

Here are this week's health care news highlights from AskaPatient:

- Drug that makes human blood poisonous to mosquitoes could help control malaria with no harmful side effects. <http://ow.ly/VuxG30o4Ybv> (03-18-19)
- Except for those with a high risk of heart disease, guidelines no longer recommend a daily aspirin to lower heart attack risk. <http://ow.ly/wHUh30o4YdS> (03-18-19)
- Blood flow restriction therapy protects against bone loss and restores function faster after ACL surgery. <http://ow.ly/MAQq30o4Yjp> (03-18-19)
- Fibromyalgia is difficult to diagnose and is often misdiagnosed, but a simple reliable test might be around the corner. <http://ow.ly/MfG530o60o2> (03-19-19)
- Small study offers evidence that two compounds in coffee slow down prostate cancer growth. <http://ow.ly/dY2V30o60ze> (03-19-19)
- Heart valve procedure reserved for those too fragile for surgery offers a faster recovery with lower risk for healthier patients, too. <http://ow.ly/2Mew30o60lt> (03-19-19)
- First study of its kind explores what it means to have avoidant personality disorder, a controversial diagnosis. <http://ow.ly/slqE30o60Vc> (03-20-19)
- Parents often worry about giving their kids commonly allergenic foods too early, but pediatric doctors say earlier is better. <http://ow.ly/hJmO30o6Zer> (03-20-19)
- University of Texas scientists examine the genetic origins of chronic pain, seek new treatment pathways. <http://ow.ly/DaiT30o6Zwr> (03-20-19)
- WHO panel to create registry to aid in protocol and transparency of all gene editing research. <http://ow.ly/tFx930o6ZEm> (03-21-19)
- Older people could improve their brain function by 60 percent by eating two teaspoons of nuts per day, study suggests. <http://ow.ly/v2SB30o7Xu4> (03-21-19)
- Oregon State scientists identify method of synthesizing anti-leukemia compounds without harvesting natural resources. <http://ow.ly/eLUn30o7Xzj> (03-21-19)
- Connecticut-based nonprofit leading the charge for fruit and vegetable prescriptions to get healthy food into low-income homes. <http://ow.ly/3zaK30o8Qxb> (03-22-19)
- Laser-targeted removal of prostate tumors is as effective as removing the entire prostate with fewer side effects. <http://ow.ly/7mm030o8QEn> (03-22-19)
- Experts suspect CBD could interact with many medications, including blood thinners and anti-anxiety drugs. <http://ow.ly/dRbo30o8QMP> (03-22-19)

- High-fructose corn syrup, the main sweetener in most sweet drinks, accelerates tumor growth in mice, study finds. <http://ow.ly/arEO30o8Smi> (03-23-19)

FDA Takes Steps to Deal with Shortages of Valsartan and Losartan-containing Products

In July 2018, the FDA joined other international drug agencies in massive product recalls because of trace amounts of cancer-causing chemicals that were found in some "**angiotensin II receptor blocker**" (**ARB**) **drugs**. ARBs are commonly used to treat high blood pressure and heart failure. Examples of ARBs include valsartan, losartan, olmesartan, telmisartan, eprosartan, and irbesartan. The contamination was linked to two generic manufacturing facilities - one in China and one in India. Diovan, the brand name for valsartan, has not been affected by the recall.

Because hundreds of lots of these drugs have been recalled since last year, valsartan is on the FDA's **drug shortage list**. Unfortunately, price gouging has occurred. According to industry analysts, Indian company Alembic Pharmaceuticals, one of the few producers not involved in a recall, more than **tripled** the price of its versions of valsartan. The FDA has taken two specific steps recently to help alleviate the shortfall:

1. On March 12, the FDA approved a **new generic form of valsartan manufactured by Alkem Laboratories** in Mumbai, India. It was approved on a priority basis because of the growing drug shortage. The drug is available in 40, 80, 160, and 320 MG oral tablets and will be distributed in the U.S. by Ascend Laboratories, LLC. At least one of Alkem Labs' India plants has had some questionable practices; an FDA inspection of a plant in Baddi in March 2017 had numerous quality inspection issues. However, for this new generic product, the FDA said it has evaluated and been satisfied with Alkem's manufacturing process. In addition, Zydus Cadila received approval for a new generic version of valsartan hydrochlorothiazide (HCT) on March 15. It will be manufactured at a plant in Alambhedra, India.
2. Consumers may not be reassured by this step, but on March 20, the FDA announced its decision to **raise the acceptable limit – temporarily – of the minimum amount of contaminant NMBA for losartan from .96 parts per million (PPM) to 9.82 parts per million (PPM) for a six month period only**. This is almost a ten-fold increase in levels of the impurity. "Agency scientists evaluated the risk of exposure at levels up to 9.82 ppm and determined that it presents no meaningful difference in cancer risk over a six-month time frame when compared to a lifetime of exposure of NMBA at .96 ppm." The FDA expects that in six months, the manufacturing issue will be solved and that many companies will be able to manufacture losartan without any impurities.

Recalls since 3/7/2019:

3/19/2019: Legacy Pharmaceutical Packaging, LLC Issues Voluntary Nationwide Recall of Losartan Potassium Tablets, USP, 25mg, 50mg, And 100mg Due to The Detection of Trace Amounts Of N-Nitroso N-Methyl 4-Amino Butyric Acid (NMBA). This recall involves **40 lots** of the drug which were distributed for consumer use to pharmacies nationwide. The product was manufactured by Hetero Labs, Ltd. Press release: <https://www.fda.gov/Safety/Recalls/ucm633664.htm>

3/7/2019: American Health Packaging is voluntarily recalling one lot of Valsartan Tablets, USP, 160 mg, distributed for use in hospital settings. The product was manufactured by Aurobindo Pharma USA, Inc. Press release: <https://www.fda.gov/Safety/Recalls/ucm632924.htm>

Sources and More Reading:

- FDA updates on angiotensin II receptor blocker (ARB) recalls including valsartan, losartan and irbesartan. Includes announcement on FDA not objecting to losartan with NMBA below 9.82 ppm remaining on the market. [FDA Press Release, 3/22/2019](#).
- FDA's List of Drug Shortages in the U.S.: complete [list](#).
- Valsartan has been included on the list of drug shortages since 8/18/2018. This [FDA page](#) includes companies and valsartan products affected, along with status. Many of them are in recall status.
- Valsartan products [recalled and not recalled](#) in Canada by Health Canada plus these update from March 9 for [Losartan in Canada](#).
- FDA [Questions and Answers](#) regarding ARBs recalls.
- "Overseas manufacturing of key ingredient leads to massive generics recalls" AskaPatient article on the [valsartan debacle](#): 11/25/2019 and updated 3/1/2019. Includes list of ARBs including valsartan, losartan, irbesartan, and olmesartan with common side effects.
- A 'one-off opportunity:' Drug company hikes price of blood pressure drugs after competitors' drugs recalled. [1/30/2019: USA Today](#).

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