Impact of Public Law 109-96 ("Plano Contact Lens Law")

On November 9, 2005, President George W. Bush signed into law Public Law 109-96 (S. 172 – the bill that reclassified plano contact lenses as medical devices rather than cosmetics). This new law definitively classifies all contact lenses as medical devices under the Federal Food, Drug, and Cosmetic Act (FDA Act).

What this reclassification as a medical device means is that all contact lenses, even plano or zero refraction lenses, come under certain specified protections afforded medical devices under other provisions of the FDA Act – specifically, Sections 351, 352, 360, and 360i of Title 21 of the United States Code, and by further provisions of those sections, also Sections 360c, 360d, 360e, 360h, and 360j. Those protections, in simplified form, are as follows [keeping in mind that the Food and Drug Administration (FDA) retains its regulatory authority to choose the correct classification category and requirements for the device]:

1. The need for a prescription to dispense the device.
2. Formal classification of the device by the FDA, which triggers other burdens on the manufacturer.
3. The manufacturer of the device being subject to registration with the Food and Drug Administration (FDA) and being subject to reporting and record-keeping requirements of the FDA.
4. Strict labeling requirements for the device and any packaging for the device.
5. Strict quality standards for the safe production and storage of the device.
6. Having to meet specified performance standards for the product.
7. Having to obtain approvals from the FDA for marketing the product.
8. Being subject to serious penalties, including fines, seizure and forfeiture, public notification and recall, bans, and criminal prosecution for certain violations of the FDA requirements and/or for placing the public health at risk.
9. Being subject to state laws as medical devices.

The reclassification as a medical device also triggers all state law requirements that previously would have applied to medical devices, but which may not have been applicable to cosmetics. During the two-year period when the FDA had classified plano lenses as cosmetics, many state law requirements were circumvented because they applied only to medical devices. Now those state medical device laws can once again be applied to plano lenses, especially state contact lens prescription laws.

Those are the major effects of the new "Plano Contact Lens Law", known officially as Public Law 109-96. The same protections afforded to typical contact lenses are now afforded to plano lenses too. No distinction is drawn between the two under the new law. However, the FDA still retains regulatory discretion to set such items as performance standards, market approvals, and prescription requirements on a case-by-case basis. The top priority of the American Optometric Association (AOA) will be to see that the FDA does not weaken or minimize any prescription requirements for plano lenses. FDA precedent for other contact lenses is a critical element in this area, and contact lenses of all kinds had previously required a prescription to dispense. So, it is legally highly unlikely that the FDA would contradict its own precedents here, as the FDA Act contains requirements that similar items be classified similarly in the absence of good and valid reasons not to do so. The second priority for the AOA will be to see that the FDA adopts a vigorous enforcement policy against any violators, especially now that the FDA has a much stronger arsenal of remedies to go after violators of the medical device provisions of the FDA Act than they did under the cosmetic provisions of the FDA Act.