January 30, 2017

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, Inc. ("1-800") respectfully submits these comments in response to the Federal Trade Commission's ("Commission") request for comments on proposed amendments to the Contact Lens Rule, ("CLR" or "Rule")[1] and other issues raised by the Agency's Notice of Proposed Rulemaking ("NPRM").[2] These comments build on the evidence and remarks that 1-800 submitted on October 26, 2015 in response to the Commission's initial request for comments on its ten-year review of the CLR.[3]

Established in 1995, 1-800 is a recognized innovator in the retail distribution of contact lenses. 1-800 began as a contact lens retailer taking orders placed through its easy-to-remember toll-free number. 1-800 built a reputation for providing customers with excellent service and competitive prices. Today, 1-800 offers its customers the convenience of ordering lenses 24/7 from any location through its website, smartphone application, and toll-free number.

As the largest seller of contact lenses in the United States, 1-800 has significant experience with the Fairness to Contact Lens Consumers Act ("FCLCA" or "Act") and CLR. Since 2004, 1-800 has filled over 48 million orders; no organization has more experience with the history or day-to-day operation of the FCLCA and CLR.

1-800 appreciates the opportunity to comment on the NPRM. 1-800 supports the Commission's conclusion that amendments to bolster prescription portability are necessary to achieve the goals of the FCLCA to advance competition and consumer choice in the contact lens marketplace. 1-800 urges the Commission to adopt the proposed amendment to require prescribers to obtain a patient's signed acknowledgment of prescription release and to retain a record of the acknowledgment for at least three years, to be made available to the Commission for inspection upon request. For the small percentage of cases where a contact lens fitting is

[1] 16 C.F.R. § 315.

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

[3] 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), *available at* https://www.ftc.gov/policy/public-comments/2015/10/26/comment-00568 ("1-800 October 2015 Comments").

completed through some means of communication outside the prescriber's office (such as by phone call), the prescriber is currently required to release the prescription to the patient when the fitting is completed, and the proposed acknowledgment form could be provided in the same manner. When the fitting is completed through a remote communication, 1-800 recommends that the Commission permit prescribers to provide both the proposed acknowledgment form and the prescription to the patient by digital images sent via email or text, or, if necessary, by facsimile or mail. The prescriber may satisfy the recordkeeping requirements of the proposed amendment by simply noting the form of the prescription transmission (email, text, facsimile, or mail) on the acknowledgement form, signing the acknowledgement form, maintaining the form, and retaining proof of that transmission. Prescribers should not be permitted to sell contact lenses to patients before providing them with a prescription and the proposed acknowledgment form.

1-800 agrees with the Commission that the FCLCA requires prescribers to provide duplicate copies of prescriptions to patients and to their designated agents upon request and urges the Commission to impose a reasonable time frame of five business days for prescribers to respond to requests from designated agents.

Regarding the Commission's initial determination that a patient or prescriber may present a prescription to a seller directly, by facsimile, or by use of a patient portal, 1-800 is concerned that privacy restrictions will prevent sellers from accessing a patient's portal account, and there is no established standard for communication between patient portals and sellers. 1-800 encourages the development of such capabilities in patient portals, but without an industry standard for communication with portals, it will be difficult for sellers to establish efficient internal procedures to collect records from thousands of prescribers using different software and platforms. 1-800 thus requests that to the extent prescribers use portals to provide sellers with prescriptions, the portal should have the ability to send the prescription to the seller directly by email, text, or facsimile, and a seller should not be required to develop direct communication links to the portal.

1-800 encourages patient access to medical records through portals, as well as prescriber use of portals to send copies of prescriptions to sellers. However, 1-800 recommends against permitting prescribers to meet their obligation to automatically release prescriptions to patients by simply posting prescriptions to a portal. Posting a prescription may provide a patient with access to the prescription, but access is not automatic. Survey evidence shows that while use of patient portals is growing, adoption and use are still very limited. Only 30% of patients were offered access to a patient portal at their last eye exam, and just 29% of patients who are provided with access to a patient portal have used the service. Moreover, patient portals do not necessarily have printing, email, facsimile, or texting capabilities. Having a patient sign an acknowledgement form after receiving a prescription will increase consumers' understanding of their rights, increase prescription portability, and provide consumers with the ability to immediately use a prescription, unrestricted by the capabilities of the portals that are adopted by their prescribers. Initial release solely to a portal would undercut the power of the proposed signed acknowledgement and recordkeeping amendment to enhance enforcement and would provide prescribers with an easy way to evade their obligations and frustrate the intent of the Rule.

1-800 supports the Commission's decision to reject recommendations to impose additional hurdles on the verification process or restrictions on the quantity of lenses consumers

can purchase based on pretextual health and safety claims. We also support the Commission's continued endorsement of automated phone systems as a lawful method for sellers to transmit verification requests to prescribers. Our detailed comments and supporting evidence follow.

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I. INTRODUCTION

In 2003, Congress passed the FCLCA to advance consumer choice and competition in the contact lens marketplace.[4] It mandates automatic release of contact lens prescriptions to patients on a nationwide basis and creates a uniform national standard for the verification of orders placed with third-party sellers. Congress directed the Commission to promulgate rules to implement the Act and to enforce those rules under its authority to prohibit unfair and deceptive acts or practices.[5] The Commission published the CLR in 2004.[6] On September 3, 2015, as part of its regular ten-year regulatory review process, the Commission published a notice in the Federal Register seeking comments on the CLR.[7] The Commission asked for comments on several broad questions, including the continuing need for the Rule, the costs and benefits of the Rule for consumers, and proposed modifications to the Rule. The Commission also asked commenters to provide an evidentiary basis for their comments and recommendations.

The Commission received over 660 comments from a broad array of stakeholders, including prescribers and their trade associations, contact lens manufacturers, retailers, and consumers. Many prescribers and their trade associations, along with contact lens manufacturers, claimed, without evidentiary support, that the current Rule puts consumer health and safety at risk. As 1-800 detailed in its October 2015 comments, prescribers and manufacturers have a long history of collaborating to restrict competition from alternative retail channels.[8] Manufacturers compete in part by appealing to prescribers, who dictate brand choice to consumers. For that reason, manufacturers have historically aligned with prescribers to restrict competition from alternative retail channels, starting with anticompetitive collusion in the 1990s that led to settlements with 32 state attorneys general and continuing to the resale price maintenance policies of recent years (often known as "unilateral pricing policies" or "UPP").[9] Refusing to reverse a lower court decision allowing a Utah state law banning these policies to take effect, the Tenth Circuit recently cited to "the industry's anticompetitive leanings" based on

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[4] Legislation was essential because, unlike most other healthcare providers, contact lens prescribers sell and profit from what they prescribe. As a result, prescribers can and do use their control over prescriptions to keep patients from shopping around for lenses, restricting competition in the contact lens marketplace. The FCLCA was passed to break that status quo. For a more detailed discussion of the history and competitive dynamics of the contact lens market, see 1-800 October 2015 Comments at 1–11.

[5] 15 U.S.C. § 7608.

[6] 16 C.F.R. § 315.

[7] 80 Fed. Reg. 5372 (Sept. 3, 2015), *available at* https://www.ftc.gov/policy/federal-register-notices/16-cfr-part-315-contact-lens-rule-request-comment.

[8] 1-800 October 2015 Comments at 1–11.

[9] The free-rider arguments that sometimes justify resale price maintenance policies on efficiency grounds do not apply here. Prescribers are paid separately for time spent on patient education and training through an exam fee that compensates them for time spent on these activities. There is no need to restrict competition in the retail sale of lenses to encourage that investment. *See* Robert Atkinson, President and Founder, Information Technology an Innovation Foundation (ITIF), Why UPP Pricing in the Contact Lens Industry Hurts Consumers and Competition, Prepared Statement to the U.S. Senator Committee on Judiciary, Subcommittee on Antitrust, Competition Policy and Consumer Rights at 6 (July 31, 2014), *available at* http://www2.itif.org/2014-senate-contact-lens.pdf?_ga=1.102515913.956727111.1440692670.

the fact that prescribers sell what they prescribe.[10] Most recently, in the face of antitrust scrutiny and a state law banning the practice, two manufacturers have backed away from UPP. Effective April 13, 2016, Johnson & Johnson Vision Care, Inc. ("J&J") discontinued their unilateral pricing policy, with Alcon following suit on December 23, 2016.[11] Some manufacturers have, however, replaced UPP with discriminatory rebates that are available only to those consumers who purchase lenses directly from a prescriber.[12]

The recommendations that prescribers and manufacturers submitted to the Commission follow this familiar pattern. These commenters took issue with nearly every provision of the Rule that facilitates competition from alternative retail channels under the guise of protecting consumer health and safety. For example, the Contact Lens Association of Ophthalmologists ("CLAO") claimed that passive verification of retail orders prevents prescribers from "addressing risky wear and care practices."[13] The American Optometric Association ("AOA") recommended that the Commission amend the Rule to allow prescribers to block the passive verification of *an accurate order based on a valid prescription* by raising "questions" or "concerns" (that the AOA never explains or defines) with a seller.[14] In the very same comment, the AOA also recommended that prescription requests by designated agents be discouraged because "the verification process also contains safeguards that requests for prescriptions do not."[15]

Manufacturers fell in line with prescribers. J&J recommended that the Commission require that prescribers confirm receipt of a verification request in order to trigger the eight-business-hour verification period, which would allow prescribers to halt verification of orders by simply ignoring requests.[16] J&J also suggested that quantity limits would benefit consumers because tearing or losing lenses would create "yet another opportunity for consumers [to talk to their prescriber] to ask questions [or] share health and other issues they may be encountering . . . ."[17]

Prescribers and manufacturers provided no credible evidence, however, to support their allegations that the current Rule or the advent of online sales had caused any harm to consumer health or safety.

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[10] *Johnson & Johnson Vision Care v. Reyes*, 2:15-CV-00257 (10th Cir. Dec. 19, 2016) at 2–3, *available at* https://www.ca10.uscourts.gov/opinions/15/15-4071.pdf ("*J&J v. Reyes*") (affirming district court order denying the manufacturers' motion for a preliminary injunction to prevent the law from taking effect).

[11] *Alcon Ends UPP Program and Will Focus on its 'Innovative Partnerships' to Support ECPs*, VISION MONDAY (Dec. 28, 2016), *available at* http://www.visionmonday.com/latest-news/article/alcon-ends-upp-program-and-will-focus-on-its-innovative-partnerships-to-support-ecps-1/.

[12] *See, e.g.*, *Johnson & Johnson Vision Care Drops Unilateral Pricing Policy for CLs*, VISION MONDAY (April 16, 2016), *available at* http://www.visionmonday.com/latest-news/article/johnson-and-johnson-vision-care-drops-unilateral-pricing-policy-for-cls-1/.

[13] CLAO (Comment #572) at 2.

[14] AOA (Comment #644) at 11.

[15] *Id.* at 13.

[16] J&J (Comment #582) at 12.

[17] *Id*. at 13.

1-800, by contrast, directed the Commission's attention towards the importance of bolstering prescription portability. The Rule requires that prescribers (1) automatically provide patients with a copy of their contact lens prescription at the end of the fitting process (the "automatic release" requirement) and (2) provide a duplicate copy to patients or designated agents upon request. 1-800 provided evidence that prescribers, on a widespread basis, were ignoring both obligations. 1-800 recommended steps to improve compliance, including amending the Rule to add a signed acknowledgment and recordkeeping requirement for prescription release to patients and a fixed time limit for prescribers to respond to prescription requests from designated agents. Other commenters, including consumer groups, online sellers, state legislators, as well as certain prescriber organizations, also urged the Commission to take steps to expand prescription portability.[18]

1-800 also defended the use of automated phone systems, explaining that its Human Initiated Voice Response ("HUVR") system is easy to understand for prescribers and the most efficient way for 1-800 to comply with the sheer number of verification requests it places each day.[19]

On December 7, 2016, the Commission issued its NPRM.[20] Based on a detailed review of the comments and evidence submitted, the Commission found no evidence that the Rule posed a risk to patient health:

> Commenters did not provide sufficient reliable empirical evidence that the current Rule leads to the increased acquisition of contact lenses without a valid prescription or increased incidence of contact lens-related eye disease or adverse eye conditions. Furthermore, despite commenters' concerns about online or mail order sales of contact lenses, the Commission has not seen reliable empirical evidence to support a finding that such sales are contributing to an increased incidence, or increase risk, of contact lens-related eye problems. In addition, the particular risks associated with contact lens use (or overuse) were previously considered by Congress and the Commission during the passage of the Act and the implementation of the Rule. The current rulemaking record does not provide any basis to disrupt this original analysis.[21]

Accordingly, the Commission rejected proposals to restrict the passive verification option and impose quantity restrictions or other limits on consumer choice and competition. The Commission also refused to prohibit sellers from using compliant automated phone systems to

[18] Consumer Union (Comment #677), Lens.com (Comment #614), Warby Parker (Comment #593), Rhode Island State Representative Kennedy (Comment #536), Utah State Senator Bramble (Comment #576), Arizona State Representative Carter (Comment #545), National Association of Optometrists and Opticians (Comment #549), Opternative (Comment #648), LD Vision Group (Comment #544).

[19] 1-800 October 2015 Comments at 20.

[20] NPRM at 88530.

[21] *Id.*

verify orders or to impose restrictions on the use of such systems beyond adhering to the Rule's current requirements.[22]

The Commission was, however, persuaded that steps were necessary to bolster prescription portability. Based on the rulemaking record, it concluded that steps to improve prescriber compliance with the automatic release requirement would further the goals of the Act and benefit consumers. In particular, the Commission concluded that:

> [T]he overall weight of the evidence in the rulemaking record—including the surveys, the high number of verifications, the ongoing pattern of consumer complaints and anecdotal reports, and the industry's long history of failing to provide prescriptions to patients, even when obligated by state law—indicates that compliance with the automatic prescription release provision could be substantially improved.[23]

After reviewing various proposals, the Commission has proposed a signed acknowledgment and recordkeeping requirement. The Commission proposed amending § 315.3 to add new sections (c) (1)–(3), which would require that, after completing a contact lens fitting and providing a patient with a copy of her prescription, the prescriber "shall request that the contact lens patient acknowledge receipt of the contact lens prescription by signing an acknowledgment form entitled, 'Patient Receipt of Contact Lens Prescription.'"[24] The simple acknowledgment form will read as follows:

> **My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice.[25]**

The form must also include the patient's name, signature, and the date executed. The prescriber may include the letterhead or address for her practice, but no additional information may be included on the form. If, for some reason, the patient declines to sign, the prescriber must note on the form that the patient refused to sign and the prescriber shall sign the form herself to confirm it was offered to the patient. Importantly, the amendment will require prescribers to maintain the signed acknowledgment for at least three years and to make the records available for inspection by the Commission. The acknowledgment form may be presented to the patient and retained by the prescriber in either paper or electronic form.[26]

The Commission also clarified prescriber obligations with regard to providing duplicate copies of prescriptions to patients and their designated agents. The Commission explained that the Act and Rule require prescribers to provide such copies to patients and designated agents upon request.[27] Regarding designated agents, the Commission declined to follow the AOA's

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[22] *Id.* at 88541.

[23] *Id.* at 88532.

[24] *Id.* at 88535.

[25] *Id*.

[26] *Id*.

[27] *Id*. at 88536.

suggestion that "requests for copies of a prescription by a duly authorized seller be discouraged."[28] The Commission concluded that the "plain language of the Act and the Rule provide for this method of acquiring a prescription" and that it was no more burdensome for a prescriber to provide a seller with a copy of a prescription than it was to verify an order.[29]

The Commission nonetheless recognized that although the Act and Rule require a prescriber to provide a duplicate copy of a patient's prescription to an authorized seller upon request, both are silent on the timing for a response. The Commission determined that it did not have sufficient evidence in the rulemaking record to propose a specific time frame for response, and asked for additional comments on (1) the costs and benefits of imposing a timeframe and (2) the appropriate amount of time for a prescriber to respond.[30] The Commission also requested comments on whether prescribers should be permitted to comply with their obligations to release prescriptions to patients and sellers by providing access to a portal.

Based on its history and experience in the contact lens marketplace, 1-800 largely supports the Commission's analysis of the rulemaking record. 1-800 agrees that proposals to restrict the passive verification option or to impose quantity limits on consumers will restrict choice and competition without a legitimate justification. There has never been any evidence that the FCLCA or CLR put consumer health and safety at risk. Indeed, to the extent the Act and the Rule make contact lenses more affordable to purchase and more convenient to obtain, they promote patient health.

1-800 also supports the Commission's determination that reform should focus on expanding consumer choice and competition by bolstering prescription portability. Towards that end, 1-800 strongly favors the Commission's proposal for a signed acknowledgment of prescription release. We also endorse the Commission's determination that the current Rule requires prescribers to release duplicate copies of prescriptions to patients and designated agents, and urge the Commission to impose a reasonable time frame of five business days for prescribers to respond to requests from designated agents.

With regard to patient portals, 1-800 encourages patient access to medical records through portals, as well as prescriber use of portals to send copies of prescriptions to sellers. However, 1-800 requests that to the extent prescribers use portals to provide sellers with prescriptions, their portal should have the ability to send the prescription to the seller directly by email, text, or facsimile, and a seller should not be required to develop direct communication links to the portal.

With regard to automatic release to patients, as discussed in detail below, even when offered access to a prescriber portal, patient use is very limited. Consequently, allowing prescribers to satisfy their obligation to automatically release prescriptions by merely offering patients access to a portal would provide prescribers with an easy way to evade their obligations and frustrate the intent of the Rule. Consequently, 1-800 recommends that the Commission not permit prescribers to comply with their obligation to automatically release prescriptions after a contact lens fitting by solely providing access to a portal.

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[28] *Id.* at 88537.

[29] *Id.*

[30] *Id.*

II. THE COMMISSION SHOULD AMEND THE RULE TO REQUIRE A SIGNED ACKNOWLEDGMENT OF PRESCRIPTION RELEASE

A. The Commission Correctly Concluded that Prescriber Compliance Rates Must Improve

As the Commission acknowledged in the NPRM, there is room for "substantial improvement" with prescription release rates.[31] Prescriber compliance today, more than ten years after the CLR was promulgated, is still extremely low. A recent survey of contact lens consumers (conducted during the week of December 12, 2016) shows that only 37% of patients are automatically provided with a copy of their contact lens prescription.[32] The results from this survey are broadly consistent with prior survey evidence submitted by 1-800 with its October 2015 comment,[33] which showed automatic release rates of approximately 35%. Survey evidence also shows that release rates have not improved over time—a 2008 *Contact Lens Spectrum Magazine* survey reported that only half of prescribers released prescriptions.[34]

Most crucially, the December 2016 survey shows that at least 24% of consumers (approximately 10 million) never receive a copy of their contact lens prescription. Prescribers are intentionally depriving these 10 million consumers of their right to use their prescription to shop for lenses without returning to their prescriber for at least one year. Under the CLR, a prescription may not expire "less than one year after the issue date . . . ."[35] The Commission defined "issue date" as "the date on which the patient *receives* a copy of the prescription at the

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[31] *Id.* at 88532.

[32] Exh. A, Consumer Study Results: Rx Release & Contact Lens Wear Habits, Survey Sampling International (Jan. 27, 2017) ("SSI 2016 Consumer Survey"). The survey was commissioned by 1-800 and conducted by Survey Sampling International ("SSI"). The survey was conducted online during the period December 12, 2016–December 19, 2016 and samples 1,000 contact lens wearers. The survey also shows that while about 30% of consumers asked for and were provided with a copy of their prescription while they were at their prescriber's office, 5% were told to either call or return to the office at a later time to receive a copy. *Id.* at 3.

[33] In 2014 and 2015, 1-800 contracted with SSI to conduct surveys of contact lens wearers. These surveys, conducted in November 2014, May 2015, and October 2015, each show that only about 35% of contact lens wearers automatically received a copy of their contact lens prescription from their prescriber. *See* 1-800 October 2015 Comments, Exhs. B–C.

The current survey shows a slightly higher percentage of customers asking for prescriptions than the prior studies, but all the studies show that at least 24% of consumers never receive their prescription. In its NPRM, the Commission raised concerns about the form of the question regarding automatic release in the October 2015 survey. In particular, the Commission expressed concern that consumers were not given the option to answer "I don't know." NPRM at 88532. In response to that concern, SSI asked consumers whether "At your last eye exam, did the doctor provide you with a paper copy of your prescription." Consumers are given the option to answer, "yes," "no," or "don't know." Only 4% of consumers answered "I don't know," and including that option had little effect on the overall compliance rate for automatic release. Exh. A, SSI 2016 Consumer Survey at 3.

[34] Carla J. Mack, *Contact Lenses 2007: A Look Back at Contact Lens Events of 2007 Including Prescribing trends, Product Recalls and Launches, Compliance Issue, Mergers and Corneal Staining*, CONTACT LENS SPECTRUM (Jan. 1, 2008), *available at* http://www.clspectrum.com/issues/2008/january-2008/contact-lenses-2007 ("[D]espite . . . federal legislation, only half of [prescribers] replied 'yes, to every patient' when asked if they release contact lens prescriptions.").

[35] 16 C.F.R. § 315.6 (2). One year is the minimum time period absent a documented medical basis. States may lengthen but not shorten the minimum expiration period of a contact lens prescription.

completion of a contact lens fitting."[36] Consequently, if the prescriber does not release the prescription, the prescription does not issue, and it does not expire. A prescriber who quietly tucks the patient's prescription into a file and a year later vetoes a verification request on the grounds that the prescription has expired violates the CLR by unlawfully restricting the length of the prescription below the one-year minimum without a documented medical reason (in addition to failing to release in the first instance). Those violations deprive patients of important consumer rights and undercut the procompetitive goals of the FCLCA.

