

Ask a Patient Health News January 23, 2022

Health News: January 23, 2022

- The U.S. FDA warned that **dental problems**, including tooth decay, cavities, oral infections, and even loss of teeth, have been reported with medicines containing **buprenorphine** taken as sublingual tablets and films dissolved under the tongue or placed against the inside of the cheek. The warnings apply to pain and opioid-use-disorder drugs [Belbuca](#), [Bunavail](#), [Cassipa](#), [Suboxone](#), [Subutex](#), and [Zubsolv](#), and generic versions. The estimated number of buprenorphine-containing prescriptions dispensed from U.S. outpatient retail and mail-order pharmacies increased from 11 million in 2014 to 16 million in 2020. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-dental-problems-buprenorphine-medicines-dissolved-mouth-treat-opioid-use-disorder>

- The FDA approved Elanco's **Zorbium** (buprenorphine transdermal solution), the first transdermal buprenorphine animal drug intended to control **pain in cats after surgery**. Because Zorbium is applied by the veterinarian and relieves pain for four days, it may eliminate or reduce the need for cat owners to administer additional pain medications at home. It also reduces the potential for abuse of the opioid medication. <https://www.fda.gov/animal-veterinary/cvm-updates/fda-approves-first-transdermal-buprenorphine-control-post-surgical-pain-cats>

- Due to the Omicron variant, the FDA says it is extending its pause on conducting inspections of **drug manufacturing facilities** in the U.S. through February 4. Foreign surveillance inspections will resume in April except for previously planned inspections that are in countries within the CDC's Level 1 or Level 2 COVID-19 travel recommendation. <https://www.raps.org/news-and-articles/news-articles/2022/1/fda-extends-temporary-halt-in-inspections-driven-b>
Related: The FDA faces a backlog of manufacturing site inspections. <https://www.fiercepharma.com/pharma/can-fda-whittle-down-its-manufacturing-site-inspection-backlog-2022>

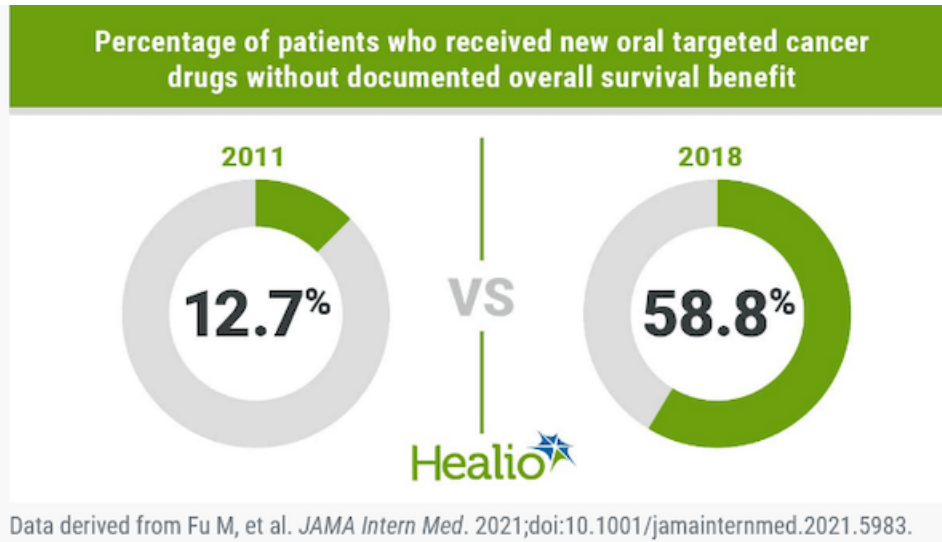
- In 2021, 88 **generic drugs** made their debut. Notable among drugs now available as generics include Amitiza (for opioid induced constipation) [Gilenya](#) (relapsing MS), [Zomig](#) nasal spray (migraine) [Chantix](#) (smoking cessation) , and [Xeljanz XR](#) (Rheumatoid Arthritis). Check out the complete list of new generics. <https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals>

