



August 22, 2002

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FEDERAL AFFAIRS DEPARTMENT

Dear Dr. Crawford,

It has come to our attention that the FDA is looking at the issue of regulation of Nonprescription Contact Lenses. There is growing concern among the membership of the American Academy of Ophthalmology about the risks to the public from use of these nonprescription lenses resulting in the attached warning released in July (attached). We strongly support FDA policy that regulates these lenses as medical devices and want to work with you to ensure that the policy is in the best interest of the public health.

Historically, all contact lenses, including tinted and costume lenses, have been considered and evaluated as medical devices by the U.S. Food and Drug Administration. Further, FDA requires a prescription from an eye health care professional, such as an ophthalmologist. Just because the cosmetic lenses have no power in them does not preclude the necessity of insuring a good fit of the lens to the cornea, which can only be performed by an eye care professional. Although contact lenses provide visual and cosmetic benefits, their use carries some risk of ocular complications, the most serious being microbial keratitis, which can lead to vision loss. Thus, proper evaluation and fitting and instruction on the care, cleaning and wear of contact lenses is important to reduce the risk of ocular complications.

Risks associated with improper wear, care and cleaning of contact lenses include allergic reactions, bacterial infections, corneal abrasions and corneal ulcers, and other changes such as epithelial keratopathy, corneal thinning, corneal neovascularization, and corneal warpage. In some patients, contact lenses may not be advisable because of significant pre-existing conditions such as eyelid abnormalities, tear film, or cornea abnormalities.

In view of problems we are seeing related to these nonprescription lenses, I would hope that the FDA would give this issue long and careful review. Thank you for your consideration. Please do not hesitate to contact Catherine Cohen in our Washington office or myself, if we can be of assistance.

Sincerely,

William Rich, III, M.D.
Secretary, Federal Affairs

For Immediate Release

July 10, 2002

American Academy of Ophthalmology Warns Young People at Risk of Eye Damage from Use of Nonprescription Contact Lenses

(San Francisco)—Recently, ophthalmologist Gail Royal, MD, of Myrtle Beach, S.C., saw several teenage and young adult patients in one week. They were all suffering from problems associated with wearing costume and tinted contact lenses they had purchased without prescriptions, mostly from beachwear stores.

"This has become a serious problem in this area," said Dr. Royal. "These contact lenses are very popular among young people. Unfortunately, they don't realize how dangerous contact lenses can be, especially when not handled correctly."

According to the Food and Drug Administration, contact lenses, including costume and tinted lenses, are considered medical devices and must be prescribed by an eye health care professional, such as an ophthalmologist.

"Many people mistakenly think that just because they aren't wearing contact lenses to correct a refractive error, like nearsightedness, they don't need a prescription," said Dr. Terrence P. O'Brien, Associate Professor of Ophthalmology and Director of Ocular Infectious Diseases at the Wilmer Eye Institute, Johns Hopkins Hospital in Baltimore, and a spokesperson for the American Academy of Ophthalmology, the Eye M.D. Association, "but that is not the case. Contact lenses are medical devices that require specific shape parameters for proper fit."

"Also," Dr. O'Brien continued, "it's a pretty safe bet to assume that people buying contact lenses from these beachwear stores aren't being told how to clean and care for the lenses, or how long they can safely be worn," he said. "This can lead to potentially serious complications, including bacterial infections, corneal abrasions, corneal ulcers and allergic reactions. To avoid such problems, it's important that people have their contact lenses fitted properly by an eye health care professional, such as an ophthalmologist. Ill-fitting lenses can result in permanent damage to the cornea, and even vision loss."

Dr. Royal said many of her patients wore the contact lenses all night while at parties or dancing. "Unless contact lenses are made from a special material that allows high oxygen absorption by the cornea, they should never be worn overnight." Furthermore, Dr. Royal emphasized, "We don't even know what materials these contacts are made of, or if they are approved by the FDA. The vials they come in that I've seen have had no labels identifying the manufacturer."

Other problems she encountered resulted from patients' swimming in their contact

lenses, or getting sand in them. She said contact lens wearers also exchange them with each other. "This is really dangerous," she said. "It can lead to the spread of bacteria, viruses, fungi and amoebae that cause eye disease. It is sad that such a frivolous choice can lead to such dire health consequences."

The American Academy of Ophthalmology is the world's largest association of eye physicians and surgeons—Eye M.D.s—with more than 27,000 members worldwide. To find out more about eye health care, visit the Academy's partner Web site at www.medem.com. To find an Eye M.D. in your area, visit the Academy's Web site at www.aao.org.

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