Are Some Generic Drugs Dangerous?

Generic drugs have long been pushed on American consumers as cost-effective alternatives to brand-name prescription medicines. But widespread manufacturing irregularities at drug factories overseas are raising troubling new questions about the safety of generics and whether they are putting Americans' health at risk.

A new analysis by the U.S. National Bureau of Economic Research reveals extensive problems with the quality of generics produced by Indian pharmaceutical companies, which supply about 40 percent of the generic drugs sold in the United States. Bureau investigators examined nearly 1,500 India-made drug samples collected from 22 cities and found that up to 10 percent of some medications contained insufficient levels of the key active ingredients—concentrations so low, in fact, that they would not be effective against the conditions they're designed to treat.

This new research adds to a growing body of evidence that the generic-drug industry, which supplies 85 percent of the prescription medications sold in the U.S., routinely violates basic quality-control standards and ships sub-par medicines to the U.S. and other countries.

What that means is that many patients prescribed generic drugs are not only getting ripped off, but may be at risk because their medications are not treating the conditions they have, says renowned cardiologist Chauncey Crandall, M.D.

Story continues below video.

"I always try to put my patients on brand-name drugs," says

Dr. Crandall, author of the ***Heart Health Report*** newsletter. "The generics are starting to give us a problem, and I'm very concerned about that."

In an interview on *Newsmax TV's Meet the Doctors* program, Dr. Crandall says he has seen firsthand among his patients the dangers posed by inferior generic medications. He recalls giving generic drugs to heart-failure patients and found the medications simply were not working.

"I put them back on the brand-name drug and their heart failure disappeared, so this led me to believe that there is something going on with generic medicines that we need to be concerned about," says Dr. Crandall, director of preventive medicine at the Palm Beach Cardiovascular Clinic and author of the No. 1 Amazon best-selling book ***The Simple Heart Cure.***

And it's not just heart drugs that are the problem, he says.

"This is a deep concern of mine that I want to emphasize," he says. "If at all possible you need to go on a brand-name drug. The insurance companies, the VA Medical System and the government want to push you to generic drugs because it lowers the cost of medicine, and this is a big concern of many physicians today—that generics are not equal to brand-name drugs."

The latest findings by the National Bureau of Economic Research adds to the growing body of evidence that the generic-drug industry in India, and possibly elsewhere, is falling short of quality standards.

International regulators found more than 1,600 errors in 15 drug applications submitted by the Indian generic giant Ranbaxy Laboratories Limited. Officials noted that these pills were "potentially unsafe and illegal to sell."

The findings come in the wake of a string of drug recalls of products made by Indian pharmaceutical companies. Some 100,000

bottles of the heart drug Toprol XL were recalled because they didn’t dissolve properly. The medication is a beta blocker taken by millions of Americans to prevent strokes, heart attacks and sudden cardiac death.

In recent months the Food and Drug Administration has banned the import of medications made at facilities owned by Ranbaxy and two other large Indian drug manufacturers, Wockhardt and Sun Pharmaceuticals Ltd.

Here are some of the drug recalls resulting from manufacturing problems at major Indian pharmaceutical firms:

- Sun Pharmaceuticals recalled nearly 400,000 bottles of the decongestant cetirizine (generic version of Zyrtec) and 251,882 of the antidepressant venlafaxine (Effexor) in May because the pills failed to dissolve properly. The drugs were distributed by the drug maker’s U.S. subsidiary Caraco Pharmaceutical Laboratories but were manufactured in India.
- Also in May, Ranbaxy recalled 30,000 packs of the allergy drugs loratadine and pseudoephedrine sulfate extended-release tablets because of manufacturing defects in packaging.
- In March, Sun recalled a batch of a generic diabetes drug bound for the U.S. after an epilepsy drug was found in it. A patient discovered the error after noticing the wrong medication in the drug bottle.
- Also in March, Ranbaxy recalled nearly 65,000 bottles of the statin drug atorvastatin calcium (Lipitor) after 20-milligram tablets were found in sealed bottles marked 10-milligrams. A pharmacist in the U.S. discovered the mix-up.
- The FDA issued an alert in 2013 over manufacturing problems occurring in one of Ranbaxy’s Indian facilities and advised U.S. customs officials to hold up importation of the medications until the company complied with regulatory standards.

In light of these developments, Dr. Crandall says patients need to talk to their doctors about the medications they are taking.

“There is a difference when we [use] generics, and it can cost the patients his life,” he says. “So at all costs I would urge [patients] to pursue the name-brand drug. I think we need to make our government officials aware of this. They are pushing you to inferior drugs, and we need to get a revolution going to get these inferior drugs off the market.”

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