Health News: June 13, 2021

- The U.S. Food and Drug Administration (FDA) approved Biogen's **Aduhelm** (aducanumab) for the treatment of **Alzheimer's**, a debilitating brain disease affecting 6.2 million Americans. Aduhelm was approved using the accelerated approval pathway, which requires a **post-approval trial** to verify that the drug provides the expected clinical benefit. Aduhelm is given by infusion every four weeks and works by reducing the development of amyloid beta plaque in the brain—a hallmark of Alzheimer's disease.
https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug

Image Source: Biogen

- The FDA's approval of Aduhelm is controversial and surprising for many, as the 10-member FDA advisory panel overwhelmingly **advised against its approval** in November 2020, citing lack of evidence of effectiveness. Three members of the FDA advisory panel resigned this week. The FDA sent the committee a memo on June 7 explaining their decision.
https://www.cnbc.com/2021/06/12/biogen-alzheimers-drug-and-the-new-battle-over-dementia-treatment-.html
- Many patients are **applauding** the FDA's decision to make Aduhelm available. Here's an example of a clinical trial patient who says the drug helps.
https://www.wtnh.com/news/health/ct-woman-taking-experimental-alzheimers-drug-reacts-to-fda-approval/
- Ronald Reagan's daughter and Alzheimer's caregiver advocate **Patti Davis** shared her concern about the new drug in a *USA Today* opinion piece. "In the early stages of my father's Alzheimer's, his eyes were usually veiled with fear. His face would tense up when he struggled to remember something or identify an object he was looking at. Sometimes he would say, "I have this thing …" It was heartbreaking. Davis worries that the drug, which is taken during the disease's early stages, could prolong patients' suffering. "What if we are stalling loved ones at the stages when fear courses through them and they are grieving over the loss of who they once were?"
https://www.usatoday.com/story/opinion/voices/2021/06/10/alzheimers-disease-new-drug-aduhelm-reagan-daughter/7621335002/

The FDA approved Novo Nordisk's **Wegovy** (**semaglutide**) **weekly 2.4 mg injection** for chronic weight management in adults with **obesity or overweight** with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol), for use in addition to a reduced calorie diet and increased physical activity. This is the first drug approved for chronic weight management in adults since

2014. Novo Nordisk's less potent **Ozempic (semaglutide) weekly .5 or 1 mg injection** was approved as a treatment for type 2 diabetes in 2017.
https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014
Questions remain as to whether Wegovy will be covered by insurance, as some insurers may consider it a "lifestyle" drug. The price has not been announced but is **expected to cost around $1,300 a month** without insurance, similar to the price of Novo Nordisk's **Saxenda** weight loss treatment.
https://www.forbes.com/sites/joshuacohen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges
Check out this related article from **Ask a Patient** on how **semaglutide**, a synthetic intestinal hormone, works to lower blood sugar and suppress appetite.
https://www.askapatient.com/news/newly-approved-type-2-diabetes-drug-joins-GLP-1-class.asp
Ozempic patient reviews

- The FDA released draft guidance for sponsors of **cancer drug clinical trials** to help make the trials reports meaningful and useful to patients. The goal is for patients to be able to "better understand symptoms they may experience and how a cancer therapy can affect their quality of life." The guidance defines which patient-reported side effects and outcomes will be measured and how they can be reported in a uniform way.
https://www.fda.gov/news-events/press-announcements/fda-brief-fda-provides-guidance-measuring-patient-reported-outcomes-cancer-clinical-trials
- Independent laboratory **Valisure** submitted a **citizen petition** to the FDA asking for recalls of more than **70 sunscreen products** that had higher than FDA's permissible levels (2 ppm only allowed if required for manufacturing) of **benzene**, a known carcinogen. Many of the products were sprays: **Neutrogena Spray Ultra Sheer Weightless Sunscreen** Spray, SPF 70 and SPF 100 were the two products with the highest concentration of benzene. Check the petition linked below, page 12, for lot numbers. Other brands on the list included CVS After-Sun, Soothing Fruit of the Earth, Raw Elements, SunBurnt, Goodsense, Banana Boat, TopCare Everyday and EltaMD. In its petition, Valisure notes that National Institute for Occupational Safety and Health (NIOSH) recommends protective equipment be worn by workers expecting to be exposed to benzene at concentrations of 0.1 ppm and defines " inhalation, skin absorption, ingestion, skin and/or eye contact" as exposure routes.
https://www.cbsnews.com/news/sunscreen-carcinogen-benzene/
The petition:
https://www.valisure.com/wp-content/uploads/Valisure-Citizen-Petition-on-Benzene-in-Sunscreen-and-After-sun-Care-Products-v9.7.pdf

More than 200 products (including some by Neutrogena) had **no detectable levels of benzene**. This table lists the tested products where no benzene was detected.
https://www.valisure.com/wp-content/uploads/Attachment-A-Table-5-of-Valisure-FDA-Citizen-Petition-on-Sunscreen-v2.pdf
Valisure is conducting a "crowdsourcing" project where **consumers can send in sunscreen samples** for testing:
https://www.valisure.com/valisure-studying-sun-care-product-contamination-2/

