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

- Listening to music helps stroke patients recover memory faster, study finds. http://ow.ly/MWBv30oz78n (04-29-19)
- Lung cancer in people who have never smoked is under-recognized, respiratory experts say. http://ow.ly/TVnz30oz7FK (04-29-19)
- Amid the current measles outbreak, public health experts warn that adults vaccinated decades ago may not have immunity. http://ow.lv/Ynmg30oz7Vu (04-29-19)
- Susceptibility to disease develops early in life with traumatic experiences and multiple allergies being major factors. http://ow.lv/cV2v30oA7Bs (04-30-19)
- Urine testing may be as effective as the smear test at preventing cervical cancer. http://ow.ly/jD9q30oA7BK (04-30-19)
- Morning exercise improves memory and decision-making throughout the entire day, especially with frequent walk breaks. http://ow.lv/7cQ530oA7Fr (04-30-19)
- Teen suicide rate spikes in the month following the release of the show "13 Reasons Why". http://ow.ly/vCZ430oA7FX (05-01-19)
- Michigan State researchers suggest adding a smell test to doctor visits in older adults. http://ow.ly/XKdF30oAYXr (05-01-19)
- Over a third of adults with type 1 diabetes are at least initially treated as type 2 diabetics, some for years. <a href="http://ow.ly/cVQa30oAYXI">http://ow.ly/cVQa30oAYXI</a> (05-01-19)
- Antidepressant use during pregnancy may increase risk of autism, but potential treatment could normalize behavior. http://ow.ly/pB4930oAZOT (05-02-19)
- EPA reaffirms previous statement that the weed killer glyphosate does not cause cancer, contradicting jury decisions. http://ow.lv/hT2n30oBFzw (05-02-19)
- Computer algorithms can be tailored improve cancer treatments by predicting gene interactions. <a href="http://ow.ly/tSPA30oBFEL">http://ow.ly/tSPA30oBFEL</a> (05-02-19)
- A class of erectile dysfunction drugs is found to slow and even reverse heart failure in a recent study. <a href="http://ow.ly/3exd30oBFKh">http://ow.ly/3exd30oBFKh</a> (05-03-19)
- Children who drink zero-calorie sweetened drinks consume as many calories overall as those who drink sugary beverages. http://ow.lv/O1i830oCsdi (05-03-19)
- Massive international study finds 20 genes associated with bipolar disorder, some of which also have ties to other psychiatric disorders. http://ow.lv/OKg230oCspl (05-03-19)
- Bioengineers clear a major hurdle that allows them to 3D print complex vascular networks. http://ow.ly/ynKt30oCsCq (05-04-19)
- California tap water could increase cancer risk over a lifetime of drinking due to cumulative effects of legal levels of contaminants. http://ow.lv/Pl6i30oCsG3 (05-04-19)

## Recent FDA Announcements

#### 1. Beware of medication-compatibility genetics testing claims

Last month, the FDA issued a **warning letter** to a genetics testing unit of a large northern Virginia hospital organization, INOVA Health Care System. The FDA claimed that INOVA Genomics Laboratory was "illegally marketing certain genetic tests that have not been reviewed by the FDA for safety and effectiveness."

The tests claimed to predict patients' responses to medications based on genetic variants. INOVA had expanded its "MediMap" genomics testing service to include a new service as a standard part of its maternity care: genetic tests for **newborns** claiming to predict medication compatibility. That test, called "**MediMap Baby**," was hailed by some as being cutting-edge and perhaps a signal of what was to come. However, since receiving the warning letter, INOVA has removed all MediMap information from its web site and no longer offers the MediMap testing service.

Most currently available genetics compatibility testing has been centered on antidepressants and psychiatric drugs. Most medications, even if approved for pediatric use, do not generally include infants. To read the FDA warning letter to INOVA, click here:

<a href="https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letter-genomics-lab-illegally-marketing-genetic-test-claims-predict-patients">https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letter-genomics-lab-illegally-marketing-genetic-test-claims-predict-patients</a>

AskaPatient article on drug suitability testing: <a href="https://www.askapatient.com/news/genetic-testing-drug-suitability.asp">https://www.askapatient.com/news/genetic-testing-drug-suitability.asp</a>

## 2. Sleep medications to include a black box warning for risk of bizarre and dangerous behavior

Some categories of "Z" drugs or insomnia medications are known to have side effects, but this week, the FDA announced that the risk of "complex sleep behaviors" leading to serious injury or death is great enough to warrant a **black box warning** on the drug labels.

The FDA recommends that if a person has a "complex sleep behavior" after taking one of these drugs, they should notify their doctor and discontinue taking the drug.

## Drugs affected by new black box warning:

1. zolpidem tartrate

(Brand names include Ambien, Ambien CR, Edluar, Intermezzo, and Zolpimist)

2. eszopiclone

(Brand name Lunesta)

3. zaleplon

(Brand name Sonata)

What the FDA calls "complex sleep behaviors" is only defined by examples, which include:

"sleepwalking, sleep driving, and engaging in other activities while not fully awake."

Also, while the serious consequences of the complex sleep behaviors are called "rare," many examples of such behaviors, which often the patient does not remember, are reported on sites like AskaPatient and also in the FDA's FAERS (Adverse Event Reporting System) database.

FDA press release on strengthened warnings for sleep medications

## 3. Valsartan-Losartan-Irbesartan blood pressure drug (ARB) recall; new information

- **Friday, May 3**: Vivimed Life Sciences (for Heritage Pharmaceuticals) released lot numbers of newly recalled losartan products: <a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vivimed-life-sciences-pvt-ltd-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-50-mg-and">https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vivimed-life-sciences-pvt-ltd-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-50-mg-and</a>
- Thursday, May 2: FDA posted <u>laboratory test results showing NDEA levels in recalled valsartan products</u> as well as an assessment of the cancer risk from NDEA in valsartan. Please note that not all lot numbers and lab results are included in the posting.
- The FDA now has **two searchable lists for researching ARB products**: One includes ARB drugs that are under review or have been cleared and are not under recall. The list of those **NOT under recall** is "Assessment of currently marketed ARB drug products." As of May 3, 2019 there are only **32 drugs that have been tested and are not under recall** and 397 products that are still being marketed but are "under review" with a status of "to be determined."

The other list is for **recalled products and now contains 1,094 products/lot numbers**. The link for the searchable recall list is: "<u>Full list of recalled angiotensin II receptor blockers (ARB)</u>." These lists replace the earlier PDF documents that contained drug names, companies, expiration dates, and lot numbers.

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