Prescribers can disregard their obligations in part because nearly half of all consumers are unaware of their rights. Survey evidence shows that about 46% of all contact lens wearers do not know that they have a right to receive a copy of their contact lens prescription.[37] As the Commission noted, this percentage may actually be higher due to a possible response error in the survey resulting from a social desirability bias.[38] Prescribers exploit poor patient awareness by effectively bundling the eye exam with the sale of lenses into a single transaction. For the majority of consumers (69%), prescribers begin the sales process while they are still in an exam room.[39] Even if a consumer ultimately receives a copy of her prescription (either automatically or in response to an affirmative request), 38% of those consumers are provided with a copy either at the same time they purchase lenses from their prescriber or after the prescriber has already closed the sale.[40] Prescribers that release prescriptions only after they close a sale deprive patients of their right to shop around for the best prices. The result is less choice and a less competitive marketplace for all contact lens wearers.

1-800 agrees with the FTC that the weight of the evidence, including survey data, the percentage of orders that require verification,[41] consumer complaints, and a long history of prescribers failing to release prescriptions when required by state law, provides substantial evidence that automatic release—a cornerstone of the FCLCA—is not working as Congress intended.

B. A Signed Acknowledgment Will Bolster Consumers' Awareness of Their Rights and Encourage Prescriber Compliance

The proposed amendment will improve compliance by requiring prescribers to (1) interact with their patients and affirmatively notify them of their right to receive a copy of their prescription and (2) maintain a record of the signed acknowledgment for inspection by the Commission upon request. Both aspects of the proposed amendment will work together to encourage greater compliance. Prescribers are far more likely to release prescriptions, without games, if they must ask their patients to acknowledge immediately afterwards that they have

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[36] 16 C.F.R. § 315.2.

[37] 1-800 October 2015 Comments, Exh. B at 5.

[38] *Id.* The Commission noted that if survey respondents were reluctant to admit that they did not understand their rights, 46% could understate the percentage of consumers who do not understand that they have a right to receive a copy of their contact lens prescription. NPRM at 88532.

[39] 1-800 October 2015 Comments, Exh. B at 7.

[40] *Id.* at 10.

[41] The Commission estimates that approximately 75% of orders placed with third-party sellers are verified. NPRM at 88531.

done just that. Moreover, the amendment will make prescribers more likely to release when it matters: *before selling and dispensing lenses*. Otherwise, prescribers risk losing patient trust. Prescribers who do not release in advance will find themselves asking patients to confirm that they have received a prescription and understand that they have the right to shop around at a time when those rights are irrelevant—as patients are on their way out the door with a six-month (or more) supply of lenses.[42] The direct interaction between prescriber and patient alone will discourage gamesmanship and encourage greater compliance with both the letter and the spirit of the FCLCA.

Recordkeeping is crucial to changing prescriber incentives towards compliance.[43] Unless prescribers are required to maintain records, there is no reason to think that they will inform patients of their rights any more frequently than they automatically release prescriptions today. Prescribers understand that releasing a prescription facilitates competition, cutting into their own profits. The sale of contact lenses provides a significant source of income for prescribers: contact lens sales make up approximately 25% of total profit for most practices.[44] Prescribers are loath to cede those profits to alternative retail channels.

Prescribers also understand that under the current standard, they can ignore their legal obligations without consequence. Although the Commission has issued warning letters to prescribers who have failed to release prescriptions, to date, the Commission has never taken enforcement action or sought fines against a prescriber. The Commission itself acknowledged 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."[45] As the Commission concluded, the weight of the evidence shows that when prescribers today weigh the costs and benefits of compliance, they choose to violate the Rule.[46] A recordkeeping requirement, particularly with regular enforcement sweeps, will create a credible threat of enforcement and fines, changing how prescribers are likely to think about compliance.

1-800 agrees with the Commission that a signed acknowledgment is more likely to change prescriber behavior than alternative proposals that focus solely on consumer notice, such as notice upon check-in or the posting of a sign.[47] Without requiring a signed patient

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[42] The amendment will not restrict speech between the prescriber and her patient, and 1-800 is not recommending any restriction on conversations between prescribers and patients. The amendment may simply encourage prescribers to delay the selling process until after the prescription has been released, which is consistent with the intent of the FCLCA and will facilitate greater choice and competition in the contact lens marketplace.

[43] Competition among prescribers for the provision of eye care services has not shown itself to be sufficient to encourage prescribers to release prescriptions to patients. Although, in theory, prescribers could compete for eye exam patients by unbundling the sale of eye exams from the sale of contact lenses by readily releasing prescriptions to patients, that strategy would be profitable only if a prescriber would gain more from added business for eye exams than might be lost through more vigorous competition for the sale of contact lenses. In light of poor patient awareness of their rights and limited enforcement actions without fines against prescribers for failing to release prescriptions, history has shown that competition alone has not fostered compliance due to the inherent conflict of interest that prescribers face.

[44] David L. Kading & Mile Brujic, *Four Strategies for Practice Growth*, 31 CONTACT LENS SPECTRUM 36 (Nov. 2016), *available at* http://www.clspectrum.com/issues/2016/november-2016/four-strategies-for-practice-growth.

[45] NPRM at 88533.

[46] *Id.* at 88532.

[47] *Id.* at 88534.

acknowledgment of rights, there is every reason to think that those same prescribers who ignore the requirement to automatically release prescriptions today are likely to do the same with any requirement to notify patients of that right. 1-800 also agrees that consumers are unlikely to notice a sign placed on a prescriber's wall.

Moreover, the statute requires automatic release. Even if more consumers understand their rights, many may be reluctant to ask their prescriber for a copy of their prescription, particularly if the prescriber moves seamlessly from examining the patient's eyes to selling her lenses. Proposals aimed at encouraging more consumers to ask for their prescription do not put the obligation to release the prescription on the prescriber where it belongs.

1-800 also urges the Commission to clarify that prescribers must provide both the prescription and the signed acknowledgment form to patients *before selling contact lenses*. Thirty-eight percent of consumers that receive a prescription—either automatically or upon request—report that it was provided to them either concurrent with or after purchasing lenses from their prescriber.[48] Although, as explained above, the signed acknowledgment may encourage prescribers to release before making a sale, inevitably some will surely follow old habits and present the acknowledgment form for signature along with the prescription—after completing a sale. When issuing a final Rule, 1-800 asks the Commission to clarify that the prescription and the acknowledgment form must be presented to the patient *after* completing the fitting and *before* selling lenses to the patient.[49]

C. A Signed Acknowledgment Will Reduce Regulatory Costs for Prescribers and Sellers Alike and Benefit Consumers

A signed acknowledgment of prescription release—coupled with a recordkeeping requirement—will be an effective and efficient method to educate consumers and bolster prescription release. In seeking its regular approval for the Rule under the Paperwork Reduction Act, the Commission itself has justified the costs of existing recordkeeping requirements, which fall largely on sellers, as critical to its ability to enforce the Rule. ("[W]ithout required records, it would be difficult to ensure that entities are complying with the Rule's requirements or bring enforcement actions based on violations of the Rule.")[50]

Despite complaints from prescribers, the added costs of the proposed amendment would be minimal. Assuming that each of the 41 million contact lens wearers in the United States received a new contact lens prescription annually, the Commission predicts that prescribers would spend a total of 683,333 hours annually complying with the proposed amendment. The Commission predicts that office clerks earning an average hourly wage of $15.33 per hour would

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[48] 1-800 October 2015 Comments at 10.

[49] The Commission previously rejected calls to require prescribers to release the written prescription before *attempting* to sell contact lenses, explaining that it was unnecessary, because the Rule prohibits prescribers from requiring that patients purchase lenses as a condition of release or verification. 1-800 requests that the Commission revisit this decision in light of ten years of poor prescriber compliance with automatic release and survey evidence showing that 46% of consumers or more may not fully understand their rights. However, to provide a clear standard and avoid a restriction on speech, 1-800 recommends that the Commission require the prescription and acknowledgment form to be presented to the patient before the prescriber completes a sale.

[50] Agency Information Collection, 81 Fed. Reg. 31939 (May 20, 2016).

handle the tasks associated with maintaining records, resulting in a total annual cost of $10,475,495 to prescribers, or one-fourth of one percent (.0025%) of the total annual revenue of the contact lens sector. This estimate likely overstates the cost to prescribers as at least five states have a two-year minimum expiration date for a contact lens prescription,[51] and the average exam frequency for patients across states is about 15 months.[52]

Offsetting these costs will be corresponding *reductions* in compliance costs for both prescribers and sellers due to fewer verification requests. As the Commission notes, a prescriber will spend significantly less time complying with the proposed amendment than handling a verification request. The Commission estimates that a prescriber would spend no more than one minute per patient collecting and maintaining a record of the signed acknowledgment, as opposed to five minutes handling a verification request.[53]

As an illustration, 1-800 currently has prescriptions on file for approximately 30% of its customers. As a result of the acknowledgement form requirement and with increased enforcement, 1-800 believes that it is reasonable that the percentage of orders with prescriptions on file should at least double to 60% of orders, meaning verification requests would decline to 40% of orders. Because of the reduction in 1-800 and other online seller verification attempts, prescribers would spend 328,000 fewer hours annually verifying online orders, which would result in an annual savings of $5,028,240.[54]

Subtracting these cost savings would reduce the annual cost burden for prescribers from the amendment to $5,447,255 or just one-eighth of one percent (.0013%) of the total annual revenue of the contact lens sector. Prescriber verification costs associated with sales through other alternative retail channels, such as big box retailers, are likely to decrease as well, so the actual cost savings may be even greater. In fact, the extent to which prescribers comply with the proposed amendment and release prescriptions will have a direct impact on their verification costs. Prescribers are capable of reducing or possibly eliminating any increase in costs with full compliance.

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[51] This number likely overstates even the gross costs of the amendment as five states require a two-year minimum for a contact lens prescription: Florida, Minnesota, New Mexico, Washington and Utah. Fla. Stat. § 484.012 (2), Minn. Stat. § 145.712.2, N.M. Stat. Ann. § 61-2-10.4 (A) (5), ARCW § 18.195.030 (1) (d), UCA § 58-16a-102 (3) (b) (ii). In a sample of prescriptions provided to 1-800 during 2015, more than 70% of prescriptions written in states with a two-year minimum had an expiration date less than two years from the issue date, violating the CLR. While patients in two-year states may wish to see their prescriber more often, and the prescriber may wish to provide a new prescription each time the patient is examined, the CLR does not require an annual prescription in these states. Voluntary action that is not required by the Rule, as well as conduct that actually violates the Rule, should not be included in an estimate of burden. According to 2015 U.S. Census data, 11% of the population lives in states with a two-year minimum. Assuming that the percentage of state residents that wear contact lenses is constant across states—which would mean that in 2015, the CLR required only biennial release to approximately 4.7 million contact lens wearers.

[52] David L. Kading & Mile Brujic, *Four Strategies for Practice Growth*, 31 CONTACT LENS SPECTRUM 36 (Nov. 2016), *available at* http://www.clspectrum.com/issues/2016/november-2016/four-strategies-for-practice-growth.

[53] NPRM at 88557.

[54] Approximately 16% of the 41 million contact lens wearers purchase online and the average size of an order is a six-month supply (meaning two verification events per year). Currently 70% of these online orders require verification, or 9,184,000 verifications annually. If only 40% of the online orders require verification, 3,936,000 online orders would no longer require verification. The annual time savings for prescribers would be 328,000 hours (assuming five minutes of labor for each verification).

This conservative estimate of costs savings only accounts for prescriber time. The amendment would also decrease costs for sellers, who would similarly rely less often on the verification system. As the Commission estimates, sellers also spend significantly less time complying with the CLR when consumers provide their prescriptions when placing orders: one minute for recordkeeping if a consumer submits a prescription when placing an order versus five minutes for verification and related recordkeeping if a consumer does not.

These simple calculations illustrate that the amendment is not likely to impose any meaningful burden on prescribers. To the contrary, the cost savings associated with the proposed amendment are potentially quite significant. And, these regulatory cost savings do not take into account the numerous benefits to consumers, which include faster shipments, time cost savings from buying online,[55] less risk that consumers will engage in the unhealthy practice of over wearing lenses, and a more competitive marketplace.

Of course, prescribers could have seen those cost savings all along by simply releasing prescriptions. Despite years of complaints about the burden of verifying orders, they have not done so. That fact alone provides strong evidence that it is the cost of competition—not the minimal cost associated with asking patients to acknowledge receipt of their prescription—that is behind prescribers' predictable objections to the proposed amendment.

D. The Proposed Amendment Will Be Easy For Prescribers to Integrate Into Procedures They Should Already Have in Place to Release Prescriptions

The signed acknowledgment will be easy for prescribers to integrate into the existing procedures to provide patients with copies of their prescriptions after completion of the contact lens fitting. If the same lens is prescribed (*i.e.*, "refit patients"), that completes the fitting process under the CLR, and a prescription should be released at the exam visit.[56] If the prescriber selects or the patient requests a new lens, the prescriber may send the patient home with a trial set and follow up at a later time to evaluate comfort and fit. A recent survey of prescribers shows that, overall, more than 90% of fittings are completed at the prescriber's office, either during the initial office visit or a follow-up visit.[57]

In about 8% of cases, prescribers send patients home with trial lenses and then follow up with patients by phone or possibly even email or text.[58] The amendment would not require prescribers to insist that patients return to their office to complete the fitting and sign the acknowledgment. If the trial lenses have worked well, the prescriber may complete the fitting process through one of these remote methods. But even in these circumstances, about 8% of fittings, the Rule nevertheless requires the prescriber to provide a copy of the contact lens

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[55] 1-800 2015 Comments at 8.

[56] "Contact lens fitting means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required . . . ." 16 C.F.R. § 315.2.

[57] Exh. B, Optometrist Study, Fitting and Patient Portal Practices, M3 Global Research (Jan. 2017) at 6 ("M3 2017 Prescriber Survey"). 1-800 contracted with M3 Global Research to conduct a survey of prescribers with regard to certain aspects of their practice, including their routine for completing a contact lens fitting. The survey sampled 753 optometrists and was conducted online between December 12, 2016 and January 4, 2017.

[58] *Id.* at 6.

prescription to the patient. Survey evidence shows that prescribers use multiple methods to deliver prescriptions to patients when completing a fitting remotely, including mail, email, and occasionally through a patient portal.[59] Eighty-three percent of prescribers report that when they complete a fitting remotely, they will sometimes call and ask the patient to return to the office to pick up her prescription.[60] In these cases, the prescriber could simply comply with the proposed amendment by providing the acknowledgment form to the patient in the same manner as the prescription.

While prescribers should be required to request that those few patients who complete the fitting process through a remote communication return the acknowledgment form to the prescriber, some patients may not comply with these instructions. However, to guarantee that prescribers transmit the acknowledgment form and prescription, and to provide a basis for Commission inspection, prescribers should be required to retain an appropriate form of proof of transmittal.[61]

The Commission can look to § 315.5 (f) (seller recordkeeping requirements for verification requests) for guidance on how to implement a recordkeeping requirement if the fitting is completed remotely. Under § 315.5 (f), if a seller places a verification request by facsimile or email, the seller is required to retain a copy of the communication and confirmation of the completed transmission, including the date and time the request was sent. If a request is made by phone, the seller is required to maintain a log describing the verification information conveyed and other logistical information associated with the call, including the date and time of the request and the names of the individual who participated in the call. While a prescription and acknowledgment form obviously cannot be conveyed by telephone, the recordkeeping requirements placed on sellers for telephone communications could be adapted for those situations where a prescriber chooses to send the prescription and acknowledgment to the patient by regular mail.

Survey evidence indicates that for the approximately 8% of fittings that prescribers complete remotely, just 9% of prescribers report that they sometimes use a patient portal to transmit prescriptions to patients.[62] The same study shows that portals are not yet widely used among prescribers or patients: only about 30% of prescribers report having a patient portal, and those that have a portal report that only about 29% of their patients have signed up to use the service.[63]

While 1-800 supports the expansion of patient portals, we do not believe that merely providing a patient with access to the acknowledgment form through a patient portal should be sufficient to satisfy the crucial recordkeeping aspects of the proposed amendment (or automatic release of prescriptions as discussed in Section IV, *infra*). If a fitting is completed remotely, the

[59] *Id.* at 8.

[60] *Id.* (Prescribers were told to select all options that apply since prescribers may use more than one method.)

[61] It is important that the Commission require prescribers to retain a record that the acknowledgment was provided to the patient even in the few cases where a fitting is completed remotely. Otherwise, prescribers may change their practices and complete fittings with a phone call or other remote communication on a routine basis to evade their recordkeeping obligations, which would undercut the value of the amendment.

[62] Exh. B, M3 2017 Prescriber Survey at 8.

[63] *Id.* at 10–11.

Commission should require that the acknowledgment form be provided directly to the patient in a manner that is subject to recordkeeping (similar to the kind of direct communication required for a seller to transmit prescription information to a prescriber for purposes of verification under § 315.5 (b)). Prescribers cannot require their patients to sign up for or use portals. Thus, merely providing a patient with access to a portal may not allow the prescriber to document that the form was actually provided to the patient. Prescribers should not be permitted to provide the acknowledgment to the patient through a portal unless mere access is accompanied by direct transmission of the form to the patient via email, text message, facsimile, or mail (a copy of which can be retained for recordkeeping purposes).

To (1) expressly prohibit prescribers from selling lenses before the acknowledgment and prescription are provided to the patient, and (2) to provide compliance guidance to prescribers for those limited situations where a prescriber completes the fitting remotely, 1-800 recommends the Commission add the following subsections and language to the Rule.[64]

§ 315.3 Availability of contact lens prescriptions to patients

* * * * *

(c) ***Acknowledgment of prescription release.***

* * * * *

(4) If a contact lens fitting is concluded by telephone, email, or other form of communication that does not occur while the patient is present in the prescriber's office, the prescriber shall inform the patient that a copy of the contact lens prescription will be provided to the patient and that the patient is free to purchases contact lenses from the seller of the patient's choice. The prescriber may present both the contact lens prescription and the acknowledgment form to the patient as a digital image sent via email or text, a copy sent by facsimile or a copy sent by mail. If not presented directly to the patient within the prescriber's office, the prescriber shall maintain a record to document that both the contact lens prescription and the acknowledgment form were provided to the patient.

(i) If the prescription and acknowledgment form are provided to the patient by email, text, or facsimile, the prescriber shall maintain a copy of the email, text, or facsimile and confirmation of the completed transmission thereof, including a record of the date and time the documents were transmitted.

(ii) If the prescription and acknowledgment form are provided to the patient by mail, the prescriber must retain a copy of the prescription and acknowledgment form in the patient file. The prescriber shall sign a copy of each document to certify that the

[64] The language suggested here is based on the Commission's suggested approach for this amendment in cases where a patient declines to sign the acknowledgment, as well as the Commission's approach to seller recordkeeping for direct communications for purposes of a verification requests.

document was sent by mail and note the patient address and the date on which the document was sent.

(iii) The prescriber shall retain the records described in paragraphs (i) and (ii) of this section for a period of not less than three (3) years and these records shall be available for inspection by the Federal Trade Commission, its employees, and representatives. A prescriber may retain the records described in paragraphs (i) and (ii) of this section in lieu of the signed acknowledgment required by paragraph (c)(3) only if the prescriber completes a contact lens fitting through a communication that occurs outside the prescriber's office and a patient does not return a signed acknowledgment to the prescriber.

(d) After completing a contact lens fitting, a prescriber must provide the patient with both (1) the contact lens prescription according to § 315.3(a)(1) and (2) the acknowledgment form required by paragraph (c) before selling contact lenses to the patient.

III. THE COMMISSION SHOULD AMEND THE RULE TO REQUIRE PRESCRIBERS TO RESPOND TO PRESCRIPTION REQUESTS FROM DESIGNATED AGENTS WITHIN FIVE BUSINESS DAYS

1-800 strongly recommends that the Commission amend § 315.3 (a) (2) to require a prescriber to respond to a request from a patient's designated agent for a copy of the patient's prescription, and to do so within five business days. Without providing prescribers with a time frame for responding to an authorized request, the requirement is unenforceable and prescribers will continue to ignore their obligations.

Section 315.3 (a) (2) requires prescribers to provide a copy of a patient's contact lens prescription to a patient's designated agent upon request. Due in large part to poor prescription release to patients, many patients cannot provide a third-party seller with a copy of their contact lens prescription at the time they place an order. Consequently, 1-800 requests permission from customers who do not submit their prescription to obtain a copy on their behalf. This is a service that customers value. With a prescription on file, 1-800 is able to ship orders faster—orders can be processed within 14 minutes of the time the order is placed. Without a prescription, 1-800 places a verification request and must typically wait eight business hours, as defined by the CLR, before shipping an order. Those eight business hours can translate into several days. If a patient places an order on a Friday afternoon, 1-800 cannot ship the order before the following Monday (unless the doctor actively verifies the prescription earlier), or longer over a federal holiday weekend.

This delay interferes with 1-800's customer service efforts and restricts an important dimension of competition—convenience and speed of delivery. It imposes an unnecessary burden on consumers who may be down to their last pair of lenses when they place an order. If forced to wait an extra day or more, consumers are more likely to wear lenses longer than recommended. Recent consumer survey evidence shows that 65% will wear lenses longer than

usual if they have only one pair left on hand.[65] Only 23% of the contact lens wearers report that they never allow themselves to run low on lenses.[66]

Despite the benefits to competition and consumer health and safety, most prescribers ignore and never respond to 1-800's authorized requests for copies of patient prescriptions. In 2016, 1-800 requested copies of approximately 558,000 prescriptions on behalf of its customers. Prescribers ignored more than half of these requests, providing prescriptions in response to just 46% of requests. Moreover, despite the large number of total requests, the burden on any individual prescriber is very low. In 2016, prescribers received, on average, only one request every four to five weeks.

