



New Jersey Society of Optometric Physicians – “Envision the Future”

October 23, 2015

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Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW.
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RE: Contact Lens Rule, 16 CFR part 315, Project No. R511995

The New Jersey Society of Optometric Physicians (NJSOP) represents 700 doctors of optometry in New Jersey. The Mission of the New Jersey Society of Optometric Physicians is to advocate for the profession and serve New Jersey optometric physicians in meeting the eye care needs of the public. NJSOP appreciates this opportunity to offer comment on the Contact Lens Rule.

1. Is there a continuing need for the Rule? Why or why not?

The Contact Lens Rule (the Rule) is required by statute, the Fairness to Contact Lens Consumers Act (FCLCA). Congress intended the law to enhance competition in the market for contact lenses by creating a federal right of patients to receive their contact lens prescriptions from their eye doctors, and establishing a process for contact lens sellers to verify the prescriptions of lenses ordered by consumers. However, as regulated medical devices that require a prescription from an optometrist or ophthalmologist, contact lenses have always been subject to government oversight. In its role, the Federal Trade Commission should seek to enhance competition in the fair and appropriate delivery of contact lenses to consumers. While most of the provisions of the Rule are required by the text of the FCLCA, the FTC should ensure that competitive practices designed for unregulated products do not undermine or elude critical contact lens patient safety protections. In other words, since the Rule must be maintained and many of its terms are proscribed by statute, moving forward the FTC should focus its efforts to enhance competition that best serves the interests of patients. Too often in the last decade, the FTC has silently allowed some sellers to gamble with patient health at the expense of innovation, improved safety, and other desirable results of competition. The FTC should not allow sellers to deceive patients in the single-minded pursuit of sales. The FCLCA provides rights to patients, so, ultimately, the Rule should protect patients with common sense safeguards.

2. What benefits has the Rule provided to consumers? What evidence supports the asserted benefits?

Consumers benefit from the Rule by receiving their contact lens prescriptions from their eye doctors, and by having their prescriptions verified when they order contact lenses. It is our understanding that consumers have benefited from a wide selection of innovative products that are prescribed by their eye doctor, allowing more of our patients the option to use contact lenses for their vision needs. However, patients don't benefit when their eye health is sacrificed by unscrupulous sellers. NJSOP fully supports the existence of a robust contact lens marketplace,

but believes competition is most beneficial when consumer safety is one of the market features. Until all sellers compete on patient safety, the FTC's lack of enforcement is more beneficial to sellers than to patients.

3. What modifications, if any, should be made to the Rule to increase its benefits to consumers? What evidence supports the proposed modifications? How would these modifications affect the costs the Rule imposes on businesses, including small businesses? How would these modifications affect the benefits to consumers?

To improve the Rule for consumers, NJSOP requests the following:

- a. The Federal Trade Commission (FTC) should prohibit the sale of contact lenses with an expired prescription. An expired prescription should be seen as an inherently invalid prescription. The FCLCA established that a prescription is required, and that eye doctors should verify those prescriptions.
- b. The FTC should require that contact lens prescriptions include a maximum quantity of lenses that can be purchased prior to the prescription's expiration.
- c. The FTC should limit the number of contact lens boxes that can be purchased from a retailer at one time. The amount should not exceed the maximum quantity noted on the patient's prescription.

4. What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers?

Despite the Rule's requirements, retailers continue to sell contact lenses without proper prescriptions or prescription verification, which deceives consumers into believing that contact lenses are simple over-the-counter products. The proliferation of contact lens retailers over the past ten years has unfortunately resulted in the emergence of certain sellers who attempt to circumvent the FCLCA patient protections and are focused on profits and the number of contact lenses they can sell. Contact lenses are regulated medical devices that require professional supervision and care to mitigate the risks of misuse.

800contacts and Lens.com have failed to abide by the FCLCA legislation specifically requiring them to communicate with the practitioner to verify the prescription allowing for 8 business hours for the practitioner to respond. In each case, they had already processed and mailed the order prior to requesting verification. In several of the cases, and in one particular case the patient was a minor, the last eye health examination was performed more than one year earlier and as such the prescription was expired and in another, the exam was not complete on a patient who has Keratoconus.

