

Bona Law PC

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Office of the Secretary
600 Pennsylvania Avenue NW.
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RE: Contact Lens Rule, 16 CFR part 315, Project No. R511995
LD VISION GROUP Comment on FTC Contact Lens Rule

INTRODUCTION

Contact lenses are a necessity for millions of Americans. Yet prices are sky-high because prescriber-gatekeepers make it hard for consumers to access alternative channels of distribution.

This comment first explains LD Vision Group's role in the market for replacement contact lenses and summarizes the Fairness to Contact Lens Consumers Act and the Contact Lens Rule. It then addresses the conflict of eye-care providers and the manner in which prescribers thwart independent retail sales based on LD Vision Group's experiences in attempting verification. Finally, it explains how manufacturers are complicit in prescriber attempts to recapture the sale and how the FTC's vigilance is demanded in addressing these issues because of the unique anticompetitive conditions of the replacement contact-lens market.

ABOUT LD VISION GROUP

LD Vision Group, Inc. is a rapidly growing direct marketer of replacement contact lenses that operates websites such as OptiContacts.com and LensDiscounters.com. LD Vision sells substantially all of the most popular brands of contact lenses, including those produced by the four dominant contact-lens manufactures: Johnson & Johnson (Acuvue), Alcon Laboratories, Bausch & Lomb, and CooperVision. The company's proprietary high-volume, low-margin business model provides contact-lens wearers with the most competitive price while maintaining high-quality customer service that attracts and retains price-sensitive consumers.

LD Vision is one of the largest contact-lens retailers in the nation: over one-million users have ordered replacement contact lenses from LD Vision's websites, enjoying prices as much as 30% to 50% less than other leading internet retailers and 75% less than independent optometrists. Its prices are consistently lower than any other online retailer, the big-box stores, and wholesale clubs.

THE FAIRNESS TO CONTACT LENS CONSUMERS ACT AND THE CONTACT LENS RULE

Congress passed the Fairness to Contact Lens Consumers Act in 2003 to create an open market where contact-lens consumers have the freedom to choose where to purchase their contact lenses. The FTC promulgated the Contact Lens Rule, 16 C.F.R. Part 315, to implement the FCLCA.

The FCLCA requires prescribers to provide patients a copy of their prescriptions and requires them to verify those prescriptions for retailers. It prohibits prescribers from conditioning the release of the prescription on the purchase of contact lenses, other

payments, or on signing a waiver.

The scheme also prohibits retailers from selling contact lenses to consumers without a prescription. Sellers must either receive a valid, non-expired prescription or verify the prescription by direct communication with the prescriber. Prescribers, in turn, must verify the prescription within eight business hours.

THE CONFLICT OF EYE-CARE PROVIDERS

The contact lens industry is unique. Its history is distinctively anticompetitive because of the role that eye-care providers play in the market—both doctor and pharmacist. Contact lens prescriptions are brand-specific, placing prescribers in an unusual gatekeeping role: eye-care providers—rather than their patients—decide what brands to prescribe, and their patients must live with that choice. That wouldn't be a problem, except eye-care providers also sell the products they prescribe. All else being equal, they will each prescribe the brands that maximize their profits.

Eye-care providers started selling lenses before they were a disposable commodity capable of an independent retail sale. They've fought to hold onto their profits ever since. Without anticompetitive advantages, prescribers cannot effectively compete with high-volume, low-margin retailers that offer the convenience of shipping to the consumer's door. They are inefficient distributors who remain in the contact-lens retail business simply because they combine the prescription service with the retail product—the equivalent of a doctor also serving as a pharmacist. Their business models are based on captivity rather than volume, price, or quality.

We should all respect the important role of the eye-care provider in eye health—and they have done a commendable job with it. But they would fail as retailers of replacement lenses in a free market where they could not use that position to capture sales. Fairness to contact lens consumers requires that free market.

