

October 26, 2015

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

Re: Comments of 1-800 CONTACTS, Inc. on the Contact Lens Rule; 16 CFR Part 315 (Project No. R511995).

1-800 CONTACTS, Inc. (“1-800 CONTACTS” or “1-800”) respectfully submits the attached comments in response to the Federal Trade Commission’s (“FTC” or “Commission”) request for comments on its review of the Contact Lens Rule, 16 CFR Part 315 (“CLR” or “Rule”).

1-800 CONTACTS is the largest seller of contact lenses in the United States through its website, smartphone application and toll-free number. Established in 1995, 1-800 has filled over 41 million orders for more than ten million customers. We have an established track record of providing excellent service and affordable prices to our customers. Our customers are very loyal: more than 80 percent of our sales come from repeat business.

In 2003, Congress enacted the Fairness to Contact Lens Consumers Act (the “FCLCA” or the “Act”) to advance consumer choice and competition in the contact lens industry. Legislation was essential because, unlike most other healthcare providers, eye care practitioners (“prescribers”) sell and profit from what they prescribe. As a result, prescribers can use their control over the prescription to steer patients to their own retail channel, leaving little room for consumer choice and competition in the contact lens industry.

The FCLCA was passed to break that status quo. It mandates automatic release of contact lens prescriptions to consumers on a nationwide basis to permit them to purchase lenses from the seller of their choice. The Act also created a flexible and efficient prescription verification process for orders placed with third-party sellers. The legislative history shows that Congress selected the verification method it determined would protect patients’ ocular health without imposing an undue burden on consumer choice or competition.

These two pillars of the FCLCA—automatic prescription release (the requirement to provide a copy to the patient whether requested or not, or to a person designated to act on the patient’s behalf) and verification—were designed to facilitate comparison shopping and spur competition on multiple dimensions, including price, convenience and customer service.

After passing the Act, Congress left it to the FTC to turn its vision into a reality. The Act required the FTC to promulgate rules to implement the FCLCA and to enforce those rules under its authority to prohibit unfair or deceptive acts or practices.

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The FTC issued the CLR in 2004. As the largest contact lens seller in the United States, 1-800 CONTACTS has extensive firsthand experience with the practical operation of the Rule over the past ten years. As detailed in this comment, the CLR has advanced the goals of the FCLCA notwithstanding ongoing bad behavior from prescribers and manufacturers. Today the 41 million American consumers that wear contact lenses have greater choice and convenience, and more affordable prices. Using the same methodology the FTC employed to calculate the implicit time cost savings from mail order contact lens sales in 2002, 1-800 CONTACTS has calculated that since the FCLCA was passed, consumers have saved \$600 million dollars in implicit time costs as a result of direct delivery of contact lenses ordered online.

But challenges remain. *Approximately 14.5 million contact lens wearers (36%) leave their prescriber's office without a copy of their prescription.* This is because *only 35% of consumers (14 million) are automatically provided with a copy of a prescription* at the completion of a contact lens fitting. Due to prescriber noncompliance, 29% of contact lens wearers (11 million) had to ask for a copy of their prescription after their last eye exam. Unfortunately, many contact lens wearers do not know to ask because *nearly half of all contact lens wearers today (46% or 18.4 million) do not know they have a right to a copy of their prescription.*

Prescribers are well aware that many consumers do not understand their rights. Yet they do little to educate their patients. Instead they exploit weak consumer awareness to avoid their obligations under the CLR, undermining the FCLCA and congressional intent (as stated in the preamble to the Act) to “provide for availability of contact lens prescriptions to patients.”

Even patients who know to ask for a copy of their prescription face hurdles. Many contact lens patients relate stories of their recent ordeal trying to wrestle a prescription away from their prescriber; repeated phone calls and multiple office visits are not unusual. Survey evidence shows that contact lens consumers perceive that it is twice as difficult to get a prescription from their eye care professional as from their primary care physician. There is no excuse for this behavior. Turning over a slip of paper is not burdensome. It is something most healthcare providers do every day without a second thought.

Ultimately, prescription verification works under the FCLCA, with verification rates exceeding 98%. Despite the fact that many prescribers respond professionally to verification requests, improvements are needed. For instance, in over 180,000 occurrences each year, prescribers provide false information in response to a verification request, by, for example, claiming that a valid prescription has expired, or providing insufficient information when stating a prescription is inaccurate or invalid. In addition, in almost 30% of verification attempts, *prescribers try to thwart the process by hanging up on our verification calls, requiring three or more additional follow up calls until the verification process can be completed.* Prescribers often employ these tactics to give themselves time to contact the patient in an attempt to make the contact lens sale themselves. This is not the kind of competition on the merits the FTC applauds. This intentional interference with the verification process violates the Rule. It imposes unacceptable and unnecessary delays on consumers who have chosen to purchase from an alternative seller, particularly those who turned to the internet for convenience and speed on refills.

While 1-800 acknowledges and appreciates the FTC’s efforts to promote consumer choice and competition in this sector, we respectfully suggest that ten years of experience with the CLR shows that further action is necessary to change prescriber behavior and effectuate the goals of the FCLCA. The CLR requires prescribers operating behind closed doors in practices across the country to go against their own economic interests. Without a meaningful risk that an individual prescriber’s violation will be detected and punished, too many prescribers will undoubtedly continue to ignore their legal obligations, undercutting the goals of the FCLCA.

We urge the FTC to take this opportunity to fix what is broken—consumer awareness and prescriber compliance. In particular, we recommend that the FTC take the following steps.

KEEP WHAT IS WORKING: RETAIN THE CURRENT VERIFICATION FRAMEWORK AND DEFINITION OF A CONTACT LENS PRESCRIPTION WITHOUT CHANGE

Passive verification. The current framework, which includes a passive verification option, achieves the balance Congress intended by providing prescribers with a reasonable opportunity to correct an order based on an inaccurate, invalid, or expired prescription without imposing a needless delay on consumers (or unnecessary costs on either sellers or prescribers). As the FTC has previously stated, “[b]ecause Congress has decided to impose a passive verification system through the Act, whether to adopt a passive verification system is not at issue” in promulgating the CLR. (Contact Lens Rule, 69 Fed. Reg. 40497 (July 2, 2004)).

Furthermore, while prescribers would prefer to eliminate mechanisms that bolster competition in the industry, passive verification has proven to be an effective means of continuing to open the marketplace. There is no evidentiary basis for Congress to reconsider passive verification at this time. Over ten years of experience with the CLR and passive verification has resulted in no demonstrated health concerns or undue burden on prescribers. In addition, evidence on the operation of the Rule over the past ten years shows that prescribers continue to battle against their affirmative obligations under the Rule, including prescription release. As Congress wisely determined, requiring prescribers to affirmatively bless every sale to a competitor would make the FCLCA unworkable.

1-800 CONTACTS’ verification processes, systems and approach are in strict adherence to the CLR, and passive verification in the industry has proven instrumental in providing greater consumer choice and lower prices. Post-sale survey evidence shows that about 80% of customers give 1-800 CONTACTS the highest score for customer satisfaction. The company’s customer ratings consistently rank among the top five of all companies in the United States. Orders are deleted as required under the CLR. Customers with invalid or expired prescriptions are directed to get an eye exam and prescription before placing another order. From the consumer perspective, passive verification is working just fine.

Eight business hours for passive verification. The eight business-hour time frame for passive verification gives prescribers sufficient time to confirm important health information and correct any inaccurate orders without imposing a needless delay on consumers who place a premium on quick delivery. Many customers are wearing their last pair of contacts when they

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place an order and need their order processed as quickly as possible. In no other healthcare sector are patients routinely left to wait eight hours to hear from their healthcare provider, and if an order is placed on a Friday, contact lens consumers are left to wait as long as 72 hours to have their order verified.

Last year 1-800 CONTACTS cancelled orders worth approximately \$40 million in response to communications from prescribers. Over the past ten years the percentage of deleted orders has remained surprisingly consistent, as prescribers attentive to patient care have used 1-800 CONTACTS' verification systems to effectively communicate under the CLR. The number of deleted orders and the value of sales cancelled demonstrate that prescribers have more than adequate time to respond when necessary.

Automated phone systems. The Act requires direct communication between a seller and a prescriber, and includes telephone contact as an acceptable form of direct communication. Automated phone systems existed at the time the Act was passed and the record indicates no effort to exclude automated phone systems and narrowly interpret telephone communications as “live” calls. We urge the FTC to retain automated telephone systems as an acceptable form of direct communication for verification purposes. 1-800 CONTACTS has experimented with other forms of direct communication and has concluded that a well-functioning automated system that incorporates the latest technology is the most efficient means of handling the large volume of verification requests that are required today. Our system has an automated voice that is clear and easy to understand. It offers prescribers user-friendly options such as the opportunity to pause the verification script or to request that the system call back at a later time. 1-800 has invested significant resources into the development of a system that is not subject to human error, provides full assurance that 1-800 is compliant with the CLR, and offers the best service to our customers. Customers place orders 24 hours a day, seven days a week. An automated system allows accurate information to be given consistently to every prescriber.

Though unfounded claims are made by self-interested prescribers against 1-800 CONTACTS' automated system, not one instance of miscommunication in over millions of communications with prescribers has been documented. In fact, when challenged during a House Energy and Commerce Committee hearing in 2006, 1-800 CONTACTS disproved claims made by a representative of the American Optometric Association regarding problems with 1-800's verification system. The evidence proved the claims were baseless and completely false, and the doctor ultimately withdrew these claims. The documented evidence confirming 1-800's 100% compliance with verification requirements was easily available because of its automated system. Any change to the status quo is unjustified, contrary to congressional intent and not in the interests of consumers.

Definition of Contact Lens Prescription. As described in detail below, the Rule requires that a contact lens prescription include eight specific pieces of information, including the patient's name, the issue and expiration date of the prescription, and the brand/material, power and base curve of the lens. The FTC previously rejected calls to also require that a prescription include the maximum quantity a consumer could purchase with an existing prescription—and for good reasons. Imposing quantity limits can inconvenience consumers and lead to unhealthy practices, such as wearing lenses longer than recommended. With a quantity

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restriction, a contact lens wearer who leaves a box of lenses at the hotel on her last business trip may return home and stretch the supply she has left until she has time to visit her prescriber (by wearing lenses longer than recommended). Patients sometimes tear lenses and need replacements. Some patients may find it more comfortable to wear the monthly lens they were prescribed for a shorter period of time and some may just want to leave an extra box in their locker at the gym. There are any number of very legitimate reasons a consumer may want to purchase what appear to be (based on simple multiplication) extra lenses and there is no valid reason to restrict that consumer's options.

In addition, as the FTC recognized in promulgating the Rule in 2004, any quantity limit would allow prescribers to circumvent the minimum expiration dates mandated by the FCLCA. Finally, if a prescriber believes a patient has ordered an oversupply of lenses, she can let a seller know during the verification process that the prescription is inaccurate. A seller must include the quantity of lenses ordered in a verification request and a prescriber can notify a seller of any order it believes is inaccurate. As the FTC explained in 2004, "[I]f a verification request indicates that a patient seeks to purchase a nine-month supply of lenses one month before the prescription expires, the prescriber may treat the verification request as inaccurate...the prescriber would be required to provide the seller with information regarding the basis for the inaccuracy as well as to correct the prescription by specifying an appropriate number of lenses to be dispensed." (Contact Lens Rule, 69 Fed. Reg. 40502 (July 2, 2004).)

There is no evidentiary basis for the FTC to revisit its decision on this issue now. Adding a quantity limit to a contact lens prescription will inconvenience patients, discourage healthy habits like changing lenses frequently and encourage prescribers to sidestep the minimum expiration dates mandated by the FCLCA and CLR.

FIX WHAT IS BROKEN: TAKE STEPS TO PROMOTE PRESCRIBER COMPLIANCE

Strengthen Automatic Prescription Release to Consumers. Automatic prescription release is a pillar of the FCLCA. Yet well under half of all contact lens consumers today enjoy that benefit due to bad prescriber behavior and weak consumer awareness of their rights.

Recent survey evidence shows that nearly half (46%) of contact lens wearers (about 18 million consumers) do not know they have a right to their prescription. Given well under half of all patients are provided with a copy of their prescription automatically, it should come as no surprise that approximately 14 million patients leave their prescribers office without a prescription in hand, and without knowing they have the right to shop around for their lenses.

In addition, even for those patients that do receive a hard copy of their prescription, prescribers often hand it over only *after completing a sale*. The same recent survey shows that, for those patients that received a copy of their prescription, only half received that copy before they purchased lenses. About 38% received their prescription either with their lenses or immediately afterwards.

To advance real notice and choice in this market, 1-800 strongly recommends that the FTC amend the CLR to require that, immediately after completing a contact lens fitting,

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prescribers *provide patients with a simple and easy to understand “Bill of Rights.”* A clear and simple written notice provided immediately upon completion of a fitting will let patients know that they have a right to their contact lens prescription, that it will be provided automatically without request, and that they have the right to purchase their lenses from the seller of their choice. Notice is necessary immediately after the fitting—at the time when uninformed patients are most susceptible to gamesmanship and pressure sales tactics from prescribers. Patients have paid for an eye exam and deserve an automatic copy of their prescription before a prescriber shifts from acting as a healthcare provider to acting as a retailer.

To ensure that consumers both receive their prescription and understand this information, express acknowledgement—through patient signature—should also be required. To facilitate investigation and enforcement of prescription release, the FTC should require that prescribers maintain a copy of the signed notice for a period of three years or the length of the prescription, whichever is longer. These records should be available for inspection by the Federal Trade Commission, its employees, and its representatives. Any record-keeping burden on prescribers is minimal and well-justified by the benefits for consumers and the need to enforce prescription release under the FCLCA without pitting the patient against her prescriber. This storage requirement is consistent with similar obligations imposed on sellers for each and every verification.

The current compliance environment seriously undercuts the goals of the FCLCA and is untenable. A signed Bill of Rights will be the most effective means available to ensure compliance with the Act.

Bolster prescription release to authorized agents. Section 315.3(2) of the CLR requires prescribers to release a patient’s prescription to an authorized agent upon the agent’s request. Due in large part to poor prescriber compliance with prescription release requirements, many customers cannot provide a third-party seller with a copy of their contact lens prescription at the time they place their order. Consequently, 1-800 typically asks our customers to authorize us to obtain a copy of their prescription, on their behalf, and to keep the prescription on file to facilitate future orders. This is a service customers want to streamline the ordering process with alternative sellers. Customers place a high value on speed in the delivery of their lenses; customer satisfaction metrics drop markedly when customers have to wait more than five days to receive an order. With a copy on file, 1-800 ships a customer’s order without delay (within 14 minutes of placement) and does not have to repeatedly contact prescribers to verify refills authorized by the same valid prescription. When asked directly on the phone with a clear description that 1-800 will contact their prescriber, request a copy of their prescription, and retain the prescription on file to facilitate future orders, 90% of 1-800 customers have responded that they grant 1-800 such agency and rights to act on their behalf. These findings have been corroborated by 1-800 customer research.

Prescribers and their trade associations fight against competitors’ legal rights to provide this service to their customers. Opposition is not born out of genuine concern for consumer rights or interests. Prescribers recognize that prescription release to authorized agents will level the competitive playing field on future sales (particularly in light of the dismal record on automatic release to patients following a fitting).

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Evidence shows that in about half the cases, prescribers ignore and never respond to 1-800's authorized requests for a copy of a customer's prescription. Today there are thousands of violations that have not been addressed and that number will continue to grow unabated without FTC action. Prescribers continue to question whether they are required to honor authorized requests for prescriptions. Those questions recently prompted the AOA to issue a notice to its affiliate organizations advising that the FCLCA requires prescribers to respond to authorized requests from sellers. Nevertheless, clarifying language in the CLR is necessary to ensure prescribers understand that they are obligated to honor prescription requests in a timely manner and that there are consequences if they do not comply. By putting prescribers on notice of their existing obligations, the Commission will encourage prescription release, significantly reduce the number of prescription verification communications between sellers and prescribers, and improve competition in the marketplace.

We therefore propose amending Section 315.3 to require that, in response to an authorized request, the prescriber send the prescription to the agent (by mail, facsimile or a digital image of the prescription that is sent via electronic mail) within eight business hours as currently defined under the Rule. In addition, to ensure this obligation is enforceable, prescribers should be required to maintain a log recording the date and time a patient's prescription was requested and released to the authorized agent. The log should be maintained for a period of three years and be available for inspection by the Federal Trade Commission, its employees, and its representatives.

Tell prescribers to stop providing false information. Many prescribers use the verification process as an opportunity to compete for sales they have already lost or to simply harass a competitor by providing false information in response to a verification request. For example, a prescriber might falsely convey to a third-party seller that a valid prescription has expired, forcing the seller to cancel the order. Prescribers need to understand that providing false information in response to a verification request violates the CLR and is subject to fines. 1-800 CONTACTS recommends that the FTC make the risk of punishment more express. In particular, we recommend that the FTC:

- amend Section 315.5(d) to clarify that it is a violation of the CLR to respond to a verification request by stating that a prescription is inaccurate or invalid without providing the basis for the inaccuracy or invalidity of the prescription; or to convey false information regarding a prescription expiration date or to convey false information regarding the inaccuracy or validity of a prescription in response to a verification request.

Deter future violations by investigating prescriber practices. Despite the widespread refusal of prescribers to release prescriptions, the FTC has taken limited enforcement action against prescribers since it promulgated the CLR in 2004. In 2007, the FTC sent warning letters to ten contact lens prescribers who failed to release prescriptions, required patients to purchase lenses from them, or imposed fees on patients before releasing prescriptions. To our knowledge, the FTC has taken no further public action against the thousands of noncompliant prescribers in the intervening eight years. Results of a prescriber survey published in *Contact Lens Spectrum Magazine* in 2008 indicated that 50% of prescribers self-reported as not releasing prescriptions as required by the FCLCA. No public action was taken following release of this survey. Prescribers today clearly believe they can disregard their legal obligations without consequence.

