

July 29, 2019

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave, NW
Suite CC-5610 (Annex C0)
Washington, DC 20580

RE: Contact Lens Rule, 16 CFR part 315, Supplemental Notice of Proposed Rulemaking

The Information Technology and Innovation Foundation (ITIF) is writing with regard to the Federal Trade Commission's May 2, 2019 request for additional public comment about the newly proposed changes to the Agency's Contact Lens Rule. ITIF strongly supported the original proposed rule from 2018 as it would impose little burden on prescribers but would give patients stronger and more enforceable rights to exercise choice in their purchase of contact lenses while at the same time providing a means to better assess prescribers' compliance with the original Contact Lens Rule. In this filing we address a number of the specific questions the Commission has raised about proposed changes.

ITIF is Washington, DC-based a non-partisan think tank whose mission is to formulate and promote public policies to advance technological innovation and productivity. Recognizing the vital role of technology in ensuring prosperity, ITIF focuses on innovation, productivity, and digital economy issues. We have a long history of working on the issue of contact lens sales because we believe that consumers' ability to use innovative sales channels, like online sales, boosts consumer welfare and economic productivity.¹ As ITIF has written, the optometry profession has a long history of working to limit competition in the sales of contact lenses, and because of their "gatekeeper" role as prescribers, they have often been able to accomplish their common goals to stifle competition and limit consumer choice.

For over two decades, optometrists have lobbied for anticompetitive state laws and engaged in a continuing array of anticompetitive behaviors to make it more difficult for their customers to buy contact lens from other channels, including online and "big box" retailers. Unlike medical doctors who sell only their services (examining, diagnosing, and treating patients), optometrists sell both their services (eye exams) and the products they prescribe: contact lenses. It is against the law for consumers to buy lenses without a

1. For example, see Robert D. Atkinson, *Public Versus Private Restraints on the Online Distribution of Contact Lenses: A Distinction Without a Difference* (Washington: ITIF, 2006) and Senate Committee on Judiciary, Subcommittee on Antitrust, Competition, Policy and Consumer Rights, *Why UPP Pricing in the Contact Lens Industry Hurts Consumers and Competition*, July 31, 2014. 113th Cong. (testimony of Robert D. Atkinson, President and Found of Information Technology and Innovation Foundation, http://www2.itif.org/2014-senate-contact-lens.pdf?_ga=1.72515347.1831456108.1435966265).

prescription. And so the profession has both a powerful economic interest (profits) and a powerful tool (the prescription) to make it more difficult for consumers to buy their lenses from lower-cost providers, such as online contact lens companies or big-box retailers.

The optometry industry has long used its unique gatekeeper power to limit patients' ability to buy lenses outside of its cartel. With the advent of disposable lenses in the 1980s and then the emergence of online contact lens sellers in the mid-1990s, it became easy for patients to shop around for the best prices. But faced with this threat, the trade association for optometrists, the American Optometrist Association (AOA), fought back.

According to a complaint filed in 1994 by 32 state attorneys general, the AOA leveraged optometrists' hold on prescriptions to pressure lens manufacturers into distributing only to licensed optometrists, not to alternative providers. The threat was clear: If manufacturers didn't play ball on optometrists' terms, then optometrists would starve the manufacturers of business by refusing to prescribe their brands. After six years of litigation, the AOA in 2001 settled with the state attorneys general and the class of consumers they represented, agreeing to pay a fine for the alleged antitrust activity and pledging to refrain from such activity in the future. But meanwhile, through their state professional associations, optometrists were pressuring state legislatures to block legislation that would require optometrists to give prescriptions to patients to fill wherever they choose. Under this pressure campaign, only 22 states were requiring optometrists to give prescriptions to patients as of 2002.

Attempting to rectify this, Congress in 2003 passed the Fairness to Contact Lens Consumers Act (FCLCA), which, among other things, gave patients the same rights when it comes to contact lenses that they have had with eyeglasses since 1979—the freedom to fill eye prescriptions anywhere they choose. But after this law made it easier for consumers to buy lenses from other distribution channels, optometrists fought back again with further restrictive practices, this time by prescribing so-called “doctor only” lenses—limited-distribution brands of lenses that are available only through eye-care professionals. This practice once again drew the ire of state attorneys general, 36 of whom banded together in 2006 to urge Congress to outlaw it.

That was not the end of the story, however. After the “doctor only” avenue of restricting competition was foreclosed, optometrists pressured most contact lens producers to adopt “unilateral pricing policies”—an arrangement in which optometrists agree to prescribe only lenses from manufacturers that impose retail price maintenance schemes, so that other providers such as big-box retailers and online sellers would have no way to compete on price. And today the industry is lobbying heavily in state capitals across the nation to ban or significantly limit the ability of patients to have their eyes examined remotely through online tools.

