

**Testimony of Dr. Oliver Schein of Baltimore, Maryland
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1101 Vermont Avenue, NW, Suite 700
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Before the Energy and Commerce Subcommittee on Commerce, Trade and
Consumer Protection, U.S. House of Representatives
Hearing on “Contact Lens Sales: Is Market Regulation the Prescription?”
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Thank you, Chairman Stearns, ranking member Schakowsky, and distinguished committee members for inviting me here to testify on the Contact Lens Consumer Protection Act.

I am Dr. Oliver Schein. I am a Professor of Ophthalmology at the Wilmer Eye Institute of Johns Hopkins University School of Medicine. I am a specialist in corneal diseases, and my research expertise is in public health and blindness prevention. Contact lenses are the most commonly used medical devices in the United States, and I have spent many years studying complications associated with contact lenses. I am here today as a member of the American Academy of Ophthalmology, the largest national membership association of Eye M.D.s. Eye M.D.s are medical doctors who provide comprehensive medical, surgical, and optical eye care. More than 90 percent of the 17,000 practicing Eye M.D.s in the United States are members of the Academy

The *Contact Lens Consumer Protection Act (H.R. 5762)*, seeks to amend Public Law 108-164, the Fairness to Contact Lens Consumers Act (FCLCA). H.R. 5762 requires contact lens manufacturers to make any contact lens they produce, market, distribute, or sell available to specified alternative channels of distribution such as mail order

companies, Internet retailers, pharmacies, buying clubs, department stores, and mass merchandise outlets. Under this system, no limited distribution programs could be implemented by any contact lens manufacturer.

As part of the Fairness to Contact Lens Consumers Act (FCLCA), the Federal Trade Commission was required to undertake a study¹ to examine the strength of competition in the sale of prescription contact lenses.

The study included these issues:

1. Incidence of exclusive relationships between prescribers or sellers and manufacturers and the impact (if any) of such relationships and competition
2. Difference between online and offline sellers of contact lenses, including price, access, and availability
3. Incidence of, as well as the effect on consumers and competition of contact lens prescriptions that specified brand name or custom labeled lenses
4. Any other issue that has an impact on competition in the sale of prescription contact lenses

¹ The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study, February 2005

In February of 2005, the Federal Trade Commission submitted the results of that study to Congress and concluded:

“Our examination of these issues – exclusive relationships, private label lenses, and limited distribution lenses – suggests that such relationships are not prevalent in the market for contact lenses and are unlikely to limit competition and harm consumers.

Exclusive relationships are rare; private label lenses, while more common, still represent a small portion of all sales of soft contact lenses; and limited distribution policies are not widely used. Moreover, our inquiry showed that a common, limited distribution lens, or its private label equivalent, was available from the overwhelming majority of outlets sampled.

Given that the FCLCA permits sellers to fill prescriptions with equivalent national brand or private label lenses, consumers have a number of channels through which to obtain such lenses. In addition, these relationships may be an efficient way for manufacturers to provide beneficial incentives to their lens distributors, which in turn may lead to increased competition among various brands of lenses.

In sum, the theory and the evidence examined do not support the conclusion that these distribution practices harm competition and consumers by allowing prescribers to lock in their patients to supracompetitively priced lenses”.

In light of these findings, the American Academy of Ophthalmology wonders why there would be any need for *H.R.5762*.

The Fairness to Contact Lens Consumers Act was signed into law on December 6, 2003 and took effect on February 4, 2004. The Federal Trade Commission issued its Contact Lens Rule to implement the Act on June 29, 2004 and the Rule became effective on August 2, 2004. After nearly two years of experience with the Contact Lens Rule, the American Academy of Ophthalmology remains concerned that this rule places the eye health of America's contact lens wearers at risk.

Of principal concern is the so-called "passive verification" of contact lens prescriptions. Mr. Chairman, the entire concept of "passive" or "default" prescription verification is unprecedented in medicine. Prescriptions for pharmaceuticals and all other medical devices are positively verified. Contact lenses are medical devices and as such, are regulated by the FDA. The Academy believes that in the interest of patient safety, contact lens prescriptions should also be positively verified prior to being dispensed to the contact lens wearer.

Unfortunately, under the current the rule, a contact lens prescription can be dispensed simply because a "prescriber fails to communicate with the seller within eight business hours" after a seller has contacted the prescriber for the purpose of verifying a contact lens prescription. In practical terms, contact lens sellers treat a non-response from a prescriber in exactly the same manner as they would a positive response; the contact lenses in both instances are dispensed to the consumer. In other words, the prescription is

dispensed unless the seller is told otherwise.

Prescriptions for pharmaceuticals and all other medical devices are positively verified and are not dispensed until the prescription is determined to be valid by the dispenser and in many if not all instances, the DEA or Medical License number of the prescribing physician is determined to be legitimate. Mr. Chairman, under the current Contact Lens Rule, the potential for serious sight threatening ocular injury occurring as a direct result of the passive verification of contact lens prescriptions is significant and real. The potential for injury is real because we know that the leading cause of consumer product-related ocular trauma is from contact lenses².

