Generic Prescription Drugs

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Last week I had a very interesting patient experience. One of my patients, who had been on a particular brand of migraine medication for many years, told me that when she took her pill recently she had an adverse effect. When she took a reduced dosage it did not appear to help her at all. I asked her to show me the medication and, upon further review, learned it was a generic version made in "Dr. Reddy's Laboratory" in India.

I must admit I was a bit surprised. As a physician, I have always been an advocate of generic medications when appropriate. However, I was not aware that pharmacies were selling prescriptions from India. This was even more confusing because it is not legal for individual Americans to purchase medications from pharmacies outside of the United States.

The healthcare system has become ever more efficient at driving patients to generics. When a generic alternative is available, doctors prescribe it 93 percent of the time, up from 83 percent in 2003, according to pharmaceutical market information company, IMS. In the first quarter of this year 77 percent of prescriptions were generic. There is of course a cost savings to insurers and a greater profit margin for manufacturers… but how can we trust our drug supply to countries whose toys we monitor.

I started to do a bit of homework and it appears that this is one rock I should never have lifted. About 40 percent of the drugs Americans take are made overseas and about 80 percent of the active ingredients in those drugs come from foreign plants. In 2009, the FDA inspected only 11 percent of the more than 3,700 foreign facilities where finished drugs and active ingredients are made for the U.S. market, according to a 2010 report to Congress from the Government Accountability Office. By comparison, U.S. plants are inspected every two years.

The issue is one of pure safety, but it appears to me it is again an issue of profit and politics.

Sixty-five years ago, Congress responded to widespread instances of unsafe drugs by directing the FDA to create a system for assuring that Americans have a drug supply they can trust will not harm them. Over forty years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines – when they are produced, distributed, prescribed, and used properly – should not only be safe but also should prevent the many complications and side effects of diseases. More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the drug's original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S. So, in essence,

it is quite ok for drug manufacturers in India or China, or wherever else the price is cheap, to bring drugs into America.

The court concluded that “unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer does not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration.” Under section 801 of the Food Drug & Cosmetic Act, only manufacturers may import drugs into the U.S. The drugs must be produced in FDA inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system, and it is legal to import these drugs. But legislation allowing consumers to import drugs directly from foreign sources would bypass the protections provided by FDA’s drug approval process and by state regulation of firms that dispense drugs within their jurisdictions. However, the FDA is clearly not applying the same vigorous process to foreign manufacturing as they do in American plants.

These are potent medications that we are placing in our bodies and frankly the guarantee of quality is just not present.

In the issue of migraine medications or pain relievers, patients often feel the result of the medication and can assess if it is helping them. However, in the instance of blood pressure pills, anti depressants, diabetes medications, we may often not know if it is effective until the patient is seen by their doctor again. At that time they are likely to be given another medication rather than the “brand” because there is an underlying assumption that all generics are equal.

In addition what assurance is there that the byproducts in the pills are not made with faulty equipment and may have low levels of contaminants that in higher amounts can be toxic to us?

In a time when we lament American manufacturing we are turning over the making of generics to foreign countries and once again shifting our Medicare tax dollars overseas.

Quality counts. If the FDA and the federal government are at peace with the deals they make with our lives then we need to be more vocal. Next time you pick up a medication ask where the generic was made and then ask for a made in America option. Also let your insurer and your political representatives know how you feel.