Finally, there appears to be evidence that many prescribers ignore their obligation to provide patients with their prescriptions in order to increase the likelihood that they will be the one making the sale. For example, a 2008 article from *Contact Lens Spectrum* found that their reader survey of optometrists “indicates that

despite this federal legislation [FCLCA] only half of the respondents replied ‘yes to every patient’ when asked if they release contact lens prescriptions.”² A 2015 survey commissioned by 1-800 Contacts and conducted by Survey Sampling International found that just 35 percent of patients were automatically given a hard copy of their prescriptions on their day of their office visit. Moreover, the same survey found that 82 percent of eye care professionals presented purchasing options to their patients before providing the prescriptions. Given that the contact lens rule (CLR) requires that upon completion of a fitting, a patient is to be provided a copy of their prescription automatically, this lax performance of eye care professionals is disturbing.

Moreover, professionals in the industry, as well as their representatives, argue that as professionals they have the best interests of the patient at heart. The lion’s share of professionals likely believe they do. But most likely believe that there is no conflict between their own interests (e.g., selling their patients contact lenses and their patient interests (getting the best price on the right lens). This is why simply relying on existing market forces and industry professional norms to advance the intent and purpose of the FCLCA and the CLR does not work because prescribers have both an incentive and ability to limit consumer choice.

There is one other key factor why federal rules to enable consumer choice and competition are in the interests of consumers. Some industries are able to benefit from economies of scale, thereby benefiting consumers with higher productivity and lower prices. The optometry industry is not one of those industries, which is why, according to the U.S. Census Bureau, in 2016 there were almost 22,000 optometry establishments in the United States, averaging 6 employees per establishment. Because it is a local serving industry where offices are located near to where people live and work it makes no economic sense to have much larger offices. In contrast, the sale of contact lenses knows no such limits. Big box stores as well as online sellers can and do attain scale economies and efficiencies in the sale of contact lenses, bringing needed productivity gains to the U.S. economy as well as lower prices and more convenience to contact lens wearers.

It is in this context of a long set of industry practices to deny consumers the benefit of choice and competition and the benefits that large-scale sellers bring that the FTC is rightly proposing new rules governing contact lens prescription release.

Question A:2 What costs or burdens would a proposed change impose and on whom?

When optometrists complain that these rules would be burdensome it is important to remember that these rules would not be necessary if optometrists were complying the letter and spirit of the FCLCA. But it is not, as the Commission clearly showed in its Federal Register Notice, and there is no evidence that the industry will not stop resisting the intent of the law.

2. Carla J. Mack, “Annual Report, Contact Lenses 2007,” *Contacts Lens Spectrum*, January 1, 2008 <http://www.clspectrum.com/articleviewer.aspx?articleID=101240>.

Moreover, the evidence provided by optometrists that these rules would increase their costs appears to be significantly overstated. For example, the Commission cites training as a potential cost, but then rightly notes that “only 44% of optometrists said additional training would be necessary.” But we are not talking about their employees going to a 3-week course on how to administer the new rules. A few minutes of instruction, coupled with reading a one- or two-page memo should more than suffice. Likewise, the notion that the three-year record hold requirement imposes a burden has no grounding in logic or fact. As noted below if the form is electronic (e.g., a doctor provides the patient with a kiosk or tablet to sign their consent) the storage costs are essentially zero. Even if a prescriber has not modernized and still uses paper, storing these forms takes up very little room and cost. They are simply attached the patient’s paper folder.

Moreover, as the Commission rightly pointed out the new rules would likely reduce overall compliance burden because it would result in more automatic approval of third-party prescriptions.

Question B: Electronic Delivery of Prescriptions

This section asks several questions.

3) Would a patient portal, email or text message be feasible methods for prescribers to provide digital copies of their prescriptions to patients?

Virtually any asynchronous electronic form of communication can effectively provide patients with their prescriptions. One additional form is to use third party, cloud-based e-prescribing applications that would easily let doctors prescribe lenses, patients to fulfill them, and third-party sellers to easily verify.

4) Should prescribers be required to keep any records documenting a patient’s verifiable affirmative consent to receive the prescription electronically?

If the record is in electronic form the minimum period should be at least five years, but there is no economic reason not to require a much longer term as the marginal cost of keeping electronic records like this stored is virtually zero given the incredibly low costs of data storage and the very small size (in bits) of a consent form.

Question C-1 (and C-3): Would the proposed Confirmation of Prescription Release provision increase, decrease or have no effect on compliance with the Rule’s requirement that patients receive their contact lens prescription after the contact lens fitting?

