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April 5, 2004

Submitted Via E-mail to contactlensrule@ftc.gov

Federal Trade Commission
Office of the Secretary
Room 159-H (Annex A)
600 Pennsylvania Avenue
Washington, DC 20580

Re: Contact Lens Rule, Project No. R411002

Dear Sir or Madam:

The American Society of Cataract and Refractive Surgery (ASCRS) appreciates this opportunity to comment on the Federal Trade Commission's proposed Contact Lens Rule, 69 Fed. Reg. 5439 (Feb. 4, 2004) ("the Proposed Rule") implementing the Fairness to Contact Lens Consumers Act, 15 U.S.C. § 7601 et seq. ("the Act") (to be codified at 16 C.F.R. § 315). ASCRS represents over 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of the more than one million cataract procedures performed annually in the U.S. In addition to being specialists in refractive surgery, a large percentage of ASCRS members practice general ophthalmology and regularly prescribe contact lenses. Many ASCRS members also dispense contact lenses from their offices and optical shops.

While ASCRS fully supports the patient's right to receive a copy of his or her contact lens prescription, we are concerned that certain provisions of the Act and the Proposed Rule will have the unintended effect of jeopardizing the ocular health of patients. The Proposed Rule also requires further clarification in a number of important areas. Our specific concerns are outlined below.

1. Verification Events: The 8-Hour Response Rule

ASCRS members are most concerned about the provisions of the Act and the Proposed Rule that permit a contact lens seller to fill a prescription if a prescriber fails to respond to a request for verification of the prescription within 8 business hours after receiving the request. 15 U.S.C. § 7603(d); 16 CFR § 315.5(c)(3). This rule sets up the distinct possibility that a seller will fill a prescription that is inaccurate, expired, or falsified simply because the prescriber has been unable to respond within 8 hours. As a result, patients could suffer serious eye injuries by wearing improper fitting contacts.

Contact lenses are prescription medical devices regulated by the Food and Drug Administration. They require regular visits to an eyecare professional and proper

care/maintenance. A patient that wears poorly fitting contact lenses could suffer very serious eye injuries, including, but not limited to:

- Corneal Ulcers
- Corneal abrasions
- Corneal edema
- Corneal dystrophy
- Corneal hypoxia
- Corneal blood vessels
- Corneal warpage
- Corneal pump cell alteration
- Conjunctival inflammation/scarring
- Acanthamoeba keratitis
- Keratitis
- Decrease in corneal thickness
- Increase in corneal curvature
- Microcyst formation
- Sterile Infiltrates
- Superior limbic keratoconjunctivitis
- Giant Papillary conjunctivitis
- Decrease resistance to infection
- Decrease in oxygen supply
- Dry Eye
- Blepharitis
- Ocular/systemic allergies
- Decreased corneal sensitivity
- Tight lens syndrome
- Ptosis
- Contact Allergy
- Dellen

(See <http://www.fda.gov/cdrh/consumer/buycontactqa.html> for the FDA's discussion of the potential harm that can be caused by wearing contact lenses issued pursuant to an invalid or inaccurate prescription.) The magnitude of the injury will depend in part on how long the patient wears improperly prescribed contacts and whether the patient wears the contacts on an extended or overnight schedule. Thus, allowing sellers to fill prescriptions that have never been verified by a prescriber raises a very real risk that patients will suffer serious injury.

The Act itself compounds this problem by failing to specify whether the clock starts ticking on the 8-hour requirement when the seller sends its request or when the prescriber receives it. Section 315.5(c)(3) of the Proposed Rule and the examples in the preamble clarify that the prescriber's obligation to respond starts "*after receiving*" the verification request. However, the agency does not adequately define the circumstances under which a prescriber will be deemed to have received the request. For instance, while it is clear that the prescriber must correct any inaccuracies in the prescription (§ 315.5(d)), it is unclear what the prescriber's responsibility is if the request for verification does not contain all the information required by the Act (§ 7603(c)) or the Proposed Rule (§ 315.5(b)). Does the prescriber have 8 hours to contact the seller and ask for complete or correct information? What if the seller sends the prescription to the wrong prescriber? For instance, sometimes a patient will see one ophthalmologist or optometrist for general eye health care, but will visit another health care professional for a contact lens fitting. In such cases, if the patient identifies, and the seller contacts, the wrong prescriber, does the prescriber who has been contacted have an obligation to respond to a request for verification within 8 hours?