- An Arizona woman in her 70s with little cartilage left in her knees found it painful to walk and had frequent falls. She responded to a newspaper advertisement for a **stem cell treatment** that sounded like a promising way to regain some of the cartilage in her knees. Two years after the injections, Roberts was thousands of dollars in debt and her cartilage issues weren't fixed. In fact, the treatments caused her fibromyalgia to flare up and some days she spent hours in bed. A Florida-based personal injury lawyer said he started getting calls complaining about stem cell treatments in early 2015 and the problem has only grown worse.
https://www.msn.com/en-us/health/medical/thousands-of-dollars-later-some-arizona-stem-cell-patients-never-got-better/ar-AAKYJln

- Doctors routinely use **stem cells** that come from **bone marrow** or blood in **transplant procedures** to treat patients with cancer and disorders of the blood and immune system. However, most other kinds of stem cell treatments are considered experimental, are not covered by insurance, and are often ineffective or even harmful to patients. **MedShadow** released a four-part series on "regenerative therapies" that chronicles the history of the therapies, early regulation, high profile failures, FDA crackdown, and guidance for patients seeking stem cell therapies.
https://medshadow.org/a-brief-history-of-regenerative-medicine-regenerative-medicine-series/

- If you have **irritable bowel syndrome**, you may have considered altering your diet to avoid certain "**Hi Fodmap**" foods, which are foods containing carbohydrates that are poorly absorbed by the small intestine. These may include wheat, apples, and/or milk. Not everyone is sensitive to each food on the "Hi Fodmap" list, so an elimination process is recommended to identify the food culprits that may be causing the irritation.
https://www.verywellhealth.com/what-are-the-fodmap-types-1944697

Covid-19: News

- **Celebrity Millennium**, the first American cruise ship to set sail since the mandatory industry shutdown in March of 2020, had two passengers test positive for COVID-19 near the end of its 7-day Caribbean cruise. These represent "break-through" cases, since all passengers were required to be vaccinated and tested prior to the cruise. The ship was **sailing at just 25% capacity** with about 500 passengers on board. The two people testing positive shared a state room and are asymptomatic.
https://journalstar.com/news/national/2-passengers-on-board-fully-vaccinated-cruise-ship-test-positive-for-covid-19/article_1cfeb6a0-0810-5245-8108-9e85c614a081.html

Image source: Cruisehive.com

- The CDC will meet on Friday, June 18 to discuss rare but **higher-than-expected** reports of **heart inflammation** following doses of the mRNA-based Pfizer and Moderna COVID-19 vaccines. Overall, 226 cases of myocarditis or pericarditis after vaccination in people younger than age 30 (mostly males) have been confirmed to meet the CDC "working definition" of myocarditis or pericarditis out of 475 reported to the Vaccine Adverse Events Reporting System (VAERS).
https://news.yahoo.com/cdc-hold-emergency-meeting-heart-191029763.html
This chart shows **expected and observed** numbers of myocarditis reports by age group.

Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. (data thru May 31, 2021)

Age groups	Doses admin	Crude reporting rate*	Expected†,‡ Myocarditis/ pericarditis cases	Observed† Myocarditis/ pericarditis reports
12–15 yrs	134,041	22.4	0–1	2
16–17 yrs	**2,258,932**	**35.0**	**2–19**	**79**
18–24 yrs	**9,776,719**	**20.6**	**8–83**	**196**
25–39 yrs	26,844,601	5.0	23–228	124
40–49 yrs	19,576,875	3.0	17–166	51
50–64 yrs	36,951,538	1.3	31–314	39
65+ yrs	42,124,078	0.9	36–358	26
NR	—	—	—	11

8.8% of doses admin

n=277 reports

52.5% of total reports

* Per million doses administered; † Assumes a 31-day post-vaccination observation window; 528 reports with symptom onset within 30 days of vaccination shown; ‡ Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8.

Chart Source: from the FDA Vaccines and Related Biological Products Advisory Committee Presentation June 10,2021 (download presentation)

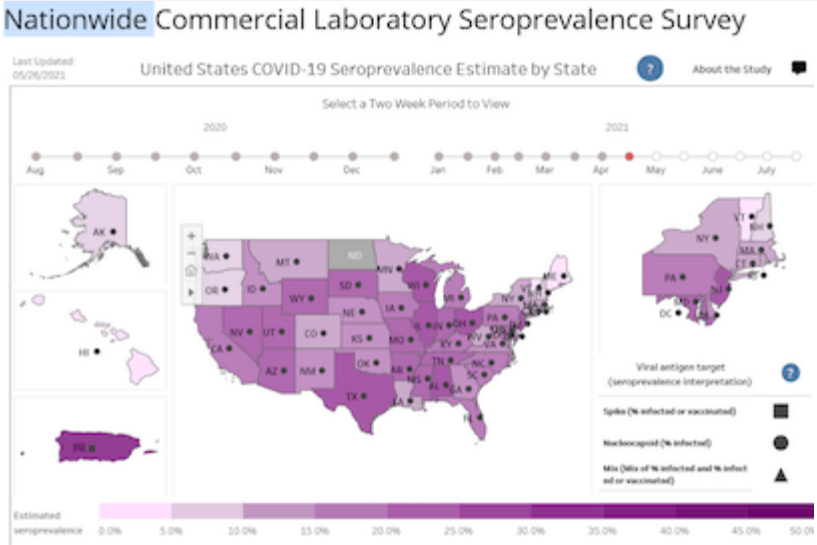
A **webcast link and agenda** is provided on this CDC page for the **June 18 meeting, which will be held from 11 am to 5 pm.** No registration is required.