As the Commission has clarified, "[t]he Act and the Rule currently require the prescriber to provide a copy of a prescription to an authorized third party, but is silent on the timing of the response."[67] 1-800 appreciates the Commission's effort to clarify that prescribers ***are required*** by the FCLCA and CLR to respond to a designated agent's request for a copy of a patient's prescription. However, without imposing a time frame for a prescriber to respond, the clarification will not improve compliance. Experience with the automatic prescription release requirement has shown that the Commission cannot simply rely on prescribers to abide by their obligations without a credible threat of enforcement. Without a required time frame, it will be impossible for the Commission to claim that a prescriber has violated the Rule. As the Commission recognized, it is no more burdensome for a prescriber to provide a seller with a copy of a prescription than to handle a verification request. Moreover, the minimal time commitment is more than justified.[68] With a prescription on hand, sellers are free to provide consumers with lenses throughout the life of the prescription without placing additional verification requests, leading to lower regulatory compliance costs for prescribers and sellers, and faster delivery and other benefits for consumers.

1-800 recommends that the Commission impose a time frame of five business days. An internal audit of 1-800's records shows that in 2016, less than half of prescribers (46%) responded to an authorized request from 1-800 for a copy of a patient's prescription. The same internal audit records show that for those that did respond, however, 90% did so within two calendar days. Consequently, requiring a response within five business days is consistent with industry practice. It will encourage compliance, while still providing the vast majority of prescribers ample opportunity to respond and avoid a Rule violation (even for small practices that may close for vacations and family emergencies).[69]

In addition, to ensure compliance, prescribers should be required to maintain a log recording the date and time a patient's prescription was requested and released to the designated agent. The log should be maintained for a period of three years and be available for inspection

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[65] Exh. A, SSI 2016 Consumer Survey at 4–5.

[66] *Id.* at 4.

[67] NPRM at 88537; *see also* 88536 (§ 315.3 (a) (2) requires a prescriber to "provide a prescription whenever a patient authorizes an agent to request one, even if the patient previously received a prescription copy from the prescriber.").

[68] NPRM at 88537.

[69] Moreover, the Commission always retains prosecutorial discretion and may decline to pursue a Rule violation if presented with proof that a prescriber was legitimately unable to respond during the required time frame.

by the Commission and its employees and representatives. 1-800 accordingly recommends that the Commission amend the Rule to include the following language to follow proposed § 315.3 (c) regarding the signed acknowledgment.

> **§ 315.3 Availability of contact lens prescriptions to patients**
>
> * * * * *
>
> **(d)** ***Release to designated agent***
>
> (1) As required under paragraph (a)(2) of this section, the prescriber shall, upon request, provide a copy of a prescription to any person designated to act on behalf of the patient within five business days.
>
> (2) A prescriber shall maintain a log setting forth (i) the date a request was received, (ii) the name of the patient on whose behalf the request was made, (iii) the form of communication used to request the prescription, (iv) the date the prescription was transmitted to the designated agent, and (v) the method of communication used to provide the prescription to the agent.

IV. PRESCRIBERS SHOULD NOT BE PERMITTED TO MEET THEIR OBLIGATIONS UNDER THE RULE SOLELY BY POSTING PRESCRIPTIONS TO ONLINE PATIENT PORTALS

In its NPRM, the Commission raised a number of issues related to the use of patient portals to facilitate prescription portability and provide alternative mechanisms for prescribers and sellers to meet their obligations under the Rule. First, the Commission made an initial determination that a contact lens seller may sell lenses (consistent with its obligations under § 315.5) if a patient or prescriber provides the seller with a copy of the prescription through a patient portal.[70] Second, the Commission considered whether a prescriber can meet its obligation to automatically provide the patient with a copy of the contact lens prescription solely by posting the prescription to a portal. Regarding automatic release to patients, the Commission did not make any initial determination, concluding that it did not have enough information to determine whether solely posting the prescription to a portal is sufficient. The Commission asked for comments on both issues.[71]

Regarding the Commission's initial determination that a patient or prescriber may present a prescription to a seller directly, by facsimile or by use of a patient portal, 1-800 is concerned that privacy restrictions will prevent sellers from accessing a patient's portal account, and there is no established standard for communication between patient portals and sellers. 1-800 encourages the development of such capabilities in patient portals, but without an industry standard for communication with portals, it will be difficult for sellers to establish efficient

[70] In other words, the phrase "directly or by facsimile" includes transmission through a patient portal. NPRM at 88538. The Commission previously determined that "directly or by facsimile" includes mail or a digital image of a prescription that is sent via email as all of these mechanisms allow the seller to view an exact duplicate of the prescription. 69 Fed. Reg. 40495 (July 2, 2004).

[71] NPRM at 88535, 88538, 88556.

internal procedures to collect records from thousands of prescribers using different software and platforms. 1-800 thus requests that to the extent prescribers use portals to provide sellers with prescriptions, their portal should have the ability to send the prescription to the seller directly by email, text, or facsimile, and a seller should not be required to develop direct communication links to the portal.

With regard to automatic release to patients, 1-800 recommends against permitting prescribers to meet their obligations by merely posting prescriptions to a patient portal. Posting a prescription may provide a patient with access to the prescription, but access is not automatic. Survey evidence shows that while use of patient portals is growing, adoption and use are still very limited. Only 30% of patients were offered access to a patient portal at their last eye exam, and just 29% of patients who are provided with access to a patient portal have used the service.[72] Moreover, patient portals do not necessarily have printing, email, facsimile, or texting capabilities. Having a patient sign an acknowledgement form after receiving a prescription will increase consumers' understanding of their rights, increasing prescription portability and providing consumers with the ability to immediately use a prescription, unrestricted by the capabilities of the portals that are adopted by their prescribers. Initial release solely to a portal would undercut the power of the proposed signed acknowledgement and recordkeeping amendment to enhance enforcement and would provide prescribers with an easy way to evade their obligations and frustrate the intent of the Rule.

Since more than 90% of fittings are completed in the prescriber's office, there is no good reason that a prescriber cannot provide the patient with a prescription at that time. For the small minority of fittings that are completed remotely, 1-800 recommends that the Commission require that the prescriber use some other direct transmission (email, text, facsimile, or mail) to ensure that the prescription and the proposed acknowledgment are actually provided to the patient and not buried in an online portal that the patient may not know exists and may find difficult to navigate.[73] Additionally, paperless options are possible even if the prescription is provided at the prescriber's office. As the Commission notes, some prescribers may have electronic recordkeeping systems that would allow patients to review and sign the proposed acknowledgment form on a tablet. These systems may also allow prescribers to complete a prescription electronically and if the patient requests, immediately send it to a patient's smartphone via email or text.

V. THE COMMISSION CORRECTLY REJECTED PROPOSALS TO RESTRICT THE PASSIVE VERIFICATION OPTION AND TO IMPOSE UNWARRANTED QUANTITY LIMITS ON CONSUMERS

In response to the Commission's initial request for comments on its ten-year review of the CLR, prescriber associations and some manufacturers made a number of recommendations that would impede consumer choice and competition based on unsubstantiated claims that restrictions were necessary to protect patient health and safety. Commenters aligned in particular to press the Commission to (1) restrict the option for prescribers to passively verify orders and (2) limit the quantity of lenses a consumer can purchase with a valid prescription. The

[72] Exh. B, 2017 M3 Prescriber Survey at 11.

[73] *See supra* Section II.D.

Commission concluded that the recommendations were not supported by credible evidence and were likely to constrain consumer choice and competition with no offsetting benefits for consumer health and safety.

1-800 supports the Commission's conclusions. Prescriber claims are not only unsubstantiated, they are in fact contrary to the existing consumer data and medical evidence, as discussed below.

A. The Commission Correctly Rejected Proposals to Limit the Passive Verification Option

Prescriber groups and manufacturers made a number of recommendations to restrict the option for prescribers to passively verify orders, including going so far as to ask the Commission to eliminate the passive verification option entirely. The AOA took a backdoor approach. It urged the Commission to amend the Rule to permit prescribers to halt the passive verification process by contacting a seller with a question or concern. The Commission appropriately rejected this proposal, explaining that the Rule already allows a prescriber to stop an order placed with an invalid prescription and to correct an inaccurate order.[74] The Commission also recognized that the proposal would undercut the FCLCA's passive verification mechanism and allow any prescriber to cancel a sale by merely lodging a "concern or question" with a seller.[75] Likely recognizing the futility of their arguments at the Commission, the Coalition for Patient Vision Care Safety, a lobbying organization comprising the AOA and the large contact lens manufacturers ("Manufacturers' Coalition") is pressing the same anticompetitive approach on Capitol Hill.[76]

The proposal's proponents base their recommendations to the Commission (as well as to Congress) in large part on data drawn from a 2015 APCO Insight Survey of online contact lens consumers, sponsored by J&J.[77] In its comments to the Commission, the Manufacturers' Coalition claims that the APCO study shows that: one-in-three consumers order lenses using an expired prescription; one-in-four consumers have received a brand of contact lenses different from what was ordered; and one-in-three consumers were advised by the online seller to substitute a non-prescribed brand.[78] Using this same study for support, the AOA is pushing its allegations even further on the Hill, claiming in lobbying materials directed to Congress that the APCO survey shows that one-in-three consumers *were able to purchase* lenses with an expired prescription, rather than *attempted to purchase* lenses.[79]

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[74] NPRM at 88542.

[75] *Id.* According to this proposal, if a prescriber contacted a seller to raise questions or concerns about a verification request, the seller would be required to contact the prescriber to address those concerns within eight business hours or cancel the order. Of course, the Rule currently allows prescribers to deny an order if the prescription is invalid.

[76] Contact Lens Consumer Health Protection Act of 2016, S. 2777, 114th Cong. (introduced April 11, 2016), *available at* https://www.congress.gov/bill/114th-congress/senate-bill/2777?q=%7B%22search%22%3A%5B%22S.+2777%22%5D%7D&resultIndex=1.

[77] This 2015 consumer survey was sponsored by J&J and submitted to the Commission with its public comment in October 2015. J&J (Comment #582) at 15.

[78] Manufacturers' Coalition (Comment #621) at 5, 9.

[79] *See* Exh. C, *AOA Supports S. 2777*.

As the Commission rightly recognized, the APCO survey provides no evidence on the percentage of patients who have actually purchased lenses using an expired prescription. Consumers were asked if they have ever *ordered* lenses on an expired prescription, not whether they have *purchased and received* such lenses.[80] The resulting data thus grossly overstates the incidence of consumers who actually purchased and received lenses using an expired prescription because such orders may have been denied by either the seller (if a prescription was provided) or the prescriber (if the seller placed a verification request).

Given the obvious problems with the survey design, 1-800 commissioned Survey Sampling International ("SSI"), a market research firm, to evaluate the APCO survey methodology and conduct an independent analysis of the same issues. In July 2016, SSI conducted an online survey of 2,000 adult contact lens wearers ("Rebuttal Survey").[81] The results refute each of the conclusions prescribers and manufacturers draw from the APCO survey. SSI found that only 11% of consumers purchase and receive lenses with an expired prescription.[82] Significantly, this number does not vary materially across retail channels.[83] Approximately the same modest percentage of consumers purchased lenses using an expired prescription regardless of whether they purchase from their prescriber, a brick and mortar retailer, or an online seller.[84] This survey shows that the Manufacturers' Coalition is overstating the extent to which consumers purchase contact lenses with an expired prescription and refutes any allegation that consumers flock to online retailers to do so.

The Rebuttal Survey also refutes other key conclusions drawn from the flawed APCO survey. In particular, the SSI data show that nearly all consumers receive the lenses they order. Only 1% of online customers report receiving *a non-approved substitute brand* of lenses in an order, that number is 2% for consumers buying from a prescriber, and 3% from other sellers (such as big box retailers).[85] These very small numbers stand in stark contrast to claims in the APCO survey that one-in-four online consumers receive a different brand of lens than the brand ordered, the difference likely attributable to APCO's flawed questions that do not distinguish between approved substitutes and non-approved substitutes.[86]

B. The Commission Correctly Rejected Proposals to Impose Quantity Restrictions on Consumers

Prescriber groups also urged the Commission to require that prescribers include a quantity limit on contact lens prescription. The Commission also appropriately rejected these

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[80] J&J (Comment #582) at 28.

[81] Exh. D, Contact Lens Consumer Study Results, Survey Sampling International (Aug. 9, 2016) ("Rebuttal Survey").

[82] *Id.* at 3.

[83] *Id*.

[84] According to the Rebuttal Survey, the percentages of consumer who were able to purchase lenses with an expired prescription by channel were as follows: prescriber 10%, online retailer 9%, and other retailer (*e.g.* big box) 14%. *Id.*

[85] *Id.* at 5.

[86] Sellers are permitted under the FCLCA to substitute private label lenses that are identical to the prescribed lenses. *See* 15 U.S.C. § 7603 (f).

proposals, finding no support for claims that consumers were stockpiling contact lenses from online sellers to avoid regular eye exams.

Here too, prescriber claims are not only unsubstantiated, they are contrary to the existing evidence. With regard to the frequency of eye exams, a June 2016 SSI survey of 2,000 contact lens wearers between the ages of 18–49 shows that contact lens wearers on average have an eye exam every 13 months.[87] The same survey shows that the average time between exams is nearly identical regardless of where the patient last purchased contact lenses:

- Last purchase online: eye exam every 13.5 months
- Last purchase from ECP: eye exam every 13.2 months
- Last purchase from other retailer (big box, other): eye exam every 12.9 months[88]

A 2016 survey of 940 of 1-800's customers also shows that the majority of its customers have an eye exam annually. The distribution of responses by frequency of exam is as follows:

- More frequently than every six months: .9%
- Between six months and one year: 2.9%
- About once a year: 52%
- Between one year and 18 months: 15.5%
- Between 18 months and 2 years: 17.3%
- Between two and three years: 9.4%
- Every three years or longer: 2%

A rough average frequency for an exam in this survey is about 16.28 months, slightly greater than the results from the SSI survey.[89] Importantly, the survey shows that only about 11% of patients report last seeing their eye care provider more than two years ago. This is consistent with a 2016 finding as reported in *Contact Lens Spectrum* noting that many contact lens wearers return to their eye care provider every 15 months.[90]

The AOA recommends that adult contact lens wearers have an eye exam every one to two years.[91] These surveys show that the vast majority of contact lens wearers are complying with the AOA's recommendations on exam frequency, with only about 11% of wearers going

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[87] Exh. E, Contact Lens Wearer Exam Frequency, Survey Sampling International (June 2016) ("SSI June 2016 Consumer Survey"). The survey was sponsored by 1-800 and conducted by SSI. Data was collected in June 2016 from their independent online survey panel of 2,000 U.S. contact lens wearers ages 18–49.

[88] This survey used a 99% confidence level with a 2.98 margin of error. Consequently, exam time across channels is statistically identical in this survey.

[89] The average frequency is determined by taking the average number of months within each range and multiplying by the frequency of responses for that range.

[90] David L. Kading & Mile Brujic, *Four Strategies for Practice Growth*, 31 CONTACT LENS SPECTRUM 36 (Nov. 2016), *available at* http://www.clspectrum.com/issues/2016/november-2016/four-strategies-for-practice-growth.

[91] *Recommended Eye Examination Frequency for Pediatric Patients and Adults*, AOA, *available at* http://www.aoa.org/patients-and-public/caring-for-your-vision/comprehensive-eye-and-vision-examination/recommended-examination-frequency-for-pediatric-patients-and-adults?sso=y.

more than two years between exams. Importantly, exam frequency does not vary by retail channel, indicating that online purchasers visit their eye care provider for an exam just as often as those who purchase from their prescribers.

Survey evidence shows buying habits near the end of the life of a contact lens prescription are also consistent across all retail channels. The Rebuttal Survey shows that about 30% of contact lens wearers purchase lenses within 30 days of the expiration of their prescription regardless of channel: 28% of consumers who buy from their prescriber buy during the last 30 days of a prescription, and 28% of consumers who purchase online do the same.[92] In addition, the same survey shows that about 70% of all sellers (prescribers, online, and brick-and-mortar retailers) notify their customers that a prescription is about to expire, and 28% of all consumers buy as a result of that reminder.[93] The consumer response to that reminder is also the same across retail channels. Online customers simply do not behave differently from customers who buy from their prescriber.

Furthermore, there is no clear correlation between the volume of lenses ordered and the frequency of eye exams. Consumers may have very legitimate reasons to purchase lenses that, if worn exactly according to the manufacturer's maximum wear schedule, could last beyond the life of a prescription. For example, some wearers may lose or tear lenses, or prefer to replace lenses more frequently. Others may have to order a particular quantity because of minimum package size.[94] The Commission should not penalize all contact lens wearers to prevent a few determined consumers from intentionally evading their prescriber's recommendations regarding the frequency of eye exams.[95]

But even assuming that consumers wear their lenses according to the manufacturer's maximum wear recommendations, data show that the average size of an order made during the last 30 days of a prescription is about six months,[96] which is consistent with 1-800's internal records for average quantity per order for every month throughout the life of a prescription.[97] For the approximately 45% of contact lens wearers who purchase a monthly lens, the standard package size is six months, meaning a six-month supply is the minimum quantity available. This evidence flatly contradicts allegations made by prescribers and their associations that consumers flock to online sellers to hoard contact lenses and avoid eye exams.

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[92] Exh. D, Rebuttal Survey at 6.

[93] *Id.* at 7.

[94] For example, for someone that wears an Air Optix Aqua monthly lens, that lens is only available in a six-month supply format. A consumer who only needed two more lenses before their scheduled eye exam would be required to purchase the additional four in order to receive their product.

[95] Of course, as the Commission recognized, quantity limits would not prevent a consumer from evading the prescriber's recommendation. A determined consumer could simply purchase lenses from a number of different sellers—including his or her eye care provider. NPRM at 88550.

[96] This estimate was calculated by SSI from the underlying survey responses that were the basis for the results presented graphically in the Rebuttal Survey.

[97] In other words, where 1-800 has a copy of a patient's prescription on file, it is able to correlate average order size to months remaining on a prescription. Its records show that average order size is about the same along that continuum. 1-800 cannot perform this estimate where it does not have a copy of a prescription and verifies the order by contacting the prescriber.

As the Commission noted, quantity limits would encourage unhealthy habits like stretching lenses past their recommended wear time. For a consumer on her last pair of lenses who is unable to purchase more until she can be seen by an eye care professional, 1-800 agrees that "there is a significant chance that the consumer will not adhere to the recommended contact lens replacement schedule and will instead try to stretch out their lenses by re-wearing them until they can visit a prescriber."[98]

C. The Medical Evidence Refutes Claims that the FCLCA or the Advent of Online Sales Has Harmed Patient Health

The medical literature also supports the Commission's decision to reject calls to restrict the passive verification option or impose quantity limits on consumers. There is simply no evidence that the FCLCA, or the advent of online sales nearly a decade before, has harmed the ocular health of contact lens wearers.

The primary ocular complication of contact lens wear is microbial keratitis, a correlation that has been well-established for decades.[99] Microbial keratitis is an inherent but acceptable risk of contact lens wear. Moderate-to-severe keratitis affects approximately five out of every 100,000 contact lens wearers and in nearly all cases is resolved without any permanent damage to the eye.[100] This incidence rate has remained consistent over time and across countries, suggesting that no relationship exists between keratitis and either the FCLCA or the advent of online sales.[101] The primary risk factors for keratitis have similarly been well-established for decades and are invariant across countries. Extended (*e.g.*, overnight) wear poses the greatest risk, followed by poor storage practices and poor hygiene.[102]

1-800 agrees with the Commission's observation that the studies purporting to link online sales with an increased risk of keratitis are not reliable and should be disregarded. A 2008 study by Fogel and Zidile supposedly shows that online shoppers have lower compliance with recommendations for healthy wear habits.[103] However, this study sampled only a small number of college students, a demographic group that cannot be translated to the broader contact lens-wearing population, and included a number of improper questions, leading to biased results.[104]

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[98] NPRM at 88549. As stated above, recent survey evidence shows that 65% of consumers will wear lenses longer than usual if they have only one pair left on hand. Only 23% of patients report that they never allow themselves to run low on lenses. Exh. A, SSI 2016 Consumer Survey at 3.

[99] Exh. F, Expert Statement of Dr. Paul Donzis.

[100] *Id*.

[101] *Id*.

[102] *Id*.

[103] Joshua Fogel & Chaya Zidile, *Contact Lenses Purchased Over the Internet Place Individuals Potentially at Risk for Harmful Eye Care Practices*, 79 OPTOMETRY 23 (2008), *available at* http://delaware.aoa.org/documents/optm-447-Fogel.pdf.

[104] For example, the study employed a number of questions that bias the results against online purchasers, including whether the respondent had an eye care specialist check the fit after purchase. Even assuming this is a valid FDA recommendation (which it does not appear to be), the study did not differentiate between purchasers of new or replacement contacts. *See* Robert D. Atkinson, *Buying Contact Lenses Online: A Critique of the Fogel and Zidile Optometry Journal Study*, THE INFO. TECH. & INNOVATION FOUND. (2008), *available at* http://www.itif.org/files/2008contactlenses.pdf.

