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IA

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(Electronically sent 4/5/04 to: contactlensrule@ftc.gov)

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

To Whom It May Concern:

**RE: Contact Lens Rule, Project # R411002**

I am writing to comment on Federal Trade Commission 16 CFR Parts 315 and 456, Contact Lens Rule; Ophthalmic Practice Rules as published in the Federal Register on February 4, 2004.

I am an ophthalmologist (a *prescriber* in your parlance) and have been in private practice in Iowa for over 21 years. The proposed rule is promoted as a means to implement the Fairness to Contact Lens Consumers Act. Nothing could be further from the truth! The rule in reality is completely unfair and offers minimal consumer protection. The only competition stimulated is between a few giant mail order and Internet firms. The small guy in the trenches (like myself) will be effectively squeezed out of the marketplace. The Act should be renamed "The 1-800-CONTACTS Welfare Act".

One role of the FTC, as I understand it, is to address imbalance in the marketplace caused by the presence of a few large entities that can control the market by virtue of their size. As the proposed rule now stands, 1-800-CONTACTS will stand to benefit by garnering even more market share by being able to unfairly price their contact lenses, yet increase my involvement and expenses with no provision for remuneration for my services.

Contact lenses are not a typical consumer product, since they involve both a service and a product. Contact lenses are a *medical device*, and in order for a patient to obtain the product (the contact lenses), he/she first needs to obtain a service (the contact lens fitting). The contact lens fitting involves time, judgment, medical expertise and carries the majority of the liability exposure. Patients, by and large, see value only in the product (the contacts), whereas doctors know the true value of safe contact lens use lies in the service (the initial fitting or subsequent refitting). The Fairness to Contact Lens Consumer Act furthers this misconception by allowing large contact lens sellers to sell the product without the responsibility of the fitting process, the cost of records maintenance, or the liability risk. The prescriber, on the other hand, carries those risks and costs.

Competition is a worthy goal of the FTC. However, this Act promotes price competition only on the product. By separating the service from the product, it provides contact sellers with an unfair advantage in the marketplace. Indeed, the Web site for 1-800-CONTACTS implies that doctors should be providing patients with contact lens fitting information as part of their routine eye exam and should not be charging patients any additional fees to provide this information.

Let's consider the work involved in fitting a patient in a pair of soft contact lenses. After the patient has received a routine eye exam, the prescription generated is valid for the purchase of spectacles. If the patient wants contact lenses, a contact lens fitting must be performed. To fit contacts in my office, a trial pair of contact lenses is placed on the eyes, the patient is taught how to insert and remove the contact lenses, and the patient then tries the lenses over a two week period before being re-evaluated in my office to see if they are happy with the contacts and to make sure that the eyes are tolerating the lenses from an eye health standpoint. The Fairness to Contact Lens Consumers Act rules, as stated, require me to give the patient a contact prescription without being able to require the patient to purchase the lenses from me. Once the lenses have been used on a trial basis by a patient, they cannot be placed back in stock and they become worthless. In order to perform these services, my office has to maintain a large inventory of lenses. I cannot continue to pay for this inventory if patients don't buy the lenses from me. I will therefore be forced to give up the contact lens portion of my practice. This is not good for the marketplace or my patients.

I have no objection to the FTC requirement that a valid contact lens prescription be given to patients at the conclusion of a contact lens fitting. I have been doing this for many years. But the patient should be required to buy at least the first lenses from the fitter. In the case of disposable lenses, complementary trial fitting lenses are provided to my office by the contact lens manufacturers, but only along with lenses purchased for my inventory. If I do not sell adequate lenses to my patients, I will be forced to purchase the trial lenses.

And updating contact lens prescriptions becomes problematic with these new FTC rules. I can only write a prescription for contacts if I am able to examine the patient with their contacts on, so that I can evaluate the fit and over-refract to calculate the new powers. Patients regularly come to my office for an updated contact lens prescription without any lenses of their own to use for the evaluation process. Under these circumstances, it is unreasonable to expect me to provide, at my cost, trial lenses for patients who are purchasing all of their contact lenses from an outside vendor.

