

Health News: October 17, 2021

- The U.S. FDA warned consumers not to purchase or use needle-free "**dermal filler**" products such as hyaluronic pens because of the risk of bruising, bleeding, scarring, infection, and allergic reactions. Marketed on social media videos as a do-it-yourself way to plump up lips or improve the appearance of facial skin wrinkles, the devices are not FDA-approved and are illegally being sold directly to consumers online.

FDA-approved injectable devices containing hyaluronic acid include Allergan's Juvederm products, which must be administered by a health care professional. Allergan is also the maker of Botox Cosmetic, which is a biological drug injectable (not a filler) used for temporary reduction of "crow's feet" around the eyes or forehead wrinkles. *(Click for AskaPatient reviews of [Botox Cosmetic](#))*

<https://www.fiercebiotech.com/medtech/fda-warns-against-using-over-counter-lip-and-facial-fillers-unauthorized-needle-free>

Needle Free Hyaluronic Pen (not approved by FDA)



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Juvederm® syringe product (approved by FDA)



Needle-free Devices: FDA [Press Release](#)

- "Filling in Wrinkles Safely" explains the different types of FDA-approved injectable dermal fillers along with their risks. It also provides a link to a database with approved dermal fillers.

<https://www.fda.gov/consumers/consumer-updates/filling-wrinkles-safely>

- The FDA approved Merck's **Keytruda** for certain types of **cervical cancer** with tumors that express the PD-L1 protein. Keytruda's drug label has been revised to include additional clinical trial results and warnings related to its use in cervical cancer. Keytruda immunotherapy was approved in 2015 and is used to treat a variety of cancer types.

<https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-combination-first-line-treatment-cervical-cancer>

- For the first time, the **FDA authorized** the marketing of an e-cigarette: RJR Vapor Company's **Vuse Solo** electronic nicotine delivery system and **tobacco-flavored** liquid e-pods. However, the FDA rejected RJR's 10 other flavored products. The agency is still reviewing the company's request to sell a menthol-flavored nicotine formula.

<https://www.forbes.com/sites/lisakim/2021/10/12/fda-approves-marketing-of-e-cigarettes-citing-benefit-for-addicted-smokers/>

- Lupin Pharmaceuticals is recalling all batches of **irbesartan tablets** and irbesartan and hydrochlorothiazide tablets - USP, 75mg, 150mg and 300mg and irbesartan and hydrochlorothiazide tablets - USP, 150mg/12.5mg and 300mg/12.5mg because of the presence of N-nitrosoirbesartan, a probable human carcinogen. Since 2018, many of the blood pressure drugs known as "angiotensin II receptor blockers," (ARBs) including valsartan, losartan, and irbesartan, have been recalled due to manufacturing quality problems of "active pharmaceutical ingredients" (APIs).

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-all-irbesartan-tablets-and-irbesartan>

AskaPatient article on history of ARB recalls:

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

- Are you taking an antipsychotic, antidepressant, or antihistamine and also have restless legs syndrome (RLS)? There might be a connection. Check out our article on the topic of **drug-induced restless legs syndrome**, along with links to patient experiences of RLS associated with taking various drugs.

<https://www.askapatient.com/news/drug-induced-restless-legs-syndrome-RLS.asp>

- Germaphobes might like these "antimicrobial" computer work stations that will soon be available. Acer announced that some of its new laptops with high-touch surfaces -- such as the chassis's exterior and hinge, the keyboard, the touchpad, mouse, screen, and the fingerprint reader -- are coated with a **silver-ion** agent. For years, research has pointed to silver ions' ability to fight bacteria.

<https://arstechnica.com/gadgets/2021/10/acers-next-pcs-fight-germs-with-silver-ions/>

- FDA issued **sodium-reduction targets** for food manufacturers, chain restaurants and food service operators for 163 categories of processed, packaged and prepared foods. The target is to decrease average sodium intake from approximately 3,400 milligrams (mg) to 3,000 mg per day, about a 12% reduction, over the next 2.5 years. Although average intake would still be above the Dietary Guidelines for Americans' recommended limit of 2,300 mg per day for those 14 and older, it is suggested that modest reductions made slowly over the next few years will substantially decrease diet-related diseases like cardiovascular disease and hypertension. Most people consume 50% more sodium than recommended.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals>

- **Phthalates**, the "everywhere chemical" commonly used in plastics and consumer products, are linked to

about 100,000 premature deaths among people age 55 to 64, according to researchers from the Grossman School of Medicine at New York University. "Our research suggests that the toll of this chemical on society is much greater than we first thought," said the study's lead author. The results were published in *Environmental Pollution*.