Commenters also rely on a 2008 study by Stapleton *et al.* that identified the online purchase of lenses as a potential risk factor for keratitis.[105] However, the same authors later clarified this result in a 2012 report that showed no correlation between online sales and moderate-to-severe keratitis.[106] Other, more recent studies definitively show no correlation between online sales and ocular complications. The CLAY group, a coalition of prescribers formed at an AOA meeting and funded by Alcon, found in a 2016 study relying on data collected by the CDC that in-office purchases "did not improve [contact lens] habits or reduce the prevalence of risk behaviors" over online purchases.[107]

Health and safety claims are merely pretextual attempts to impede competition from alternative sellers, and the medical evidence does not support any link between the FCLCA or online sales and ocular health. The Commission correctly determined that such claims should be disregarded.[108]

VI. THE COMMISSION SHOULD CONTINUE TO PERMIT SELLERS TO USE COMPLIANT AUTOMATED PHONE SYSTEMS TO TRANSMIT VERIFICATION REQUESTS

1-800 agrees with the Commission's position that the FCLCA permits automated calls as a method of placing verification requests. Certain commenters proposed imposing limits on automated calls, complaining that the calls are a burden on prescribers.[109] This ignores the facts. Of the approximately 100,000 verification calls 1-800 makes each week using its HUVR system, internal data show that the average prescriber receives only one verification request per week. 1-800's verification call lasts only 149 seconds and prescribers have the option to skip introductory material and shorten the message to just 101 seconds. As 1-800 has previously explained, we have invested significant resources into developing a system that assures strict compliance with the FCLCA and CLR, while also allowing us to quickly process a large volume of orders and provide excellent service to our customers.[110] Furthermore, prescribers can limit the frequency of verification calls by simply releasing prescriptions to patients and responding to 1-800's authorized requests for copies of customer prescriptions in a timely manner.

1-800 supports the Commission's decision to continue to permit compliant automated phone systems as a method of direct communication while also taking steps that reduce the

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[105] Fiona Stapleton et al., *The Incidence of Contact Lens-Related Microbial Keratitis in Australia*, 115 OPHTHALMOLOGY 1655 (2008).

[106] Fiona Stapleton et al., *Risk Factors for Moderate and Severe Microbial Keratitis in Daily Wear Contact Lens Users*, 119 OPHTHALMOLOGY 1516 (2012).

[107] Robin L. Chamers et al., *Is Purchasing Lenses from the Prescriber Associated with Better Habits Among Soft Contact Lens Wearers?* 39 CONTACT LENS AND ANTERIOR EYE 435, 435 (2016).

[108] The health claims repeated in this rulemaking have been rejected by other state and federal lawmakers, including the 32 state attorneys generals who pursued antitrust claims against manufacturers and prescribers in the 1990s, as well as Congress in passing the FCLCA a decade later. *See* 1-800 October 2015 Comments at 3–7; *J&J v. Reyes* at 2–3.

[109] *See, e.g.,* Comments of Stahl (#19), Lum (#21), Peterson (#22), Maanum (C#23), Matthews (#25), Borsky (#26), Easton (#432), Louie (#657).

[110] For more detail on 1-800's HUVR system, see 1-800 October 2015 Comments at 20.

frequency of verification requests for both sellers and prescribers by strengthening prescription portability.

VII. CONCLUSION

1-800 greatly appreciates the Commission's consideration of these comments. The CLR is critical to implementing the Congressional vision for the FCLCA and delivering choice and competition to the 41 million contact lens wearers in the United States today. With its NPRM, the Commission has taken an important step towards furthering the goals of the FCLCA. We urge the Commission in particular to adopt the proposed acknowledgement and recordkeeping requirement and to impose a reasonable time limit of five business days to respond to requests from designated agents for copies of patient prescriptions.

Respectfully submitted,

Cynthia Williams

Cynthia Williams
General Counsel
1-800 CONTACTS, Inc.

EXHIBIT A

1 800 contacts®

Consumer Study Results:
Rx Release & Contact Lens Wear Habits

Report prepared by Survey Sampling International
for 1-800 CONTACTS

January 27, 2017

Overview

Objectives

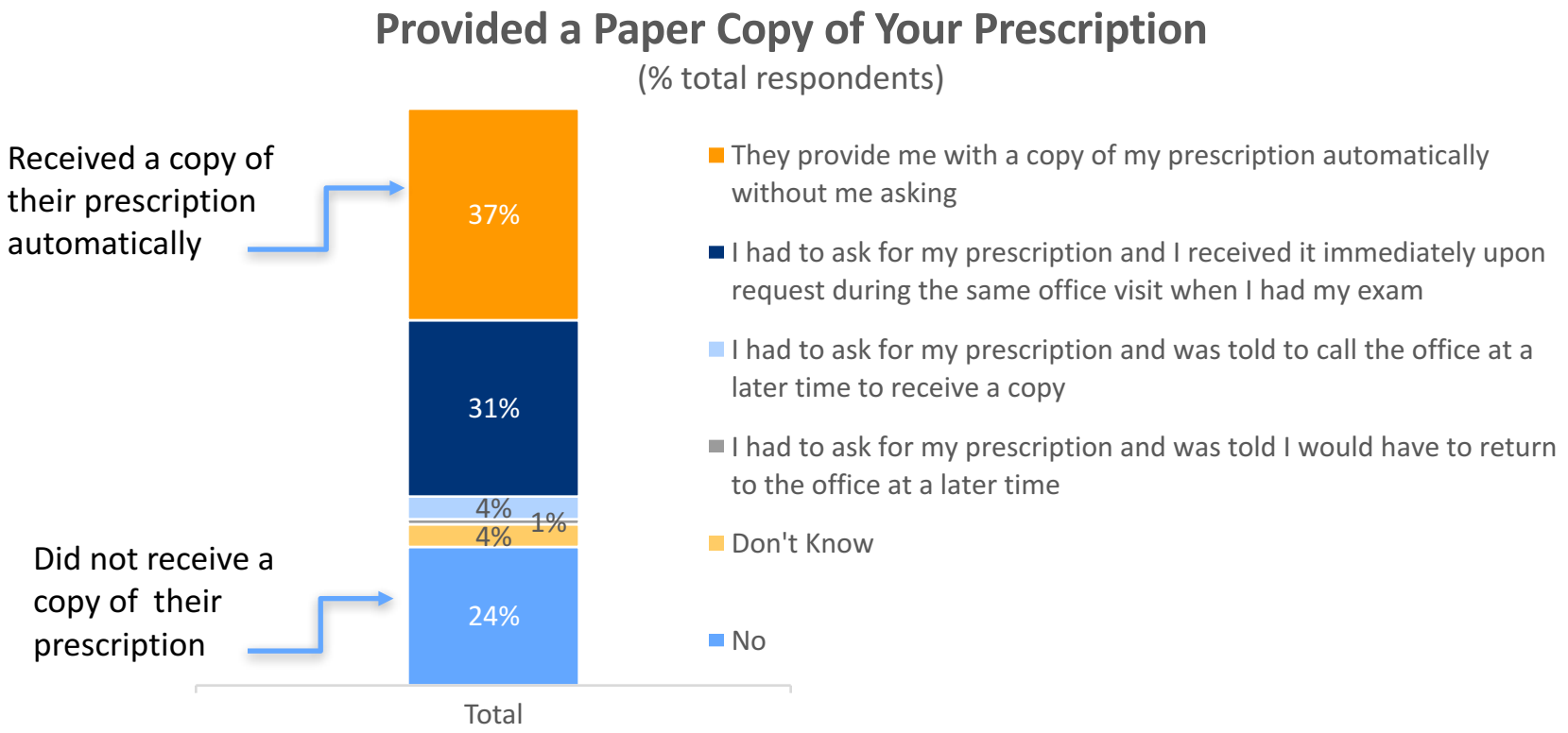
- Understand consumer experiences related to:
  - Receipt of prescription (including 'don't know')
  - Consumer wear habits when down to last pair of lenses

Methodology

- Online study conducted among contact lens wearers in the US
  - Target respondent: 18+ years old and uses soft contact lenses regularly
  - Completes collected between December 12th, 2016 and January 3rd, 2017 (Total N=1000)

Only 37% of consumers were provided a copy of their prescription automatically

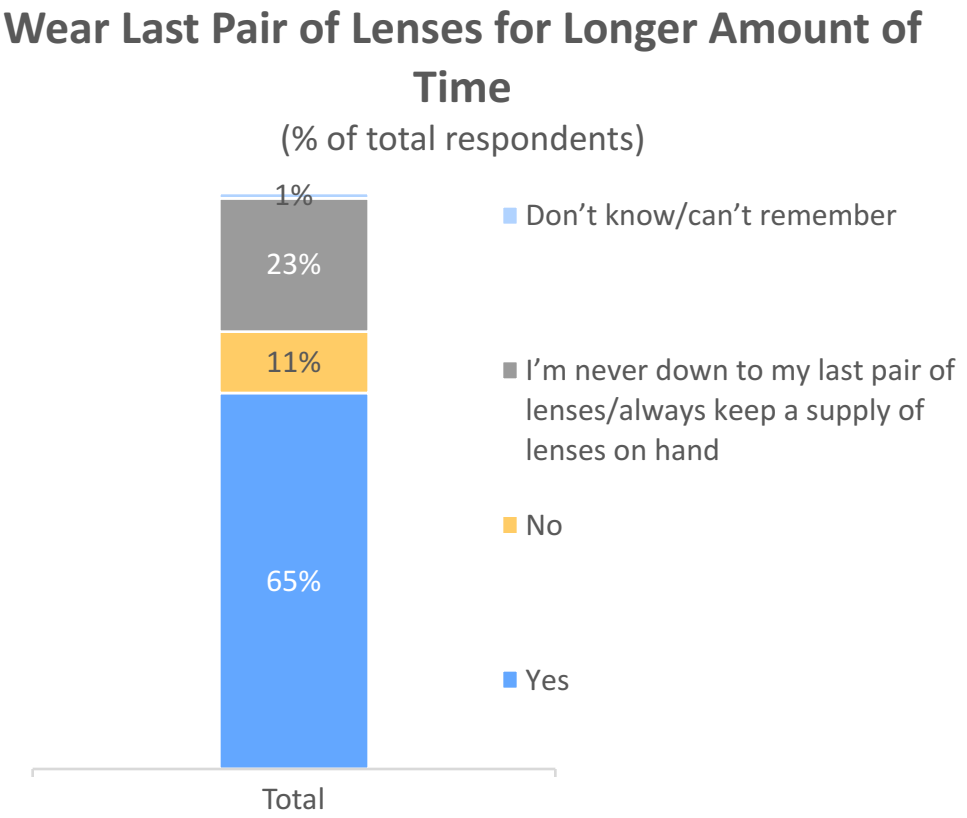
One-fourth (24%) of consumers did not receive a copy at all



Q3. At your last eye 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)

About two-thirds (65%) of consumers wear their last pair of contacts for longer

Only about one-fourth (23%) of consumers always have additional supply on hand

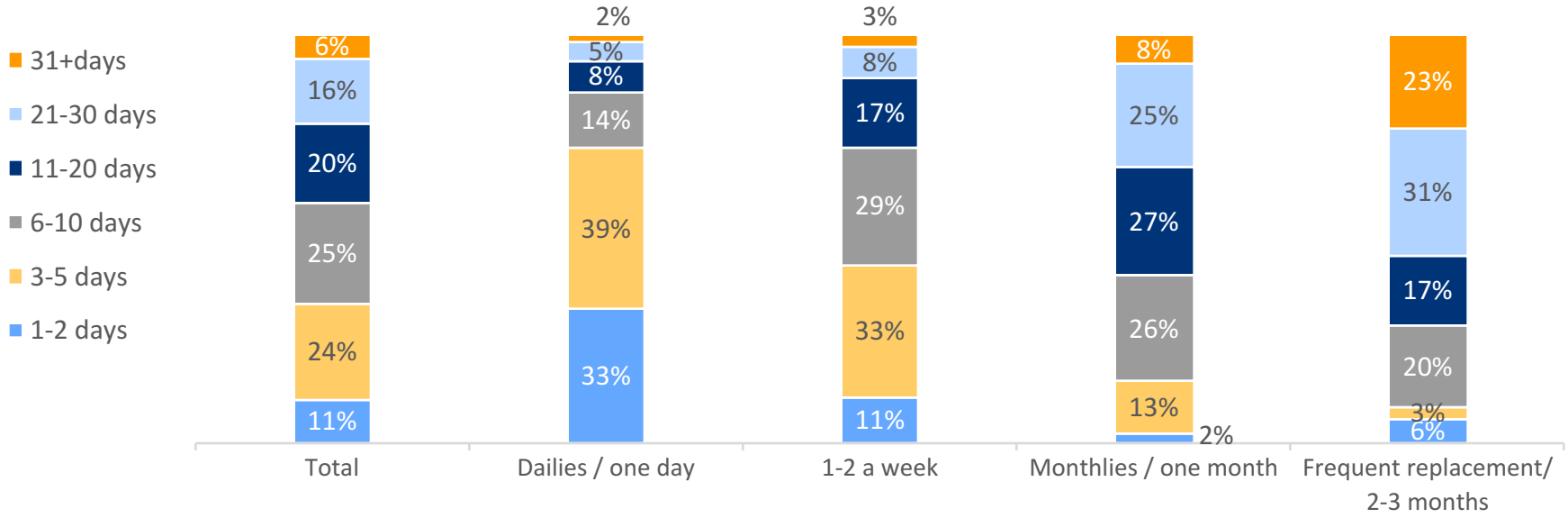


Q5. Thinking about times when you are down to your last pair of lenses and have no more lenses left - do you tend to wear your last pair of lenses for a longer amount of time than you do in instances when you have a supply of lenses on hand? (All respondents, n=1000)

67% of consumers wear their last pair of contacts 6 or more days longer than usual

Time Spent Wearing Last Pair of Contact Lenses

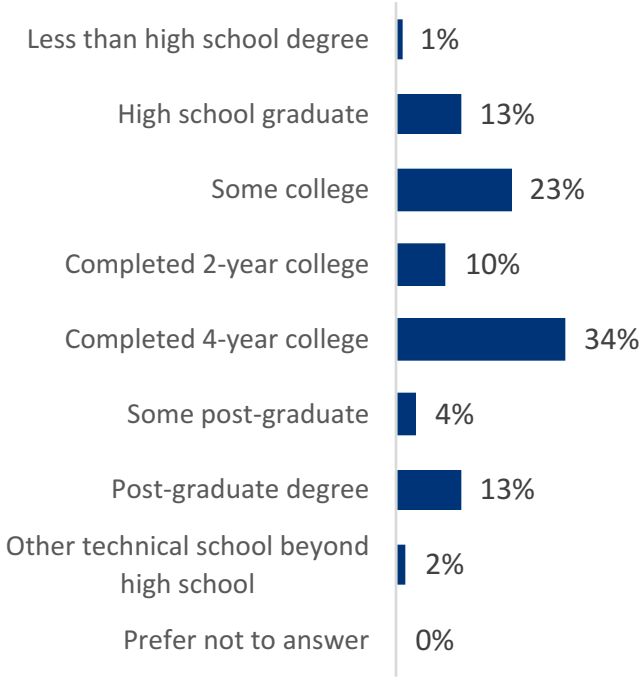
(% of respondents who tended to wear their last pair of lenses for a longer amount of time than usual)



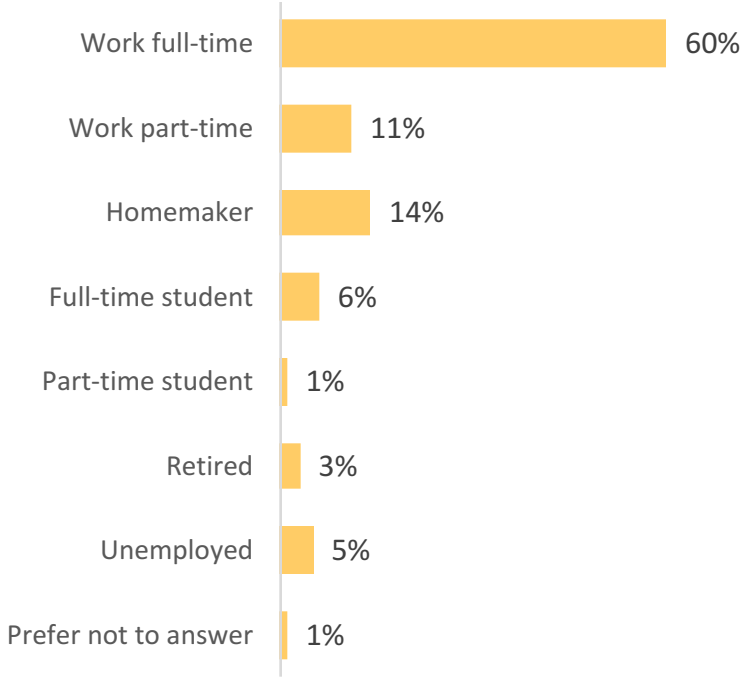
Q6. Approximately, how many more days longer do you wear your last pair of contact lenses? (Tended to wear your last pair of lenses for a longer amount of time, n=649)

Q7. What type of contact lenses do you wear? (All Respondents, n = 1000)

Education



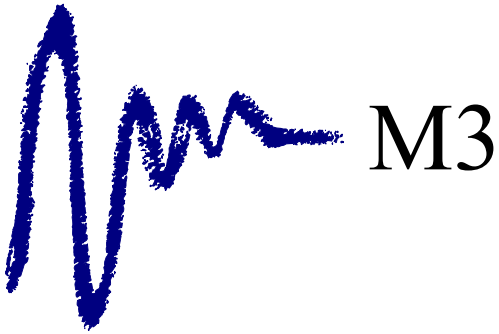
Employment



D1. What is the last grade of school you completed? (All respondents, n=1000)
D2. Which of the following best describes you?

EXHIBIT B

1 800 contacts®



Optometrist Study January 2017: Fitting and Patient Portal Practices

Prepared by M3 Global Research for

1800contacts®

Study Objectives/Methodology

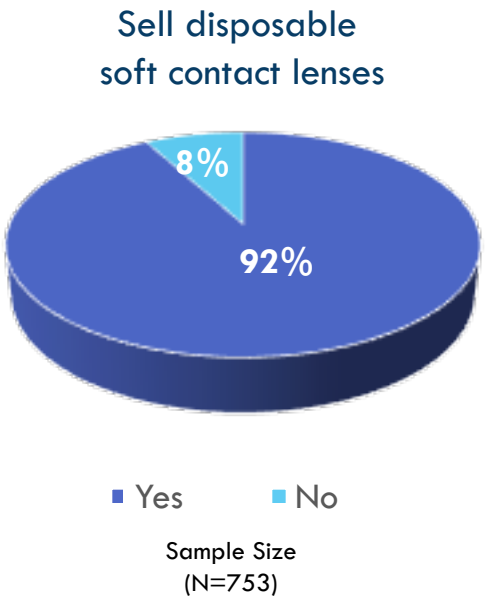
Objectives

- Better understand the disposable soft contact lens fitting practice in the United States.
- Determine the penetration of patient portals or websites.

Methodology

- Online panel study conducted among optometrist in the United States
- Completes collected between December 12, 2016 through January 4, 2017 (Total N=753)
  - Average Length of Survey: 10 mins
  - Study Incidence Rate: 96%

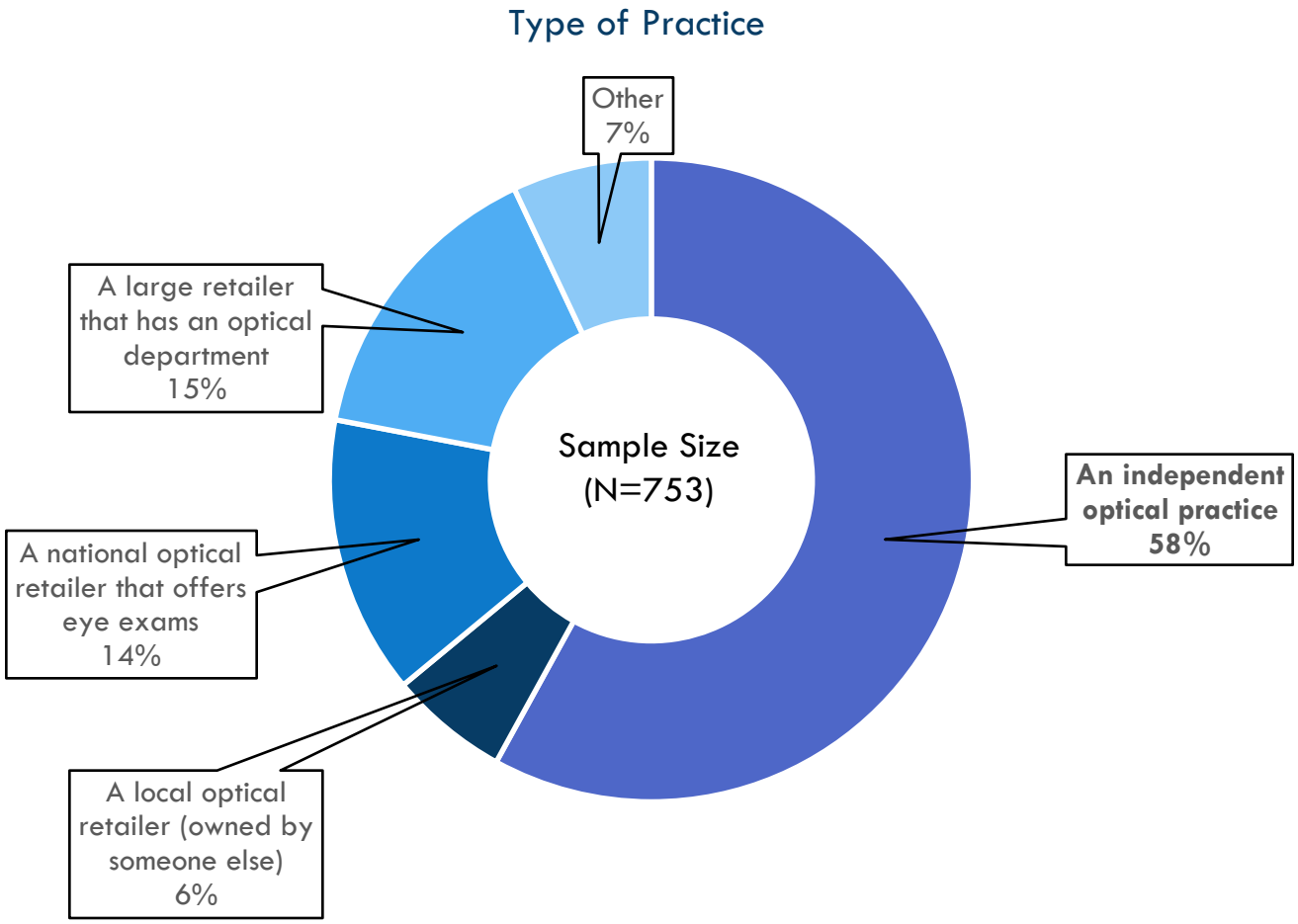
Most optometrists sell contact lenses.



