Letters

ALARMED ABOUT GENERICS

With many physicians' recent shift to generic ophthalmic products, clinicians must begin to police these agents themselves, because it seems obvious that the normal agencies do not. Every ophthalmologist remembers the problems several years ago with generic diclofenac and the associated corneal melting. We have now seen three cases of corneal problems with generic ketorolac and bromfenac associated with the use of these agents around the time of cataract surgery.

That stated, we do not understand why generic ophthalmic medications are only required to show bioequivalence or a comparable rate and extent of absorption. Branded drugs must show preclinical data to establish efficacy and safety in both animal and clinical models, whereas generics are not required to undergo the same rigorous requirements for ophthalmic products. Obviously, all physicians have seen problems with generic formulations. The most obvious is generic prednisolone acetate 1%. Most ophthalmologists realize that the generic is not equivalent to the branded product in terms of efficacy and potency. Assessing bioavailability with systemic medications through blood testing is much easier than monitoring bioavailability in the eye.[1] It is for this reason that we believe generics should be held to the same testing regimens as their branded counterparts with regard to ophthalmic preparations. The preparations are comparable with regard to their chemistry and manufacturing, but their inactive ingredients can vary considerably. Preservatives, pH adjusters, thickening agents, and buffers can differ.[1]

What can physicians do? As with diclofenac, they can begin reporting cases to the appropriate agencies and pushing for generics to be held to the same standards as their branded counterparts. Practitioners should keep clinical photographs and document cases well, because the manufacturers of these products will deny it is in fact their product until adequate proof is given. For the time being, physicians should monitor their patients' use of generic nonsteroidal anti-inflammatory drugs with a watchful eye. We think we will see more of these problems in the near future. ❑

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1. Cantor LB. Ophthalmic generic drug approval process: implications for efficacy and safety. *J Glaucoma.* 1997:6(5):344-359.