

June 23, 2003

Honorable Henry Waxman
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Waxman,

On behalf of the 57,000 pediatricians represented by the American Academy of Pediatrics, I write to express our support for H.R. 2218, legislation that would ensure that non-prescription (e.g., colored or decorative) lenses be classified by the Food and Drug Administration (FDA) under the strict standard of medical device to reduce the risk of injury or infection by consumers.

The AAP wrote Secretary Thompson in September 2002 expressing our opposition to efforts by the FDA to reclassify colored contact lenses from a medical device to the status of a cosmetic. We were disappointed to learn that in April 2003, the FDA announced that it now considers decorative lenses to be cosmetics.

In the image-conscious world of adolescence, non-corrective colored contact lenses are viewed as a harmless novelty. However, like prescription contact lenses, there are significant risks with improperly using lenses and use can result in medical complications such as severe infections, ulceration, lacerations or in extreme cases, scarring of the cornea.

It is essential that anyone wearing any kind of contact lenses be properly fitted for those lenses and receive guidance from medical professionals as to their appropriate use. If the wearer does not adhere to specific medical and safety precautions (i.e., proper sanitation of the lenses, limiting hours of daily use, etc.) their risk of complications is greatly increased and can result in short and long term health implications ranging from eye pain to serious cornea disease and even blindness. Unless Congress acts, colored/decorative contact lenses would be reclassified as a cosmetic, thus becoming widely available over the counter without any guarantees that they have been properly manufactured or that they can be used safely.

The Academy thanks you for your work on this legislation and welcome the opportunity to work with you to move this forward. Please feel free to contact Elaine Vining, Department of Federal Affairs (202/347-8600), or me if I can be of further assistance.

Sincerely,



E. Stephen Edwards, MD, FAAP
President

EHV/kdg