Why Do So Many Drugs Get Recalled?

It seems like every week we hear about another drug recall, and many people shrug it off as a common occurrence. While some recalls affect very few people, the drug Vioxx was recalled after five years on the market when it was found to double the risk of a heart attack. Unfortunately, more than 38,000 deaths were reported before the connection was made. (1) Recalls are becoming more common, and the numbers are staggering. More than 2,000 drugs were recalled between January 2013 and July 2014, almost as many recalls as the previous nine years combined.

Why Are Drugs Recalled?

Drugs may be recalled for a wide variety of reasons such as mislabeling (incomplete or incorrect directions or the wrong product), poor packaging, contamination, or adverse reactions. (2) The majority of the recalls in 2013 and 2014 were defined as Class II, which is "…use of, or exposure to, a violative product that may cause temporary or medically reversible adverse health consequences." (3) In other words, the drugs were contaminated in some way before they hit the consumer market.

What's Being Done to Help Prevent Recalls?

While many may suspect that drug contamination is nothing new, the 2012 outbreak of fungal meningitis, which resulted in over 60 deaths, spurred a revamping of the FDA oversight on drug production and compounding facilities. Many compounding pharmacies were found to have possible microbial

contamination, and several manufacturing facilities were caught violating current good manufacturing practice (cGMP) as defined by the FDA. (3) When you figure one compounding pharmacy or manufacturer usually produces a dozen or more drugs in the same facility, it becomes obvious why the recalls are issued.

In the 10 years before the meningitis outbreak, the FDA inspected nearly 200 compounding facilities and found violations of safety conditions in roughly one-third of the businesses. (4) In comparison, after the crackdown, inspections of almost 150 facilities resulted in violations at nearly 90 percent of the businesses.

What Can You Do to Avoid Being a Recall Victim?

While there's no way to be sure your medicine is safe before a recall is issued, you can be proactive by signing up for email notification of all FDA recalls. (5) If you are notified that a drug you're taking or a medical device you use has been recalled, don't panic. Call your doctor immediately and ask what procedure is in place to ensure your health is protected. If the recall is for a dietary supplement, food, or cosmetics, you should return the item to the place of purchase for a refund. If you believe your health has been compromised due to a recalled product, you should see your medical provider as soon as possible for any necessary testing.

You can also be proactive in keeping the FDA on its toes when it comes to inspections of pharmacy compounding facilities and drug manufacturing plants. Contact your local congressman and request they keep the pressure on drug manufacturers to produce the drugs we use in a safe and violation-free environment.

Sources:

(1) *The Deadly Cost of Product Recalls* – Results You Deserve

(2) *What is a drug recall?* – Web M.D.

(3) *Number of Drug Recalls Surges* – RAPS

(4) *Compounding Pharmacy Recalls* – U.S.A. Today