S1: Do you sell prescription disposable soft contact lenses at your practice? (n=753)

Organization Type

More than half (58%) had an independent optical practice

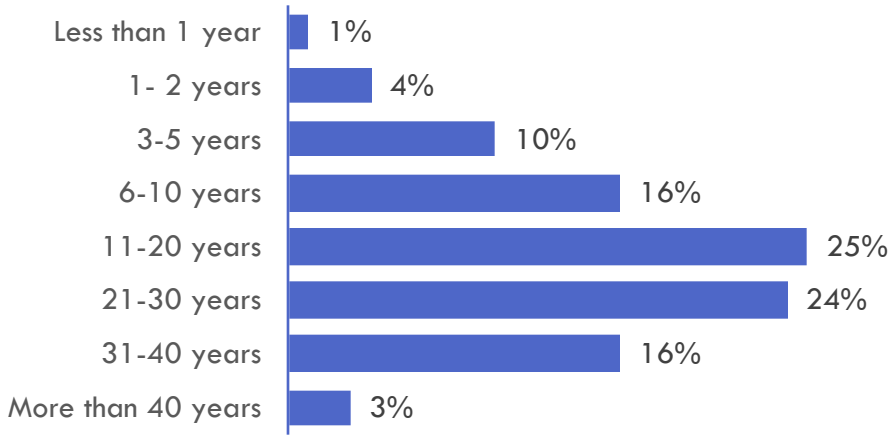


S3: Which of the following best describes the type of practice where you work? (n=753)

Optometrist Practice

- About half (49%) practiced between 11-30 years.
- Average number of patients served annually were 3,800 with a median of 3,100

Years of practice



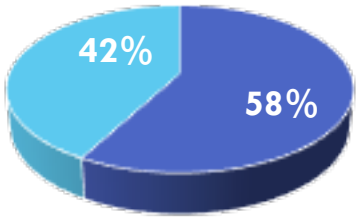
Sample Size
(N=753)

Patients practice serves annually

Mean	3,800
Median	3,100

Sample Size
(N=753)

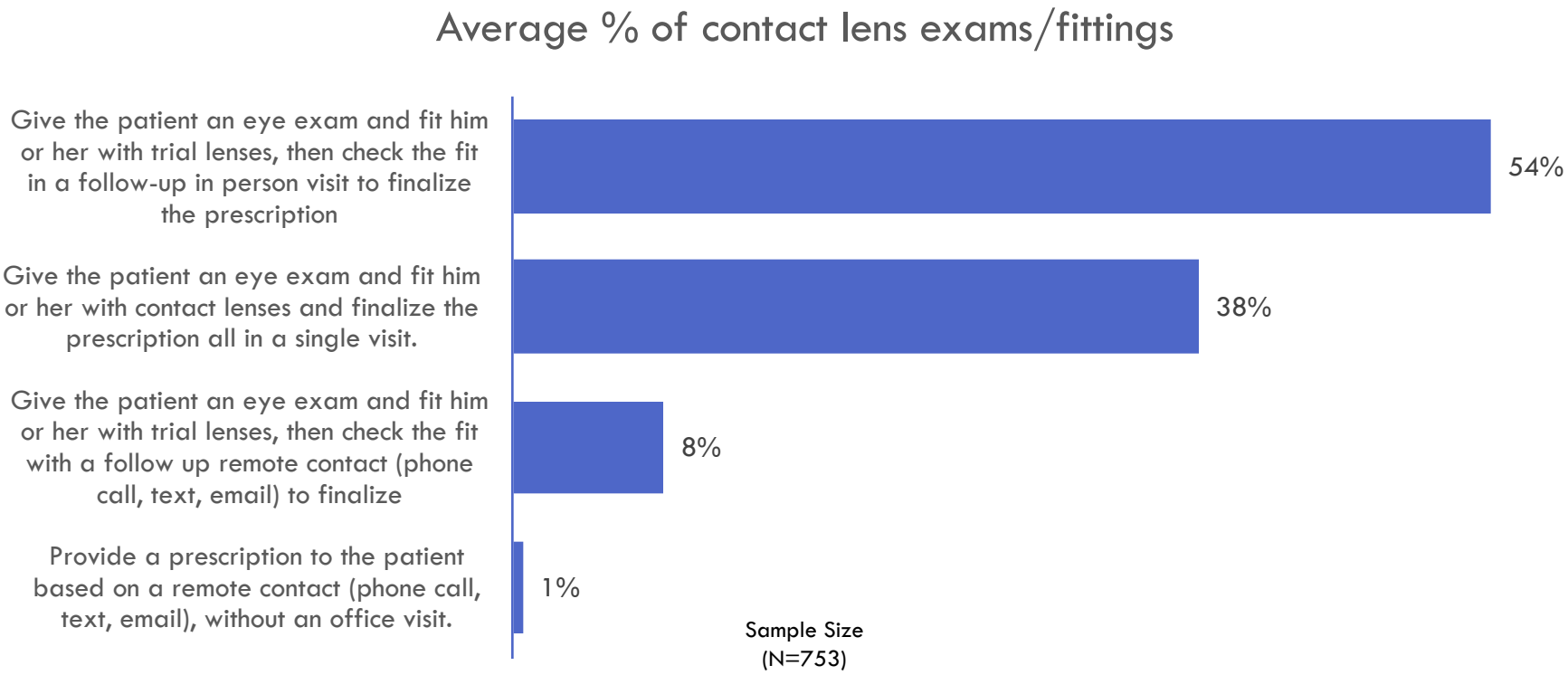
Gender



Sample Size
(N=753)

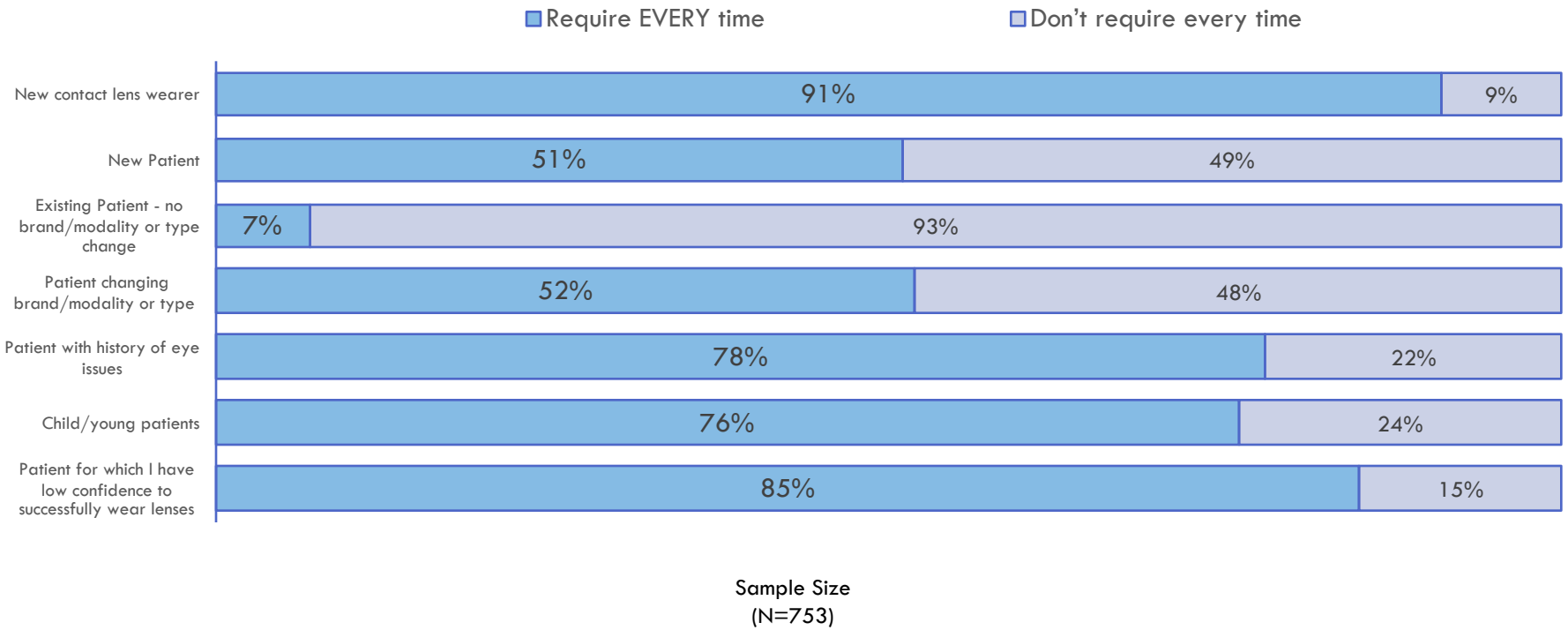
D2:How many years have you been practicing as an optometrist? (n=753)
D3:Approximately, how many total patients does your practice serve annually? (n=753)
D4:Are you…? (n=753)

92% of contact lens fittings are completed in-person.



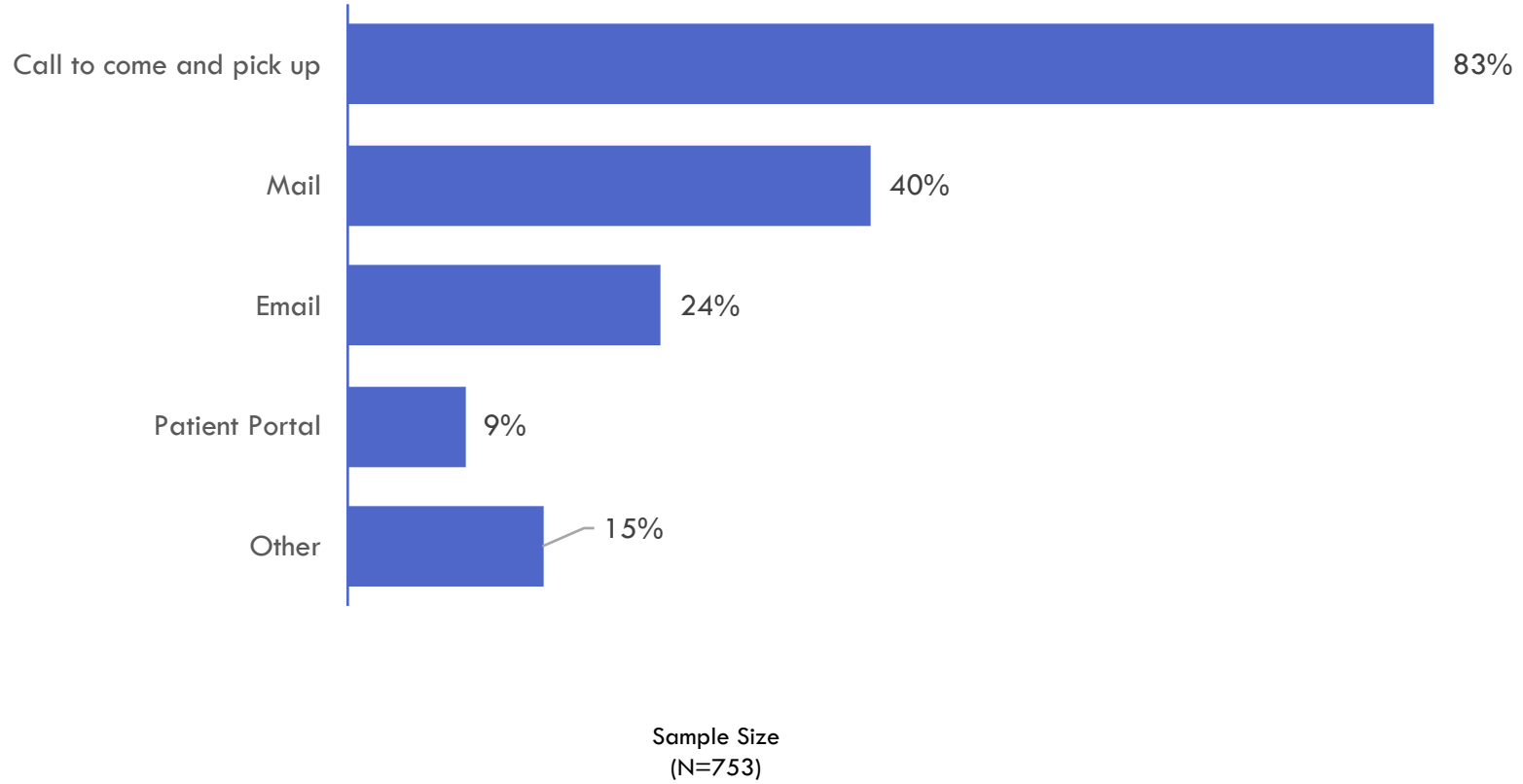
Q1: Thinking about all of the contact lens exams/fittings that you have performed over the past year, what percentage looked like the following scenarios? (n=753)

Most patient types are required to have an in-person follow-up to complete a fitting.



Q2. Are there any patient cases where you **definitely** require an in-person follow-up visit for fitting contact lenses? (n=753)

Optometrists use a variety of methods to provide Rx to patient if complete fitting through a remote communication.

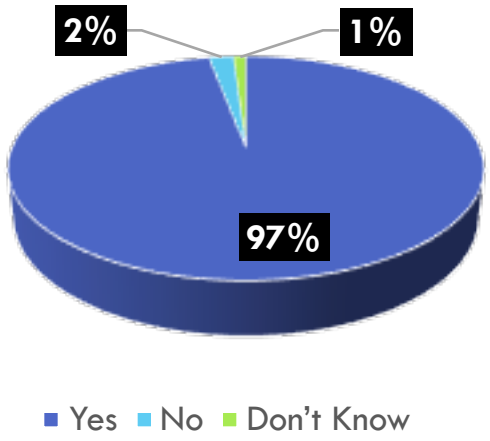


Sample Size
(N=753)

Q3A: For cases when you do not have an in-person follow-up visit to fit a patient for contact lenses, how do you deliver that patient's contact lens prescription? (n=753)/Total exceeds 100% (multiple choice permitted)

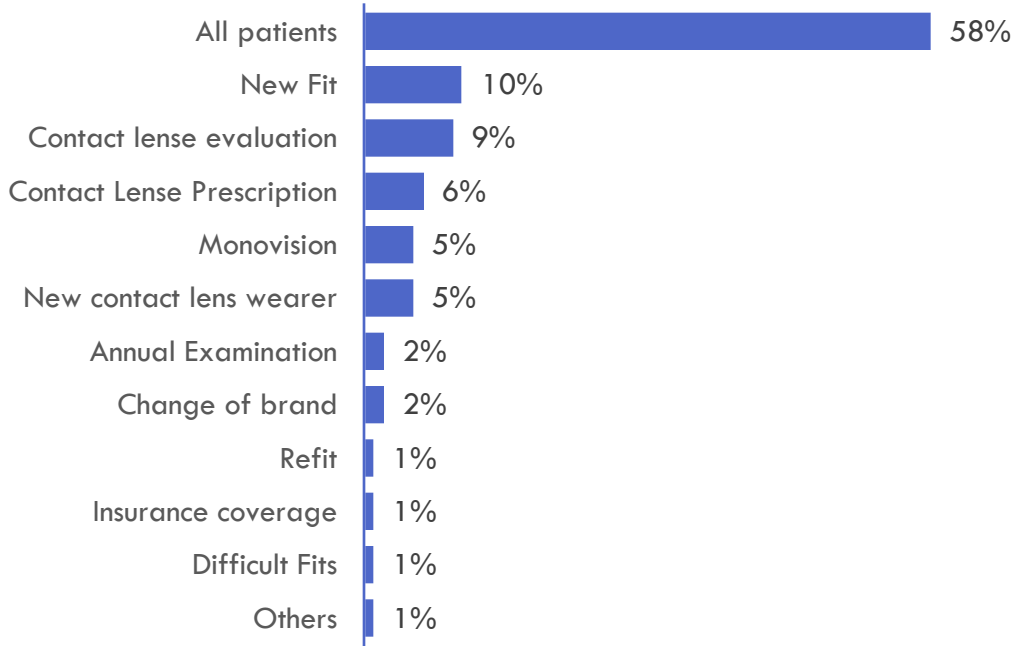
Almost all practices charge a separate fitting fee for contact lenses to all patients.

Charge separate fitting fee for contact lenses



Sample Size (N=753)

Cases where separate contact lens fee charged

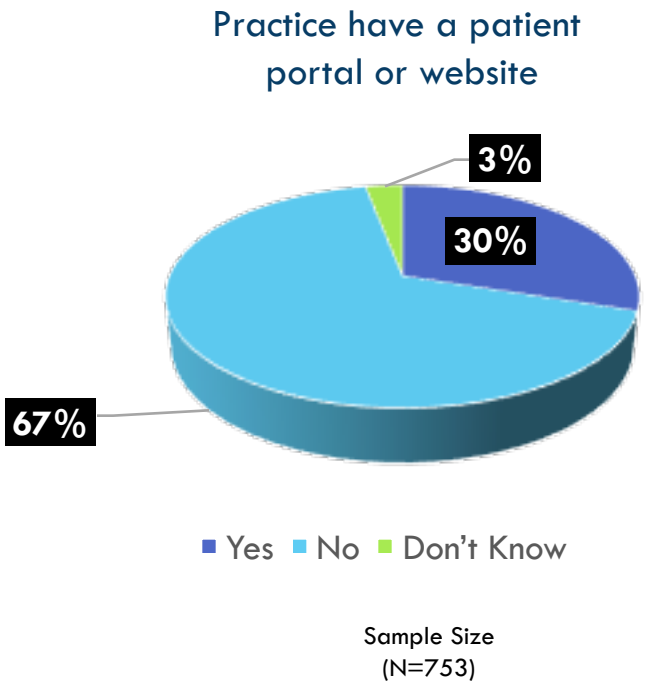


Sample Size (N=730)

Q3B: Do you charge a separate fitting fee for contact lenses? (n=753)

Q3C: What specific patient cases do you charge a separate contact lens fitting fee? (n=730)

67% of practices do not have a patient portal.



Sample Size
(N=753)

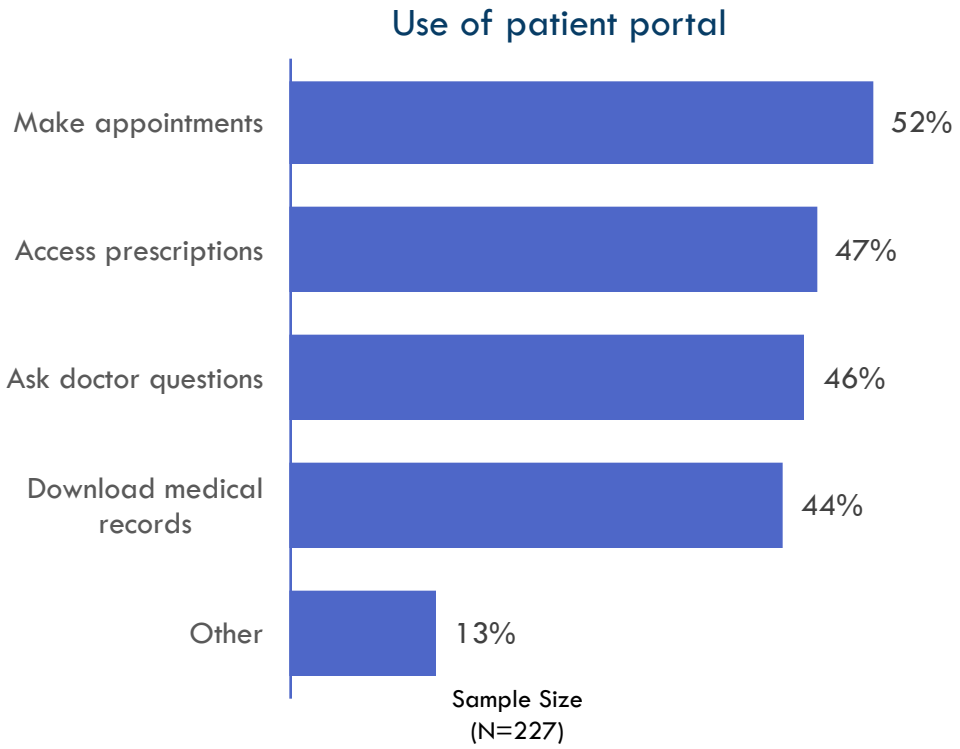
Q4: Does your practice have a patient portal or website, in other words, a secured online resource that gives patients access to their personal vision health information? (n=753)

29% of patients sign up/access a patient portal when offered.