To change that dynamic the FTC must send a message to complacent prescribers. First, 1-800 recommends that the FTC investigate prescriber practices and issue warning letters or take enforcement actions against prescribers that violate their obligations, particularly with regard to automatic prescription release to patients. This should be done on a regular basis in a way that mirrors the agency's enforcement sweeps to encourage compliance with the so-called funeral rule. Enforcement will not only change the behavior of the prescribers that are the target of the investigation, but more importantly, it will send a signal to prescribers across the country that the FTC is paying attention.

In addition, 1-800 CONTACTS recommends that the FTC amend Section 315.9 to clarify that any violation of the CLR—by either sellers or prescribers—constitutes an unfair act or practice in violation of the Federal Trade Commission Act (and is enforceable under the same standards and subject to the same fines and penalties).

Finally, to facilitate enforcement, 1-800 recommends that the FTC create a user-friendly online complaint process for consumers. The current FTC online complaint assistant is difficult to navigate and does not ask the appropriate questions to identify a CLR violation. For example, to report a complaint associated with contact lenses, the consumer is asked whether “the company involved failed to release your contact lens prescription upon request.” The standard is automatic release, not release upon request. 1-800 recommends that the FTC modify the online complaint process to make it simpler for consumers and others with knowledge of a violation to report CLR violations.

1-800 greatly appreciates the FTC's consideration of these comments.

Respectfully submitted,


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I. INTRODUCTION

1-800 CONTACTS welcomes the opportunity to provide these comments in association with the FTC's review of the Contact Lens Rule.

As the largest contact lens seller in the United States, 1-800 has had extensive firsthand experience with the practical operation of the Rule over the past ten years. As described below, the CLR has advanced the goals of the FCLCA notwithstanding ongoing bad behavior from prescribers and manufacturers. Today the more than 40 million American consumers that wear contact lenses have greater choice and convenience, and more affordable prices.

But serious challenges remain. Almost half of contact lens wearers today are unaware of their rights under the FCLCA. Prescribers are exploiting poor consumer education by refusing to automatically release prescriptions. Ten years of experience has shown that the basic structure of the Rule, which includes an eight business-hour passive verification system, is a good one. The problem for consumers today is prescriber compliance.

As described below, 1-800 CONTACTS respectfully requests that the FTC retain what is working well and fix what is broken. We submit the evidence and comments below to assist the FTC in that effort.

II. HISTORY OF THE CONTACT LENS MARKETPLACE

1. Background

Competition and consumer choice in the marketplace for contact lenses is shaped in part by the federal and state regulations that govern the sale of this product. Most importantly, contact lenses cannot be sold without a valid prescription, and the prescribers licensed to conduct exams and authorize prescriptions are also permitted to sell lenses directly to patients. Prescribers are thus well-positioned to steer patients to their own retail channel, and of course, have an economic incentive to do so.

Brand restrictions also play a critical role in the relationship between manufacturers and prescribers. Under the FCLCA, prescriptions must include a brand and/or material in addition to other specific parameters, including power, base curve, and diameter. Sellers may not substitute brands across manufacturers, even if competing brands are made of the same material and classified as functional equivalents by the FDA.¹ Consequently, manufacturers have a strong incentive to cater to the interests of prescribers—rather than consumers—because it is the

¹ The FCLCA permits a seller to substitute the same contact lens produced *by the same manufacturer* under a different label. 15 U.S.C. § 7603(f). If the consumer wants to purchase a brand produced by a different manufacturer, she will typically need to revisit her prescriber and obtain a new prescription. Moreover, because there are no substitutions across manufacturers, there are no generic options for patients, even for products that have been off patent for years.

prescriber who is their ultimate customer.² It is the prescriber who typically dictates which brand and modality a consumer should wear.

There was a time when these dynamics mattered less for consumers. Thirty years ago, contact lens technology effectively required the bundled sale of eye exams and lenses. Contact lenses were made from rigid material that was designed to last for a year or more. Patients were required to remove and clean lenses daily and only replaced lenses during the life of a prescription if the lenses were lost or damaged. New lenses had to be custom fit for patients by a prescriber. There was simply little demand for off-the-shelf sale of lenses from alternative channels.³

Today, the technology is radically different. Beginning in the 1980s, manufacturers began to sell standardized soft, disposable lenses designed to be replaced on a daily, weekly or monthly basis. The vast majority of lenses purchased today are mass-produced disposable lenses that are identical regardless of the distribution channel.⁴ The innovation in lens technology thus created demand for new methods of distribution and opened the door to lower prices, greater convenience and expanded choice for consumers.

Of course, when innovation generates competition from new technologies and business models, incumbents often resist by seeking regulatory protection,⁵ and, in some cases, engaging in the kind of “self-help” that can violate the law. The FTC has seen and battled this dynamic over and over in a range of sectors using its enforcement,⁶ rulemaking⁷ and advocacy tools.⁸ As

² Even without prescriber collusion, which as detailed below is part of the history of this industry, competition among prescribers is not sufficient to protect manufacturers from retaliation (and break the alliance between manufacturers and prescribers) because consumers are not likely to have the information necessary to select a prescriber based on the brands he will prescribe.

³ FED. TRADE COMM’N, *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses* (A Report from the Staff of the Federal Trade Commission) (March 2004) at 1 (“Anticompetitive Barriers to E-Commerce”), available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/possible-anticompetitive-barriers-e-commerce-contact-lenses-report-staff-ftc/040329clreportfinal.pdf.

⁴ FED. TRADE COMM’N, *The Strength of Competition in the Sales of Rx Contact Lenses: An FTC Study* (Feb. 2005) at 5 (“The Strength of Competition”), available at <https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf>.

⁵ As one Commissioner has recognized, “...just as government should not directly decide how future competition should unfold, so too is it inappropriate for existing competitors to exercise control over the firms they compete with. In all too many situations, we at the FTC encounter these ‘Brother May I?’ scenarios. This situation occurs when a new competitor effectively has to request permission from the incumbent firms to enter the market.” *Sharing Some Thoughts on the “Sharing Economy,”* Prepared Remarks of Commissioner Maureen K. Ohlhausen, “Sharing Economy Workshop (June 9, 2015), available at https://www.ftc.gov/system/files/documents/public_statements/671141/150609sharingeconomy.pdf.

⁶ As a recent example, on June 17, 2010, the Commission filed an administrative complaint against the North Carolina state dental board for violating the antitrust laws by engaging in concerted action to exclude competition from non-dentists in the provision of teeth-whitening services. *In the Matter of the North Carolina Board of Dental Examiners*, FTC Docket No. 9343, available at

the agency has already recognized, the contact lens sector is a case study in the business strategy and political economy of disruptive competition.⁹ Key events in the history of the sector are described below.

2. State Regulation

In the late 1990s, pressure from prescribers pushed states to consider and in some cases adopt restrictions that impeded competition for the sale of replacement lenses from alternative channels, such as mail order and internet. In 2002, the Connecticut State Board of Examiners for Opticians conducted a proceeding to determine how state regulations on the sale of optical products should be applied to the sale of replacement contact lenses. FTC staff testified in that proceeding and argued that the “overly restrictive interpretation of Connecticut statutes and regulations,” which would have required a contact lens seller to obtain a special license and/or permit in order to sell such lenses, would “adversely affect consumer welfare by raising prices for at least some consumers without offsetting benefits in health or safety.”¹⁰ Notably, the staff pointed out, that because of the high costs associated with contact lenses, consumers tend to “over-wear their lenses, which diminishes the health benefits”— a health problem easily fixed, said the FTC, since consumers would replace their lenses more frequently if the lenses were less costly.¹¹ The FTC also documented how the cost to a consumer in time and travel in picking up lenses from a brick and mortar store could exceed the dollar cost of the lenses themselves. Specifically, the FTC calculated that an hour-long trip to a mass merchandiser had “an implicit

<https://www.ftc.gov/sites/default/files/documents/cases/2011/12/111207ncdentalopinion.pdf> The Fourth Circuit upheld a Commission decision finding that the Board’s conduct was anticompetitive and not immune from antitrust scrutiny under the state action doctrine. *North Carolina State Bd. of Dental Examiners v. FTC*, 717 F.3d 359 (4th Cir. 2013). The Fourth Circuit’s decision on state action immunity was appealed to the Supreme Court and affirmed. *North Carolina State Bd. of Dental Examiners v. FTC*, 135 S. Ct. 1101 (2015).

⁷ See e.g. Eyeglass Rule 16 C.F.R. 456.

⁸ See e.g. FTC Staff Comments Before the District of Columbia Taxicab Commission Regarding Second Proposed Rulemakings Regarding Chs. 12, 14, and 16 of Title 31 (June 7, 2013), available at <http://www.ftc.gov/policy/policy-actions/advocacy-filings/2013/06/ftc-staff-comments-district-columbia-taxicab>; FTC Staff Comment to the Honorable Debbie Ossiander Concerning AO NO. 2013-36 Regarding the Regulatory Framework for the Licensing and Permitting of Taxicabs, Limousines, and Other Vehicles for Hire in Anchorage, Alaska (Apr. 19, 2013), available at <http://www.ftc.gov/policy/policy-actions/advocacy-filings/2013/04/ftc-staff-comment-anchorage-assembly-member-debbie>; FTC Staff Comment Before the Colorado Public Utilities Commission *In The Matter of The Proposed Rules Regulating Transportation By Motor Vehicle*, 4 Code of Colorado Regulations 723-6 (Mar. 6, 2013), available at <http://www.ftc.gov/policy/policy-actions/advocacy-filings/2013/03/ftc-staff-comment-colorado-public-utilities>.

⁹ Comments of the Staff of the Federal Trade Commission, Intervenor, In Re: Declaratory Proceeding on the Interpretation and Applicability of Various Statutes and Regulations Concerning the Sale of Contact Lenses, State of Connecticut Department of Public Health, Connecticut Board of Examiners for Opticians (March 27, 2002) at 1, 10 (“FTC Connecticut Board Comments”).

¹⁰ *Id.* at 2.

¹¹ *Id.* at 10.

time cost of between \$10.96 and \$26.00,” which represented “a markup of between 50 and 130 percent over the cost of a multipack.”¹²

3. Contact Lens Antitrust Litigation

Facing increasing competitive pressure, prescribers and manufacturers did more than lobby legislators. In the late 1990s, attorneys general from 32 states¹³ and a national class of consumers brought an action against contact lens manufacturers, the American Optometric Association (“AOA”), other optometry groups, and thirteen individual optometrists for conspiring to impede competition from alternative retail channels.¹⁴

The evidence revealed that the defendants had unlawfully agreed to a broad scheme to block emerging competition. Understanding that prescription release would ultimately foster a more competitive marketplace, the prescribers and their trade associations, had (among other things) agreed to block prescription release to patients. The plaintiffs also had compelling evidence that AOA and other prescriber associations knowingly publicized false and misleading information regarding health risks associated with purchasing contact lenses from anyone other than a prescriber. Other evidence showed that the defendants had also engaged in a group boycott to inflate the price of lenses by restricting the supply to alternative sellers.

The last defendant in the litigation settled after six weeks of trial.¹⁵ The manufacturers and prescribers agreed to injunctive relief requiring them to discontinue their anticompetitive practices, and to pay collectively over \$80 million in compensation.¹⁶ The AOA also agreed to injunctive relief for a period of four years (ending in 2005) intended to put a stop to its anticompetitive conduct. In particular, the AOA expressly agreed not to:

- Object to the release of contact lens prescriptions to patients, unless an optometrist documented that not releasing a prescription is necessary to protect the health of a specific patient;
- Encourage prescribers to boycott certain lens manufacturers or to write prescriptions for lenses based on the lens manufacturer’s relationship with alternative sellers;

¹² *Id.* at 10.

¹³ Plaintiff States included: Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Texas, Utah, Virginia, West Virginia, and Wisconsin.

¹⁴ *In re Disposable Contact Lens Antitrust Litig.*, MDL 1030 (M. D. Fla.).

¹⁵ Attorney General Lockyer Announces Settlement of Contact Lens Antitrust Lawsuit (May 22, 2001), available at <https://oag.ca.gov/news/press-releases/attorney-general-lockyer-announces-settlement-contact-lens-antitrust-lawsuit>

¹⁶ See Anticompetitive Barriers to E-Commerce.

- Enter into an agreement with any manufacturer to restrict the supply of contact lenses to alternative sellers;
- Represent directly or indirectly that ocular health may be compromised by purchasing contact lenses from an alternative seller rather than a prescriber.¹⁷

III. THE FAIRNESS TO CONTACT LENS CONSUMERS ACT

In the wake of this activity, Congress enacted the FCLCA in 2003 to guarantee consumers the right to automatically receive copies of their prescriptions and to have their prescriptions verified when purchasing from third-party sellers.

In a report from the House Subcommittee on Commerce, Trade, and Consumer Protection, the Chairman of the subcommittee, Representative Cliff Stearns, spoke to the need for the FCLCA by saying “...some eye doctors will refuse to release prescriptions or will condition release on the purchase of contact lenses from the doctor’s practice. Clearly, these are anticompetitive practices that limit options and increase prices. [This bill] is designed to eliminate this market-altering practice.”¹⁸

In the same subcommittee meeting, Representative Gene Green addressed the inherent conflict of interest in a field where prescribers also act as salesmen, saying: “The obvious difference between prescriptions for contact lens prescriptions and drugs, however, is that the pharmacy filling the prescription drug isn’t relying on its competitor for verification, since medical doctors cannot fill the prescriptions they write. So, we need to devise a standard that creates a level playing field for all contact lens sellers and allows consumers full and open access to them.”¹⁹

Representative Tauzin further underscored the need for the FCLCA to address the “competitive problems festering in the contact lens marketplace”:

“Back in the 1970s, the Federal Trade Commission enacted a rule that required eye care professionals to provide patients with a copy of their eyeglass prescription. That rule was necessary because

¹⁷ Specifically, the settlement agreement stated: “The AOA shall not represent directly or indirectly that the incidence or likelihood of eye health problems arising from the use of replacement disposable contact lenses is affected by or causally related to the channel of trade from which the buyer obtains such lenses. Specifically, the AOA shall not represent directly or indirectly that increased eye health risk is inherent in the distribution of replacement disposable contact lenses by mail order, pharmacies, or drug stores. This paragraph shall not prohibit the AOA from making such representations where such representations are supported by valid, clinical or scientific data.” *In re Disposable Contact Lens Antitrust Litigation*, Settlement Agreement at 9 (May 22, 2001) available at <http://apps.americanbar.org/antitrust/at-committees/at-state/pdf/settlements/us-district/11th-circuit/lensaoa.pdf>.

¹⁸ House of Representatives, Committee on Energy and Commerce, Subcommittee on Commerce, Trade and Consumer Protection, Subcommittee Meeting on Fairness to Contact Lens Consumers Act at 2 (September 9, 2003).

¹⁹ *Id.* at 3 (Statement of Rep. Green).

doctors and optometrists would refuse to release prescriptions to consumers or would condition release on the purchase of eyeglasses. While the eyeglass rule radically changed the competitive landscape—today there is vibrant competition among eyeglass providers—contact lenses were not included in that rule. Today we see the same competitive problems festering in the contact lens marketplace as we saw in the eyeglasses market 25 years ago.”²⁰

In its report recommending that the FCLCA pass, the House Energy and Commerce Committee detailed the difficulties consumers had faced when they tried to fill prescriptions with third-party sellers due in part to obstacles sellers faced when attempting to verify prescriptions. The Committee explained in that same report that mandated prescription portability and verification were intended to enable American consumers to fill their prescriptions at “the business of their choice.”²¹ With full compliance, the FCLCA would encourage market forces to break the now insidious link between the provision of eye exams and the sale of replacement disposable lenses.

As Chairman Sensenbrenner told the House, the FCLCA “ensures that unscrupulous eye doctors will no longer be able to hold consumers’ contact lens prescriptions hostage” and that, “[p]roviding consumers with an automatic right to their prescriptions will allow them to shop around for contact lenses based on price, service, and convenience.”²² Sensenbrenner concluded by reiterating the fundamental need for the FCLCA, explaining that “[c]ompetition among contact lens companies will result in lower prices, a greater choice of lens providers, and more convenient ways to fill contact lens prescriptions.”²³

²⁰ Statement of Rep. Tauzin, *Id.* at 4.

²¹ House Report 108-318 to Accompany H.R. 3140, Fairness to Contact Lens Consumers Act, Background and Need for Legislation, Oct. 15, 2003, *available at* <http://www.gpo.gov/fdsys/pkg/CRPT-108hrpt318/html/CRPT-108hrpt318.htm>.

²² Hon. F. James Sensenbrenner, Jr., Speech to House of Representatives on Fairness to Contact Lens Consumers Act, Congressional Record—Extension of Remarks, E2434, November 23, 2003, *available at* <http://www.gpo.gov/fdsys/pkg/CREC-2003-11-23/pdf/CREC-2003-11-23-pt1-PgE2434.pdf>.

²³ *Id.*

IV. THE MARKETPLACE TODAY²⁴

1. The Vision for Consumers

Today there are 41 million contact lens wearers in the United States, spending an estimated \$4.5 billion dollars annually on contacts.²⁵ The scenario envisioned by Congress is one in which these millions of American consumers, after receiving their eye exam, are fitted for contact lenses and then handed—without prompting—a copy of their prescription. Armed with their prescription, a consumer is able to consider the costs and convenience of various shopping alternatives and make the decision that is best for her. That decision may be purchasing a six-month supply on the spot from a prescriber, or in today’s digital economy, tapping a smartphone app to check for a better price, or comparison shopping on the web at a more convenient time. If a consumer chooses to purchase from a third-party seller, she can either provide a copy of her complete prescription and have her order shipped immediately, or place her order without immediately providing a copy of her prescription and wait eight business hours for the seller to verify the prescription and ship her order. If she loses her prescription, she can authorize her regular seller to obtain a copy from her prescriber to allow future orders to ship more quickly.

