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FDA recalls are a reminder that China controls much of world's drug supply

"If we were ever in an international incident with China, they would literally have their hands around our necks in terms of critical drugs."

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By Maggie Fox

The Food and Drug Administration [has broadened a recall](#) of the common blood pressure drug valsartan, saying some batches have been contaminated with a potentially cancer-causing chemical.

Several generic valsartan products sold in the U.S. have been found to be contaminated with NDMA, which has the potential to cause cancer. The process used to make some generic versions of valsartan has the potential to generate the compound, said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research.

"These are present at very minute levels. But because they are toxic to the DNA, you have to control them," Woodcock told NBC News.



The Zhejiang Huahai Pharmaceutical Co. in Shanghai, China. The company has recalled valsartan, which that may be contaminated with a cancer-causing chemical. *Imaginechina via AP file*

The FDA has told patients to keep taking their drugs until they can be sure that they're either using an unaffected brand or that they can be switched to a safer one. The threat is not immediate, Woodcock said.

"It is the lifetime exposure to this that is dangerous. It's not like it would give you cancer tomorrow," she said.

But the case does illustrate the challenges that FDA must overcome in regulating a drug market that's increasingly outsourced to other countries, especially China.

While Woodcock says the FDA is on top of things, other experts say these cases illustrate just how vulnerable the U.S. is when it depends on other countries to make essential drugs.

"China doesn't have anything like the consumer protection laws and product liability laws like the United States does," said Rosemary Gibson, a health care expert at the Hastings Center who wrote a book titled "[China Rx: Exposing the Risks of America's Dependence on China for Medicine.](#)"

A Chinese manufacturer was the [source of contaminated heparin](#) – a commonly used blood thinner – that killed at least 81 people in 2007 and 2008. An FDA inspection showed that the Chinese factory where the contaminated product was made had serious deficiencies in what's known as good manufacturing practice.

Woodcock said the FDA has other ways of ensuring product safety. It regularly sends inspectors to scrutinize Chinese facilities, for instance.

“We have the exact same standards for drugs marketed in the U.S. regardless of where they are made,” she said.

“Food has been used as a weapon of war. Our medicines can be used like that, too.”

But no inspection would have found the NDMA contaminant, which is a byproduct of processing foods such as bacon and is a water contaminant as well, Woodcock noted. It had to be discovered using a specific chemical test designed to find this particular compound.

“We are planning to test all the valsartan products in the United States for this impurity,” she said.

Woodcock said the FDA has issued new guidance to all makers of drug ingredients to make sure that NDMA and other potential cancer-causing chemicals that can be made as part of the manufacturing process stay out of any finished product.

Still, Woodcock said, it’s a big job.

“The field is stretched,” she said. FDA inspectors must keep an eye on U.S. makers of pharmaceuticals, including large and small outfits that make specialty compounded drugs. “But we do what we can. We get to the highest-risk places every year,” she added.

Outside experts point out that the FDA cannot control what manufacturers in other countries do, and say no amount of FDA inspection can ensure a reliable supply of vital medical products.

“It’s a major national security risk for us in two ways,” said Mike Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota and an expert on biosecurity. “We are very concerned about the quality of these drugs.”

And the Trump administration has been engaged in months of [verbal and bureaucratic battles with China](#) over tariffs.

“Now we are caught up in an economic war in the sense of tariffs,” Osterholm added in an interview. “If we were ever in an international incident with China, they would literally have their hands around our necks in terms of critical drugs. They wouldn’t even have to fire a shot.”

Gibson estimates in her book that 80 percent of the ingredients in U.S.-branded pharmaceuticals and over-the-counter drugs start out in either China or India.

“Food has been used as a weapon of war. Our medicines can be used like that, too,” she said.

China made a strategic decision to develop its pharmaceuticals industry and has succeeded, Gibson said, undercutting prices and grabbing market share from other countries.

“Penicillin is a good example,” she said. “We don’t make penicillin ingredients in this country anymore. That happened because Chinese companies came in and dumped it on the global market at a very low price. Now they are the largest producer of penicillin industrial ingredients in the whole world.”

The U.S. market is vulnerable to products that are contaminated but is even more vulnerable if some kind of accident, problem or disaster shuts down factories, Gibson said.

“Imagine if a major earthquake hit or civil war broke out in some of the major pharmaceutical-producing cities,” Gibson said.

“It would be disastrous. India still produces some of the drugs for us but most of the essential compounds for them come from China, so they would shut down too.”

Osterholm points to the damage done in Puerto Rico after Hurricane Maria last year. Medical supplier Baxter [makes a large percentage of saline solution](#) in Puerto Rico, and the 2017 hurricane shut down manufacturing for months, worsening an ongoing shortage of saline intravenous drip bags.

“If we think the IV bag situation in Puerto Rico was serious, it pales in comparison with what could happen with any kind of hiccup with China,” he said.

Gibson agreed.

“I can think of nothing that would make us more vulnerable than shutting off all these drugs we depend on every day,” she said.

“Hospitals would become centers of chaos and death. We are not talking about expensive designer drugs. You couldn’t do surgery. You wouldn’t have anesthesia. You couldn’t provide dialysis.”



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