We urge the FTC to clarify that the prescriber's obligation to respond within 8 hours does not begin until a complete and accurate request is actually received by the *correct* prescriber or a designated staff person in his or her office. The agency should further clarify that the seller has an obligation to confirm that the prescriber has received the request for verification, either through telephone follow up, or email or fax response.

Even with a clearer definition of when the prescriber has "received" the request, it is simply unrealistic to think that ophthalmologists, optometrists, and other prescribers in small practice settings will always be able to respond to a request for verification within 8 hours. Many solo practices, and particularly those outside large urban areas, close their offices when the ophthalmologist or optometrist goes on vacation, attends a professional conference, or suffers a personal illness or a family crisis. In such cases, the prescriber should not be deemed to have received a request for verification until the first business hour after he or she has returned from vacation or other legitimate, verifiable absence from the office *and* the office has re-opened. Accordingly, the prescriber should not have to respond until 8 business hours have elapsed from that time. This conclusion is based on the same principle that the FTC applied in defining "business hour" to exclude hours on evenings, weekends, and federal holidays. In other words, the 8 hour rule should not apply until the prescriber has received a request for verification during *normal business hours*, which means when the prescriber's office is open (or has re-opened) to patients. While this may occasionally cause some delays in filling prescriptions, these delays are necessary to prevent the dispensing of contacts based on invalid, inaccurate, or expired prescriptions that could cause serious eye injuries.

In cases where a prescriber's office is closed due to the prescriber's extended absence, the office could be required to have its answering service, voicemail system, or answering machine notify sellers seeking prescription verifications that the office is closed and when it will re-open. However, sellers should not be permitted to rely on the lack of response to a verification request sent by email or fax as a deemed verification since it is possible that the email or fax was not actually received. Instead, they should be required to telephone the prescriber for confirmation of receipt in such circumstances. The seller will then learn, through the prescriber's answering machine or answering service, that the office is closed and when it will re-open.

Similarly, prescribers often have one or more satellite offices, away from their main facility, that are only open only 1-2 days per week. This is especially true for prescribers outside urban areas. Patient records are typically kept in the office that the patient actually visited, but calls may come into the main office when the satellite office or offices are closed. In such cases, the 8-hour rule can impose a major burden on a prescriber if the prescriber or the prescriber's limited staff has to travel significant distances to retrieve a patient's medical records from a closed satellite office within 8 business hours of receipt of a verification request. Prescribers should be allowed to satisfy their obligation under this rule by informing a seller, within the 8-hour time limit, that the patient's records are located at a satellite office, by giving the seller the date and time that the satellite office will next be open and by indicating that the prescriber will respond within 8 business hours of that opening time.

The FTC should also clarify that prescribers can delegate the responsibility for responding to requests for verification to another qualified prescriber within the same practice or a health care professional acting under the prescriber's supervision such as a physician's assistant, nurse, optical technician, or licensed optician. For instance, the language of the § 315.5(c)(1), (2), and (3) of the Proposed Rule each could be amended to add the words "and his or her qualified designee" after "The prescriber". It makes no sense for a physician or optometrist to spend his or her valuable time sending the actual response to a verification request or, even worse, playing telephone tag with the seller's representative (i.e., if voicemail is not available).

Lastly, to protect patient safety, the FTC should interpret the verification provisions of the statute to preclude a seller from filling a prescription if the seller knows or should know that the prescription is invalid, inaccurate, or has expired. While we recognize the purpose of the law is to ensure patient's have timely access to their prescriptions, there is no indication that Congress intended to authorize sellers to knowingly or negligently fill invalid prescriptions and jeopardize the ocular health of patients. Violations of this requirement should be subject to the same enforcement process as other violations of the Act.

