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Moman's Eyecare  
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FDA Colored Contact lens issue  
Docket #03D-0118

To whom it may concern:

It is my understanding that the FDA has made a ruling that colored contact lenses are no longer to be classified as medical devices and therefore a prescription is no longer necessary to purchase these lenses. As an eye doctor, let me share with you why this is a dangerous decision. First of all let me assure you that the reason for my feelings are not financial in any respect. Businesses such as 1-800-Contacts have made the private doctor's margin on contact lenses disappear. I release my patient's prescription at their request and allow them to purchase their contacts wherever they chose, because it is just not worth the hassle for the small amount of revenue generated in my practice.

Everyday I see patients who abuse their contact lenses. Not just colored lenses, but all contact lenses. Patients do not understand that although there is some oxygen transmitted to the cornea through a contact lens, it is not as if you have no lens in place. Patients also wear their lenses past the useful life of the lens, wearing lenses with protein deposits and tears. I have seen these problems cause corneal abrasions and ulcerations, routinely. Opaque colored lenses have a print on the lens that make proteins adhere more vigorously. There is also the issue of fit with these lenses. Because the lens is partially opaque, it is crucial for the lens to center correctly for the patient to have clear vision. Just yesterday I saw a patient who was wearing opaque lenses that were badly decentered and it was affecting her acuity. I had to change the base curve of the lens to get an appropriate fit. How does a patient or an untrained sales clerk determine whether a lens is fitting correctly? More importantly, how does a patient or clerk know if damage is being done to the cornea after lens wear? It has been my experience that even the most compliant patient can have contact lens complications. It doesn't seem fair to me that I have patients who are very compliant who have ulcerations and wear issues and at the same time I have other patients who abuse their lenses without incident. The problem is there is no way to determine which patients can tolerate the abuse and those who can not tolerate compliant wear. If clear lenses are considered a medical device because they affect the physiology of the eye, then colored lenses should be considered in the same way. They also affect the physiology of the eye and the health of the eye needs to be followed by a licensed professional.

Sincerely,

*Karen D. Smith, O.D.*

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