In many respects, the system is working well. The FCLCA provided the market certainty necessary for third-party sellers to make investments in the technology and infrastructure necessary to compete by providing customers with great service and better prices for contact lenses. When the FCLCA was passed in 2003, there were less than 200 online sellers. Today there are more than 25,000 online sellers, including many thousands of prescribers who are selling online themselves today.²⁶ While 1-800’s revenue has grown by 38% since 2003, the sales of all other online providers have increased by 138%.²⁷ The growth in alternative sales channels has also forced manufacturers to focus less than they otherwise would have on their relationship with prescribers; attention has turned more than it otherwise would have to competition with rivals, particularly through advertising and innovation in lens technology.

²⁴ The evidence and discussion presented in this section focus on the continuing need for the Rule, as well as the benefits and costs to consumers and business in response to questions 1, 2, 4, 5, 7, and 9 in the Request for Comments. We also provide detailed discussion and evidence on current compliance with the rule in response to question 11.

²⁵ The Vision Council Research, *Consumer Barometer* (June 2015).

²⁶ A 2014 Survey Sampling International study of 51,000 optometrists shows that 85% have an online presence, and of those with an online presence, 58% sell contact lenses online (on file with 1-800 CONTACTS).

²⁷ Vision Council Industry Survey 2014 (on file with 1-800 CONTACTS).

When the FCLCA was passed, 1-800 sold 37 different brands and types of disposable lenses. Today 1-800 sells more than 90.²⁸

1-800 CONTACTS has witnessed the market developments firsthand. In 2003, approximately 50% of 1-800's orders were placed by mail order or phone, taking consumers between five and fifteen minutes to place an order. Today 80% of our orders are placed online or through our mobile app, reducing the average time for consumers to place an order to well under four minutes. 1-800 has made significant investments in the technology and systems to satisfy growing consumer demand for speed and convenience. The FCLCA and CLR provided 1-800 with assurance that those investments were justified by the opportunity to compete on the merits in an open nationwide marketplace.

Using the same methodology the FTC employed to calculate the implicit time cost savings from mail order contact lens sales in 2002, 1-800 CONTACTS has calculated that since the FCLCA was passed, American consumers have saved \$600 million dollars in implicit time costs as a result of direct delivery of contact lenses ordered online.²⁹

Today consumers have greater choice and convenience; competition was leading to more affordable prices. But with every step forward, manufacturers and prescribers find new ways to undercut the goals of the FCLCA, resorting to anticompetitive market tactics and outright refusal to comply with the CLR. The current array of anti-consumer tactics is described below.

2. Manufacturers Adopt Unilateral Pricing Policies

Contact lens manufacturers today are—once again—engaged in a concerted and widespread attempt to limit competition in the contact lens industry by imposing a “unilateral pricing policy” (“UPP”) on the resale of their most popular products. These policies have effectively gutted the goals of the FCLCA by taking price competition largely off the table and essentially eliminating the benefit of prescription portability. Over the past year and a half, all four major contact lens manufacturers—Johnson & Johnson, Alcon, Bausch & Lomb, and Cooper Vision—have enacted almost identical pricing policies. These regimes are designed to protect prescribers from encroachment of their retail businesses by artificially controlling price competition from alternative channels. This goal is express. As Laura Angelini, President of Johnson & Johnson Vision Care said “This [pricing model] gives the optometrist the ability to improve his or her capture rate in the office. Now the patient has no incentive to shop around.”³⁰

²⁸ See e.g. Testimony of Joe Zeidner, Hearing before the Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy and Consumer Rights (July 30, 2014), available at <http://www.judiciary.senate.gov/imo/media/doc/07-30-14ZeidnerTestimony.pdf>.

²⁹ Based on one-hour trip per year that consumers did not have to make because their lenses were delivered, and growth in online sales from approximately 3.4 million customers in 2003 to approximately 7.4 million customers in 2015.

³⁰ *Johnson & Johnson Vision Care Introduces Unilateral Pricing Policy on ‘Strategic Brand’ CLs, Discontinues Some Acuvue Brands*, Vision Monday, July 2, 2014, available at <http://www.visionmonday.com/latest->

Unsurprisingly, the effect of UPP has been to increase prices in the contacts lens market, in some cases drastically.³¹

As of this writing, the UPP policies still remain formally in place, although they have come under tremendous attack. The policies are the focus of active antitrust investigations by multiple state Attorneys General and have drawn harsh criticism from independent entities such as Consumers Union and the American Antitrust Institute.³² In addition, approximately sixty consumer antitrust class action complaints have been filed across the country, all alleging that the programs have increased prices to consumers. Those actions have been centralized into a single federal case and are moving forward.³³

Legislative bodies have also investigated UPP. The U.S. Senate Antitrust Subcommittee held a hearing in July 2014 to consider the harmful effects of these programs.³⁴ At the conclusion of the hearing, several committee members indicated their intent to develop further evidence on the impact of the manufacturers' programs.

A number of states also began considering antitrust legislation to address the new pricing policies. Legislation was recently introduced to invalidate UPP pricing policies in Arizona, California, Florida, Mississippi, New York, Idaho, Illinois, Oregon, Washington, and Utah.

Utah was the first to act. On March 27, 2015, Utah Governor Gary Herbert signed into law S.B. 169, which went into effect on May 12, 2015. The law had broad support from national retailers, including not only 1-800 CONTACTS, but also Costco Wholesale and Lens.com. The Utah law forbids (among other things) a contact lens manufacturer from taking "any action, by

[news/article/johnson--johnson-vision-care-introduces-unilateral-pricing-policy-on-strategic-brand-cls-discontinues-some-acuvue-brands-1/](http://www.1800contacts.com/news/article/johnson--johnson-vision-care-introduces-unilateral-pricing-policy-on-strategic-brand-cls-discontinues-some-acuvue-brands-1/)

³¹ In an open letter calling on both the Federal Trade Commission and United States Department of Justice to investigate UPP, the American Antitrust Institute ("AAI") estimated that when UPP was first implemented, it would eliminate the ability of sellers to discount lenses that accounted for 40% of the market, a figure that was likely to rise to 80%. AAI reported that UPP was likely to increase the price of Johnson & Johnson lenses anywhere from 40 to over 100 percent. Letter from the American Antitrust Institute to Edith Ramirez, Chairwoman, Federal Trade Commission and William Baer, Deputy Assistant Attorney General, U.S. Department of Justice, Antitrust Division (October 24, 2014), available at <http://www.antitrustinstitute.org/sites/default/files/AAI%20Letter%20on%20RPM%20in%20Contact%20Lenses.pdf>.

³² See ConsumerReports.org, *Contact-Lens Pricing-Policy Shift Is a Bad Prescription for Consumers, The Change Could Mean the End of Discounted Lenses* (Aug. 1, 2014); Letter by American Antitrust Institute to the Dept. of Justice and FTC (Oct. 24, 2014), available at <http://www.antitrustinstitute.org/content/aai-urges-action-minimum-price-policies-contact-lens-industry>.

³³ See Transfer Order, MDL 2626, Docket Item 186 (J.P.M.L. June 8, 2015) ("At issue in all actions are defendants' pricing policies that allegedly prevented resale of the subject contact lenses below a minimum price.").

³⁴ Hearings Before the U.S. Senate Committee on the Judiciary, Subcommittee for Antitrust, Competition Policy and Consumer Rights: Pricing Policies and Competition in the Contact Lens Industry: Is what You See What you Get? (July 30, 2014).

agreement, unilaterally, or otherwise, that has the effect of fixing or otherwise controlling the price that a contact lens retailer charges or advertises for contact lenses.”³⁵

Three of the manufacturers filed suit in federal court in Utah, challenging the law as beyond the power of the Utah legislature to enact. Following briefing and oral argument, the U.S. District Court for the District of Utah rejected the manufacturers’ arguments and agreed with the Utah Attorney General that the law was a valid exercise of Utah’s power to promote price competition in the industry.³⁶ The court rejected the manufacturers’ discrimination arguments, finding that Section 905.1 applies equally to manufacturers within and outside of Utah. The court also found that the law treats all retail sales of contact lenses in Utah the same by requiring that the manufacturers “refrain from mandating price fixing within the state of Utah and from discriminating against Utah retailers for reasons related to price fixing.”³⁷ According to the court, the new law “merely protects Utah retailers and consumers from activity that the State of Utah believes violates principles of fair competition.”³⁸ The court refused to enjoin “a law that the “Utah Legislature determined was necessary to protect consumers and promote free competition in the retail market for contact lenses.”³⁹

3. Prescribers Resurrect Discredited Health Claims to Support UPP

The AOA supports the manufacturers’ anti-consumer pricing policies precisely because they reduce consumer incentives to shop around. Resurrecting the same false and misleading health claims that gave rise to the *Disposable Contact Lens Antitrust Litigation* more than a decade ago, the AOA argues that policies that limit comparison shopping are good for consumers because comparison shopping for lenses from third-party sellers puts ocular health at risk.⁴⁰

These false and misleading health claims were rejected at both the state and federal levels more than a decade ago. In support of the FCLCA, the Chair of the Contact Lens Working Group of the National Association of Attorneys General Antitrust Task Force testified that such health claims have no evidentiary basis and do not justify restraining consumer choice.

³⁵ Utah Code, § 58-16a-905.1 (2015).

³⁶ *Alcon Labs, Inc. v. Reyes*, No. 2:15-cv-00252-DB (D. Utah May 11, 2015).

³⁷ *Id.* at 13.

³⁸ *Id.* at 12.

³⁹ *Id.* at 17-18. The Tenth Circuit has refused to stay implementation of the new law. It heard oral argument on the issue on August 27, 2015, and a decision is expected soon.

⁴⁰In essence, the AOA argues that eliminating competition is good for consumers because it strengthens the prescriber/patient relationship. Of course, what the AOA is really advocating is a *de facto* tying arrangement forced on the consumer by removing choice without any credible medical basis. *AOA Fights for Patient Safety in Contact Lens Legislation* (June 18, 2015), available at <http://www.aoa.org/news/advocacy/aoa-fights-for-patient-safety-in-contact-lens-legislation?sso=y> The AOA position is a frontal assault on the goals of the FCLCA—“to enhance competition in the market for contact lenses by providing consumers with greater ability to fill their contact lens prescriptions from sellers other than their prescribing eye care practitioner.” *The Strength of Competition* at 1.

Sales by ECP competitors do not give rise to any eye health problems that AOA can support by valid, clinical or scientific data. Indeed, the AOA has not provided any evidence of consumer harm... Disposable contact lenses were introduced and alternative channels began selling them in the late 1980s. The States would expect that any consumer harm flowing from the sales of replacement contact lenses by alternative channels to have become manifest by now if there were such evidence.⁴¹

The FTC similarly concluded that there is no evidence of consumer health or safety issues arising from the purchase of contact lenses from alternative channels. “The [FTC] workshop, the Commission’s Rule review, the multidistrict litigation, and the Commission’s staff’s own consultations with industry experts have revealed no systematic evidence that sales through alternative channels, such as internet or mail order, pose any additional health risk as long as the retailer sells in accordance with a valid prescription.”⁴²

And importantly, Congress has already spoken. It made the determination that competition from alternative retail channels is good for contact lens consumers. It adopted the FCLCA to level the playing field for retail competition in the sale of contact lenses. That framework for retail sales left to prescribers, *in their role as healthcare providers*, the obligation to educate their patients on proper lens hygiene during an exam or lens fitting regardless of whether the patient later chooses to purchase lenses from the prescriber.

Contact lenses today are mass produced and shipped in pre-packaged boxes to all suppliers (prescriber retailers and independent retailers alike). Any health risks associated with poor contact lens hygiene habits today are the responsibility of prescribers who fail to adequately educate their patients. There is no evidence that those health risks differ based on whether the consumer later purchased lenses directly from a prescriber or a third-party retailer.⁴³ The appropriate way to bolster healthy contact lens habits is greater prescriber attention to their role as healthcare providers (and less to their role as retailers), not anticompetitive restraints on consumer choice that are inconsistent with the FCLCA. The AOA’s misleading health claims

⁴¹ Fairness to Contact Lens Consumer Act, Hearing Before the Subcommittee on Commerce, Trade and Consumer Protection, House Committee on Energy and Commerce, 108th Cong. 193, n. 18 (September 12, 2003).

⁴² Anticompetitive Barriers to E-Commerce at 12; *see also* Contact Lens Report at 5, 54; FTC Connecticut Board Comments at 4.

⁴³ A recent study by the Centers for Disease Control and Prevention (“CDC”) concluded that more than 99% of contact lens wearers engage in at least one contact lens hygiene behavior that could raise the risk of infection. CDC, *Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections—United States, 2014*, (Aug. 21, 2015), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6432a2.htm>. However, the CDC did not conclude that there was any difference in either habits or health risks based on whether the patient bought her lenses from a prescriber or a third-party retailer. The FTC has previously rejected the claim that consumers that purchase lenses from alternative channels compromise their ocular health. To the contrary, the FTC concluded that competition from alternative channels would drive down prices and improve patient health by allowing patients to replace lenses more frequently. *See* Connecticut Board Comments at 8.

and support for UPP are a transparent attempt to benefit the economic interests of its prescriber members and interfere with the operation of the Act and nothing more than that.⁴⁴

4. Widespread Failure to Comply with the CLR

In the face of continued attacks on alternative distribution models, effective prescription portability and efficient verification are even more critical to preserving the competition and consumer choice the FCLCA was meant to create. However, as described below, the reality is that prescribers are interfering with the ability of sellers to compete on even convenience and customer service grounds because they refuse to comply with either the prescription release or verification requirements of the CLR. These compliance failures are more fully described below.

a. Failure to Automatically Release Prescription to Consumers

Section 315.3(a)(1) of the CLR requires that prescribers provide patients with a copy of their contact lens prescription after completing a fitting—regardless of whether the patient requests a copy. Prescribers may not condition prescription release on the purchase of contact lenses, additional payment or require the patient to sign a waiver or release.

Approximately 14.5 million contact lens wearers (36% of contact lens wearers) leave their prescriber’s office without a copy of their prescription.⁴⁵ This is because only 35% of

⁴⁴ It is important to emphasize that the AOA is claiming that competition itself is the problem because choice limits the bond between prescriber and patient. The AOA is not making, and has no basis to make, the kind of “free riding” argument that can sometimes justify certain vertical restrictions under the antitrust laws. The important distinction is that prescribers are already paid separately for time spent on patient education through an exam fee. There is no need to restrict competition (intradbrand or otherwise) 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.

⁴⁵ In 2008, *Contact Lens Spectrum Magazine* published a prescriber survey showing that prescription release in 2007 was well under 50%. See *Contact Lens Spectrum Magazine*, Annual Report, Contact Lenses 2007 at 4 (Jan. 1, 2008), available at <http://www.clspectrum.com/articleviewer.aspx?articleid=101240>. More recent survey evidence confirms this result and provides additional information on both consumers awareness of their rights and prescriber behavior on prescription release. The more recent evidence is based on an independently conducted survey based on a random sample of 803 contact lens wearers between the ages of 18-49 in October 2015 (“October 2015 survey”). That survey showed that 46% of patients are unaware that they have a right to their contact lens prescription. The same survey showed that only 35% of contact lens wearers were automatically provided with a copy of their prescription. A second set of independent surveys based on random samples of 2000 contact lens wearers, conducted in November 2014 and May 2015, showed that between 45% and 48% of contact lens wearers received their prescription automatically (“November 2014/May 2015 surveys”). These surveys were sponsored by 1-800 CONTACTS and conducted by an independent market research company. The differences in percentages could be attributed to many factors, including small variations in the way questions were phrased. The striking conclusion is that in multiple consumer surveys, prescription release falls well under 50%, which is consistent with outcome of the

consumers (14 million) are automatically provided with a copy of a prescription at the completion of a contact lens fitting. Due to prescriber noncompliance, 29% of contact lens wearers (11 million) had to ask for a copy of their prescription after their last eye exam. Unfortunately, many contact lens wearers do not know to ask because nearly half of all contact lens wearers today (46% or 18.4 million) do not know they have a right to a copy of their prescription.

Prescribers are well aware that many consumers do not understand their rights. Yet they do little to educate their patients. Instead they are exploiting weak consumer awareness to avoid their obligations under the CLR, undermining the FCLCA and congressional intent (as stated in the preamble to the Act) to “provide for availability of contact lens prescriptions to patients.

Even patients who know to ask for a copy of their prescription face hurdles. Many contact lens patients relate stories of their recent ordeal trying to wrestle a prescription away from their prescriber; repeated phone calls and multiple office visits are not unusual. Survey evidence shows that contact lens consumers perceive that it is twice as difficult to get a prescription from their eye care professional as from their primary care physician.⁴⁶ There is no excuse for this behavior. Turning over a slip of paper is not burdensome. It is something most healthcare providers do every day without a second thought.

Finally, even when prescribers release a prescription, they often do so only after completing a sale to the consumer. Prescribers typically shift from their role as health care provider to their role as retailer even before an examination is complete, using the influence they wield as a trusted medical professional to advantage their retail operations. Approximately 32% of contact lens wearers report that their prescriber began to discuss contact lens purchase options while the eye exam was ongoing.⁴⁷ For those patients that received a copy of the prescription (either automatically or after asking), 38% report that they received a copy either with or after purchasing lenses from their prescriber.⁴⁸

After-the-fact release is not what Congress envisioned when it passed the FCLCA. More than 10 million contact lens wearers today are getting their prescription when it no longer matters in terms of the choice and competition the FCLCA was passed to create. By effectively tying exams and lenses, after-the-fact release diminishes competition by foreclosing an additional 25% of the market to alternative sellers.⁴⁹

Contact Lens Spectrum Magazine study in 2008—confirming that things have not improved with time. The results from these surveys are attached as Exhibits A, B and C to this comment.

⁴⁶ Exhibit B (October 2015 Survey at 4).

⁴⁷ *Id.* at 7.

⁴⁸ *Id.* at 10.

⁴⁹ Evidence from the October 2015 survey shows that of the about 65% of all contact lens consumers that eventually obtain a copy of their contact lens prescription, 38% obtain the copy after purchasing lenses. There are approximately 41 million contact lens wearers in the market today.

b. Refusal to Provide Prescription to Authorized Agent

Pursuant to the FCLCA, a patient can authorize a third-party seller to stand in her shoes and request and receive a copy of her prescription. The FTC imports this same language into the CLR, making a prescriber's failure or refusal to comply with a request from a patient's agent to obtain a copy of the patient's prescription an unfair or deceptive act or practice.

