United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510-6300

September 4, 2002

The Honorable Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

I am writing because I understand, and the Los Angeles Times has recently reported, that the Food and Drug Administration is proposing to classify colored contact lenses that do not correct vision as cosmetics and no longer regulate them as devices under the Federal Food, Drug, and Cosmetic Act. In my view, this change would be a serious mistake, both as to its immediate effect and its broader effects on public health. I urge you to stop any such move.

Most significantly, a contact lens that is not properly designed, manufactured, and fitted can cause serious injuries to the eye, including blindness, as reports of injuries related to use of black-market contact lenses in Myrtle Beach, South Carolina, show. Regulation of colored contact lenses as cosmetics – for which there are no premarket review by FDA, no adequate labeling requirements, no good manufacturing practice requirements, and no requirements that they be dispensed by prescription – simply would not provide adequate assurance to the public that these products are safe.

In addition, I understand that the rationale for this decision is that these lenses are not "intended" to correct vision and are only "claimed" to color the eye, and so are not devices . This interpretation of the law is unprecedented and it sets a terrible precedent in other areas. It is critical that, whatever decisions FDA makes with regard to specific products, the broad authority of the agency must be maintained and not undermined by novel interpretations of that authority that would have a profound, negative impact on public health.

First, color contact lenses obviously and unavoidably affect oxygenation and wetting of the cornea, and so must be understood as intending those effects on the structure or function of the body. As such, they are subject to regulation as devices under the Federal Food, Drug, and Cosmetic Act.

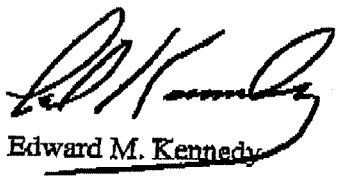
Second, saying the statutory term "intended" means "claimed" flies in the face of the plain meaning of the statute. It also equates FDA's regulation of the intended use of products with regulation of claims about those products. This places FDA's jurisdictional regulation of

intended use, which does not implicate the First Amendment of the Constitution, squarely under the First Amendment. Simply put, this interpretation of the statute could eviscerate FDA's regulatory authority, thwart Congressional intent, and severely harm public health, all under the guise of the First Amendment.

I also have serious concerns about the process that FDA is using to make this unprecedented change. In my view, this change of interpretation – if permissible under the Federal Food, Drug, and Cosmetic Act at all – requires notice and comment rule making under the Administrative Procedure Act. At minimum, it requires compliance with the procedures for the development of guidance documents under FDA's statute. Yet, according to the Los Angeles Times, the FDA apparently intends to make this change after a private meeting with a company that requested the change, without the agency seeking public input from health professionals, from patients and consumers, and from the regulated industry. This is simply unacceptable.

FDA's plan to deregulate colored contact lenses is bad policy and bad law. I urge you to put a halt to this plan, before it endangers the public health and the nation's confidence in the FDA's ability and determination to protect the public health.

Sincerely,



Edward M. Kennedy