlboro	NY	12542	156	10	69	14	5
7.456	XXX	Voorhees	NJ	08043	113	95	2	1	0	XXX	Pennsauken	NJ	08109	69	17	71	0	11
7.575	XXX	Des Moines	WA	98198	67	80	14	2	1	XXX	Federal Way	WA	98023	65	18	69	6	4
7.627	XXX	Manchester	CT	06042	152	73	10	11	3	XXX	East Windsor	CT	06088	56	3	75	21	0
7.707	XXX	Long Beach	CA	90804	75	86	8	4	1	XXX	Carson	CA	90746	209	17	69	11	1
7.910	XXX	Houston	TX	77059	193	73	19	5	1	XXX	Pearland	TX	77581	188	14	72	12	1
7.919	XXX	Lemon Grove	CA	91945	52	84	9	5	0	XXX	Chula Vista	CA	91910	58	17	74	6	1
8.386	XXX	Lakewood	CO	80227	113	67	18	8	5	XXX	Highlands Ranch	CO	80129	71	14	70	11	4

Prescribing Patterns

Miles Apart	Pract #1	City	State	Zip	Total Order Count	Vistakon %	Alcon %	Cooper %	BL %	Pract #2	City	State	Zip	Total Order Count	Vistakon %	Alcon %	Cooper %	BL %
8.916	XXX	Tinker AFB	OK	73145	264	75	14	6	3	XXX	Choctaw	OK	73020	71	5	78	9	5
8.956	XXX	China Grove	NC	28023	75	86	12	1	0	XXX	Salisbury	NC	28146	152	7	80	9	1
9.013	XXX	River Falls	WI	54022	75	68	17	13	1	XXX	Hudson	WI	54016	130	21	67	8	1
9.098	XXX	Flushing	NY	11355	338	92	4	1	0	XXX	Brooklyn	NY	11236	117	25	66	5	1
9.395	XXX	Asheville	NC	28801	70	80	11	5	2	XXX	Fairview	NC	28730	53	18	71	5	3
9.436	XXX	Washington	PA	15301	162	71	17	2	8	XXX	McMurray	PA	15317	188	14	76	2	7
9.475	XXX	Worth	IL	60482	108	84	3	6	5	XXX	Harvey	IL	60426	65	26	69	4	0
9.501	XXX	Milwaukee	WI	53209	125	67	21	6	3	XXX	Greenfield	WI	53228	94	10	67	12	9
9.571	XXX	Stanhope	NJ	07874	95	78	12	4	4	XXX	SPARTA	NJ	07871	68	27	72	0	0
9.631	XXX	Tomball	TX	77375	290	71	15	8	4	XXX	Magnolia	TX	77354	324	23	72	1	1
9.663	XXX	San Antonio	TX	78205	430	70	10	13	5	XXX	San Antonio	TX	78245	94	9	84	4	2
9.670	XXX	Toms River	NJ	08755	113	90	4	1	3	XXX	Jackson	NJ	08527	291	7	66	17	5
9.813	XXX	Hernando	MS	38632	121	71	18	9	1	XXX	Coldwater	MS	38618	165	6	78	9	6
9.818	XXX	Chicago	IL	60640	98	83	7	1	8	XXX	Wilmette	IL	60091	143	25	70	3	0
9.990	XXX	Raleigh	NC	27615	61	78	9	3	8	XXX	Raleigh	NC	27603	73	23	73	1	1