

**Congress of the United States**  
**House of Representatives**  
**Washington, D.C. 20515**

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**Rep. Boozman and Rep. Waxman Introduce  
Bipartisan Bill to Protect Consumers from Unsafe Contact Lenses**

Rep. John Boozman (R-AR) and Rep. Henry A. Waxman (D-CA) today introduced legislation to require that the Food and Drug Administration (FDA) regulate noncorrective colored contact lenses as medical devices. H.R. 2218 was introduced just several weeks after the FDA began to regulate these lenses as cosmetics, eliminating many safety standards. Contact lenses that are improperly manufactured or used without appropriate medical supervision can cause serious eye infections and loss of vision.

“As an eye doctor, I am well aware of the dangers that colored lenses pose. Optometrists and ophthalmologists have seen significant injuries from the misuse of these lenses and unfortunately, in many cases, it is a teenager who is trying to follow the latest fad,” said Rep. Boozman, who is an optometrist. “These injuries will continue if we do not close this loophole and regulate colored contact lenses the same way as prescription contact lenses.”

“As long as FDA treats colored contact lenses in the same class as lipstick, consumers are in danger,” said Rep. Waxman. “These products can cause blindness if poorly made or misused and must be regulated as medical devices to ensure safety.”

For years, FDA properly regulated noncorrective contact lenses as medical devices. On October 21, 2002, FDA warned consumers against using these lenses without a prescription or professional fitting.

In an April 4, 2003, notice in the *Federal Register*, FDA announced that the agency now classifies noncorrective lenses as cosmetics. As a result, FDA cannot review the safety of these lenses before they are sold to the public, cannot set “good manufacturing practices” for manufacturers, cannot require the supervision of a health care professional, and cannot require that adverse events be reported promptly. While FDA has taken action to detain imported noncorrective lenses prior to sale, the agency can only protect consumers from dangerous domestic products after they have already been marketed and consumers are at risk.

The sale of noncorrective colored contact lenses in flea markets, gas stations and video stores has been reported across the country. Eye care practitioners have called attention to a number of serious injuries, including among children who are often unaware and uninformed of the proper use and care of contact lenses.

Organizations supporting Rep. Boozman and Rep. Waxman's bipartisan effort include major professional, patient advocacy, and industry groups. These include the American Optometric Association, the American Academy of Ophthalmology, the Contact Lens Association of Ophthalmologists, Prevent Blindness America, and the Contact Lens Institute.

Five House members who are medical professionals are original cosponsors of the legislation.