- Germany's BioNTech and US Pfizer are developing a **shingles vaccine** using the same mRNA technology used for the Covid Vaccine, with clinical trials to begin in the second half of 2022. If an mRNA vaccine against shingles produces less side effects than the currently available Shingrix, it could be a game changer. (Patient reviews for [Shingrix](#) and AskaPatient [article](#) on the vaccine). Moderna is using its mRNA technology to develop a vaccine against **Epstein-Barr virus** (EBV), the cause of mononucleosis. <https://healthwise.punchng.com/pfizer-biontech-to-develop-mrna-based-shingles-vaccine/>

- In the most comprehensive report to date on the global impact of **antimicrobial resistance** (AMR), researchers say that AMR has become a leading cause of death worldwide, killing about 1.2 million people in 2019. While AMR poses a threat to people of all ages, young children were found to be at particularly high risk, with one in five deaths attributable to AMR occurring in children under the age of five in 2019. The study was published in the January 19 edition of the Lancet. <https://www.theguardian.com/society/2022/jan/20/antimicrobial-resistance-antibiotic-resistant-bacterial-infections-deaths-lancet-study>

- Has the FDA's accelerated approval drug program gone too far, with unproven drugs being taken routinely by too many cancer patients? Cancer drugs without documented clinical benefit account for a substantial amount of **health care**

spending, according to results of two studies published in *JAMA Internal Medicine*. Under the FDA's "**accelerated approval**" path, the FDA can approve a drug after a shorter-than-normal review if the agency believes that the drugs could fill an unmet medical need and should be brought to market sooner. Drugs receiving accelerated approval must be monitored in clinical trials after approval in order to confirm safety and efficacy, but often the trials are never completed, and yet the drugs stay on the market anyway.



- In 2021, the CDER approved **14 of the 51** novel drugs (28%) under the Accelerated Approval pathway. These included: Aduhelm, Amondys 45, Exkivity, Jemperli, Lumakras, Pepaxto, Rybrevant, Scemblix, Tepmetko, Tivdak, Truseltiq, Ukoniq, Voxzogo, Zynlonta. (An additional 23 drugs also received expedited approval using other pathways such a Fast Track, Breakthrough Therapy, or Priority Review.) Check out our roundup of 2021's new drugs.

<https://www.askapatient.com/news/list-new-drugs-approved-2021.asp>

- Many **rural area pharmacies** are closing, creating hardships for patients who now must drive far from home to reach a drugstore. Pharmacists lament that the main reason they are driven out of business is because of the steeply rising fees charged by **Pharmacy Benefits Managers** (PBMs) and the low or below-cost medication reimbursement rates that the PBMs provide. Listen to what rural patients and pharmacists are going through in this 4 minute story presented by April Ehrlich of Oregon Public Radio.

<https://wamu.org/story/22/01/22/rural-residents-cant-get-their-medicines-or-covid-19-help-with-pharmacies-shuttering/>

- For more than ten years, this Gaithersburg, Maryland woman experienced puzzling episodes of illness that lasted a month or two and typically included **severe eye pain, darkening vision**, shortness of breath, nausea and crushing fatigue. Two doctors attributed her symptoms to stress. Another advised her to eat more fiber. The symptoms also aligned with multiple sclerosis symptoms, but that was not the eventual diagnosis. Check out Sandra Boodman's latest **medical mystery**.

<https://www.msn.com/en-us/news/us/im-going-blind-somebodys-got-to-help-me/ar-AASOp24>

Covid-19 News: Rapid Tests

- The Biden administration recently launched two programs that aim to get **rapid Covid tests** into the hands of every American. But the design of both efforts creates more **barriers** to people who have the least access to the tests to start with. Those in multi-family residences, with low income or little internet access, those without checking accounts, and those only with Medicare insurance are not being helped by these programs.

