THE FAMILY PHARMACIST

A QUICK READ FOR YOUR OTC NEED!

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ARE GENERIC DRUGS THE SAME AS THE BRAND NAMES?

Pharmacists would like to answer this question with "yes." Unfortunately, the answer seems to be "maybe." Many over-the-counter (OTC) drugs were at one time prescription drugs. So this question with regard to equivalency of generics to brand names is basically the same for both prescription and OTC drugs.

Ever since the passage of the Hatch-Waxman bill in 1984, generic drugs and their effectiveness have been studied and debated. Hatch-Waxman allowed generic drug companies to provide only limited tests to prove their drugs were equivalent to brand name drugs and performed in the same manner in the human body to brand name pharmaceuticals. This is known as *bioequivalence*. No longer did generic drug companies have to prove the safety and effectiveness of their drugs from the ground up as the brand companies did with costly long-term clinical trials. This led to a feeding frenzy of drug companies into the generic drug market.

The mission of the Food and Drug administration (FDA) is to safeguard the American public by enforcing the Food, Drug, and Cosmetic Act of 1938, which required safety studies on all drugs sold in the US; and the Kefauver-Harris Amendment (1962) which required manufacturers to prove their drugs not only safe, but effective. However, Katherine Eban's new book published in 2019, *Bottle of Lies,* discloses some disturbing facts about how the FDA's mission overseas has been undermined. Eban, an investigative journalist, documents ten years of findings about the world of overseas generic drug manufacturing. I mention Eban's book because OTC ingredients are produced overseas just like prescription drugs, and they are regulated by the Food and Drug Administration. According to Eban, "roughly 40 percent of our generic drugs are manufactured in India. A full 80 percent of the *active ingredients* in all our drugs, *whether brand-name or generic*, are made in India and China (italics mine)."

Generic drugs can and should be bioequivalent to brand name drugs. So what's the problem? According to Eban, globalization has transformed FDA employees' job responsibilities, making it difficult for them to be vigilant in seeing that this is done.

One critical piece in understanding brand vs generic drugs is the active ingredient. In drug jargon, this is called the ***active pharmaceutical ingredient (API).*** As one company states, "the pharmaceutical industry is rapidly changing. Companies no longer handle every step of the drug-making process. One company used to create the API, build the capsule, and package the medicine—but no longer." What this means is that the product you pick off the shelf in the drug store may have been "manufactured" in the United States, but the active ingredient, the API, most likely was made in India or China. To confuse matters even more, the FDA considers the *country of origin* the place where the product was manufactured (that is, assembled as a tablet, capsule, packaged, etc.), *not* where the ingredients are made.

How does this affect our confidence in the OTC drugs we buy every day? The FDA states: "Over-the-counter drugs are defined as drugs that are safe and effective for use by the general public without a prescription. More than 100,000 OTC drug products are marketed, encompassing about 800 significant active ingredients. There are more than 80 classes (therapeutic categories) of OTC drugs, ranging from acne drug products to weight control drug products. As with prescription drugs, the Center for Drug Evaluation and Research (CDER) oversees OTC drugs to ensure that they are properly labeled and that their benefits outweigh their risks."

With this FDA promise to consumers in mind, consider a couple of OTC generic medications available locally for which I tried to find the source of the API. Walgreens sells their Wal-Dryl™ Allergy Minitabs—a generic for Benadryl Allergy Ultratabs, and CVS Pharmacy sells Nighttime Sleep Aid tablets—a knock-off of the brand Unisom™ Sleeptabs, a sleep medicine. When you examine store "brands" (generics) like these you will often notice on the packaging the name of the "distributor" or where the product is manufactured. But as noted above, that doesn't tell you where the ingredients are made. Many store brands will include a toll-free telephone number that you can call with questions. I did this for the above mentioned OTC drugs, and it's pretty obvious that the makers of these generics don't want you to know where the API is made, likely because of the 80 percent made in India and China. One company representative told me the information was "proprietary."

But there are also good examples of disclosure. The brand name product, Children's Benadryl,™ states that the product is distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division. And the package clearly states that the active ingredient is made in Japan. Providing all of this information is good corporate policy on the part of McNeil. These are the brands I prefer to buy.

According to Eban, India and China are suspect. In the past, the FDA's inability to control the culture of fraud and deceit in these two countries has led to widespread contamination of products distributed throughout the world. Some tainted ingredients have entered the United States with disastrous results.

Even if a product is formulated in the United States, where the FDA can easily make unannounced inspections at the facility, there is no guarantee that the API is made in the States. It may come from India or China. Based on a phone call to the FDA, a pharmacist I spoke with agreed that it is virtually impossible for the individual consumer (or even health professionals) to be able to find out the source of the API for all of the drugs available to us.

The bottom line is this. For OTC or prescription drugs, it is no longer a sim-

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ple question of "are generic drugs the same as the brand names?" The question now is, where does the stuff I take come from? Whether it is a brand name or a generic drug, prescription medicine or OTC item, none of us can completely avoid ingredients made in India or China.

I have started buying more brand name products from companies I know manufacture the API in the US, where surveillance by the FDA is more certain. If possible, stay with companies that have a track record of integrity, McNeil, Johnson & Johnson, Pfizer, and so on. However, brand names will cost more. I still buy generics, but I make an effort to determine if the API is made in the United States, or at least not India or China, if possible. Read labels to see if the country of origin for the API is given. For example, McNeil Consumer Pharmaceuticals does this on many of its products, like Pepcid AC, stating on the box label, "*Famotidine* (active ingredient) made in Hungary, Processed in Canada."

All of this doesn't eliminate the risk of getting substandard products, but it does reduce it somewhat. Also, you can use the toll-free numbers on OTC drug containers to call the company and ask where the API is made. In time, formulators and manufacturers will know that consumers are holding them accountable.

References on file

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