The answer is most assuredly that it would increase compliance. If prescribers must have patients affirmatively acknowledge that they can get a copy of their own prescriptions and fill them where they would like, and if prescribers must store this information with the knowledge that they could be audited, patients will be more aware of their choices (and more empowered to fill the prescription with a third party) and prescribers will be more likely to let patients know they have a choice.

A requirement to prescribers to maintain evidence of confirmation of prescription release for three years would increase compliance because they know that they might be audited, and it would better enable the Commission to audit prescribers because there would be clear records to review.

Question C-9: Does the new proposal to allow prescribers to satisfy the Confirmation of Prescription Release requirement by (when expressly consented to by the patient) releasing a digital copy of the prescription to the patient, such as via online portal, electronic mail, or text message increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

In general, digital release would increase compliance, in part because these are easy-to-use methods that automatically store digital copies for later compliance. However, it is important that any rule allowing a doctor to prescribe a lens in a portal also require an affirmative message (e.g., a text message) to the patient at the time of prescription that the prescription is in the portal. Otherwise, doctors may use portals as a way to make it less likely for patients to know that they have received their prescription so they will fill it with their local optometrist.

Question C-11: Does the new proposal to allow prescribers to choose from different delivery methods and devise their own language for the Confirmation of Prescription Release increase, decrease, or have no effect on the burden placed on prescribers? Why?

This change would reduce the already small burden but on prescribers because if more optometrists embraced electronic health records, including portals, they would reduce their administrative costs and also reduce the number of calls third party lens sellers have to make to verify prescriptions. The federal Office of the National Coordinator for Health Information Technology (ONC) clearly shows that medical practices benefit economically, including reduction of labor inputs in practices, from the adoption of electronic patient health records.³ And of relevance to optometry, studies have shown that even in small medical practices the payback period for adopting electronic health records systems (which include electronic prescriptions) is very strong (less than 2.5 years payback).⁴ An article in *Optometric Management* makes the same point, finding, even several years ago when systems and technology were more expensive, that paybacks are less than 3 years.⁵ So,

3. "Medical Practice Efficiencies & Cost Savings," HealthIT.gov, <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/medical-practice-efficiencies-cost-savings>.

4. Robert H. Miller et al., "The Value of Electronic Health Records In Solo Or Small Group Practices," *Health Affairs*, vol. 24, no. 5, (September – March 2005), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.24.5.1127>.

5. Scot Morris, "EMR The Real Costs," *Optometric Management*, July 1, 2007, <https://www.optometricmanagement.com/issues/2007/july-2007/emr-the-real-costs>.

to the extent that optometrists can comply using electronic delivery as part of overall electronic health record system, they will benefit economically and consumers will benefit from more convenience and choice.

Question C-12. If prescribers choose to comply with the Confirmation of Prescription Release provision by providing a digital copy of the prescription (if the patient gives verifiable affirmative consent), what costs or burdens are associated with retaining evidence that the prescription was sent, received, or made accessible, downloadable, and printable?

The costs are essentially zero. As consumers, many of us enjoy significant amounts of free cloud-based data storage through our email systems or smart phone operating systems. This is because the cost of digital storage is now incredibly cheap. It costs just 5 cents to store 1 gigabyte of digital information, and a 1 gigabyte drive can hold 542 copies of *War and Peace*.⁶ So the costs to optometrists is insignificant.

Question C-15: What other factors should the Commission consider to lower the cost and improve the reliability of executing, storing and retrieving Confirmations of Prescription Release?

One challenge patients face is that many do not know that they have the legal right to request their prescription and have it filled at a third-party seller. One step that would help with this would be to mandate that all lens manufacturers print clear and easy to understand labels on contact lens boxes and interior materials stating something like “As a contact lens consumer you have the right to fulfill your prescription with any legally authorized seller of contact lenses.” While this particular FTC order may not be able to include this, the FTC should consider a requirement like this in the future.

Question C-21: How do contact lens manufacturers compete for consumers businesses?

Contact lens manufacturers find themselves in a difficult situation because they are dependent on a profession to allow consumers to buy their product. And unlike the pharmaceutical industry where doctors cannot sell the drugs they prescribe, optometrists also sell the product, not just prescribe it. So, they have the ability to favor or shun particular manufacturers. The major contact lens manufacturers are well aware of this ability by optometrist gatekeepers and so historically they have competed in ways to limit consumer choice so that eye care professionals will prescribe their product.