There is little doubt that the passive or default verification of contact lens prescriptions increases the likelihood that expired or inaccurate prescriptions will ultimately be dispensed to consumers. This likelihood is increased when some contact lens sellers make it difficult, if not impossible, to be contacted by prescribers who are trying to inform the seller that the prescription in question is not valid or inaccurate and therefore should not be dispensed. The inability of dispensers to be contacted by prescribers is a clear violation of the FCLCA and FTC, to date, has issued several warning letters to dispensers requesting that they provide prescribers with a reasonable opportunity to communicate with them regarding prescription verification requests.

Mr. Chairman, what concerns me as an ophthalmologist is the possibility that countless

² Consumer Product-Related Ocular Trauma, Claude L. Cowan Jr., MD, et al, Washington, DC

contact lens prescriptions that are expired, are being dispensed by sellers as a result of “passive” or “default” verification.

The responsible and ethical contact lens practitioner endeavors to optimize the safety and comfort of his or her patients by first evaluating the patient, fitting the lenses and then managing the patient’s contact lens wear. Accordingly, ongoing periodic evaluations after the initial prescription are very important to the patient’s overall eye health.

However, because patients can obtain replacement lenses so easily from online providers, they often neglect follow-up exams.

Unlike glasses, with contact lenses there is a greater opportunity to endanger your eye health. Poorly fit contact lenses, along with poor maintenance and hygiene leave patients susceptible to corneal inflammation, bacterial, and other infections that can ultimately be sight threatening.

It is not uncommon for an eye care professional to see patients that have not maintained periodic follow up evaluations. Such patients typically present with an assortment of chronic corneal conditions that could easily have been prevented or ameliorated by regularly scheduled evaluations by an eye care professional.

There is consensus in eye care practice that there is a direct correlation between non-compliance and poor hygiene practices and contact lens related adverse events.

Moreover, it is understood that 50 percent of all contact lens wearers, to some degree, are non-compliant with the hygiene instructions that they DO receive so it should come as no

surprise that up to 80 percent of contact lens complications can be traced to poor patient compliance with recommended lens care guidelines³. Mr. Chairman, these statistics underscore the importance of regularly scheduled evaluations for contact lens wearers and why the dispensing of expired contact lens prescriptions by way of passive verification undermines patient safety.

When a contact lens wearer is required to present a new or current prescription to order contact lenses, it increases the likelihood that the patient will undergo an ophthalmic evaluation by an eye care professional. This, in turn allows for the early detection of contact lens-associated adverse events. It also provides the opportunity to evaluate and improve the patient's compliance with optimal hygiene protocols. It is important that all contact lens wearers receive professional eye care on a regular basis, at the very least, to reinforce good contact lens hygiene practices.

One of my colleagues recently reported that a 45 year-old patient had his contact lenses dispensed by a contact lens seller for *three years* without an eye exam. The patient presented in August of 2005 with a severe bacterial corneal ulcer, requiring a three day hospitalization. Nine months later, the corneal scar still exists with diminished visual acuity to 20/30. As recently as last week, I treated a college student in Baltimore with a severe contact lens-related keratitis. She obtains her contact lenses from internet sources and has not had regular care in several years. When I investigated her contact lens hygiene practices, I learned that she has used the same small bottle of cleaning solution for more than 3 years. Whenever, it approached being empty, she refilled it from a larger

³ Clinical Survey of Lens Care in Contact Lens Patients, Susan Stenson, MD, et al

bottle. The same bacteria growing in her cornea was cultured from that small bottle. These sorts of stories are familiar to corneal specialists across the United States. The implication is not that internet purchase causes such infections. It is that internet purchase reduces the likelihood of periodic examinations and review of sound contact lens practice.

Extended wear lenses, are regulated as class-three medical devices, which is the most highly regulated FDA medical device category. Passive or default verification of contact lens prescriptions undermines the status of contact lenses as FDA regulated devices and in essence, denigrates the need for a prescription at all. Passive verification is a flaw in the FCLCA that the American Academy of Ophthalmology believes lowers the bar for patient safety and opens the door for prescription verification failures that can ultimately result in patient harm. Unless the seller has a copy of the prescription or it has been positively verified by the doctor, any other verification system seems at odds with FDA's medically based decision to regulate contact lenses as medical devices.

In conclusion, the ocular health of consumers should not be placed at risk by methods used by contact lens sellers that are designed solely to augment the sales and dispensing of contact lenses. Since the Contact Lens Rule went into effect in August 2004, dispensers have compiled a long history of verification abuses that consistently place contact lens sales before patient safety.

The American Academy of Ophthalmology remains hopeful that Congress will put the ocular health of America's contact lens wearers first by re-examining the practice and

occurrence of passive or default contact lens prescription verifications and then opting to eliminate them altogether.

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