Section 315.3(2) of the CLR requires prescribers to release a patient's prescription to an authorized agent upon the agent's request. Due in large part to poor prescriber compliance with prescription release requirements, many customers cannot provide a third-party seller with copy of their contact lens prescription at the time they place their order. Consequently, 1-800 asks our customers to authorize us to obtain a copy of their prescription, on their behalf, and to keep the prescription on file to facilitate future orders. This is a service customers expect to streamline the ordering process with alternative sellers.

Customers place a high value on speed in the delivery of their lenses; customer satisfaction metrics drop markedly when they have to wait more than five days to receive an order.⁵⁰ With a copy on file, 1-800 ships a customer's order without delay (within 14 minutes of placement) and does not have to repeatedly contact prescribers to verify refills authorized by the same valid prescription. When asked directly on the phone with a clear description that 1-800 will contact their prescriber, request a copy of their prescription, and retain the prescription on file to facilitate future orders, 90% of 1-800 customers have responded that they grant 1-800 such agency and rights to act on their behalf. These findings have been corroborated by 1-800 customer research.

Prescribers and their trade associations fight against competitors' legal rights to provide this service to their customers, which would level the competitive playing field on future sales. Prescriber opposition is not born out of genuine concern for consumer rights or interests. In no other healthcare sector do prescribers impose these roadblocks on their patients. Consumers routinely pick up the phone to refill a prescription at their local pharmacy. Pharmacists will sometimes need to contact the prescriber to verify that the refill is authorized. Prescribers *never* respond by picking up the phone to call their patient to confirm that the pharmacist is authorized to have the patient's prescription or to question their patient's decision to fill their prescription at pharmacy X rather than pharmacy Y.

These battles over agency are simply not an issue where the doctor does not have the conflict of interest that is the real motivation for the roadblocks prescribers continue to erect in the contact lens sector. Evidence shows that in about half the cases, prescribers ignore and never respond to 1-800's authorized requests for a copy of a customer's prescription. Today there are hundreds of thousands of violations that have not been addressed and that number will continue to grow unabated without FTC action

⁵⁰ Internal 1-800 post-sale customer satisfaction survey data.

c. Issuing Prescriptions with Incomplete Information

Even in those cases where patients are—eventually—provided with a copy of their prescription, it often does not include all the information necessary to immediately fill an order. By law a contact lens prescription must include the following eight pieces of information:

- (1) Name of the patient;
- (2) Date of examination;
- (3) Issue date and expiration date of prescription;
- (4) Name, postal address, telephone number, and facsimile telephone number of prescriber;
- (5) Power, material or manufacturer or both of the prescribed contact lens;
- (6) Base curve or appropriate designation;
- (7) Diameter, when appropriate; and
- (8) In the case of private label contact lenses, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.⁵¹

However, despite these express requirements, most prescribers refuse to provide complete contact lens prescriptions in accordance with the law. According to a sample of 803 prescriptions on file with 1-800, less than 20% had all of the information outlined above. Of the remaining more than 80%, the prescriptions were incomplete in the following ways:

- (1) Date of exam missing: 63%
- (2) Contact information for prescriber missing: 43.10%
- (3) Issue date missing: 24.65%
- (4) Parameters missing: 22.64%
- (5) Expiration date missing: 17.52%
- (6) More than 80% of the private label prescriptions in the sample did not include the required manufacturer or national brand name.

⁵¹ 16 C.F.R. 315.2.

While the occasional mistake is to be expected, the numbers imply more than ordinary human error. At the very least, the evidence suggests that even when prescribers turn over a prescription, they do it with disregard for consumer rights. Incomplete prescriptions interfere with the customer service efforts of third-party sellers and impose unnecessary costs on the marketplace. When the patient submits an incomplete copy of her prescription to a third-party seller, the seller must nevertheless verify the order, adding unnecessary time and expense to the transaction. If nearly half of all consumers do not know they have a right to their prescription, it is highly likely that even less know what should be written on a prescription. Patients are certainly not well-positioned to ask their prescriber to correct errors or omissions on their prescription and should not be expected to do so. The responsibility to supply the patient with a complete portable prescription belongs to the prescriber. Failure to comply violates the CLR.

d. Imposing Hurdles on the Verification Process

Prescription verification is the second pillar supporting the FCLCA. Even with perfect compliance by prescribers on automatic prescription release (something far from the reality today), some patients will inevitably submit orders without a copy of their prescription, making verification critical to the operation of the Act. And where automatic prescription release is well under the 50% mark, as it is today, verification is what allows consumers to obtain contact lenses from their seller of choice.

As stated in both the FCLCA and CLR, prescribers “shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.”⁵² To verify a prescription, the seller must provide the prescriber with specific information detailed in the FCLCA and CLR. In particular, the seller must provide:

- (1) the patient’s full name and address;
- (2) the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate;
- (3) the quantity of lenses ordered;
- (4) the date of patient request;
- (5) the date and time of verification request;
- (6) the name of a contact person at the seller’s company, including facsimile and telephone numbers; and

⁵² 16 C.F.R. 315.3(a)(2).

- (7) if the seller opts to include the prescriber’s regular business hours on Saturdays as “business hours” for purposes of calculating the period for passive verification, a clear statement of the prescriber’s regular Saturday business hours.⁵³

Each week, 1-800 places approximately 100,000 calls to prescribers to verify prescriptions. The average prescriber receives one verification request from 1-800 CONTACTS per week.⁵⁴ We place our verification calls primarily using an automated human initiated voice response (“HUVR”) phone system. Our system has an automated voice that is clear and easy to understand. It offers prescribers user-friendly options such as the opportunity to pause the verification script or to request that the system call back at a later time. The complete phone script is 2 minutes, 29 seconds (149 seconds) in length and prescribers familiar with the system have the option to skip the first 48 seconds of the message to reduce the total time of the message to 1 minute, 41 seconds (101 seconds).

All calls are initiated by live 1-800 CONTACTS agents. We use live agents to initiate calls to guarantee that all calls are placed to the intended prescribers. When our message is left on an answering machine, the live agent remains on the line during the entire automated message to ensure that the complete message is conveyed to the prescriber.

Calls are placed as orders are received. 1-800 receives orders 24 hours a day, seven days a week. Many orders are received on weekends or during the evening hours. We *never* ship an order under the CLR passive verification provisions until eight business hours, as defined under the Rule, have passed, regardless of when a particular call was placed to a prescriber. Prescribers express concern about calls placed after hours or on weekends because they do not understand our process. ***Prescribers are always afforded eight business-hours to correct or otherwise respond to a verification request if they choose to do so—regardless of when the call is placed.*** For example, if a verification call is placed at midnight on Friday night, the verification clock does not begin until the following Monday at 9:00 am in the prescriber’s time zone.

We leave our verification messages shortly after orders are received because we have learned with experience that a continuous call process is logistically efficient and prevents a shipping bottleneck at a single hour each day. Our system is designed to be both compliant with the CLR and to provide our customers with the high level of service that they expect. 1-800 has invested significant resources into the development of a system that is not subject to human error, provides full assurance that 1-800 is compliant with the CLR, and offers the best service to our customers.

Nevertheless, some prescribers use the verification process to compete for a sale they have already lost or to simply harass a competitor. In over 180,000 occurrences each year, prescribers provide false information in response to a verification request, by, for example,

⁵³ 16 C.F.R. 315.5(b).

⁵⁴ The highest volume office in 1-800’s records received on average six calls per week in 2014.

claiming that a valid prescription has expired, or providing insufficient information when stating a prescription is inaccurate or invalid.⁵⁵ Prescribers sometimes share that advice with colleagues in chat rooms.

Yep – always have the staff call the patient to try to win back the business. Maybe you can match the price, inform her Rx is incorrect, and ship them to his/her door.⁵⁶

In addition, many prescribers that respond to a verification request by stating that a prescription is inaccurate or invalid do not unilaterally correct the prescription and specify the basis for the inaccuracy or invalidity as required by the CLR. In some cases prescribers are willing to violate the law and ignore the best interests of their own patients to merely stop alternative sellers from making a sale.

5:20AM fax from 1800 contacts with the wrong Rx (more minus than what I prescribed). I noticed my tech had been correcting them. I crossed out the correction with a sharpie and let them know it's not what I prescribed and I don't authorize the fill.⁵⁷

I had a pt try to order +7.50 ou when real rx is -7.50 ou. Thought about not correcting it but costal had a spot to fill in correct parameters. Normally we just say wrong and don't fix.⁵⁸

V. RECOMMENDATIONS⁵⁹

The FTC is required to promulgate rules to effectuate the FCLCA and to enforce violations of those rules as unfair or deceptive acts or practices. While 1-800 CONTACTS acknowledges the FTC's efforts to promote competition and consumer choice in the contact lens industry, 1-800 has witnessed firsthand the widespread lack of compliance with the CLR over the past ten years. 1-800 respectfully suggests that the FTC adopt a more vigorous enforcement agenda to promote automatic prescription release and compliance with other prescriber obligations (as described below) to ensure that consumers enjoy the choice and competition the FCLCA was meant to provide. Without the FTC's direct involvement through enforcement, prescribers will continue unabated in their anti-consumer conduct. In particular, 1-800 CONTACTS recommends the FTC take the following steps.

⁵⁵ Based on 1-800 study of prescriber responses where an active prescription was on file.

⁵⁶ ODs on Facebook, entry dated April 25, 2005.

⁵⁷ ODs on Facebook, entry dated April 21, 2015.

⁵⁸ *Id.*

⁵⁹ This section focuses primarily on proposed modifications to the CLR and the benefits and costs of the proposed modifications, primarily in response to questions 3,5,6, 8, 10 and 12 in the Request for Comments.

KEEP WHAT IS WORKING: RETAIN THE CURRENT VERIFICATION FRAMEWORK AND DEFINITION OF CONTACT LENS PRESCRIPTION WITHOUT CHANGE

1. Retain the Passive Verification System

The current framework, which includes a passive verification option, achieves the balance Congress intended by providing prescribers with a reasonable opportunity to correct an order based on an inaccurate, invalid, or expired prescription without imposing a needless delay on consumers (or unnecessary costs on either sellers or prescribers). As the FTC has previously stated “[b]ecause Congress has decided to impose a passive verification system through the Act, whether to adopt a passive verification system is not at issue” in promulgating the CLR.⁶⁰

Furthermore, while prescribers would prefer to eliminate mechanisms that bolster competition in the industry, passive verification has proven to be an effective means of continuing to open the marketplace. 1-800 CONTACTS’ verification processes, systems and approach are in strict adherence to the CLR, and passive verification in the industry has proven instrumental in providing greater consumer choice and lower prices. Post-sale survey evidence shows that about 80% of customers give 1-800 CONTACTS the highest score for customer satisfaction. The company’s customer ratings consistently rank among the top five of all companies in the United States. Orders are deleted as required under the CLR. Customers with invalid or expired prescriptions are directed to get an eye exam and prescription before placing another order.⁶¹ Moreover, there is no meaningful difference in customer satisfaction based on the method used to verify an order.⁶² Customers are equally happy with orders that shipped after passive verification as with orders that shipped after confirming against a prescription on file. If passive verification were leading to the shipment of inaccurate lenses, customers would surely let us know. From the consumer perspective, passive verification is working just fine.

2. Retain the Current Eight-Hour Time Frame for Passive Verification

The eight business-hour time frame for passive verification gives prescribers sufficient time to confirm important health information and correct any inaccurate orders without imposing

⁶⁰ Contact Lens Rule 69 Fed. Reg. 40497 (July 2, 2004).

⁶¹ As the FTC recognized in promulgating the CLR, there is of course, room for error. Any regulatory framework must necessarily strike a balance between cost and benefits and both Congress and the FTC have concluded that passive verification strikes the right balance between the costs and benefits associated with the risk of shipment of an inaccurate prescription and the benefits to consumers from promoting a competitive marketplace through passive verification. Moreover, the FTC emphasized that the responsibility for shipment of inaccurate orders rests primarily with the prescriber, not the seller. “If the seller is not informed that a verification request is incomplete, however, a sale based on an expired inaccurate or otherwise invalid prescription may occur after eight business hours. Because this may pose health risks to patients, the Commission encourages *prescribers* to inform sellers if they receive incomplete verification requests.” Contact Lens Rule, 69 Fed. Reg. 40498 (July 2, 2004).

⁶² Internal 1-800 CONTACTS customer satisfaction survey evidence.

a needless delay on consumers who place a premium on quick delivery. Many customers are wearing their last pair of contacts when they place an order and need their order processed as quickly as possible. In no other healthcare sector are patients routinely left to wait eight hours to hear from their healthcare provider, and if an order is placed on a Friday, contact lens consumers are left to wait as long as 72 hours.

Last year 1-800 CONTACTS cancelled orders worth approximately \$40 million in response to communications from prescribers. Over the past ten years the percentage of deleted orders has remained surprisingly consistent, diligent prescribers have used 1-800 CONTACTS' verification systems effectively to communicate under the CLR. The number of deleted orders and the value of sales cancelled demonstrate that prescribers have more than adequate time to respond when necessary.

3. Continue to Permit Direct Communication through Automated Phone Systems

The Act requires direct communication between a seller and a prescriber, and includes telephone contact as an acceptable form of direct communication. Automated phone systems existed at the time the Act was passed and the record indicates no effort to exclude automated phone systems and narrowly interpret telephone communications as “live” calls. We urge the FTC to retain automated telephone systems as an acceptable form of direct communication for verification purposes. 1-800 CONTACTS has experimented with other forms of direct communication and has concluded that a well-functioning automated system that incorporates the latest technology is the most efficient means of handling the large volume of verification requests that are required today. Our system has an automated voice that is clear and easy to understand. It offers prescribers user-friendly options such as the opportunity to pause the verification script or to request that the system call back at a later time. 1-800 has invested significant resources into the development of a system that is not subject to human error, provides full assurance that 1-800 is compliant with the CLR, and offers the best service to our customers. Customers place orders 24 hours a day, seven days a week. An automated system allows accurate information to be given consistently to every prescriber.

4. Retain the Current Definition of Contact Lens Prescription.

As described above, the Rule requires that a contact lens prescription include eight specific pieces of information, including the patient's name, the issue and expiration date of the prescription, and the brand/material, power and base curve of the lens. The FTC previously rejected calls to also require that a prescription include the maximum quantity a consumer could purchase with an existing prescription—and for good reasons.⁶³ Imposing quantity limits can inconvenience consumers and lead to unhealthy practices, such as wearing lenses longer than recommended. With a quantity restriction, a contact lens wearer who leaves a box of lenses at the hotel on her last business trip may return home and stretch the supply she has left until she

⁶³ Contact Lens Rule 69 Fed. Reg. 40487-88 (July 2, 2004).

has time to visit her prescriber (by wearing lenses longer than recommended). Patients sometimes tear lenses and need replacements. Some patients may find it more comfortable to wear the monthly lens they were prescribed for a shorter period of time and some may just want to leave an extra box in their locker at the gym. There are any number of very legitimate reasons consumers may want to purchase what appear to be (based on simple multiplication) extra lenses. There are no valid reasons to restrict those consumers' options.

In addition, the FTC recognized that prescribers would have the incentive to manipulate any quantity restriction to circumvent the minimum expiration dates mandated by the FCLCA and CLR.⁶⁴ Finally, if a prescriber believes a patient has ordered an oversupply of lenses, she can let a seller know during the verification process that the prescription is inaccurate. A seller must include the quantity of lenses ordered in a verification request and a prescriber can refuse to verify any order it believes is inaccurate.⁶⁵ As the FTC explained in 2004, “[I]f a verification request indicates that a patient seeks to purchase a nine-month supply of lenses one month before the prescription expires, the prescriber may treat the verification request as inaccurate...the prescriber would be required to provide the seller with information regarding the basis for the inaccuracy as well as to correct the prescription by specifying an appropriate number of lenses to be dispensed.”⁶⁶

There is no evidentiary basis for the FTC to revisit its decision on this issue now. Adding a quantity limit to a contact lens prescription will inconvenience patients, discourage healthy habits like changing lenses frequently and encourage prescribers to sidestep the minimum expiration dates mandated by the FCLCA and CLR.

FIX WHAT IS BROKEN: TAKE STEPS TO PROMOTE PRESCRIBER COMPLIANCE

5. Strengthen Automatic Prescription Release to Consumers

Automatic prescription release is a pillar of the FCLCA. Yet well under half of all contact lens consumers today enjoy that benefit due to bad prescriber behavior and weak consumer awareness of their rights. Recent survey evidence shows that nearly half (46%) of contact lens wearers (about 18 million consumers) do not know they have a right to their prescription. Given less than half of all patients are provided with a copy of their prescription automatically, it should come as no surprise that approximately 14 million patients leave their prescriber's office without a prescription in hand, and without knowing they have the right to shop around for their lenses.

⁶⁴ *Id.* at 40488 (“After reviewing the comments, the Commission has decided not to modify the definition of contact lens prescription to require the inclusion of the quantity of lenses or refills allowed...if the quantity of lenses is included on the prescription, then prescribers may use quantity limits to impose prescription expiration dates that are effectively shorter than the one-year period imposed under the Act.”)

⁶⁵ *Id.*

⁶⁶ Contact Lens Rule, 69 Fed. Reg. 40502 (July 2, 2004).

In addition, even for those patients that do receive a hard copy of their prescription, prescribers often hand it over only after completing a sale. The same recent survey shows that, for those patients that received a copy of their prescription, only half received that copy before they purchased lenses. About 38% received their prescription either with their lenses or immediately afterwards.

To advance real notice and choice in this market, 1-800 strongly recommends that the FTC amend the CLR to require that, immediately after completing a contact lens fitting, prescribers provide patients with a simple and easy to understand “Bill of Rights.” A clear and simple written notice provided immediately upon completion of a fitting will let patients know that they have a right to their contact lens prescription, that it will be provided automatically without request, and that they have the right to purchase their lenses from the seller of their choice. Notice is necessary immediately after the fitting—at the time when uninformed patients are most susceptible to gamesmanship and pressure sales tactics from prescribers. Patients have paid for an eye exam and deserve an automatic copy of their prescription before a prescriber shifts from acting as a healthcare provider to acting as a retailer.

