

Health News: April 4, 2021

- The FDA issued a drug safety communication and drug label change for seizure and bipolar medication **Lamictal (lamotrigine)** because of increased risk of **heart rhythm problems**, called arrhythmias, in patients with heart disease. The FDA plans to evaluate whether other medicines in the same drug class have similar effects on the heart and are also requiring safety studies on those medicines. Note: **LAMICTAL** (lamotrigine) is distinct from **LAMISIL** (terbinafine), an antifungal drug.

FDA Safety Communication

Read [patient comments](#) from people who experienced heart palpitations or irregular heart beats while taking Lamictal.

- The FDA is investigating numerous medical device reports (MDRs) of patient **infections** associated with **reusable urological endoscopes** —devices used to view and access the urinary tract. Previously, the FDA encouraged health care providers to transition to partially disposable endoscopes to minimize infection risk caused by the devices, which are used to visualize the stomach and intestines.

<https://www.fiercebiotech.com/medtech/fda-cites-potential-infection-risks-reusable-urological-endoscopes>

- Johns Hopkins School of Public Health researchers analyzed more than 600,000 **pharmacy transactions** that took place between 2017 and 2019 and made two significant findings: First, the **vouchers and coupons** offered by pharmaceutical companies to defray patients' out-of-pocket drug costs is concentrated among a **small number of drugs**. 80% of the coupons were used for only about 150 drugs (out of more than 2,500 total). About half the coupons were provided by drug makers for brand name drugs and the other half were "PBM-pharmacy offsets" for generic drugs provided by **Pharmacy Benefit Managers** through pharmacy discount cards or online apps.

The other significant finding was that while point-of-sale copayment "offsets" significantly reduce patient costs, they are **not targeted to patients who most need the price reductions**. In the case of brand name drugs, researchers suggest that a coupon program's purpose is more about maintaining market share than helping those who can least afford medications. The study was published in *JAMA Internal Medicine*.



Image Source: JHU

<https://hub.jhu.edu/2021/03/30/drug-coupons-vouchers-study/>

- *JAMA* has previously published articles on the **hidden costs** of **brand name drug coupons**. For example,

if a drug company uses a \$25 copay coupon to sell a \$300 brand name drug, it may then recoup \$275 more in revenue from the employer program providing coverage, thereby increasing insurance prices. (Copay coupons are not allowed in the Medicare and Medicaid programs). Another study found that copay coupons can also increase out-of-pocket consumer costs, because co-pays may still be higher compared with alternative treatments.

<https://ldi.upenn.edu/david-grande-jama-hidden-costs-prescription-drug-coupons>

- The COVID-19 pandemic has slowed or halted FDA's **drug-manufacturing inspections**, causing **concerns about potential drug safety** consequences. Between March 2020 and October 1 2020, the FDA conducted just 52 inspections of U.S. pharmaceutical plants, compared with 400 during the same months in 2019, according to the G.A.O. (General Accounting Office). Even worse, there have been no inspections of foreign manufacturing facilities. Some industry and public health experts say that federal drug inspections are essential, and that the agency should bypass travel restrictions by taking precautions, including wearing proper personal protective equipment.

<https://www.fiercepharma.com/manufacturing/fda-s-inspection-woes-to-grow-if-agency-doesn-t-address-covid-19-backlog-gao>

Only about 20% of manufacturers that make active pharmaceutical ingredients (APIs) used in FDA-approved drugs are located in the U.S. (See our article on valsartan recalls for pie chart of API manufacturing facilities location by country.)

<https://www.askapatient.com/news/generic-api-valsartan-worldwide-recall.asp>

- A mysterious **brain disease** afflicting more than 40 people in the New Brunswick province of Canada is baffling doctors. While it does not appear to be a "prion disease" (such as Creutzfeldt-Jakob), a number of the symptoms are similar, including memory loss, vision problems and abnormal jerking movements.

<https://www.theguardian.com/world/2021/mar/30/mystery-brain-disorder-baffles-canadian-medicine>

- Dartmouth University's large-scale study on the **neuroscience of the placebo effect** finds that placebo treatments meant to reduce pain, known as placebo analgesia, **reduce pain-related activity in multiple areas of the brain**. In particular, the study shows reduced activity in the posterior insula, which is one of the areas of the brain involved in early construction of the pain experience. The study was published in *Nature Communications*.

<https://news.dartmouth.edu/news/2021/03/study-provides-deep-dive-neuroscience-placebo-effects>

- Under a new federal price transparency rule that went into effect on January 1, **hospitals** are required to disclose prices for common procedures on their web sites. However, a *Wall Street Journal* investigation revealed that many hospitals made the **price information difficult to find** by blocking the data from **search engines**.

<https://www.beckershospitalreview.com/consumerism/how-hospitals-hide-pricing-data-from-web-search-results-wsj.html>

- Healthgrades released its list of the **top 50 U.S. hospitals** for 2021. The top 50 hospitals are listed by state, and not every state has a hospital making the list.

<https://www.beckershospitalreview.com/rankings-and-ratings/healthgrades-50-top-hospitals-for-2021.html?>

- An Exeter University study found health improvements in participants drinking two servings of **beetroot juice** a day for ten days. Participants experienced lower levels of mouth bacteria linked to disease and inflammation and an average five point (mmHg) drop in systolic blood pressure. "Our findings suggest that adding nitrate-rich foods to the diet – in this case via beetroot juice – for just ten days can substantially alter

the **oral microbiome** (mix of bacteria) for the better." Study participants were healthy individuals age 70-80.