Eye health for contact-lens users depends upon affordable, readily available replacement lenses. Unfortunately, some prescribers put retail profits ahead of their patients' health by making it difficult for those patients to access affordable lenses through alternative channels of distribution, where fierce competition results in the lowest possible prices anywhere. The current verification system under the Contact Lens Rule contributes to this problem by leaving too many opportunities for prescribers to thwart the patient's attempt to purchase her lenses from an independent seller, leading to delays for replacement lenses and rising costs for users.

Indeed, a rising number of contact lens users over-wear their contact lenses, which can cause light sensitivity, blurred vision and eye pain in the short term and very serious eye and visual problems—including conditions that cause blindness—in the

long term.¹ Even the slightest deviation from a replacement schedule can damage the eyes.² It is thus important that the FTC consider amending the Contact Lens Rule to make it more difficult for prescribers to attempt to thwart independent sales that ensure consumers have the contact lenses they need, when they need them, and at the best price the market offers.

Passive Verification Allows Prescribers to Re-Capture the Sale

Though the Fairness to Contact Lens Consumers Act's mandatory prescription release provision has greatly improved the freedom of consumers to purchase contact lenses through non-prescriber channels of distribution at the lowest prices on the market, the passive verification system under the Contact Lens Rule leaves plenty of room for prescribers to thwart and attempt to re-capture a non-prescriber retailer sale.

Notwithstanding the Contact Lens Rule, some prescribers go so far as to render a prescription incomplete by one of the following, forcing an unnecessary verification to occur:

- Omitting a signature from the prescription
- Omitting the date of the prescription
- Including incomplete or not readily identifiable contact-lens parameters
- Including complete parameters but for a non-existent combination
- Writing in code or unidentifiable short-form (e.g., AOA, which could mean Acuvue Oasys for Astigmatism or Air Optix for Astigmatism) and/or omitting the base curve
- Omitting the brand altogether

Some prescribers will still refuse to verify even with the law in place, stating (incorrectly) that HIPAA or a state privacy rule prohibits release of the prescription and that only the patient can ask for it. Other prescribers will respond with extreme brevity denying verification with statements such as “not a patient,” “do not fill,” “no CL rx,” or “incorrect.” A retailer either must seek clarification or lose the sale. Oftentimes, the actual reasons behind these incomplete responses are:

- Not a patient: not a current contact-lens patient, but had a regular eye exam for health/glasses.
- Do not fill: could be expired, could be that the prescriber requires a follow-up for finalization (often to capture a “fitting fee”), or other various reasons, whether valid or invalid.

¹ See *Contact Lens Overuse and How to Avoid It*, available at <http://www.eyecarelawrence.com/whats->

² *Id.*

- Incorrect: could mean that the prescription contains incorrect information not necessary to the prescription or that the prescription is incorrect, but does not include correcting information.
- No CL rx: the patient had an eye exam and received trial lenses, but did not return for a prescriber-imposed follow-up.³

With these responses, a retailer must often tell the customer that it doesn't have complete or accurate information, that the doctor didn't have the prescription, or that it was not verified. The retailer loses the sale when this occurs. Prospective customers assume the retailer must be incompetent because they couldn't find or verify a prescription that the customer knows is valid.

The verification requirement is not about ensuring accurate prescriptions, but rather to ensure regular eye-health examinations.⁴ Patients, rather than prescribers or competition authorities, should ultimately have the freedom to make decisions regarding their eye health. That is, a patient should be *advised* to seek regular eye care, but they should not be *forced* to do so by regulations promulgated by a federal competition authority.⁵ Moreover, documented prescriber abuses of the verification system warrant modifications that empower patients, ensure lower prices, and ultimately reduce patients' lens over-use.⁶

Solutions:

Amend 16 C.F.R. § 315.5(d) to deem any inadequate, incomplete communication by a prescriber as a failure to communicate under § 315.5(c)(3).

