## **Are Generics Good? Good Question!**

More than three-quarters of all prescription drugs taken by patients in the US today are generics. There's a good chance that you have a generic drug in your medicine cabinet right now. Despite their widespread use, misunderstandings and misperceptions about generics remain. Even if you take a generic, you may have questions about how they stack up to brand-name drugs. **We have answers.** 

## Q. Is a generic drug different from a brand-name drug?

**A. Not really.** Unlike generic consumer goods, such as laundry soap or paper towels, generic drugs are highly regulated products that are only approved by the FDA after they are shown to be as safe and effective as their brand-name forms. The biggest difference between a brand-name and generic drug is that a generic drug is no longer protected by a patent, so the drug can be made and sold by multiple manufacturers who compete based on price. This often means that generic drugs cost as little as one-tenth the price of an equivalent brand-name drug.

### Q. Are generics as safe as brand-name drugs?

**A. Yes,** they are just as safe as the equivalent brand-name drugs, because they are chemically identical in their active ingredients. Before a generic drug can be sold, the FDA requires scientific studies showing that it works in an identical way to the brand-name drug, so for the vast majority of people, the risks and benefits are the same. The FDA collects detailed information on adverse drug events reported by doctors, patients, and manufacturers. The FDA has found that generic drugs have no more side effects than their brand-name counterparts (see <a href="here">here</a> for more).

However, it is always possible that an individual will have a bad reaction to a particular inactive ingredient in a generic or a brand-name drug (such as a filler or coating), in which case you should try a different product.

#### Q. Do generics work as well as brand name drugs?

**A. Yes.** The FDA, which approves all brand-name and generic drugs, requires that a generic drug be "bioequivalent" to their brand-name counterpart, meaning "the generic version must deliver the same amount of active ingredient into a patient's bloodstream in the same amount of time." Generics must be identical in the strength of the active ingredients, the dosage form (pill vs. tablet), and route of administration (injected, taken by mouth, etc.). Learn more about how FDA regulates the effectiveness and bioequivalence of generic drugs <a href="here">here</a>.

### Q. Are brand-name drugs more powerful than generics?

**A. No.** A generic drug contains the same active ingredient, in the same amount, as the brand-name drug. Actually, about half of the generic drugs sold in the US are manufactured by the same manufacturer as the brand-name drug, but then sold under the generic drug's name by another company. Regardless of who makes the generic drug, every generic drug on the market must meet the same batch requirements for identity, strength, purity, and quality as its brand-name counterpart. The FDA holds generics to the same good manufacturing practice standards. A company making a generic drug must prove to the FDA that its raw materials, chemistry, manufacturing process, and finished products meet the same quality standards as brand-name drugs.

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# Q. I heard about a new brand-name drug on TV, but the pharmacist said it's not available as a generic. What are my options?

You should ask your doctor or pharmacist about therapeutic alternatives. For example, if you are choosing between an older, established generic drug and a new brand-name drug for the same medical condition, it may be that the generic is safer than the new drug. That is because the generic drug has been around much longer and many patients have used it, giving doctors a better understanding of the drug's benefits and risks. By contrast, thanks to massive marketing campaigns, patients rushed to use some brand-name drugs (like Vioxx, Avandia, and Baycol) until news broke of their life-threatening side effects. When a drug has serious side effects that outweigh its promised benefits, the FDA will make the manufacturer label it with a strong warning, or maybe even recall it from the market long before it is available as a generic.

# Q. What if I get a coupon, so the brand name drug costs me the same amount out-of-pocket as a generic? Shouldn't I go with the brand name?

**A. No.** Even though your out-of-pocket cost may be the same, your health plan or employer will likely pay a lot more for a brand-name drug than for a generic drug. This will drive up the costs of your premiums. In some cases, there may be reasons to take a brand-name drug instead of a generic. If you have cost concerns, talk to your doctor or your pharmacist about whether there is a generic drug option appropriate for you. If there is no generic equivalent, there may be a generic in the same class with a similar mechanism that is effective for your condition.

Switching to generic alternatives for expensive brand-name drugs may save you money and help keep your health plan's total costs down. Due to new rules under health reform, if your plan's cost stays below the premiums you paid, you may be eligible for a rebate at the end of the year.

**To find out more** about generic drugs, visit these on-line resources:

- <u>Consumer Reports</u>, a non-profit website sponsored by Consumer Reports Magazine that recommends the best generic or brand-name drugs for more than 27 conditions. Also available in <u>Spanish</u>.
- The Independent Drug Information Service (http://www.RxFacts.org) a non-profit
  website sponsored by the Alosa Foundation that recommends the best generic or
  brand-name drugs for over 14 conditions, including 7 in Spanish and Portuguese.
- FDA: Understanding Generic Drugs a site by the US Food and Drug Administration.
- www.<u>ChoosingGenerics</u>.com, a website sponsored by the generic drug manufacturer, Mylan pharmaceuticals.

This resource is provided by Community Catalyst, a national, nonprofit consumer advocacy organization dedicated to making quality affordable health care accessible to everyone. It is for general education only, and should not be viewed as a substitute for a consultation with a medical or health professional. Always consult a qualified health care provider for professional medical advice, diagnosis and treatment of a medical or health condition, and to discuss the risks and benefits associated with taking or not taking any particular drug.

While this resource may recommend some on-line resources, we do not maintain the websites referenced, and are not responsible for any information or claims provided on them. Our intent is to enhance your communication with your clinician, rather than to replace it. Please share this resource with your medical or health provider to initiate a conversation about the affordability and effectiveness of your care.

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