<https://khn.org/news/article/biden-administrations-rapid-test-rollout-doesnt-easily-reach-those-who-need-it-most/>

- Kaiser Health News put together a list of answers to questions about the "free" at-home Covid Tests, including: **Is it really free?** Will the insurance company just swallow those imposed costs and if so why haven't my premiums gone up? Will the tests

cost me money directly? Will this help bring down the costs of at-home tests and make them easier to find?

<https://khn.org/news/article/5-things-you-should-know-about-free-at-home-covid-tests/>

- The FDA has authorized **14 antigen over-the-counter (OTC) at-home test** products. Rapid antigen tests work best when you are symptomatic or at least 5 days have passed since you had a close contact with someone who had Covid-19. They are more likely to give false negatives if you are asymptomatic or take the test too early. Check out the list of products on the link below and filter for over-the-counter by typing "OTC" in the search box at the top of the table. You can also click on the link to read the patient insert with directions for taking the test. **Authorized brands** include BinaxNow, CliniTest, Quidel QuickVue, Orasure InteliSwab, Ellume, Access Bio's Carestart, BD Veritor. Check the FDA list for the latest information.

FDA List of Authorized [Covid Antigen Diagnostics](#)

- Wondering if Covid testing kit results will still be accurate if they are left outside in the **cold** (such as in a metal mailbox or on a door step)? WUSA9 investigated the topic and found out that it depends on the brand.

<https://www.wusa9.com/article/news/verify/are-covid-kits-left-in-the-cold-okay-to-use/65-e249d2e3-5030-4ee7-8bfb-76ee7f8a4deb>

Covid-19 News: Vaccine Booster Research

In the January 21 edition of *MMWR Weekly Report*, the CDC reported on three studies that offer evidence that a third dose of an mRNA vaccine is key to fighting the Omicron coronavirus variant. The CDC hopes to encourage more people to get a booster shot, as **only about 82.5 million, or 39%**, of fully vaccinated Americans have received a COVID-19 booster dose.

In one of the studies, those who received 3 doses of mRNA COVID-19 vaccine (compared with unvaccinated and with receipt of 2 doses) were less likely to have symptomatic SARS-CoV-2 infection compared with test-negative controls.

FIGURE. Weekly trends in age-standardized incidence of COVID-19 cases (April 4–December 25, 2021) and deaths (April 4–December 4, 2021) for unvaccinated compared with fully vaccinated persons,* overall and by receipt of booster doses† and national weighted estimates of variant proportions‡ — 25 U.S. jurisdictions*

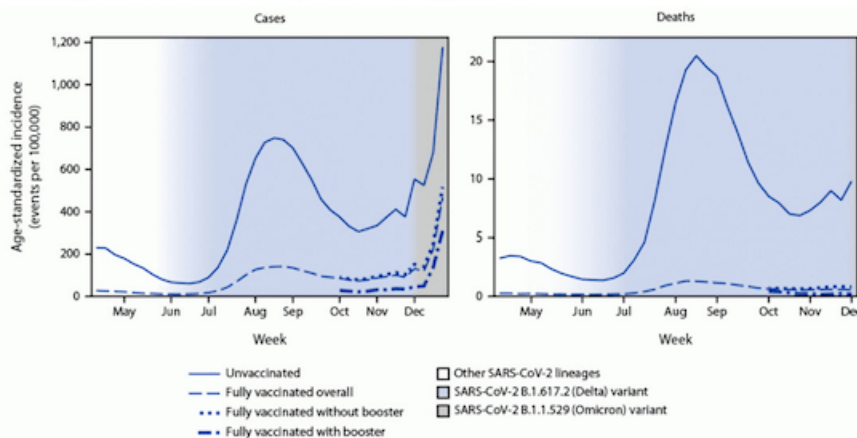


Image and Research Source:

<https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e2.htm>

U.S. jurisdictions included in the referenced study: Alabama, Arkansas, California, Colorado, District of Columbia, Florida, Georgia, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Nebraska, New Jersey, New Mexico, New York, New York City (New York), Rhode Island, Seattle/King County (Washington), Tennessee, Texas, Utah, and Wisconsin.

