

## Ask a Patient Health News December 11 2022

### Health News: December 11, 2022

- The U.S. Food and Drug Administration (FDA) approved Ferring Pharmaceuticals' **Rebyota** for preventing the recurrence of **C.diff** (Clostridioides difficile infection) in patients 18 and older following antibiotic treatment for recurrent C.diff. The C. diff **bacterium** can cause diarrhea, inflamed colon, and colitis, and tends to infect people who are taking antibiotics for an extended time. The drug is administered rectally as a single dose. This is the FDA's first approval of a fecal microbiota transplant product. The application was granted Fast Track, Breakthrough Therapy and Orphan designations.

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product>

- The FDA added safety label updates for over-the-counter sleep aid **Unisom SleepTabs** (doxylamine succinate) with warnings NOT to take it with any other product containing **doxylamine** (an antihistamine) and NOT to take it unless you have **time for a full night's sleep**. It also advises to ask a doctor or pharmacist before using if you are taking any other sedative or any other sleep-aid, tranquilizer, or antihistamine. New language on the label warns to not drive a motor vehicle or operate machinery after taking the drug.

- The FDA is falling down on the job of policing **online tobacco retailers**, according to a highly critical new report from the US Department of Health and Human Services' Office of **Inspector General**. The report criticizes the FDA for its lack of oversight, saying that children's use of tobacco remains of "high concern" and that online sales are a potentially easy way for kids to buy tobacco products without having to verify their ages.

<https://www.cnn.com/2022/12/09/health/fda-tobacco-online/index.html>

- The FDA fast-tracked Emergent Biosolutions' application for the approval of **over-the-counter** version of **Narcan**, the **nasal-spray form of naloxone**, a life-saving drug that can reverse the effects of an **opioid** or **fentanyl overdose**. Price could be a barrier for some, however. A single Narcan spray kit today can cost between \$22 to \$60, which is much more expensive than the cheapest available injectable version. In some states and at some pharmacies in the U.S., consumers can already get naloxone without a prescription, but need to consult with a pharmacist.

<https://gizmodo.com/over-the-counter-narcan-spray-fda-approval-1849860949>



Narcan Product Image source: [DailyMed](https://www.dailymed.com)

- Most of the **12,892 full-time employees** at the U.S. Centers for Disease Control, including CDC Director Rochelle Wolensky, **work remotely** all or part of the time, according to data that Kaiser Health News obtained via a Freedom of Information Act request. Experts say the lack of face-to-face work will likely be a substantial obstacle to the top leadership's effort to overhaul the agency after its failures during the pandemic - a botched testing rollout, confusing safety guidance, the slow release of scientific research, and a loss of public trust.

<https://khn.org/news/article/much-of-the-cdc-is-working-remotely-that-could-make-changing-the-agency-difficult/>

## Private Equity in Every Niche of Healthcare

- After finding success investing in lucrative corners of American medicine, including **surgery centers** and **dermatology practices** — **private equity firms** have moved aggressively into the industry's more hidden niches, including **clinical drug trials**. For example, Headlands Research, formed in 2018 by private equity investment giant KKR, announced in 2020 that it won coveted contracts to **run clinical trials of covid-19 vaccines**, including shots for AstraZeneca, Johnson & Johnson, Moderna, and Pfizer. Headlands' sites also ran clinical studies on treatments for Type 2 diabetes, postpartum depression, asthma, liver disease, migraines, and endometriosis, according to a review of website archives and the federal website ClinicalTrials.gov.

<https://khn.org/news/article/business-clinical-trials-private-equity/>

Kaiser Health News made a "**video primer**" that explains the concept of private equity in health care:

<https://khn.org/news/article/video-private-equity-investing-in-health-care/>

## Research News

- Florida State University College of Medicine researchers have linked **aspartame**, an **artificial sweetener** found in nearly 5,000 diet foods and drinks, to anxiety-like behavior in mice. Along with producing anxiety in the mice who consumed aspartame, the effects extended up to two generations from the males exposed to the sweetener. The U.S. Food and Drug Administration (FDA) approved aspartame as a sweetener in 1981. The study is published in the *Proceedings of the National Academy of Sciences*.

<https://www.eurekalert.org/news-releases/973939>

- Many women with two or three breast tumors can get by with **lumpectomy** surgery instead of having their whole breast removed, according to a new study by the Mayo Clinic. In recent years, more patients with multiple tumors have been identified, a result of more sensitive imaging techniques. In the past, doctors would say these women needed mastectomies. In this study, researchers followed nearly 200 women (age 40 to 87) with two or three tumors in one breast (less than 5 centimeters and separated by 2 to 3 centimeters of normal breast tissue) who had lumpectomies followed by radiation. After five years, **just 3% saw cancer come back**, similar to rates from previous lumpectomy studies in patients with only one tumor. The study, supported by the National Institutes of Health, was presented at the San Antonio Breast Cancer Symposium.

<https://apnews.com/article/health-cancer-tumors-breast-surgery-a7794aec38fce48b89803a48167a45ef>

- Starting a new prescription is easy. If the label says, "**take once a day with food**," you know exactly what to do. But there is little guidance on how to stop medications. Heather Ashton developed detailed protocols to help patients withdraw from benzodiazepines (like Xanax or Valium) after long-term use with a very slow tapering regimen. Pharmacist Joe Graedon discusses how meds like benzos, cortisone-types (prednisone), PPIs, antihistamines like certrazine, antidepressants, sedatives/sleeping pills like ambien, and even nonaddictive pain pills like tramadol can cause **problems for patients who are ready to stop taking them**. More than 25 readers comment on the topic.

