# WHEN EQUAL IS NOT EQUAL



Two ophthalmic surgeons discuss the differences between branded and generic medications, as well as when branded medications should be used instead of generics.

BY JODI I. LUCHS, MD, AND BARRY A. SCHECHTER, MD

The following article summarizes a video that features a question-and-answer session on the latest research and clinical data on the use of branded versus generic medications in ophthalmology, and it highlights the formulation differences and challenges faced by surgeons. This video is the second of a four-part series and can be viewed in its entirety at eyetube/series/when-equal-is-not-equal/substituting-branded-with-generic-medications.

**Jodi I. Luchs, MD:** Physicians feel increasing market pressure to prescribe generic medications. For example, when we prescribe certain branded medications, we get phone calls from insurance companies that want us to prescribe generics. Why the pushback? And are generic medications acceptable substitutes, particularly for patients scheduled to undergo ophthalmic surgery?

**Barry A. Schechter, MD:** We certainly face pushback from both insurance companies and patients about the cost of medications, and that can extend to their preference for cheaper generics over branded drugs. In my practice, I find that patients with certain specific diagnoses do well on generic medications—for example, patients with nonsight-threatening acute or allergic conjunctivitis. However, for most other patients, especially patients scheduled for surgery, I think that it is very important to specify branded medications, not generics.

Patients have high expectations for the refractive outcomes of today's technology-driven cataract surgery. Branded medications help us deliver those outcomes. They also meet patients' expectations for ease and convenience with simple protocols, low side effect profiles, and fast action.

**Dr. Luchs:** Why do you specify branded medications for surgical patients? What differences exist between branded and generic medications?

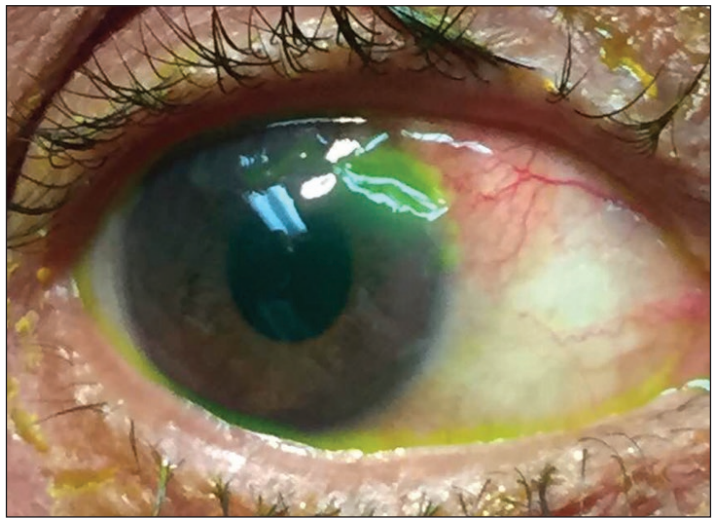

**Figure. Peripheral corneal melt secondary to excessive use of topical nonsteroidal anti-inflammatory drugs.**

**Dr. Schechter:** There are real differences, beginning with the processes for developing branded versus generic medications. When a company is granted a patent by the FDA, it has 20 competition-free years to develop a product, get it to the marketplace, and use it exclusively. When the patent expires, competitors can manufacture an equivalent medication. To be deemed a generic equivalent by the FDA, the competitors' compounds must have the same active component, concentration, and delivery system.

The first issue with these equivalent generics is bioavailability. Generic medications are tested in healthy volunteers, not patients with ocular disease. Bioavailability in unhealthy eyes can vary up to 20% from the branded medication and remain within the FDA's parameters for approval.[1]

The other issue is variability in the formulation. Although

branded and generic drugs contain the identical active compound, the use of different vehicles and additives can have an impact on the drug's efficacy, safety, or tolerability.

**Dr. Luchs:** FDA policies for developing generic medications are based on systemic oral medications, which are subject to the first-pass effect of the liver and do not directly access the target site. But in ophthalmology, we are putting drugs directly on the eye. What are the ramifications of this model? If we apply a generic medication with the same active ingredient as its branded counterpart directly to the eye, is the result identical? Or should we be concerned that differences in the formulation may cause adverse effects?

**Dr. Schechter:** Products with the same active ingredients certainly can produce different results. A sobering example occurred in the late 1990s, when surgeons using a generic compound of diclofenac, substituted for Voltaren (Alcon), found that it caused a significant number of corneal melts.[2] The effects were devastating, and the generic product was discontinued (Figure).

When companies develop new medications, they spend years perfecting the formulation to ensure that it minimizes complications and side effects. Generic formulations do not always receive the same level of study. As you mentioned, the topical nature of ophthalmic medications makes this formulation variability a more delicate issue than we see with systemic generic drugs.

**Dr. Luchs:** When one of your patients is scheduled for cataract surgery, what do you prescribe?

**Dr. Schechter:** I prescribe branded versions of all pre- and postoperative medications. Usually, I have patients start two medications 1 to 3 days preoperatively, depending on any pre-existing pathology such as an epiretinal membrane, ocular surface disease, or history of diabetes.

I prescribe once-daily bromfenac (Prolensa; Bausch + Lomb), a topical nonsteroidal anti-inflammatory eye drop. Bausch + Lomb has continued to refine the active compound, so the drop now contains the lowest possible concentration of the active ingredient while maintaining its efficacy in reducing inflammation and pain. I also prescribe besifloxacin (Besivance; Bausch + Lomb), which is the first fluoroquinolone developed specifically for ophthalmology. Because the drug has not been used systemically, theoretically it should have a lower resistance rate.

Postoperatively, I prescribe loteprednol etabonate gel (Lotemax; Bausch + Lomb). It is an ester modification of a previous steroid, so estrates break down the medication quickly without creating the increase in intraocular pressure that is sometimes seen with steroids. The drug's gel formulation is also very gentle to the ocular surface.

**Dr. Luchs:** What about cost pressure? Insurance companies have said they want us to prescribe generics. For certain branded medications, they deny coverage or charge high copayments. We also know that our patients want to spend wisely, and pharmacists often persuade patients to buy a cheaper generic version of the branded medication we prescribe. Are we missing something? If a generic medication is less expensive, should we be factoring cost into our prescription decisions?

**Dr. Schechter:** In the kind of cases I mentioned where I trust generics, I am happy to save everyone some money. However, for cases where we practitioners feel strongly that a patient's best surgical outcomes are dependent on using a branded medication, then we have an obligation to prescribe that medication, even if it costs somewhat more than the generic.

We also need to educate patients that branded medications are necessary for certain conditions and to not be persuaded at the pharmacy to accept the generic drug substitute. We are up against pharmacies that receive money to push generic formulations, so we need to prepare patients to refuse the generic medication option.

When I explain this to my patients, the conversation centers on the fact that this drug choice will affect their visual outcome. Whether my patient is routine or high risk, will receive a monocular implant or a premium IOLs, I want that individual to have the best possible outcome, and I know that the branded drug will facilitate that outcome. Patients having surgery are sometimes paying out-of-pocket expenses, and the branded drug will help ensure that their investment of time and money pays off with the fullest possible visual advantages. ■

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1. Brian S, Jayat C, Desmis A, et al. Pharmaceutical evaluation of the quality and delivered dose of US latanoprost generics. Abstract presented at: Presented at: ARVO; May 6-9, 2012; Ft. Lauderdale, FL.
2. Department of Veteran Affairs. Corneal melts associated with topically applied nonsteroidal anti-inflammatory drugs. *Trans Am Ophthalmol Soc.* 2001;99:205-210; discussion 210-212.