800CONTACTS and Lens.com are using deceptive techniques by sending prescription verification request without the permission of the patient. If the request was authorized, it would allow 800contacts to refill prescriptions for an additional year avoiding the proper eye health examination of the patient. This is an obvious method by 800contacts to circumvent the requirements of the FCLCA which was passed to foster the proper clinical care of the patient, not just collect credit card numbers and fraudulently represent the patient without permission. In some cases, fulfilling orders for minors and others with exams greater than (1) year or more.

5. What significant costs, if any, has the Rule imposed on consumers? What evidence supports the asserted costs?

While contact lenses are generally safe and effective medical devices, NJSOP is concerned that there is a widespread public misunderstanding regarding the need for appropriate care of lenses and physician oversight when using contact lenses. In 2014, the Centers for Disease Control and Prevention (CDC) reported that annually Americans make an estimated 930,000 visits to doctors' offices and outpatient clinics and 58,000 emergency room visits annually due to eye infections, adding \$175 million in health care costs connected to keratitis—a typically preventable eye infection associated with improper contact lens use.¹ NJSOP members frequently care for patients who have experienced contact lens related infections and complications. The eye care visits and treatments associated with these events is an increased cost to consumers.

We have documented one case that had the potential of becoming a “life threatening issue” due to the patient history of metastatic cancer with potential for ocular involvement.

Patient presented for an exam on 04-03-2015. He has very significant medical history that can have a direct relationship to his eyes and potential for life threatening events - having a metastatic testicular cancer. He had previously received lenses delivered to him from lenscom.uk and more recently was supplied lenses from a friend that works for 800contacts. He was wearing Acuvue Oasys improperly for 3-4 weeks.

The issue in this case is the most fearful of all scenarios. The patient, even though is doing well, is being treated for metastatic cancer which has spread to vital organs of the liver and kidney. The high potential of ocular and brain involvement is very high and requires regular eye health care so that we can work with the oncologist. In the case, his friend working at 800contacts has directly violated the law as well as probable 800contacts corporate policy in supplying lenses to the patient with complete disregard for his friend's well-being.

In another case we can document they are selling products at or near “expiration” as an inventory “fire sale”. Close to or expired products is a consumer safety issue. Lenses near or at expiration have the risks of

- a. Contamination due to old blister pack seals
- b. Risk of parameter changes due to pH shifts in the packing solution leading to corneal compromise and discomfort to the patient

6. What modifications, if any, should be made to the Rule to reduce any costs imposed on consumers? What evidence supports the proposed modifications? How would these modifications affect the benefits provided by the Rule?

At a minimum, the basic patient safeguards outlined in the FCLCA must be enforced to protect patients and reduce unnecessary costs. Retailers should be punished for selling contact lenses without a valid prescription, which increases risks for the patient and ultimately leads to higher

¹ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a3.htm>

health expenses. Individuals who attempt to sell products via social media and the companies that host the social media sites must be informed of the legal requirements surrounding the sale of contact lenses. The FTC should prevent the sale of large quantities of contact lenses when that sale could compromise a patient's eye health. Additionally, more needs to be done to ensure that patients are aware that contact lenses are regulated medical devices, whose safe use and optimal performance depends on eye examinations and professional supervision.

7. What benefits, if any, has the Rule provided to businesses, including small businesses? What evidence supports the asserted benefits?

Although the Rule was intended to increase competition, the online contact lens market is dominated by one large business. On July 30, 2014, during a hearing before the Senate Judiciary Committee's antitrust panel, R. Joe Zeidner, General Counsel for 1-800 CONTACTS, indicated that his company controlled approximately three quarters of the online contact lens retail market.² So, while the FCLCA was intended to increase competition, an unintended consequence has been the emergence of one dominating online retailer.

8. What modifications, if any, should be made to the Rule to increase its benefits to businesses, including small businesses? What evidence supports the proposed modifications? How would these modifications affect the costs the Rule imposes on businesses, including small businesses? How would these modifications affect the benefits to consumers?

To improve the Rule for small business, including the practices of doctors of optometry, NJSOP requests the following:

- a. FTC should no longer allow the use of robocalls for verifying patient prescriptions. This would protect thousands of small businesses from these disruptive calls which, too often, communicate incomplete information or are difficult to understand.
- b. FTC should require that for larger contact lens retailers, the retailer must make available more than one individual at a company to act as the contact person for physician questions and concerns.
- c. FTC should develop a distinct complaint submission process for contact lens related concerns.

