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Congress of the United States

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COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5074
FACSIMILE (202) 225–3974
MINORITY (202) 225–5051
TTY (202) 225–6852

www.house.gov/reform

August 26, 2002

The Honorable Tommy G. Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

Dear Secretary Thompson:

I am writing to alert you to a plan apparently set in motion by the Chief Counsel of the Food and Drug Administration (FDA) to reclassify colored contact lenses that do not correct vision as cosmetics instead of medical devices, essentially deregulating these products. Under current law, manufacturers of colored lenses must meet federal standards of hygiene and sterility and can sell their products only with a prescription. FDA's new plan, however, would eliminate these rules, make colored lenses available over-the-counter without adequate directions for safe use, and depend on an underfunded cosmetics enforcement division with limited safety authority to protect consumers. It would also establish a precedent that could lead to the deregulation of many more potentially hazardous prescription drugs and devices.

Because poor-quality or misused contact lenses can cause severe eye infections, painful corneal disease, and even blindness, the FDA plan virtually guarantees serious medical complications. Indeed, the recent over-the-counter sale of colored lenses in beachwear stores in Myrtle Beach, South Carolina, led to an epidemic of eye injuries, including some in teenagers who had purchased the products without their parent's permission. Ophthalmologists and optometrists find no justification to treat colored lenses differently from corrective contact lenses. I urge you to intervene personally and stop what is a legally unsound and medically dangerous policy. The rest of this letter explains these concerns in more detail.

Colored Contact Lenses and the Law

All contact lenses are currently regulated as medical devices under the Food, Drug, and Cosmetic Act (FDCA). As a result, contact lenses must meet federal requirements, called "good manufacturing practices" (GMPs), which include standards on sterility and hygiene. As medical devices with a potential for harm, contact lenses can be dispensed only with a prescription from

an appropriate health care professional, and must provide adequate directions for safe use, cleaning, and storage.

It makes perfect sense for contact lenses to be considered medical devices. The FDCA defines a medical device as:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is – (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[1]

Contact lenses all qualify as medical devices under the third part of the above definition, as a product that is "intended to affect the structure or any function of the body of man." Lenses unavoidably alter the structure of the body by profoundly altering the biology of the eye. As one leading ophthalmology textbook states:

> A contact lens may be considered to be an optical patch and bandage. As a patch it reduces the availability of oxygen to and the dissipation of carbon dioxide from the cornea. As a bandage it creates pressure on the underlying tissues and reduces wetting of the ocular surface and dissipation of material from between the contact lens and the cornea.[2]

These effects are unavoidable and foreseeable. Any manufacturer of contact lenses that intends for users to place the products in the eye must also intend for these effects to occur.

This longstanding and fair reading of the law, however, has apparently been rejected by the Chief Counsel of FDA, Daniel Troy. Mr. Troy appears to believe that a product is only a "medical device" if it is marketed expressly as something that will affect the structure or function of the body. His argument seems to be that since colored noncorrective contact lenses are not marketed as something to correct a problem (like poor vision), these products cannot be classified as medical devices.

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[1]FDCA, Section 201(h).

[2]Myron Yanoff and Jay S. Duker, *Ophthalmology* (1999).

This reasoning is both wrong and dangerous. It is wrong because of legislative history,[3] administrative precedent,[4] and legal precedent,[5] including cases in which courts have acknowledged FDA's ability to regulate products on the basis of evidence other than express marketing claims.[6] Indeed, two such cases have expressly found that colored noncorrective contact lenses are medical devices.[7] It is dangerous because of its logical consequence. If a medical device or a drug (which is defined using similar terms) must be expressly marketed as a treatment to fall under the FDCA, then manufacturers can simply use their marketing claims to evade regulation altogether. Breast implants and collagen injections marketed for aesthetic appeal and condoms marketed for pleasure would not be medical devices. Botox marketed for cosmetic purposes would not be a drug. A company might even attempt to market valium as "fun" to evade drug regulation.