<https://www.cnn.com/2021/10/12/health/plastic-chemical-early-death-wellness/index.html>

- Guidance is changing about whether seniors should take a daily regimen of **low-dose aspirin** (81 milligrams to 100 milligrams) if they have a high risk for heart disease. The U.S. Preventative Services Task Force has posted revised [proposed guidelines](#) and will receive comments until November 8, 2021. They strongly recommend that people over 60 who are not already taking daily aspirin under the direction of their doctor should not start, because of the risk of internal bleeding. People ages 40 to 59 who are at higher risk for cardiovascular disease and do not have a history of cardiovascular disease should decide with their clinician whether to start taking daily aspirin. The task force is also retreating from its 2016 recommendation to take baby aspirin for the prevention of colorectal cancer.

<https://www.usatoday.com/story/news/health/2021/10/12/baby-aspirin-no-longer-recommended-prevent-first-heart-attack/6103264001/>

- Pharmacist Joe Graedon discusses the dilemma faced by some people with **how to stop** their aspirin regimen without experiencing side effects.

<https://www.peoplespharmacy.com/articles/how-dangerous-is-it-to-stop-taking-aspirin>

Covid-19 News

- An FDA advisory committee unanimously made recommendations about **booster shots** for those folks who have already been fully vaccinated with the following vaccines:

1. **Moderna**: Half-dose boosters recommended for people 65 and older, anyone 18 and older with underlying conditions, and those frequently exposed to the virus.

<https://abcnews.go.com/Politics/expect-fda-panel-boosters-moderna-johnson-johnson-vaccines/story?id=80561477>

2. **Janssen (J&J)**: Full-dose boosters recommended for people 18 years and older (not just those with underlying conditions), to be taken at least two months after the first.

<https://www.npr.org/sections/health-shots/2021/10/15/1046374353/an-fda-panel-of-experts-backs-j-j-covid-vaccine-booster>

- The FDA will make the final decision within days regarding booster shots for Moderna and J&J and will likely follow the recommendations of the advisory committee. The FDA already authorized full-dose booster shots of the **Pfizer** vaccine for those 65 and older, 18 and older with underlying conditions, and those frequently exposed to the virus. The FDA may also consider recommending "mix and match" booster combinations among vaccine brands.

- The U.S. FDA's Antimicrobial Drugs Advisory Committee (AMDAC) will meet November 30 to discuss Merck and Ridgeback's request for an emergency use authorization (EUA) for **molnupiravir**, an investigational antiviral drug to treat mild-to-moderate Covid-19 in adults.

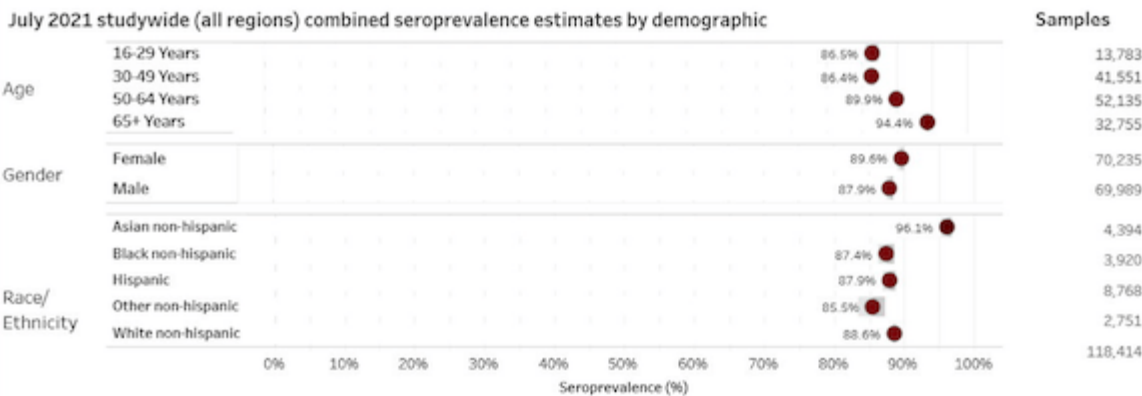
Covid Statistics

- If the average Covid-19 vaccine efficacy rate across all brands administered in the U.S. is 80%, and 189 million Americans so far have been vaccinated, then one might estimate that close to 38 million of them (20%) will eventually have a "breakthrough" Covid-19 infection that may be symptomatic or asymptomatic. We don't know how many **breakthrough infections** have occurred, because the CDC does not keep track of these cases. However, based on data received from states, the CDC reports that a total of 31,895 patients in the U.S. with COVID-19 vaccine breakthrough infection have been hospitalized or died.