Here are the major complaints that come to our office on a regular basis:

- a. We have received numerous calls from members who state the following: 800contacts will call repeatedly regarding the same patient using multiple record or reference numbers to try to seek verification. The majority of these calls are received on "off hours" primarily during evening hours – after hours (11 pm to 6:00 am) and Sundays when office are obviously closed.
- b. They will also call providers other than the original prescriber. In many instances, they will call other "doctors" in the same town or area code whom are not optometrists not

² <http://www.judiciary.senate.gov/hearings/watch?hearingid=12e98234-5056-a032-52ea-90f98e940d9b> (minute 111)

ophthalmologists in an attempt to document that “they called the doctor”. In these cases, they can document they “tried to call the patient’s doctor, but there was not response, so they filled the order”.

- c. Almost since the inception of the 800contacts business there has been the one name given to providers to call as the point person for questions, is Brad Scott. To this date – we have tried many times to call “Brad Scott”. When you call 800contacts and ask for a supervisor an excessive run-around starts.

9. What significant costs, if any, including costs of compliance, has the Rule imposed on businesses, including small businesses? What evidence supports the asserted costs?

Physician small-business owners spend significant time responding to prescription verifications that are inaccurate or incomplete. Robocalls, which automatically redial until a message is fully communicated to someone at a physician’s practice, are a cost to businesses as it often interferes with treating patients and can tie up phone lines that may be needed for urgent patient matters. An inability to reach a human at a large contact lens retailer is another cost to physician small businesses who may spend significant time on hold or attempting to use various phone numbers or automated prompts to reach live person. The costs that physician small-business owners expend related to the Rule are actually most often related to non-compliance on the part of retailers. If physician small-business owners only received accurate prescription verification requests for lenses, there would be no added costs related to robocalls or an inability to appropriately reach contacts at retailers.

10. What modifications, if any, should be made to the Rule to reduce the costs imposed on businesses, including small businesses? a. What evidence supports the proposed modifications? b. How would these modifications affect the benefits provided by the Rule?

Eliminating robocalls, providing verifications in writing, and requiring more than one contact person at a retailer to be available to discuss prescription concerns would reduce the burden on the small businesses of doctors of optometry.

11. What evidence is available concerning the degree of industry compliance with the Rule?

800contacts has implemented a “passive – updating records” method without patient permission. The patient did not request an order nor authorized any communications for 800contacts to “phish” for information. 800contacts will have already sent lenses to the patient, as seen in many of the following cases, and then several days later sent a communication with the following paragraph:

Dear Eyecare provider (‘not specific to the office):

We are requesting the contact lens prescription for the following customer pursuant to the Fairness to Contact Lens Consumer Act (Public Law 108—164) which requires the prescriber provide a copy of the contact lens prescription to any person designated to act on behalf of the patient. This customer has authorized 1-800-contacts to request this information on his/her behalf. This is not a contact lens order verification request.

Please either (A) send us a copy of the customer's actual prescription, or alternatively, (B) complete and send back to us the prescription form below, including all parameters, applicable dates and signature.

In many cases 800contacts has not even sought permission from the patient and is requesting this record update in order to solicit the patient for an order. This is a method of data collection and a passive form of luring the doctor into supplying confidential patient information even though the patient has NOT requested 800contacts to do so. By luring the doctor to filling in the form – 800contacts is falsely representing the patient by asking the doctor to complete the information that will allow 800contacts to solicit the patient.

12. What modifications, if any, should be made to the Rule to account for changes in relevant technology or economic conditions? What evidence supports the proposed modifications?

The use of robocalls must be banned. This change would account for changes in technology and an overall shift in public opinion regarding the use of automated phone calls that has occurred in the 10 years since the Rule was drafted.

13. Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how? What evidence supports the asserted conflicts? With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not?

The Rule is in conflict with New Jersey State Board of Optometry Rule 13:38-2.4 – Requirements for issuing prescriptions and dispensing medications. This rule requires the Optometrist to use a prescription blank as authorized by the state of New Jersey for contact lens prescriptions. The regulation includes a requirement that the signature of the prescriber be handwritten. The Rule allows for the automatically filling of prescriptions without proper authorization.

Thank you for the opportunity to comment on this important issue. If you need additional information, please contact Howard R. Cooper, Executive Director at 609 323-4012 x 116 or at hcooper@njsop.org

Sincerely,

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