Mr. Troy's view apparently is that colored noncorrective contact lenses should be regulated as cosmetics. The impact of this change would be tremendous. FDA cannot review cosmetics for safety or effectiveness before they are sold to the public, cannot require cosmetic manufacturers to test for safety problems, does not set "good manufacturing practices" for cosmetics, cannot require a prescription or any medical supervision for cosmetics, does not require that cosmetics carry directions for safe use, has no formal means to learn of the existence or location of cosmetics manufacturers, and can only take action against cosmetic manufacturers

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[3]*See, e.g.,* the House Report on the Medical Device Amendments of 1976, "The Secretary may consider . . . use of a product in determining whether or not it is a device." H.R. Rep. 853, 94th Cong., 2nd Sess. 14 (1976).

[4]FDA's regulations that define "intended use" establish an "objective intent" standard, which means the agency can infer intent from the effects of the product rather than the marketing. *See* 21 CFR 801.5.

[5]It is a well established legal principle that "the law presumes that every man intends the legitimate consequences of his own acts" *Agnew v. United States*, 165 U.S. 36, 53 (1897). The impact on the structure of the eye is a legitimate consequence of the sale of contact lenses.

[6] *United States. v. Undetermined Quantities . . . "Pet Smellfree,"* 22 F. 3rd 235 (10th Cir. 1994); *United States v. Storage spaces Designated Nos. "8" and "49,"* 777 F.2d 1363 (9th Cir. 1985), *cert. denied*, 479 U.S. 1086 (1987); *United States v. An Article of Device . . . Labeled in part: "Cameron Spitler Amblo-Syntonizer,"* 261 F. Supp. 243, 245 (D. Neb. 1966).

[7]*United States v. International Hydron Corp.*, No. 87-2129 (E.D.N.Y. 1986); *United States v. Articles of Device . . .*, Case No. 79-1529-SAW (N.D. 1980) (unpublished decision).

once consumers have been harmed. Furthermore, there is no adverse event reporting for cosmetics comparable to what exists for medical devices, making it far more difficult for the agency to detect problems. FDA's enforcement of the very limited post-marketing controls applicable to cosmetics is woefully underfunded, and the agency would not be able to police the market effectively.

The Dangers of Deregulating Colored Contact Lenses

A legal decision to classify colored lenses as cosmetics rather than devices would also have profound medical consequences. As foreign bodies in the eye, contact lenses pose serious risks. The products can cause staining, inflammation, swelling, blistering, and painful ulceration of the cornea, the protective outer layer of the eye. They can lead to loss of oxygen to the eye, severe eye infections, giant papillary conjunctivitis, and even loss of vision.[8] Deregulation of some of these devices, as planned by FDA, can be expected to cause harm in at least five ways.

First, without a prescription that specifies the right size, many consumers will purchase lenses that do not fit their eyes properly. Some consumers will purchase lenses that are too tight, reducing the flow of oxygen to the eye's surface and increasing the risk of inflammation and infection. Others will purchase lenses that are too loose and are constantly shifting position and obscuring vision. A few particularly unfortunate consumers, whose eye characteristics make contact lens wear inherently dangerous,[9] will receive no warning of this ahead of time. Because of the need for professional supervision, FDA currently advises consumers, "Contact lenses that are not properly fitted by an eye doctor might not work well, or even worse, may harm your eyes."[10]

Second, without the requirement of a prescription, many contact lens wearers will not obtain needed followup medical care. FDA currently warns:

> Contact lens wear causes many changes to cells and tissues of the eye, and sometimes wearing contact lenses can damage the cornea (the clear window of the eye). *Even if you are currently experiencing no problems, the lenses may be causing damage to your eyes.*

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[8]Myron Yanoff and Jay S. Duker, *supra* note 2.

[9]American Academy of Ophthalmology, *Information Statement: Use of NonPrescription Contact Lenses* (August 2002).

[10]U.S. Food and Drug Administration, *Buying Contact Lenses on the Internet, by Phone, or by Mail: Questions and Answers* (May 21, 2001) (online at http://www.fda.gov/cdrh/consumer/buycontactqa.html).