To ensure that consumers both receive their prescription and understand this information, express acknowledgement—through patient signature—should also be required. To facilitate investigation and enforcement of prescription release, the FTC should require that prescribers maintain a copy of the signed notice for a period of three years or the length of the prescription, whichever is longer. These records should be available for inspection by the Federal Trade Commission, its employees, and its representatives. Any record-keeping burden on prescribers is minimal and well-justified by the benefits for consumers and the need to enforce prescription release under the FCLCA without involving the consumer in an evidentiary squabble with her prescriber.⁶⁷ This storage requirement is consistent with similar obligations imposed on sellers for each and every verification.⁶⁸

The current compliance environment seriously undercuts the goals of the FCLCA and is untenable. A signed Bill of Rights will be the most effective means available to ensure compliance with the Act’s stated intent to “provide for availability of contact lens prescriptions to patients.”

⁶⁷ In justifying the automatic release standard under the Eyeglass Rule, the FTC stated that “the right of the consumer to this prescription should be immunized from an evidentiary squabble over whether the consumer actually did or did not request the prescription.” Eyeglass Rule, 43 Fed. Reg. 23998 (June 2, 1978). Consumers should also be immunized in an evidentiary squabble over whether or not their prescriber automatically released their contact lens prescription.

⁶⁸ It should take a prescriber no more than a few minutes to present the form to the patient to obtain a signature. Forms could be presented in either hard copy or for digital signature on a tablet or laptop depending on how the prescriber organizes her records and could be maintained in the patient’s ordinary file using the prescriber’s ordinary record-keeping system.

§315.3 Availability of Contact Lens Prescriptions to Patients.

(c) *Acknowledgment of prescription release.* Immediately after a prescriber completes a contact lens fitting and before engaging in the retail sale of contact lenses, the prescriber:

(1) Shall have the contact lens consumer acknowledge their rights by signing a statement indicating “I confirm that after my contact lens fitting, my eye care practitioner provided me with a copy of my contact lens prescription. I understand that I am free to purchase contact lenses from any seller I choose.”

(2) The prescriber shall maintain records of acknowledgments under paragraph (c)(1) for a period of 3 years or the length of the prescription, whichever is longer, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

We urge the FTC to implement this recommendation, which would (i) give patients the information they need to fulfill the intent of the Rule, (ii) increase the likelihood that prescribers will comply, and (iii) provide the FTC with a basis to more easily investigate compliance in appropriate circumstances. A proposed template is attached as Exhibit D.

6. Bolster Prescription Release to Authorized Agents

As described above, prescribers routinely ignore requests from authorized agents (sellers) for a copy of a patient’s prescription. In 1-800’s experience, prescribers respond to only about 50% of our authorized requests to obtain, on behalf of a customer, a copy of their prescription to speed future orders. Moreover, prescribers continue to question whether they are required to do so. Those questions recently prompted the AOA to issue a notice to its affiliate organizations advising that the FCLCA requires prescribers to respond to authorized requests from sellers.⁶⁹

The FTC has an obligation to clarify prescribers’ obligations. New language is necessary to ensure that prescribers know that they are obligated to honor these requests and that there are consequences if they do not comply. Prescribers should not be permitted to interfere with our customer service efforts by contacting customers that have authorized 1-800 to obtain a copy of their prescription under the guise of verifying agency. Prescribers must presume agency is valid

⁶⁹ The AOA advisory memo to its affiliates states that “Prescribers have an obligation under the FCLCA to respond to requests for prescriptions from retailers acting as the patient’s agent.” New York State Optometric Association, FCLCA Enforcement Update from the AOA, posted on August 5, 2015, *available at* <http://www.nysoa.org/page/current-news-articles-4/news/fclca-enforcement-update-from-aoa-39.html>.

and if either prescribers or customers have grounds for a complaint they can raise that with the FTC.⁷⁰ Contacting customers is just another example of the kind of anticompetitive “self-help” that prescribers employed in *In re Disposable Contact Lens Antitrust Litigation* to curb competition from alternative channels. By putting prescribers on notice of their obligations, the Commission can encourage compliance without investing the resources that would be required to pursue the thousands of violations that occur on a regular basis.⁷¹

We therefore propose amending Section 315.3 to require that in response to an authorized request, the prescriber send the prescription to the agent (by mail, facsimile or a digital image of the prescription that is sent via electronic mail) within eight business hours as currently defined under the CLR. In addition, to ensure this obligation is enforceable, prescribers should be required to maintain a log recording the date and time a patient’s prescription was requested and released to the authorized agent. The log should be maintained for a period of three years and be available for inspection by the Federal Trade Commission, its employees, and its representatives.

§315.3 Availability of Contact Lens Prescriptions to Patients.

(a) *In general.* When a prescriber...

(b) *Prescription release to authorized agent*

(1) A prescriber shall, upon the request of any person authorized to act on behalf of the patient, provide such person with a copy of the patient’s prescription by mail, facsimile or electronic mail within eight (8) business hours.

⁷⁰ Prescriber refusal to honor authorized requests for prescriptions are nothing new. In 2006, the AOA encouraged its members to seek written proof of agency from 1-800 CONTACTS before releasing prescriptions and to notify patients to inform them of the request and confirm agency. American Optometric Association, Bulletin from the Office of Counsel, Bulletin No. 5 (August 29, 2006). The FTC informed 1-800 CONTACTS that written proof of agency is not required and that any disputes over the existence of an agency relationship should be resolved between the prescriber and seller. See Letter from Mary K. Engle, Associated Director, Federal Trade Commission Division of Advertising Practices to Joe Zeidner, General Counsel, 1-800 CONTACTS (October 4, 2006) (“We do not believe that the FCLCA or the Contact Lens Rule permit the prescriber to impose the burden of this written authorization requirement on 1-800. If 1-800 is the agent of the consumer, then the prescriber has an obligation under the FCLCA and the Contact Lens Rule to provide the consumer’s prescription to 1-800...In the event that a prescriber who receives a letter from 1-800...knows that 1-800 is not in fact that consumers agent, the prescriber should inform 1-800 that he or she is refusing to provide it based on the absence of the agency relationship and submit to 1-800 its affirmative evidence...This information should serve as the basis for the prescriber and 1-800 to resolve *between themselves* the issue of agency with regard to a particular request. If these communications do not resolve the issue, prescribers and sellers, of course, can submit complaints and supporting information to the FTC.” (emphasis added). These communications are attached as Exhibit E.

⁷¹ 1-800 CONTACTS has evidence of more than 300,000 violations of the CLR by prescribers since July 2014. All of these violations have been documented and could be filed with the FTC.

(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 released and (v) the method of communication used to provide the prescription to the agent.

(c) *Limitations*

7. Tell Prescribers to Stop Providing False Information in Response to a Verification Request

Many prescribers take every opportunity to frustrate the verification process by employing delay tactics. These delay tactics include hanging up on verification calls before a seller can convey all the information required by the CLR, or providing false information in response to a verification request, by, for example, stating that a valid prescription has expired. Providers need to understand that these tactics violate the CLR and are subject to fines; they need to be held accountable. 1-800 CONTACTS recommends that the FTC make the risk of punishment more express. In particular, we recommend the FTC:

Amend Section 315.5(d) to clarify that it is a violation of the CLR to respond to a verification request by stating that a prescription is inaccurate or invalid without providing the basis for the inaccuracy or invalidity of the prescription; or to knowingly convey false information regarding a prescription expiration date or the basis for the inaccuracy or invalidity of a prescription in response to a verification request.

8. Deter Future Violations by Investigating Prescriber Practices

Despite the widespread refusal of prescribers to release prescriptions, the FTC has taken limited enforcement action against prescribers since it promulgated the CLR in 2004. In 2007, the FTC sent warning letters to ten contact lens prescribers who failed to release prescriptions, required patients to purchase lenses from them, or imposed fees on patients before release prescriptions. To our knowledge, the FTC has taken no further public action against the thousands of noncompliant prescribers in the intervening eight years. Results of a prescriber survey published in *Contact Lens Spectrum* in 2008 indicated that, by their own admission, 50% of prescribers were not releasing prescriptions as required by the FCLCA.⁷² Prescribers today clearly believe they can disregard their legal obligations without consequence.

To change that dynamic the FTC must send a message to complacent prescribers. First, 1-800 recommends that the FTC investigate prescriber practices and issue warning letters or take

⁷² Exhibit A (*Contact Lens Spectrum* at 4).

enforcement actions against prescribers that violate their obligations, particularly with regard to automatic prescription release to patients. This should be done on a regular basis in a way that mirrors the agency’s enforcement sweeps to encourage compliance with the so-called funeral rule. Enforcement will not only change the behavior of the prescribers that are the target of the investigation, but more importantly, it will send a signal to prescribers across the country that the FTC is paying attention.

In addition, 1-800 CONTACTS recommends that the FTC amend Section 315.9 to clarify that any violation of the CLR—by either sellers or prescribers—constitutes an unfair act or practice in violation of the Federal Trade Commission Act (and is enforceable under the same standards and subject to the same fines and penalties).

§315.9 Enforcement

Any violation of this Rule, **by either prescribers or sellers**, shall be treated as a violation of a rule under Section 18 of the Federal Trade Commission Act...

Finally, to facilitate enforcement, 1-800 recommends that the FTC create a user-friendly online complaint process for consumers. The current FTC online complaint assistant is difficult to navigate and does not ask the appropriate questions to identify a CLR violation. For example, to report a complaint associated with contact lenses, the consumer is asked whether “the company failed to release your contact lens prescription upon request.” The standard is automatic release, not release upon request. 1-800 recommends that the FTC modify the online complaint process to make it simpler for consumers and others with knowledge of a violation to report CLR violations

In addition, 1-800 requests that the FTC investigate prescriber practices with respect to CLR compliance and issue warning letters or take enforcement action against those offenders. 1-800 believes that these steps would send a powerful message to the prescriber community and raise awareness about prescribers’ obligations under the CLR.

VI. CONCLUSION

1-800 CONTACTS greatly appreciates the FTC’s consideration of these comments. The Contact Lens Rule is critical to implementing the congressional vision for the FCLCA to promote consumer choice and a more competitive marketplace for contact lens wearers. The basic structure for the Rule has the potential to achieve that goal, but today prescribers are standing in the way. Current consumer understanding of their rights and the current prescriber compliance record is unacceptable and interfering with the important and achievable goals of the FCLCA. As described in this comment, these problems can be solved with a few simple and necessary steps. We respectfully urge that the FTC take those steps now.

EXHIBIT A

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ANNUAL REPORT
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.



By Carla J. Mack, OD, FAAO

Dr. Mack is director of clinic services and an associate professor of clinical optometry at The Ohio State University College of Optometry.

In 2007, the contact lens industry was graced with growth and product innovations; it was also once again immersed in solution controversy and more than one voluntary product recall. Several patient surveys have made it clear that our patients need better education, both on compliance and availability of current products. For practitioners, this is an opportunity for increased patient communication and practice growth. The global contact lens industry continually amazes me in that it varies so drastically by region and country, yet the good news for all is that industry growth continues.

Market Trends

Controversy aside, the ophthalmic sector as a whole is up 250 percent over the last five years, which is far ahead of the S&P 500. The contact lens industry remains healthy with industry analysts predicting 7 percent to 8 percent growth both for the United States and worldwide over the next few years. Data obtained from Jeff Johnson, OD, MBA, a senior medical technology analyst with Robert W. Baird & Co. Inc., estimate the worldwide soft contact lens market at \$4.8 billion and the U.S. market at \$1.8 billion. The worldwide GP lens market contributes another \$250 million. Market share by company is similar for the United States and worldwide with Johnson & Johnson dominating at nearly 45 percent. Worldwide soft lens market share for CIBA Vision is 19 percent, followed by CooperVision at 16 percent and Bausch & Lomb at 15 percent.

Worldwide soft lens market share is greatest for daily disposables at 33 percent, followed by a combined silicone hydrogel sphere and toric category at 24 percent (Figure 1). The U.S. daily disposable market share is at 10 percent (Figure 2), up from 7.5 percent in 2005 and 8.5 percent in 2006.

Silicone Hydrogels Silicone hydrogel conversion continues, particularly in the United States at 46 percent of the U.S. contact lens revenue compared to just 15 percent in 2004. The second half of 2007 saw the

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entry of CooperVision's Biofinity and the re-emergence of CIBA Vision's O₂Optix. It should come as no surprise that silicone hydrogel torics are also growing rapidly with nearly 45 percent silicone hydrogel toric penetration expected for 2007 versus less than 10 percent penetration in 2005. Looking at revenue, Figure 3 shows silicone hydrogel revenue for the last few years and a projection of revenue for 2008 in the United States. Figure 4 shows the revenue breakdown of silicone hydrogel lens modalities for 2007. Silicone hydrogel toric lenses account for nearly 35 percent to 40 percent of all toric lens revenue. With both industry and survey data indicating that all silicone hydrogels will continue to grow over the next few years, expect revenue driven by this option — which commands a premium price — to grow as well.

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Lens Care Market A.C. Nielsen data on solution market share through 2007 shows that private-label solutions represent one quarter, with all Alcon products at 39 percent. Multipurpose solutions still dominate share at about 89 percent with hydrogen peroxide-based systems at about 11 percent. ClearCare claimed 9 percent of the 11 percent share. These data do not include Wal-Mart or "club segments" (Costco, Sam's Club, BJ's) but do include other mass merchandisers and grocers. These data also reflect AMO Complete MoisturePlus through May 2007 and Complete Multi-Purpose Solution Easy Rub Formula's entry in August.

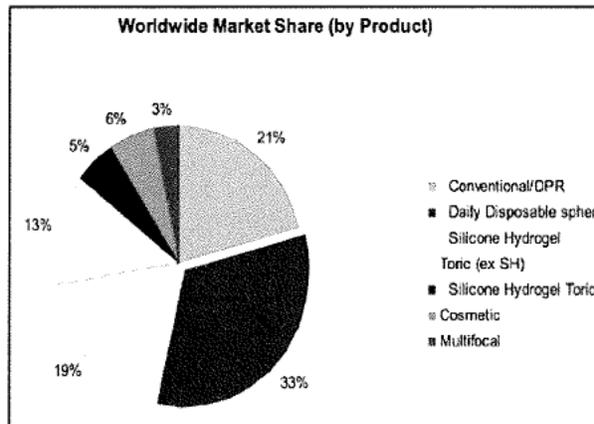


Figure 1. Daily disposable spherical lenses are most prescribed globally.
 Source: Company reports, Robert W. Baird & Co, Inc. estimates.

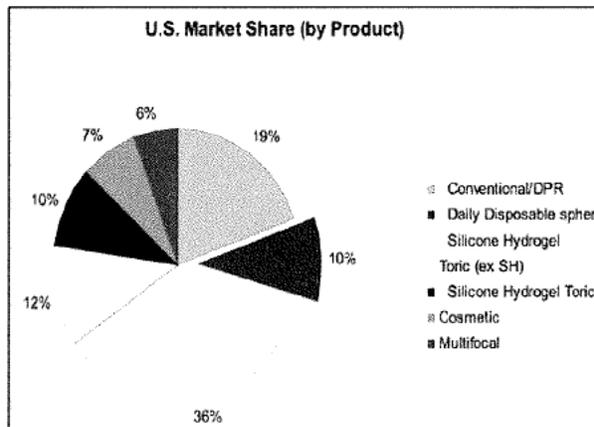


Figure 2. Silicone hydrogel lenses lead the U.S. market.
 Source: Company reports, Robert W. Baird & Co, Inc. estimates.

According to data on file from CIBA Vision, 3rd quarter 2007 retail sales showed the hydrogen peroxide category accounted for 14 percent of retail sales in the total disinfectant category, the highest share achieved in the United States since 2005.

Daily Disposable Lenses A survey of 227 *Contact Lens Spectrum* readers revealed that 52 percent of new fits and refits were with a silicone hydrogel material compared to 35 percent with hydrogels, with 12 percent of all soft lens refits and new fits in a daily disposable

Contact Lens Spectrum is the only publication in the contact lens industry for daily, weekly, and monthly disposable contact lenses. Each month, it offers timely editorial on fitting, overcoming complications, utilizing new technologies, gaining patient compliance and more — written by contact lens practitioners, opticians, and optometrists. Cost shares valuable information in the weekly, monthly, and quarterly issues.

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overshadowing its convenience and possible compliance and health benefits. Our reader survey indicates that 66 percent of respondents feel they will increase their daily disposable business in the next year.

Consumer data provided by CIBA indicates that 87 percent of Focus Dailies wearers are compliant with this modality, compared to 35 percent of total soft lens wearers. Our readers reported that about 22 percent of daily disposable wearers are compliant with the daily disposable modality and that 44 percent of two-week lens wearers are compliant with replacement schedules. However, they feel that only 8.5 percent of patients who require a lens care system are compliant with lens care instructions.

Our readers also see their toric and multifocal/bifocal businesses growing (58 percent and 71 percent, respectively).

Legislation

In April 2007 the Contact Lens Consumer Health Protection Act (CLCHPA), HR 2012, was introduced to the U.S. House of Representatives. The AOA is working with Representatives Mike Ross (D-AR), Ed Whitfield (R-KY) and John Boozman, OD (R-AR) to build support for HR 2012. The CLCHPA seeks to amend the Fairness to Contact Lens Consumers Act (FCLCA) of 2004 to require all contact lens sellers to provide a toll-free phone number and dedicated e-mail address for the purpose of receiving communication from prescribers.

