Recalling

what to do with a Recall

By Narendra Singh, MD

Recalls are common in the automotive world, toy industry and increasingly the food industry. Lately, in medicine, we are seeing more recalls of drugs and devices. Knowing what to do in such cases is very important to reduce the risk for harm.

Currently a number of commonly used antihypertensives have been recalled such as valsartan, losartan and amlodipine. The guidance has been unclear and left many patients confused. This recall is not related to the active ingredient as they are well-proven and safe compounds. The recall is related to the manufacturing process where the filler used to hold the pill together is contaminated with a cancer-causing agent NDMA (N-nitrosodimethylamine) or NDEA (N-nirtosodiethylamine). Fortunately, the risk is low and related to long-term exposure.

Here are some steps to take if you are potentially taking a recalled product.

1. Review guidance from the national agencies such as the FDA (Food and Drug Administration) and the CDC (Center for Disease Control).
2. Contact your pharmacist first to see if you have an affected lot number. If so, see if they can replace it with a non-contaminated product using the same drug.
3. If replacement is not possible, call your doctor's office for an alternative medication.
4. Do not stop the drug without first checking with your health care provider as sudden discontinuation can often do more harm.
5. When getting a replacement generic drug ask for products that are manufactured in the United States or Canada. The quality control for these drug makers tends to be better than those seen in India and China.
6. Remember that a generic product can be anywhere between 80% to 125% of the strength of the brand name product so when a switch is made monitor closely for both adequate effect and side effects.

Recall of devices such as pacemakers, defibrillators or other implants is often more challenging.

1. Once again, review guidance from the national agencies such as the FDA (Food and Drug Administration) and the CDC (Center for Disease Control) as well as the manufacturer.
2. Contact your doctor's office to see if your product serial number is on the recall list.
3. Explanting the device may be an option but often this is not possible.
4. A second device may have to be implanted-the manufacturer should cover any costs not picked up by your insurer.
5. Closer monitoring both remotely and through office visits is required. It is important to not miss these appointments as they serve as an early warning system for potential device failure.
6. Hacking of devices has been postulated but to date this have never occurred, and cyber security software is being put into most new devices.

So while recalls are frustrating, they can be handled safely and effectively. ■

NARENDRA SINGH, MD,
FRCP(C), FACC, FAHA
Clinical Assistant Professor, Medical College of Georgia at Augusta University,
Director,Clinical Research-Atlanta Heart Specialists,
1400 Northside Forsyth Drive, Suite 200
Cumming,GA, 30041
678-679-6800 Cell 404-384-7227
www.heartdrsingh.com