³ These fittings are unnecessary for eye health, and different levels of providers (optometrists, ophthalmologists, and opticians) have varying procedures that may not even incorporate them. According to the Vision Council of America, comprehensive eye exams are the best way to ensure healthy vision. Many eye conditions and visual impairments have early warning signs that an eye-health exam will diagnose. Follow-up fittings and training sessions, however, are not necessary and should not invalidate a prescription.

⁴ Federal Trade Commission, *Possible Anticompetitive Barriers to eCommerce: Contact Lenses*, at 11–12 (Mar. 2004) (“Consumers are generally unlikely to ‘self-prescribe’ vision-correcting contact lenses. . . . [Rather,] the medical purpose of the prescription requirement . . . is to induce the customer to have regular eye exams. . . .”)

⁵ British Columbia recently abolished a prescription requirement for replacement contact lenses because “there is no medical evidence to suggest the changes could impact people’s health.” CBC News, *B.C. Changes eyewear regulations*, Apr. 23, 2010, <http://www.cbc.ca/news/canada/british-columbia/b-c-changes-eyewear-regulations-1.904446>. Removing and relaxing regulations with anticompetitive consequences, such as the verification system, can “generate substantial reductions in spending on care without substantial reductions in quality of care.” OECD Competition Committee, *Enhancing Beneficial Competition in the Health Professions* (Dec. 16, 20115), available at <http://www.oecd.org/regreform/sectors/35910986.pdf>.

⁶ OECD, *supra* note 5, at 11–12.

And

Amend 16 C.F.R. § 315.3(b) to prohibit a prescriber from requiring more than an eye-health examination for a contact-lens prescription renewal unless the prescriber determines that additional evaluation is necessary to the ocular health of a particular patient.

And

Create an online reporting mechanism for sellers and consumers to report unfair prescriber practices in violation of the Contact Lens Rule. Prescribers that abuse the verification process should be prosecuted for Unfair Trade Practices in accordance with the Fairness to Contact Lens Consumers Act and the Federal Trade Commission Act.

And

Allow any patient to waive the verification requirement by confirming with the seller that they (a) are aware of the risks associated with the improper use of contact lenses and (b) are aware that it is recommended that a patient receive an eye-health examination every year.

Though prescribers must have a medical reason to prescribe contact lenses with an expiration date with less than one year, they are not similarly prohibited from limiting the quantity of replacement lenses authorized under the prescription. Some prescribers do, in fact, limit the quantity of replacement lenses, despite the lack of any medical reason for ever doing so—a consumer’s need for additional lenses could arise for a number of reasons. Other prescribers will fill expired prescriptions at their office, but will not renew a prescription for use elsewhere without a payment or a re-fitting on top of their eye-health examination.

Solution:

Amend 16 C.F.R. § 315.6 to include a provision stating that “A contact lens prescription shall be valid for an unlimited quantity of lenses regardless of any prescriber-imposed limitation to the contrary.”

MANUFACTURER/PRESCRIBER STRATEGIES DESIGNED TO THWART CONSUMER FREEDOM

The unique power of prescriber-retailers in the contact lens industry makes them a dominant group of retailers for reasons other than established competitive virtues. That all of the major manufacturers of contact lenses have acquiesced to these strategies—strategies which make no economic sense for the manufacturers but for the prescribers’ gatekeeping role—should raise significant anticompetitive concerns at the FTC.

Private Label Lenses

Some prescribers will prescribe unpopular or private-label lenses without published equivalents or for which the equivalents are confusing. In addition to the current requirements for prescribers, manufacturers should be required to provide retailers with brand equivalency information.