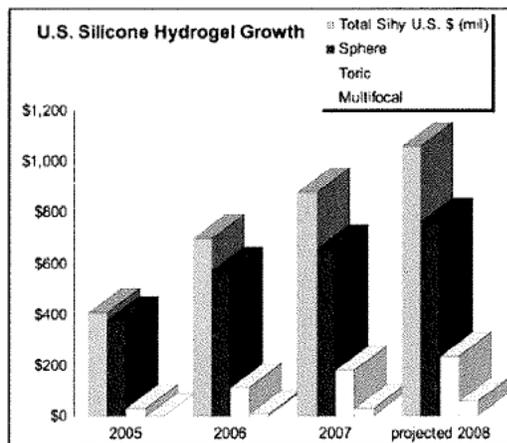


Figure 3. Current and projected silicone hydrogel revenue growth for the U.S. market.

Source: Company reports, Robert W. Baird & Co, Inc. estimates.

The bill stipulates that when a prescriber communicates a question or concern about the accuracy of a prescription to the seller, the seller must then obtain affirmative confirmation of the accuracy of the prescription before it's considered verified. The bill would allow prescribers to provide a seller with written notification stipulating the prescriber's preferred method of communication for contact lens prescription verification requests. It would mandate that no contact lens seller overfill a prescription for contact lenses, defined as providing more lenses than the prescription specifies or more lenses than the number required to fill a prescription for the period beginning on the date it's filled through its expiration date. It would also seek to impose stiff penalties on those who fail to comply with this bill.

1-800 Contacts ceased advocating legislation that supported consumer rights to fill contact lens prescriptions from the business of their choice after signing long-term supply agreements with CIBA Vision, CooperVision and Vistakon, its three largest suppliers. 1-800 had been purchasing directly from Bausch & Lomb since 2001.

In August the Federal Trade Commission (FTC) sent letters to 10 prescribers who failed to release contact lens prescriptions in accordance with the Contact Lens Rule of the FCLCA, following

complaints filed with the FTC. Our reader survey also indicates that despite this federal legislation, only half of the respondents replied "yes, to every patient" when asked if they release contact lens prescriptions.

Mergers and Acquisitions

2007 proved to be a year of many mergers, acquisitions and partnerships. ABB Optical and Con-Cise took advantage of automation efficiencies and an enhanced ability to stock infrequently ordered lens parameters by merging operations to become ABB•Con-Cise, the largest contact lens distributor in the United States.

Fenway Partners, a private equity firm, entered into a merger agreement with 1-800 Contacts. 1-800 sold its flat-pack technology to Menicon Co., Ltd., which is Japan's largest independent contact lens manufacturer. 1-800 sold its subsidiary ClearLab's manufacturing, distribution and customer support to Mi Gwang Contact Lens Co., a Korean based contact lens manufacturer.

Menicon partnered with UltraVision CLPL in the United Kingdom and Ireland for exclusive distribution of its new silicone hydrogel lens PremiO.

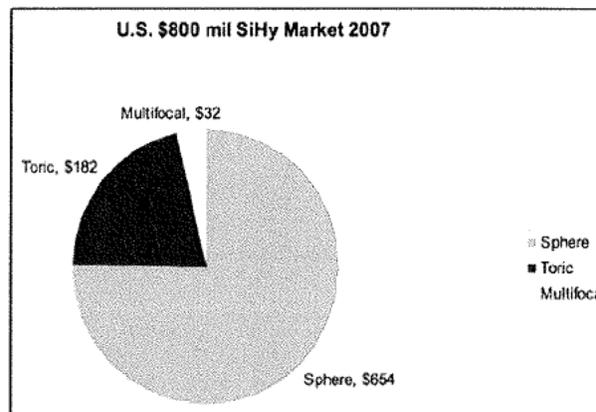


Figure 4. Modality breakdown for silicone hydrogel lenses in the U.S. in 2007. Source: Company reports, Robert W. Baird & Co, Inc. estimates.

Art Optical partnered with UltraVision CLPL for custom soft contact lenses and lathe cut soft contact lens technology.

On May 16, Bausch & Lomb entered into a merger agreement with private equity firm Warburg Pincus. Advanced Medical Optics entered the bid process, but withdrew its offer to purchase B&L on Aug. 1. Warburg Pincus completed the acquisition of B&L on Oct. 26.

Recalls

After seven non-serious complaints and no serious adverse events globally, CIBA Vision issued a letter to eyecare professionals on Jan. 12 detailing its voluntary recall of selected lots of O₂Optix contact lenses. The affected lenses fell below standard for ion permeability, which put wearers more at risk for persistent discomfort and superficial corneal staining. While CIBA Vision moved to implement manufacturing process improvements, significant back orders continued through the first half of the year.

In March, after three customer reports of discolored contact lens solution, Bausch & Lomb issued a limited and voluntary recall of 12 lots of its ReNu MultiPlus lens care solution because of an elevated level of trace iron. The iron in combination with other compounds could cause discoloration and a shortened shelf life.

Following Centers for Disease Control and Prevention data indicating that patients using AMO's Complete MoisturePlus had a seven times increased risk of developing *Acanthamoeba* keratitis (AK), AMO announced an immediate voluntary recall on May 25. In January the CDC initiated a retrospective survey of 22 ophthalmology centers nationwide to assess whether cases of AK were increasing in the United

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FCLCA STUDY

Focus on Prescription (Rx)

October 15, 2015

Brought to you by the 1-800 CONTACTS Marketing Strategies and Insights Team

BACKGROUND

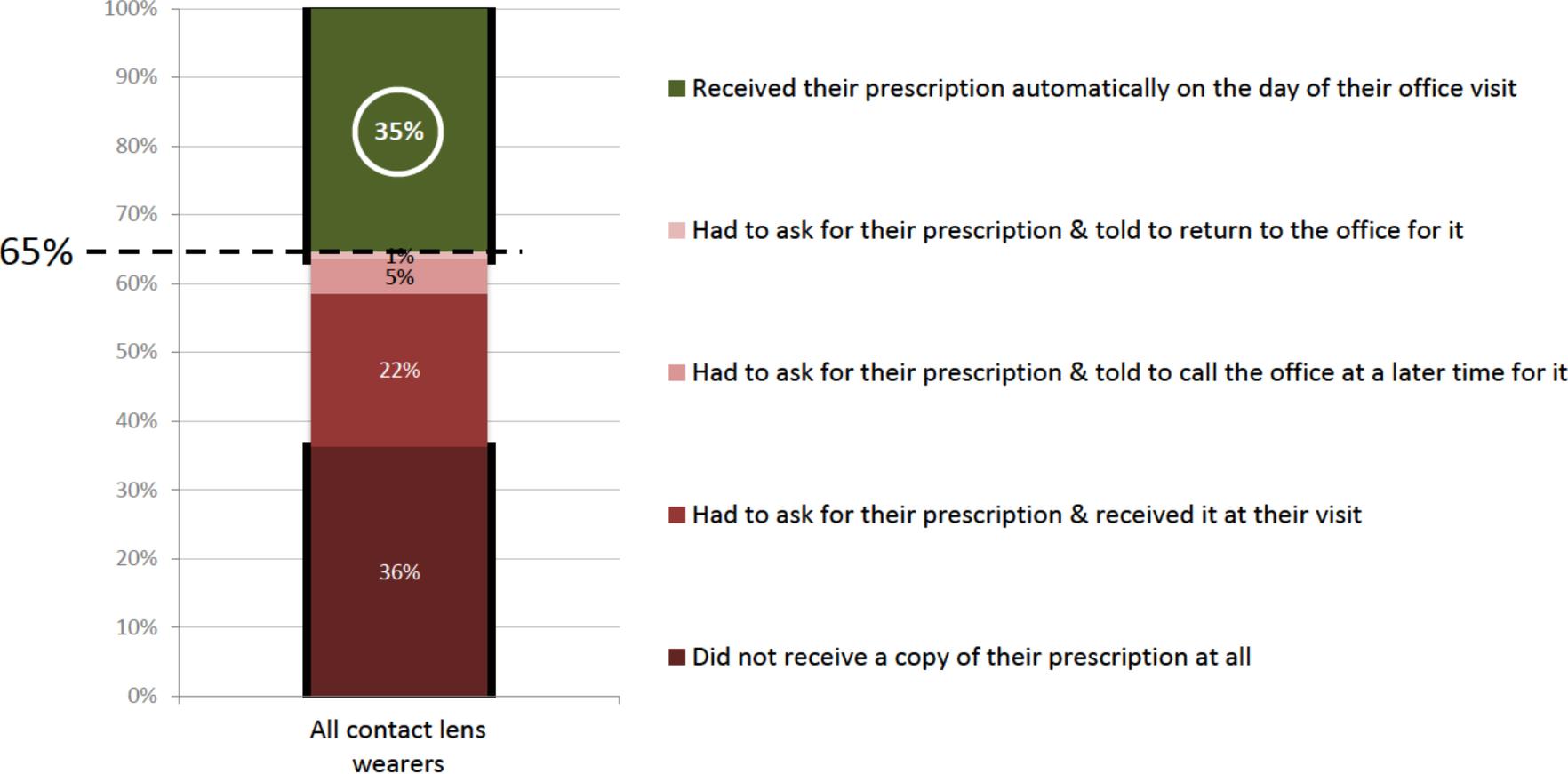
Data Collection

1-800 Contacts contracted Survey Sampling International (SSI), a third party vendor, to field the online survey among a national sample (ages 18 to 49 years old) during the dates of Thursday, October 1, 2015 through Tuesday, October 6, 2015.

Sample Design

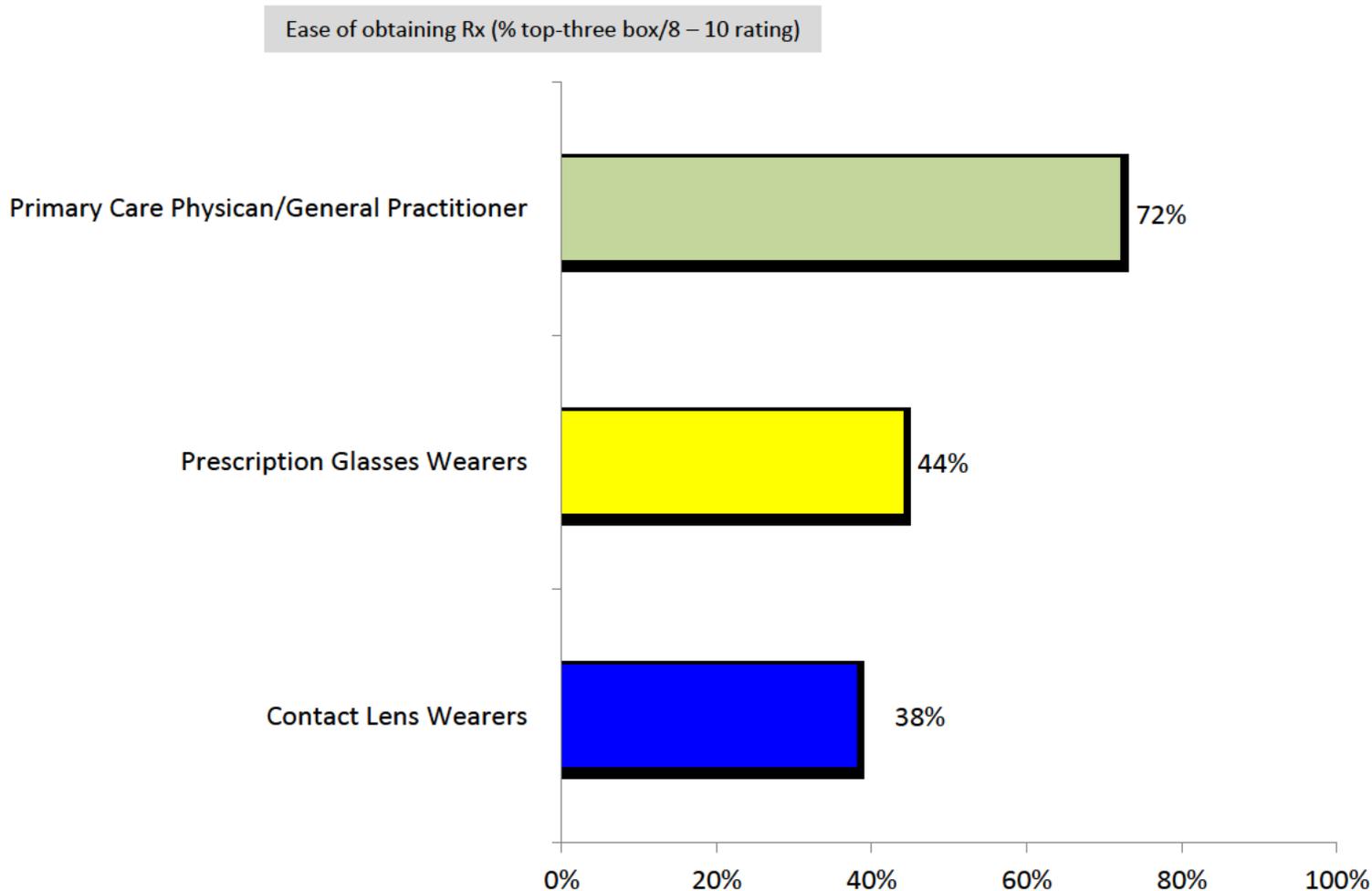
A total of 803 surveys were completed which is comprised of 500 Contact Lens wearers (62%) and 303 Prescription Eye Glasses wearers (38%).

Only 35% of contact lens wearers report receiving a copy of their prescription in accordance to FCLCA.



At your last eye exam, did the doctor provide you with a hard copy of your prescription?
Which of the following best describes how you received an actual hard copy of your prescription?

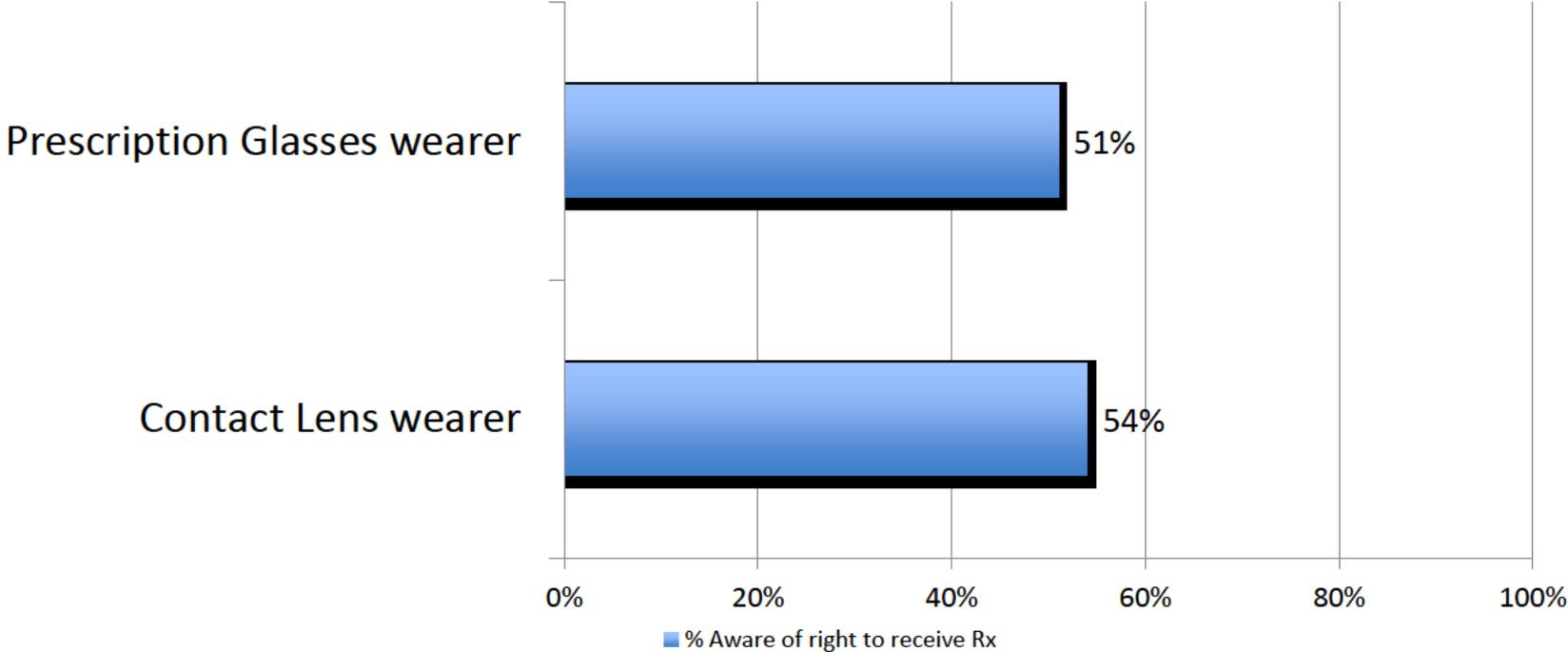
It is twice as hard for contact lens wearers to obtain their prescription from their eye care professional compared to obtaining their prescriptions from a primary care physician.



