FDA recall of blood pressure pills due to cancer-causing contaminant may point to higher safety risks in older generic drugs

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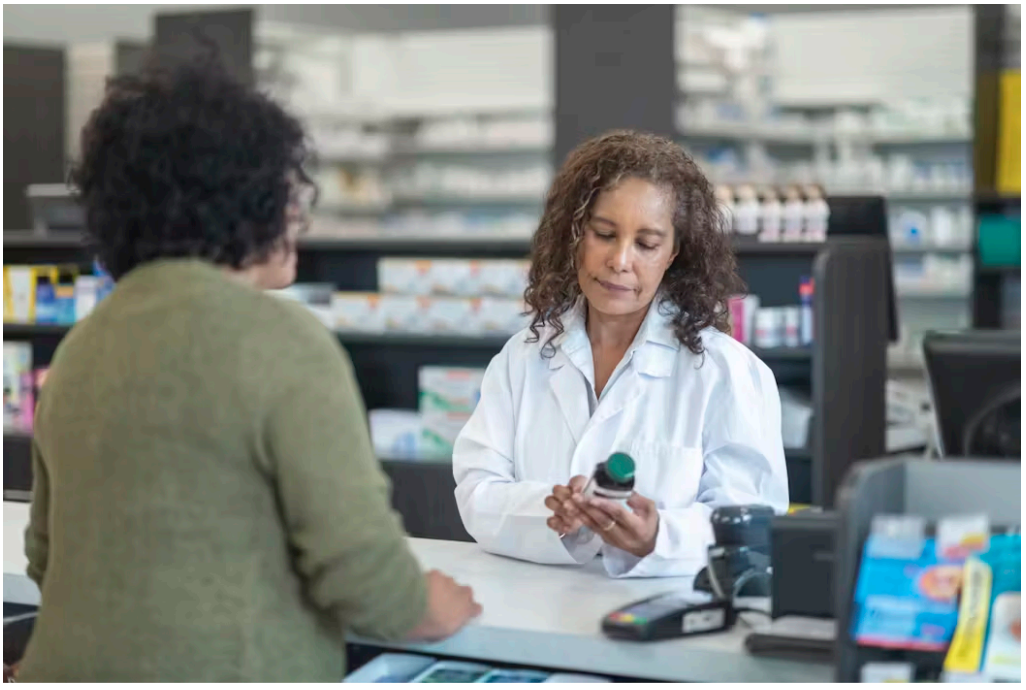

Nitrosamines are by-products of many common chemical reactions.

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A generic blood pressure drug called prazosin, made by Teva Pharmaceuticals, is being recalled by the Food and Drug Administration because it contains elevated levels of cancer-causing chemicals called nitrosamines.

The recall, which Teva announced on Oct. 7, 2025, affects more than 580,000 prazosin capsules. Prazosin is prescribed to around 510,000 patients yearly and is used to treat post-traumatic stress disorder as well as high blood pressure.

I am a pharmacologist and pharmacist who has studied nitrosamine contamination of popular blood pressure, diabetes and heartburn drugs, as well as other issues in generic drug manufacturing.

Prazosin has been available as a generic medication for more than 25 years and, like many generics that have been around that long, is now produced by multiple manufacturers. This ratchets up competition on price, which may explain why older generics are more prone to manufacturing issues that may harm patient health.

What are nitrosamines and where do they come from?

Nitrosamines are by-products of many common chemical reactions. They form when a type of chemical building block called a nitrite group interacts with another type called an amine group.

Industrial processes like rocket fuel, rubber and sealant manufacturing can produce high concentrations of nitrosamines during chemical reactions. Bacon, pepperoni and salami are high in nitrite preservatives that interact with the amine groups in the meats to form small amounts of nitrosamines. The chemical reaction that happens when chlorinated water interacts with naturally occurring chemicals that contain nitrogen and oxygen can also form small amounts of nitrosamines.

Occasional and small exposures to nitrosamines are not thought to be dangerous. But some studies have found that certain nitrosamines are carcinogenic when ingested in high amounts for long periods of time

European regulators first discovered in 2018 that prescription drugs could also be contaminated when testing revealed that an active ingredient in a blood pressure drug called valsartan contained a nitrosamine chemical. Since the Chinese company that made the drug’s active ingredient sold it to multiple manufacturers of valsartan tablets, many companies, including Teva Pharmaceuticals, recalled the drug at the time.

Drugmakers have identified nitrosamine contamination in many widely used drugs.

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The FDA then launched a major effort to identify nitrosamines in prescription and over-the-counter drugs and to define unsafe levels for tablets and capsules. It published an initial industry guidance in 2021 and an updated version in 2024.

Based on the agency's new testing requirements, drugmakers have identified nitrosamine contamination in widely used blood pressure, diabetes, heartburn, antibiotic and smoking cessation drugs. Most of the recalled drugs were contaminated during the chemical processing at a manufacturing plant.

What should people who take prazosin do?

Teva Pharmaceuticals' prazosin is just one of many generic versions – but it's the only one that is contaminated. You can determine whether your medication came from Teva by looking at your prescription label. Search for the abbreviations MFG or MFR, which stand for "manufacturing" or "manufacturer." If it says "MFG Teva" or "MFR Teva," that means Teva Pharmaceuticals supplied the medication.

The first four numbers of a National Drug Code, abbreviated as NDC on the prescription label, also reveal the manufacturer or distributor. Teva products have the number 0093.

If Teva Pharmaceuticals is the distributor, a pharmacist can cross-reference your prescription number to obtain the lot number and compare it with the posted lot numbers on the FDA website for recalled prazosin. If your product has been recalled, your pharmacy may have other generic versions of prazosin in stock that are not part of this recall.

Based on its risk assessment for these tablets, the FDA gave the recall a Class II status, which means that the medication could cause “temporary or medically reversible adverse health consequences.” If no other prazosin version exists at your pharmacy, do not stop taking your drug without talking with your physician first. The risk of temporarily taking tablets with an elevated amount of nitrosamines may be less than the risk of suddenly stopping this medication.

Your physician may also be able to prescribe an alternative treatment such as clonidine or trazodone.

Do older generics made overseas pose higher risks?

Until recently, it wasn’t possible to compare whether the safety records of generic drugs manufactured overseas differed from the same generics made in the U.S., because the FDA does not disclose which manufacturing plants companies use to create their tablets and capsules. But in a 2025 study, researchers managed to triangulate that information from an FDA dataset.

They found that the risk of serious adverse events was 54.3% higher with generics made in India as compared with those made in the United States. And the longer a drug has been available in generic form, the greater the difference in safety risk between its U.S.- and India-made forms. As my colleague and I wrote in a commentary accompanying the study, the findings suggest that when the market for generic drugs is crowded by multiple manufacturers, lower-priced options naturally sell better. As a result, manufacturers in developing countries are more apt to produce poorer quality products that are less expensive to produce.

Teva Pharmaceuticals has manufacturing plants around the world, including in India. The company has not disclosed where its recalled prazosin capsules and their active and inactive ingredients were manufactured.

The FDA publishes ratings on generic drug quality and claims that generics with an “A” rating meet the same manufacturing quality standards and achieve the same blood concentrations as brand-name drugs. But pharmacies can’t tell from those ratings if a drug comes from manufacturing plants that are at higher risk for quality issues.

Patients are at the mercy of choices pharmacies make in the generic versions of drugs they procure for their stores. In my view, if pharmacies could access reliable information about quality, they might be able to make choices that are safer for American consumers.

C. Michael White does not work for, consult, own shares in or receive funding from any company or organization that would benefit from this article, and has disclosed no relevant affiliations beyond their academic appointment.