

**Here are this week's healthcare news highlights from AskaPatient:**

- While most research on antibiotic resistance is about finding stronger antibiotics, one team is trying to slow bacterial evolution. <http://ow.ly/B1iW30mF9NI> (11-19-18)
- New study adds evidence linking sustained exposure to traffic-related noise to obesity risk. <http://ow.ly/liRz30mFa01> (11-19-18)
- Scientists identify a new anti-inflammation inhibitor that could treat or prevent autoimmune diseases. <http://ow.ly/9e7I30mFa8H> (11-19-18)
- Brain cancer cells travels quickly via fluid in the brain, but a new drug may be able to slow the spread. <http://ow.ly/u1Op30mG7v5> (11-20-18)
- Poor vision doubles risk of falling in older adults and increases fear of falling, making them more likely to limit activity. <http://ow.ly/lmHK30mG7vt> (11-20-18)
- New proposed peanut allergy treatment involves building up tolerance against accidental peanut exposure. <http://ow.ly/PcAn30mG7Hi> (11-20-18)
- People who both vape and smoke cigarettes are no more likely to kick the habit than those who just smoke cigarettes. <http://ow.ly/6OaE30mH6f2> (11-21-18)
- UGA scientists develop a tool that can predict which animal viruses will spread to people. <http://ow.ly/n9xq30mH6mr> (11-21-18)
- Depression increases risk of atrial fibrillation, but treatment with antidepressants appears to reduce this risk. <http://ow.ly/MZYe30mH6xi> (11-21-18)
- Millions of type 2 diabetics that need insulin do not have access to it, and experts predict it will get worse. <http://ow.ly/YV0m30ml1Sl> (11-22-18)
- Hackers are not the biggest culprits when it comes to hospital data breaches, instead most originate from internal factors. <http://ow.ly/kFle30ml20x> (11-22-18)
- A map of prescription patterns across the U.S. reveals urban areas tend to favor more expensive, brand name drugs over generics. <http://ow.ly/MnXF30ml2eZ> (11-22-18)
- CDC advises consumers to throw out romaine lettuce as they investigate a widespread E. coli outbreak. <http://ow.ly/80k530ml23Y> (11-23-18)
- While screening for colorectal cancer does not reduce mortality, it does reduce the need for chemotherapy and emergency surgery. <http://ow.ly/kogo30mlJoO> (11-23-18)
- Drawing pictures is much more effective for memory retention than writing things down, no matter how good or bad the drawings are. <http://ow.ly/bRos30mlJxV> (11-23-18)
- New target for breast cancer treatment revealed as researchers find the disease can recruit bone marrow cells to grow. <http://ow.ly/Y2GJ30mJCAq> (11-24-18)

**The debacle of valsartan recalls in 2018; now the recall expands to include some losartan and irbesartan products in the U.S.**

In early July of this year, the European Medicines Agency (EMA), Health Canada, and drug agencies in Japan, Taiwan, and Hong Kong began a recall of certain suppliers' versions of valsartan, a popular blood pressure drug. Chinese manufacturer Zhejiang Huhai had reported to international regulators that trace amounts of a contaminant N-nitrosodimethylamine (NDMA) were detected in its valsartan product. NDMA is known to be a cancer-causing carcinogen in animals and is considered to be a probable carcinogen in humans. NDMA can make

its way into products as a result of certain manufacturing processes. For example, it is a byproduct from some fish processing and pesticide manufacturing and is also an organic chemical used in making liquid rocket fuel. While this sounds alarming, the amounts of impurities detected in tests by the EMA and the FDA have been very small and unlikely to have caused harm in patients who have already consumed them.

### **FDA Response**

By mid-July of this year, the U.S. FDA joined in the recall for valsartan drugs tied to Zhejiang Huhai, the Chinese manufacturing facility. Since then, two other plants, including another in China and one in India, have been linked to the NDMA impurity or a similar contaminant called NDEA (N-nitrosodiethylamine). Just last week, on November 21, the FDA updated its recall list to include two other generic blood pressure drugs in the angiotensin II receptor blocker (ARB) treatment category: losartan by Sandoz (one lot due to NDEA) and irbesartan by ScieGen (some lots due to NDEA). The FDA put Zhejiang Huahai Pharmaceutical Co. on its import alert list as of September 28, 2018, and will not allow drugs manufactured using ingredients produced at that plant to be marketed in the U.S.