How difficult or easy was it for you to receive your contact lenses/eye glasses prescription? (Scale: Extremely Easy = 10/Extremely Difficult = 1)

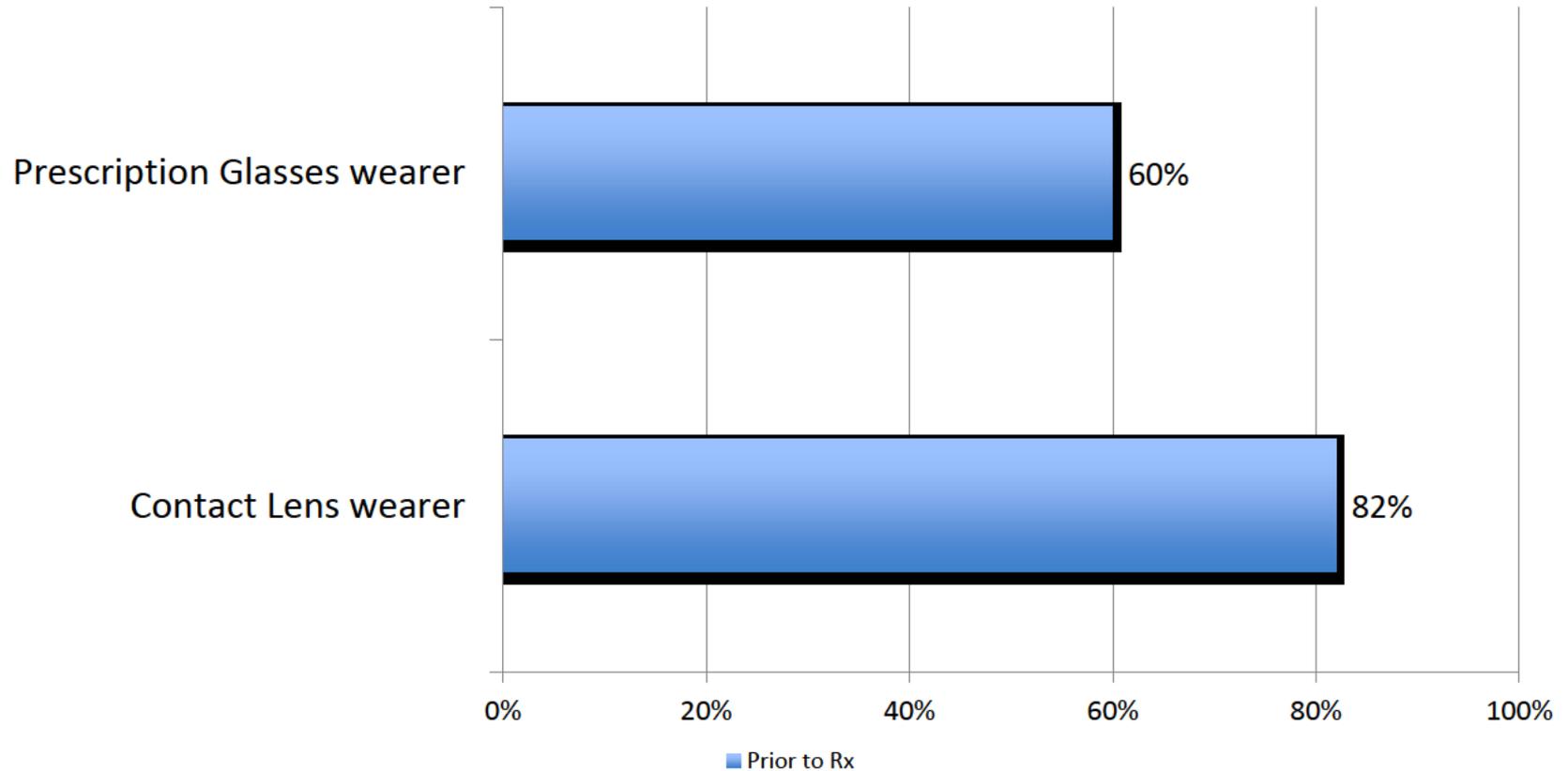
Contact lens wearers were slightly more aware of their right to receive an Rx hard copy relative to prescription eye glasses wearers.

% Aware of right to receive Rx



Are you aware that it is your right under federal law, as a patient to receive a hard copy of your contact lens/eye glasses prescription from your eye exam provider?

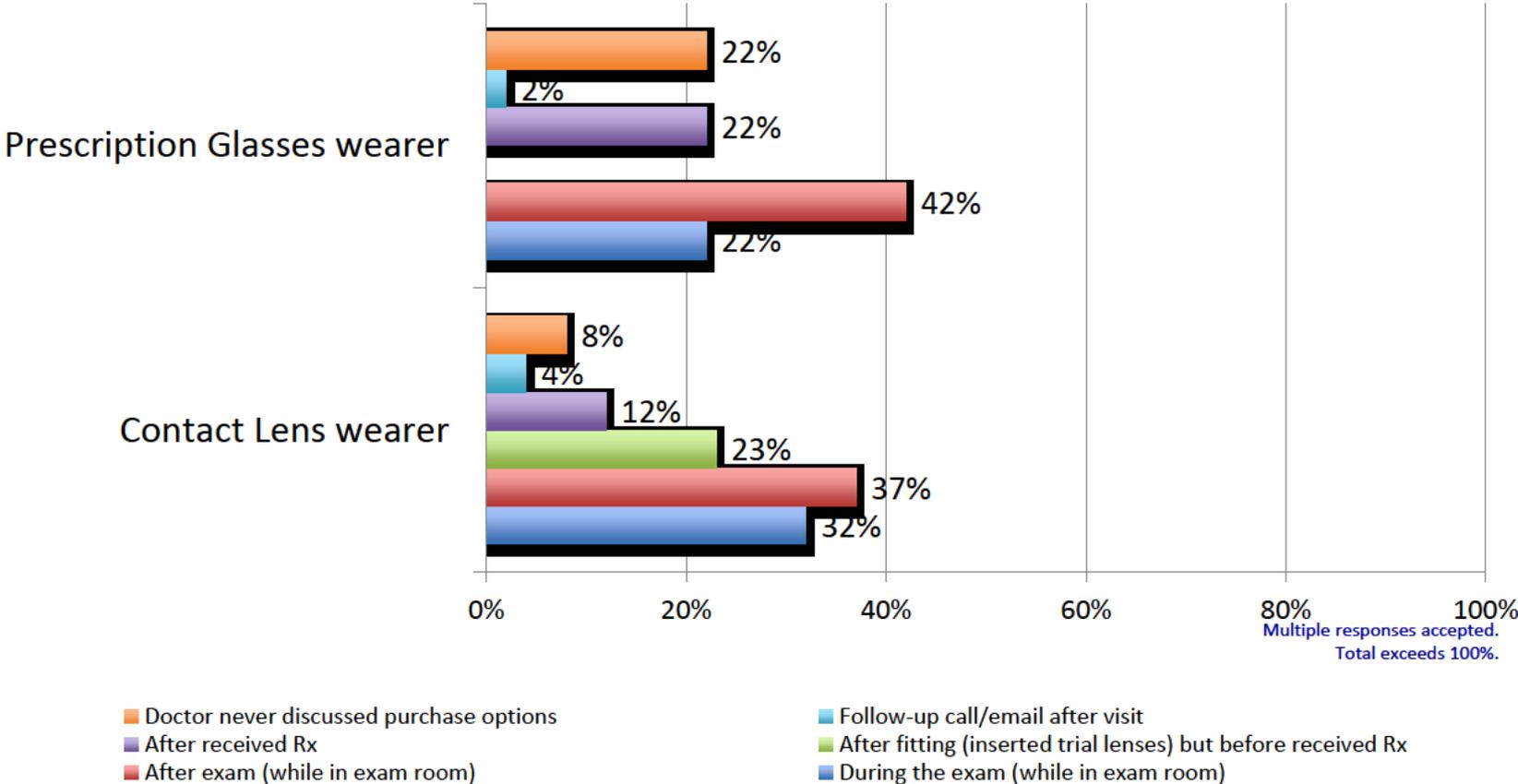
Eye care professional present purchase options to the majority of their patients prior to providing the Rx .



At what point during your visit did the doctor discuss your prescription eyeglasses purchase options (e.g. brand and what the costs were)?

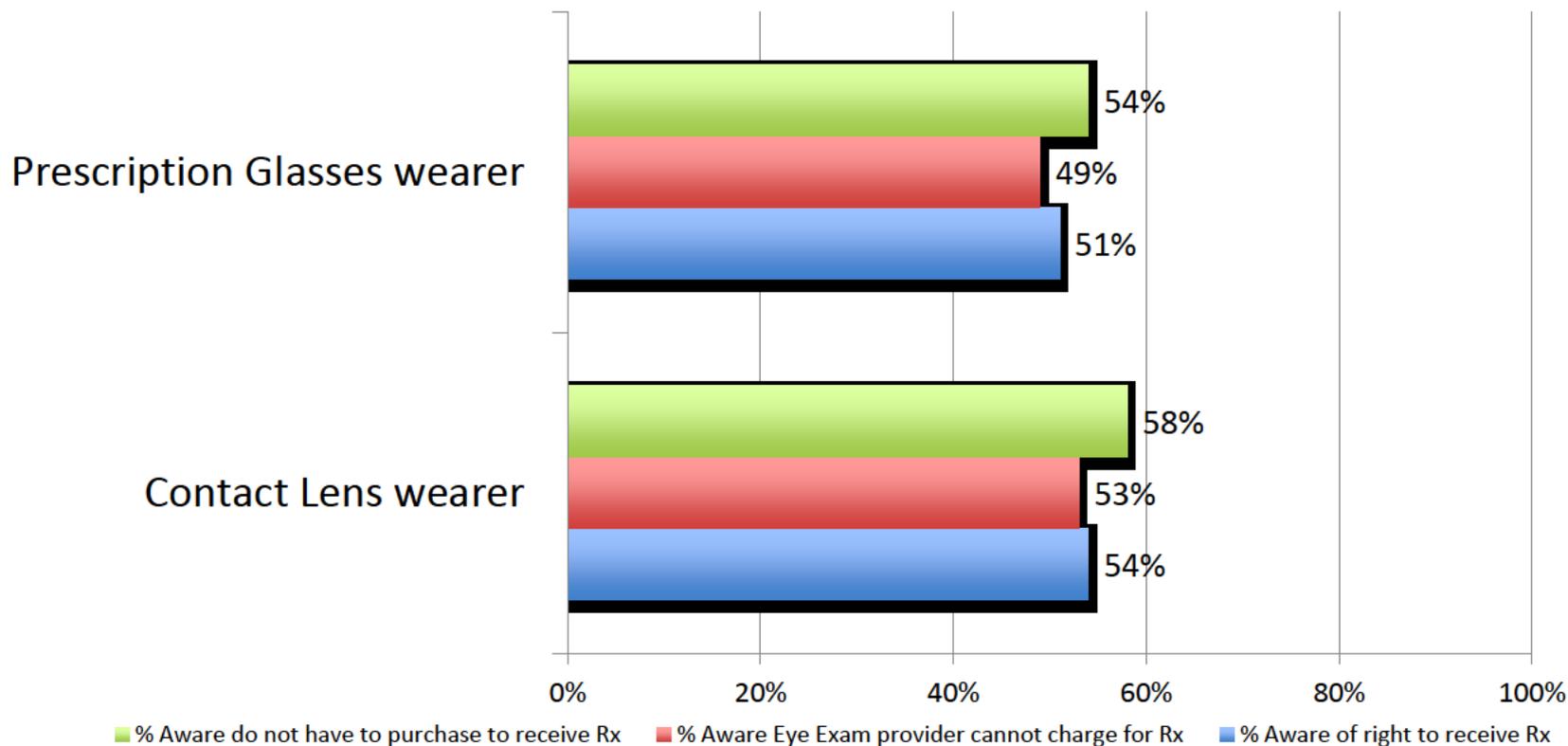
At what point during your visit did the doctor discuss your contact lens purchase options (e.g. brand, wearing schedule, or how many you could buy and what the costs were)?

Eye care professional present purchase options after the exam while patients are still in the exam room. Follow-up calls/emails is another channel used to inform patients about their purchase possibilities.



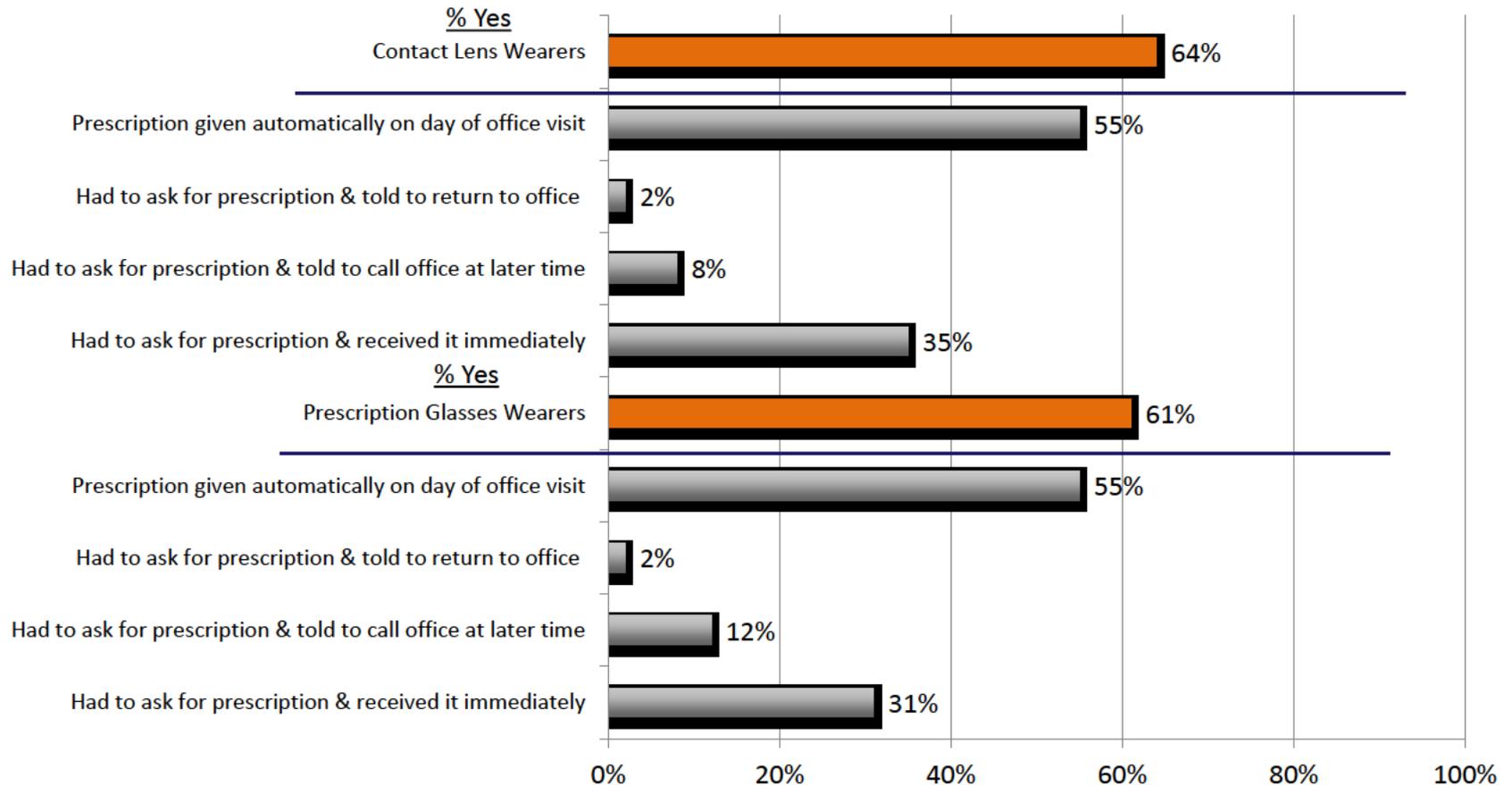
At what point during your visit did the doctor discuss your prescription eyeglasses purchase options (e.g. brand and what the costs were)?
At what point during your visit did the doctor discuss your contact lens purchase options (e.g. brand, wearing schedule, or how many you could buy and what the costs were)?

Awareness levels surrounding Rx rights were consistently in the 50 percentage range. Contact lens wearers were slightly more aware of their Rx rights relative to prescription eye glasses wearers.



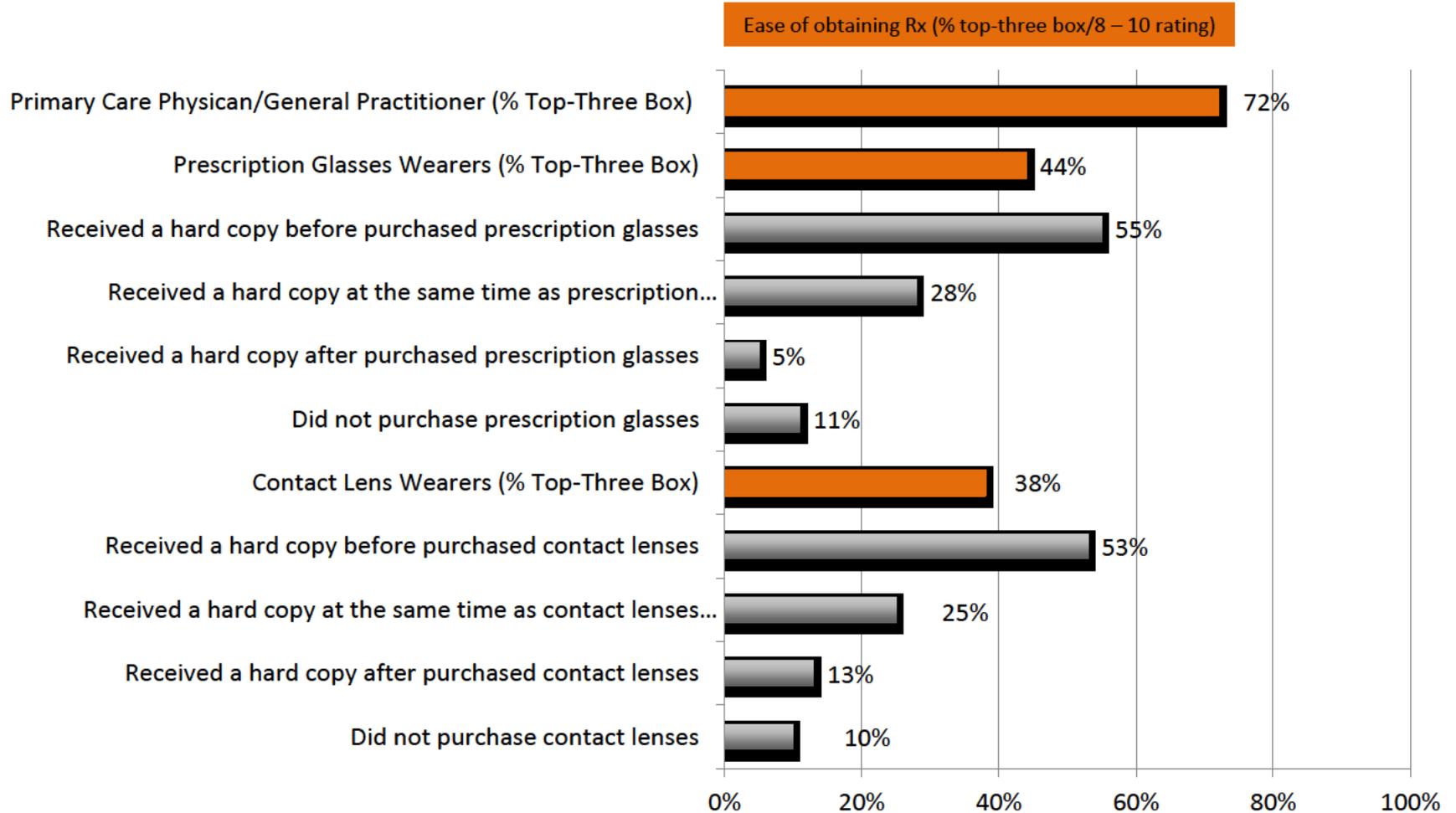
Are you aware that it is your right under federal law, as a patient to receive a hard copy of your contact lens/eye glasses prescription from your eye exam provider?
Are you aware of the following... - Your eye exam provider cannot charge you for an actual hard copy of your prescription?
Are you aware of the following... - You do not have to purchase anything from your eye exam provider to receive an actual hard copy of your prescription?

