**Patient Safety: NDMA Contamination in Drug Recalls: What Do We Need to Know?**

**Learning Objectives:**

At the end of this continuing education activity, the learner will be able to

1. Describe details of recent ranitidine and metformin drug recalls
2. Differentiate between categories of drug recalls
3. Identify appropriate patient education regarding recalled medications

**Pharmacist Post-test Questions**

**1. Mr. Taylor takes over-the-counter ranitidine for acid reflux. He heard news of a recent recall online pertaining to ranitidine products. He approaches the consultation counter to ask you for guidance. He has tried antacids without any relief. What do you advise Mr. Taylor to do?**

a. Continue taking the ranitidine he has at home because it was backordered, not recalled

b. Contact his doctor because you are unsure of the right medication to recommend

c. Take over-the-counter famotidine since it is safe and therapeutically equivalent

**2. The FDA has classified ranitidine as a class two recall. Which description below appropriately classifies a Class II recall?**

a. Can cause non-life-threatening adverse events or a slight threat of a serious event

b. Most severe and use of the product might lead to serious health problems or death

c. Least severe and less likely to cause harm; often related to a labeling concern

**3. Mrs. Banks hears about a metformin recall through a friend and calls your pharmacy to ask if her metformin ER has been recalled. You check the lot numbers, realize that the manufacturer she received is on the recall list, and inform Mrs. Banks of this news. She is frantic and no longer wants to take her medication. What is the best advice for Mrs. Banks?**

a. “You’re right, Mrs. Banks. It is not safe to continue taking metformin ER because it has been recalled. You should schedule an appointment with your doctor as soon as possible to discuss other medications you can take instead.”

b. “I understand why you want to stop taking your medication, but it is best to continue taking it to control your blood sugar until you are able to speak with your doctor. If you’d like, I can reach out to your doctor to discuss alternative medications to manage your diabetes. How does that option sound to you?”

c. “I understand your concerns, Mrs. Banks, but it is not safe to completely stop taking your medication. You wean off the medication slowly from once daily to one tablet every other day until you are able to see your doctor about switching your therapy regimen.”

**4. Which of the following may have led to NDMA contamination of drug products?**

A. Free radical activity of unstable byproducts

B. Side reactions during drug synthesis

C. Frequent solvent replacement during manufacturing

**5. Which of the following is a flaw in the FDA’s acceptable limit of NDMA per tablet or capsule?**

A. Some drugs are dosed multiple times per day, increasing daily exposure.

B. Lab technicians only tested one strength of each manufacturer’s tablets.

C. The FDA’s one-and-done testing strategy only tests one dosage unit of each strength.