Image of Beetroot (Source: Exeter University)

https://www.exeter.ac.uk/news/homepage/title_851446_en.html

Covid-19 News

- Backed by millions in public and private cash, **rapid covid tests** will soon be available for consumers. Test screening accuracy varies, as does the way consumers get results: collection kits mailed back to a lab, devices synced with artificial intelligence-enabled apps on a smartphone that spit out results within 15 minutes, and credit card-sized tests with strips of paper that must be dipped into a chemical substance. Recently, the demand for covid testing has waned as people scramble to get in the queue to receive a vaccine.



Image Source: Hannah Norman/KHN

<https://khn.org/news/article/rapid-covid-tests-over-the-counter-marketing-public-private-investment/>

- The FDA authorized **over-the-counter** (OTC) **antigen tests** for "serial screening" of COVID-19 (testing asymptomatic individuals multiple times on a routine basis), such as testing twice a week in schools or other settings. To date, the FDA has authorized four OTC at-home antigen tests, one OTC molecular test, and six OTC antigen tests for serial screening programs. The OTC tests do not require a prescription from a doctor or health care professional.

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-april-2-2021>

- Data was withheld from World Health Organization investigators who travelled to China to research the **origins of the coronavirus epidemic**. "The international expert study on the source of the SARS-CoV-2 virus was significantly delayed and lacked access to complete, original data and samples," Australia, Canada, the Czech Republic, Denmark, Estonia, Israel, Japan, Latvia, Lithuania, Norway, Korea, Slovenia,

Britain, and the United States said in a joint statement. (The European Union did not sign the joint statement.)

<https://www.reuters.com/article/us-health-coronavirus-who-china-report-idUSKBN2BM26S>

Covid-19: Vaccine News

- If you were infected with Covid-19, just **one dose** of mRNA vaccine may be enough to protect you from reinfection. In addition, that first dose will likely have more severe side effects if you had Covid-19 previously than if you have never been exposed to the virus.

<https://www.beckershospitalreview.com/pharmacy/study-1-dose-of-mrna-vaccine-may-be-enough-for-those-previously-infected-with-covid-19.html>

- A mistake at Emergent Biosolutions, Janssen's subcontractor in Baltimore Maryland responsible for manufacturing its Covid-19 vaccine, **ruined 15 million doses**. According to the *Baltimore Sun*, the facility had a history of quality control violations.

<https://www.wbal.com/article/507218/188/report-mistake-at-emergent-biosolutions-ruined-15m-covid-19-vaccine-doses>

- Despite a CDC program to make vaccines available to long term care facility workers, the "Federal Pharmacy Partnership for Long Term Care," only about **half of nursing home staff received vaccinations** for Covid-19. The CDC's partnership with CVS and Walgreens to bring 63,000 vaccines to long term care facilities is now closing up shop. The low vaccination rates are not surprising for those familiar with this healthcare setting: seasonal flu vaccination rates are consistently low among long-term care facility workers. Attitudes could be shifting: a recent survey of 2,300 long-term-care workers by human resources firm OnShift showed that 62% were willing to take the vaccine, nearly double the share in December.

<https://www.npr.org/sections/health-shots/2021/03/31/982772372/federal-program-to-bring-vaccine-to-nursing-homes-missed-around-half-of-staff>

- Pfizer says that trials of its vaccine in **kids age 12 -15 show 100% efficacy** in preventing symptomatic Covid-19. BBC reports that the trial **did not include** testing for **asymptomatic infection**. It is expected that Pfizer will submit an application with the FDA for approval for this age group very soon.

<https://www.bbc.com/news/health-56591429>

- In some states and jurisdictions, people age 16 and up are now eligible for vaccination, and many others will be eligible by the end of April. This map of the U.S. shows the latest **eligibility requirements by state**, but some states have requirements that vary by county.

<https://www.nytimes.com/interactive/2021/us/covid-19-vaccine-eligibility.html>

Another list with more detail, along with local links:

<https://www.usnews.com/news/best-states/articles/covid-19-vaccine-eligibility-by-state>

Covid-19: Statistics

- As of April 2, the CDC reports that over **59 million people** (18% of the U.S. population) are fully vaccinated, and **104 million people** (31% of the U.S. population) have received at least one dose of a 2-dose vaccine.

- COVID-19 cases have increased in the past 12 days in the U.S. The average number of new cases per day over the past week was 63,280 while the average number of new cases per day the previous week was

57,343. The percent of people testing positive for covid-19 (positivity rate) is 5% on average in the U.S. in the past week.

Source: [CDC Data Tracker](#)

For links to more statistics, including global cases statistics, check out our [Guide to Coronavirus Web Sites](#).

Have you received a Covid-19 vaccine? Click to read comments about these Covid-19 vaccines and/or add your experience:

[Pfizer](#) [Moderna](#) [Janssen](#)

Alain OSTA, a doctoral student at the University of Nicosia in Cyprus is conducting a study on the use of online platforms/chatbots in Online Health Communities (OHCs). A chatbot is a software application dedicated for users to conduct an online conversation via text-to-speech or text in lieu of providing direct contact with a live human agent. Click here to participate in the survey: www.surveymonkey.com/r/7PJ5FRW

(Ask a Patient has no connection with this study, so please contact the student with any questions.)

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