One private label, for example, is purportedly available with an 8.3 or 8.6 base curve, while the brand-name lens—though it is the exact same lens—is purportedly available with an 8.4 or 8.7 base curve. An outside retailer may not figure this out or, if they do figure it out, must list “8.3/8.4” and “8.6/8.7.” Either way, the customer may believe the retailer does not have the proper lens in stock. She may be confused or think the dual listing is a different prescription than hers. She might inquire with the retailer—making the sale much less convenient for her—or simply decide to purchase them from the prescriber because they will know what lenses match a prescription they wrote. This is what the prescriber hopes for in using this tactic.

One manufacturer offers four different lenses under a private label: standard, plus, premium, and premium plus, but the national-label equivalents do not use the same identifiers. The difference between plus and premium plus, for example, is that one is a two-week and one is a four-week lens. The Act allows retailers to dispense national-brand equivalents of private labels and requires prescribers to list equivalent information. Prescribers do not always comply with this requirement (or may not know). Without manufacturer-confirmed equivalents, the retailer must either refuse to dispense unknown equivalents or make assumptions based on intentionally misleading private-label designations and risk dispensing the wrong lenses to the potential detriment of their customers’ eye health.

Solutions:

Amend 16 C.F.R. Part 315 to require prescribers to annotate a private-label lens prescription with the brand-name equivalent. If a name-brand equivalent is unavailable, the private-label prescription must be medically necessary for that particular patient.

And

Amend 16 C.F.R. Part 315 to require manufacturers of contact lenses to make brand equivalency information available to all sellers.

Or

Amend 16 C.F.R. Part 315 to require manufacturers to make brand equivalency information available on private-label and brand-label packaging.

Vertical Price Restraints

The major contact-lens manufacturers have undertaken a significant effort to enforce pricing policies against retailers whose volume and cost efficiencies have made contact lenses more affordable for the millions of Americans who need them. Vertical price restraints occur in the contact lens industry because prescribers collectively wield the unique unilateral power to control interbrand competition through their prescription authority. Contact lens prescriptions are manufacturer-specific, and therefore it is the prescriber—rather than the end-user consumer—for whom manufacturers must compete to win over. All else being equal, prescribers will prescribe those brands of lenses that yield them the most profit—brands for which they are least likely to lose the sale to high-volume, low-cost retailers like LD Vision Group.

Though the U.S. Supreme Court recently held that resale price maintenance can, under certain circumstances, have procompetitive benefits, it also warned that “vertical price restraints might be used to organize cartels at the retailer level.” *See Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 893 (2007). This is particularly true in the contact lens industry, where powerful retailers (prescribers) use their clout to prevent “[r]etailers with better distribution systems and lower cost structures . . . from charging lower prices by the agreement.” *Id.*

Though resale price maintenance has more impact on the contact-lens industry than many other industries, the Fairness to Contact Lens Consumers Act and the Contact Lens Rule do not directly address it. But the anticompetitive structure that led to these unjustifiable price restrictions in the market for replacement contact lenses demands vigilance in implementing the Fairness to Contact Lens Consumers Act. The revisions to the Contact Lens Rule discussed in this comment are a step toward softening the anticompetitive effects of the special gatekeeping role of prescribers that is responsible for the sky-high prices for millions of Americans whose vision depends upon contact lenses.

The verification system currently in place may force consumers to get regular eye exams necessary for preventative ocular health. But verification, along with high prices, only leads consumers to replace their contact lenses less often than they should. Over-use of contact lenses damages the eyes and can have irreversible consequences for ocular health. If ocular health is of fundamental concern to the Contact Lens Rule, its first priority should be to ensure consumers have affordable and easy access to replacement contact lenses.

CONCLUSION

The Fairness to Contact Lens Consumers Act and the Contact Lens Rule are a step toward contact-lens consumer freedom. But the verification system remains problematic; its limitations on sellers are exploited by certain prescribers who seek to re-capture a sale that they lost the old-fashioned way: through competition. The FTC should amend the Contact Lens Rule to close the loopholes that allow prescribers to prevent consumers from purchasing lenses at the lowest price from the retailer of their choice.

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*On behalf of
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