> Regular check-ups will reduce the likelihood of damage going undetected. [Emphasis in original.][11]

If contact lenses are sold as cosmetics at flea markets or beachwear stores, consumers will have little opportunity to recognize the essential need for followup – increasing the risk of complication.

Third, because lenses marketed as cosmetics cannot be required to be labeled with adequate directions for use, purchasers may not be informed of the potentially severe hazards of overwear of the products.[12] For example, teens who purchase colored contact lenses for a party and fall asleep wearing them can suffer severe eye injuries, including painful and scarring corneal disease, by the morning.

Fourth, without manufacturing standards on sterility and hygiene, products are far more likely to be sold contaminated with organisms that can cause severe eye infections. Such organisms include the bacteria *Pseudomonas* and the amoeba *Acanthamoeba*, both of which can cause blindness.[13]

Fifth, treating colored lenses as cosmetics poses a special risk to children. Without their parents' permission or even knowledge, teens (as well as younger children) will be able to purchase lenses and even share them with their friends (increasing the risk of infection). In no other area of medicine are children allowed to expose themselves to such risky medical practices without their parent's consent and participation.

These risks are not hypothetical. Early this summer, some beachwear stores in Myrtle Beach, South Carolina were selling colored contact lenses over the counter in violation of federal law. The adverse health effects were immediate. According to Dr. Gail Royal, an ophthalmologist at Coastal Eye Group in Myrtle Beach, "This year we're having an epidemic . . .

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[11] *Id.*

[12] E-mail communication from Dr. Allan Slomovic, Chairperson of the Canadian Cornea/External Disease and Refractive Society, to minority staff of the Government Reform Committee (Aug. 21, 2002).

[13] E-mail communication from Bruce H. Koffler, M.D., President, Contact Lens Association of Ophthalmologists, to minority staff of the Government Reform Committee (Aug. 21, 2002).

I'm seeing everything from corneal swelling to blistering of the cornea to ulcers. I saw one child who tore his entire corneal surface."[14]

The Myrtle Beach experience is a harbinger of what is in store for the rest of the country should FDA deregulate these products. A leading ophthalmologist in Cleveland has also reported several severe eye complications in teenagers associated with illegally dispensed cosmetic colored lenses, including one who required a corneal transplant to preserve vision.[15]

Leading eye experts have told me that there is medical justification for treating colored noncorrective (or plano) lenses and those that correct for visual problems. Rob Davis, former chair of the contact lens and cornea section of the American Optometric Association, said, "the very real health considerations associated with improper fit and wearing of lenses applies equally to both plano [non-corrective] and corrective lenses."[16] Dr. Bruce H. Koffler, president of the Contact Lens Association of Ophthalmologists (CLAO) agreed: "It absolutely does not matter whether a contact lens is prescribed as plano. . . or prescribed with a specified power for vision correction. The physical and physiological impacts are the same, as is the great concern of the possibility of ocular infection."[17]

Conclusion

FDA's plan to deregulate colored contact lenses may prove to be a financial windfall for some companies, but it will penalize real people, including teenagers, who will wind up with severe eye infections, painful corneal disease, and even blindness. It is ill-advised health policy

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[14]*Colored Contact Lenses Pose Risk; Serious Eye Problems Can Result From Using Popular Beachfront Store Items*, The State (June 30, 2002).

[15]E-mail communication from Thomas L. Steinemann, M.D., Eye Clinic Director of MetroHealth Medical Center, to minority staff of the Government Reform Committee (Aug. 22, 2002).

[16]Fax communication from Rob Davis, O.D., to minority staff of the Government Reform Committee (Aug. 21, 2002).

[17]Bruce H. Koffler, *supra* note 13.

to treat corrective contact lenses as medical devices requiring strict government oversight, but colored contact lenses as cosmetics – when both have similar impact on the structure of the eye and pose the same risks to consumers.

I urge you to stop this plan before it takes effect and endangers the American public.

Sincerely,

Henry A. Waxman
Ranking Minority Member