We saw this clearly in with the evolution of “doctors only” lenses—lenses that could not be purchased elsewhere even with a prescription. After the passage in 2003 of Fairness to Contact Lens Consumers Act, optometrists fought back with further restrictive practices, in this case prescribing “doctors only” lenses. These private label lenses made it almost impossible for consumers to buy their lens from third parties. So, any lens

6. Andy Klein, “Hard Drive Cost Per Gigabyte,” *BACKBLAZE*, July 11, 2017, <https://www.backblaze.com/blog/hard-drive-cost-per-gigabyte/>.

manufacturer that did not go along and sell private label lenses knew that many prescribers would favor their competitors' lenses who went along with this practice. Because of these restrictive practices the American Optometric Association, was sued by 32 state attorneys general and ultimately paid a fine and agreed to not collude with manufacturers, and to cease making unsubstantiated claims that one's health is impacted by where one's lenses are purchased. But in this settlement with AOA and a number of contact lens manufacturers, at least one major provider was not included, CooperVision/OSI. As a result, optometrists made it known that if CooperVision/OSI sold "doctors only" lenses that they would prescribe these lenses instead of a competitor's. The "doctors only" contact lens marketing practice was designed to shield prescribers from competition, making the lenses more expensive and more difficult to obtain.

We saw a similar dynamic in the push by contact lens manufacturers to support "unilateral pricing policy" (UPP)—essentially resale price maintenance policies. The best way to understand UPP policy is by looking at game theory and in particular the prisoner's dilemma game. The prisoner's dilemma is a type of non-zero-sum game in which two players try to get rewards from a jailer by cooperating with or betraying the other player. In the prisoner's dilemma, an individual has a strong incentive to defect (i.e., to claim that they are innocent, and their partner is guilty), so that the only possible equilibrium for the game is for all players to defect. Contact lens manufacturers are in their own prisoner's dilemma. Like prisoners in the game, their optimal strategy is to cooperate and sell all their lenses without UPP. Such an agreement would benefit the industry because contact lens wearers would pay lower prices and therefore replace their lenses more often, leading to higher industry sales. If both consumers and the manufacturers would benefit from widely distributed lenses, why did many contact lens manufacturers announce UPP policies? The answer is that like a prisoner ratting on his fellow prisoners so he can get off, each individual lens producer can gain market share over other manufacturers by selling UPP lenses. Optometrists will be more likely to sell UPP lenses because they will know that their customer cannot find a better price by going online or to a big box distributor. By selling UPP lenses that virtually guarantee patient lock in, contact lens producers knows that optometrists are much more likely to prescribe their company's lenses. Unfortunately, what makes economic sense for an individual company, just as what makes economic sense for the individual prisoner in the prisoner's dilemma game, produces a suboptimal result for both the entire industry and for consumers.

But how do optometrists convey this desire to prescribe UPP lens to producers or to engage in other kinds of company favoritism? The answer is in large part through professional norms. As Dean Harvey writes in a *California Law Journal* article entitled "Anticompetitive Social Norms as Antitrust Violations," "Robust, anti-competitive, price fixing social norms may flourish in a market structure of low entry barriers and very low

concentration levels.”⁷ In the case of the eye care industry, the collusion may not be in a smoke-filled room, but it’s collusion all the same.

In the optometry profession, these anticompetitive social norms are expressed in a variety of means, particularly in articles in professional journals and on social media channels that send a clear message to optometrists that they should prescribe doctors ‘-only lenses. For example, in an article in *Review of Cornea and Contact Lens* Gary Gerber, OD, writes:

One of the biggest benefits to practitioners of UPP is that it instantly creates a perfectly level playing field; volume discounts for large practices and online retailers go away. While this may create friction with buying groups, the benefits outweigh any ancillary issues. More importantly, however, it forces practices to focus on something other than price to keep prescriptions in their office—if all ‘retailers’ sell the lenses for the same price, the method and environment under which they are sold will be the factors that determine where a patient decides to purchase their lenses.⁸

He goes to in essence to say, with UPP, optometrists will prescribe the UPP lens:

Manufacturers also benefit from UPP because retail price erosion can be stopped. With a race to the bottom from aggressive price cutting eliminated, motivations to fit a particular lens increase; this has the ability to support and protect brand equity... All things being clinically equal (which of course they rarely are), savvy practitioners will give serious thought to prescribing UPP lenses. For example, if you have a patient with astigmatism and they can wear a UPP lens, and a non-UPP lens is clinically equivalent, a smart doctor will choose the UPP option.⁹

He concludes by stating what is obvious to everyone in the industry, “Finally, the actual price mandated by UPP has so far been higher than lenses that do not have a UPP. This has afforded higher profit margins and created a new sense of excitement surrounding contact lenses.”¹⁰ Likewise, in an article in *Review of Optometric Business*, Paul Kopeck, OD, FAAO wrote in favor of UPP, stating “One other exciting

7. Dean Harvey, “Anticompetitive Social Norms as Antitrust Violations,” *California Law Review*, vol. 94, no. 3, (May 2006): 79-791, <https://www.jstor.org/stable/20439048>.