Aware & Sign up
Of patient portal

Average % of patients aware of patient portal/website	**40%**
Average % of patients signed up to access patient portal/website	29%

Sample Size
(N=227)

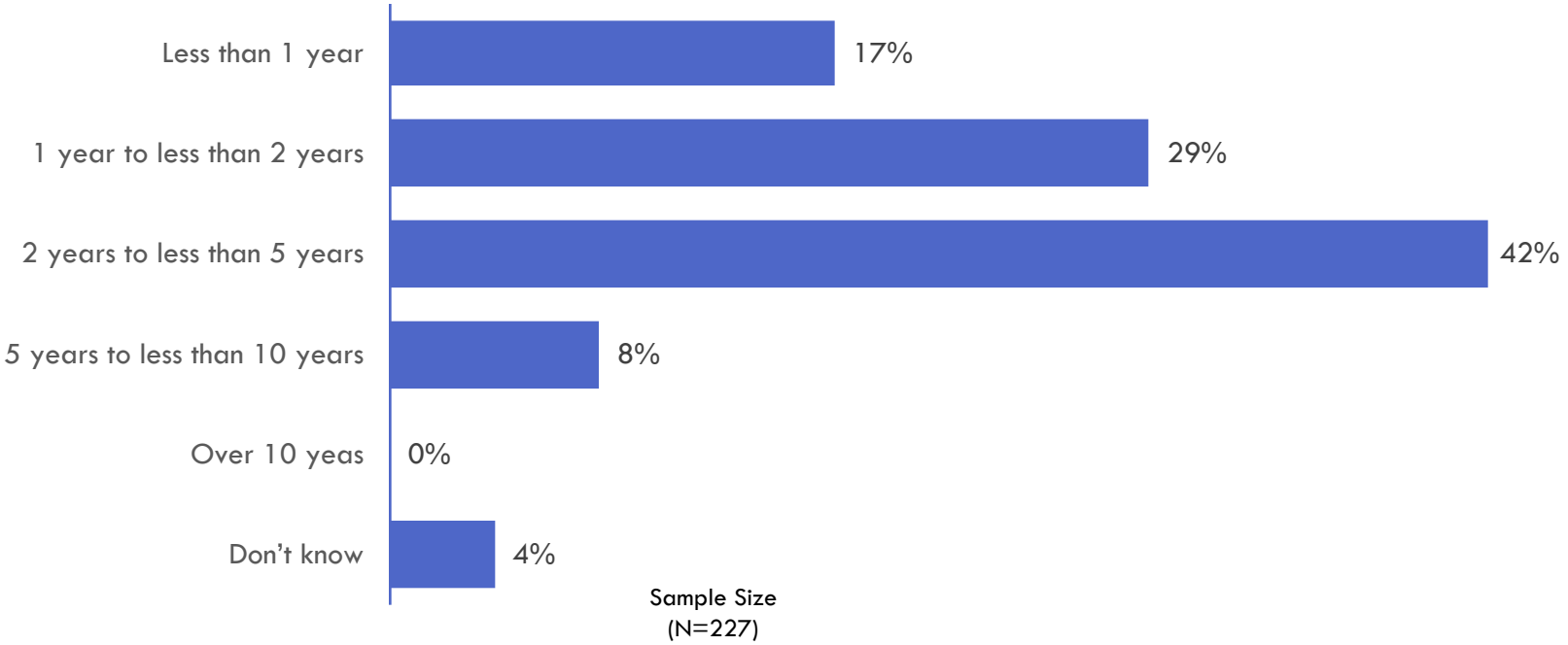


Q7: From your best guess, approximately what percentage of patients at your practice are aware of the patient portal or website (n=227)

Q8: Approximately, what percentage of patients at your practice have signed-up to access the patient portal or website? (n=227)

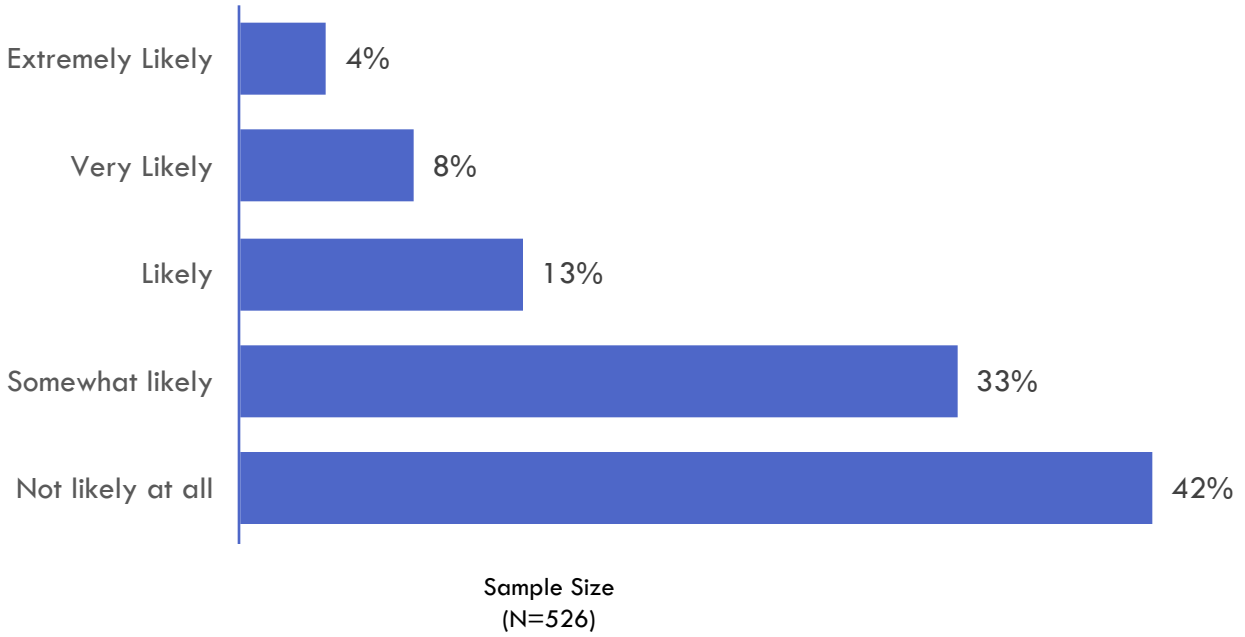
Q9: From what you've seen or heard from patients in regards to the portal or website, which features are used by patients? (n=227)/Total exceeds 100% (multiple choice permitted)

Most practices that have a patient portal adopted within the last 5 years.



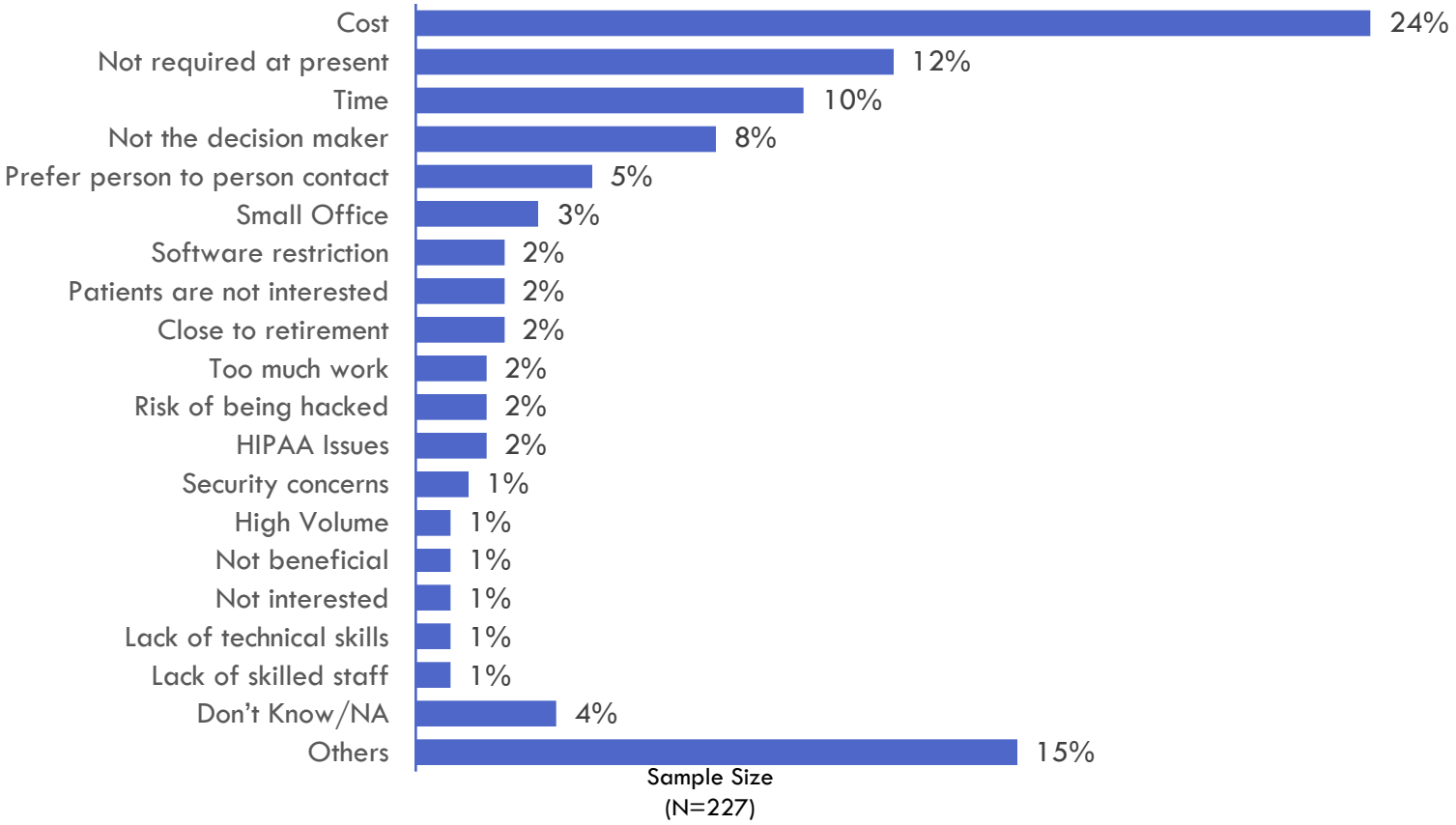
Q5: Approximately, how long has your practice had a portal or website available for patients to use? (n=227)

42% of optometrists are ‘not likely at all’ to develop a patient portal in the next 12 months.



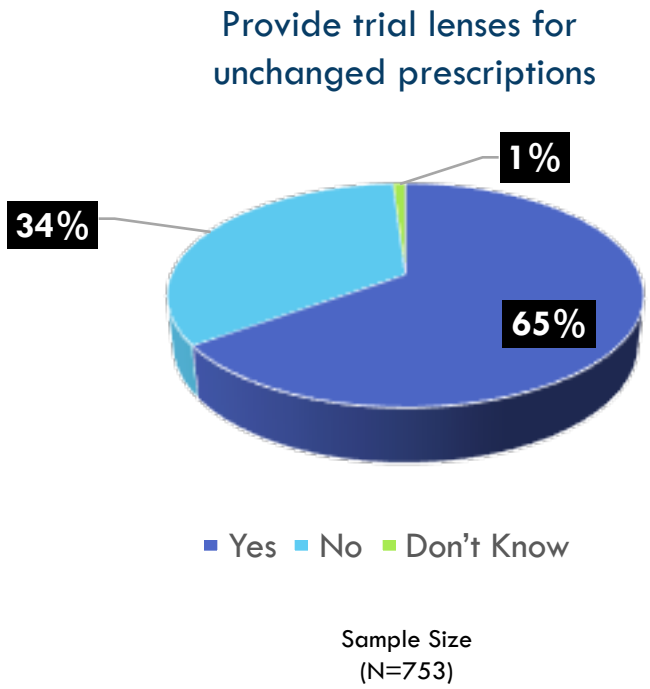
Q10: What is the likelihood that your practice will develop a patient portal or website that will give patients access to vision health information in the next 12 months? (n=526)

Cost is the primary barrier to developing a patient portal.



Q12: What are some reasons why your practice does not want to develop a patient portal? (N=227)

65% of optometrists provide trial lenses to patients.



Sample Size
(N=753)

Q13A: Over the past year, when it comes to providing free trial contact lenses to patients, approximately what percentage of each type of patient below do you provide of trial contact lenses? (n=753)

Q13B: Do you give trial contact lenses to a patient whose prescription has not changed? (n=753)

EXHIBIT C

1 800 contacts®

AOA Supports S. 2777 to Crackdown on Unscrupulous Internet Contact Lens Sellers

AMERICAN OPTOMETRIC ASSOCIATION

AOA Supports S. 2777

- *Senator Bill Cassidy (R-LA), a medical doctor, has introduced the **Contact Lens Consumer Health Protection Act (S. 2777)** to crack down on unscrupulous Internet-based contact lens sellers that are placing contact lens wearers at risk by selling without proper verification of prescriptions, by overfilling orders, by filling orders with expired prescriptions or by filling orders with lenses other than those that were prescribed.*

- *S. 2777 is a public health and safety bill aimed at holding Internet sellers accountable for deceptive, abusive and illegal sales tactics, especially those that cause harm and result in added health care costs.*

- *AOA supports S. 2777 and urges Senators to co-sponsor the bill.*

Contact lenses have long been recognized in law and regulation as medical devices. Today, with advances in lens design, new products and healthy competition, they are chosen by tens of millions of Americans for their vision correction needs, as well as for cosmetic or therapeutic reasons. All contact lenses, even purely cosmetic ones, require a prescription and must be properly fitted and prescribed by a doctor of optometry or other eye doctor (ophthalmologist) following an eye health examination to determine a patients suitability for contact lens wear.

Although contact lenses are safe and effective, their improper use can lead to serious health complications, including infections and other sight threatening conditions. In 2014, the U.S. Centers for Disease Control and Prevention (CDC) released a report that concluded that annually there are nearly 1 million emergency room and urgent doctor visits and about $175 million in added health care costs arising from keratitis, an infection linked to improper contact lens use.

Many contact lens wearers choose to purchase their lenses online through Internet mass retailers. As a patient health safeguard, the *Fairness to Contact Lens Consumers Act* (FCLCA) requires online sellers to verify the validity of contact lens prescriptions with the patient's doctor before fulfilling an order. Eye doctors and patients report that some Internet sellers are not following these health, safety and common sense requirements in the law and are placing patients needlessly at risk. In 2015, one large Internet mass retailer went so far as to begin using a pre-checked box on its order forms designating the company as the patient's "agent" for future contact lens purchases. This deceptive tactic remained in force until the American Optometric Association (AOA) complained, though without a firm public statement by Federal enforcement officials a similar sales scheme may be used again by sellers seeking to maximize profits at the expense of patient safety.

According to a March 2016 survey conducted by the AOA Contact Lens and Cornea Section regarding FCLCA compliance, nearly one-half of doctors with contact lens-oriented practices reported that at any given time they are seeing that dozens of their patients are receiving contact lenses from Internet retailers that are different lenses from what was prescribed. Moreover, a 2015 consumer survey found that among contact lens patients who ordered their lenses online:

- 1 in 4 have reported receiving a different contact lens brand than prescribed by their eye doctor, without any advance warning;
- 1 in 3 have had their online retailer advise them to substitute a non-prescribed lens due to supply issues; and
- 1 in 3 were able to purchase lenses using an already expired prescription.

AOA Supports S. 2777 to Crackdown on Unscrupulous Internet Contact Lens Sellers

AMERICAN OPTOMETRIC ASSOCIATION

AOA Supports S. 2777

In spite of mounting doctor and patient complaints about FCLCA abuses by unscrupulous Internet sellers and letters in 2015 from 40 Members of Congress – led by Senator David Perdue (R-GA) and Representative Derek Kilmer (D-WA) – to the Federal Trade Commission (FTC) urging stepped up enforcement of the law, the threat of patient harm continues to increase. The FTC's inadequate enforcement efforts stand in contrast to active public health and safety initiatives mounted in recent years by the CDC and the Food and Drug Administration (FDA), pointing to the need for S. 2777 to be a priority on Capitol Hill.

The *Contact Lens Consumer Health Protection Act (S. 2777) will:*

- ***Hold sellers accountable for illegal sales tactics and false claims, and make increased enforcement to safeguard public health a priority for the FTC.***
- ***Establish a live patient safety hotline allowing doctors to provide sellers with patient health information and ensure that the doctor-patient relationship is respected***
- ***Ban use by Internet sellers of disruptive automated "robo calls" into doctor offices as a mechanism for verifying patient prescription information, and allow doctors to choose live phone calls or emails from sellers instead.***
- ***Ensure contact lenses are dispensed exactly as the prescription is written by the doctor.***
- ***Direct the Centers for Disease Control to study the public health and health care cost impact of Internet seller abuses.***
- ***Increase fines to sellers to $40,000 per infraction.***

The *Contact Lens Consumer Health Protection Act (S. 2777) is endorsed by:*

- ✓ **American Optometric Association**
- ✓ **American Academy of Ophthalmology**
- ✓ **AdvaMed — Advanced Medical Technology Association**
- ✓ **American Association of Diabetes Educators**
- ✓ **Association of Schools and Colleges of Optometry**
- ✓ **Coalition for Patient Vision Care Safety**
- ✓ **Contact Lens Institute**
  - **Alcon**
  - **Bausch + Lomb**
  - **CooperVision**
  - **Johnson & Johnson Vision Care**

Status of the bill:

- S. 2777 was introduced on April 11, 2016, and was referred to the Senate Committee on Commerce, Science and Transportation.
- Senators are urged to co-sponsor this bill by contacting Pranay Udutha (Sen. Cassidy) at 202-224-5824.

For more information, please contact Alicia Kerry Mica at 703.837.1373 or akmica@aoa.org.

The members of the American Optometric Association — America's Family Eye Doctors — are the nation's frontline providers of eye and vision care. Doctors of Optometry serve patients, including America's seniors, school-aged children, veterans and military service personnel, in about 6,500 communities across the country.

EXHIBIT D

1 800 contacts®

US Contact Lens Consumer Study
August 9, 2016
Executive Summary

Overview:

In July 2016, Survey Sampling International – on behalf of 1-800 CONTACTS – conducted an online survey of 2,000 U.S. adult contact lens consumers. The purpose of this study was to generate a comprehensive understanding of U.S. contact lens consumer experiences and satisfaction with current retail and brand choices, prescription restrictions, and industry-wide practices.

The survey establishes that the passive verification system works as Congress intended in that in the vast majority of cases consumers purchase lenses with a valid prescription and receive the brand prescribed by their Independent Eye Care Provider (IECP).

Key Findings:

1. The purchase of contact lenses by consumers whose prescription has expired is uncommon and does not vary across retail channels. The study shows that customers purchase lenses without renewing their prescription from IECPs at the same modest rate as from online retailers.

    a. In total, 11% of consumers in the survey indicated that they had purchased lenses after their prescriptions had expired; 10% of those purchased from their IECP, 14% purchased from other retailers[1], and 9% purchased from online retailers.

[1] Consumer segment based on the survey question: "Which of the following best describes where you last purchased contact lenses for your personal use?" IECP ("An eye doctor such as an ophthalmologist or optometrist"), Online ("An internet, online or mail order retailer such as 1-800 CONTACTS") and Other Retailer (all others).

b. Half of all consumers (51%) report that they received some form of permission from their doctor to wear contact lenses after their prescription had expired (e.g., received trial pairs, had a prescription extended without an exam, received authorization for sale, or sold without an eye exam).

2. Nearly all consumers receive the lenses they ordered. Only 2% of those purchasing from IECPs and 1% of those purchasing from online retailers report having received a different and non-approved substitute brand of contact lenses than what they ordered. This study dispels any prior contention that one in four online consumers receives a different brand than what they ordered.

3. It is regular industry practice across all types of retailers, including IECPs, brick and mortar, and online to send reminders to consumers at the end of the life of the prescription. The percentage of consumers that buy as a result of this reminder is the same between IECPs and online retailers. Retailers have adopted this common-sense practice because it reminds consumers to renew their prescription and to consider whether they have sufficient supply to prevent unhealthy behavior such as stretching their lenses.

    a. It is relatively common for consumers to purchase lenses with less than a month left on their prescription expiration regardless of the retail channel used (28%, 35%, and 28% for consumers of IECPs, other retailers, and online retailers respectively).

    b. The medical evidence establishes that there is no greater health risk to consumers who purchase contact lenses near the end of a prescription as those who purchase at the beginning of a prescription.

4. Consumers are satisfied with their purchasing experiences across all retail channels and find their online retailer as reputable and trustworthy as their IECP.

    a. 72% of all contact lens consumers are overall "Very Satisfied" with their last purchase experience (70%, 70%, and 83% for consumers of IECPs, other retailers, and online retailers respectively). Consumers consider their IECP and their online retailer to be equally reputable.

Survey Design:

Previous contact lens consumer surveys such as the APCO Insights studies for Johnson & Johnson (August 2015 & Sept/Oct 2015) were highly biased and incomplete in their design – and as a result have generated misleading and unreliable data.[2] Specifically:

1. Not all questions were asked to all consumers. One survey was conducted only among online contact lens consumers and as a result neglected to collect and report out data on consumers who purchase from doctors and other brick-and-mortar retailers as a fair and balanced basis of comparison.

2. Question design often used the phrase "have you ever" rather than "at your last purchase" which resulted in the reporting of falsely inflated self-reported behaviors.

3. The online survey collected and reported out statistics on online consumers of contact lenses of extremely low significance - the n=104 online consumers that were subject to

[2] This data has in turn been falsely interpreted and publicly disseminated, see, e.g., The Coalition for Patient Vision Care Safety, Comments Regarding the FTC's Regular Review of the Contact Lens Rule (Oct. 26, 2015), *available at* https://www.ftc.gov/system/files/documents/public_comments/2015/10/00621-99429.pdf); Johnson & Johnson Vision Care Patient Testimonial, *available at* http://jnjvisioncareinfo.com/sites/default/files/Final%20Patient%20Testimonial.pdf.

the survey provides a statistical confidence level of only 69% (margin of error of 9.61%).

