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Comment to FTC on Contact Lens Rule, 16 CFR Part 315, Project No. R511995

Thank you for inviting comments on how this and other existing rules are functioning, and what can be done to improve them. In the interests of full disclosure, I am a member of the New Jersey Society of Optometric Physicians, and serve on its board of directors. We think of members of the public, who might otherwise be called "contact lens consumers" in the retailing context, as our patients, patients that are using a regulated prescription medical device. I hope that my comments will be read in that light.

A condensed summary of my recommendations regarding the Contact Lens Rule can be found in the "text box" comments submitted online simultaneously with this attachment.

There were certainly legitimate public concerns that led to the initial adoption of the Fairness to Contact Lens Consumers Act legislation and the Contact Lens Rule, notwithstanding some later unintended and likely unforeseen consequences. It is helpful to recall what those initial concerns were that served as an impetus for the Act and the Rule.

The primary public complaint was that some patients were not being provided a copy of their contact lens prescription by their eye doctor (usually an ophthalmologist or optometrist) at the conclusion of their contact lens fitting, and that they were therefore having difficulty getting it filled by a third-party contact lens retailer. In an era before patients could use their smart phones to easily take a photograph of a prescription and permanently store the image or send it to any interested party, a secondary complaint was that, when a patient misplaced or otherwise couldn't



provide their Rx, some prescribers were apparently resistant to confirming its details to a retailer over the phone.

On the other hand, there were complaints that third-party contact lens retailers, particularly those on the internet, were recklessly selling contact lenses, a prescription medical device, without a prescription of any kind. Because of the usually inter-state nature of the transaction, states have difficulty enforcing the requirement for a prescription on online retailers. (A similar problem occurs with online sales of prescription medications.)

The requirement that eye care prescribers provide a copy of a prescription to their patients upon completion of a contact lens fitting was appropriate and proper, and only reinforced what was an existing standard practice in optometry and ophthalmology. There are very few subsequent problems or concerns regarding that aspect of the Rule.

The problems and negative side-effects come more from one particular aspect of the Rule's third-party prescription verification scenarios: the "eight (8) business hours" loophole that allows the retailer to avoid the "direct communication" requirement for verification. This loophole is probably the biggest actual real-world effect of the Rule, and yet seems to be under-appreciated and overlooked. For example, the "Invitation To Comment" at the top of the comment form for the Rule (<https://ftcpublic.commentworks.com/ftc/contactlensrule/>) doesn't even mention it in its description of the Rule, and neither does this "Rule Summary" page:

<https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/contact-lens-rule/>

Despite its relative apparent obscurity, this aspect of the Rule that authorizes a contact lens retailer to sell a year's supply of a regulated medical device if the doctor that is claimed to supposedly be the prescriber "fails to communicate with the seller within eight (8) business hours



after receiving from the seller..." what is usually a robo-call or automated fax requesting verification, is unfortunately the source of most of the Rule's shortcomings. The FTC may not be aware how large of a proportion of internet contact lens sales take place utilizing this loophole, without the retailer actually seeing a prescription (which the Rule already requires eye care practitioners to provide to their patients) and without a successful verification attempt. I would urge the Commission to collect information from the online contact lens industry regarding the frequency with which lens sales take place as a result of this "eight (8) business hours" exception to the "direct communication" requirement for prescription verification, both the actual number of transactions and the fraction of total sales.

The most common complaints from eye care practitioners regarding the Rule, in my experience, are about abuse of the "eight (8) business hours" provision to fill a non-existent, expired, or incorrect Rx, as well as about contact lenses being shipped - and even delivered - before any eight-hour period has expired. Dispensing a medication because the supposed prescriber doesn't respond to an automated prescription verification request within eight business hours would of course not be allowed in a pharmacy, internet or otherwise!

Another common concern among prescribers is, for example, a prescription for a year's supply of contact lenses getting filled one month before it expires, eleven months after the exam and fitting; or for example, a prescription for a year's supply of contact lenses getting filled twice by two different retailers. There should be pro-rating in the filling of a contact lens prescription based on how much usage is actually remaining before the expiration date, as well as based on either the prescriber or retailer being aware of previous fills of the Rx. In other words, if contact lenses are ordered six months before the prescription's expiration date, then the retailer should be authorized to only dispense a six-month supply; or if during the verification process, the retailer is informed by the prescriber that the patient has previously been dispensed nine months' worth



of contact lenses, then the the retailer should be authorized to only dispense a three-month supply.

One clear problem in the Rule's implementation is the unstated but implicit assumption that the doctor's office being contacted is truly the patient's/customer's actual "prescriber" (if there even is one). The Commission may not be fully aware of the disturbing frequency with which eye doctors get verification requests with names of people that have never been their patients. A prescriber of course has a responsibility to communicate their patient's prescription to anyone the patient authorizes and delegates, but a busy optometry or ophthalmology office cannot be expected to diligently respond to automated communications that are not regarding their actual patients and seem to have been mistakenly sent to their practice. If the retailer has not received an image of the actual prescription (which smart phones should now facilitate significantly, compared to when the Act and Rule were first enacted), it should at least obtain some confirmation that the customer really is a patient of the prescriber that is being contacted for verification. After all, the contact lens fitting is supposed to have taken place within less than twelve months of the attempted purchase, and was probably paid for with a card and/or covered by insurance, both of which would create a paper trail. Those patients that cannot provide a prescription, or any documentation at all of having had an exam, are of course also likely to be the least compliant with proper contact lens wear, hygiene and care, and are in the greatest danger of serious medical complications, such as infectious corneal ulcers - a condition often caused by poor contact lens care practices - which can be vision-threatening.

In order to allow eye doctors and the Commission to be able to track in detail what happens to internet contact lens orders after the verification request is sent, I would urge the FTC to require online retailers to have a follow-up communication with the prescriber, which would state whether the transaction was cancelled or completed, and if so, what exactly was shipped and exactly when. A simple shipping tracking number (e.g., from UPS or USPS), if the retailer were



required to provide it to the doctor, would document whether the lenses may have actually been sold before any "verification" took place.

And finally, to make the "eight (8) business hours" deadline a little more manageable to meet for a busy eye care practice, I would urge the Commission to make it "eight (8) business hours or twenty-four (24) clock hours, whichever is later". The FCLCA legislation gives the FTC the flexibility to do make that modification, in referring to "8 business hours, or a similar time as defined by the Federal Trade Commission". That change would still not prevent the situation where, for example, a verification request comes in on a holiday weekend and the prescriber's office is closed for an extra day off, or when a practice is not open on Wednesdays, but at least it would mean that the prescriber would have a little more of an opportunity (especially at the beginning or end of the workday) to correct any errors in the verification request, before the order is shipped and it's too late. It would also help address the fact that many practices do not keep the "9 to 5" hours assumed by the Rule. Most online contact lens sales occur during off-hours in any case, so the distinction between eight business hours vs. twenty-four clock hours wouldn't mean much of a change in order processing time.

Thanks for your time and attention,

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