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

- Doing chores around the house may help keep your brain (slightly) younger. http://ow.ly/qQkR30ouK9x (04-22-19)
- Penn Medicine and CHOP team uses CRISPR to treat lethal lung disease before birth in animal model. http://ow.ly/FOpX30ouKaP (04-22-19)
- China to consider tighter restrictions on research involving human genes and embryos. http://ow.ly/P0ES30ouKcZ (04-22-19)
- Brazilian study highlights cumin's capability to prevent or combat stomach cancer. http://ow.ly/wPZH30ovpRZ (04-23-19)
- Half of patients referred to a clinic with a schizophrenia diagnosis do not actually have the disease, study finds. http://ow.lv/RK4N30ovpSt (04-23-19)
- More than 100 high risk genes for schizophrenia identified, may lead to more targeted treatment development. http://ow.lv/5o1K30ovpSP (04-23-19)
- Many kids do not drink any water for entire days, opting instead for sugary drinks which may contribute to obesity. http://ow.ly/FISI30owbio (04-24-19)
- U.S. files its first charges against a major drug distributor over fueling the nation's opioid epidemic. http://ow.ly/Hglh30owbm4 (04-24-19)
- Walgreens to raise the minimum age to buy tobacco products to 21 after being found as a top violator of sales laws. http://ow.ly/NQNF30owbnm (04-24-19)
- Study finds potentially harmful bacterial and fungal contaminants in many e-cigarette products. http://ow.ly/OEd630owP3i (04-25-19)
- New insight into how 'bad' cholesterol accumulates on artery walls points researchers towards treatments aimed at specific proteins. http://ow.ly/bxgK30owPi7 (04-25-19)
- For patients in heart failure, a low dose blood thinner may significantly reduce risk of heart attack and stroke. http://ow.lv/1lcV30owPNA (04-25-19)
- Genetic testing of women newly diagnosed with breast cancer could help many avoid chemotherapy. http://ow.ly/YQ7y30owR6c (04-26-19)
- New topical treatment for plaque psoriasis wins FDA approval and claims to undercut competitor prices by 50 percent. http://ow.ly/m5i030oxCl0 (04-26-19)
- Decoding device gives a voice to those who can't talk by translating brain signals into speech. http://ow.ly/FvxD30oxCOZ (04-26-19)
- Penn Medicine collaboration yields microrobots that can destroy biofilms including dental plaque. http://ow.ly/Hqk630oxCTW (04-27-19)
- There is no safe amount or stage during pregnancy for alcohol consumption, study concludes. http://ow.ly/c6QJ30oyBgd (04-27-19)

Losartan Recalls

More ARB blood pressure drug recalls were announced this week from Teva, Torrent, and Legacy. See the following FDA announcement for lot numbers:

https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan

For background on the recall debacle, which began in summer of 2018, check out article on our web site: https://www.askapatient.com/news/generic-api-valsartan-worldwide-recall.asp

Low-Power Electrical Brain Stimulation: FDA Approves Device for At-Home Treatment of ADHD

On April 22, the FDA announced the approval of a device to be used for the treatment of ADHD in children age 7 to 12 who are not also taking prescription ADHD medications. Neurosigma's "Monarch External Trigeminal Nerve Stimulation System" is a cellphone-sized device that is powered by a 9 volt battery and has two wired patches that attach to the patient's forehead. The patches emit a low energy electrical stimulation to the trigeminal (or transfacial) nerve, a major nerve pathway to the brain that also acts as a hub for regulating pain and mood. The patient wears the patches for about eight hours a day (usually while sleeping) for four weeks.

The clinical study supporting Neurosigma's product application involved just 64 pediatric patients, so the FDA will certainly be interested in any post-marketing patient reports of efficacy. This is the first non-pharmaceutical treatment for ADHD, and the first FDA-approved at-home device of its kind. In Europe and Canada, the device has been approved for age 7 and up for ADHD and also for depression and epilepsy indications.

Some caveats: the device must not be used near cell phones and other devices that emit radio frequency-electromagnetic fields. While not specifically mentioned by the manufacturer, this would probably include smart meters, wifi hubs, and wifi-connected devices like home computers.

Side effects appear to be mild and may include trouble sleeping, headache, teeth clinching, drowsiness, and increase in appetite. Cost of the device: According to Monarch web site, the Monarch eTNS System starter kit is €800 (about \$1,000 U.S.)

Approval implications: This approval most likely opens the door for FDA consideration of its use for all age groups and for other indications, such as depression and epilepsy.

Sources and More Reading

- FDA permits marketing of the first medical device treatment for ADHD: FDA Press release
- Monarch web site: http://www.monarch-etns.com/
- Neurosigma web site: http://www.neurosigma.com/
- AskaPatient article on <u>magnetic "neuro-stimulation" treatments</u>, with a focus on depression. Note that the various brain stimulating treatments vary in their invasiveness (surgical or external), the part of the brain targeted, the kind of stimulation (e.g. magnetic or electric), and the strength and type of the electric current. The Monarch "eTNS System" just recently approved has a low-power current
- Trigeminal Nerve Stimulation May Not Be Effective for the Treatment of Refractory Partial Seizures: journal article. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3763599/
- Neuromodulation therapies and treatment-resistant depression. This article provides a literature review of various kinds of brain stimulation therapies along with results: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3496963/
- Research in the area of neuro-stimulation is exploding. Some research has even focused on using the technology to reverse memory decline. In the study described below, the working memory of the older group temporarily improves to match younger group. https://www.theguardian.com/science/2019/apr/08/scientists-use-electrical-pulses-reverse-memory-decline-ageing

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