

**SUMMARY OF VIEWS FOR FEDERAL TRADE COMMISSION WORKSHOP ON
“POSSIBLE EFFORTS TO RESTRICT COMPETITION ON THE INTERNET”**

**GERALD M. OSTROV
COMPANY GROUP CHAIRMAN
JOHNSON & JOHNSON VISION CARE, INC.**

Thank you for the opportunity to testify at the Federal Trade Commission’s upcoming public workshop on “Possible Anticompetitive Efforts To Restrict Competition On the Internet.” The Federal Register notice of the workshop posed a number of questions to be addressed regarding the contact lens industry. Below is a summary of my views on these issues, which I expect to discuss at the workshop and in formal written comments to be submitted at a later date.

1. “What type of state regulations limit online sales of contact lenses?”

The short answer is that no state laws or regulations prohibit or limit online sales of contact lenses.

Unlike many of the other products that are the subject of this workshop, contact lenses are federally regulated medical devices. Federal law requires that contact lenses must be sold based on a valid prescription. The Food and Drug Administration (“FDA”) is the federal agency charged with regulating contact lenses. Without FDA approval, we cannot sell or distribute our disposable contact lenses. Every letter of FDA approval that Johnson & Johnson has received for its lenses recites that contact lenses are prescription devices and warns that, if the lenses are sold in a manner inconsistent with the conditions under which they been approved, the FDA may withdraw its approval. We take that obligation very seriously.

Consistently with the status of contact lenses as prescription devices, many states have laws specifying that contact lenses must be sold on prescription. Some states have enacted laws or regulations specifying that contact lens prescriptions must be in writing and/or must contain certain

elements. Also, some state statutes or regulations require contact lens sellers to obtain state licensure or registration.

These prescription, licensure and registration laws, however, do not target Internet sellers. They apply across the board to all contact lens sellers, including eye care professionals, traditional storefront retailers, and online businesses. In other words, state regulations regarding sale of contact lenses do not require anything more of online contact lens sellers than they require of traditional retail outlets.

Internet contact lens sellers that follow the law and sell contact lenses based on valid prescriptions provide a viable and appealing distribution alternative to consumers. Johnson & Johnson currently sells its contact lenses to 17 online sellers that comply with applicable federal and state laws and regulations that govern the sale or dispensing of contact lenses. These Johnson & Johnson accounts include individual eye care professionals that operate websites, retail chains like Cole Vision that maintain online sales operations, and authorized Internet/mail order sellers like Lens Express, Contacts for Less, and Affordablelenses.com. Together, these businesses maintain more than 100 URL addresses on the Internet, offering consumers a wide variety of opportunities for online purchases.

2. “What are the costs to consumers” associated with the regulation of online sales of contact lenses?

The regulation of online contact lens sales does not impose any costs on consumers. As previously stated, consumers who choose to shop online may purchase Johnson & Johnson contact lenses from a variety of authorized Internet sellers nationwide.

Furthermore, online sellers do not incur any incremental costs of compliance with state prescription, registration or licensure laws that are not also experienced by traditional retail sellers. As a condition of their authorization as Johnson & Johnson accounts, 17 Internet and mail order sellers have agreed to comply with all applicable federal and state laws and regulations governing the sale of contact

lenses. More than half of these sellers have lowered their retail prices for Johnson & Johnson lenses since becoming authorized accounts.

Similarly, application of state laws and regulations to Internet and mail order contact lens sellers does not come at a cost to consumer convenience. Consumers who enjoy the convenience of buying online can purchase from Johnson & Johnson's authorized Internet accounts. Furthermore, consumers who adhere to a two-week wearing schedule for disposable or frequent replacement lenses use approximately 8 multipacks a year, and they tend to buy lenses 2 or 3 times a year. Many consumers buy lenses at the time they have an eye examination in any event, and others regularly shop in mass merchandiser stores for a variety of items, including contact lenses. In addition, many consumers who want the convenience of door-to-door delivery do not have to purchase lenses online to get it – they have the option of purchasing from eye care professionals who participate in Johnson & Johnson's Acuvue® Patient Delivery program, which offers shipment of lenses to the patient at the doctor's direction.

3. **“What are the health justifications”** for regulations of online sales of contact lenses, and **“how valid are they?”**

As an initial matter, the FDA has determined that contact lenses are to be sold only on a valid prescription from an eye care professional. In its guide to consumers concerning the purchase of contact lenses on the Internet, the FDA explains the importance of purchasing contact lenses on prescription with regular check-ups:

Contact lens wear causes many changes to cells and tissues of the eye, and sometimes wearing contact lenses can damage the cornea (the clear window of the eye). *Even if you are currently experiencing no problems, the lenses may be causing damage to your eyes.* Regular check-ups will reduce the likelihood of damage going undetected.

