Are generic medications as effective as brand-name medications?

Before 1984, generic medications had to undergo the same regulatory efficacy and safety testing required for original medications. This requirement often made it non-economical for generic-drug manufacturers to bring generic medications to the market. At that time, only 19 percent of all prescriptions were for generics.

A new law introduced in 1984 simplified the approval process for these products (see Chapter 51), and the law had its intended effect. In 2006, generic medications accounted for 63 percent of all prescriptions with average retail prices between 20 percent and 50 percent of brand-name product costs (see Chapter 17). The use has now increased to about 70 percent.

What is the FDA’s position regarding generics?
When the patent protection for a brand-name drug expires, generic versions of that drug can be approved for sale by the FDA. All generic medications undergo a rigorous, multi-step review process regarding ingredients, quality and performance. The FDA also inspects manufacturing facilities and monitors drug quality. The generic version should work exactly like the brand-name drug; it should be in the same dosage, strength, and performance; and it should have the same approved use. Interestingly, approximately half of all generic drugs are made by the brand-name manufacturers.

What are the differences between generic and brand-name medications?
Generic medications look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect the safety or effectiveness of the generics. Trademark laws in the U.S. do not allow a generic drug to look exactly like other drugs already on the market.

A recent report about the effectiveness of generic extended-release medications has received public attention. Many drugs have unique extended or slow release formulations, which allow medications to be taken once a day, rather than two or three times daily. It has been reported that a dozen generic versions of brand-name extended release medications may differ in their efficacy and safety. The problem surrounds the controlled release of the active drug during 24 hours. The extended-release formulation of some generic medications (including bupropion XL 300) appears to be inferior to the brand-
Chapter 8 - Are generic medications as effective as brand-name medications?
name formulation (including Wellbutrin XL 300). A similar problem has been reported for metoprolol XL and its generic version.

However, the FDA investigated these reports and concluded that “the generic form of bupropion XL 300 (Teva Pharmaceuticals) is bioequivalent and therapeutically equivalent to (interchangeable with) Wellbutrin XL 300.”

**What are the similarities?**
The generics contain the same amount of the active compound as their brand-name equivalents and they undergo strict regulatory and manufacturing reviews. The FDA states that it “makes it tough to become a generic drug in America so you can feel confident about taking your generic drugs.” The agency provides a Web site with more information about generic drugs, at www.fda.gov/cder/ogd.

Some patients may erroneously assume that the cost difference between a brand-name medication and its generic equivalent reflects a difference between the two. However, the manufacturing cost of most brand-name medications is less than 5 percent of the retail price. The high price of brand-name medications is a result of developmental costs, advertising and profit. Generic medications have low developmental costs, yield small profits, and are not promoted.

**Why is there still some skepticism?**
Most patients are content with their generic medications, with the exception of patients who have developed a strong belief and confidence in their brand-name product. If this belief and confidence can be transferred to their generic, the satisfaction with the latter is not likely to drop. The role of expectations is discussed in Chapter 24.

We typically expect more expensive merchandise to be better than something cheaper, and this carries over to medications. In one study, patients reported better pain relief from an “expensive placebo” compared to a “cheap placebo” (See Chapter 27).

For a variety of reasons, some physicians continue to prescribe brand-name products even after less-expensive generics become available. Their loyalty to the manufacturers of brand-name drugs is costly to both patients and society. Pharmaceutical companies with medications going off patent are exerting subtle, direct, and indirect efforts to discourage switches to generic medications. These efforts are directed at prescribing doctors as well as consumers through direct-to-consumer advertising (see Chapter 55). On the other hand, cost-conscious health plans and patients are directly and indirectly pushing for switches.
Key messages

✓ Generic drugs have the same active ingredients as the original brand-name drugs.
✓ The pharmacological actions of generic drugs are comparable to their brand-name counterparts.
✓ Generic drugs may differ from original drugs in their shape, color and packaging.