Roughly, sixty percent of both contact lens and prescription eye glasses wearers report receiving a hard copy of their prescription. Similarly, the largest share of both wear segments were given their prescription automatically on the day of the office visit.



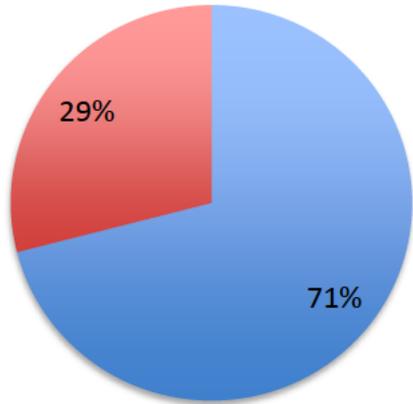
At your last eye exam, did the doctor provide you with a hard copy of your prescription?
Which of the following best describes how you received an actual hard copy of your prescription?

Ease of obtaining prescriptions from primary care physicians is easier compared to receiving prescriptions from eye care professionals.

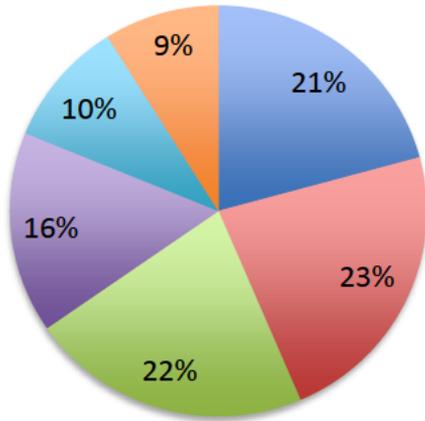


How difficult or easy was it for you to receive your contact lenses/eye glasses prescription? (Scale: Extremely Easy = 10/Extremely Difficult = 1)
Thinking about the last time you had an eye exam, which of the following best describes when you received an actual hard copy of your prescription (contact lenses/prescription glasses)?

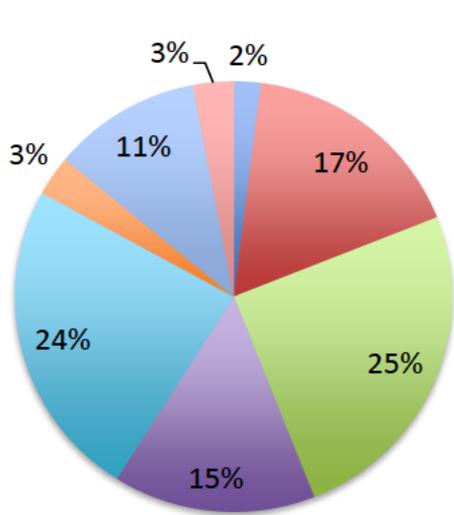
Females make up the majority. Those under 35 years old account for the largest share. Education levels fall in the high school/college range.



- Female
- Male



- 18-24 years old
- 25-29 years old
- 30-34 years old
- 35-39 years old
- 40-44 years old
- 45-49 years old



- Less than high school
- High school graduate
- Some college
- Completed 2 year college
- Completed 4 year college
- Some post-graduate
- Post-graduate degree
- Other technical school

EXHIBIT C

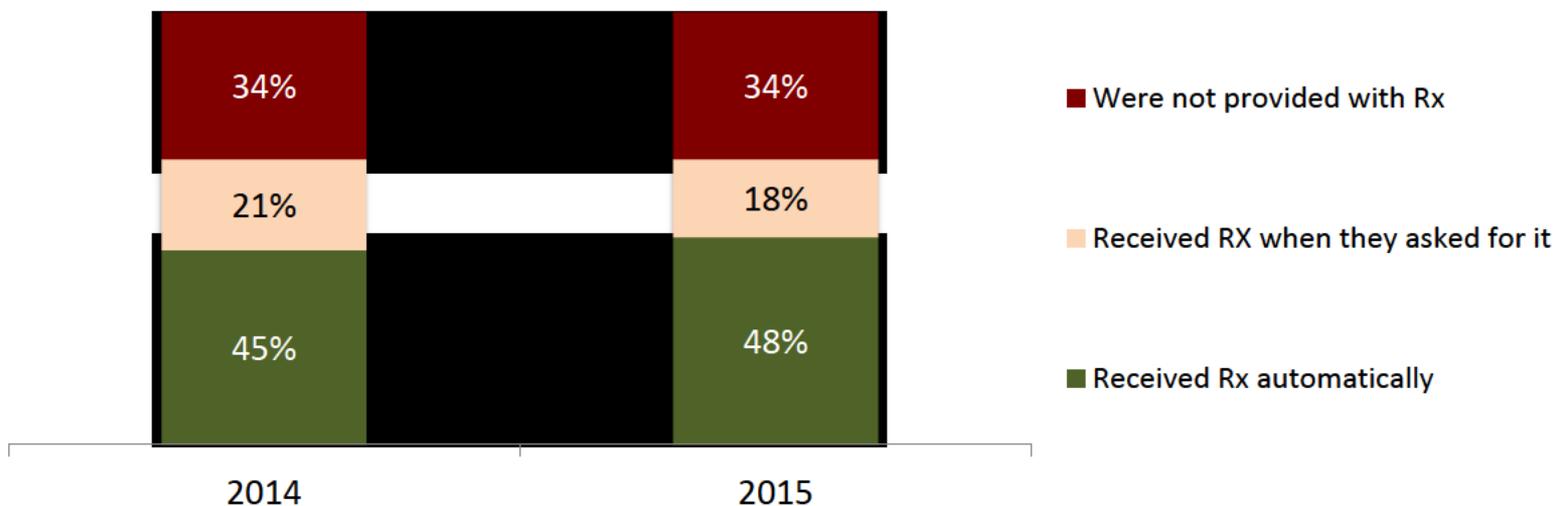
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Less than half of all lens wearers were automatically provided with an Rx at last exam

34% were not even given their prescription.

At your last eye exam, did the doctor provide you with a hard copy of your prescription?



Data collected November 2014 and May 2015 by Survey Sampling International from their independent online survey panel participants. N=2,000 US adult contact lens wearers, ages 18-49 for each study.

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Acknowledgement of Prescription Release

To be signed by patient following completion of contact lens fitting.

YOU HAVE RIGHTS AS A CONTACT LENS CONSUMER under the Fairness to Contact Lens Consumers Act (15 U.S.C. 7601 *et seq.*) and the Contact Lens Rule (16 CFR 315).

After completion of a contact lens fitting, your prescriber is required to automatically provide you with a copy of your contact lens prescription.

You do not have to ask.

You are free to use that prescription to purchase your lenses from the seller of your choice.

I confirm that after my contact lens fitting, my eye care practitioner provided me with a copy of my contact lens prescription.

I understand that I am free to purchase my contact lenses from any seller I choose.

Date of Completion of Contact Lens Fitting

Date of Prescription Release

Patient Name (Printed)

Patient Signature

Signed prescription release acknowledgements must be retained by prescriber for three years pursuant to the Contact Lens Rule 16 C.F.R. 215.3(c)(2).

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American Optometric Association

243 N. Lindbergh Blvd. • St. Louis, MO 63141 • (314) 991-4100

FAX: (314) 991-4101

FOR ACTION

**BULLETIN
FROM THE
OFFICE OF COUNSEL
BULLETIN NO. 5**

VOLUME NO. 65

August 29, 2006

DATE: August 29 , 2006

SUBJECT: Fairness to Contact Lens Consumers Act (FCLCA)

CONTACT: Elizabeth Ortmann-Vincenzo, Associate General Counsel

TO: AFFILIATE PRESIDENTS, PRESIDENTS-ELECT & STATE EXECUTIVE DIRECTORS

DIST: Officers, Trustees, Executive Directors, Center & Section Chairs, Center Directors, FRC, News Editor, R. Pieper, ILAMO, WO Library

BACKGROUND:

FCLCA requires that..."(w)hen a prescriber completes a contact lens fitting...the prescriber shall, as directed by any person designated to act on behalf of the patient, provide...the contact lens prescription by electronic or other means". This is different from a request for verification. This portion of the law requires that the prescriber actually provide a patient's agent with the actual written prescription. The patient's designated agent might be a family member, another doctor, or an online contact lens seller.

PROBLEM OR ISSUE TO BE ADDRESSED:

DOCTORS MUST PREPARE THEMSELVES TO RESPOND TO A NEW COMMUNICATION AND REQUEST FROM ONLINE CONTACT LENS SELLERS THAT HAS NOT BEEN

REPORTED BEFORE NOW. Online contact lens sellers are reportedly invoking this section of the FCLCA statute via faxes or other writing to ODS, requesting doctors to fax a copy of the prescription itself to the contact lens seller. A [sample of such a letter](#) is attached to this bulletin.

ACTION REQUIRED

1. If presented with such a request, doctors should immediately: a) send a request in writing to the contact lens seller requesting proof of agency in the form of a HIPAA- compliant signed document from the patient designating the seller as authorized to make the request on behalf of the patient, and b) contact the patient to inform them of the request in order to determine its validity; if agency is verified orally by the patient, ask for the patient to also send a signed document designating agency. (A sample of such a release is attached to this Bulletin.) Be sure to document whether the patient does or does not verify that he or she has designated the contact lens seller as authorized to obtain a copy of the prescription, rather than just authorized to verify the prescription information.
2. If and when agency is verified via a HIPAA compliant release, doctors should comply immediately by providing a written copy/fax of the prescription to the contact lens seller.
3. Doctors should also document all details of such communications and provide them to AOA, including a) copies of the letters, b) details of correspondence with the contact lens seller, and c) details of communications with the patients including whether a patient verifies agency. Please remember to fulfill all privacy/HIPAA obligations in doing so. Please contact Elizabeth Ortmann-Vincenzo at 314-983-4236 or caortmann-vincenzo@aoa.org if you have any questions about this matter.

ATTACHMENTS:

[1800 FCLCA Letter](#)

[Sample HIPAA Release](#)

_____, O.D.
[address]
[phone number]
[fax number]
[E Mail]
[office contact person]

AUTHORIZATION FOR RELEASE OF IDENTIFYING HEALTH INFORMATION

Patient name _____
Patient number _____
Patient address _____
Patient phone number _____

I authorize the professional office of my optometrist named above to release health information identifying me [including if applicable, information about HIV infection or AIDS, information about substance abuse treatment, and information about mental health services] under the following terms and conditions:

1. Detailed description of the information to be released:
2. To whom may the information be released [name(s) or class(es) of recipients]:
3. The purpose(s) for the release (if the authorization is initiated by the individual, it is permissible to state "at the request of the individual" as the purpose, if desired by the individual):
4. Expiration date or event relating to the individual or purpose for the release:

It is completely your decision whether or not to sign this authorization form. We cannot refuse to treat you if you choose not to sign this authorization.

If you sign this authorization, you can revoke it later. The only exception to your right to revoke is if we have already acted in reliance upon the authorization. If you want to revoke your authorization, send us a written or electronic note telling us that your authorization is revoked. Send this note to the office contact person listed at the top of this form.

When your health information is disclosed as provided in this authorization, the recipient often has no legal duty to protect its confidentiality. In many cases, the recipient may re-disclose the information as he/she wishes. Sometimes, state or federal law changes this possibility.

[For marketing authorizations, include, as applicable: We will receive direct or indirect remuneration from a third party for disclosing your identifiable health information in accordance with this authorization.]

I HAVE READ AND UNDERSTAND THIS FORM. I AM SIGNING IT VOLUNTARILY. I AUTHORIZE THE DISCLOSURE OF MY HEALTH INFORMATION AS DESCRIBED IN THIS FORM.

Dated _____ Patient signature _____

If you are signing as a personal representative of the patient, describe your relationship to the patient and the source of your authority to sign this form:

Relationship to Patient _____ Print Name _____
Source of Authority _____



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Division of Advertising Practices

October 4, 2006

Joe Zeidner, Esq.
1-800 Contacts, Inc.
66 East Wadsworth Park Drive
3rd Floor
Draper, Utah 84020

Dear Mr. Zeidner:

I am writing in response to your September 27, 2006 letter regarding 1-800 CONTACTS, Inc.'s ("1-800") recent practice of requesting that contact lens prescribers provide copies of patients' contact lens prescriptions. To provide further guidance concerning these requests, the Federal Trade Commission staff offers the following views.

As you are aware, the Fairness to Contact Lens Consumers Act ("FCLCA") and the Contact Lens Rule state that when a contact lens fitting has been completed, the prescriber "shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means." 15 U.S.C. § 7601(a)(2); 16 C.F.R. § 315.3(a)(2). Neither the FCLCA nor the Contact Lens Rule requires that sellers provide prescribers with written proof that they have been designated as the agents of consumers. *See* Contact Lens Rule, Statement of Basis and Purpose, 69 Fed. Reg. 40,482 at 40,493 (July 2, 2004). Thus, upon receiving a request from 1-800 as the agent of a consumer without any written proof of this agency relationship, the prescriber must provide 1-800 with a copy of the prescription or verify the prescription information.

At the time that they want to order contact lenses, some consumers have neither their prescription nor sufficient information about their prescription for 1-800 to prepare a proper verification request. In these circumstances, 1-800 cannot communicate a proper verification request to the prescriber, and therefore may ask that the prescriber provide a copy of the prescription. Upon receipt of a valid prescription from the prescriber, 1-800 can ship lenses to the consumer.

Your letter raises the concern that a prescriber may question whether a particular consumer in fact has designated 1-800 to act on his or her behalf. Specifically, your letter reports that a recent audit of 264 requests for a copy of a customer's prescription shows that 46% of prescribers did not respond within five business days. Your letter also reports that the American Optometric Association has advised its members to demand that 1-800 provide the written documentation that prescribers may typically require from others before releasing medical information under the Health Insurance Portability and Accountability Act ("HIPAA") of 1996 and its implementing

HIPAA Rule.

We do not believe that the FCLCA or the Contact Lens Rule permit the prescriber to impose the burden of this written authorization requirement on 1-800. If 1-800 is the agent of the consumer, then the prescriber has an obligation under the FCLCA and the Contact Lens Rule to provide the consumer's prescription to 1-800. The Commission has made clear that this disclosure is permitted without written authorization under HIPAA and the HIPAA Privacy Rule.¹ On the other hand, if 1-800 is not the agent of the consumer, then the prescriber has no obligation under the FCLCA and the Contact Lens Rule to provide the prescription at all.

In addition, we have discussed with you adopting changes in 1-800's practices that should reduce prescriber concerns related to the existence of an agency relationship between 1-800 and consumers. As a result of these discussions, 1-800 has made two changes in its practices. First, 1-800 has taken steps to clarify for consumers that they are designating 1-800 to act as their agents. In taking telephone orders, 1-800 has commenced disclosing, immediately after obtaining prescriber contact information, that it will act as the agent of consumers in seeking verification or a prescription from their prescriber. In taking on-line orders, 1-800 has begun disclosing, adjacent to the location on the order form for prescriber contact information, that it will act as the agent of consumers in seeking verification or a prescription from their prescriber. Second, 1-800 now includes the express statement that it is the consumer's agent in its letters to prescribers seeking copies of prescriptions.

These changes in 1-800's practices likely will eliminate many concerns as to the existence of an agency relationship. In the event that a prescriber who receives a letter from

¹ The Contact Lens Rule's Statement of Basis and Purpose ("SBP") noted that the HIPAA Privacy Rule permits a covered entity to use or disclose protected health information without patient authorization for treatment, and that providing, confirming, or correcting a prescription for contact lenses constitutes "treatment" under the HIPAA Privacy Rule. SBP at 40,501. In addition, the SBP notes that the HIPAA Privacy Rule allows covered entities to use or disclose protected health information without patient authorization if the use or disclosure is "required by law." *Id.* A disclosure of information required under the FCLCA and Contact Lens Rule is a disclosure required by law under the HIPAA Privacy Rule.

Joe Zeidner, Esq.
October 4, 2006
Page 3

1-800 requesting a consumer's prescription knows that 1-800 is not in fact the consumer's agent, the prescriber should inform 1-800 that he or she is refusing to provide it based on the absence of an agency relationship and submit to 1-800 its affirmative evidence that the seller is not the consumer's agent.² This information should serve as the basis for the prescriber and 1-800 to resolve between themselves the issue of agency with regard to a particular request. If these communications do not resolve the issue, prescribers and sellers, of course, can submit complaints and supporting information to the FTC.

We hope the foregoing is helpful to you. Please feel free to contact Thomas Pahl at (202) 326-2128 or Kial Young at (206) 220-6351 with any further questions or concerns regarding this matter.

Very truly yours,

Mary K. Engle
Associate Director

² The FCLCA and the Contact Lens Rule do not preclude prescribers from contacting their patients to inquire whether they have designated 1-800 as their agent. If the patients indicate orally that 1-800 is their agent, prescribers should not impose the unnecessary burden on their patients of completing an extensive written authorization form to confirm the agency relationship.