- Three shots of the Pfizer and Moderna vaccines were about 67% effective against omicron-related symptomatic disease compared with unvaccinated people, according to one of the CDC studies. **Two doses, however, offered no significant protection against omicron** when measured several months after completion of the original series, the researchers found.

<https://www.pennlive.com/coronavirus/2022/01/booster-shots-help-fend-off-omicron-new-cdc-studies-show.html>

- People are tired of getting vaccinated, and while some news reports have mentioned the benefits of a fourth booster, Pfizer Chief

Executive Albert Bourla said a **once-a-year vaccine** is what they envision. He said that a redesigned vaccine to fight Omicron and other variants, and mass produce it, will be ready as soon as March.

<https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-ceo-sees-annual-covid-vaccine-rather-than-frequent-boosters-2022-01-22/>

Other Covid-19 News

- In a preliminary paper, researchers from the Belgian Rega Institute report that mice and hamsters infected with the Omicron variant had **less damage in their upper and lower respiratory tracts** than those infected with Delta, suggesting that the Omicron illness is less severe than earlier strains of the virus because it attacks the lungs differently. Delta may scar the lungs and cause breathing difficulties in both humans and animals. The study has not been published in a medical journal and has not yet been peer-reviewed.

https://www.upi.com/Health_News/2022/01/03/covid-19-omicron-lung-damage-animal-studies/6811641220695/

- Authorities in Hong Kong said that they will kill about 2,000 small animals, including hamsters, after several tested positive for the Delta variant of the coronavirus at a pet store where an employee was also infected. The city will also stop the sale of hamsters and the import of small mammals, since the infected hamsters had been imported from the Netherlands. Dr. Jose Arce, president of the American Veterinary Medical Association, said that most animals can recover from the virus quickly and if necessary can be treated with antibiotics and steroids. A pets section of the [CDC web site](#) says that the risk of transmission from pets to humans is low and explains **what to do if you think your pet has Covid-19**.

<https://www.usatoday.com/story/news/world/2022/01/18/2000-hamsters-small-animals-hong-kong-covid/6568460001/>

Statistics

Cases & Testing

The average U.S. 7-day average daily case load was 744,616 cases a day as of January 19. This is a 5% decrease in cases compared with last week's 7-day-average. The average percentage of COVID-19 NAATs (nucleic acid amplification tests) that are positive (percent positivity) for the week ending January 22 was 26%, down 1.4% from the previous seven days.

https://covid.cdc.gov/covid-data-tracker/#cases_positivity7day

Vaccines

As of January 22, 2022, 85.4% of those age 12 and up have received at least one vaccine, while 72.1% of those age 12 and up are fully vaccinated. Approximately 29% of children age 5 to 11 have received a vaccine (about 8.3 million children). 63% of people age 65 and older have received a booster dose and 95% of people age 65 and up have received at least one vaccine. Only 39.7% of those eligible for a booster dose have received one.

https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

Deaths

As of January 22, 2022, the 7-day moving average of new deaths (1,749) has decreased .3% compared with the previous 7-day moving average (1,754).

New Hospitalizations

The 7-day daily average number of new hospitalizations of patients admitted to a hospital who also tested positive for Covid-19 for January 12 –January 18, 2022 was 20,990. This is a 1.1% increase from the prior 7-day average (20,751) from January 5 – January 11, 2022.

New hospital admissions data is from the Unified Hospital Dataset, which tracks newly admitted patients who test positive for Covid-19. The reason for the patient's hospital admission may not be for Covid-19 illness.

The World Health Organization reports that over 18 million new cases were reported globally the week of 10-16 January 2022, a 20% increase as compared to the previous week. Over 45,000 new deaths were reported, a similar number to last week.

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Despite a slowdown of the increase in case incidence at the global level, all regions reported an increase in the incidence of weekly cases with the exception of the African Region, which reported a 27% decrease. The South-East Asia region reported the largest increase in new cases last week (145%), followed by the Eastern Mediterranean Region (68%).

<https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---18-january-2022>

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