(Center for Devices and Radiological Health, FDA, *Buying Contact Lenses on the Internet*, by Phone, or by Mail: *Questions & Answers*, at 2, available at <http://www.fda.gov/cdrh/consumer/buycontactqa.html>). The FDA's judgment and expertise provide

ample justification for the requirement that Internet sellers, as well as traditional retailers, require valid prescriptions before selling contact lenses to consumers.

Just a few weeks ago, the Ohio Attorney General sued several companies for selling non-corrective lenses without prescriptions. One young woman nearly lost her eyesight and had to have corneal transplant after she purchased and wore these lenses that were not prescribed for her. As a press release issued by the Ohio Attorney General’s office stated, “[w]ithout proper supervision from an eye care professional, consumers risk severe and permanent damage to their eyes.” An agreed injunction has already been ordered against one of these companies to stop the unlawful sales. Incidents like this one, which could also occur as a result of sale of corrective lenses without prescriptions, highlight the need for compliance with prescription requirements to protect the eye health of consumers.

4. Are there **“separate issues for replacement lenses or disposable lenses?”**

Some people argue that there is little need for professional supervision in the dispensing of replacement disposable lenses, because, unlike conventional lenses, replacement disposable lenses are manufactured to uniform specifications and sold to consumers in quantities of several months’ supply at a time. It is true that disposable lens technology has eliminated the need to have each individual replacement disposable lens fitted on the patient’s eye by an eye care practitioner. Nevertheless, even after the initial fitting process for disposable lenses has been completed, the patient still needs to return to his or her eye doctor for routine eye examinations and follow-up care. Thus, a contact lens prescription, which typically expires after a certain time and/or specifies the number of lenses that a consumer may purchase, is just as important for replacement disposable lenses as for conventional lenses.

5. **“How should prescription requirements be administered?”**

Prescription requirements must be administered so that the contact lens seller receives verification of a consumer’s prescription from an eye care professional before a sale is made. Without a

prescription or oral order from the prescriber, the seller is not selling contact lenses consistently with the federal prescription requirement. In some states, in addition, laws or regulations specifically require that a contact lens seller must receive a written prescription.

Some companies, including some Internet companies, sell contact lenses without receiving any written or oral verification from an eye care professional. This practice essentially makes the federal and state prescription laws meaningless. And, of course, regardless of whether this practice violates the law, these companies are not protecting the eye health of consumers that buy contact lenses from them.

Some Internet sellers justify their failure to obtain a prescription or oral order of the prescriber before selling contact lenses on the ground that eye doctors refuse to release prescriptions to consumers so that the consumers can provide Internet sellers with copies of their prescriptions. However, the FTC's own data does not support this argument. In 1995, the FTC did a survey to determine whether to amend the eyeglasses rule, which requires release of spectacle prescriptions to consumers, to include contact lenses. The FTC found that 92% of consumers who requested a copy of their contact lens prescription received it. Johnson & Johnson's authorized Internet sellers also do not report any difficulty in obtaining prescriptions from consumers or oral verification from doctors.

At the end of the day, the issue of how often consumers need to see their eye doctor in order to wear contact lenses safely and comfortably is one of health policy, not competition policy. Johnson & Johnson respectfully suggests that questions concerning whether replacement disposable contact lenses should be available without a prescription and how prescription requirements should be administered or enforced are properly addressed by the FDA and state regulatory authorities, rather than by the FTC.

6. “Have manufacturers limited the supply of contact lenses to online vendors, and if so, why?”

From the introduction of its ground-breaking Acuvue® disposable lenses in 1988 until November 2001, Johnson & Johnson exercised its business judgment and sold its lenses only to the eye

care professionals who were licensed to fit and prescribe Johnson & Johnson lenses to their patients. Johnson & Johnson believed that this policy was the best way to grow its business: it provided eye doctors and retail businesses with a reason to prescribe Johnson & Johnson's lenses, while still offering consumers a variety of choices among retail outlets.

In connection with the settlement of an antitrust lawsuit challenging Johnson & Johnson's distribution policy, Johnson & Johnson changed its sales policy and agreed to sell its lenses directly to mail order and Internet businesses, pharmacies, and other companies without eye doctors, provided that these businesses sold lenses based on valid prescriptions and complied with federal and state laws concerning the sale of contact lenses.

Johnson & Johnson takes its new distribution policy and its obligations under its settlement agreement very seriously. It is committed to selling to any appropriate retailer of contact lenses, as long as the retailer will agree to comply with federal and state laws governing the sale and dispensing of contact lenses and to sell lenses based on a valid prescription. Since November 2001, 18 businesses – Internet sellers, mail order sellers, and a pharmacy distributor – have met these conditions and have become authorized Johnson & Johnson accounts, and Johnson & Johnson receives new applications frequently. Johnson & Johnson treats these Internet and mail order accounts just like its other accounts, and does not limit the supply of lenses to these Internet, mail order or pharmacy accounts in any way. Therefore, consumers have online access to an unlimited supply of Johnson & Johnson contact lenses sold by a number of online vendors.