8. Gary Gerber, “What’s UPP, Doc?,” *Review of Cornea & Contact Lenses*, June 15, 2014, http://www.reviewofcontactlenses.com/content/d/practice_management/c/48867/.

9. Ibid

10. Ibid.

development: Independent practice optometry becomes reinvigorated with contact lens prescribing as a profitable specialty and practice differentiator.”¹¹

We see similar statements on optometrist social media sites. On the Facebook site “ODs on Facebook”, a post from a person listed as Steve Silberberg (who lists himself as “ODwire.org supporting member”) on the topic “J&J goes to universal pricing” writes with regard to having to give “No more rebates etc. and 1-800 etc. goes away if they all follow B&L Alcon and now J&J. Cooper next.” In other words, he is saying with UPPs competitors like 1-800 Contacts that sell for less will go out of business. And he is not so subtly encouraging CooperVision to also use UPP pricing. Another ODwire.org supporting member listed as Stephen McDaniel writes in response to J&J adopting UPP pricing, “Wow, great news. Now I might actually fit more of their lenses. Hopefully Cooper gets on board with this soon.” In other words, he is saying that he prescribes lenses based on what level of profit he makes. And he is implying that if CooperVision doesn’t also adopt UPP then he will not prescribe their lenses. Another member, listed as Joe DiGiorgio, OD, writes in response to a question of how to tell your patients that these prices of industry regulated lens: “I think I’ll tell my patients that the onliner must have been selling counterfeit contacts. Why else would they suddenly raise their prices to what I’m selling them.” And they express this collective desire in meetings with industry representatives. For example, in the Facebook OD site, a person listed as Kerry Kordet Giedd, writes, “At the Ultra launch last week with 300+ ODs from around the country present there was a Huge applause (honestly, it was quite an overwhelming response) when B&L (Bausch and Lomb) announced the UPP. Without a doubt they were largely pleasing their OD base when they followed Alcon’s lead on the UPP.... I think B&L will gain far more than they lose in practitioner loyalty and support of this policy.”

In other words, manufacturers know that they are dependent on the good will of the profession and that if they do not enlist on the side of the optometrists for both commercial practices and political support or opposition of particular laws and regulations governing the profession that prescribers can and will favor their more compliant competitors.

Questions D1 and D2: Should the Commission require prescribers respond to such requests within a certain period of time? Would forty business hours... be an appropriate amount of time to respond to a request for an additional copy of the prescription?

Unless the Commission requires prescribers to respond to requests within a certain period of time, history has shown that a not insignificant number will simply not respond at all. Forty business hours is more than enough for prescribers to respond.

11. Paul Karpecki, “Unilateral Contact Lens Pricing: How it Works for the Good of Optometry,” *Review of Optometric Business*, June 18, 2014, <http://www.reviewob.com/unilateral-contact-lens-pricing-how-itworks-for-the-good-of-optometry.aspx>.

Question E3: Automated Telephone Verification Messages: When using an automated message for a verification request, what are the costs and burdens to sellers of meeting each of the proposed requirements, especially recording the entire call and making the message repeatable at the prescriber's option?

Automated phone verification lowers costs and minimizes errors, both of which mean that sellers can keep prices lower. Moreover, optometrists have avoided prescription verification by hanging up on live calls. The proposed provisions for clarity, replay and identification of the seller are reasonable proposals which will help ensure compliance. However, requiring the entire outbound call to be recorded is more problematic. First, most sellers use the exact same recording script for every call, varying it only by patient name and lens information. Recording tens of thousands of the same call would be redundant. Moreover, some states have laws requiring consent of both parties to record the call in these states prescribers could deny that permission and simply hang up on the call. Also this would impose a higher standard on automated calls than on live calls. If there are sellers that are abusing automated calling the FTC should investigate and prosecute if warranted. Indeed, if optometrists believe that some sellers are abusing the letter or intent of the rule, they can record calls themselves and submit these recordings to the FTC for enforcement action. Finally, if the concern that is motivating the recording requirement is brand switching, making sellers record calls will not help with this. Rather, targeted enforcement would.

ITIF thanks the Commission for its consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Robert D. Atkinson". The signature is written in a cursive, flowing style.

Dr. Robert D. Atkinson
President, Information Technology and Innovation Foundation