Workers' Comp

Warnings about impurities in Zantac® and blood pressure medicines

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In September 2019, the U.S. Food and Drug Administration (FDA) reported the discovery of low levels of an impurity in brand, generic, and over- the-counter (OTC) versions of a popular heartburn medication, Zantac® (Ranitidine HCl) [1], prompting a flurry of manufacturer recalls, national distribution halts, and product removals from retail pharmacy shelves. Ranitidine is an H2 (Histamine-2) blocker approved as a prescription medicine for treatment and prevention of GI ulcers and gastroesophageal reflux disease (GERD). OTC versions are approved for relief of acid indigestion and sour stomach. H2 blockers (like Tagamet, Pepcid, and Zantac) act by reducing the amount of acid produced by cells lining the stomach. The impurity, N-nitrosodimethylamine (NDMA), is the same as that discovered in a number of blood pressure and heart failure medications earlier this year.[2] NDMA is a known environmental contaminant, also found in water, foods, meats, dairy products, and vegetables. The FDA is currently working to discover the source of NDMA in affected medicines and evaluating whether the low levels discovered in ranitidine to date pose a risk to patients or not. They are not calling for individuals to stop taking Ranitidine at this time, but instead, advise patients who may wish to discontinue their use to discuss other treatment options with their health care professional. Persons taking OTC ranitidine products may consider other OTC medications approved for their condition.[1] There are numerous OTC remedies approved for dyspepsia and heartburn. Because NDMA is a common factor in both of these medication warnings, some now challenge the ability of a pharmaceutical supply chain that is increasingly global, far flung, and complex, as well as the ability of a U.S. regulatory agency to assure the ongoing effectiveness and safety of U.S. medicines from afar.[3] “Unbeknownst to many consumers… 80 percent of Active Pharmaceutical Ingredients are produced abroad, the majority in China and India; however, the FDA only inspected one in five registered human drug manufacturing facilities abroad last year,” according to Senator Chuck Grassley (R-Iowa).[4] Since their market introduction, H2 antagonists have yielded to other antiulcer medications in popularity, primarily Proton Pump inhibitor medications (Omeprazole, Nexium, etc.) with prescription purchases representing approximately 15% of all First Script antiulcer medications. First Script will continue to monitor any developments related to these warnings and take appropriate action as warranted by new findings.

1 *https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine* 2 *https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan* 3 *https://www.washingtonpost.com/opinions/we-rely-on-china-for-pharmaceutical-drugs-thats-a-security-threat/2019/09/10/5f35e1ce-d3ec-11e9-9343-40db57cf6abd_story.html* 4 *https://www.finance.senate.gov/chairmans-news/grassley-urges-hhs-fda-to-implement-unannounced-inspections-of-foreign-drug-manufacturing-facilities*



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