<https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>

- Vaccines are leading to improved **blankets of immunity** to Covid-19 in the U.S. population. According to the CDC's Nationwide Blood Donor Seroprevalence Survey, the estimated percentage of the U.S. population age 16 and older that have **developed antibodies** against SARS-CoV-2 was **88.8% from infection, vaccination, or both** as of July 2021. Check this CDC page for an interactive chart with monthly data from July 2020 to July 2021 on prevalence of infection-acquired and vaccine-acquired antibodies. The chart below is for combined infection/vaccination antibody prevalence as of July 2021. AskaPatient will reach out to the CDC to find out if more recent seroprevalence data is available.

<https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence>



- As of October 16, more than 77% (age 12 and up) of those eligible to receive a vaccine in the U.S. have received at least one dose. Around 14.3% of people age 65 and older have received a booster dose.

https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total12

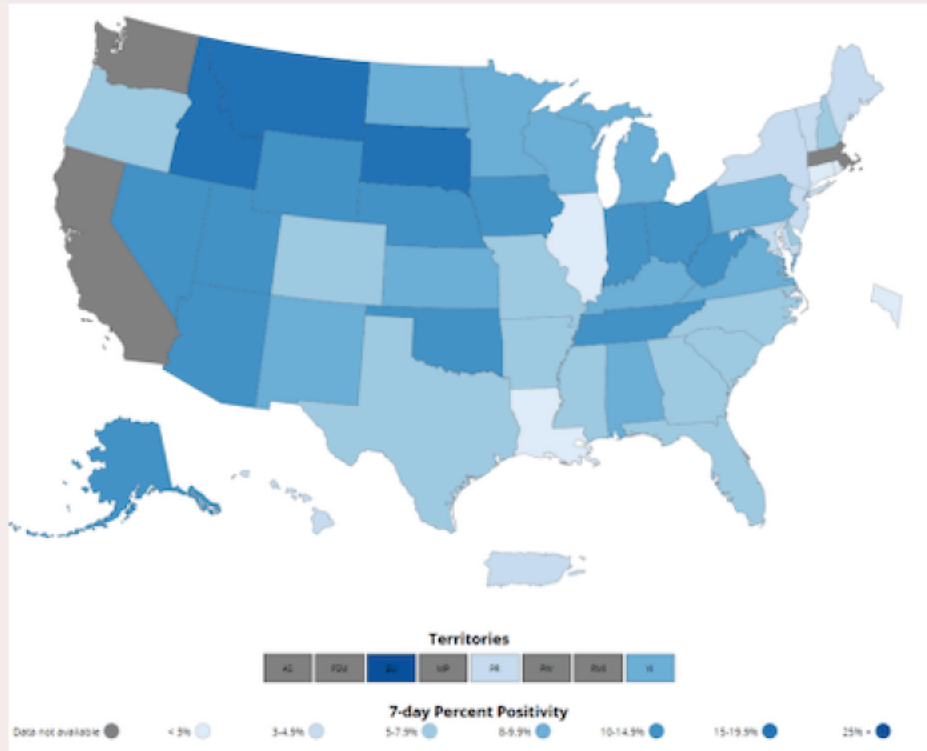
- COVID-19 cases decreased by 12.2% for the week ending October 13 compared with the previous week. The average daily number of new cases as of October 13 was 84,555 while the average number of new cases per day the previous week was 96,666. Hospitalizations for Covid-19 decreased by 14.9% since last week.

Source: [Covid Data Tracker Weekly Review](#)

- The percent of people testing positive for Covid-19 (positivity rate) continues to decline: 5.7% of tests were positive on average in the U.S. in the past week, a decrease from 6% on average last week.

Source (also for map below): [Covid Data Tracker Weekly Review](#)

COVID-19 NAAT Laboratory Test 7-day Percent Positivity by State/Territory (October 1 – October 7, 2021)



- The World Health Organization reports that the global number of new COVID-19 cases was 2.8 million for the week ending October 13, a decline of 7% from the previous week. Apart from the European Region, which reported a 7% increase in new weekly cases, all the other regions reported a decline. The largest decrease in new weekly cases was reported from the African Region (32%), followed by the Western Pacific Region (26%)

<https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---13-october-2021>

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

[Pfizer Moderna Janssen](#)

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