2. Communications Between Sellers and Prescribers

In response to the FTC's question, we think it would make sense for the prescriber to have the option to include the prescriber's email address in the prescription. This is likely to be one of the predominant, most efficient forms of communication between sellers and prescribers. However, it should not be mandatory as not all prescribers use email.

The definition of "direct communication" in § 315.2 of the Proposed Rule tracks the Act, stating that it means "completed communication by telephone, facsimile, or electronic mail." The Proposed Rule also applies the direct communication requirement to both sellers and prescribers, whereas the Act only appears to apply this requirement to prescribers. This is generally a positive change from our perspective as it requires the seller, as well as the prescriber, to ensure that a communication is received by the intended recipient. However, the means by which the Agency suggests the direct communication requirement may be satisfied do not necessarily satisfy the completed communication standard.

For instance, the preamble states that a "completed communication" includes leaving a voicemail message on the telephone answering machine of the intended recipient. This is a welcome interpretation of the language of the Act as it will help to avoid extended games of telephone tag regarding a request for verification. However, the preamble also states that direct communication by fax or email would require that the intended recipient actually receive the communication. This places an extraordinary burden on prescribers, who are required to respond to requests for verification through direct communication. In essence, it means that the prescriber has to telephone the intended recipient to make sure that person has received an email or fax response. Otherwise, the prescriber has no way of knowing that the intended recipient actually has received the response. Fax machines will confirm whether the transmission was successful, but do not tell the sender if the intended recipient actually received the fax. Likewise, some email programs permit the sender to receive a notice that the addressee has received and/or read the email, but at some companies, the person who reads the email may not be the intended recipient. This would be especially true if the seller sends the prescriber an email from a generic or departmental email address (i.e., an address accessible to several people rather than a personal email address such as customerservice@contactsusa.com).

To fix this problem, the Proposed Rule should be modified to clarify that, just as an intended recipient is presumed to receive his or her voicemail messages, a direct communication is presumed to be completed if (a) the prescriber sends the response by fax to the number listed in the request for verification and receives confirmation of a successful transmission, or (b) the prescriber sends the response by email to the address of the contact person provided by the seller and does not receive a transmission error notice. Prescribers, of course, can further protect themselves by sending a verification response by email using the return receipt option available in some email programs, but not all email services offer this option and for those that do, not all prescribers are facile enough with email to use it. As discussed above, because of the 8-hour rule, we do not believe these presumptions should apply to sellers' requests for verification. Instead, as noted above, they should be required to telephone the prescriber's office to ensure that a fax or email has been received if they do not receive a response within 8 business hours.

3. Definition of "Contact Lens Fitting"

The definition of "contact lens fitting" in 15 U.S.C. § 7610 and 16 C.F.R. § 315.2 should be clarified to define "when a successful fit has been achieved" and the scope of the examination and evaluation process. First, the proposed rule should clarify that the initial evaluation includes giving the patient a pair of contacts to take home and wear on a trial basis and that the fitting is not complete until the doctor settles on a final prescription. This is important so that prescribers are not required to release or verify a prescription before it is finalized.

Second, with respect to the FTC's question whether it should define the term "medically necessary follow-up exam," ASCRS's view is that this term *should not* be defined by the FTC; rather, the Proposed Rule should state that whether a follow up exam is medically necessary should be "as reasonably determined by the prescriber." The FTC should not be in the business of defining medical terms or otherwise regulating the practice of ophthalmology or optometry.

Third, with respect to the agency's question whether prescribers itemize charges and fees in a manner that distinguishes the amount the patient is paying for an eye examination, fitting, and evaluation from the amount he or she is paying for other goods and services, the answer is that prescribers typically do charge separately for the examination, fitting, and evaluation from other ophthalmic goods and services that they may provide.