<https://www.peoplespharmacy.com/articles/do-doctors-know-how-to-help-patients-stop-medications>

Check out our related [poll](#) on this topic (see bottom of this newsletter).

- The Federal Trade Commission (FTC) gathered public comments on how it should regulate harmful commercial surveillance of consumers and lax data security.

The **Center for Digital Democracy** (CDD) specifically focused its comments on **health** or **healthcare marketing**, saying "Pharmaceutical advertisers and medical marketers are broadly deploying the latest tactics that leverage data to track and target the public. These include "identity graphs," artificial intelligence, surveilling-connected and smart TV devices, permission-based first-party data, and cookie-less targeting. "Programmatic advertising enables you to really pinpoint individuals and now follow them around wherever they go on their devices," said the CDD Director. **PharmedOut**, a Georgetown University nonprofit that examines industry influence on medicine, commented on the **relative ease with which marketers can re-identify people** when supposedly "anonymized" or "de-identified" patient information is sold to

private companies who then may study individuals' behavior.

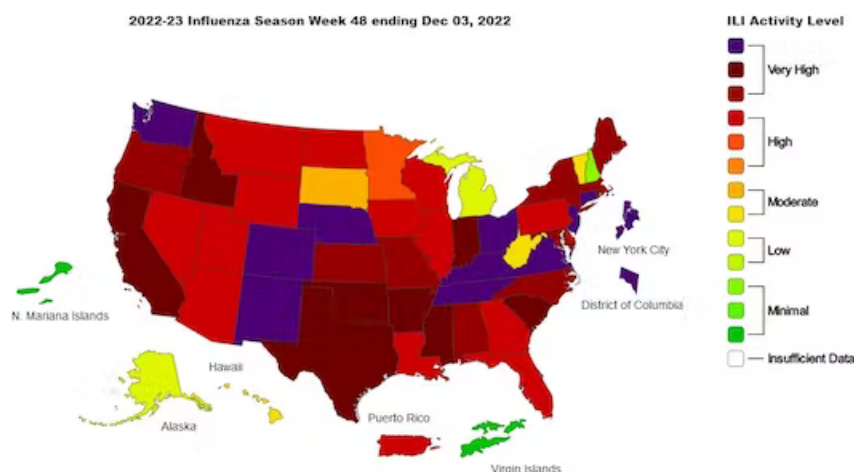
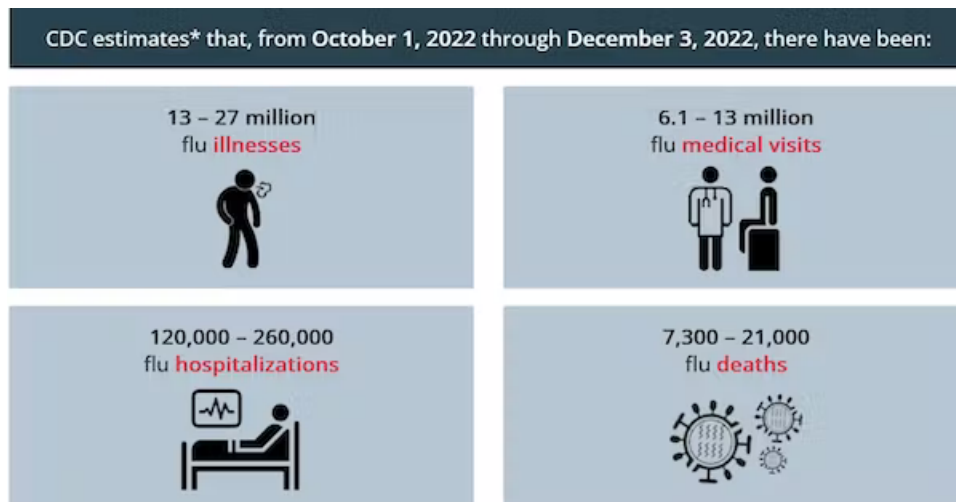
<https://www.mmm-online.com/home/channel/pharmas-digital-marketing-in-crosshairs-as-ftcs-plan-to-curb-commercial-surveillance-gains-steam/>

### Covid-19 & Influenza News

- With the latest CDC and FDA authorizations for children age 6 months to 5, new **bivalent COVID-19 vaccines may now be received by the entire population age 6 months and up**. However, the vast majority of children in the youngest age group have not received even their first Covid vaccine; only about 6.5 percent of those under 2 have received at least one shot. Just 9 percent of kids age 2 to 5 have had least one dose. Far fewer have completed their primary series.

<https://www.cdc.gov/media/releases/2022/s1209-covid-vaccine.html>

Cases of **flu-like illness** continue to grow around the U.S., with most states experiencing high or very high levels of influenza-like activity. The CDC estimates that in just two months, from October 1 2022 through December 3, 2022, there have been 13 – 27 million flu illnesses, 120,000 – 260,000 flu hospitalizations and 7,300 – 21,000 flu deaths.



*Please answer our new reader poll:*

**Have you ever had trouble discontinuing a medication? If so, which type was the most problematic?**

- Have not had trouble
- Pain Meds
- PPI (like omeprazole)
- Antihistamine/Allergy
- Antidepressant

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- Antianxiety

- ADHD

- Other

**VOTE!**

<https://www.askapatient.com/resources/healthcarepoll.asp>

Dear Readers,

The newsletter will be on break and resume January 8. Starting in 2023, Ask a Patient® Health News will be split into two biweekly newsletters: one will focus on **drug news**, the other on **healthcare**. We hope the shorter format will be more readable. You will automatically be subscribed to both, with the option to unsubscribe if you prefer to just receive one or the other.

**Happy Holidays from Ask a Patient!**