To directly address the above challenges to validity, this study:

1. Included all questions within a single survey with a single sample of consumers purchasing from a variety of sales channels to provide a more representative sample of contact lens purchasers.

2. Phrased questions to more accurately measure self-reported behaviors by using the phrase "at your last purchase" (rather than "have you ever").

3. Over-indexed for online contact lens consumers to achieve statistical confidence level of 99.99% (margin of error of 3.1%).

Contact Lens Consumer Study Results

Report prepared by Survey Sampling International
for 1-800 CONTACTS

August 9, 2016

Overview

Objectives

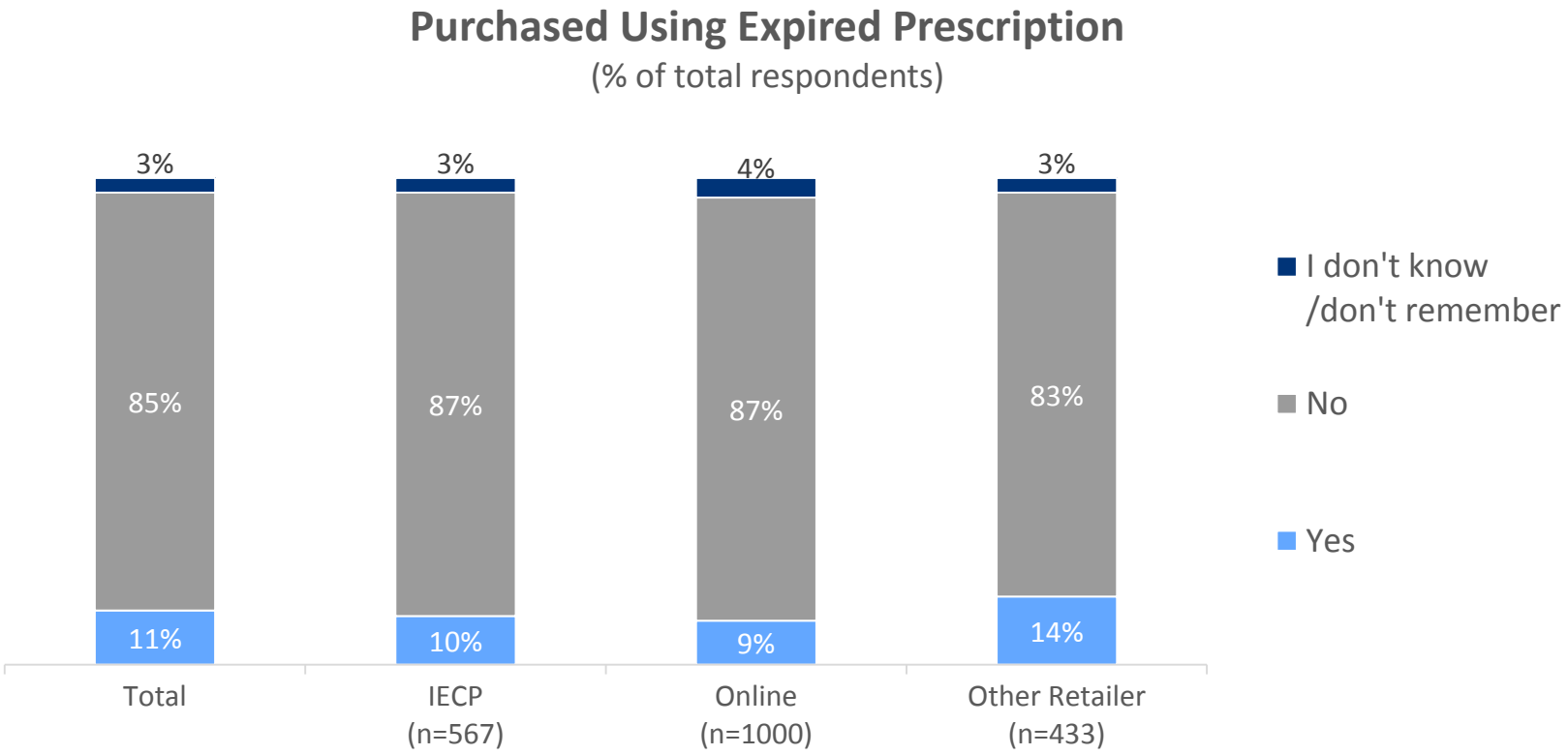
- Understand contact lens consumer experiences and satisfaction with current retail and brand choices; prescription restrictions; and industry-wide practices.

Methodology

- Online study conducted among contact lens wearers in the US
  - Target respondent: 18 - 49 years old and purchased soft contact lenses in past 6 months
- Completes collected between July 12-15, 2016 (Total N=2000)
  - Sample split between online purchasers (n=1000) and non-online purchasers (at IECP, retail chain location, etc., n=1000)
- Total values weighted according to the Vision Council: IECP 40%, Online 16%, and Other Retailer 44%*.
  - Study oversampled online customers to get a readable base

* Consumer segment based on question: "Which of the following best describes where you last purchased contact lenses for your personal use?" IECP ("An eye doctor such as an ophthalmologist or optometrist"), Online ("An internet, online or mail order retailer such as 1-800 CONTACTS") and Other Retailer (all others).

Purchasing contact lenses with an expired prescription is uncommon and the incidence does not vary across retail channels.



Q4. Thinking about the last time you purchased and received contact lenses for your personal use, did you use a contact lens prescription that was already expired? (All respondents, n=2000)

*Total calculated on estimated market size according to the Vision Council; IECP 40%, Other Retailer 44%, and 16% Online

Half of all consumers report receiving some form of permission from their doctor to wear contact lenses based on an expired Rx.

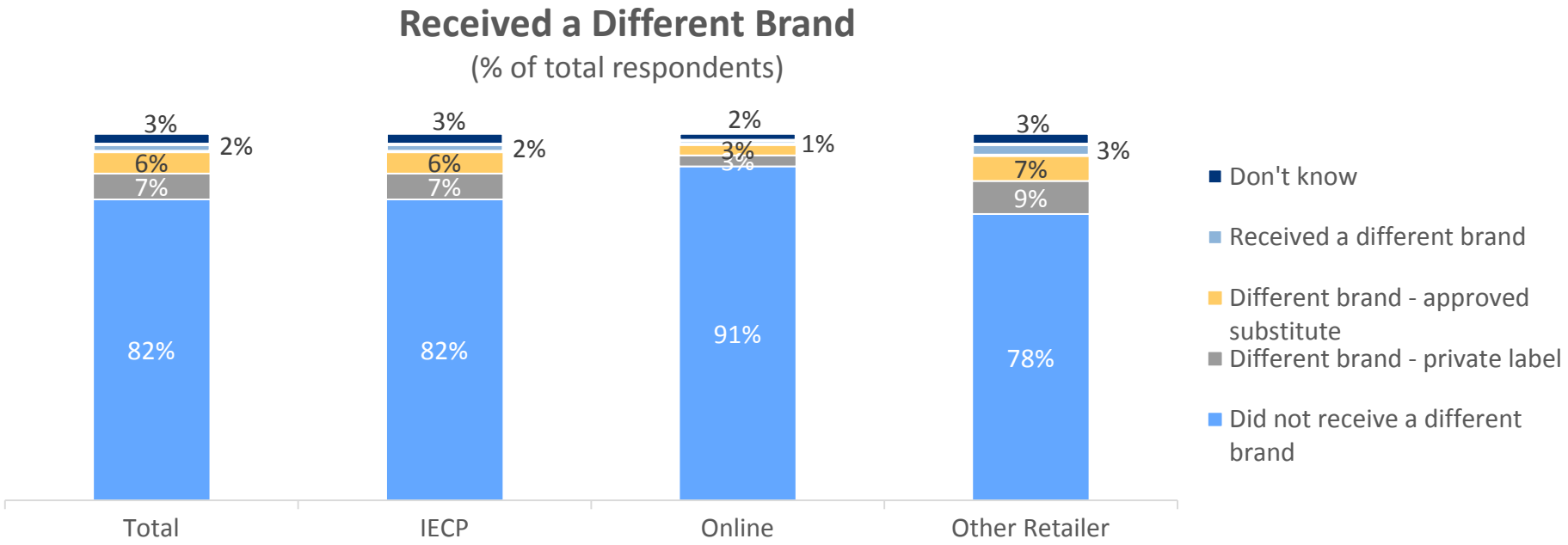
35% have received trial lenses while 13% had a prescription extension, 9% received authorization for sale (or sold) lenses, and 5% sold CLs entirely devoid of an eye exam.

	Total (N = 2000)	IECP (n=567)	Online (n=1000)	Other Retailer (n=433)
Gave you free trial contact lenses to hold you over until your next comprehensive, in-person eye exam	35%	35%	32%	36%
Extended your contact lens prescription without giving you a comprehensive, in-person eye exam	13%	11%	9%	15%
Authorized another retailer to sell you contact lenses without giving you a comprehensive, in-person eye exam	9%	9%	7%	10%
Sold you contact lenses without giving you a comprehensive, in-person eye exam	5%	5%	3%	6%
None of the above	49%	49%	58%	47%

Q4b. Has your eye doctor ever done any of the following, after your prescription expired? (All respondents, n=2000)
*Total calculated on estimated market size according to the Vision Council; IECP 40%, Other Retailer 44%, and 16% Online

Consumers receive the brand ordered almost 100% of the time.

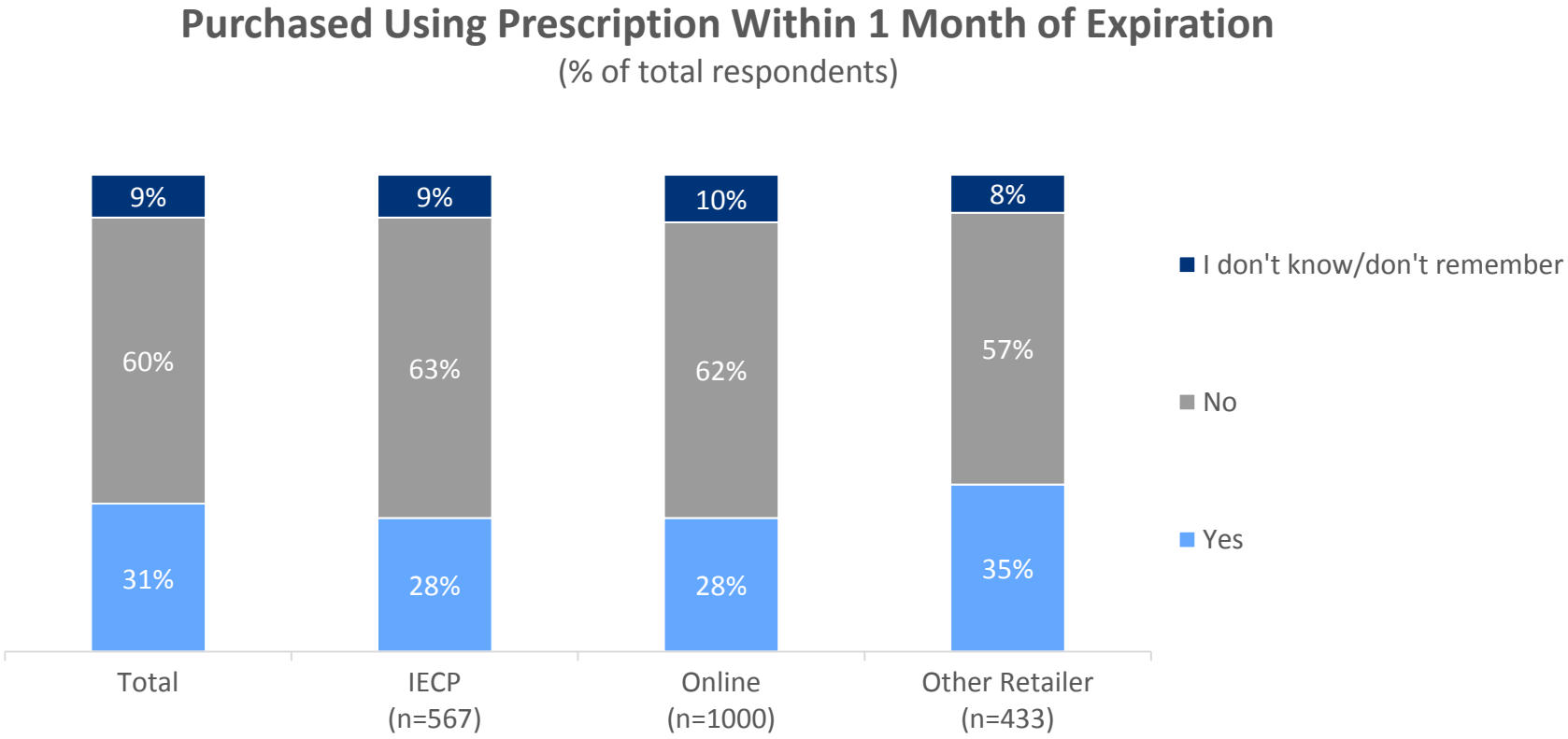
Only 2% of consumers of IECP and 1% of consumers of online retailers report having received different and non-approved substitute brand of lenses than they ordered.



Q8a. When you last purchased contact lenses, did you end up receiving a different brand of contact lenses that was different than the brand you ordered/intended to purchase? (All respondents, n=2000)
Q8b. Was the last brand of contact lenses that you intended to purchase a private label brand? (Respondents who received a different brand of contact lenses, n=259)
Q8c.Was the last brand of contact lenses you intended to purchase (the brand that you were switched from) any of the following brands? (Respondents who don't intend/didn't remember to buy private label brand, n=147)
*Total calculated on estimated market size according to the Vision Council; IECP 40%, Other Retailer 44%, and 16% Online

It is relatively common for consumers to purchase lenses with less than a month remaining on their prescription, across all sales channels.

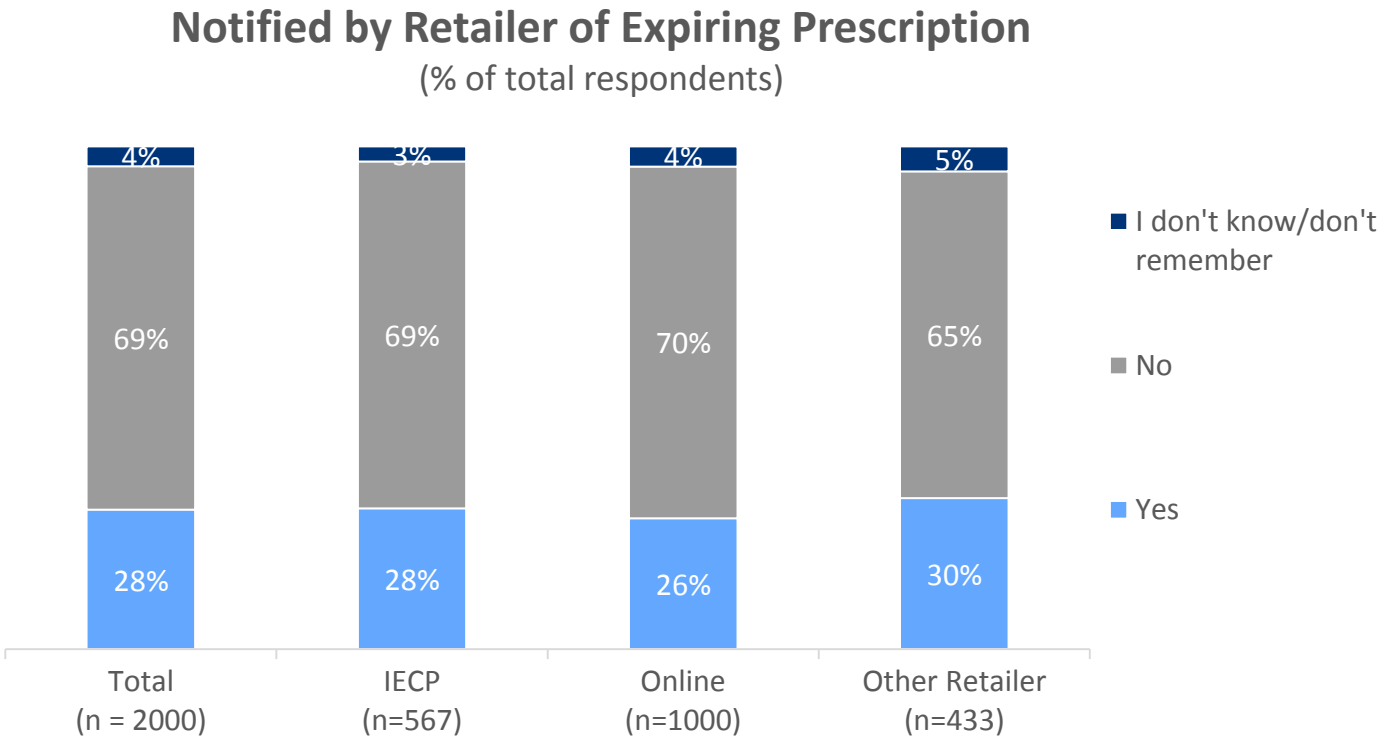
Across all retailers, 31% of all consumers purchase lenses with less than one month left on their prescription expiration.



Q3. Thinking about the last time you purchased and received contact lenses for your personal use, did you buy your contacts using a contact lens prescription that was less than a month from its expiration date? (All Respondents, n=2000)
*Total calculated on estimated market size according to the Vision Council; IECP 40%, Other Retailer 44%, and 16% Online

Both IECPs and online retailers remind consumers that their prescription will be expiring.

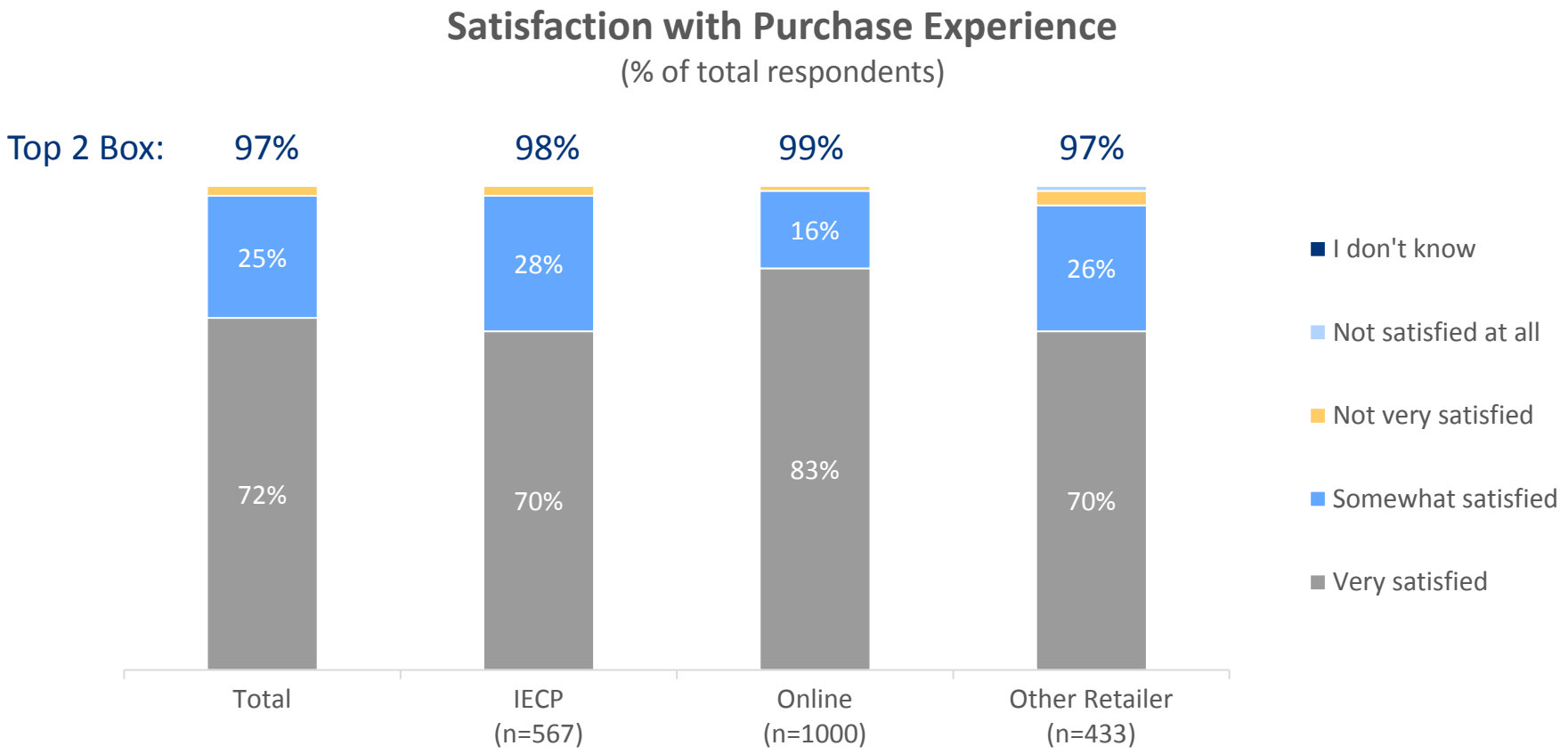
28% of all consumers buy as a result of this reminder.



Q5a. Thinking about the last time you purchased and received contact lenses for your personal use, did you do so in response to a notification (email, letter, or phone call) from your eye doctor reminding you that your contact lens prescription was expiring soon? (Respondents who purchased contact lenses at an eye doctor, n=567)
Q5b. Thinking about the last time you purchased and received contact lenses for your personal use, did you do so in response to a notification (email, letter, or phone call) from your retailer reminding you that your contact lens prescription was expiring soon? (All respondents, n=2000)
*Total calculated on estimated market size according to the Vision Council; IECP 40%, Other Retailer 44%, and 16% Online

Consumers are satisfied with their purchasing experiences across all retail channels.