4. Definitions of "Contact Lens Prescription"; "Contact Lenses"

The definition of "contact lens prescription" in 15 U.S.C. § 7610 and 16 C.F.R. § 315.2 should distinguish a traditional prescription from a custom-made lens, which the Act clearly is not intended to cover. Custom-made lenses are designed for each individual patient by the ophthalmologist working in close coordination with a specialized manufacturer. Since these are non-standard lenses that require extensive interaction between the physician and the manufacturer, it would be inappropriate for prescriptions for these lenses to be subject to the requirements of the Act. It should be up to the prescriber to determine whether the manufacturer is capable of producing the custom lens and is willing or able to work closely enough with the prescriber to create these more sophisticated lenses. Thus, custom lenses should not be covered by the Act or the Rule.

The preamble to the Proposed Rule asks whether the agency should define contact lenses and, if so, whether that definition should exclude cosmetic lenses because consumers do not need a prescription to purchase them. ASCRS does not think it is necessary to define contact lenses in the Rule, but, as noted above, the agency should make clear that custom-made contacts are not covered by the Rule.

ASCRS feels strongly that cosmetic lenses should only be dispensed pursuant to a prescription obtained from ophthalmic professionals who have been trained to fit, examine and instruct patients in the proper use of contact lenses. According to the FDA, cosmetic contact lenses can cause a variety of eye injuries and conditions, including corneal ulcers, internal ocular infections, corneal scarring, vision impairment, and, in extreme cases, blindness and eye loss. Other risks include conjunctivitis; corneal edema; allergic reaction; abrasion from poor lens fit; and reduction in visual acuity, contrast sensitivity, and other visual functions, resulting in interference with driving and other activities. 68 Fed. Reg.16520-21 (April 4, 2003). Unfortunately, because cosmetic lenses are classified by the FDA as cosmetics rather than medical devices, they are available without prescription. Thus, it is unclear to us how the FTC can include them in the Rule, which implements a statute that regulates the release and verification of *prescription* contact lenses. Nonetheless, we would support efforts by the agency to restrict the marketing and distribution of cosmetic contact lenses without the involvement and supervision of an ophthalmic professional.

5. Patient Designees

The Act (§ 7601(a)(2)) and the Proposed Rule (§ 315.3(a)) require prescribers to provide or verify the prescription to "any person designated to act on behalf of the patient." This language is so broad that it leaves the door open for manipulation and fraud by unauthorized or bogus sellers seeking to gain information about patients for marketing purposes. This provision should be clarified to require written proof of designation so that the prescription is not given to someone who is not actually authorized to act on behalf of the patient. This can be accomplished simply by requiring a designation to act on behalf of a patient to be in writing signed and dated by the patient.

6. Limits on Requiring Immediate Payment

Many ASCRS members have expressed confusion over the limit on requiring immediate payment before a contact lens prescription can be released or verified (15 U.S.C. § 7602; 16 CFR § 315.4). More specifically, many prescribers are under the misimpression that the law prevents them from charging their patients for examination, fitting and evaluation services until a prescription is provided. Others are confused about the proof of insurance language.

We think the intent of Congress is plain, but the language of the Act could be clearer. We suggest that the agency clarify that this provision is meant to indicate that prescribers may require payment for an eye examination, fitting, and evaluation as a condition of releasing or verifying a contact lens prescription only if they have a policy and practice of requiring payment immediately before or after office visits for these services regardless whether glasses, contact lenses, or other ophthalmic goods are prescribed.

The statement that proof of insurance coverage shall be deemed to be a payment for purposes of this section should also be clarified to mean that prescribers who accept proof of insurance coverage as a form of payment may, at their option, require proof of insurance coverage as a condition of releasing or verifying a prescription if they normally require immediate payment or proof of insurance coverage even if ophthalmic goods are not prescribed. More importantly, the FTC should further clarify that this provision is not intended to *require* prescribers to accept proof of insurance coverage as a form of payment and therefore require them to release or verify a prescription upon presentation of proof of insurance.

7. HIPAA

The Proposed Rule asks whether the HIPAA Privacy Rule will limit or otherwise affect prescribers' ability to respond to a verification request. We believe the law will not conflict with the HIPAA Privacy Rule. The preamble to the August 14, 2002 HIPAA Privacy Rule specifically addresses this issue and indicates that disclosure of protected health information by an eye doctor to a distributor of contact lenses for the purpose of confirming a contact lens prescription is treatment, and the disclosure is permissible under Sec. 164.506 of the Privacy Rule. *See* 67 FR 53219 (2002).

