MINORITY STAFF
COMMITTEE ON GOVERNMENT REFORM
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FACT SHEET

FDA's New Policy on Noncorrective Contact Lenses

Noncorrective contact lenses, such as those with colors and special designs, pose the same health risks as clear contact lenses that correct vision. Without appropriate care and medical supervision, consumers wearing noncorrective lenses can suffer eye infections, scarring, and blindness.[1] Children who have purchased these products illegally have suffered injuries severe enough to require corneal transplant.[2]

Until recently, the Food and Drug Administration (FDA) has publicly claimed jurisdiction over all contact lenses, including noncorrective lenses, as medical devices. Medical devices must be screened by the FDA before marketing and are subject to rigorous requirements to ensure their safety. On April 4, 2003, however, the FDA announced that it now considers noncorrective lenses to be cosmetics,[3] a classification that eliminates most of the safety requirements imposed on medical devices.

According to legal and eye care experts, the FDA's decision to regulate noncorrective lenses as cosmetics places the public at risk from unsafe products and could undermine confidence in all contact lenses.

Here are several key points on FDA's new policy:

- **Regulating noncorrective contact lenses as cosmetics risks eye injuries**

  Medical device regulation is the most protective level of oversight FDA can apply to any product that is not a drug. FDA must review the safety and effectiveness of devices before they are ever sold to the public. Companies must follow standardized

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1 See, e.g., R. Snyder, M. Brenner, L. Wiley, et. al., *Microbial Keratitis Associated with Plano Tinted Contact Lenses*, Contact Lens Association of Opthalmologists Journal, 252-5 (1991); Myron Yanoff and Jay S. Duker, *Opthalmology* (1999).

2 *Health Concerns Tinge Use of Contact Lenses*, Los Angeles Times (Aug. 26, 2002).

3 65 CFR 16520–16522.

manufacturing processes to reduce the risk of injury or infection to consumers. FDA can require that a device be available only by prescription. If adverse events occur, companies must report them quickly to FDA. FDA can also require specific labeling, including directions for safe use.

By comparison, FDA's authority to regulate cosmetics is quite limited. FDA does not review cosmetics for safety or effectiveness before they are sold to the public. While the agency can detain suspect imported cosmetics prior to sale, FDA can only take action against products manufactured domestically after they have already been marketed. The agency cannot require cosmetic manufacturers to test for safety problems, cannot set "good manufacturing practices" for cosmetics, cannot require reporting of adverse events, and cannot require that cosmetics carry directions for safe use. FDA cannot require that cosmetics be used under the supervision of an eye care professional. Unlike for medical devices, FDA does not even have a formal mechanism to learn of the existence or location of cosmetics manufacturers.

- **When noncorrective contact lenses are cosmetics, related products do not need to pass safety standards**

  Prior to FDA's April 4 announcement, all solutions used to clean and preserve contact lenses were automatically regulated as medical devices by FDA. This classification allowed the agency to impose manufacturing standards to assure sterility and safety. FDA's decision to reclassify noncorrective contact lenses as cosmetics, however, has opened the door for manufacturers to market solutions only for the cosmetic lenses. FDA would not be able to apply any safety standards to these products prior to marketing, risking additional eye injuries.

- **FDA's recent actions to protect the public from noncorrective contact lenses can be challenged and evaded**

  While FDA recognizes the danger posed by noncorrective lenses in the absence of strict oversight, it can only take half measures to protect the public under cosmetics law. On April 4, FDA issued an import alert to allow for the detention of decorative contact lenses.[4] The agency cited three grounds for the action: (1) the products are adulterated by the matrix of the contact lens; (2) the products may contain color additives not specifically approved for use in cosmetics; and (3) the instructions for use may be inadequate.

  All of these grounds may be challenged in court. A company could argue that the matrix of the lens is no different from the matrix in approved device lenses and therefore cannot be physically adulterated. It could show that all of its color additives are approved, and it could add some instructions for use to the package. The products might then be sold

[4] 65 CFR 16520–16522

without safety standards for manufacturing, adverse event reporting and without necessary medical supervision.

Moreover, FDA's ability to detain cosmetics prior to sales is limited to imports. A domestic company manufacturing decorative lenses could market dangerous products first and then force FDA to seek a court order to stop them after consumers have already been injured. The ensuing proceeding could be expensive and time-consuming, and the burden of proof on FDA could be high. Meanwhile, the lenses would remain on the market.

- **With FDA unwilling to reverse its judgment, a new law is urgently needed**

FDA's justification for changing the regulatory status of noncorrective lenses relates to a separate debate over classification of products in food and drug law. Others outside the agency disagree with the FDA's position. Regardless, with FDA unlikely to reverse course on its own, Congress should pass a law clarifying that all contact lenses are medical devices. Such a step would maintain the level of safety oversight that has existed until now and could be crafted to be neutral on the legal dispute over the classification of products in food and drug law.

Unless Congress acts, noncorrective, colored contact lenses could become widely available over-the- counter without any assurance that they have been properly manufactured or that they can be used safely.