What has become apparent to consumers from this debacle is that despite numerous pharmaceutical companies holding regulatory agency approvals to manufacture the same generic drug, in reality there are just a handful of production sites that manufacture and supply the vital ingredients (or "active pharmaceutical ingredients") to the many generic drug companies worldwide. So when NDMA and NDEA contaminated the valsartan production from just three plants located in China and India, it affected the supply available to dozens of generic pharmaceutical companies worldwide and in turn the availability of the treatment for tens of thousands of patients.

Three manufacturing facilities are responsible for producing the valsartan ingredient that triggered massive drug recalls so far in 2018:

### **1. Zhejiang Huahai Pharmaceutical Co. Ltd. (China) NDMA contamination**

#### **U.S. suppliers**

Torrent Pharmaceuticals  
Solco Health\*  
Teva

#### **Solco relabler** Remedy Repack

HJ Harkins  
NuCare Pharmaceuticals

#### **Torrent relabler** Remedy Repack

#### **Teva relabler** Actavis

#### **Canadian Suppliers**

Sandoz  
Teva Canada  
ACT  
Sanis  
Sivem  
Pro Doc

### **2. Hetero Labs (India) NDEA contamination**

#### **U.S. suppliers**

Camber

#### **Camber resellers**

Preferred Pharmaceuticals, Inc.  
AvKARE

Bryant Ranch  
Northwind Pharmaceuticals  
Remedy Repack

A third facility, **Mylan Laboratories Limited in Hyderabad, India**, has been plagued with quality problems for a number of years. On November 19, 2018, the EMA announced that in addition to a recall, it has banned all products (not just valsartan) produced at this facility from being sold or distributed in the European Union. Furthermore, other companies marketing valsartan products in the EU have been asked to test their products for the impurities. The EMA plans to work with the pharmaceutical companies to determine how to reduce or eliminate the impurities from future production batches. Unfortunately, authorities do not know how long ago the problem began. Drugwatch.com reports that the contaminants may have been present in the products since 2012 or earlier.

Not all valsartan-containing products have been recalled. The original brand name versions of the drug, **Diovan** and **Diovan HCT** by Novartis, are not affected by recalls in any country. However, Novartis' generics company Sandoz recently announced a recall of **losartan** in the U.S. and Sandoz Canada issued a recall on some of its valsartan products in July.

Below is a list of FDA-identified companies that produce valsartan products that have **not** been recalled in the U.S. Note that some companies appear on **both** recall and non-recall lists, so double check with your pharmacist or the FDA (see link below) to find out if your medication is affected by the recall:

**COMPANIES WITH SOME VALSARTAN PRODUCTS THAT ARE NOT AFFECTED BY THE RECALL (see FDA link below for product names and lot numbers)**

Alembic Pharmaceuticals

Allergan

American Health

Amneal

Aphnea

Apotex

Aurobindo

AvPak

Camber

Cardinal Health

Carrillon Materials

Gavis Pharma

Juliblant Cadista

Lucid Pharma

Lupin

MacLeods

Mylan

Northwind

Novel Laboratories

Ohm Laboratories

Par

PD-Rx

Preferred Pharma

Proficient Rx

Sandoz

Teva

Unichem

**Common Side Effects of Valsartan**

as reported to FDA and on AskaPatient

[Dizziness from valsartan](#)

[Weight gain from valsartan](#)

[Fatigue/Sleepiness from valsartan](#)

[Shortness of breath from valsartan](#)

[Headache from valsartan](#)

**Sources and More Reading:**

[FDA Press Release, 11/21/2018](#): FDA updates on angiotensin II receptor blocker (ARB) recalls including valsartan, losartan and irbesartan.  
[FDA Import Alert list](#) a list of companies that have effectively been barred from providing ingredients for drug products in the U.S.: "Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs." The list includes Zhejiang Huahai Pharmaceutical Co in China which is associated with some of the valsartan recalls.

[Valsartan products not](#) under recall in U.S. (15 pages PDF document)

[Valsartan products under recall in U.S.](#) (7 pages PDF document)

Valsartan products [recalled and not recalled](#) in Canada by Health Canada

FDA [Questions and Answers](#) regarding ARBs recalls

EPA (Environmental Protection Agency) technical sheet on [NDMA](#)

[List of ARBs](#) including valsartan, losartan, irbesartan, and olmesartan on AskaPatient web site with links to reviews

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