8. Issue Date; Expiration Dates of Less Than One Year

The Act and Proposed Rule set forth standards for when a prescription may expire. The expiration dates are measured from the time of the "issue date" of the prescription. Section 7604(c) of the Act and § 315.1 of the Proposed Rule define "issue date" to mean the date the patient receives a copy of the prescription. This is very problematic. The only relevant issue date for the purposes of a prescription is the date the prescriber writes the prescription, which is typically at the time of the patient office visit. The patient might not actually receive the prescription until several days, weeks, or months later. For instance, the patient could walk out of the prescriber's office without a copy of the prescription and call back six months later and ask for a copy. It makes no sense for the expiration date for that prescription to be measured from the date the patient "receives" the prescription. Instead, the issue date should be the date the physician writes the original prescription during the office visit.

In § 315.6 of the Proposed Rule, if the prescriber wants to impose an expiration date of less than one year, the prescriber must provide legitimate medical reasons and document those reasons in the medical record "with sufficient detail to allow for review by a qualified professional in the field." The quoted language is not in the Act itself, and the Proposed Rule does not define "qualified professional in the field." The preamble (at 5443) states that a prescriber must provide sufficient detail to allow a "qualified *medical* professional" to determine the reasonableness of the shorter expiration date. (Emphasis added.) This ambiguity needs to be clarified. The Proposed Rule does not define what a "qualified professional in the field" means and whether this term is intended to mean "qualified medical professionals," as stated in the preamble.

If this term is not limited to medical professionals, it leaves open the possibility that a non-physician could be second-guessing the medical judgment of an ophthalmologist, which is problematic from a medical perspective and could jeopardize the patient's health in some circumstances. Therefore, ASCRS urges the agency to revise the Proposed Rule to clarify that the review of a prescriber's decision to impose an expiration date of less than one year must be documented in the patient's record with sufficient detail to allow for review by a qualified *medical* professional.

9. Paperwork Reduction Act Estimates

ASCRS recognizes that the paperwork and other burdens created by the Act are largely beyond the FTC's control. However, the agency's estimates of those burdens are based on some misguided assumptions.

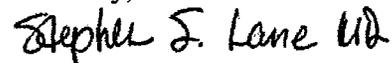
For instance, the estimate that prescribers will spend an average of one minute providing each prescription to a patient or authorized seller is much too low. One minute may be an accurate estimate of how long it will take for a prescriber to write out a prescription while a patient is in the office, but much more time will be required to respond to requests for prescriptions or verification well after a patient's office visit. In such cases, the prescriber's staff will have to pull the patient's file and find the most recent prescription. Staff will then give the file to the prescriber (or, as proposed above, his or her designee acting under the physician's supervision). The prescriber or designee will review the file and prepare the response. Either the prescriber or the prescriber's staff will then spend time emailing or faxing the response to the seller, or possibly making one or several calls trying to find the appropriate person at the seller's place of business. These burdens will be even greater if the requirement that a direct communication be completed is not clarified per our request in Section 2 above.

For the reasons described above, we also would challenge the FTC's conclusion (at 5445) that the burdens that the Act and implementing regulations will impose on small entities that prescribe contacts "are likely to be relatively small." While we agree that most of these burdens are mandated by the Act, they will nonetheless be quite substantial. Also, while the burden of giving patients their prescriptions immediately following an examination will be minimal, that most certainly will not be the case with respect to releasing or verifying prescriptions to patients or sellers weeks or months after the patient's examination. And, as the agency acknowledges, most of the prescribers affected by this statute will be small entities (i.e., those with less than \$6 million in revenues).

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Thank you for the opportunity to submit these comments on the Proposed Contact Lens Rule. We would be happy to meet with FTC staff to answer any questions that they may have about contact lens prescribing practices or to discuss our concerns with the Proposed Rule. Please contact Nancey McCann at (703) 591-2220 if you have any questions or would like to arrange a meeting.

Sincerely,



Steven S. Lane, MD
President