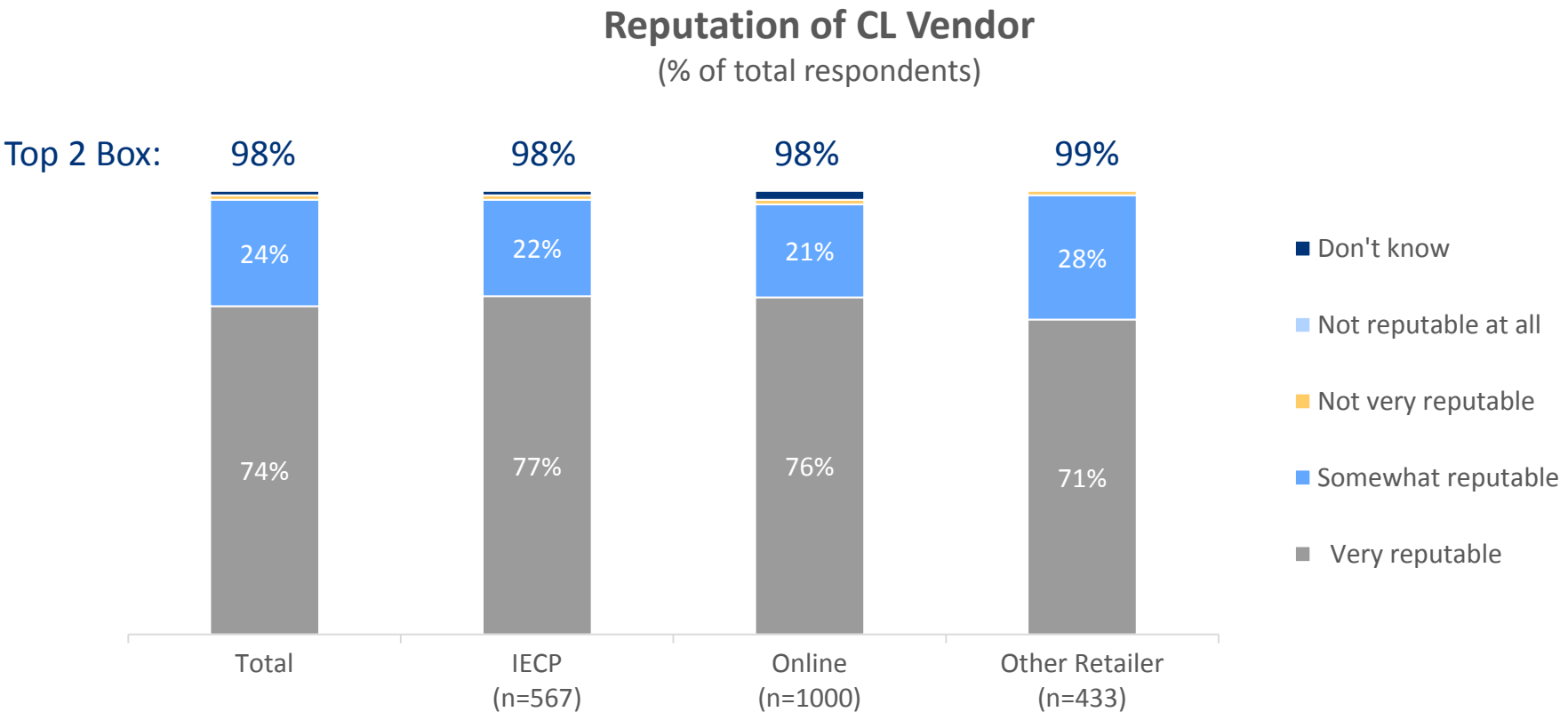
72% of all contact lens consumers are 'Very Satisfied' with their last purchase experience, while 74% think their retailer is 'Very Reputable.'



Q2a. How would you rate the overall reputation of where you last purchased or received your contact lenses? (All respondents, n=2000)
Q2b. Thinking about the last time you purchased and received contact lenses for your personal use, how satisfied were you with the overall purchase experience? (All respondents, n=2000)
*Total calculated on estimated market size according to the Vision Council; IECP 40%, Other Retailer 44%, and 16% Online

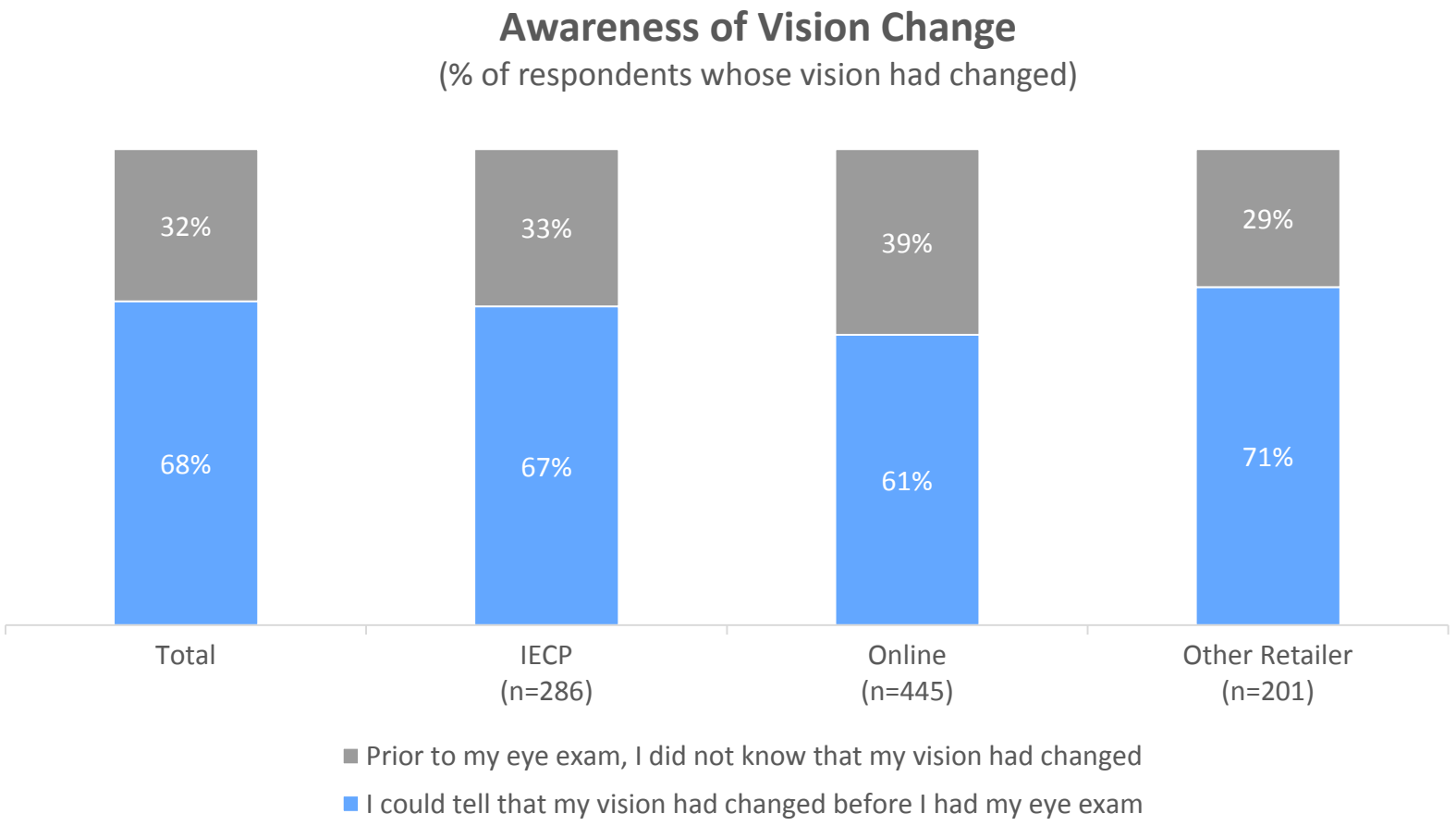
Majority of respondents feel their contact lens vendor is reputable.

An overwhelming majority of respondents feel that online contact lens vendors are essentially as reputable as doctors, and more reputable than other retailers



Q2a. How would you rate the overall reputation of where you last purchased or received your contact lenses? (All respondents, n=2000)
*Total calculated on estimated market size according to the Vision Council; IECP 40%, Other Retailer 44%, and 16% Online

Over two-thirds (68%) were aware that their vision changed prior to their exam.



Q13. Were you aware that your vision had changed before you had your eye exam, or did the results from your eye exam reveal that your vision had changed? (Respondents whose vision has changed, n=932)
*Total calculated on estimated market size according to the Vision Council; IECP 40%, Other Retailer 44%, and 16% Online

EXHIBIT E

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Online buyers get eye exams about as frequently as IECP buyers

Approximately how frequently do you have an eye exam?	Online		IECP		Other Retailer	
	Percentage	Est. Months	Percentage	Est. Months	Percentage	Est. Months
More frequently than every 6 months (x3)	9.6%	0.3	1.6%	0.0	10.1%	0.3
Between every 6 months and less than every year (x9)	16.7%	1.5	8.3%	0.7	17.7%	1.6
About every year (x12)	42.1%	5.1	68.1%	8.2	48.2%	5.8
Between every year and less than every 1 1/2 years (x15)	14.6%	2.2	11.1%	1.7	9.1%	1.4
Between every 1 ½ years and less than every 2 years (x21)	5.0%	1.1	4.4%	0.9	5.1%	1.1
About every 2 years (x24)	8.6%	2.1	5.4%	1.3	7.2%	1.7
Between every 2 years and less than every 3 years (x30)	1.7%	0.5	1.0%	0.3	.9%	0.3
Every 3 years or longer (x45)	1.7%	0.8		0.0	1.7%	0.8
TOTAL estimated months		**13.4**		**13.2**		**12.9**

Data collected June, 2016 by Survey Sampling International from their independent online survey panel participants. N=2,000 US adult contact lens wearers, ages 18-49.
Customers identified by question "where did you make your last purchase of contact lenses?" Online buyers identified as respondents who identified last purchase as 1-800 CONTACTS, Lens.com, Visiondirect.com and Coastalcontacts.com.

EXHIBIT F

1 800 contacts®

EYE INSTITUTE of Marina del Rey™

Paul B. Donzis, M.D.
Fellowship trained corneal specialist
Diplomate, American Board of Ophthalmology

2222 Santa Monica Blvd, Suite 107
Santa Monica, CA 90404
Tel: 310-822-0022 pdonzis@donziseye.com

January 9, 2017

To Whom It May Concern:

I have been asked to address and summarize the health care concerns raised by the Federal Trade Commission (FTC) and the comments on the FTC website regarding the Contact Lens Rule (Rule). While we all recognize that health issues related to contact lens use are a serious concern, the claim that source of supply, prescription length, and prescription requirements have an adverse effect on eye health, are not supported by the scientific literature, which I will demonstrate.

The concerns raised are important given the morbidity of microbial keratitis. In a 2010 CDC report, it was noted that microbial keratitis accounts for $175 million dollars annually in direct health care expenditures, and the leading cause for microbial keratitis was noted to be contact lens wear. But prescribers and commenters have been spreading false and merely anecdotal health claims to support rulemaking that has limited or no relationship to patient health. The fact is that no studies have shown any additional health risks for contact lens wearers in the United States who buy their lenses from alternative retail channels such as chain or warehouse stores or online retailers. Additionally, no relationship has been shown between the current passive verification system and patient health, here in the United States and elsewhere.

The most serious health care concern with contact lens use is keratitis, which is an inflammation of part of the cornea. It is generally caused by bacteria or other micro-organisms and can range from mild to severe. It rarely presents with any permanent vision loss and treatment is generally limited to antimicrobial eye drops. A 2010 Center for Disease Control Study (CDC) noted that most cases resolved completely with only one visit to the eye doctor.[1]

It is important to note that keratitis is an inherent but acceptable risk associated with contact lens wears. There is no way to fully prevent the development of keratitis in some patients. The overall incidence of keratitis is about 2 – 5 cases per 10,000 contact lens wearers per year. The overall incidence of moderate and severe keratitis, which has the potential for temporary or permanent vision loss is about 5-11 cases per 100,000 contact lens wearers per year, with daily disposable lenses having the lowest rates of keratitis and vision loss.[2]

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[1] Morbidity and Mortality Weekly Report, 2014:63(45);1027-1030.
[2] Stapleton F and Carnt N, Eye 2012:26;185-193

The rate of keratitis has remained stable over the last 2 decades, despite advances in contact lenses such as daily disposable lenses and newer materials. The main risk factors for contact lens related keratitis include overnight (extended) wear, poor lens case hygiene, and poor hygiene in general. Extended wear of contact lenses has been shown to be the number one risk factor for decades and across all geographic areas in numerous publications. There is about a 5 times relative risk of keratitis for extended wear users compared to daily wear users depending on the particular study. Poor lens case practices include not replacing the lens case every 3 to 6 months, topping off solutions in the case, and using tap water in the case. Poor hygiene practices such as not washing hands and not replacing the contact lens in a timely fashion (stretching the use of the lens beyond the recommended time to replace). These improper hygiene practices have also been associated with increased risk of keratitis.[3]

There have been many anecdotal factors noted by the American Optometric Association, limited case reports, and comments from the FTC website that have no proven correlation with increased overall risks of keratitis. These claims include online versus in-office purchases of contact lenses, increased number of people buying online, the introduction of the passive verification system, the use of expired prescriptions, the substitution of the contact lens for a different brand, and one-year versus two-year prescriptions as permitted by state law. For example, one claim is that online versus in-office purchases increases the risk of keratitis. No study in the United States has supported such a claim. Although one 2008 study in Australia identified online purchases as a potential risk factor, it concluded that this may have been due to "care attitudes and behaviors." Additionally, the same authors noted in a later 2012 study that the location of purchase had no significant correlation with the incidence of moderate and severe keratitis.[4] And most recently, a multi-center large scale United States study noted that "in-office SCL purchase did not improve SCL habits or reduce the prevalence of risk behaviors."[5] The study concluded that the training from the Eye Care Provider on best practices for soft contact lens use "occurs primarily when the patient first begins to use lenses, evidenced by the fact that subsequent years of wear did not change the risk for complications." Furthermore, the study also notes that "SCL wearers who purchase lenses on the internet or telephone were no more likely than wears who purchase in person at an ECP or retail store to report know risk behaviors with their SCL's."

The studies that allegedly support adverse health effects due to online purchases are essentially using flawed methodology. For example the FTC commented on a 2008 study by Fogel and Zidile, and a 2010 study published byWu, et. al. The FTC stated that the "Fogel and Wu studies have relatively small samples of consumers who purchased

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[3] Keay L, Stapleton F, Schein O. Epidemiology of contact lens-related inflammation and microbial keratitis: a 20-year perspective. Eye Contact Lens 2007;33:346–63.
[4] Stapleton F, Edwards K, Keay L, et al. Risk factors for moderate and severe microbial keratitis in daily wear contact lens users. Ophthalmology 2012;119:1516–21.
[5] Chalmers RL, et. al., Is purchasing lenses from the prescriber associated with better habits among soft contact lens wears?, Contact Lens and Ant. Eye: 2016 Dec;39(6):435-441.

contact lenses over the Internet and the sample recruiting methodologies call into question whether the results are generalizable to the national population. In addition, the results of these studies link purchase locations to consumer behaviors such as having a doctor check the contact lens fitting after purchase or awareness of recommended follow-up visit, rather than actual adverse eye health outcomes."

A Johnson & Johnson Vise Care APCO survey from 2015 had results that diverged from general clinical observations and the American Optometric Association (AOA) guidance that recognized that "vision generally remains stable" for those 19-40 years of age.

A 2014 CDC study regarding contact lenses and keratitis did not list location of purchase as a risk factor. Rather, the emphasis was on poor wear and care behavior, something that is not affected by online sales as noted above. Thus, the CDC made specific recommendations to reduce the risk of infection with contact lenses. They stated as follows: "Prevention efforts could include vigorous health promotion activities that encourage contact lens wearers to improve their hygiene behaviors, such as keeping all water away from contact lenses, discarding used disinfecting solution from the case and cleaning with fresh solution each day, and replacing their contact lens case every 3 months." It should be noted that two-thirds of the patients in this study purchased lenses directly from the eye care provider and less than a quarter of the patients purchased the lenses online. Yet over 99% of the patients surveyed showed at least one contact lens hygiene risk factor. This is consistent with the 2016 article above.

With regards to the use of an expired prescription, it should be noted that in adults the shape of the cornea, and hence the fit of the contact lens, is extremely stable. Furthermore, with regards to the prescription strength, very little change typically occurs in adulthood. Thus, claims that expired prescriptions cause harm are greatly exaggerated since it is rare that the prescription changes significantly. Furthermore, an incorrect lens power would result only in a blurring of vision. As noted above the AOA recognizes that vision generally remains stable in adults.

The bottom line from all the research and contact lens studies with regards to keratitis over the past several decades is best summarized in a statement from the 2007 Stapleton article (which is just as accurate today):

> "The past 20 years have produced a number of large, methodologically strong epidemiological studies on the rates and risk factors of microbial keratitis among contact lens wearers. These studies have been remarkably consistent in their findings across time and geography. Most importantly, the absolute risk of disease has remained more or less constant for daily-wear and extended-wear soft lenses. Furthermore, the principal risk factor has remained overnight wear of contact lenses."[6]

[6] Keay L, Stapleton F, Schein O. Epidemiology of contact lens-related inflammation and microbial keratitis: a 20-year perspective. Eye Contact Lens 2007;33:346–63.

In conclusion, based on authoritative scientific articles (and my own personal experience as a corneal specialist treating numerous contact lens patients both with and without keratitis), it appears that alternative retail and online sales of contact lenses, which benefit consumers not only in price but also in obtaining access to a fresh supply of lenses, have not contributed to any increase in the incidence of contact lens related microbial keratitis or any behaviors that put patients at risk for developing keratitis.

Sincerely,

Paul B. Donzis, M.D.
Associate Clinical Professor of Ophthalmology
Cornea Division, UCLA School of Medicine

PAUL B. DONZIS, M.D., M.B.A., ESQ.

Diplomate, American Board of Ophthalmology

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CURRICULUM VITAE

Revised January 1, 2017

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Manhattan Beach Office Director
UCLA Jules Stein
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(through 2013)

Attorney at Law, Partner
Law offices of Robin Vialla
11400 W. Olympic Blvd., Suite 200
Los Angeles, CA 90064
(310) 445-8845

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Associate Clinical Professor in Ophthalmology
Jules Stein Eye Institute
UCLA School of Medicine, Los Angeles, CA

Adjunct Professor of Business
W. Edwards Deming School of Business
William Howard Taft University, Santa Ana, CA

SUBSPECIALTY

Corneal and external disease consultation
Medical\Legal ophthalmic evaluation
Qualified Medical Examiner (QME), State of CA

PERSONAL DATA

Birthdate: July 7, 1956 in Los Angeles, CA

EDUCATION

College: Princeton University
A.B. in Economics, Magna Cum Laude
June 6, 1978

Medicine: Washington University in St. Louis
M.D., May 21, 1982.

Business:	William Howard Taft University M.B.A., Summa Cum Laude November 30, 1999
Law:	Law Office/Judge's Chamber Study Program, State Bar of California May 14, 2000

POST GRADUATE TRAINING

Internship:	University of California, Los Angeles San Fernando Valley Program Internal Medicine: June 1982 - June 1983
Residency:	Tulane University Ophthalmology: July 1983 - June 1986
Fellowship:	UCLA, Jules Stein Eye Institute Cornea-External Disease July 1986 - June 1988

GRANTS

National Eye Institute Research training grant: July 1986 - June 1987
Heed Ophthalmic Foundation Fellowship: July 1987 - June 1988

BOARD AND SPECIALTY CERTIFICATION

American Board of Ophthalmology: May 1988
Qualified Medical Examiner: State of California: 1994- present

LICENSURE

Medicine:	California	#A042774
Law:	California	#210918

MEMBERSHIP IN PROFESSIONAL ORGANIZATIONS

American Society of Cataract and Refractive Surgery
International Society of Refractive Surgery
Cornea Society
American Board of Ophthalmology
Bar of the Supreme Court of the United States of America
State Bar of California
American Bar Association
Fellow of the American College of Legal Medicine
Los Angeles County Bar Association
American Association of Justice
Consumer Attorneys of Los Angeles

HOSPITAL STAFF POSITIONS

Marina Del Rey Hospital
UCLA Medical Center

AWARDS AND HONORS

Governor's Scholar, State of California: 1974.

Beverly Hills High School Scholar Athlete: 1974.

John Glover Wilson Award: Honorable Mention,
Princeton University, Dept. of Economics: 1978.

Robert Carter Medical School Award for meritorious research and academic achievement, Washington University School of Medicine: 1982.

Award of Excellence, Outstanding first year resident in the Dept. of Ophthalmology, Touro Infirmary, Tulane University: 1984.

C.S.O'Brien Professorship Award for outstanding research and resident presentation: Dept. of Ophthalmology, Tulane University: June 1984, 1985, 1986.

Residents and Fellows Day Award for outstanding Clinical Research: Jules Stein Eye Institute, UCLA School of Medicine: April 1987.

Named as one of America's Top Ophthalmologists by Consumer's Research Council of America

Named to Marquis Who's Who in America and Who's Who in American Law

LASER CERTIFICATION

Visx Star S2, S3, S4
Summit Apex
Alcon Autonomous Ladarvision
Allegretto Wavelight

JOURNAL REVIEWER

British Journal of Ophthalmology
American Journal of Ophthalmology
JAMA, Ophthalmology
Cornea

PUBLICATIONS

ARTICLES

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