FDA official says ongoing blood pressure drug investigation will probably uncover more tainted pills

There's no end in sight for one of the largest prescription drug recalls in recent memory. The US Food and Drug Administration is continuing an investigation and recall of a class of drugs used by millions that began last summer, yet there's still "more to find," an agency director says.

Starting in July, separate lots of blood pressure medications from various companies were pulled from pharmacy shelves. They're known as [angiotensin II receptor blockers or ARBs](https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm) and contain either valsartan, losartan or irbesartan. The reason? These blood pressure drugs contained impurities that pose a cancer risk to users.

The investigation isn't concluded," [Dr. Janet Woodcock](https://www.fda.gov/AboutFDA/CentersOffices/ucm193984.htm), director of the FDA's Center for Drug Evaluation and Research, told CNN this week. Working with regulators from around the world, she said, she anticipates more tainted drug lots will be found.

### **When did the contamination begin?**

Woodcock said the problem appeared to occur sometime after 2010, when a Chinese manufacturer made changes to its synthetic processes.

A spokeswoman for the agency later said that, based on available information in this ongoing investigation, the FDA estimates the first possible appearance of NDMA was in 2014.

Yet the FDA did not begin its recall of the drug until [July 13](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm), one week after [22 other nations](https://www.cnn.com/2018/07/06/health/valsartan-heart-drug-recall-intl/index.html) had already pulled the plug on specific manufacturers of valsartan pills to safeguard patients. In fact, two months earlier, [European Union regulators](https://www.ema.europa.eu/en/news/ema-reviewing-medicines-containing-valsartan-zhejiang-huahai-following-detection-impurity-some) had initiated a review following reports that valsartan-containing drugs imported from Zhejiang Huahai Pharmaceuticals were tainted by an impurity known as NDMA (N-nitrosodimethylamine).

Used to make liquid rocket fuel, NDMA is a byproduct from manufacturing some pesticides, yet it can also be unintentionally introduced through certain chemical reactions.

Nitrosamines are genotoxic, meaning they affect DNA replication and possibly cause cancer, Woodcock explained. Testing a variety of ARB drugs, the FDA found additional lots made by several manufacturers that had been tainted by NDMA and, in some cases, another nitrosamine known as NDEA (N-Nitrosodiethylamine).