- The first **non-genetic vaccine** for COVID-19 may be available soon in the U.S. In contrast to the three vaccines already authorized, which contain genetic instructions that cause the body to make the spike protein and which then trigger the associated immune response, **Novavax**'s vaccine contains the spike protein itself, along with an adjuvant that enhances the immune system's response. This is Novavax's first product to be brought to market. Other so-called "protein subunit vaccines" already on the market include vaccines for Hepatitis B and pertussis.
https://www.wnpr.org/post/new-type-covid-19-vaccine-could-debut-soon

- For a complete list of vaccines either approved in at least one country or in late-stage development, check out the RAPS Covid-19 **global vaccine tracker**.
https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker

- To avoid wasting 200,000 doses of vaccines that are **about to expire**, the FDA determined that the shelf

life of Janssen's (J&J) vaccine could be extended for another month and a half (to 4.5 months total when stored at 2-8 degrees Celsius) and also has determined that about 10 million doses produced in two batches at the **Emergent Biosolutions** facility in Baltimore, Maryland are suitable to be used. Many more must be thrown out due to potential contamination. The FDA revised the letter of authorization for the Janssen vaccine to help facilitate **potential export of usable products** to other countries.
https://www.fda.gov/news-events/press-announcements/fda-takes-steps-increase-availability-covid-19-vaccine
- If you already received the Janssen vaccine, there is no reason for concern about **whether your dose was contaminated**, because officials say that all J&J doses administered in the U.S. so far were manufactured at the firm's Janssen plant in the **Netherlands**, not at the troubled **Baltimore, Maryland** location. That facility, which J&J contracted with to make the vaccines, was not set up as a manufacturing plant; FDA records from inspections last year described the plant as a contract testing laboratory that 'did not manufacture products for distribution.' The *New York Times* was told that J&J must throw out 60 million vaccines, but this has not been confirmed by the FDA or J&J.
https://www.msn.com/en-gb/news/world/breaking-news-fda-orders-jandj-to-throw-out-60m-covid-19-vaccine-doses/ar-AAKWJnV
- In Texas, it is estimated that more than **30% of the population** has been infected with Covid-19, based on a CDC-sponsored sampling program. Nationally, it is estimated that **22% of people have been infected with Covid-19** (many of them asymptomatic). Check your state to find out what percent of people have had COVID-19 based on **nucleocapsid testing**. While vaccinated people will test positive for the spike protein, they won't test positive using the nucleocapsid test unless they actually were infected with the virus that causes Covid-19.



Source: CDC Nationwide Commercial Lab Seroprevalence Survey (covers through April 30, 2021
https://covid.cdc.gov/covid-data-tracker/#national-lab

Covid-19: Statistics

- As of June 10, the CDC reports that over **172 million people** (61.5% of people age 12 and up) have received at least one dose of a vaccine, and **141.6 million** people (50.5% of people age 12 and up) have been fully vaccinated.
- COVID-19 cases per day continue to decrease. The average number of new cases in the U.S. per day

over the past week as of June 10 was 13,997 while the average number of new cases per day the previous week was 14,890. The percent of people testing positive for Covid-19 (positivity rate) is **1.8% on average** in the U.S. in the past week. The overall U.S. level of transmission is in the yellow or "moderate" zone. Seven states are in the orange or "substantial" zone for level of transmission.

Source: CDC Data Tracker and Covid Data Tracker Weekly Review

- The World Health Organization (WHO) reports that the number of new COVID-19 cases and deaths globally decreased the week ending May 31 with over 3 million new confirmed cases (a 15% decrease over the previous week) and over 73,000 deaths. In **India**, the number of cases are still very high but are declining and are now less than 1 million new cases a week. The situation in **South America** is still dire, with increases in weekly cases in Colombia, Peru, and Brazil. The total number of vaccines distributed is over 2.1 billion worldwide.

https://covid19.who.int/table

- WHO announced a new naming system for Covid-19 **variants of interest** that uses letters of the **Greek alphabet**. Check this page for a chart of variants with lineages and associated countries where the virus variants were first documented.

https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/

For links to more statistics, including global cases statistics, check out our Guide to Coronvirus 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**

Ask a Patient Health Newsletter: June 13, 2021

Visit us and subscribe: https://www.askapatient.com

Contact with questions, comments, and suggestions: admin@askapatient.com

Subscribe