If, as the rules are now promulgated, I am required to give the patient a valid contact lens prescription at the conclusion of the fitting, or refitting, process, this should be more than adequate for any reputable outside vendor to dispense contact lenses to patients, without any more input from my office. Patients have a right to shop around to purchase their contacts from outside sources. But with rights come responsibilities. Their written prescription is a valuable document. It should be the patient's responsibility to provide the outside source with the written prescription. But large outside vendors make little or no

effort to obtain a copy of this prescription from the patient. 1-800-CONTACTS essentially discourages patients from sending a copy of the prescription, instead routinely faxing a verification form to my office. My office has been getting multiple requests a day from 1-800-CONTACTS. Each request involves significant staff time to retrieve the patient record, compare the verification form to the office records, complete the very detailed verification form, then fax the information back to the outside vender. The new FTC regulations now will prohibit my office from making any charge for these valuable services.

Besides extracting free services from me, the verification rules pose other significant problems as well. The eight-hour time frame is totally unreasonable. Besides fitting contact lenses, I am a physician. There may be entire days that I am out of the office, in surgery, for instance. I suppose the work of responding to an outside vender request could be delegated to one of my clerical staff, but this truly is not in the best interest of patient safety and may be in violation of another set of government rules, HIPAA. If the verification is done the next time I am in the office, the eight hours could very well have expired. The eight-hour time frame is not designed to enhance patient safety or improve competition in the marketplace. It gives large outside venders another way to sell contacts to patients at my expense.

I find the FTC verification rules, as proposed, completely unreasonable. If, for any reason, a requester does not receive verification, then this is considered to be equivalent to verification. Only in the eyes of the government does "no verification = verification"! If this rule is implemented, the FTC will put patient health at risk by receiving incorrect or outdated contact lenses. There are numerous reasons why verification might be withheld or delayed. As noted above, the doctor may reasonably be out of the office, HIPAA guidelines may necessitate a signed release from the patient (which would be impossible in an eight hour timeframe). The doctor's office might need to obtain more information about the patient's condition or previous contact lens purchases, etc. Indeed, the contact lens wearer may not even be a patient in that particular office, but unless a response is made, that patient is then enabled to purchase contacts without a valid prescription.

Here is an example of how the eight-hour verification rule will be abused by outside venders. 1-800-CONTACTS sent a verification request on a patient whose contact lens prescription was outdated (three years old). I dutifully wrote "EXPIRED" in four prominent places on their form and faxed it back within eight hours. Over the course of the next few hours, we received three more verification requests for the same patient. Since I had already faxed them notification that the prescription had expired, I did not respond to the other requests. 1-800-CONTACTS went ahead and dispensed the contacts to the patient. When I subsequently contacted them (this is nearly impossible by phone) I was told that merely writing "expired" on the verification form is not sufficient notification; i.e. since I had not filled out every line on the verification form, they considered it invalid. And since I had not responded to one of the other requests, this was considered to be verification by non-response!

I suggest that the Fairness to Contact Lens Consumers Act be as follows:

- Require prescribers to give a written contact lens prescription, after the fitting is completed. This would be required for any and all outside venders to dispense lenses.
- Allow prescribers to require patients to purchase the lenses that were fit, since they do cost the prescriber money, and the lenses cannot be subsequently used for other patients.
- Allow outside venders to dispense contact lenses only with a valid prescription. This prescription should be obtained from the patient, since it was dispensed at the time of fitting. If the patient does not have the prescription anymore, then the patient should be required to obtain a new one from the prescriber. This would solve any HIPAA issues.
- If the patient requests that the outside vender obtain the prescription directly from the prescriber, the patient should provide the prescriber with written authorization, as per HIPAA rules.
- If an outside vender requests verification, a time frame more reasonable than eight hours should be established.
- Verification should mean verification. Not receiving verification should not be the same as verification.
- Prescribers should be allowed to charge a reasonable fee for providing verification services to their competition (although patients could continue to directly receive copies of their contact lens prescription at no cost).

Without rules as outlined above, I will not be able to continue selling contact lenses. And if I cannot sell contact lenses, my office cannot continue to fit or prescribe them. I am sure most independent ophthalmologists and optometrists will be impacted in the same way, and might consider giving up the contact lens portion of their practices. If that happens, patients will be left with contact lens care mainly at large discount operations, such as Walmart. I would hope that the FTC will see the challenges that the Fairness to Contact Lens Consumers Act, as proposed, creates for the "little guy" and changes the rules to better provide true competition in the marketplace.

Sincerely,

David S. Dwyer, M.D.